ANNEXURE – I

Report of National Consultations on Bt-Brinjal prepared by Centre for Environment Education

National Consultations on

Bt Brinjal

Report

Prepared by the Centre for Environment Education (CEE) for Ministry of Environment and Forests (MoEF), Government of India

10th February 2010

CEE
Centre for Environment Education

Government of India
Ministry of Environment & Forests

CMYK

National Consultations
on
Bt Brinjal

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Content

The Centre for Environment Education (CEE) Ahmedabad is a national institution established in 1984, supported by the Ministry of Environment and Forests, Government of India and associated with Nehru Foundation for Development. The aim of CEE is to create awareness and understanding of environment and sustainability issues among children, youth, decision makers and the general community. CEE develops innovative programmes and materials and field tests them for their validity and effectiveness. CEE enriches public policy through its publications, seminars, training programmes and consultations. The aim is to develop models that can be adapted to suit local conditions.

Preface

The proposed introduction of Bt Brinjal, the first genetically modified vegetable into India, has generated great debate across the country. Earlier, the Expert Committee on Bt Brinjal based on environmental risk assessment data had concluded that the Bt Brinjal event EE-1, being highly specific in its action on target organisms, would have no adverse impact on non-target organisms including beneficial organisms and soil micro-flora. The committee was of the opinion that no accumulation and persistence of Bt protein in the soil takes place, that no differences with respect to susceptibility to pests and diseases had been noticed and that the introgression of cry1Ac gene had in no way affected the outcrossing potential or the weediness characteristics of Bt Brinjal.It also noted that no instances of natural inter-specific hybridization with wild species have been reported for cultivated brinjal and that consequently,the introduction of Bt Brinjal was not likely to destroy the country's biodiversity.

The Genetic Engineering Approval Committee (GEAC) in its meeting held on 14.10.2009, had concluded that Bt Brinjal is safe for environmental release taking into consideration the findings of the review by three high-level technical committees namely; the Review Committee on Genetic Manipulations and two Expert

Committees constituted by the GEAC in 2006 and 2009. The decision of the GEAC on the safety of Bt Brinjal for environmental release was, in the view of the GEAC, based on scientific facts/data generated during 2002-2009 as well as the international experience with GM crops.

Following a careful consideration of the recommendations of the Genetic Engineering Approval Committee (GEAC) on Bt Brinjal, Shri Jairam Ramesh, Minister of State (IC), Ministry of Environment and Forests, Government of India, decided on the following course of action.
"1. The report of the Expert Committee (EC-II) submitted to the GEAC on October 8th, 2009 that formed the basis of the GEAC's decision of October 14th, 2009 is being made public with immediate effect. It is being uploaded straightway on the website of the Ministry of Environment and Forests (www.moef.gov.in). All previous reports and studies on Bt Brinjal are already in the public domain. Comments on the EC-II report are being sought by December 31, 2009 and I actively encourage their submission,

2. During January and February 2010, I propose to have a series of consultations in different places with scientists, agriculture experts, farmers' organizations, consumer groups and NGOs. All points of view will be represented in these consultations.

Strong views have already been expressed on the Bt Brinjal issue, both for and against. My objective is to arrive at careful, considered decision in the public and national interest. The decision will be made only after the consultation process is complete and all stakeholders are satisfied that they have been heard to their satisfaction."[1]

On 5 January 2010, CEE received the order from the Ministry of Environment and Forests to facilitate the organization of a series of national consultations in seven cities across the country, the first one to be held on 13 January, and submit the final report by 10 February 2010. Although a huge challenge, considering its national importance, its role in creating public awareness and in democratic decision making, the whole CEE team saw it as an honour to be associated with the process. The process started with creating awareness about the consultations, developing a primer on Bt Brinjal in 11 languages, organizing the consultations and compiling the views, propositions and concerns expressed at the consultation as well as others that were invited or received by the Ministry and CEE This very challenging task could be achieved and the demanding deadline met because of the unstinting support and cooperation of senior officials of MoEF and the efforts of the indefatigable team at CEE.

The consultations offered a platform to a wide variety of stakeholders. There were individual farmers, farmer organizations, groups focused on organic agriculture, consumer groups, scientists, agriculture experts and students, NGOs, environmentalists, veterinary doctors as well as representatives of the company, Mahyco (Maharashtra Hybrid Seed Company), which has proposed the introduction of the Bt seeds. Politicians, groups affiliated to different political parties and representatives of the State Governments also actively participated in these discussions. It was obvious that not everyone was used to such discussions. The 'culture' of dialogue was clearly different for each of these groups. At times the Minister had to even remind scientists that "they should speak as scientists and not as NGOs". To some scientists it seemed like an unwarranted intrusion into the technicalities of their world. After all, they argued, this was a 'scientific' issue and one should have a closed-door meeting with the concerned scientists and decide. For others it was an economic and commercial issue. So it was “Let the farmer decide”,or “ if someone does not want the Bt seeds they don't have to sow them.” To yet others this was a consumer issue, “How can you introduce something where the consumer does not have a choice and no way of knowing what he/she is eating?”

The consultations brought about much needed connections between Indian Science and the larger society. Speaking at the 71st Session of the Indian Science Congress at Ranchi in January 1984, Prime Minister Smt. Indira Gandhi had told the gathering, “The concern of scientists should not remain confined to their own fields of specialization or the projects in which they are directly involved. Coordination and to work on an inter-disciplinary basis among scientists themselves with those engaged in planning and production are essential. Scientists should take greater interest in planning, which is, after all, the application of science and reason to national problems.”[2]

Nearly 6000 participants registered for the seven consultations and an estimated 2000 more attended or demonstrated outside the venues. More than 9000 written submissions, some of them of book length, were presented to the Minister. Shri Jairam Ramesh personally sat through and chaired the over 25 hours of heated consultations. What emerged was a rich array of concerns, comments, insights and opinions. Many of these can be further investigated to check their validity. While some are based on research, many are observations or are based on related experiences. They have, in this report, been formulated as propositions. A number of research papers were also collected. From what was collected we have generated a bibliography with over 450 entries.

The comments were not confined to Bt Brinjal but extended to the larger issue of genetically modified (GM) crops and to the process of approval of GM products. The process of removal of the brinjal from India's biodiversity list was also brought to the notice of the authorities. We have therefore added a chapter based on the approval process and comments received on this.

From the papers and scientific reports received, it prima facie seems that research data is available on only a small number of the propositions. The consultations thus do throw up a large research agenda.

There have been concerns on the issues of independence/dependency, loss of biodiversity, implications on the environment and on health in different contexts. The consultation has thrown up issues of the funding of science and the need for more field-based locale-specific research. The process sets the agenda for science rather, and therefore can be viewed as supplementing it.

On the other side, many scientists have spoken strongly in support of the technology, being of the view that India cannot afford to ignore this technology. Some farmers have seen this as a breakthrough and a way to improve their livelihoods. It is argued that Bt technology needs to be further pursued (whether Bt Brinjal is introduced or not) as part of India's research agenda for food security.

The proposed step is a major one in the 4000-year history of brinjals in India. In the absence of a regulatory mechanism, it is an irreversible step and therefore needs to

be taken with the utmost regard for every possible consequence. The consultations have certainly revealed the passionate nature of public opinions on the subject and this does need to be respected.

Democracy needs new tools and platforms in a rapidly changing technological environment. Long gone are the days when people thought problems could be solved based on the knowledge of a single discipline. Climate Change is only the most recent and perhaps the most important sign of the unanticipated and unintentional consequences of human intervention in the unique balance of natural systems. It was not that Diclophenac Sodium, a drug used in veterinary medicine, was not adequately studied for its impact on the target species. But all the same, it caused the disappearance of over 90 per cent of vultures on our subcontinent. The problem was that it had not occurred to the researchers on the drug to conduct such an impact study. This is why it is so important to bring multiple perspectives to bear on a problem and generate lists of propositions for study. The Bt Brinjal discussion has answered precisely this need

While consultations are good for airing different perspectives, they cannot be used as forums to gauge the strength of feelings or views in the larger community. Perhaps mistaking the consultation for an opportunity for a show of strength on a particular point of view,there were attempts by some to crowd the forum with “supporters”. Shri Jairam Ramesh made it a point to explain the process of consultation. He reminded people that the consultation was not a voting process and adding numbers was not necessary to make a point.

Amartya Sen has well described what such a process can do. “If people are capable of being reasonable in taking note of other people's points of view and in welcoming information, which must be among the essential demands of open-minded public dialogue, then the gap between the two approaches would tend to be not necessarily momentous”[3] He goes on to add, “By and large, all of us are capable of being reasonable through being open minded about welcoming information and through reflecting on arguments coming from different quarters, along with undertaking interactive deliberations and debates on how the underlying issues should be seen."[4]

While this may not have always been the spirit in which the discussions took place at the Bt Brinjal National Consultations, it is one of the reasons consultations are organized. The Minister did have to urge the participants to listen and to understand alternative points of view rather than shout down opposing points of view or accuse people of having ulterior motives.

At the consultations, an important principle that needs to be followed while taking such decisions was highlighted. This was the precautionary principle which "states that if an action or policy has suspected risk of causing harm to the public or to the environment, in the absence of a scientific consensus that harm would not ensue, the burden of proof falls on those who would advocate taking the action. Effectively, this principle allows policy makers to make discretionary decisions in situations where there is evidence of potential harm in the absence of complete scientific proof. ... The protections that mitigate suspected risks can be relaxed only if further scientific findings emerge that more robustly support an alternative explanation."[5].

One of the primary foundations of the precautionary principle, and globally accepted definitions, results from the work of the Rio Conference, or the 'Earth Summit' in 1992. Principle #15 of the Rio Declaration notes:

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[6]

This is the critical issue before India. The process of consultations has truly been a landmark as a process in democratic and transparent decision making. The Ministry and, in particular, Shri Jairam Ramesh had to maintain enormous patience to truly listen to the voices of different stakeholders. The media too has played its role and made a much larger group aware and involved in the discussion. It is now for the Government to take the right decision, but whatever the final decision, the consultations have certainly enriched the process.

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Director
Centre for Environment Education (CEE)

References

1. Jairam Ramesh quoted in a press release by the Press Information Bureau, Govt. of India, October 15, 2009. http://www.pib.nic.in/release/release.asp?relid=53217

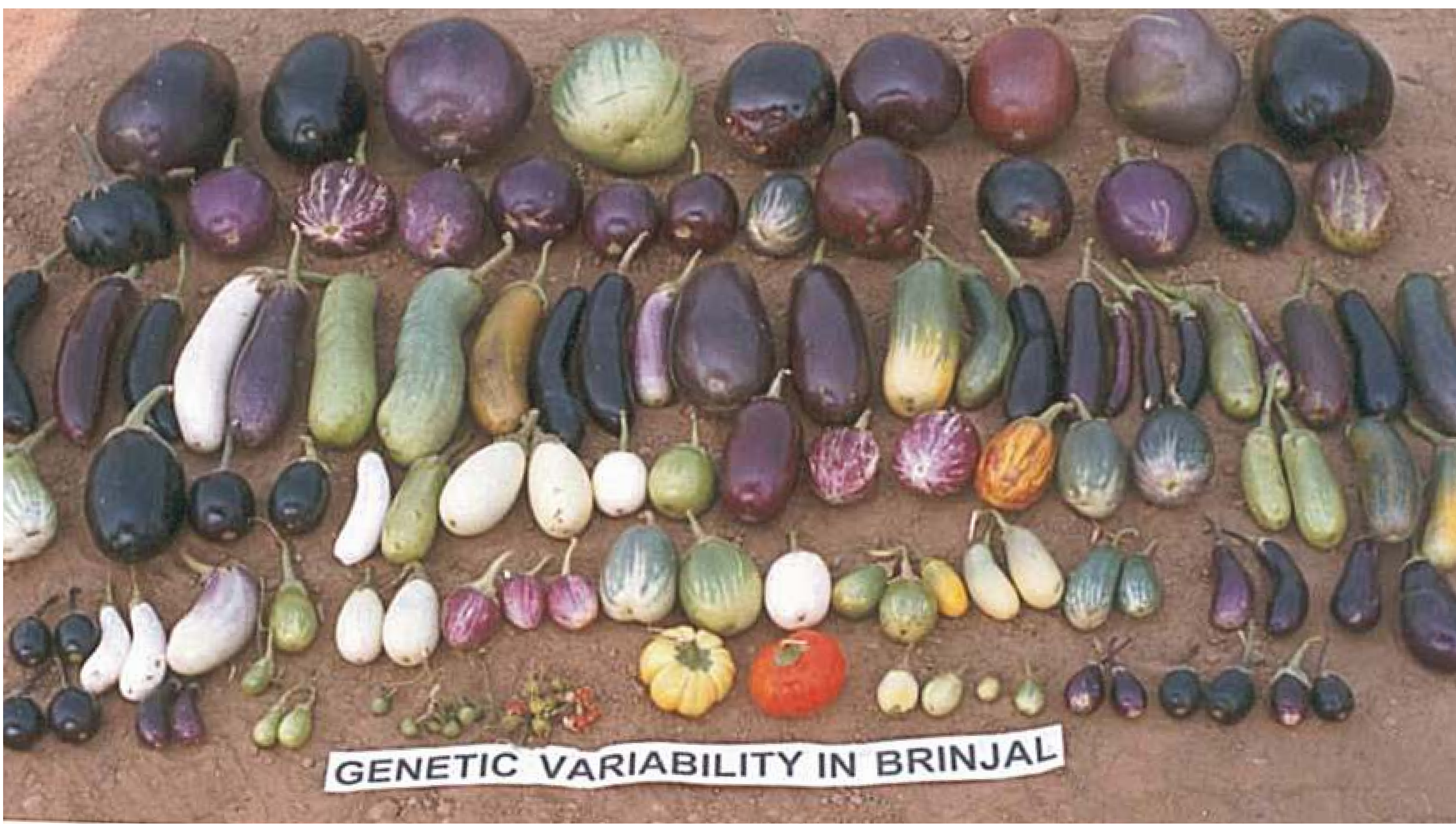
2. MoEF. 2009. *Indira Gandhi on Environment & Forests*,. Ministry of Environment & Forests, Government of India, New Delhi, pp. 115-116.

3. Amartya Sen. 2009., The Idea of Justice, Allen Lane. p, 43.

4. Ibid, p 43.

5. Miguel A. Recuerda. 2006. “Risk and Reason in the European Union Law”, 5 European Food and Feed Law Review, Quoted in Wikipedia.

6. Rio Declaration on Environment and Development. 1992. Principle 15. http://www.unep.org/Documents.multilingual/Default.asp?DocumentID=78&ArticleID=1163. Accessed 2 February 2010.



Introduction

Bt Brinjal, the first genetically modified food crop, has generated much debate in India. The Ministry of Environment and Forests (MoEF) received strong views both in favour of and against the commercialization of Bt Brinjal in India from various stakeholders. In response, the Ministry decided to hold nationwide public consultations with various stakeholders before taking a final decision. The main objective of the consultations was to arrive at a carefully considered evaluation in the public and national interest. The Centre for Environment Education (CEE), an autonomous organization engaged in Environment and Sustainability Education, was entrusted with the task of organizing and facilitating these consultations. Seven consultations were held in seven cities between 13th January and 6th February 2010.

Selection of Locations

Seven cities were selected by the MoEF for holding the consultations. Once the consultations started, several other states requested that similar consultations be held there. Shri Jairam Ramesh clarified that these seven cities were selected only to get a sample of the perspectives of different stakeholders.

Kolkata and Bhubaneshwar were both located in states that are leading producers of brinjals. Hyderabad and Bangalore are representative of centres of science and research in agriculture and biotechnology. Nagpur and Ahmedabad are in states that have extensive experience with Bt Cotton, the first GM crop commercialized in India. Finally Chandigarh was included to represent a state which has been at the centre of the green revolution.

The Consultations

No.	Location	Date	Time	Venues
1	Kolkata	13th Jan,2010	11:00 am-3:00 pm	Bose Institute
2	Bhubaneswar	16th Jan,2010	2:30 pm-6:00 pm	KIIT University Auditorium
3	Ahmedabad	19th Jan,2010	12:00 noon-3:00 pm	Ahmedabad Management Association
4	Nagpur	27th Jan,2010	11:30am-2:30pm	Indian Medical Association
5	Chandigarh	29th Jan,2010	1:00pm-4:00pm	Bar Council of Punjab and Haryana
6	Hyderabad	31st Jan,2010	10:00 am 1:00 pm	Central Research Institute for Dryland Agriculture (CRIDA)
7	Bangalore	6th Feb,2010	10:00 am 2:00 pm	Jnana Jyoti Auditorium, Central College Campus

Consultation Process

The consultations were structured as public hearings, chaired by the Minister for Environment and Forests, Shri Jairam Ramesh. The public consultations provided a space for discussion and networking across the board for multiple groups with a stake in Bt Brinjal. The history of the locations opened each consultation to the propositions and concerns specific to that area. The consultations also allowed more regional-level interaction towards a more holistic understanding of Bt Brinjal. The consultations were open to all members of the public.

A range of stakeholders' groups attended the consultations. They included farmers, scientists, agricultural experts, farmers' organizations, consumer groups, citizens' forums, NGOs/CBOs, government officials, media, seed suppliers, traders, doctors, lawyers, etc. These diverse groups helped each consultation gain a distinct sense of the local and regional viewpoints on the issues of Bt Brinjal. By the use of the local language and Hindi, CEE made sure that

Map of India showing brinjal cultivation areas and Bt Brinjal National Consultation locations

Solid shading indicates traditional brinjal growing areas while light shading indicates sparsely spread areas under brinjal cultivation.

Source: Series of Crop Specific Biology Documents, Biology of Brinjal. Ministry of Environment and Forest and Department of Biotechnology, Government of India each consultation had the widest possible participation. CEE attempted to ensure that the consultations were conducted in as democratic, transparent, objective and scientific a manner as possible.

Primer on Bt Brinjal: A team from CEE put together a layperson's primer on Bt Brinjal. The primer attempts to provide information on the importance of brinjal in India and some basic information on genetically modified crops and Bt Brinjal. The primer also provides a brief commentary on the prospects and the concerns among various stakeholders about the possible commercialization of Bt Brinjal. It is an unbiased account of reported results of the studies conducted and concerns expressed by multiple stakeholders. Importantly, it refers to the report of the Expert Committee (EC-II) on Bt Brinjal. The primer seeks to acquaint the representative stakeholders with the current situation in India. This information base proved beneficial during the consultation process. As it was made available in 11 major languages, namely, English, Hindi, Gujarati, Marathi, Kannada, Telegu, Oriya, Bengali, Punjabi, Tamil, and Malayalam, the primer was used and appreciated by a very wide audience. It was distributed to all who registered at each consultation.

Exhibit Panels: Five panels were developed, based on the primer, to start a discussion on the salient features of the ongoing debate. The panels were translated into the local languages. As these were regional consultations, at some locations, the panels were translated into more than one local language. These panels are now available in 10 languages

Planning of Multi-location Consultations: The secretariat for the consultations was based at CEE's head office in Ahmedabad. CEE's regional and state offices collaborated with the secretariat to organize the consultations. Translation and printing of the primer and the exhibit panels was done in the concerned regions. The logistics of each consultation was handled by the regional team.

Reaching out to Stakeholders: Unbiased stakeholder lists were prepared for each consultation. The lists incorporated names of representatives of groups with significantly divergent viewpoints, which included all prominent organizations, institutions, political parties and groups who have been involved in research, activism or commentary on Bt Brinjal. Invitations were dispatched by the local CEE teams through email, post, fax and telephonic communication. Additionally, through CEE networks several other groups were contacted, with requests that the details and the invitation to the consultations be advanced to other people or groups.

A webpage was created on the CEE website www.ceeindia.org, making all the information and reading materials on Bt Brinjal available to the public. An email ID brinjal@ceeindia.org was made functional for all consultation-related communication.

Media Coverage: Newspaper advertisements appeared in English and the local language in leading newspapers in the state of each consultation. These appeared a day prior to each consultation announcing the time and venue of the consultation. Some CEE regional teams held press conferences prior to the consultation to announce the event. The local language newspapers and the English dailies also covered the consultations through articles and editorials on the process of consultation and the debate on Bt Brinjal.Several prime-time news channels covered the discussions at each consultation, offering details of the consultations or panel discussions. All of this provided considerable additional coverage to the consultations.

Venue Arrangements: The venue was selected as one which was accessible, appropriate to a public gathering of this nature and could accommodate the numbers expected. Provisions were made to enable PowerPoint presentations. Banners in English and the local language were displayed at prominent locations at the venues. The timings of the consultations differed, however as each consultation although scheduled for three hours, sometimes carried on for up to an hour longer. At each consultation, stakeholders shouting slogans and protesting were seen outside the auditoriums.

Appropriate security arrangements were made at the venues to maintain the law and order situation. The local police stations were contacted and alerted but organizers were careful to ensure that the security arrangements were not in any way intimidating and did not inhibit public demonstrations. Groups were free to demonstrate their opinions inside as well as outside the auditorium

Projections: At each location, a considerably larger number of people attended than had been expected. CEE ensured that alternative and additional arrangements were made to accommodate these stakeholders. These arrangements differed from location to location. Typically stakeholders who came after the main auditorium was full were accommodated in an auxiliary room. This was connected to the main consultations by way of a projection and sound system. Thus even stakeholders not accommodated in the larger auditorium were able to see and hear the entire proceedings.

Registration: Attending participants were identified by the interest groups they represented; each group was distinguished by a colour-code. A large registration counter at each consultation was meant for farmers; a second counter was for business people, traders, individuals, representatives of industry and citizen groups: the third counter for people from non-governmental organizations, activists, consumer group representatives and farmer group representatives; the fourth counter was for scientists and experts; the fifth counter was for researchers and students; and the sixth counter was for active and retired government officials and members of public trusts. Each registered participant was given a coloured sheet with a printed number. The colour of the sheet was indicative of the interest group under which they had registered themselves. This system of colour coding ensured that the Minister could address propositions of representatives of different interests and the numbering ensured that each stakeholder was registered under a unique number and was thus identifiable. The registration desks were set up about three to four hours prior to the consultation. The registration was open even after the consultation had begun and this continued till the end of consultation. The Primer in English and local language was distributed to the participants. The seating in the auditorium was also on a first-come first-served basis with no prior reservations for anyone besides the Press.

Information Media: A PowerPoint presentation based on the information in the Bt Brinjal primer was prepared. This presentation allowed those who are unable to read or fully comprehend the primer to get a clearer idea of the discussions before the launch of the open forum. The exhibit panels were displayed at every consultation at prominent, informal locations outside the auditoriums. These were widely appreciated by the participants as they were able to look through the panels before the consultation began.

On-site Documentation: Wireless mikes were circulated during the consultation for stakeholders to voice their comments. Video recording or audio-video recording was done at every consultation. The wireless mikes were connected to the video documentation thus documenting the raw footage of the entire consultation. A photographer was also present, to capture specific moments before, during and after each consultation. CEE rapporteurs also documented the proceedings. Additionally, written comments from various stakeholders were collected. These have been preserved as documentation of comments raised at the consultations.

Other Arrangements: Arrangements were made for tea and snacks or lunch for participants at the consultations.

Consultation Proceedings: After a brief welcome address to the participants gathered in the auditorium, the PowerPoint presentation on Bt Brinjal was made. This was delivered in the local language at every location by a CEE staff member prior to the commencement of the actual consultation. The Minister then addressed the consultation explaining his rationale for arranging the consultations. The forum was subsequently opened up for discussions. Using the colour coded number sheets, the Minister addressed participants from the different stakeholder groups. CEE staff ensured that translation was available for the Minister for comments made in a local language and for stakeholders comments raised in English were translated into the local language. Each consultation concluded with a brief address from the Minister.

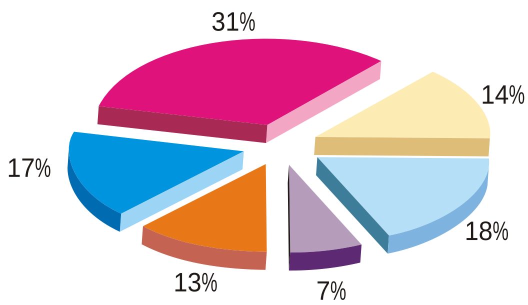
Demonstrations: Groups who demonstrated their views for and against Bt Brinjal were observed at every consultation. These demonstrators brought creative placards, posters and banners, with slogans and artwork. CEE staff wherever possible involved the leaders of such groups in the discussions at the consultations. Subsequent to the consultation in the auditoriums, the Minister also interacted and exchanged views with these groups.

Display of Brinjal varieties: A participant-led display of a diverse variety of Brinjals was seen at some consultations. Brinjals were tagged with their local and scientific names. Bouquets of brinjals and flowers were distributed by some groups.

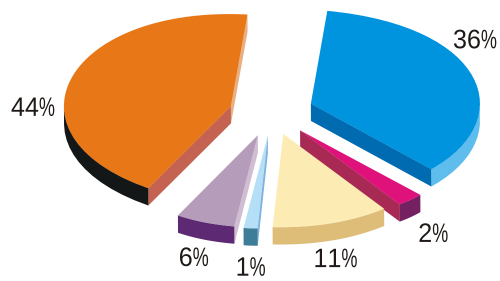
Collection of Submissions: Submissions were collected at all locations including registration counters and at the Minister's dais. These include letters addressed to the Minister, published studies, research papers, books, informal notes and signed handouts and opinion forms.

Participant Profiles

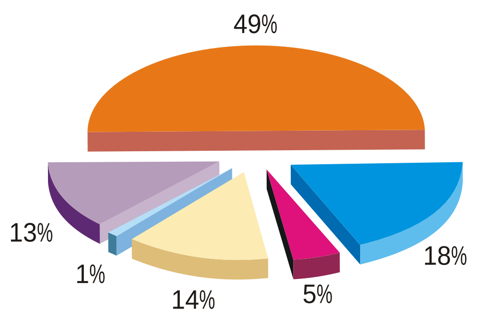
Kolkata,13 January 2010



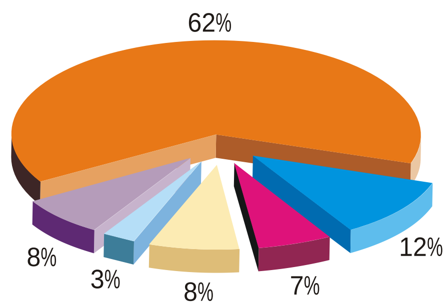
Bhubaneswar, 16 January 2010



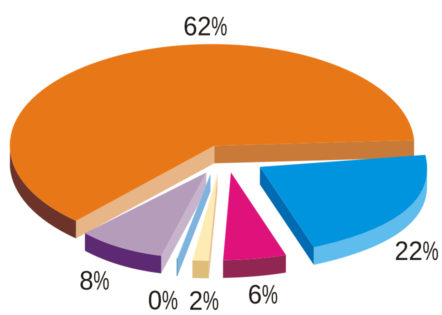
Ahmedabad, 19 January 2010



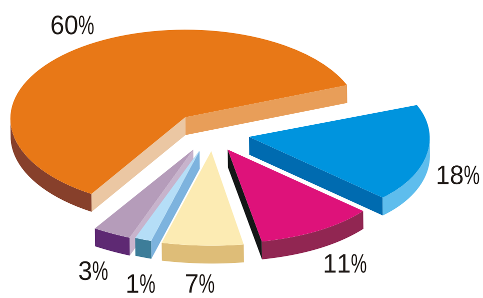
Nagpur, 27 January 2010



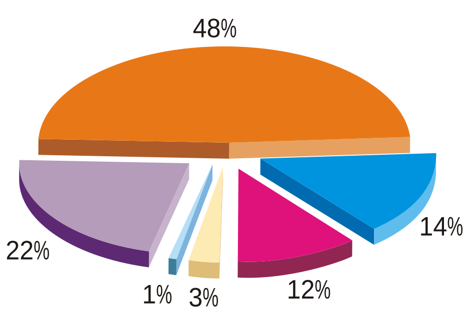
Chandigarh, 29 January 2010



Hyderabad, 31 January 2010



Bangalore, 6 February 2010



- Farmers/Farmer Organisations
- NGOs/Consumer Forum/Environmentalists
- Scientists, Experts
- Students, Researchers
- Government Officials, Politicians/Elected bodies/members
- Individuals, Citizen Groups, Business, Traders, Industries

Post Consultation

The proceedings of every consultation were compiled into regional reports. This included the entire on-site documentation,the raw video and audio footage, photographs and rapporteurs' report. Additionally the entire video documentation was cross-checked to ensure that no proposition that was voiced went undocumented. The media coverage of each consultation was also documented.

Comments and studies sent via email, post or by hand to regional offices and to the central Secretariat have been compiled. The comments handed over by participants during the consultations were collected at the various locations and included in the report.

A literature review was conducted to locate the research relating to the propositions. This has resulted in a bibliography which will add weight to the comments raised and provide the Ministry and the public with references to readings that will enable further deliberations in this area. All the submissions have been referenced and are being submitted with this report.

Limitations

Every consultation drew far greater numbers than were initially expected by the Ministry or CEE. This demanded that CEE reconsider its logistics and replan it strategy for every location.

The protestors outside each consultation were often difficult to manage and had to be very diplomatically handled. This was extremely complicated in some locations, as at Hyderabad where it was noted that several chairs and some mikes were broken by some irate participants at the consultation.

Some NGOs questioned the selection of locations for the consultations. There was significant pressure on CEE to make an active attempt to include additional states such as Kerala, Bihar, Tamil Nadu and Madhya Pradesh for the consultations. As CEE was unable to meet these requests, there was some criticism.

Last minute changes in the Minister's schedule (dates and times) at four out of the seven consultations also had considerable impact on CEE planning and expenditure schedules. Venues had to be rebooked and invitations had to be resent. CEE also faced discontent and censure from participants who could not be contacted in time.

Images from the National Consultations

Kolkata

Bhubaneswar

Ahmedabad

Nagpur

Chandigarh

Hyderabad

Bengaluru

Media

Propositions and Concerns

Biodiversity and the Environment

\+ 1. Evolution in nature cannot be stopped. Issues of food security cannot be addressed if Bt is disallowed. Organic farming is an excellent solution but it cannot be practised in a country like India.

\+ 2. Bt has been cleared by scientists after extensive tests and people should understand the technology and its benefits.

\+ 3. The impact of gene flow to wild relatives of cultivated brinjal (*S.melongena*) has been considered. It has been reported that there is no natural crossing among cultivated and wild species of brinjal including *S. incanum* and *S. insanum* (Rao, 1979). Under forced crossing situations, even if crossing was possible, the viability and subsequent development of fertile seeds have not been successful. Hence the perception about destruction of brinjal diversity in India due to introduction of Bt Brinjal is unfounded in science. *Solanum melongena* is crossable only with *S. incanum*, and that, too, under assisted conditions. The various species of Solanum have co-existed for millennia with no loss of biodiversity inspite of *S. melongena* being widely cultivated.

\+ Argument in favour of Bt Brinjal
\- Argument against Bt Brinjal/ Concern

+ 4. The crossability studies have been repeated by IIVR, and it has been reported that crossing was not possible with representative wild relatives except *S. incanum* where limited crossing could be achieved through artificial pollination.

+ 5. Post release of Bt Brinjal for commercial cultivation, there is no isolation distance requirement.

- 6. The origin of cultivated brinjal is uncertain, with differing views put forward by scientists. South America and Indo-China are thought to be the areas of origin. India is considered a centre of diversity.

    a. Genus Solanum is predominantly of Central and South American origin. The question of the centre of origin of *S. melongena* is yet to be resolved (Khan,1979). Evidence seems to indicate that it originated in Asia.

    b. SouthWest Asia including Arabia, Indo-Burma region, Japan and China have been suggested as probable places of origin by different authors (Hooker, 1885; Vavilov, 1951; Bailey, 1947; Watt, 1908). It cannot be categorically concluded that brinjal originated in India.

    c. Karihaloo and Gottileb (1995) through their study on allozyme variation in *S. melongena* and similar wild and weedy forms suggested that *S. melongena* originated from an African species, *S. incanum*. Migration of *S. incanum*, or its derivative wild ancestor of *S. melongena*, into South and Southeast Asia would have taken place either by humans through land routes or by sea dispersal of fruits (D'Arcy and Pickett 1991; Lester and Hasan 1991).

- 7. Brinjal is a crop with 2- 48% cross-pollination (refer All India Coordinated Vegetable Improvement Project of ICAR). Bt Brinjal will pollute our vegetable germplasm. Transgene cross-pollination is an irreversible risk, as evident from Bt cotton experiences in Gujarat.

- 8. The brinjal belongs to the family Solanaceae the same as that of potato, chillies, tomato and tobacco. The mutation of the transgene and horizontal gene transfer may create long term and far reaching adverse consequences. Prof T.K. Bose, former Vice Chancellor of Bidhan Chandra Agricultural University, and a veteran agricultural scientist, warns that the release of Bt Brinjal would also likely result in the contamination of the entire Solanaceae family of crops to which brinjal belongs.

- 9. Bt toxin is killing beneficial or friendly insects as well. No systematic studies have been conducted to protect the diversity of friendly insects.

- 10. Variability and adaptability are the most important traits of diversity in brinjal. These would be lost due to gene pollution through cross-pollination in open fields.

- 11. Bt Brinjal requires to be further studied by a trans-disciplinary, independent and impartial team of scientists keeping in mind the short-term and long-term consequences in terms of genetic pollution linked to acute and chronic toxicity of food chain.

- 12. India hosts at least two important global centres of exceptionally rich, uncultivated, indigenous biodiversity the Western Ghats and North-eastern India which are also at high risk from the new genetically tampered plant species.
- 13. Genetically tampered 'Terminator Seeds' or 'Suicide Seeds', originally developed by the US Department of Agriculture and some seed MNCs, contain a 'Terminator Gene' that prevents plants from producing fertile seeds. The intent of such engineered sterility was to force farmers to buy new seeds every year, rather than save and replant from their own harvest. But once the terminator seeds are released into a region, the trait of seed sterility can pass to other non-genetically-engineered crops and plants, making most or all of the seeds in the region sterile.
- 14. Following worldwide condemnation of the terminator seeds, the UN's Convention on Biological Diversity (2000) recommended a de facto moratorium on their field-testing and commercial sale. This was re-affirmed in 2006. But now, there is a new push by companies like Monsanto to overturn the moratorium and try to re-introduce terminator seeds, ironically under the guise of 'bio-safety'.
- 15. If this GM farming is approved it will destroy all the indigenous varieties that India has.
- 16. The Bt may cause contamination of genetic diversity due to cross-pollination. Such a technology should not be imposed, especially in haste, since it brings about irreversible changes.
- 17. The functions of ecosystems would be hampered by possible cross-pollination of Bt Brinjal with indigenous varieties.
- 18. GM crops have adversely affected honeybee populations in many countries including India, USA, Australia, Germany by disrupting their communication mechanisms which are critical for their food-finding and other life processes. Reduction in the population of honeybees will harm floral diversity as they are the main pollinating agents.
- 19. The number and types of non-target species studied by Mahyco are not adequate.
- 20. The spread of Bt genes into the wild relatives of cotton, brinjal etc through cross-pollination will certainly seriously disrupt natural biological communities.
- 21. The brinjal is included under the genus Solanum which is one of the largest genera with more than 1,500 described plant species. India, and specifically Orissa, has a rich variety of brinjal species. So, there is absolutely no need for any new methodologies to improve the vigour of the brinjal crop.
- 22. All pests are a creation of nature, with equal rights to feed and survive, and the mere 5 10 % loss due to pest attack in no way hampers the production rate of brinjal.
- 23. In addition to the pollen pathway, there are also other routes through which Bt gene can contaminate. Once released, the transgene could never be traced or controlled in case of a future negativity.
- 24. Small and marginal farmers have very small land holdings and cannot maintain isolation distance to check transgene out-pollination.
- 25. The pollen flow and gene pollution studies have not been conducted scientifically.
- 26. Monoculture of Bt Brinjal will quite risky under epidemic and changing climate conditions.

- 27. Bt Brinjal will lead to homogeneity and monotonous similarity of the fruits.
- 28. It can have long term implications on human health, farming methods, native varieties, adjoining non-Bt crop cultivations, environment, soil, ecology, biodiversity and the web of life.
- 29. Soil pollution will also occur due to shoots and leaves falling on the ground.
- 30. To mitigate climate change people are turning to traditional agricultural practices and organic faming while GM crops need more water and pesticides.
- 31. The un-sustainability issue linked with Bt crops should be considered.
- 32. The GM technology may appear lucrative, but would not help civilization and protection of the environment in any way.
- 33. The cross-pollination studies do not take into account the possibility of contamination by bees and other insects.
- 34. The fertility of the soil has been reduced and has practically disappeared after cultivating Bt cotton for a few years.
- 35. Local traditional varieties have been developed by farmers over a long period of time based on the climatic and edaphic conditions of the area. These varieties are very important for combating the menace of climate change. The monoculture introduced throughout the state of Gujarat will cause irreparable damage to the ecosystems and the socio-economic conditions of the farmers.
- 36. Sustainable agriculture depends on a functional and supportive soil-food web, which determines the fertility of the soil. The introduction of Bt toxin may badly disturb this soil-food web due to the destruction of several types of useful micro-organisms, in addition to its biochemical impacts.
- 37. We have a native variety of brinjal called '*Kantawala* brinjal' in Saurashtra (Gujarat), famous for its taste and life-promoting qualities. Such local species will be threatened by the introduction of Bt Brinjal.

- 38. The introduction of Bt cotton has led to rapid depletion of nutrients and micro-organisms from the soil. Minor pests are qualifying as major pests.
- 39. Countless varieties of brinjals are cultivated all over the nation at varied agro-climatic zones. Will the GM crop match up to the naturally available climate resistance as in case of the indigenous brinjal varieties?
- 40. India is rich in brinjal diversity. Bt has transgressed into 40 local varieties of cotton, thus eroding native diversity. Similar will be the case with Bt Brinjal. Native diversity of Solanum species will be eroded.
- 41. In recent years the incidence of fruit and shoot borer has come down and there is no need for Bt technology.
- 42. Trees are not growing in places where Bt cotton is grown. Also crops like pulses do not grow well on those lands. Soil fertility is being reduced due to decomposition of Bt leaves in soil. The toxic residue is said to remain in the soil for a year. Sheep have been known to have died after grazing in cotton fields. Effects on soil fertility should be studied from the point of view of direct, residual and cumulative additions of Bt toxin to soils.
- 43. Studies have proved that it affected actinomycetes which break down soil to form humus.
- 44. Bt trait is variable under different weather conditions. It will be unsustainable under circumstances of climate change. Ours is a large country with several agro-climatic zones. Therefore, large numbers of trials should have been conducted on farmers' fields in different parts of the country.
- 45. No environment impact assessment for Bt has been done in our country. It can be introduced only after such clearance.
- 46. Bt cotton may have used less pesticides than non-Bt cotton but it requires far more fertilizers, which has serious implications regarding soil pollution.
- 47. Horizontal DNA transfer from Bt cotton is suspected to have destroyed citrus and teak plantations in Vidarbha, Maharashtra.
- 48. Bt strains can be detrimental to many scheduled wild species, especially avifauna, and ungulates.
- 49. The complexity as well as inter-relatedness of species within ecosystems is such that the prediction of impacts from human interventions can not be made with certainty, nor can the time frame within which the impact will escalate be predicted. The precautionary principle is, therefore, paramount in giving clearance to any major or widespread intervention.
- 50. Bt toxin will hugely affect a large number of lepidopteran pollinators that provide crucial eco-system services for the agro-ecosystems. It has already been affected considerably due to chemical toxins. Bt toxin will aggravate the conditions.
- 51. With extreme fragmentation of land in West Bengal, and with a population density of 990 persons per sq. km, where intensive cultivation of vegetables is often done in plots even less than 900 sq m the major germplasm would be totally contaminated by Bt crops within a period of 2 years if released for commercial cultivation. Also, with such small holdings, it is impossible to keep a minimum distance of 30 m to protect non-GM Brinjal varieties from contamination.
- 52. Brinjal is insect-pollinated, hence the distance travelled by pollen depends on how far the pollinator carries it, which can never be confined to 30 m.

- 53. GM Canola cultivation in Canada has resulted in no non-GM Canola remaining in the entire country. The genes have contaminated the entire seed stock of the nation.
- 54. Local high-yielding varieties are there in India, like Pusa Kranti and Pusa Navkiran developed by Indian Agricultural Research Institute. Then, why Bt Brinjal?
- 55. With over 50 more genetically modified (GM) crops reportedly in the pipeline in India, we must exercise utmost caution. Once released, the damage, if any, can never be undone.
- 56. We cultivate Bt cotton in Haveri District of Karnataka and have not experienced any soil contamination. It has also given us financial independence.
- 57. Karnataka has 40 varieties of brinjal, and there is no need for any specific technique to be invented.
- 58. A single Bt variety will push out all local nutritive land races.
- 59. Mattu Gulla is a special brinjal endemic to Udupi in Karnataka. Its skin is thin, seeds are not bitter and, after cooking, the pieces retain their firmness and has a special taste. Caution must be taken that such local varieties are not wiped out because of the introduction of GM seeds. It should be registered under Geographical Indication (GI) of Goods and Registration and Protection Act 1999.
- 60. We have many important medicinal weeds and crops in the Solanacae family. What will happen if those get contaminated?

Pest Management

+ 61. The use of Bt cotton has resulted in a decrease in the types and quantity of pesticides, thus financially benefiting farmers.
+ 62. Chemical pesticides fail to prevent pest caterpillars from entering brinjal fruits. Only the Bt technology is found to reduce fruit damage effectively.
+ 63. A survey of more than 3,063 farmers in Andhra Pradesh, Madhya Pradesh, Maharashtra, Gujarat and Karnataka growing Bt and non-Bt cotton (ACNielsen ORG-MARG, 2004) revealed that, due to control of bollworm, on an average, the Bt crop showed an increase in yield by 29% and reduction in pesticide sprays by 60% as compared to non-Bt cotton.
+ 64. All traditionally available methodologies are inadequate for the control of pest infestation in brinjal. In this context, Bt Brinjal will be a boon to farmers.
+ 65. Much of the pesticides and insecticides applied have killed the natural competitors of root and stem borer insects and thus have depleted the protection offered by nature against pest attack on brinjal.
+ 66. Pesticides do not degrade easily. This accumulation may have serious consequences if left unchecked. It not only degrades the soil quality but may also contaminate water bodies, associated organisms and the ecosystem as a whole. GE does not create such problems.

\+ 67. The potential application of GM crops in developing countries is limited because of a lack of knowledge about GM crops. The technology is not to be blamed.

\+ 68. Bt is a better alternative to conventional pesticides which pollute the environment.

\+ 69. The criticism of Bt cotton and Bt Brinjal by farmers is baseless as they have often used Bt spray as a pesticide.

\+ 70. Bt protein is highly degradable and it does not contaminate other crops easily.

\+ 71. Through conventional breeding there is the problem of finding the resistant variety for fruit and shoot borer. There is nothing wrong in welcoming a new technology like Bt in this situation. Benefit is more important than unfounded fears. Scientists cannot go forward with obstacles like these.

\+ 72. Bt technique is scientific and good for environment as well. In the current situation it is not possible to follow organic farming or Integrated Pest Management (IPM) to increase the yields even though they are good practice.

\+ 73. The fact that farmers continue to use insecticides in large quantities implies that non-pesticide practices are not preferred by majority of the farmers. GM crops can be made resistant to powerful herbicides.

\+ 74. Sixty percent of the plant protection cost is for controlling fruit and shoot borer.

\+ 75. Small and marginal farmers use 25-80 sprays of pesticides in brinjal cultivation.

\+ 76. Larvae are often hidden in the fruit and do not come in contact with the insecticides. Also, the application of pesticides has to be critically timed by farmers in such a way as to kill the larvae before they bore into shoots and fruits.

\+ 77. Bt Brinjal will reduce the pesticide usage in cultivation by 80%.

\+ 78. Existing non-pesticide pest management practices are not sustainable at the field level.

\+ 79. With Bt, the use of systemic and contact insecticides against FSB (25-80 in number) will reduce by 70% ,and thus will also reduce insecticide residues significantly.

\+ 80. Reduction in insecticide sprays will improve soil quality over a period of time.

\+ 81. Mahyco studies involved recording observations of the most commonly observed non-target pests. All the studies were based on protocols approved by experts in respective areas of research.

\+ 82. During Mahyco research, observations on non-target pests were recorded at over 60 locations during 2004-2008, spread across different agro-climatic conditions, in replicated trials and different sampling time points in an exhaustive manner.

\- 83. New as well as currently minor pest species (like mealy bugs) will replace fruit borer and fruit & shoot borer. This will create a need for a new technology.

- 84. Non-chemical IPM and organic farming need minimum pesticides, create no pollution, and offer more yield. Hence they, rather than GE technology, need to be promoted.
- 85. Bt cotton in India was more susceptible to leaf-curl virus and root-rot disease and suffered greater damage during drought than traditional non-Bt cotton varieties.
- 86. At the late developmental stage of Bt cotton, its resistance to bollworm decreases because Bt gene expression decreases.
- 87. GM increases resistance to diseases and herbicide.
- 88. Oriya farmers still practise organic farming at large. Chemical fertilizers and pesticides are not used in large amounts in Orissa as compared to other states. Therefore, there is absolutely no point in introducing Bt Brinjal to reduce the use of pesticides.
- 89. Bt Brinjal is not needed when safer, affordable, sustainable and farmer-controlled alternatives exist for pest management. Integrated Pest Management (IPM) and Non-Pesticidal Management (NPM) work well for pest management in brinjal cultivation.
- 90. We are talking of genetic modifications for controlling the attack of FSB (fruit and shoot borer) only. The rest of the many insects are often more of a problem and may even make the engineered crop more susceptible to sucking insects.
- 91. What if the targeted insect develops immunity in future? Is this the only solution to control pests in India?
- 92. International experience shows that even after the introduction of genetically engineered crops, the use of pesticides does not go down. Hence the introduction of Bt Brinjal will not reduce the use of toxic pesticides, and the environment will continue to be polluted.
- 93. We have bio-pesticides prepared by ICAR which are equally effective against pest infestation. Then why use a genetically modified crop like Bt Brinjal?
- 94. A Canadian Government study showed that after just 4-5 years of commercial growing, herbicide-resistant GM oilseed rape (canola) had cross-pollinated to create invasive super weeds resistant to up to 3 different broad-spectrum herbicides. Similarly, a recent analysis of data from the US Department of Agriculture (USDA) reveal that the cultivation of GM corn, soybeans and cotton has increased the overall use of toxic herbicides by 318 million pounds in the U.S. over 13 years from 1996 to 2008 because of the emergence of herbicide-resistant super weeds infesting millions of acres. About 46% of this increase occurred over the last 2 years, 2007 and 2008, for which data were available. In our Indian agro-climatic conditions, such problems are expected to manifest much faster.
- 95. Brinjal is one of the highest produced and consumed vegetables in India, and there is no current shortage. There are various traditional holistic methods of protecting brinjals against pests that have been practised for hundreds of years.
- 96. In Karnataka, the horticulture department has ranked brinjal 14th in pesticide consumption and it is not the main guzzler of toxic chemicals. Hence the need for Bt technology in brinjal is in question.
- 97. There is no point in replacing one toxic, unsustainable technology with another, that too with a technology that may have irreversibly harmful consequences.
- 98. The superiority of Bt technology over other methods has not been clearly established.

- 99. Bt Brinjal, once released, cannot ever be recalled, nor can the ecological chain reactions it unleashes be stopped.
- 100. If the Bt gene is to be used, its use must be selective - only where it will have a clear advantage over other approaches. Currently, almost 40 % of Indian transgenic research is based on the Bt gene. Overuse of the Bt gene and the planting of Bt crops in all crop seasons will ensure faster build up of resistance in the pest and collapse of the Bt strategy of pest control.
- 101. The biology of the target pest and its susceptibility to a range of insecticidal proteins (non-Bt as well as Bt sources) both parts of its critical evaluation are not understood well.
- 102. Even though Bt has proved effective for cotton, introducing Bt for a less economic crop like brinjal is debatable. It is required for other major crops like rice and wheat.
- 103. Development of resistance is a fact of evolution and this is definitely going to happen in Bt over time.
- 104. Bt is being promoted as alternative to pesticide-based pest control. But there are several non-chemical alternatives available for this. Bt controls only fruit and shoot borer but there are other pests like whitefly and the infestation will increase in the absence of the fruit and shoot borer. Again, one has to depend on pesticides for controlling this phenomenon. This will increase the cost when the seed cost itself is high.
- 105. In changing climatic conditions one cannot predict what might happen in pest ecology.
- 106. No yield differences are observed between organic and chemical methods. These alternatives should be evaluated and promoted by scientific institutes instead of bringing in Bt.
- 107. Perceived benefits should be checked with IPM. The technology per se is not sustainable and bio-magnification in life forms will happen over time.

- 108. Due to Bt cotton Heliothis left and pink boll worm took over and they are inserting another gene. This story will continue further until several genes are introduced.
- 109. GMO-based agriculture needs fifty times as much energy as organic farming.
- 110. Pests / insects are major problems for our agriculture. We have been using various expensive pesticides for many years now but we have learned over a period of time that all pests should not be killed but managed or controlled. If farmers adopt such practices then there is no need to accept Bt Brinjal.
- 111. At Nanded, Maharashtra, in case of white flies, 25% Bt crop had high incidence, which was 3 % higher than non-Bt cotton. In case of mites and aphids, 22.5% and 28.4% Bt cotton had high incidence, respectively while the incidence on non-Bt cotton was 16.6% and 19.7%, respectively. Thus, though Bt cotton has reduced infestation of boll worm, other pests are replacing it now.
- 112. At Nanded, Maharashtra, an average 1.24 insecticide spray per acre is applied for controlling boll worm on Bt cotton plants for every spray for non-Bt varieties.
- 113. The weight of a Bt cotton boll is less than non-Bt varieties.
- 114. FSB resistant natural Indian varieties already exist. Government should initiate research programmes for their improvement and propagation.
- 115. Bt cotton has altogether failed as a crop. The essential inputs in terms of fertilizers and pesticides have been significantly more than in case of non-GM cotton.
- 116. Official data from major producer countries US, Argentina and Brazil confirm that pesticide (both insecticides and herbicides) use increases with GM crops, including the use of toxic chemicals banned in some European countries.
- 117. Fruit and shoot borer is a minor problem in brinjal cultivation in West Bengal. The major constraints in the state are serious infestations of bacterial wilt caused by *Pseudomonas solanacearum* and 'little leaf disease' caused by phytoplasma.
- 118. Is there any comparative study of Non Pesticidal Management, indigenous variety and organic farming including mixed cropping?
- 119. Controlling pests with single toxic molecules either produced in factory or plant cell is an unscientific way of managing pests. Pests should be managed, not killed.
- 120. According to studies under National Agriculture Technology Project (NATP) by ICAR, 1. mixture of tobacco, water and soap and 2. use of Kochila (*Strichnos nuxvomica*)-mixed cow dung compost are very effective chemical-free options to control FSB. Such options need more research and commercial use.
- 121. Bt Brinjal conflicts with India's Environment Protection Act notification.

Economy and Livelihoods

+ 122. Inadequate knowledge among the farmers as to the cultivation of Bt cotton results in loss; the technology itself does not have problems as such.
+ 123. Unlike other hybrid varieties, Bt Brinjal seeds can be reused, which will save the cost of purchasing fresh seeds.

+ 124. If Bt Brinjal helps in getting higher profits, it should be allowed.

+ 125. If Bt Brinjal is raising the crop output, income and profit then some farmers have no problem in cultivating it.

+ 126. The United Nations Millennium Development Goals support the need and use of biotechnology for the advancement of food security.

+ 127. The World Health Organization upholds the importance of biotechnology in food crops.

+ 128. I find a great change in the standard of living of the rural agriculturists. Their children now attend schools and universities and they are living in moderately good buildings and riding motor cycles. The time has arrived when agriculture grew into industry because of the growing use of mechanical technology and biotechnology.

+ 129. Bt Brinjal's high yield would spell greater economic stability and mitigate the financial problems of farmers that are caused by poor yield due to traditional cultivation.

+ 130. Isolation distance in brinjal or other crops is required for seed production purposes, and farmers are used to maintaining such stipulated distances when they are undertaking such activity. Therefore, it is not correct to say that farmers cannot maintain isolation distance required in case of Bt Brinjal cultivation.

+ 131. Cultivation of Bt Brinjal will reduce insecticide use against FSB by 70% and so the pesticide costs for the farmer will be significantly reduced. The cost of seed to the farmer is less than 3% of the cultivation costs of Bt Brinjal and hence the question of substantial increase in input costs does not arise.

+ 132. Tamil Nadu Agriculture University (TNAU) and University of Agricultural Sciences, Dharwad are fully geared to multiply commercial seeds of Bt Brinjal for distribution to farmers soon after the grant of approval for commercial production of FSBR resistant seeds by the Regulatory Authority. They would commence the seed production activity on their own land, and both the universities have a very strong capacity to multiply and distribute seeds to resource-constrained farmers. Thus, fears of monopoly of a multinational company over seeds are unfounded.

+ 133. Although on a national scale while Punjab & Haryana may not be high in brinjal production, farmers located close to the highways like GT Road have sizeable brinjal plantations, and their produce easily reaches the markets of Delhi, and even as far as Kashmir. Such farmers will favour Bt Brinjal if it promises higher yields and brings them more income.

+ 134. The farmers are also getting commercially-minded nowadays, and want to produce for profit. If new technologies promise higher profits, the farmers have a right to choose. If they do not find the technology feasible they will reject it, and the companies will be forced to shut shop. Thus, the government should not shy away from introducing Bt Brinjal.

+ 135. At present, the percentage of organic brinjal growers/exporters is negligible in the total production of brinjal in the country.

+ 136. The pricing of the seeds will be based on a cost-recovery model, making it affordable for all farmers, whether the seed comes from the private sector or the public sector.
+ 137. Because of Bt technology, cotton yield has increased from 120 kg of lint per acre in 2000s to more than 200 kg per acre now.
+ 138. We have been able to economically benefit considerably from Bt cotton; my children now study in good schools.
+ 139. Bt Brinjal can be further made use of by farmers, because non-Bt can only be cultivated in the monsoon while Bt Brinjal can be cultivated at any time with less water.
+ 140. Cotton production in Gujarat has increased since the introduction of Bt Cotton from 25-30 lakh to now over100 lakh bales.
+ 141. Organic farming will never feed the country or ensure food security. The only alternative when pesticides fail to improve yield, is GM crops.
+ 142. Bt Brinjal was developed to ensure profitability for small and marginal farmers.
+ 143. India was the fifth or sixth ranking nation in the world in cotton production and now it is second. This is because of Bt cotton.
+ 144. The marketable fruit yield is more than 95% and significantly reduces the need for pesticides in case of Bt Brinjal.
- 145. A monopoly of multinational companies in seed production and sale of the seeds is not in the economic and political interest of India.
- 146. Seeds with a herbicide-tolerant trait should not be permitted in India as it will displace agricultural labour and destroy valuable plants used as food, fodder and medicines.
- 147. Production of Bt cotton decreases over subsequent years. Hence it is not profitable for farmers in the long run.

- 148. Bt Brinjal production in excess of demand will reduce its price in the market and, thus, profit margins for the farmers will shrink.
- 149. Bt cotton seeds have dominated markets due to manipulative systems, and farmers as consumers are forced to purchase it due to difficulties in purchasing non-Bt varieties.
- 150. Farmers in Maharashtra and Andhra Pradesh have committed suicide due to losses occurring from Bt cotton crop failure and heavy investment farming.
- 151. Compensation packages for farmers in case of Bt cotton production being lower than estimated need to be worked out and implemented.
- 152. Farming of GM crops is contaminating the soil. Thus, organic farmers are incurring financial losses because of denial of accreditation by certifying agencies.
- 153. India should be self-reliant in developing new technologies, which will help avoid drain in profits, and technologies will be based upon locale-specific issues.
- 154. Soil contamination from Bt cotton has affected small and marginal farmers the most.
- 155. Farmers will need to buy Bt Brinjal seeds every year if seed quality is not good. Small farmers cannot afford this.
- 156. GE is not an answer to food security; better storage, distribution, pricing and marketing strategies will eliminate the need for the risky GE technologies.
- 157. Traditional seeds make farmers self-reliant in terms of storage and re-use, Bt technology will make them dependent on market forces.
- 158. Bt technology has helped only large (1-2%) land owners, not small land owners (70-80%). So, it requires reconsideration.
- 159. Tribal, poor and marginalised people depend on forests and natural areas for food. GM crops will destroy the natural gene pool and thus threaten these sections of the society in the long run.
- 160. GE does not increase the production of a crop. In developing countries like Mexico, Vietnam, Thailand and Egypt there has not been substantial increase in yield. Production of Bt cotton at Hainan, Southern China has never increased compared to northern China.
- 161. Bt products are economically not viable.
- 162. Brinjal is already produced in huge amounts all over the state of West Bengal, so much so that the surplus goes to cattle feed. So what is the need for Bt Brinjal?
- 163. Poor farmers will get even poorer if forced to consume Bt Brinjal and face health hazards as a consequence. They are afraid of running to doctors and spending their limited income on unnecessary health problems which may result from the consumption of Bt Brinjal.
- 164. High brinjal production will lower prices and farmers may not recover even the production cost. There are several instances of farmers dumping onions and suffering heavy losses.
- 165. In case of Bt cotton, the production costs are very high and unaffordable for the small and marginal farmers. The same situation will occur in the case of Bt Brinjal, too.
- 166. Farmers will have to pay high prices for Bt Brinjal seeds, and the burden will be passed on to consumers.

- 167. There are chances that the pests build resistance to the Bt toxin. Will this not make our agriculture, and thereby the farmers, more and more dependent?
- 168. Almost 80% of India's farmers still follow the traditional system of saving, sharing and exchanging/bartering seeds, and hence do not buy them. It is important to maintain sovereignty of these farmers and their traditional methods.
- 169. No cotton seeds apart from Bt are now sold in Amaravati, Maharashtra; the local farmers there (as also in Andhra Pradesh) have no choice but to buy Bt.
- 170. The Chairperson of India's Agricultural Scientists Recruitment Board projected that even a 6% expansion in GM crop area would lead to a doubling of chemical fertilizer consumption. Already, India's annual fertilizer subsidy bill stands at a whopping Rs 1.2 lakh crore, a recurrent and mounting expenditure. So, the use of GM crops will be a financial disaster for India.
- 171. GM crops are strictly prohibited in organic farming anywhere in the world, as pointed out by the International Federation of Organic Agriculture Movements (IFOAM). Presence of GM in any crop immediately debars it from organic certification, with serious consequences for organic exports, a "sunrise sector of the global economy."
- 172. After four years of study and deliberations by an international panel of over 400 agricultural scientists from 60 countries, the final report of the 'International Assessment of Agricultural Science and Technology for Development' (IAASTD) was released in April 2008. It recommended that small-scale farmers and agro-ecological methods are the way forward, with indigenous knowledge playing an important role. It pointedly noted that GM crops are not the answer to hunger, poverty or climate change.
- 173. Crops like rice, especially basmati rice, soybean, tea, spices etc in which India has trading interests must not be genetically engineered since that will result in lost export markets.
- 174. The programme to genetically engineer medicinal plants must be stopped. These will be unacceptable in the international market. It is highly likely that rearranging of the genetic material could result in changes in the constitution and profile of plant metabolites that confer the healing properties.
- 175. Organic farmers should receive as much support from the state as investment in biotechnology, as only the subsidies make these types of seeds economically viable.
- 176. Bt cotton has caused a considerable increase in the use of child labour in Gujarat.
- 177. The girl child is sent to work in the Bt cotton fields instead of to school.
- 178. Are we certain that any increase in brinjal production by Bt Brinjal cultivation will ensure an increase in our exports? Experience shows that several nations will not accept Bt foods.
- 179. GM crops have been banned in many nations as it has been observed that the condition of labour in these areas is extremely bad. The long term impacts on daily labour has been considerable.
- 180. Due to the fact that the seeds are considerably expensive, it has been found that the daily labourers are paid less or made to work harder than before to compensate for the increased costs.
- 181. No actual study has been done in India to evaluate the conditions of workers engaged in Bt cotton cultivation, but the suicide rate among Bt cotton farmers is well documented.

- 182. The cost recovery model for seed pricing suggested by Mahyco has not been explained.
- 183. Even though the company (Mahyco) has suggested that the Bt cotton seeds can be re-used it has been noted that the production in the second generation reduces considerably, making this an unviable and pointless suggestion.
- 184. Seed prices of GM crops have seen massive increases. There could be sudden and direct impacts on farmers who begin to cultivate this variety if the price rise were to occur in India.
- 185. No suicides have been noted among organic farmers. As traditional farming has already become very high-input cost-farming. The high cost Bt Brinjal seeds will make it additionally so.
- 186. With an increase in the supply of brinjal through the introduction of Bt Brinjal, there is no guarantee of an increase in effective demand for it in the domestic markets.
- 187. The tribal belts of Gujarat have developed and progressed solely on Bt cotton.
- 188. Any increase in the production of Bt Brinjal does little to challenge the issues of food security in this country.
- 189. Any increase in the production of cotton in Gujarat is because of the farmers having developed local, improved varieties and not because of Bt cotton.
- 190. Farmers need support in terms of electricity, land rights, irrigation etc. Bt Brinjal will not solve any of these problems.
- 191. I have a larger debt than my father's: I grow Bt cotton and if I was economically doing well this would not be the case.
- 192. Small and marginal farmers will be forced to abandon agriculture and join the ranks of agriculture labourers and subsequently live in urban slums.
- 193. Organic farming prohibits the use of any genetically modified inputs. With the advent of GM crops, the problems of contamination have increased tremendously. There is a risk of losing out potential export market worth Rs. 1,00,000 crore for fruits and vegetables.
- 194. The introduction of Bt Brinjal would raise suspicion in the international community regarding other vegetables too (due to horizontal gene transfer within the family) and would adversely affect our exports.
- 195. The gene revolution may reduce farmers' control over their own seeds.
- 196. The Bt seeds will be very expensive. Also, they can be used only once, which further raises the cost of cultivating Bt Brinjal.

- 197. In India, 85% are marginal farmers. They require small or low cost technology. Bt or GMO technology is not affordable for them.
- 198. The crop lost by the two pests is only 20%, and the economic loss is 10%. If this technology fails to stop pest attacks, the farmers will have to bear additional economic loss.
- 199. If Bt is so controversial and expensive then what is the need for it, especially when the developed countries have already rejected Bt crops such as maize and cotton?
- 200. If there is enough profit then farmers will cultivate Bt Brinjal. Otherwise not.
- 201. Bt is stress-intolerant. Hence, farmers may suffer huge economic loss due to failures of crop in case of droughts or floods.
- 202. The GM crop will destroy the livelihood of several marginal and landless labours.
- 203. Many consumers might not prefer eating Bt Brinjal, hence the marginal farmers who cultivate Bt Brinjal might incur huge financial losses.
- 204. There would be problem of seed security and it would lead to dependence on MNCs for seeds.
- 205. The herbicide-tolerance trait must not be permitted in India as it will displace agriculture labour, especially women, who earn wages from weeding and other farm activities.
- 206. Application of herbicides will destroy the surrounding biodiversity which is used by the rural poor as supplementary food, fodder and medicinal plants. It will also make it impossible to practise mixed farming.
- 207. Exhaustive socio-economic studies are necessary to assess the impact of transgenic crops on traditional agricultural systems and indigenous crops.
- 208. Bt cotton fails like any other crop will if the monsoon fails. However, if water is ensured the crop has been seen to be profitable.
- 209. There is no study that is able to directly co-relate farmer suicides and Bt cotton production.
- 210. At present, 30% of seed production business in India is in the hands of multinational companies, and further increase is not good.
- 211. GM crops require irrigated land and are not suitable for dryland farming. Most farmers have gone bankrupt because of Bt cotton farming in Vidarbha of Maharashtra.
- 212. The seed cost of open pollinated varieties ranges from Rs. 1500 to Rs. 2000 a kg whereas the cost of Bt seeds ranges from Rs. 5000 Rs. 8000 per kg. Moreover, an efficient farmer keeps the seeds for years together and hence that is part of sustainable agricultural practices.
- 213. The productivity and production of Bt Brinjal and the earnings of farmers may increase in the short run, but positively not in the long run. On the other hand, the cost of cultivation will increase greatly after a few years.

- 214. Organic farming, if holistically adopted, can revitalize society, enhance the environment and safeguard future generations.
- 215. Cuban Organic Farming Association showed that organic agriculture is a key to both food security and environmental sustainability.
- 216. West Bengal is already surplus in brinjal production and in another decade the surplus would be around 58%.
- 217. A vast majority of GM crops are not grown by or destined for the world's poor. They are used for animal feed, bio-fuels, or highly processed food products in rich countries.
- 218. Most commercial GM crops are grown by large farmers in a handful of countries with industrialized, export-oriented agricultural sectors.
- 219. It is widely accepted that GM crops do not necessarily yield more as they have no specific genes for high intrinsic yield; and in some cases they yield less than conventional crops.
- 220. The technology may cause undesirable degeneration and low quality product may be obtained.
- 221. It is worth noting that almost all farmer suicides have taken place in belts where Bt cotton has unleashed a chain reaction of pesticides, seed monopolies and debt. No pesticide dealer or GM seed dealer is ever reported to have committed suicide. This is a pointer to the reality.
- 222. Punjab farmers grow food for the whole nation. But in the last 40 years they have got only debt and suicides as rewards, thanks to the imposition of pesticides and foreign seeds. Now Bt cotton and Bt Brinjal are going to push them further into the same cycle of debt.
- 223. Sustainable development is the model of development that favours local people and community needs. Propagating GM seeds is against local people and it favours big multinationals for reasons that include intellectual property issues.
- 224. Additional burden of chronic diseases related to GMOs essentially will translate into economic burden due to increased cost of treatment and loss of productivity related to person-days lost on account of illnesses.
- 225. If consumers do not buy Bt Brinjal then farmers may suffer losses.
- 226. The production of Bt varieties will be 300-600 quintals/hectare. Our average indigenous brinjal gives us 600-700 quintals/hectare. A fully organic field can give up to 1000 quintals/hectare.
- 227. In sustainable agricultural practice, we grow beans, coriander, marigold etc. with brinjal, which gives us extra income.

Consumer Concerns

+ 228. Organic farming cannot sustain the rate of production and would ultimately lead to unchecked price rise, which will hamper our economic status for sure.

+ 229. Bacteria are microscopic and they need not necessarily enter the food chain only through Bt Brinjal as they can enter it otherwise also. The manifested symptoms thus cannot be necessarily accounted for by Bt toxin in brinjal.

- 230. Bt Brinjal will dominate the market and reduce availability of traditional varieties to consumers.

- 231. Bt Brinjal should be marked for differentiation through labelling so that consumers have a choice.

- 232. Bt cotton has increased production but cotton prices have not come down. On the other hand the costs are increasing. If a similar fate meets Bt Brinjal, consumers will not benefit from it.

- 233. Brinjal is not a costly vegetable (Rs. 8 to Rs. 24 per kg, depending on seasons and places). Thus it is not an important crop that needs genetic manipulation.

- 234. Many districts (Kandhamal in Orissa in particular) cultivate brinjals that are known throughout the state for their excellent taste and nutritive value - no artificially engineered brinjal can match up to its vigour.

- 235. If Bt Brinjal is approved, consumer choice will be violated forever, as they will have no way of knowing whether the brinjal they are consuming is GM or not. This will be a violation of the right to know, right to safe food and right to informed choice with regard to food.

- 236. GM seeds contain genes of animals and insects and this is totally unacceptable in the context of the Indian ethos.

- 237. If Bt Brinjal infiltrates the market, significant sections of people, conscious of its hazards, may be forced to stop eating brinjals altogether. They would thus be deprived of a cheap and excellent source of vitamins, minerals and amide proteins.

- 238. It is significant that brinjal is one of the most affordable vegetables abundantly available all over India, second only to the potato in the total quantity grown and consumed. Why should we take chances with its availability to poor citizens?

- 239. With GM pushing up production costs, mal-distribution of income and hunger are sure to rise among the poorest sections, apart from malnourishment and cumulative toxemia.

- 240. Bt Brinjal, involving a gene insert from another organism, cannot be accepted as a pure vegetarian food.

- 241. Consumers should have the right to select non-GM.

- 242. GMOs were opposed by many European countries and Japan. Then, why is India opting for it? This violates consumers' right to safe food.

- 243. Will Bt Brinjal be tasty, nutritious and healthy?

- 244. Consumer's right to choice for non-Bt Brinjal has to be asserted by proper labelling of the product, which is not properly regulated in India.

- 245. A monoculture that could result from Bt Brinjal will completely destroy the local cuisines made from specific varieties of brinjal.

- 246. Bt cotton has gradually monopolized the market. So, even if one were to choose to buy non-Bt seeds, they are considerably difficult to find.
- 247. If this crop gets commercialized, we as independent consumers trying to make an educated choice need separate shops for Bt and non Bt Brinjal. Will the government be prepared to provide the same?
- 248. As a citizen, I demand that I get food Bt free and pesticide free.
- 249. The introduction of Bt gene has reduced photosynthetic capacity of the plants by 20%. Hence, calorific value has been reduced by 50%.
- 250. A number of GM crops currently exist in the food chain such as maize, soyabean, potato, canola, papaya, cotton, to name some. Also, there is no labeling required once the product has been deregulated.
- 251. The issue of the Bt gene having an effect on the medicinal properties of other Solanum species is erroneous and unscientific.
- 252. The taste of brinjal is gradually decreasing due to pesticide use. Bt might help to address this.
- 253. The simple reason for saying no is that it introduces toxins into my system, and I do not want it even if it does not harm me.
- 254. Health impact assessment has not been done properly. When GM foods were introduced in USA there was an increase in allergic problems by up to 70%. As an Indian I have the right to choose between Bt and non-Bt. Non-labeling will obstruct our fundamental right to choose.
- 255. Toxic food is not food security.
- 256. The natural taste and flavour of brinjal will be lost.
- 257. Commercialisation of Bt Brinjal and its use could impact the life-span of consumers.

- 258. How will Government put into practice the concept of labeling in case of a product like brinjal? If the consumer does not know what he/she is buying and eating, it is an infringement of the individual's right to information and right to informed choices.
- 259. Bt Brinjal is just a test, the beginning of an invasion of our food platters with GM crops, and an invasion of our consumer rights, the long-term impacts of which none of us realizes.
- 260. We the Jains will consider all GM foods as non-vegetarian because of the presence of bacterial gene, and we demand strict labeling of such food items.
- 261. Bt cotton had increased production but still the prices have not come down. This may happen again with Bt Brinjal.
- 262. According to the Consumer Protection Act 1986, a consumer has the right to know what he is paying for. This would be violated as Bt Brinjal is indistinguishable from the natural brinjal without laboratory testing.
- 263. While biotech industry insists on the Principle of Substantial Equivalence and thus Generally Regarded As Safe (GRAS) concept for GM foods a consumer cannot avoid Bt Brinjal unless he avoids brinjal altogether, and this violates his right to eat brinjal
- 264. To a consumer's mind the scientists who aggressively promote GM technology and GM products are suspect, especially when they trivialize doubts and refuse to engage in point-to-point discussion. The fact that in many universities, multi-national seed corporations are funding research adds to these doubts.
- 265. When we note that Monsanto, Archer-Daniels-Midland and WalMart have official status on KIA (Indo-US Knowledge Initiative in Agriculture) Board, it leads one to wonder if there is external influence on India's agriculture and food policies.

Human Health and Bio-safety

+ 266. Rigorous biosafety tests have been done as required by the Indian regulatory system. This includes acute toxicity tests in laboratory rats, sub-chronic oral toxicity studies, allergenicity studies on rats and rabbits and feeding studies in fish, chicken, goats, and milking cows.
+ 267. In nature also, cross pollination of crops produce natural aberrations which will survive or die based on the survival of the fittest. In GM crops, as back- crossing is adopted, they get stabilized in a year. We have accepted wild races which are domesticated. In Ayurvedic medicines without even knowing the medicine what it is - people take medicines. Bacteria do not have positive or negative effects and therefore it becomes immaterial whether the brinjal eaten is Bt or non-Bt. Western foods like pizza ad burgers are being relished by Indians which are also harmful.
+ 268. Bt Brinjal carrying Cry1Ac protein shall not lead to health problems in any other organism because of high specificity. Voluminous literature is available on this. More powerful evidence is that in USA people are eating GM crops for the past 13 years and no adverse effects have been observed. Regulatory bodies and policies are in place in India. If they made all transactions in a transparent way, the apprehensions can be allayed. There should be initiation for large-scale trials comparing with all alternatives for FSB control practices. This should be done with public participation so that public awareness will increase. Non-pesticide control should also be checked vis-a-vis Bt Brinjal.

+ 269. The cattle deaths are due to high concentration of nitrates and pesticide residues but not Bt. Bt protein content was 5 micrograms which is within tolerance limits. However more trials are required to ascertain this.

+ 270. Organic farming also sprays Bt bacteria and even after thorough washing, the bacteria enter through food into our system. If that is safe for us, Bt Brinjal is also safe.

+ 271. The Bt gene breaks down during digestion into common amino acids, which are part of the normal diet and are neither toxic nor allergic.

+ 272. About 11 lakh tonnes of Bt Cotton oil is consumed annually by people, directly or through vanaspati. Mahyco claims, "As the Bt gene present in cotton is identical to that used in brinjal, there is a strong precedence for safety of the gene itself."

- 273. Transgene may enter human gut bacteria over the long term. The foreign gene and the protein they create will be harmful for us.

+ 274. In India, the vast majority of brinjal is consumed in the cooked form. Different cooking methods include deep frying, shallow frying, roasting and boiling. Apart from the fact that Cry1Ac is rapidly digested in gastric fluid, studies with Bt Brinjal showed that the Cry1Ac protein is not detectable within 1 minute of cooking by any of the various methods.

+ 275. Bt Brinjal is not the first GM crop entering the food chain. Bt Cotton-seed oil and cotton-seed cake are used in significant volumes and are already in the food chain since 2002.

+ 276. The Cry1Ac protein used in Mahyco studies is identical to the in plant Cry1Ac protein in Bt Brinjal. This has been established by scientific experiments as required by the regulatory authority

+ 277. Cry1Ac protein, expressed in Bt Brinjal, has been proven safe by various studies all across the world.

+ 278. Cry1Ac has a record of safe use of over 40 years worldwide, and is non-allergenic from the standpoint of stability, susceptibility to gastric fluid, sequence analysis etc.

+ 279. The pesticide decontamination procedures, particularly washing, will not remove pesticide residues from the fruit surface whereas cooking degrades the Cry 1Ac protein.

+ 280. During Mahyco studies, mammalian models were used for biosafety studies as humans cannot be used for these studies directly. Study protocols were reviewed and approved by experts in respective fields working under regulatory authorities. All studies were carried out at independent testing agencies based on the expertise required for the conduct of such tests.

+ 281. The Cry1Ac protein inserted into Bt Brinjal event EE-1 has been extensively studied for its safety. It has been well established that the Cry1Ac protein cannot cause any toxic effect in mammals because of lack of highly specific receptors and alkaline environment in the gut of mammals.

+ 282. It has been reported that 90 -110 days of age (mating age) of rats is considered equivalent to 21-25 years age of humans.

+ 283. Cry1Ac protein has a history of safe use for human and animal consumption as GM crops such as Bt Maize and Bt Potato containing Cry proteins including Cry1Ac protein have been consumed by millions of people with no adverse effects.

+ 284. During Mahyco studies, sub-chronic (90 days) feeding studies were carried out using goat, rabbit and rats, which are recommended across the world. No adverse effects were observed during these studies.

+ 285. A number of GM crops exist in the food chain such as GM cotton, soybean etc. So far no incident of allergenicity has been reported. Moreover, Bt Brinjal is no different in its composition compared to its non -Bt counterpart. Thus Bt Brinjal is as safe as non-Bt Brinjal.

+ 286. GM crops are the most studied and documented products in agriculture.

+ 287. A large number of recombinant DNA medical products developed by using genetic engineering, such as vaccines, insulin, etc are being used to alleviate human suffering and provide medical relief to patients in millions worldwide. Many products developed as a result of genetic engineering are being used in the area of human health in India.

+ 288. Cry1Ac protein has been shown to rapidly degrade (in 30 seconds) in simulated gastric fluid.

+ 289. In Punjab and Haryana, a number of farmer mortalities happen due to exposure during pesticide spraying operations. If Bt Brinjal can reduce pesticide use, why not allow it?

+ 290. Not just Bt Cotton or Brinjal, the government should quickly bring in a lot of other Bt crops so that pesticide use is reduced, production is increased and farmers' profits rise.

+ 291. The US regulatory agencies have released as many as 14 food items produced with GM techniques. Why not try to understand about their health impacts if any? We have experimented with only one and why are we scared of just the second GM crop in India?

+ 292. Fodder from GM crops (Bt cotton) has no adverse impacts on the health of cattle, sheep and goat.

+ 293. Expression level of toxic gene in Bt crops is very low and does not cause any health impacts on human beings.

+ 294. Using Bt crops is good for health as it does not need the spraying of hazardous pesticides.

+ 295. Upon heating and cooking under pressure the toxicity gets diluted or, in most cases, gets nullified. As brinjal is often cooked, this is bound to happen.

+ 296. Protein content is high in GM food.

+ 297. The non-Bt Brinjal crop is sprayed heavily with pesticides before sale in the market. The residue remains. This can reduce with Bt Brinjal.

+ 298. Oil from Bt cotton seeds has been available in the market for several years now, and no health impacts have been seen.

+ 299. The health problems that occur in India are an outcome of the very high pesticide residue on food.

+ 300. The weight of the pump used in spraying pesticide on crops, especially a crop like brinjal which has to be sprayed several times, is heavy, and its health impacts must be considered. Bt Brinjal will considerably lessen this burden.

- 301. Long-term studies on allergicity and toxicity have not been carried out prior to getting the approval for commercialisation of Bt Brinjal.

- 302. Consumption of Bt cotton fodder has resulted in mortality of cattle.

- 303. The understanding of health impacts from Bt Brinjal (cancer, allergies etc.) is not adequate and needs up to date research for a final conclusion.

- 304. Some farm workers exposed to Bt pesticide were seen to have developed skin sensitization and IgE antibodies to the Bt spore extract.

- 305. GM crops affect the reproductive system (fertility) in human beings.

- 306. CaMV 35 is Bt gene promoter for GM cauliflower and has been observed to activate dominant viruses.

- 307. Brinjal and many other crops with specific properties are used in traditional Ayurvedic, Siddha medicines; GM crops will be harmful if used in Ayurvedic treatment or availability of non-GM varieties may be difficult for Ayurvedic practitioners.

- 308. The experiences of Bt cotton cannot be applied to Bt Brinjal as brinjal is a food crop consumed by human beings as well as other creatures. Hence it needs stringent research before commercial use.

- 309. Mahyco and ECII report mentions only Cry1Ac protein while Bt Brinjal contains a fusion of Cry1Ab and Cry1Ac. Thus conclusions mentioned in these reports are not accurate and further studies based on the fusion (chimerical construct) are needed.

- 310. The EC II study is shoddy and superficial in a number of aspects other than the above, which have been criticised by many, and to the extent that no reviewer for a respectable journal would have considered it for publication.

- 311. The small numbers of rats used in the toxicity studies and the small numbers of brinjals used in the “compositional analysis” by Mahyco severely confound any attempts at statistical analysis of the results to the extent that only large, gross effects would appear as statistically significant in the data.

- 312. The statement that the transgenic insertion in Bt Brinjal “confers no advantage to recipients in terms of aggressiveness or growth characteristics” is hardly warranted by the data in the Mahyco study. It would require much better designed and careful ecological studies to arrive at such a conclusion.

- 313. CryAc protein has been observed experimentally to survive and indeed bind to mammalian gut. Additional 'in vivo' studies are required not only to look at the stability of the entire protein, but also to examine the degree of degradation that occurs, what kind of peptide fragments are generated on what time scale, and whether these breakdown products might have effects distinct from the intact protein.

- 314. The presence of marker genes which are antibiotic resistant in Bt Brinjal is a matter of grave concern. Bt Brinjal has two antibiotic resistance genes and they may express in human bodies in unexpected ways.

- 315. GM crops are not safe for infants, children, old people and pregnant women.

- 316. GM food can carry unpredictable toxins.
- 317. Bt toxin Cry1Ac has recently been shown to be a potent oral/nasal antigen and adjuvant.
- 318. Bt toxin Cry1Ac has recently been shown to be a potent oral/nasal antigen and adjuvant.
- 319. The after effects on cattle from eating raw Bt Brinjals is yet another sensitive question to be answered by experts as research in this area is lacking.
- 320. No field trials of the crop have been carried out till date; all are mere laboratory reports.
- 321. One gene is not meant for one function. Any foreign gene can produce some novel protein which may lead to cancer or some unknown diseases.
- 322. Monitoring of 1st, 2nd, 3rd and 4th generation results is essential to know the effects of the mutant gene of Bt Brinjal.
- 323. Bt Brinjal contains two antibiotic resistance genes, one for kanamycin resistance and another for neomycin resistance. Horizontal gene transfer to human gut bacteria is a proven fact and hence poses the threat of antibiotics resistance among human beings who consume Bt Brinjal.
- 324. GM crops impact internal organs of mammals.
- 325. GM crops have the potential to cause unexpected allergies, and increased immune response to other food articles.
- 326. Little is known of the long term effects the alkaloids will have on the human body as a result of consumption of Bt Brinjal.
- 327. GM crops have the potential to reduce reproductive capacities in animals.
- 328. Infants and children are most vulnerable to any allergens that may have gone undetected in GE food.
- 329. No assessment has been made on the potential impacts (toxicity or ineffectiveness) of Bt Brinjal on Indian systems of medicine, given that brinjal and related plants are used in ayurveda, siddha, and so on.

- 330. No study has been conducted as to the possible long term impacts of consuming Bt Brinjal on people of different age groups and physical conditions.
- 331. Altering the gene structure of brinjal will change its nutrient composition.
- 332. Bt Brinjal is not the natural state of brinjal and it takes longer to get digested.
- 333. Upon digestion, Bt Brinjal leaves behind a high amount of toxic and poisonous amino acids.
- 334. Bt Brinjal, unlike other fruits and vegetables, leaves an acidic residue upon digestion, hindering the optimum functioning of the body, thereby adversely affecting health.
- 335. The residual harmful effects on human body are not thoroughly studied and published and, therefore, the introduction of Bt Brinjal is very risky at this stage.
- 336. From food and nutrition point of view, brinjal is not a priority crop, and this technology is not required.
- 337. Genetic engineering technologies are not mature, and there are chances of deleterious effects.
- 338. Bt Brinjal is based on the modification of Cry protein of *Bacillus thurengiensis.* This modification consists of changes in 6 amino acids as compared to native protein. Even the change of one amino acid can cause diseases or an increase of susceptibility. The change of 6 amino acids will surely produce major changes in our genome and will make us vulnerable to many diseases like cancer and neurological disorders.
- 339. When modified Cry protein can kill the pest, is it not possible that it can also harm the normal flora in our guts and do unforeseen DNA damage which is beyond our control?
- 340. Abnormal protein (toxin for pest) may increase sister chromatid exchanges, which increases our susceptibility to cancer and other diseases.
- 341. The genetically tampered crop uncontrollably generates its noxious pesticide, 24x7, deep in every part and cell of the plant including leaf, root and the vegetable. There is no possibility whatsoever of washing off the toxin. 'The poison is potently inescapable'..
- 342. There is no mandatory labelling of Bt Brinjal required to warn consumers, mocking their right of free choice, and thus trampling upon a fundamental right enshrined in our constitution.
- 343. It is quite possible that the increased health problems in the US in the last decade are due to increased consumption of GM corn and soy.
- 344. The longest toxicity tests by Mahyco done on Bt Brinjal were for only 90 days. Thus, they did not assess possible long-term effects like the development of cancerous tumours or effects on succeeding generations fed on the Bt crop.
- 345. The effects of Bt Brinjal consumption on young children, pregnant women, the aged and diseased, as well as the synergistic 'cocktail effects' of multi-toxins have also not been studied at all.
- 346. In May 2009, a leading US association of physicians, the American Academy of Environmental Medicine (AAEM) released its position paper on GM foods, stating that they "pose a serious health risk, … (particularly) in the areas of toxicology, allergy and immune function, reproductive health, and metabolic, physiologic and

genetic health." The AAEM called for a moratorium on GM foods, and immediate implementation of long term safety testing and labelling of GM foods.

- 347. Genes inserted in GM food crops transfer into the DNA of bacteria living inside intestines of human beings and continue to function. Thus, long after we stop eating GMOs, we may still have potentially harmful GM proteins produced continuously inside of us.
- 348. A clear protocol of mandatory bio-safety tests must be prescribed for agencies producing transgenic organisms, so that tests are comprehensive and standardized.
- 349. It is not completely proven that these types of genetically modified crops are safe for human consumption.
- 350. Commercial cultivation of genetically-modified Bt Brinjal had the potential to threaten bio-diversity, destabilise eco-systems and limit future agricultural possibilities.
- 351. This new technology is going to affect our soil, water and biodiversity.
- 352. The calorific value of the Bt products should be tested and proven for safety with regard to health.
- 353. In West Bengal, brinjal farming consists of 85% indigenous brinjal variety and rest 15% hybrid. In this scenario genetic pollution cannot be avoided. It will be a blunder if such issues are not discussed.
- 354. The experiments on human safety were insufficient and Bt Brinjal can cause gastric ailments and diarrhoea.
- 355. A period of 7 years is not sufficient to draw any conclusion when human health and environment are at stake.
- 356. Human trials as with medicine should be conducted.
- 357. The EC II Report does not state any plans for post marketing surveillance study. There is no chance of retraction of product once it is released.
- 358. The Indian society depends much on biomass for fuel and other purposes. Has any study been done to check if the fumes of Bt plants contain toxins or any adverse impacts?
- 359. During animal studies, infertility, organ and tissue damage, adverse effects on growth and development, decreased immunity and ill effects on the offsprings have been observed.
- 360. Upon adoption of GE technology for insertion of gene/s, a number of mutations may take place. Therefore, tests including chronic toxicity studies should be carried out before it is approved.

- 361. When Bt Brinjal was fed to animals the following effects were observed, which the GEAC has not refuted appropriately by quoting studies:
  a. Significant differences in blood chemistry were observed according to the sex of the animal or periods of measurement.
  b. Other effects were on blood clotting time (prothrombin), total bilirubin (liver health), and alkaline phosphate in goats and rabbits.
  c. Changes in lactating cows were observed in terms of increased weight gain, intake of more dry roughage matter and milk production up to 10-14 percent as if they were treated by a hormone.
  d. Rats fed by Bt Brinjal had diarrhoea, increased water consumption; decrease in liver weight, and liver to body weight.
- 362. Bt Maize induced alteration in intestinal and peripheral immune response of weaning and old mice.
- 363. GM Maize has been found to cause hepatorenal toxicity.
- 364. Certain studies have shown that GM crops can alter the cell structure itself.
- 365. GMO are inherently unpredictable.
- 366. There is evidence that long strands of DNA survive for extended periods after ingestion.
- 367. When pregnant animals were fed foreign DNA, fragments may be traced to small cell clusters in foetuses and newborns.
- 368. Studies should be done especially on reproductive effects on mothers and teratogenic effects on children.
- 369. Bt Brinjal appears to have 15 percent less calories and different alkaloid content compared to non-GM Brinjal. It contains 16-17 mg/kg Bt insecticide toxin.
- 370. It is strongly recommended by scientists that impact on kidneys and liver is particularly important, as there were negative impacts on rats on feeding with GM maize.
- 371. Often along with genetic modification, certain hormones are also introduced into the seed to change the colour or increase the size of the crop. This may prove harmful for health.

- 372. Just as Bt toxin attacks the pests and kills it, it also attacks beneficial micro-organisms in the human body, thus causing irreversible damage to our immunity.
- 373. When brinjals get left behind in the market, we feed them to stray cows. What will happen to them if they are fed rotten Bt Brinjal?
- 374. Intergenerational studies need to be carried out that rule out teratogenic effects as well as the possibility of cancer.

- 375. There are several unanswered questions. Bt protein degrades in human system. How much is degraded? Even if 2 per cent is left out it will accumulate over time, with possible side effects.

- 376. Hilbeck et al. showed the ill effects on green lace wing when fed on GM corn.
- 377. There are no receptors in the human body. What about people with different blood groups and different genomes? Is there any guarantee that people with rare blood groups will not have any receptors?
- 378. Chronic toxicity tests have not been done. In the past five years, a number of sheep and goats died in Warangal and Adilabad districts due to grazing on Bt Cotton stubble. The postmortem samples were sent to Indian Veterinary Research Institute but they sent them back saying that they do not have the necessary facilities to test Bt toxicity. The histopathological tests indicate chronic necrosis due to cumulative exposure to Bt toxin, which specifically effects certain animals through stress and immune reduction.
- 379. The Bt gene might trigger metabolic processes that have been lying dormant . It has been said that cooked brinjal is safe but the temperature at which the toxin will be neutralised is not given. The traditional cooked dishes include half-cooked brinjal in fries and pickles.
- 380. A single gene may produce more than one messenger RNA, and a given messenger RNA may have more than one reading frame and thus may produce more than one protein
- 381. It is very important that trials are conducted in a country like India where 46 per cent children are undernourished and prone to diarrhea and their antigen intestinal barriers are very weak. The DNA toxins can easily cross over into the body of children. This is important to investigate before release. Thirty per cent of the adults are also undernourished, and with TB, HIV and other immuno compromisations, these molecules can cross over into the body. With the evidence that animal intestine is affected it is important to conduct trials. Similarly allergenicity studies and other tests should be done. There should be a moratorium until all the tests are done.
- 382. Biosafety tests should be done in a participatory way not depending on the data given by the companies. Civil societies and research institutes should be involved. And the results should be made accessible to all.

- 383. Post monitoring is very important which has not happened in the case of Bt Cotton. Foliage, skin sensitization and soil tests have not been done.
- 384. Bt impact is observed among cotton growers and workers in Warangal. Problems like allergies, swelling of body parts, cattle deaths etc. have been observed. The technology is not benefitting people, but it is benefitting the multinational companies.
- 385. Doctors are not exposed to new situations. Food as medicine is important rather than medicine as food. There should be strengthening of the medical system and infrastructure to deal with new issues like this. It is better to wait until the systems are in place instead of going forward.
- 386. Bt is not a fortified food but has a toxin. There is a need to understand how it works in the human system. More research is required. Brinjal is not a scarce commodity. As it has to do with introducing a toxin into human body through food, advantages and disadvantages should be carefully weighed before taking the decision
- 387. French scientist Eric Gills has conducted studies on the issue and said that Bt Brinjal might lead to liver dysfunction, disrupt hormonal balance, cause diarrhea etc. An independent research laboratory of international standards should be set up and complete tests should be done. Until then there should be a moratorium on Bt Brinjal.
- 388. Tests for chronic toxicity have not been done for animals and humans. Another danger is evolution/selection of bio-resistant insects. Also, there is no way one can prevent the spread of Bt pollen thus contaminating all species of the selected genera. The alternative pesticide is not Bt, but No Pesticide.
- 389. Black spots are developing on the faces of people who go for picking Bt Cotton, and allergies among them are common. The Bt Brinjal might harm health.
- 390. With food safety standards, procedures and enforcement machinery in a nascent stage, Bt introduction is a violation of consumer rights. The government cannot take steps that endanger public health.
- 391. Analysis shows that Mahyco used antibiotic-resistant markers which will have harmful consequences on the health of the India population which has a high rate of prevalence of communicable diseases and a high rate of incidence of multidrug-resistant tuberculosis.
- 392. The reduced calorific value (15 per cent less) of Bt Brinjal will further affect the malnourished population.
- 393. There is evidence that the use of Bt Brinjal is associated with elevated serum bilirubin levels, which suggest hepatic dysfunction. Studies on lactating cows showed hormonal imbalance.
- 394. New analysis of a rat-feeding study with a genetically modified maize reveals signs of hepato-renal toxicity
- 395. The technology is based on inexact science. The exotic genetic material that is inserted in a host could become truncated, fragmented, inverted or multiplied. It could get mixed up with other genes. Host genes could get mutated, deleted, permanently turned off or on, change the level of expression, etc.
- 396. Labourers, farmers, mill workers and others in Madhya Pradesh, who are in constant contact with Bt Cotton, have developed skin diseases like pruritis,

erythema, papilo-vesicular eruptions, oedema. They also develop irritation and swelling in the eyes, watering of the nose and constant sneezing.

- 397. Interaction of Bt toxin with other ingredients in Indian recipes has not been studied and hence Bt Brinjal may not be safe for consumption. Health studies are required to consider spatial and temporal factors in case of food crops. Research on isolated criteria which is not applicable in real life situations is not acceptable.
- 398. GM-fed animals have shown growth retardation, problems with organ development, organ damage and low immune response, high offspring mortality rate, premature births, lower birth weights, carcinogenic developments in gut and bleeding disorders, and low reproductive ability due to decreased sperm count,
- 399. An Austrian Government studies confirm GM threatens human fertility and health safety.
- 400. The Italian Government's National Institute of Research Institute on Food and Nutrition reports that GM-fed mice show disturbance in the immune system.
- 401. In Kerala, brinjal recipes include spices and tamarind, which create an acidic medium and prevent decomposition of amino-acids which may leave the toxin unchanged
- 402. In Mahyco studies on goats fed with Bt Brinjal, blood took longer to coagulate and the bilirubin count increased indicating liver damage

- 403. In Mahyco studies on rabbits, salt levels, glucose, platelet count and red blood cell percentage altered indicating anaemia
- 404. In Mahyco studies, in cows, milk production and composition changed by about 14 per cent. There was more milk which indicated that the animals were given hormones.
- 405. Rats fed on GM Brinjal had diarrhoea and liver weight decrease during Mahyco studies
- 406. Bt Brinjal produces a protein which can induce resistance to Kanamycin, an antibiotic
- 407. In Mahyco studies, sample size of Bt and non-Bt Brinjals to determine compositional difference of the crops is inadequate
- 408. Mahyco studies do not have any data to show compositional difference in varying climatic conditions of India.
- 409. Mahyco research lacks coverage of reproductive studies of animals, which is a crucial parameter in biosafety studies.
- 410. Acute toxicity tests were not done using the GM protein that people would eat. Instead, Mahyco used proteins that were produced by GM bacteria engineered to produce GM protein
- 411. The use of antibiotic resistance markers is proof of the inaccuracy and unreliability of genetic engineering as a technology. If GE works 100 per cent for every single GM plant and in every geoclimatic condition, what is the need of marking inserted genes?
- 412. Antibiotic resistance genes can, in principle, cross species, genera and even kingdoms. This is identified as the process behind the emergence of new and virulent streams of pathogens in 1980s. GE can support the horizontal gene transfer as it uses vectors like viruses, plasmids and transposons which are promiscuous and aggressive.
- 413. Agrobacterium tumefacieus, the vector used in Bt Brinjal, causes cancerous tumours known as crown galls in plants. In addition, Ca MV 35S, a virulent promoter, has been used as a viral promoter. Both these can have serious adverse impacts on plants and animals.
- 414. The safety of microbial Bt sprays (as proven by Mahyco studies) cannot be taken as proof of safety of transgenic Bt. Every test focusing on biosafety must use transgenic Bt.
- 415. Bt toxins are both immunogens (a substance that provokes an immune response) and immunoadjuvants (a substance that enhances immune response) in mammals. Also, the toxins bind to mammalian intestines and can affect their functioning.
- 416. Bt Brinjal is a crop that will be directly consumed by people, and will thereby expose them to serious health hazards
- 417. Unlike medical genetic engineering where the technology is used within the laboratory confines and only the products of genetically modified organisms are released for commercial use, crop genetic engineering releases the modified genes straightaway into natural ecosystems and for direct consumption.
- 418. Integration of foreign DNA into an established genome may have unanticipated side effects, e.g. chromatin change, genome instability, unexpected protein products from transgenes and influence on overall organismal gene expression patterns in quantitative as well as qualitative terms, of the recipient organisms (WHO 2005)

- 419. The EU countries have banned GMOs because of serious concerns relating to potential adverse effects on human health
- 420. Bt Brinjal infuses 16-17 mg/Kg of Bt insecticide toxin into the recipient's body.
- 421. Genetically altered micro-organisms consumed with food products may consolidate with the human and animal organism. This combination can cause depredation, metamorphosis or any other strange organism.
- 422. Metabolism of the toxin produced by the Bt gene of Bacillus thuringiensis should be studied in chimpanzees, who are genetically very similar to human beings.
- 423. Studies should be done to understand in what form the metabolic end product of Bt toxin is excreted, how long does it stay in the living body, does the end product produce any toxic effect on the living body and ecosystem, does the Bt toxin undergoes bioaccumulation or biomagnification, and if so, up to what level is it safe for human body.
- 424. Scientists are not aware of functional genomics. How the alien gene-construct along with the promoter functions is not clear.
- 425. Bt gene acts only in the alkaline environment found in the gut of insects. The human digestive system is acidic only in the stomach while the rest of it is alkaline. The study done by Mahyco on rats allegedly does not address possible human dangers such as cancer, infertility and kidney damage.
- 426. No intergenerational studies have been carried out by the promoters of Bt Brinjal or anyone else, and the genetic safety aspect has not been addressed at all.
- 427. There are discrepancies between Mahyco's internal data and the conclusions and data shared in the public domain pertaining to biosafety studies. The study itself was inadequate in scope.
- 428. The aspect of congenital defects has been totally neglected.
- 429. In a country where 10 million people suffer from TB and the number is rising, and where the resistance of the disease to antibiotics is on the rise, it is unwise to release or even experiment with a food crop in which antibiotic-resistance markers are being used.
- 430. Long-term exposure to GM foods will weaken our resistance to disease, and in future we are likely to see more frequent and more severe outbreaks of diseases such as swine flu.
- 431. It has been proven during tests on mice, that consumption of Bt corn led to kidney and liver damage, and reduction in hormones in the blood.
- 432. The inventor of DDT got a Nobel Prize but his invention is today banned in most countries. A supposedly beneficial product was found to be lethal, and has shown up even in mother's breast milk. Why do we want to repeat a similar experiment with Bt Brinjal?
- 433. As many as 65 diseases have now been correlated with the consumption of genetically modified foods. In tests done on mice and rabbits, some diseases were found to express themselves only in the second or third generation, but so far the longest tests on Bt Brinjal have been only 90-day tests on mice. This is totally inadequate.
- 434. GM foods will eventually result in a chronic disease burden, and it will directly translate into economic burden for the nation.

- 435. India's health systems are as yet ill-equipped to manage any emergencies arising due to the development of new, hitherto unexpected, diseases or health symptoms as a result of GM foods.
- 436. The internal destruction of pests is dangerous to the health of the consumer.
- 437. As Bt Brinjal is created to produce the Cry1Ac toxin in every cell, the 'pesticides' have actually moved from outside to the inside of brinjal, and this cannot be removed by washing as in the case of the usual pesticide at present.
- 438. Brinjal itself has an inherent property of allergenicity which may be enhanced further in the Bt variety.
- 439. Studies on the accumulation or wash-out time span on this specific endotoxin in Bt Brinjal have not been done. Historically the absorption and accumulation of the endotoxins can be carcinogenic to humans.
- 440. Scientists have opined that just chemical analysis of macro/micronutrients and known toxins is inadequate and dangerous. Most sophisticated analytical methods such as mRNA fingerprinting, proteomics, secondary metabolite profiling and other profiling techniques are required.
- 441. A promoter from a virus is used as a gene switch during genetic insertion. This gene switch can react with the inserted gene and other genes creating allergens, toxins, carcinogens and mutogens.
- 442. The existing GM process is unpredictable. The resultant new species created cannot be recalled, even if detected to be harmful subsequently, unlike agrochemicals which are recalled (e.g. DDT) when found toxic after release.
- 443. Health impacts due to Bt crops like immune reactions and allergies have been clearly demonstrated through dose-response relationship.
- 444. Distortions in lipid and carbohydrate metabolism accelerate ageing. Possible accumulation of reactive oxygen species (ROS) in human beings are suspected to be result of the GM crops.
- 445. Kanamycin, the Antibiotic Resistant Marker genes used in the GE process in GM feeding trials can seriously jeopardize the National Tuberculosis Control Programme due to the grave pre-existing problem of Multi Drug Resistant (MDR) and Extreme Drug Resistant (XDR) Tuberculosis in India and other parts of the world.
- 446. The graph of general morbidity in countries like USA seems to be rising concurrently with a rise in consumption of GM foods.
- 447. A pesticide-tolerant gene called the 'liberty link' in GM crops could result in permanent pesticide production by the plant body.
- 448. A study conducted by Newcastle University, UK, on seven human volunteers, found that a relatively large proportion of GM DNA survived the digestive process. In three of the seven volunteers it was found that bacteria had taken up a herbicide resistant gene from the GM food at a very low level, and that too after a single meal. Dr. Michael Antoniou, senior lecturer at Kings College in London considers these studies to be significant as they strengthen the suspicion of GM plant DNA in gut bacteria.
- 449. In an Austrian Government study, GM-fed female rats died within three weeks as compared to 10 per cent death rate among the natural soya-fed control group.
- 450. In the same study, GM-soya-fed male rats showed changes in the colour of their testicles from normal pink to dark blue and had a lower sperm count.

- 451. GM-corn-fed mice had fewer babies which were also smaller than normal as per Austrian Government study. Also, since the DNA parts of transgenes have been found in the foetal tissue, concerns about Teratogenic effect on unborn foetus exist.

+ 452. In the US, thousands of pigs fed on certain GM corn varieties became sterile.

- 453. Scientific invention alone is not the basis for large scale application of a technology.

Approval Process

+ 454. Indian scientists and companies are in the process of developing safer Bt pesticide and need time and government support to compete with multinational companies.

+ 455. If Bt Brinjal is introduced commercially, it should be allowed in a small-scale and highly monitored manner so that in case of any detrimental effect, it can be immediately withdrawn

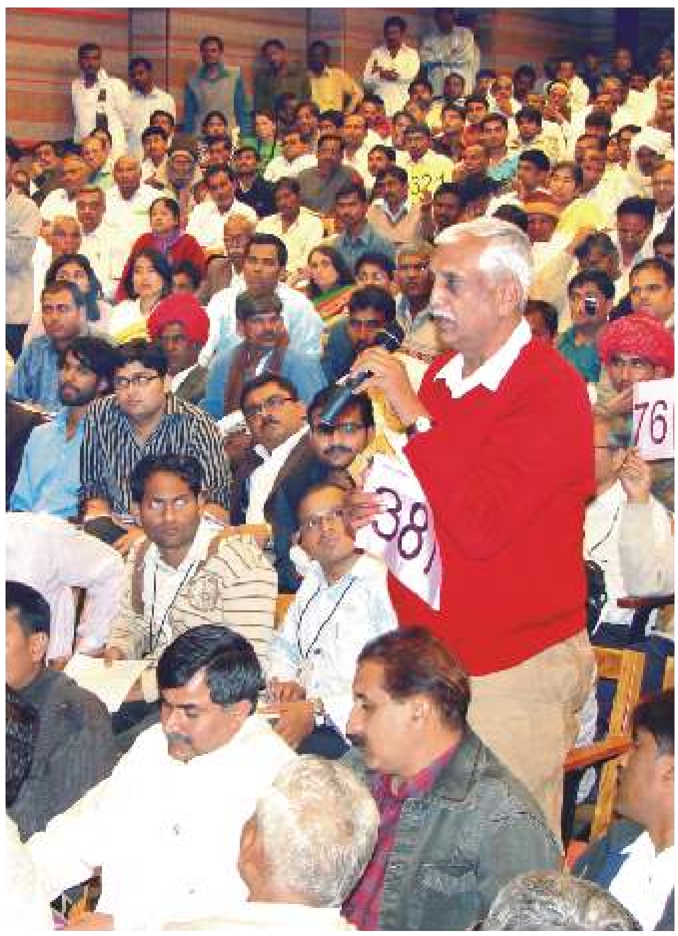
+ 456. The traditional knowledge of farmers is being insulted by these accusations that Bt Cotton is unsuccessful in India. The widespread adoption of Bt Cotton is only because it has been more successful than traditional varieties.

+ 457. Bt Brinjal technology can be adopted for five years on a pilot basis, and if not found satisfactory should be legally rejected.

+ 458. Ministry should do the needful to clear the apprehensions which is not only about Bt Brinjal but also helps all biotechnology initiatives through proper explanations from genetic experts.

+ 459. Philippines and Bangladesh have found the Indian dossier (on Bt technique) thorough and exhaustive. Today in both these countries public partners are in advanced stage of agronomical studies and both countries are considering de-regulation of GM crops.

- 460. The studies done and analytical reports collected so far are not adequate to declare Bt Brinjal safe in terms of human health and ecological biosafety. Since India is a major centre of origin, the genetic diversity will be altered. It is essential to study the effect of toxicity of Cry1AC and other genes upon consumption. Reputed organisations like ICMR, WHO, FAO, NIN, CFTRI etc should conduct studies and present proof with analytical reports.



- 461. Brinjal originated in and is endemic to India with 3531 cultivated and 337 wild varieties (National Bureau of Plant Genetic Research, ISAAA: Brief 38). This genetic diversity must be protected. Natural rights of farmers must be protected as the contamination may end up with gene theft as the introduced gene is patented and protected.
- 462. Decisions made by US FDA (Food and Drug Administration) are used as benchmark reference. The truth is that the Biotech industry executives move to government jobs to oversee biotech industry. The industry follows self certification which is approved by FDA and other government agencies. Inadequate testing requirements are another norm among GM crop regulators. Regulators have ignored evidence that some Bt crops fail the three allergenicity tests and may cause allergies. Scientists test protein made from bacteria and not from the actual GM crop.
- 463. There is not enough data or proof that the Bt gene is safe in the long run to our soil. It is difficult to accept the Bt Brinjal.
- 464. Every citizen has a fundamental right to safe food. It is the duty of the government to protect this right. A company or one approval committee cannot take away this right by giving approval to Bt Brinjal.
- 465. The issue is not only limited to whether to accept or reject Bt Brinjal, but that the entire GM approach for agriculture must be justified. Which problem in agriculture does the transgenic crop attempt to address? It should not be accepted just because Bt gene is available for licensing.
- 466. India does not have regulatory systems in place to ensure that there will be no illegal, black market sale of seeds as was the case with Bt Cotton.
- 467. Bt Corn in the United States has not been approved for human consumption.
- 468. Decisions related to GM crops need cautious case-by-case approach to take into consideration concerns raised by each stakeholder. Bt Cotton and Bt Brinjal are different types of crops with different implications and thus the experience with Bt Cotton is not valid for Bt Brinjal.
- 469. The approval of Bt Brinjal will open the flood gate for GM agricultural crops in our country. This strategy is fraught with the risk of accommodating the clauses of the Indo-US KIA.
- 470. Approval of Bt Brinjal is a move towards establishing complete control by the corporate multinational stranglehold over agricultural and food production in India.
- 471. There has been no shortage of brinjal production in the country so far. Hence there is no need to alter or substantially increase the production pattern of this food crop
- 472. EC I recommendations for flavour and safety analysis of Bt and non-Bt crops has not been adhered to by EC II prior to approval. Skin sensitization tests on guinea pigs recommended by EC I was also overruled by EC II.
- 473. There should be a moratorium on the introduction of Bt Brinjal and GM foods for a certain period. During this period the government should set up a credible and transparent public sector institutional structure sufficiently equipped for undertaking longer and medium-term laboratory and field studies vis a vis the bio-safety of GM food crops including Bt Brinjal.
- 474. We have come to know that there have been surreptitious open field trials on Bt Brinjal in Kajla village in North 24 Paraganas in West Bengal, and we strongly condemn this act.

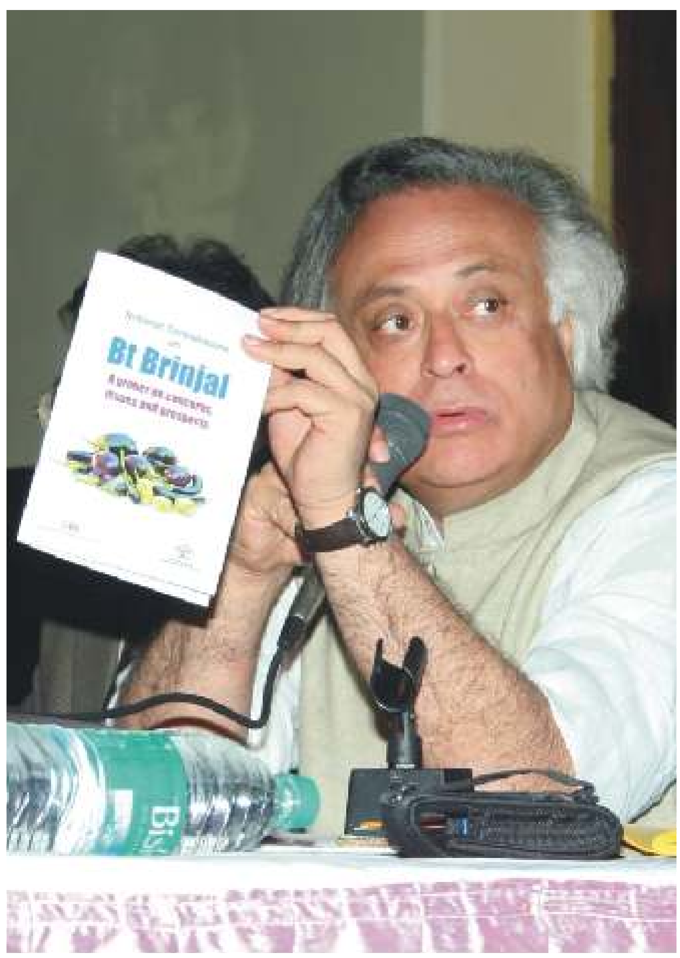
- 475. The technology used in developing Bt Brinjal is outdated technology that uses antibiotic resistance marker genes. This can create imbalances in the genetic stability of the concerned varieties and these imbalances too will be transferred to other indigenous varieties
- 476. Tests to differentiate between Bt and non-Bt Brinjal must be promoted and made public before launching Bt Brinjal.
- 477. Enough research and observation time must be allotted before launching Bt Brinjal.
- 478. Some time back when Bt scientists thought of introducing the Bt gene into tobacco for controlling Spodoptera, America had rejected tobacco imports from us. When it was denied on a crop like tobacco, why is it being introduced into Brinjal which is a food crop?
- 479. Brinjal cannot be looked at in isolation; this debate is relevant to all GMOs in agriculture. Talking only about brinjal while ignoring the rest is akin to debating whether to add another floor to a house that is built on a heap of sand.
- 480. There is no reason to introduce brinjal in India which is the home of brinjals, where there is no shortage. Illegal field trials were done in AP and those who did them should be severely punished. It is reported that there is no laboratory in India which is equipped to test GM foods. One fails to understand how the GEAC recommended the cultivation of GM foods in India.
- 481. Plant and vegetable varieties in India have not been at any stage adequately researched. This lag in research does not allow the accurate evalution of the environmental losses that could occur if Bt Brinjal becomes a monoculture.
- 482. Bt Brinjal will not pass the MoEF environmental impact assessment test on the grounds of possible impacts on the biodiversity, human health etc.
- 483. India needs to follow a precautionary approach, examine all legislations and treaties (like Cartagena) before it approves Bt Brinjal.

- 484. One core issue is the competence, the transparency and the conflict of interest in the regulatory process prior to the grant of licence to market Bt Brinjal.
- 485. If there is no strict legislation on handling and storage of Bt Brinjal germplasm produced for scientific research. Thus it may proliferate and cause environmental contamination.
- 486. We doubt that the inquiry into the safety of Bt Brinjal is unbiased, rigorous and scientific.
- 487. GEAC has not been transparent in the process of evaluating Bt Brinjal.
- 488. Introduction of Bt Brinjal on a commercial scale in our country is an open breach of internationally accepted policy of not disturbing the centre of origin as a safeguard to biotechnology.
- 489. On 20-1-2010, the Supreme Court of India asked the Indian Government to detail the steps including the rules and implementation mechanisms/measures it has put in place to protect India's traditional crops and plants from possible contamination by field trials of genetically modified seeds. How will the Government ensure that the minimum prescribed isolation distance of 300 metres between Bt Brinjal and other old native varieties is not violated by commercial Bt growers, researchers or corporate interests?
- 490. Even if the human wellbeing mandate is seen as insignificant in the discussion, the precautionary principle itself lays down that when there is even a semblance of doubt on the environmental implications of this crop, it cannot be commercialized.
- 491. The MoU between the public institutions that are to develop the Open Pollinated Varieties (OPVs) is not public, so the conditions under which the patents have been passed is unclear.
- 492. The details on how the OPVs can and will be shared across the country is unclear.
- 493. Bt Brinjal is in conflict with Para 4.4 in the Water Mission and Para 4.7 in the Environmental Action Plan of the Indian National Climate Action Plan.
- 494. Bt Brinjal would not pass an environmental impacts assessment test.
- 495. The commercialization of Bt Brinjal is in conflict with the Constitution of India Articles 14, 16 and 19.
- 496. Bt Brinjal cannot be accepted, without any independent testing, verification or long-term tests for health effects, on the principle of substantial equivalence when the company which owns the technology has been able to patent this very same Bt technology on the basis of substantial transformation and earns millions of dollars in patent or technology fees.
- 497. A thorough Needs Assessment must constitute the first step before starting research on GM crops. Is Bt Brinjal really needed? Which problem in agriculture does the transgenic crop attempt to address? Are there alternative approaches? Has conventional breeding failed to solve the problem?
- 498. The so called "Expert Committee (EC II)" set up by the GEAC to conduct tests on Bt Brinjal has lost its credibility as many of the members are associated with the GM crop development company (Monsanto). How come we can rely on such a committee whose chairman now says, "We are not sure about the safety of Bt Brinjal"? Recently, the Chair of the EC II admitted in a media interview again that several tests on Bt Brinjal were not done and "without them, at this stage, we do not know whether Bt Brinjal is safe or not". The Chairperson also says that

"Genetically Engineered food products will not be equal to the non-genetically engineered food products. That's for sure. Now, how much damage, we do not know at this stage".

- 499. Scientific experiments carried out on Bt Brinjal have the following limitations:
  a. IICT lab has no capacity for testing to check whether the samples provided came directly from the market of a non-Bt variety brinjal
  b. Rationale for choosing a particular analysis is not made clear
  c. Experimental details are not given, thus no evidence is available that it is IICT Hyderabad data
  d. Experiments done to check allergicity and toxicity are grossly inadequate from the point of view of ICMR guidelines for Safety Assessment of Foods Derived from Genetically Engineered Plants
  e. Baseline susceptibility studies and toxic Bt protein in case of cooked brinjal, full data is not shared in the public domain.
  f. India does not have a certified and professionally reliable and competent laboratory facility to assess all the risks
- 500. The same level of precautions which are taken for pharmaceuticals need to be taken for GM foods and Bt Brinjal. Human trial should be conducted, as in medicines.
- 501. To grow Bt crop safely, a minimum of 30 metres of isolation is required, but in India there is hardly any plot which can fulfil this condition. This can cause various health hazards, soil contamination and other imbalances in the environment.
- 502. The proof given by GEAC on Bt Brinjal is incomplete, baseless and false. The data represented in the report is not clear and does not support the scientific arguments.
- 503. There were many scientific errors in the tests and samples provided by Monsanto during Bt Brinjal studies. No studies were done on the effects of Bt on soil microbial species, on soil nutrients, or on cattle microflora.
- 504. As cross-pollination in brinjal is possible even with an isolation distance of three kilometres or more, how can the government ensure that the pollinating agents of nature, the bees, etc., do not transgress the prescribed limit of 30 metres that seems rather arbitrary?
- 505. Genetic contamination of the brinjal cannot be regulated. Hence Bt should not be allowed and the gene pool should be conserved.
- 506. There will be social, political and economic unrest due to forcible cultivation of Bt Brinjal.
- 507. Absence of a regulatory framework and the protection of rights as well as the lack of biosafety measures in no way support the cultivation of Bt Brinjal in India.

- 508. The monopoly of hybrid varieties and the creation of an alternative technology make its usage compulsory.
- 509. There should be provisions to protect the rights of non-Bt farmers.
- 510. After introduction of Bt Brinjal if anything goes wrong and farmers suffer due to that, will the government take responsibility and pay compensation?
- 511. Subsidy to the farmers is a better idea than Bt Brinjal.
- 512. In West Bengal which cultivates over a hundred indigenous varieties to produce 30 per cent of India's output of brinjal more than 90 per cent of the farmers have small or marginal holdings, each touching the next. Thus, even a 30 metre isolation distance may be extremely difficult or impossible to ensure. This is also true of Orissa, Bihar and several other states. How then does the government propose to protect such small farmers and their many traditional varieties from contamination?
- 513. Genetic contamination of Solanaceae family (potato, tomato, chilli) will have disastrous consequences to the nutritional security and livelihood security of consumers and farmers.
- 514. Bt Brinjal should be tested just as medicines are, as it too is for direct consumption. Bt Brinjal will not pass the Indian Medical Council testing.
- 515. India completely lacks post-marketing surveillance and regulatory mechanisms. In such a scenario, how will we monitor any impacts of Bt Brinjal, once it is released in the open market and open environment?
- 516. From the health regulation point of view, who will take liability for eventualities such as adverse drug reactions occurring due to Bt consumption?
- 517. No tests have been done at all on sick people, aged people, pregnant women, and other similar high-risk groups. Simple feeding and allergy tests on mice will not be sufficient.
- 518. While Mahyco shared the truncated gene *cry1Ac* construct they developed with the public sector research institutions, there are conditions in the MoU stopping these institutions from developing their own hybrids, or having a free hand in the marketing of the Open Pollinated Varieties.
- 519. None of the public sector products would reach the market for another two years as they are yet to complete their trials. By then Mahyco, who have their GM Brinjal hybrids ready, would completely dominate the market. Thus, the technology sharing agreement is just a Trojan horse to get their product into the market.
- 520. Why are Monsanto and their subsidiaries not doing



anything to address the real shortages and crunch situations in India sugar, foodgrains? Why are they so interested in brinjal alone?

- 521. Who will protect the rights of a farmer if he wants to grow only non-GM Brinjal but cannot get guarantee of obtaining pure seed because in a few years all the varieties in cultivation may get contaminated with GM genes?

- 522. Indian farmers through their traditions have kept alive nearly 2500 varieties of brinjal for 4000 years. This natural diversity will get wiped out by the spread of GM Brinjal and no one will be able to reverse the process.

- 523. Let farmers have the right to decide which brinjal varieties they want to grow. There should be no imposition from any agency.

- 524. "Percy Schmiezer was sued by Monsanto for violating their patent rights even though he denied having used GM seeds. His 50-year collection of non-GM seeds was confiscated. Now when GM gene contamination will take place in India due to open pollination in nature, how will any (non-GM user) farmer ensure that his seeds are not violative of Monsanto's 'patent rights'? Moreover who will protect the small farmer if tomorrow Monsanto were to stake a claim on native brinjal varieties, saying these have now become GM?"

- 525. In their quest for profits, cotton farmers went for Bt cotton and the indigenous cotton suffered and failed. But they realized losses within a few years since the Bt crop yield also has started declining and new pests have invaded it. Bt Brinjal too will very soon fall prey to new pests, new diseases, and farmers will then have no option except to buy Monsanto's patented pesticides. Non-Bt Brinjal may not be available by then, due to contamination. Thus there will be a virtual takeover of a crop by foreign companies and their subsidiaries. This is a conspiracy.

- 526. Department of Biotechnology guidelines prescribe in vivo and in vitro immunological assays for the detection of reactogenic antibodies in the test sera. The in vivo assay was allegedly not done.

- 527. The introduction of Bt Brinjal in India calls for a "holistic", rather than a "reductionist" approach, particularly because it is a favourite vegetable.

- 528. Export of brinjals at present is to the tune of 1.71 crores only. Chances of getting high foreign exchange returns from Bt Brinjal are very low.

- 529. MoEF has dropped 190 plants from the protection of the Biodiversity Act. This included brinjal and almost all endemic varieties that constitute the genetic wealth of India. Biological Diversity Act applies to all biological resources of the country. In case any use (as defined in the Act) of any biological resource is to be undertaken, and such use includes genetic engineering per the Act, then first and foremost the permission of the regulatory authorities under this Act has to be sought to use the biological resource. It is only on securing such approvals can any genetic modification be undertaken. In the case of the Mahyco promoted Bt Brinjal, there has been no conformance whatsoever with the Biodiversity Conservation Act, and thus the entire approval by GEAC fails because of this fundamental violation.

- 530. Bt Brinjal has been developed independently from point zero to final validation of the biosafety and agronomical safety assessment without any external help through partnership between public sector, private companies and Indian research institutes.

- 531. Mahyco acquired Bt gene from Monsanto during the 90s and the public sector have full freedom to deliver the product to the farmers without sharing any economic benefits with Monsanto. Monsanto is nowhere related either as royalty collector or stipulator of terms.

- 532. Bt Brinjal decision must be taken with scientific temperament and the apprehensions addressed scientifically through the involvement of Independent Researchers.
- 533. 'Committee may be constituted, headed by a Supreme Court Judge if possible, with proper representation from all stakeholders and premier scientific bodies to have an in depth understanding of the Bt Brinjal before commercial cultivation instead of 50:50 happy and unhappy situation and throwing the GM crop to a plethora of suspicion among farmers and consumers and creating opportunities for agitations (that reduce the value of scientific research and studies).The Committee can seek required information, involve themselves to study , understand and take a final view and consequently the MoEF can clear Commercial cultivation of the crop. Instead of this if banning of the crop is done it will affect even other crops in the pipeline and it can endanger food safety'.
- 534. While the consultation process is on, it is expected that status quo is maintained for brinjal.
- 535. As the brinjal has gone out of the list, it has to be put back under the Protection of Biodiversity Act.
- 536. The process by which species are taken off the list should be clarified to the public.
- 537. Many international organizations such as International Assessment of Agricultural Science and Technology for Development (IAASTD), Research and Information System for Developing Countries (RISDC), and International Federation of Organic Agriculture Movements (IFOAM) have expressed the view that GM crops are not compatible with organic or sustainable agriculture and will not play a role in addressing climate change, hunger, poverty and food insecurity.
- 538. Since our country does not conduct regular studies or keep careful records, we need to do allergenicity studies in great detail before GM food is permitted for human consumption.
- 539. When all the developed nations have rejected the use of GM crops, then why is the Government of India trying to introduce this crop in the food chain?
- 540. Inspite of GE and other modern technologies being practised for many years, the US government gives heavy subsidies to its farmers. Then how can a similar strategy offer a solution to India?
- 541. As many nations have banned GM food crops, there is no justification for India to accept the development and commercialization of the Bt Brinjal.
- 542. Attempts to push GM foods into India are a form of “food colonialism” and an attack on India's food sovereignty.
- 543. In the last 40 years, the real truth behind slogans like “Green Revolution” has been exposed. After a few years of good yield, failures started showing up and we have been made dependent on monopolistic trade in seeds and pesticides. Now the “GM revolution” is going to be the next attempt to monopolize India's agriculture and food independence.
- 544. Why are we giving way to foreign companies who simply want control over our biggest strength, that is, food?

Regulatory Process and Legislation

Overview of Legislation and Regulatory Regime for GMO in India

More than 60 per cent of India's population depends on agriculture and agriculture related livelihoods. Today food and agricultural systems have to respond to several changes and challenges such as increasing international competition, globalization and rising consumer demands for improved food quality, safety, health enhancements and convenience. The promoters of modern biotechnology claim that biotechnology, involving the use of genetic engineering, has emerged as a powerful tool with many potential applications for improving the quantity and quality of food supply. The stated aim of genetically modified (GM) crops entering India is to enhance productivity, decrease the use of certain agricultural chemicals, modify the inherent properties of crops, improve the nutritional value, or even increase the shelf life of food products.

As more and more GM crops are being developed and released for field testing and commercialization, concerns have been expressed about potential risks associated with their impact on human health, environment and biological diversity. These apprehensions arise because the experience with chemical pesticides shows that risk assessment often does not have the capacity to predict medium and long-term effects (even intergenerational, inter-species impacts) in a comprehensive manner. Also genetic engineering crosses the species barrier as compared to classical selection techniques. Therefore a regulatory regime devolves from the understanding of the risks as well as other impacts and of the need to regulate both research and trade of GM crops.

The information on the regulatory process and legislation related with GMOs given in this chapter is taken from MoEF's *Regulatory Framework for GMOs in India.*[1]

Regulation of GM crops in India happens mainly through the Environment Protection Act (1986) 1989 Rules. These Rules are called the "Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms, Genetically Engineered Organisms or Cells" and deal with modern biotechnology use in agriculture (environmental release) as well as pharma sectors.

The two main agencies responsible for implementation of the rules are the Ministry of Environment and Forests (MoEF) and the Department of Biotechnology (DBT), Government of India. The rules have also defined competent authorities and the composition of such authorities for the handling of various aspects of the rules. As per the rules, there are six competent authorities:

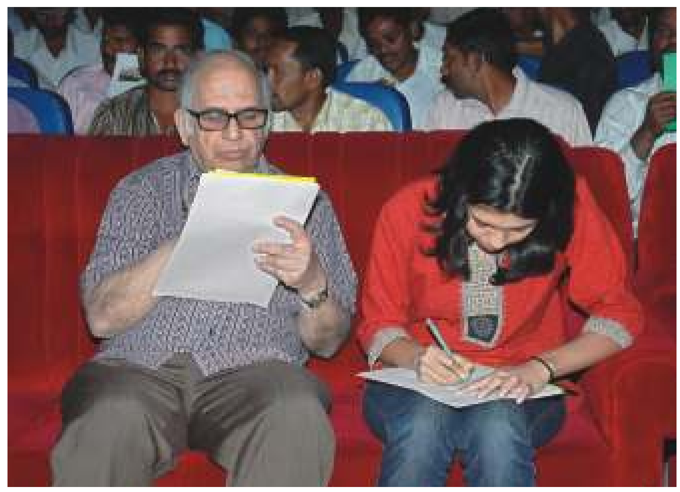
1. Recombinant DNA Advisory Committee (RDAC): This advisory committee is under the Department of Biotechnology. It reviews biotechnology development across the world and recommends safety regulations.

2. Genetic Engineering Approval Committee (GEAC): A multi-ministerial body located in the MoEF, it is the apex authority for Environmental Clearance/approvals related to large-scale use and release into environment of GMOs. The GEAC has the power to permit the use of GMOs and products thereof for commercial applications. It can adopt procedures for restriction or prohibition, production, sale, import and use of GMOs, both for research and applications under EPA. It authorizes large-scale production and release of GMOs and products thereof into the environment. It can also authorize agencies or persons to have powers to take punitive actions under the Environment Protection Act. The State biotechnology coordination committees and district level committees are supposed to assist the GEAC in its enforcement function.

3. Review Committee on Genetic Manipulation (RCGM): This body under the DBT has assumed the regulatory role of approvals and review of GMOs in research and field

1 Ministry of Environment and Forests. 2007. *Regulatory Framework for GMOs in India*, Project Coordinating and Monitoring Unit (PCMU) GEF World Bank Capacity Building Project on Biosafety. MoEF, Government of India, New Delhi, in association with Biotech Consortium India Limited.

experiments. It authorizes imports of GMOs and transgenes for research purposes. It permits experiments in Risk Group III category and above. It lays down procedures for restriction or prohibition, production, sale, import and use of GMOs both for research and applications. Over time, RCGM also started authorizing field experiments in 20 acres in multi-locations in one crop season, with up to one acre at one site (MLRTs), until May 2006, when the Supreme Court ordered that all such approvals have to come from GEAC as per the EPA. The current procedure involves the RCGM recommending and the GEAC endorsing. The RCGM is also entrusted with the job of bringing out manuals or guidelines specifying procedures for regulatory process on GMOs in research, use and applications, with a view to ensure environmental safety. It reviews all ongoing r-DNA projects involving high risk category and controlled field experiments mainly through the Monitoring & Evaluation Committees (MECs). MECs also draw in experts from the State Agriculture Universities to oversee MLRTs (Multi Locational Research Trials, also referred to as Multi Locational Field Trials or Limited Field Trials) and based on their field visits during the trials, report back findings to the RCGM for appropriate decisions. The RCGM acts as the link between the Institutional Biosafety Committees of the crop developing institution and the GEAC after the MLRT stage.



MECs: They undertake field visits at the experimental site(s), to review the design of experiments/trials and collection of data during limited open field trials, to assist in collecting, consolidating and analyzing field data for evaluating environmental risks emanating from transgenic plants, to recommend those transgenic crops which are found to be environmentally safe and economically viable to RCGM and to GEAC for consideration to release into the environment.

4. Institutional Biosafety Committees (IBSC): This is a statutory body to be created at the crop developing institution level, for approvals up to Risk Category I and II experiments in an institution. IBSC is supposed to inform the State Biosafety Coordination Committees and District Level Committees about such research work. For Category III experiments, IBSC recommends to the RCGM for its approval.

5. State Biotechnology Coordination Committees (SBCC): With at least nine members and powers to inspect, investigate and punish for statutory violations, for post-release monitoring, the SBCC is supposed to act as the state nodal agency, with representatives drawn from different concerned departments

6. District Level Committees (DLC): Convened by the District Collectors (the highest administrative authority in a district), this District Level Committee acts as the district nodal agency with at least eight members drawn from related departments.

7. Chief Medical Officer, District Agricultural Officer etc. It monitors the safety regulations in installations engaged in the use of genetically modified organisms/ hazardous micro-organisms and their applications in the environment.

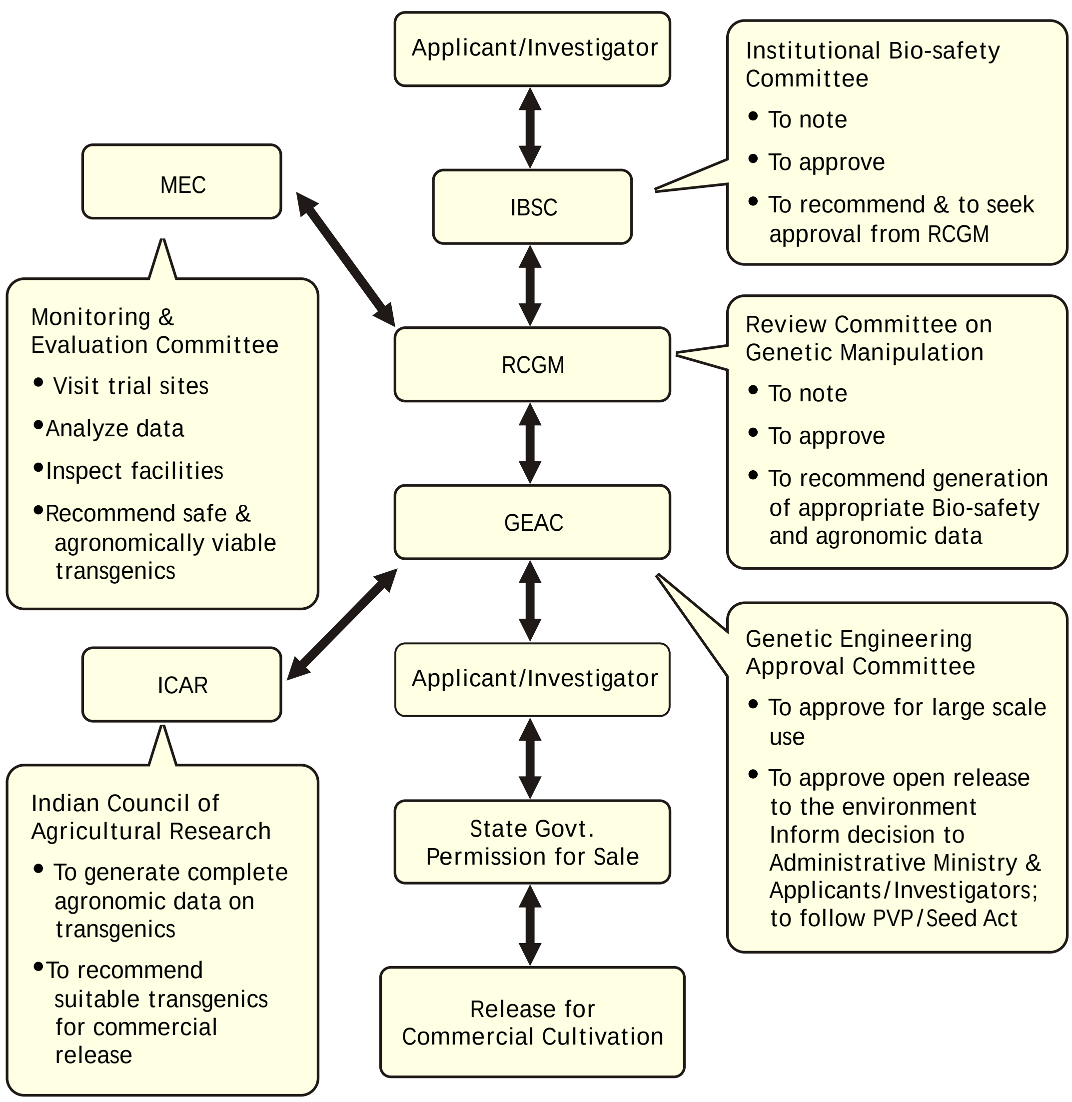
Of these, the three agencies that are involved in approval of new transgenic crops are:

1. IBSC set up at each institution for monitoring institute level research in genetically modified organisms.

2. RCGM functioning in the DBT to monitor ongoing research activities in GMOs and small-scale field trials.

3. GEAC functioning in the MoEF to authorize large-scale trials and environmental release of GMOs.

The following is the schematic representation of the current procedures for approval of GM crops in India.



Every applicant is supposed to first constitute an institution-level "Institutional Biosafety Committee" (IBSC) in consultation with the Department of Biotechnology and with a representative of DBT in the IBSC. The IBSC then takes up research with protocols approved by the DBT up to the limited field trials stage. Recently, the system has been recast to call the first level of research as BRL I (Biosafety Research Level I), followed by large-scale trials and further tests called BRL II (Biosafety Research Level II). In the case of BRL I, the ECGM scrutinizes and approves research while the GEAC just endorses these permissions. In the case of BRL II, the GEAC takes the final view, after obtaining recommendations from ECGM and others in the NARS (National Agricultural Research System).

Ministries and Departments Involved in Regulation of GM Food.

Several central ministries and departments are involved in India's program of food quality and safety and hence each one of them has a role to play in the activities related to GM foods in India. These include:

1. Ministry of Environment and Forest: This ministry holds the Secretariat of the Genetic Engineering Approval Committee, the apex body that gives approval for manufacture, sale, import and export of all GMOs and products thereof including foodstuff, ingredients in foodstuff and additives using genetically modified organisms or cells.

2. Department of Biotechnology: This department holds the Secretariat of the Review Committee on Genetic Manipulation that gives approval for research and small-scale field trials involving GMOs and products thereof. It also interacts with the Institutional Biosafety Committees (IBSCs) set up in all organizations undertaking activities involves GMOs.

3. Department of Health in the Ministry of Health and Family Welfare (MoHFW): This Department is responsible for implementation of the PFA Act under which the quality and safety of food is regulated. The Directorate General of Health Services has also been designed as the nodal Ministry with the Codex Alimentarious Commission.

4. The Indian Council of Medical Research (ICMR) is the apex body in India for the formulation, coordination and promotion of biomedical research under the Ministry of Health and Family Welfare. ICMR acts as an advisory body for MoHFW on various issues including GM foods.

5. Ministry of Agriculture: It is the nodal ministry for agriculture growth in the country. It comprises three Departments, namely the Department of Agriculture and Cooperation, Department of Agricultural Research & Education/Indian Council of Agricultural Research (ICAR) and Department of Animal Husbandry & Dairying. The officials from ICAR and Ministry of Agriculture have an important role to play in the approval of GM crops as per Seed Policy, 2002.

6. Ministry of Commerce and Industry: This ministry is responsible for the formulation of the Export and Import (EXIM) Policy in the country. It implements a legislation prescribing a system of quality control and inspection for both export/import.

7. Ministry of Food Processing Industries: This ministry is responsible for the formulation of policy for the healthy growth of the food processing industries and provides developmental support to these industries. It encourages research and developmental activities and assists the industries in active participation in laying down of food standards as well as their harmonization with international standards. This ministry is also the licensing authority for processed fruits and vegetable industries.

Research Institutions Involved in Regulation of GM Food

1. National Institute of Nutrition (NIN), Hyderabad, is India's premier nutrition research institute working under the aegis of Indian Council of Medical Research (ICMR), Ministry of Health and Family Welfare, Government of India. ICMR proposes to set up a GM Food Safety Cell in NIN.

2. Central Food Technological Research Institute (CFTRI), Mysore, is a premier institute working under the Council of Scientific and Industrial Research. Its multi-disciplinary spread (across 16 R&D departments) covers almost every field of scientific investigation connected with foods and their relationship to humans, including the cutting edge area of food biotechnology.

3. The Defense Food Research Laboratory (DFRL), Mysore, under the aegis of Defense Research Development Organization (DRDO), caters to the varied food challenges for military and paramilitary forces. This laboratory is engaged in research and development of traditional indigenous foods and their preservation.

4. Industrial Toxicology Research Centre (ITRC), Lucknow, a constituent laboratory of the Council of Scientific & Industrial Research (CSIR), is dedicated to provide health safeguards to industrial and agricultural workers through its rich knowledge-base, created painstakingly over the years.

5. National Bureau of Plant Genetic Resources (NBPGR), New Delhi, is the nodal organization in India for collecting, introducing, evaluating and conserving plant genetic resources. NBPGR is also responsible for plant quarantine activities relating to exotic samples.

6. Centre for DNA Fingerprinting and Diagnostics (CDFD), Hyderabad, is an autonomous institution supported by the DBT and is engaged in providing services for DNA fingerprinting and diagnostics in addition to basic research in related areas. DNA fingerprinting services are also being provided to various government and law enforcement agencies.

Comments on the Regulatory Process

1. Genetic Engineering may be seen as an innovative technology and we must encourage it for crop development, health and other specified areas and we must understand its potential in Climate Change Mitigation. Neglecting it due to public outcry or due to lack of knowledge base is going to damage our Food Security and welfare of the citizens and could even prevent our taking appropriate measures for protecting all our Bio diversity.

2. The results of all tests should be given in the form of a booklet to all scientists for evaluation and should also be made open to the public.

3. A decision should be taken after thorough risk analysis and completely proven scientific experimentation. Patents and royalties should be taken care of. Food Safety Standards Authority of India, which operates under the Ministry of Health and Family Welfare, should also be involved

4. The GEAC mechanism should be revised. The research should happen first in the public sector and only then should it go to the private sector. This is important to maintain seed quality as well as ensure reasonable cost. Science is for society and not just for the sake of science.

5. There should be an independent infrastructure to check both public and private research

6. In India 60 per cent of the population is dependent on agriculture and this population will be controlled by multinationals through the control of seed and agrochemicals production.

7. The seed companies will charge Rs. 1250 as trait fee for what costs them Rs 300 to 500 to produce. This is unfair.

8. There should be a proper seed policy. In India the seed policy, instead of protecting the farmer's rights to seed collection, preservation, use and exchange is abridging them.

9. A national policy is required on GM crops. Needs analysis and crop prioritization should be done.

10. There is neither a Seed Act nor a MRTP Act to control monopoly and seed supply. Every year spurious Bt seeds are being sold with no action. We request the Union Government to strengthen the research facilities at ICAR and State Agricultural Universities so that they themselves can conduct research on sustainable technologies. Public seed supply systems like National Seed Corporation, AP State Seed Development Corporation, universities etc. should be strengthened.

11. Safety norms on GM crops are not being enforced.

12. Government should also evolve a GMO policy which is farmer friendly and not corporate-centric.

13. According to Patents Act, 1970, the methods of cultivation and plants are excluded to ensure farmers' right over seed. Now farmers will be made to depend on MNCs for seed. If GM seed is permitted, farmer's right under Plant Varieties Protection and Farmers Rights (PVFR) Act of 2001 will be denied.

14. World hunger is caused solely by inequitable distribution of food and not by food shortage. In this light the claims being made about 'GMOs for food security' are baseless. Similarly, to address micronutrient deficiencies, only access to safe, clean drinking water and providing meaningful wages will help.

15. Now that the seeds have been developed what will stop the company from selling the same in the black market?

16. No consent has been sought from the local Biodiversity Management Committees (BMC), State Biodiversity Boards and committees set up by Village Panchayats under the Biodiversity Act. All these bodies have been constituted under the Biodiversity Act to protect, conserve and promote sustainable use and equitable sharing of biodiversity.

17. The need for a particular new technology must be discussed right in the beginning when it is proposed by a promoter. If after thorough research, no traditional or alternate solution can be discovered, only then should permission for research be given to the promoter of the concept.

18. Germplasm imported under license of research must not be used for its propagation for commercial application.

19. Scientists are unable to conduct independent research on GM crops as patents prevent full access to research materials and the ability to grow and study plants.

20. In case of divided opinion among Indian states about GM crops, states that refuse GM crops must have the legal ammunition to prevent the spread of the GM crops through bio-piracy, smuggling etc.

21. GEAC has approved the first genetically engineered food drop (Bt Brinjal) with unprecedented haste.

22. The environmental risk, relevance of technology and socio-economic impacts must be critically looked into prior to approval of commercialization of such crops.

23. In no other country in the world are food crops with toxins, particularly vegetables, being forced on cultivators by a national government.

24. Humanity has a collective right over the use of biodiversity and germplasm that have been preserved by the farming community from age-old times. By changing a gene or two, a company should not be entitled to claim patent on it and make a profit.

25. WHO and FAO insist that antibiotic resistance marker genes shall not be used in food crops.

26. EC II Report fails to say how a farmer can safeguard his non-Bt Brinjal from contamination by a transgene from a neighbouring farm sown with Bt Brinjal.

27. The regulatory authorities are using circular arguments, each one quoting the other and then finally quoting the industry and companies' data and research as proof of safety. This is unacceptable.

28. Justice Balakrishnan's bench had directed that Mahyco's biosafety dossier on Bt Brinjal be posted on the GEAC's website. But all that the GEAC put out was Mahyco's analysis and conclusions.

29. The expert committee concluded that Bt Brinjal was "safe for environmental release in India" and that its benefits "far outweigh the perceived and projected risks". The committee's report came out on October 8 and the GEAC gave its clearance six days later.

30. How will GM food be labelled in a country where vegetables are not sold only in supermarkets? And how feasible is it to maintain the segregation from the field to the market?

31. As per the Cartagena protocol, to which India is a signatory, transgenic versions of crops for which we are the country of origin should not be permitted.

32. A system of post-release monitoring must be put in place before commercial release is allowed into the environment to assess the performance and impact.

33. A proper system of labelling of GM crops must be put in place, with public awareness to enable informed choice.

34. A system of public participation in decision- making and in regulatory bodies must be put in place.

35. All regulatory data and bio-safety data should be available to the public.

36. A law of liability must also be in place before commercial release is permitted so that companies are liable for health and environmental damage that might ensue.

37. Many points like the farmer's freedom of choice, environmental impact analysis, long- term sustainability, increase in cost of production, etc. have been ignored deliberately.

38. MoEF should consider conflict of interests among stakeholders before approving reports submitted by its departments.

39. The information related to funding sources and methodology of research/committees' reports constituted by MoEF must be in the public domain

40. There should be concern about the existing protocols and systems before giving a final answer on the safety of GM crops.

41. Some studies undertaken in the matter lack unbiased scientific approach and transparency.

42. Implicit monopoly of profit-oriented corporates is against public interest and may lead to dependence of our farmers on them, as they will have to acquire fresh seeds every year because GM seeds are not reusable.

43. Why does the government not establish its own credible scrutiny and regulatory system?

44. The right of farmers to remain GM-free will be snatched away.

45. How can it be ensured that a legal framework exists to tackle the issue if anything goes wrong?

46. There is total absence of any systematic study related to the impact of GM crops on biodiversity, germplasm, ploughable land, non-target organisms and the environment.

47. GM crops are totally prohibited in most countries. In much of Europe, including UK, Germany, Switzerland, Austria, the ban continues in defiance of WTO directives. Over 85 per cent of global GM cultivation is confined to just 4 countries: US, Canada, Argentina and Brazil; and to a mere four crops corn, soya bean, cotton and canola. India should learn from the experience of other countries.

48. Rice, pigeon pea, mustard are already under open field trials for GE; to be followed by wheat, jowar, ragi, bajra, corn, cassava, potato, onion, sugarcane, tea; and also various pulses, oilseeds, vegetables, fruits and spices. This is against the precautionary approach advised by India's Planning Commission Task Force set up to review GM policies and laws.

49. For any truly independent system of objective evaluation, India must set up a lab of her own, which has high public credibility, which must be governed and staffed by an impartial body of people with unquestionable integrity who have no economic link/s whatsoever (direct or indirect) with any GM producing or marketing company. It is such a body that

must undertake in a totally transparent, peer-reviewed manner all the required biosafety and related tests, monitoring, assessment and evaluation, including multigenerational studies. This has been stressed by the Supreme Court appointee, Dr Bhargava, on the Planning Commission Task Force on GM policies and laws.

50. According to the legal framework , the 1989 Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms, Genetically Modified Organisms and Cells, (and subsequent amendments), the statutory authority to take decisions on the release of GMOs rests with the Genetic Engineering Approval Committee (GEAC) which is India's apex decision-making body. However the decision-making process must be democratic and must take the views of all stakeholders from different socio-economic groups into consideration.

51. The head of GEAC must be a technically competent person, not whoever happens to be posted as Additional Secretary in the Ministry of Environment and Forests.

52. Commercial release of GM crops should be held back till a proper regulatory framework with appropriate systems is in place. However, research should continue.

53. India must develop a new, stand-alone Gene Technology legislation like other countries have done. We have copied the American system of parking our regulation under the Environmental Protection Act although our situation is entirely different.

54. A comprehensive environmental, legislative, socio-economic needs-assessment research is needed to check whether GE is the only way to achieve food security, or whether organic and non-GE techniques with a sound management strategy are more practical ways towards food security.

55. We need to create structures to enable public participation in decision making on GMOs. This should be done after a stakeholder dialogue to determine the levels and nature of public participation.

56. The regulatory system must have an unequivocal requirement for assessing the socio-economic impact of a new transgenic crop on traditional agricultural systems, agrobiodiversity and the traditional knowledge of communities. This is required by the Biosafety Protocol.

57. There must be an unambiguous definition of what will constitute 'Confidential Business Information'. Barring this, all other biosafety data must be available for public scrutiny.

58. This must be preceded by a public education exercise so that the label is not merely a coloured sign on the package but offers the opportunity for informed choice to the consumer. For labelling to make sense, it will have to be preceded by a system for segregation, traceability and Identity Preservation of GM crops.

59. ICAR-IARI should not become junior partner to MNCs.

60. Why should Indian agriculture be based on what MNCs dictate?

61. National Biotechnological authorities have to regulate the price of the seed.

62. There are no biosafety measures and regulations in place; hence there is no way of evaluating the Bt crops.

63. GM risk assessment has not been done for Indian conditions, hence we need a stricter regulatory process.

64. The GM policy should essentially include an action plan for quick withdrawal of the product as soon as some detrimental effects are observed, even if that is after a considerably long period of time.

65. The results in the field are significantly different from those in the laboratory, hence a cautious approach to this issue is required.

66. The science behind GM is very strong but the risk assessment is very meagre. The Government should ensure that a through risk assessment is conducted before giving the green signal.

67. There is a need for a regulatory body that ensures the ethical functioning of the GEAC.

68. Invest adequate resources in biosafety testing and monitoring at various stages. Public sector agencies complain they get research grants for research on transgenics but not for risk assessment.

69. A risk benefit analysis of every transgenic crop should be conducted with public participation.

70. India has proven time and again its inability to pin liability on these transnational entities when things go wrong, tragically so, as in case of Bhopal. So, looking at the past experience, we will have no recourse when things go wrong, which they will, considering the lax regulatory process. With no liability and redressal system we have no right to contaminate our food with an alien gene and irreversibly threaten our biodiversity.

71. There are chances of theft of the good traditional varieties which could not be patented as they are already in the public domain. They may be patented at a later stage by keeping their seeds in laboratories. There are also chances of transmigration of local species without our knowledge.

72. Internationally, about 30 tests are prescribed before a country can allow GM seeds. However, India has done only six or seven tests. "Those too have been done by Monsanto itself or samples provided by the company, which is trying to push GM seeds in India," notes Dr Pushpa Bhargava.

73. Our country can't remain independent because MNCs will control our farmers who account for 70 per cent of our population.

74. Only Mahyco was permitted to import Bt Cotton seed for research trials. Nuziveedu Seeds Limited (NSL) in Gujarat had Bt Cotton seeds which it might have imported illegally, or NSL is part of Mahyco or through Mahyco trial experiments through cross pollination process. This shows the poor monitoring mechanisms in place in our country.

75. Pharmacovigilance in India is very weak. This puts into doubt the viability and effectiveness of any regulatory mechanism for GM foods in general, considering also the impossibility of labelling in a diverse market in a country where several levels of poverty and illiteracy exist at the same time.

76. There is asymmetry of information between the buyer and seller. This could lead to market failure.

77. There are serious inadequacies in the study design itself and all the studies claiming safety of the product have been either done or sponsored by the same company that is pushing the technology.

78. Most of the Good Laboratory Practices (GLP) procedures are not capable of detecting fraud or wilful manipulation, or of ensuring the absence of these practices.

79. The protocols for biosafety need to be updated. More sophisticated analytical methods like mRNA fingerprinting, proteomics; secondary metabolite profiling and other profiling techniques may be required.

80. Scientists are not informing the public about the health hazards that people will have to face and about the results of the operative studies.

81. Indian labs do not have adequate and updated technologies and skills to detect serious genetic issues.

82. To ensure that access to seed is ensured, the Intellectual Property Rights (IPR) regime must retain farmer's rights and must not reduce flexibilities in Indian law.

83. A formal clearance from the Ministry of Health should be mandatory before the release of any GM food/drug/other crops. Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH). AYUSH must be a stakeholder in the approval process.

84. The GM crop issue does have great public policy significance and cannot be confined to the scientists alone. Scientists, like everyone else, know what they know and do not know what they do not know. They are not omniscient. Even when totally objective, whatever they say is based only upon the present state of their knowledge. Thus legislations must consider concerns of stakeholders that extend beyond science.

85. Scientific invention alone is not the basis for large scale application of a technology. It is for society to draw up their limits based on ethics and plain good sense and whatever they come up with by remaining within those limits, decide what is acceptable and what must be rejected. A very simple but related example is that of Basmati Rice. Scientists at Pusa Institute developed a hybrid closely resembling the premium pure Basmati minus its flavor. the new Evolved Basmati should have remained in their labs. Instead, it was released in the market. Who benefitted? It benefitted the adulterators for whom it is an ideal adulterant. Major importing countries were forced to evolve strict standards and even DNA based methods to check the adulterated Basmati. But the Indian consumer continues to pay a high price for a highly adulterated product happily believing it to be pure Basmati. Did it benefit the Basmati farmer or the consumer? No. Is any regulation and control working? No.

86. Ministry may explore the possibilities of patenting rights to the Universities or Government itself instead of giving a partnership right to the companies or originators. They can come out with a clean chit and show that the Government of India is not inclined to the interests of MNCs but that serving farmers interests and India's pride as a source of Intellectual Resources (which was once enjoyed by the developed nations) is its primary motto.

87. Public consultations are mandated in the Cartagena Protocol to which India is a signatory. The MoEF is right in setting a precedent like this.

Acronyms

AAEM	American Academy of Environmental Medicine
AYUSH	Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy
BMC	Biodiversity Management Committees
BRL I	Biosafety Research Level I
BRL II	Biosafety Research Level II
Bt	*Bacillus thuringiensis*
CaMV	Cauliflower Mosaic Virus
CBO	Community Based Organisation
CDFD	Centre for DNA Fingerprinting and Diagnostics
CFTRI	Central Food Technological Research Institute
CRIDA	Central Research Institute for Dryland Agriculture
CSIR	Council of Scientific and Industrial Research
DBT	Department of Biotechnology
DFRL	Defense Food Research Laboratory
DLC	District Level Committee
DNA	Deoxyribonucleic acid
DRDO	Defense Research Development Organization
EC-I	Expert Committee I
EC-II	Expert Committee II
FAO	Food and Agriculture Organisation
FSB	Fruit and Shoot Borer
GE	Genetic Engineering
GEAC	Genetic Engineering Approval Committee
GLP	Good Laboratory Practices
GM	Genetically Modified
GMO	Genetically Modified Organisms
GRAS	Generally Recognized as Safe
IAASTD	International Assessment of Agricultural Science and Technology for Development
IBSC	Institutional Biosafety Committee
IC	Independent Charge
ICAR	Indian Council of Agriculture Research
ICMR	Indian Council of Medical Research
IFOAM	International Federation of Organic Agriculture Movements
IgE	Immunoglobulin E
IICT	Indian Institute of Commerce and Trade
IIVR	Indian Institute of Vegetable Research
IPM	Integrated Pest Management
IPR	Intellectual Property Rights

ISAAA	International Service for the Acquisition of Agri-biotech Applications
ITRC	Industrial Toxicology Research Centre
KIA	Knowledge Initiative in Agriculture
LAIS Centre	Laboratory Animals Information Service Centre
MDR	Multi Drug Resistant
MEC	Monitoring and Evaluation Committee
MLRT	Multi-locational Research Trials
MNC	Multinational Corporation
MoEF	Ministry of Environment and Forests
MRTP Act	Monopolies and Restrictive Trade Practices Act, 1969
NARS	National Agricultural Research System
NATP	National Agricultural Technology Project
NBPGR	National Bureau of Plant Genetic Resources
NGO	Non Governmental Organisation
NIN	National Institute of Nutrition
NPM	Non-pesticidal Management
NSL	Nuziveedu Seeds Limited
OPV	Open Pollinated Variety
PCMU	Project Coordinating and Monitoring Unit
PVFR	Plant Varieties Protection and Farmers Rights
RCGM	Review Committee on Genetic Manipulation
RDAC	Recombinant DNA Advisory Committee
RISDC	Research and Information System for Developing Countries
ROS	Reactive Oxygen Species
SBCC	State Biotechnology Coordination Committee
TB	Tubercle Bacillus (Tuberculosis)
TNAU	Tamil Nadu Agricultural University
UN	United Nations
USA	United States of America
US FDA	United States Food and Drug Administration
US DA	United States Department of Agriculture
WHO	World Health Organisation
XDR	Extreme Drug Resistance

Glossary

Actinomycetes: group of bacetria found in soil and water that convert complex nutrient into simple ones for use by plants

Allergenicity: phenomenon of inducing allergic reaction by a foreign substance in body of an organism

Bilirubin: yellow breakdown product of normal heme catabolism. Heme is found in hemoglobin, a principal component of red blood cells. It is excreted in bile and its level increases in certain diseases

Carcinogen: substance responsible for cancerous growth

Centre of Diversity: a geographical location or local region where a particular taxon exhibits greater genetic diversity than it does anywhere else.

Centre of Origin: a geographical area where a group of organisms, either domesticated or wild, first originated and developed its distinctive properties

Cross Pollination: natural and or man-induced transferring pollen from the flowers of one plant of a species to the of another plant of the same species Cry1AC: protein produced by Bacillus thurengiensis to control insect pest

Endemic Organism: organism confined (found) only to a particular geographical area

Erythema: redness of skin caused by hyperemia of the capillaries in the lower layers of the skin. It occurs with any skin injury, infection, or inflammation

Gene: a sequence of DNA that either codes for the synthesis of a specific protein or has a specific regulatory function.

Genetic Engineering: a term covering all laboratory or industrial techniques used to alter the genetic material of organisms. These techniques assist organisms to produce new substances or perform new functions. For example increase yields of compounds already produced by the organism, form new compounds, or allow organisms to adapt to drastically altered environments.

Genetic Marker: a sequence of DNA with a known location on a chromosome and is known to be associated with a particular gene or trait. Some genetic markers are associated with certain diseases. Detecting these genetic markers in the blood can be used to determine whether an individual is at risk of developing the disease. They are also used as a reference point for mapping other genes.

Genetic Modification: any process that alters the genetic material of living organism. This includes duplicating, deleting or inserting one or more new genes or altering the activities of an existing gene. It can be performed on microbes, plants or animals (humans included). Genetically Modified Organism (GMO): an organism (plant, animal, bacteria, or virus) that has had its genetic material altered, either by the duplication, insertion or deletion of one or more new genes, or by changing the activities of an existing gene.

Genome: all of the genetic information or hereditary material possessed by an organism.

Hispathological Tests: microscopic examination of tissue in order to study the manifestations of a disease.

Horizontal Gene Transfer: any process in which an organism incorporates genetic material from another organism without being the offspring of that organism.

Integrated Pest Management: approach to managing pests by combining biological, cultural, mechanical and chemical tools in a way that minimizes economic, health and environmental risks

Isolation Distance: distances used in regions where genetically modified (GM) and conventional or organic crops are grown in co-existence. The "isolation distance" between fields refers to the area separating them, on which genetically modified pollen can settle without fertilising non-GM crops.

Lepidoptera: group of insects with scales that include butterflies, moths etc.

Monoculture: natural vegetation or farm composed of a single species

Mutogens: physical or chemical agent that changes the genetic material, usually DNA, of an organism and thus increases the frequency of mutations above the natural background level. Oedema: an abnormal accumulation of fluid beneath the skin or in one or more cavities of the body. Principle of Substantial Equivalence: a concept, developed by OECD in 1991, that maintains that a novel food (for example, genetically modified foods) should be considered the same as and as safe as a conventional food if it demonstrates the same characteristics and composition as the conventional food. Mutation: a change of the DNA sequence within a gene or chromosome of an organism resulting in the creation of a new character or trait not found in the parental type.

Proteins: chemical substances which mediate the form and function of cells and organisms either by forming part of definite structures or by acting as biological catalysts in living processes. Proteins are chains of different amino acids, and the order of amino acids and length of the chain are unique for each kind of protein.

Proteomics: large-scale study of proteins, particularly their structures and functions

Pruritus: an itch or a sensation that makes a person want to scratch which is caused by various skin diseases

Reactive Oxygen Species: very small molecules that include oxygen ions and peroxides and can be either inorganic or organic and have important roles in cell signaling

Terminator Gene: a specific genetic sequence inserted into a seed's DNA. Once activated by a synthetic chemical catalyst of the manufacturer's choosing, the sequence renders the seed and crop it produces sterile.

Transgene: a segment of DNA containing a gene sequence that has been isolated from one organism and is introduced into a different organism. Vector: something used as a vehicle for transfer. A bacteriophage, plasmid, or other agent that transfers genetic material from one cell to another. It can often be used carry foreign DNA into a host cell.

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ANNEXURE – II

Letters from States/MPs

(5)

V. S. ACHUTHANANDAN
CHIEF MINISTER
KERALA

D.O.NO.631/ VIP/CM/09. Dated: 13/10/2009

Dear Dr. Manmohan Singh Ji,

I am addressing an important issue here - the introduction of GM crops and food in Kerala as well as in the rest of the country. I understand our stand on the GM crops and foods was already made very clear to the Union Agriculture Minister, Shri. Sharad Pawar, and to you by our Agriculture Minister, Shri. Mullakara Ratnakaran and the Chairman of the Kerala State Biodiversity Board, Dr.V. S. Vijayan respectively.

We are concerned about the introduction of the GM crops into the State. We had conducted a national workshop on the desirability of the GM crops in April 2008. At the end of the two day workshop, a resolution was taken that the GM crops and foods should not be allowed in the State. A copy of the resolution is enclosed for your ready reference.

May I reiterate that Kerala State has already taken a policy decision not to allow GM crops, even for trials, until the debate on the issue of GM that is going on the world over is settled for ever. We are convinced with the available information that:

(a) GM crops are not economically viable for the farmers,
(b) GM crops and foods lead to unimaginable health hazards,
(c) GM crops contaminate the local and wild varieties, the damages of which are irrevocable and, such contamination of our traditional varieties cause irreparable damage to food security of the country
(d) GM denies the farmers right to choose what he / she wants to sow in his/her own farm, and ultimately,
(e) the country's sovereignty over food and agriculture will be endangered.

Secretariat, Thiruvananthapuram-695 001
Tel: (0471) 2333812 & 2333682; Fax: (0471) 2333489; email: cmkerala@vsnl.net
chiefminister@kerala.gov.in

Moreover, we are convinced that the Genetic Modification of crops is not a solution for hunger as has been wrongly advocated by the proponents of the GM, because the genetic modification is done not to increase productivity, but to control mainly the insect pests or the weeds. I am sure, you would agree with me that there are several cheaper and environment-friendly options to control the pests and weeds or even to improve productivity.

The State Government is very concerned about the protection of its biodiversity since 35% of the country's biodiversity is in Kerala. One of the main concerns among the scientific community and policy makers is about the environmental contamination of genetically modified organisms.

It may also be noted that the Task Force on Application of Biotechnology on Agriculture headed by Prof. M. S. Swaminathan is unambiguous that the mega-diversity centres and biodiversity hotspots like Western Ghats shall be kept free of any GM experiments/ crops.

The Task Force report further recommends that even the transgenic research should not be undertaken in crops/commodities where our international trade will be affected.

In this context, you may please note that Kerala is a State heavily dependent on international market for its agricultural commodities. Any contamination from genetic modification can cause further damage to the trade prospects of the State..

Kerala is also an important centre of diversity of medicinal plants and heritage of traditional medicines like ayurveda. Serious concern has already been expressed by the Ayurveda practitioners on GM research being undertaken on various crops.

You may kindly note that the State has already declared an Organic Farming Policy, Strategy and Action Plan in 2008. Accordingly, the entire food crops would be converted to organic within five years and the cash crops within another five years.

This will, apart from helping to feed the people with non-poisoned food, enhance our export possibilities with a high premium. However, introduction of GM crops will certainly defeat the very purpose of organic farming, because genetic contamination is a certainty once GM crops are released in to the environment. It would also kill the State's trade prospects.

Considering all these, the Government of Kerala has taken a decision to prohibit all environmental release of GMOs and keep the State totally GM free. We would request the Honourable Prime Minister to reconsider the policy on GM in the national scale and declare a moratorium at least for the next 50 years, so that we could learn the desirability of GM from other countries where it is being practised in large scale.

I request you to respect the well informed decision of the State Government and issue necessary orders to all concerned Ministries not to permit any GM research or release of GMOs within the boundaries of the State. Such an order from the Union Government will further strengthen the federal fabric of our nation as enshrined in the constitution.

With kind regards

Yours sincerely,

(V. S. ACHUTHANADAN)

Dr. Manmohan Singh
Prime Minister of India
New Delhi.

अर्ध. शास. पत्र क्र./2180 दिनांक 23 OCT 200

चन्द्रशेखर साहू

मंत्री

कृषि, पशुपालन, मत्स्य पालन, एवं श्रम विभाग

छत्तीसगढ़ शासन

माननीय श्री रमेश जी,

मुझे समाचार पत्रों से जानकारी हुई है कि जैव प्रौद्योगिकी नियामक एजेंसी (जी.ई.ए.सी.) ने जैनेटिक मॉडिफिकेशन से तैयार किए गए बी.टी. बैगन की खेती को अपनी मंजूरी दे दी है। जी.ई.ए.सी. की मंजूरी वाली रिपोर्ट केन्द्र सरकार के पास अंतिम निर्णय के लिए लंबित है। इस विषय में मेरा सुझाव है कि इस बी.टी. बैगन सहित जैनेटिक माडिफिकेशन से तैयार अन्य सभी फसलों की खेती की भारत में मंजूरी न दी जाए। .

बी.टी. बैगन में अनुवांशिक परिवर्तन के लिए डाला जाने वाला जीवाणु बैगन में ऐसे विषैले पदार्थ उत्पन्न करता है, जिससे बैगन में लगने वाले कीड़े मर जाते हैं। ऐसे विषैले पदार्थ पैदा करने वाले बी.टी. बैगन खाने वाले मनुष्यों, पशुओं के साथ–साथ खेती के लिए भी खतरनाक और हानिकारक हो सकते हैं। छत्तीसगढ़ सरकार बी.टी. बैगन की राज्य और देश में खेती करने की मंजूरी देने के पक्ष में नहीं है। छत्तीसगढ़ सरकार बी.टी. बैगन खाने के बाद मनुष्य तथा अन्य जीव–जंतुओं के सभी शरीर, उसके पाचन तंत्र और अन्य जैविक क्रियाओं पर होने वाले प्रभावों के लिए सख्त परीक्षण करने के उपरान्त ही इसकी व्यावसायिक खेती को मंजूरी देने के पक्ष में है।

भारत में बी.टी. बैगन की व्यावसायिक खेती को केन्द्र सरकार की मंजूरी मिल जाने से भारतीय किसानों को इसके महंगे बीजों के लिए उस कम्पनी पर निर्भर रहना पड़ेगा, जिसके पास इसके उत्पादन और विपणन का अधिकार होगा। साथ ही यह बीज किसानों को हर साल खरीदने होंगे। इससे देश के गरीब किसानों पर अतिरिक्त आर्थिक दबाव बढ़ेगा और देशी बैगन की प्रजातियां समाप्त होने का खतरा भी बना रहेगा। ऐसी फसलों की खेती से भूमि की उर्वरा क्षमता पर भी विपरित प्रभाव पड़ेगा। महाराष्ट्र, आंध्रप्रदेश और पंजाब सहित देश के विभिन्न क्षेत्रों में किसानों द्वारा आत्म हत्या के अधिकांश प्रकरणों का कारण इसी तरह के जैनेटिक माडिफिकेशन से विकसित बी.टी. कॉटन और अन्य फसलों से होने वाले नुकसान और कमियां हैं।

अन्तर्राष्ट्रीय स्तर पर भी अमेरिका और कई यूरोपीय देशों ने भी अपने यहां बी.टी. बैगन जैसे जैनेटिक माडिफिकेशन से विकसित फसलों की खेती को मंजूरी नहीं दी है। साथ ही जी.ई.ए.सी. के वैज्ञानिक भी ऐसे फसलों की खेती के लिए एक मत नहीं हैं। जी.ई.ए.सी. के ही वैज्ञानिक डॉ. पी.एम. भार्गव जोकि माननीय उच्च्तम न्यायालय के पर्यवेक्षक भी हैं, ने भी इस प्रकार की खेती को मंजूरी न देने का मत व्यक्त किया है। डॉ. भार्गव ने ऐसे किसी भी फसल के व्यवसायिक खेती से पहले उसके विषैले प्रभावों के विषय में 29 बायोसेफ्टी परीक्षण करने की भी सलाह दी है।

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छत्तीसगढ़ शासन

चन्द्रशेखर साहू

मंत्री

कृषि, पशुपालन, मत्स्य पालन, एवं श्रम विभाग

छत्तीसगढ़ शासन

आस्ट्रेलिया में जैनेटिक मॉडिफिकेशन तकनीक से विकसित खाद्य पदार्थों के उपयोग से स्थानीय लोगों में नपुंसकता और बांझपन के मामले भी सामने आए हैं। देश के कई राज्यों की सरकारों ने भी बी.टी. बैगन की खेती को अपने राज्यों में मंजूरी न देने का मन बना लिया है।

बैगन मूलतः भारत की गरीब ग्रामीण जनता की मुख्य सब्जी है। भारत में ही बैगन की करीब 35 हजार से अधिक स्थानीय प्रजातियां पाई जाती हैं। साथ ही स्थानीय प्रजातियों का उत्पादन और उत्पादकता भी अच्छी है। ऐसी स्थिति में भारत में बी.टी. बैगन की खेती की आवश्यकता समझ से परे है।

आप के माध्यम से केन्द्र सरकार को छत्तीसगढ़ सरकार का और व्यक्तिगत रूप से मेरा यह सुझाव है कि बी.टी. बैगन की देश में व्यावसायिक खेती को मंजूरी देने से पहले उसके मनुष्यों और दूसरे जीव–जंतुओं पर पड़ने वाले सभी जैविक और हानिकारक प्रभाव का सफल परीक्षण कर लिया जाए, ताकि विश्व अर्थ व्यवस्था की रीढ़ खेती किसानी और मानव के अस्तित्व की रक्षा की जा सके।

सादर

(चन्द्रशेखर साहू)

प्रति,

माननीय श्री जयराम रमेश जी,
केन्द्रीय पर्यावरण मंत्री
भारत सरकार
नई दिल्ली

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B. S. YEDDYURAPPA
CHIEF MINISTER

VIDHANA SOUDHA
BANGALORE - 560 001

Date : 23-01-2010
CM/77/601/2010

Dear Sri Jairam Ramesh ji,

This has reference to your letter No.1-58/09-MOS(EF)-2457 dated 10th November, 2009 regarding the views of Government of Karnataka on Bt Brinjal.

Bt Brinjal, a genetically modified brinjal, with Bt gene is supposed to have resistance to pests like brinjal fruit borer and shoot borer and is cleared by the Genetic Engineering Approval Committee [GEAC] of Government of India for its commercial release in the country. This has generated heated debate all over the country.

This issue has been examined in detail and the considered opinion of our Government is as follows:

1) Brinjal is grown in about 15,000 ha. in Karnataka with an annual production of about 3.60 lakhs tons. This accounts for 3.5% in area and 5.0% in production of the total vegetable crops in the State. About 50 varieties of brinjal are grown by the farmers. Many of these are local varieties, which are hardly sprayed with pesticides, because pest management in traditional brinjal varieties is fairly easy, as these varieties are grown in specific geographical locations and congenial seasons. Any occurrence of pests can be controlled by spraying commonly used botanical or bio-digester extracts. As such, there has been no demand from the farming community for a new variety in brinjal.

2) Bio-safety of Bt brinjal, though assured by scientific fraternity supporting Bt brinjal, is based on assumptions without long-term research. The bio-safety of Bt brinjal with respect to soil, flora and fauna particularly beneficial micro-organisms, which are highly useful in enhancing the soil health, is a matter of great concern, which needs to be suitably examined. Therefore, the nutritionalists, human and animal health care professionals and environmentalists need to look into all these issues on a long-term basis to assess the bio-safety of Bt brinjal.

... 2/-

B. S. YEDDYURAPPA

VIDHANA SOUDHA

Date : 23-01-2010
CM / 77 / 501 / 2010

3) Local and traditional brinjal varieties are being widely used in Indian Systems of medicines like Ayurveda, Sidha and many traditional home remedies. The Bt gene in traditional brinjal varieties could pose potential danger to preparation of such medicines.

4) The farmers are not depending on external agencies for supply of seeds of local varieties at present. However, introduction of Bt brinjal will make the farmers totally dependent on Multi National Companies for supply of seeds which is not a healthy trend and hence certainly not in the interest of the farmers.

In view of the above, the commercial release of Bt brinjal should be deferred till the issue is thoroughly examined from all the angles by taking into account the views of all the stakeholders and conducting a long term research for its bio-safety and its consequent contributions to food security and farmers well being.

With regards,

Yours sincerely,

[B.S.Yeddyurappa]
Chief Minister

Shri Jairam Ramesh,
Hon'ble Minister of State (Independent Charge) for
Environment and Forests,
Government of India.
NEW DELHI – 110 003.

No. CMS / 2009 / 114

Narendra Modi
Chief Minister, Gujarat State

25 NOV 2009

Respected Shri Jairam Rameshji,

I am in receipt of your D. O. Letter No. 1-58/09(MOS)/2457 dated November 10, 2009 regarding the utilisation of Bt. Brinjal on commercial basis.

We will be back with our views in this regard.

With kind regards,

Yours sincerely

(Narendra Modi)

Shri Jairam Ramesh
Hon. Minister of State (Independent Charge)
Environment and Forests
Government of India
New Delhi - 110 003

Chief Minister's Office (ISO 9001:2000 Certified)
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CHIEF MINISTER
MAHARASHTRA

No. CMS/09/96067
November 16, 2009

Dear Shri Jairam Ramesh*ji,*

I am in receipt of your demi-official letter No. 1-58/09-MOS(I/C)/2457, dated November 10, 2009 regarding Bt-Brinjal.

I am getting the matter examined. I shall revert to you soon after.

With regards,

Yours sincerely,

(Ashok Chavan)

Shri Jairam Ramesh,
Minister of State (Independent Charge) for
Environment & Forests,
Government of India,
Paryavaran Bhavan,
CGO Complex,
Lodi Road, New Delhi 110 003.

CHIEF MINISTER
BIHAR

PATNA

D.O. No- 4610442/C.M.S. Dated- 08.12.2009

Dear Shri Jairam Ramesh Ji,

Please refer to your D.O. No. 1-58/09-MOS(IC) 2457 dated 10.11.2009 wherein you had sought the opinion of the State Government on Commercialization of Bt-Brinjal. This issue was carefully considered by the Rajya Kisan Ayog. The Ayog after deliberations with farmers, agricultural scientists and agriculture officers was of the opinion that there should be an adequate number of trials to see its performance in different agro-climatic conditions in the State. Such trials should be held involving agricultural research institutions in the State.

The Ayog also noted that no data has been provided on the commercial aspect of cultivation Bt-Brinjal which is so important from the point of view of farmers who are mostly small and marginal farmers. The Ayog is therefore not in favour of introduction of Bt-Brinjal in the State at this point of time.

The recommendation of the Rajya Kisan Ayog has been considered by the State Government and the State Government fully endorses the view of the Ayog.

With warm regards,

Yours Sincerely,

(Nitish Kumar)

Shri Jairam Ramesh,
Ministry of State (Independent Charge),
Environment & Forests
Government of India.
New Delhi-110003

PS

মুখ্যমন্ত্রী
পশ্চিমবঙ্গ
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Imp
PS

D.O No. 90 -CM
November 19, 2009

Dear Shri Jairam Ramesh,

Thank you very much for your letter of 10th November, 2009 seeking the views of the Government of West Bengal on the commercial cultivation of Bt-Brinjal.

As you are aware there is a serious public debate on the issue. Some of the issues are being repeatedly raised through scientific and economic analysis. Use of technically modified seeds represents a radical departure from the cultivation of the traditional hybrids. In cultivation of GM-crops, it is important to look at each crop on a case specific basis and assess its specific risk profile. There are clear reasons to be concerned about commercial cultivation of Bt-Brinjal. One of the worries is about "gene spills" or the contamination of the landraces by the engineered variety. This means that it has potential to threaten bio-diversity, destabilize important ecosystems, and limit the future agricultural possibilities in a region.

In addition, there remain vital questions of the impact of GM-Crops on human health, particularly when genetic engineering introduces the possibilities of physiologic or biochemical effects on the target varieties. The current generations of commercially available crops also raises concerns linked to pesticide uses as Bt-crops are designed to internally create their own pesticides. While in the short term, one might expect some decrease in pesticides use; in the long run it may not be very effective. In the developed countries, particularly in Europe, consumers can have choice between non-GM products and GM-products, but in our country the retail markets are not developed enough to make such a distinction. This leaves consumers without any choice.

Continuation Sheet

Further, there are also concerns about the economics of use of GM-crops in developing countries. The commercial producers of Bt-Brinjal seeds claim that poor farmers will benefit from cultivation of the crop through higher productivity, but in reality it may not be so in the long run. The farmers may not only become dependent on the monopoly supplier for the seeds but also for other inputs as 98% of the World GM-seed market is controlled by only six companies.

I have got the report of the Expert Committee of the Genetic Engineering Approval Committee downloaded. I feel that the matter needs through examination by the experts in the field. I am requesting some members of the erstwhile State Agricultural Commission to examine the report and forward their views to the government to enable us to take holistic view on the subject.

With regards,

Yours sincerely,

(Buddhadeb Bhattacharjee)

Shri Jairam Ramesh,
Minister of State (Independent Charge),
Environment and Forests,
Government of India,
New Delhi – 110 003

Dr. DAMODAR ROUT
MINISTER
Agriculture, Co-operation, Fisheries & Animal Resources Development
Orissa

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D. O. No. 35/MHCF

BHUBANESWAR

Date 15-1-2010

Dear Sir,

I extend my hearty welcome to Hon'ble Minister of State (I/C), Govt. of India, Ministry of Environment and Forests on his visit to the State of Orissa.

The Government of Orissa is happy to note that the Hon'ble Minister of State (I/C) E&F, Govt. of India is organizing a public consultation in the State of Orissa on Bt. Brinjal. However, in view of the fact that 82% farmers of Orissa are small and marginal, they are dependent on indigenous varieties of Brinjal for its cultivation. It may lead to monopoly of a few seed producers in the country, detrimental to interest of the farmers of Orissa. Further, there have not been sufficient trials on this crop in the State, the Govt. of Orissa does not support the introduction of Bt. brinjal at this stage unless and until sufficient trials are made and interests of small and marginal farmers of the State are safe guarded.

Warm Regards

Yours sincerely,

(Dr. Damodar Rout)

To
Sri Jairam Ramesh
Minister of State (I/C), Govt. of India,
Ministry of Environment and Forests

BASUDEB ACHARIA, M.P.
LEADER
CPI-M GROUP IN LOK SABHA
CHAIRMAN
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(LOK SABHA)

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No.BA/ARD/2010

23.1.2010

Respected Prime Minister,

Sub:- Introduction of Bt. Brinjal

As you are kindly aware the Genetic Engineering Approval Committee (GEAC) has given approval for environmental release of Bt. Brinjal which has been put on hold due to vehement protest by peasant organisations, scientific community and NGOs. A number of important brinjal producing states have written to the Govt. of India protesting introduction of Bt. Brinjal in their states. Ministry of Environment & Forest, Govt. of India, in view of genuine protest by a large section of the population, learned to have decided to delay the introduction of Bt. Brinjal. The issues pertaining to genetically modified seed need to be addressed, especially after witnessing the impact of Bt. Cotton on farming community before taking any decision on introduction of Bt. Brinjal. In this connection I would like to draw your kind attention to the following:

Introduction of Bt. Cotton- An experience

After GEAC had given approval to Monsanto to launch its Bt. Cotton Monsanto charged an exorbitant trait value (Royalty) of Rs. 1200/- (per packet of 450 kg). Bt. Cotton seeds were being sold at an exorbitant price of Rs. 1800/- to Rs. 2000/- per packet. Based on the complaint the matter was referred by Govt. of Andhra Pradesh to Monopolies and Restrictive Trade Practices Commission (MRTPC). MRTPC indicted Monsanto and passed an interim order stating that Monsanto is indeed following restrictive trade practices and this had resulted in some relief to the farmers. Despite this Bt. Cotton seed prices are still priced at Rs. 750/- per packet of 450g which includes 120g Bt. Refugia (seeds that are not Bt. transformed or treated with Bt. Planted to generate resistance to psets) which is useless to farmers. Even now the royalty is high at Rs. 175/- per packet. The MNCs continue to retain the monopoly over seeds and there is no regulation on them.

Though the cotton yield has increased with the introduction of Bt. Cotton, the main beneficiary has been Monsanto and not the farmers. According to a study more than 50% of the benefits of additional yield has gone straight into the Monsanto's pocket and Govt. of India has no measure in place to protect the farmers from monopoly prices of Monsanto.

Studies also show that though Bt. Cotton has led to higher yields in most areas, the high cost of seeds has led to farmers spending much more on pesticides to protect such plants from non Bt. Pests, thereby defeating one of the major purposes of Bt. Introduction.

In case of Bt. Cotton there have also been reports of huge yield losses but the company did not pay compensation to farmers for yield losses despite the fact that the existing "Plant Variety Protection" law binds them to pay the same.

Measures to be taken

The Govt. of India, the Controller General of Patents, Designs and Trademarks should take immediate steps to rein in the MNCs that are following restrictive Trade practices and infringing upon the MRTPC provisions. There should be a cap on fixation of royalty, which should ensure that the seeds are available at affordable prices and an Agri-Biotec Regularity Authority be set up to ensure that the farmers are protected.

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The GOI must ensure stringent safeguards for the farmers who are using exorbitantly priced GM seeds with exaggerated claims of productivity and make the company accountable to losses suffered due to under performance

In addition to these measures the Ministry of Agriculture should take adequate measures to promote participatory plant breeding through an interface between the farming and the scientific community with attractive incentives, provide remunerative prices for seeds developed through this mechanism and also ensure certification to counter the seed monopolies and ensure self sufficiency.

Environmental release of Bt. Brinjal & concerns :-

In the event the decision coming into effect Bt. Brinjal will be the first transgenic vegetable to be cultivated and sold in the Indian Market. This is happening even as there are many unresolved issues surrounding the environmental release of transgenic vegetables as well as genuine concerns expressed over its safety for human consumption.

A number of groups have raised the issue of bio-safety of human consumption of Bt. Brinjal. It is also contended that the approval of Bt. Brinjal has been done by GEAC entirely based on Monsanto – Mahyco data. It is not clear what studies have been done regarding possible adverse effects due to introduction of Bt. Into the food chain. You would appreciate before Bt. Brinjal is approved by the govt., there needs to be an open and transparent procedures through which Monsanto-Mahyco's claims on the bio-safety and other concerns can be verified. Concerns regarding the health and environmental risks associated with GM crops are too serious to be disregarded.

It is relevant to mention that a number of states have drawn the attention of the Union Govt. pointing out irregularities and violations in the conduct of field trials on Genetically modified brinjal, rice etc. The need for rigorous bio-safety tests has also not been met by the company in a manner to dispel doubts raised about the implications of these crops for humans, animals and the environment.

A Padma Bhushan awardee, Founder director of Centre for Cellular and Molecular Biology, Hyderabad and one of most cited Indian scientists in the world, Shri PM Bhargava while talking about the techniques being used to test any harmful impact of the modified vegetables has expressed his views terming the approval of genetically modified brinjal in open market as the "biggest disaster to hit the country after independence".

Moreover, you would agree that new technologies should be consistent with the safety of the environment and our people. It should not lead to monopoly- the seeds produced by such advance technology should not lead to global MNCs controlling Indian Agriculture. Bt. Brinjal seeds would be controlled by Monsanto who have entered into an agreement with ICAR for this purpose. There is also the added threat of all future seeds and therefore Indian agriculture to come under the control of global MNCs and the charging of extortionate prices from Indian farmers.

The concerns like a) would the seeds be hybrid or would they breed true? b) Would the farmers be able to store the seeds and use it next year? c) What would be the price of these seeds and what would be the component of licence fees paid to Bt. Brinjal? d) What are the terms and agreement between ICAR and Monsanto-Mahyco should be redressed before introduction of Bt. Brinjal. Transparency from GEAC in making public the nature of the trails carried out and the bio-safety of the products should also be shown.

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One more concern relating to agro-economic which needs to be looked into is that using pest resistant varieties such as Bt. Cotton would lead to Bt. Resistance within the pests. The Monsanto solution for this is to intersperse Bt. Refugia and Bt. Cotton (in the US non Bt areas is from 20-50%) so that Bt. Resistant pests do not arise. However, while this may be easy in the US, where farmers may have hundreds of acres, if the land holdings are small and fragmented, may be difficult to implement. The net result would be the appearance of super pests very quickly and only short term gains to Indian agriculture.

In view of forgoing you would appreciate there is need for 1) a "National Biotechnology Regularity Authority" which will examine the agro-economic issues involved and also regulate the prices of seeds. 2) taking up the issues related to bio-technology monopoly – specially either creating alternative technology sources or using the compulsory licensing provisions of the patents Act if any such patent stand in the way 3) broadbased consultation on Bt. Brinjal involving all peasant organisations, scientific community, NGOs and state governments.

I sincerely hope you would ensure appropriate action on the above issues in the interest of the Indian Agriculture, farming community as well as in the interest of safety of humans, animals and the environment.

With kind regards,

Yours sincerely,

(BASUDEB ACHARIA)

Dr. Manmohan Singh,
Hon'ble Prime Minister,
Govt. of India,
New Delhi.

Copy to :- 1) Shri Jairam Ramesh, Minister of State (Independent Charge) Environment & Forest, Govt. of India.

(BASUDEB ACHARIA)

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K. ROSAIAH HYDERABAD

CHIEF MINISTER
ANDHRA PRADESH

Dt.3.2.2010.

Dear Sri Jairam Ramesh ji,

Please refer to your letter dated 10th November, 2009, requesting the views of the State Government on the issue of commercialization of Bt. brinjal.

The issue has been examined in consultation with the Vice-Chancellors of the Acharya N.G. Ranga Agriculture University (ANGRAU) and Andhra Pradesh Horticulture University (APHU). The Vice-Chancellors of both Universities have examined the GEAC Report published on their website, and have also held widespread consultations with Department officials, Scientists of the Universities, Bio Diversity Board, Non Government Organisations, Farmers Organisations, Seed Companies, National Institute of Nutrition, ICRISAT and Osmania University. Thereafter, the ANGRAU & APHU have submitted their report on the commercialization of Bt.brinjal which is enclosed.

The State Government have examined the issue in detail. It is clear that the data generated, the tests conducted and the information disseminated by GEAC are not sufficient for suggesting the commercial release of Bt.brinjal. The issues raised in the enclosed Report need to be addressed, and until safety parameters in terms of the environment, human and animal health are clearly established, release of Bt.brinjal for commercial cultivation is to be deferred. Further, we request that the Government of India may involve ANGRAU & APHU also in conducting trials and in development of the data base on the safety of G.M. technology in general, and Bt.brinjal in particular.

With regards,

Yours sincerely,

K. Rosaiah

(K. ROSAIAH)

Sri Jairam Ramesh,
Minister of State (Independent Charge),
Environment & Forests,
Government of India,
New Delhi – 110 003.

Report on "Bt Brinjal – Issues and Concerns"

Bt brinjal is a genetically modified brinjal created by inserting cry 1Ac gene from the *Bacillus thuringiensis* bacterium into the Brinjal plant. Insertion of this gene gives resistance to two important pests of brinjal viz., Fruit and Shoot Borer (*Leucinodes orbonalis*) and Fruit Borer (*Helicoverpa armigera*). Several events by different organizations are in different stages of development of Bt brinjal. The Bt brinjal developed by M/s Mahyco is now in advanced stages of trials for commercial release. So far strong views both in favour and against the commercialization of Bt brinjal in India are being expressed from various stake holders including Farmers, Civil societies, NGOs and Scientists.

In the light of the above facts, two meetings were organized by ANGRAU on 22-12-2009 and 16-01-2010 by involving all stake holders to present their views on the issue of Bt brinjal. The out come of these two meetings has clearly shown that there are some concerns, apprehensions and allegations as expressed by several stake holders participated in the above two meetings. Subsequently, the discussions were held in the chambers of Special Chief Secretary (Agri) and Hon'ble Minister for Agriculture. The gist of the out come of these meetings is given here under to facilitate the formulation of further course of action about the whole issue.

The Genetic Engineering Approval Committee (GEAC)'s guidelines, their compliance and certain observations on the issue of Bt Brinjal are submitted for kind perusal

The hybrids shall undergo a minimum of 2 seasons of LST/ICAR (2007 and 2008) prior to its further consideration for commercial release, if any. The LST/ICAR trials for assessing the environmental safety and agronomic advantage of Bt brinjal shall be carried out at minimum 11 locations within the institutional/research farms of IIVR/ICAR/SAU as per the protocol prescribed by the Director IIVR, Varanasi.

Seven Bt brinjal event EE-1 hybrids (MHB-4Bt, MHB-9 Bt, MHB-10 Bt, MHB-11 Bt,MHB-39 Bt, MHB-80 Bt and MHBJ-99 Bt) were evaluated for LST/ ICAR trials for two seasons i.e. Kharif 2007 and Kharif 2008 in various agro -climatic zones under the direct supervision of Director, IIVR , Varanasi.

- Data on environmental safety produced in respect of weediness characterization of *S. melongena*, germination, vigour and aggressiveness were conducted by MAHYCO but not by any government or public institution. The environmental safety, eco-toxicological tests were done by private laboratories - INTOX, Pune & Rallis India (Accredited by GOI) and also Desigen. Its suggested that the above information need to be generated by public institutions (ICAR Institutes/ SAUs/other Govt. Institutes) for more validity and transparency.

- Field based studies to assess impact on non target pests and beneficial insects indicated that number of non target sucking pests did not vary in Bt Brinjal. These studies were confined to only one season. Moreover, there is no data on the incidence of Mealy Bugs and other secondary pests in the trials. In the light of the reports of incidence of Mealy Bugs in Bt Cotton, data on the incidence of secondary pests in Bt Brinjal is essential.

- Since the pest scenario in a particular crop is very dynamic depending upon the concepts of secondary pest out break, it is necessary to develop a comprehensive management strategy for the minor pests which has the potential to become major pests. As this secondary pest out break is a gradual phenomena we have certain cushioning period to develop and keep the technologies ready for dealing the above mentioned situations.

- The management strategy for tackling possible secondary pests / new pests need to be worked out on the basis of the data available on pest status studies in brinjal and made available by the firms based on the tests conducted by public institutions (ICAR Institutes/ SAUs) for more validity and transparency.

- The studies have shown that the beneficial insects and other non target organisms were not affected by Bt protein (Chapter 5, p72, Vol-1 & p85-88, Vol-1). However, while the report did not mention about variations in the populations of non target and beneficial insects. By considering the dynamics of insect ecology it is important to conduct the studies with a location specific approach to get more clarity on this issue before commercialization of the technology.

- Soil impact studies have not assessed the variation in the population of useful soil microbes such as *Pseudomonas*, VAM and *Trichoderma*, in Bt Brinjal fields. However, already available data on the effect purified Bt Toxin in in-vitro conditions on *Pseudomonas* has been provided. This will not hold good under field conditions, because of the various interfering factors.
- In a similar study conducted at IARI, it is evident that no absolute counts of soil microflora were taken as a parameter which is essential to decide whether there is any adverse effect on microflora than depending on indirect parameters studied. More elaborative studies in this regard is needed.

- The agronomic advantage of 71% more yield of marketable brinjal has to be assessed in a long run on the sustainability of higher yield; reduction in yield per unit area because of mandatory refugia crop. More than agronomic advantage, economic advantage needs to be established by NCEAP (ICAR). Similarly, the yield advantage in Bt brinjal need to be compared with existing IPM package.

- Practically, the farmers are not growing refugia in Bt cotton and the damages of not growing refugia i.e. Development of resistance build up is experienced in Bt cotton now. Since Bt brinjal is grown in smaller areas (holdings), the maintenance of refugia is neither economical nor practical. Technically, in the absence of refugia there is every possibility of selection pressure on target insect and thereby development of resistance after some years will be expected. In the light of this, any new technology developed for control of any target pest should always come with necessary steps for avoiding the possibility of resistance build up also. Development of suitable IPM modules will serve the purpose.

The pollen flow shall be recorded during the field trials every 10 m up to 300 m in one trial plot at a minimum 6 locations representing different agro climactic zones for a period of two seasons. The pollen flow study should be conducted with a minimum of around 100 standing plants, planted to reconfirm the pollen flow over two seasons as per the revised design.

Pollen flow studies were conducted during 2007-08 and 2008-09 at two locations instead of six locations at Jalna (Maharashtra) and Nizamabad (Andhra Pradesh) experiments have to be conducted at six locations as stipulated.

- With regard to the pollen flow studies, they were conducted to demonstrate the extent of out crossing among different species of *Solanum*. Due the extent of out crossing the pollen flow within *Solanum melongena* in which more than thousand cultivated varieties exist in India, which are closely related and crossable with each other, will certainly enhance leading to erosion of genetic variability. Hence, pollen flow studies should be conducted within the species of *Solanum melongena* (varieties) atleast six locations as stipulated.

- Further, since these studies were conducted by MAHYCO only; it is suggested that these studies need to be conducted by public institutions for more validity and transparency.

- The information with regard to field trial of Bt brinjal in Nizamabad was not made available to State Authorities/ SAU/SBCC

- Being a often cross pollinated crop the risk of gene flow on long term further studies need to be done.

The field trials shall include a minimum of one location (at IIVR, Varanasi) to assess the extent of crossability of any one hybrid of Bt brinjal (*Solanum melongena*) with *S. incanum*. The trial should also record the findings with respect to weediness and invasiveness of Bt *S.melongena*.

Crossability studies were carried out by IIVR for two seasons. The studies showed that pollen mediated crossability from *S.incanum* and *S. melongena* is possible to a limited extent. However, pollen flow from *S.incanum* to *S. melongena* is easy as compared to *S. melongena* to *S. incanum*. The plots were also examined for aggressiveness as well as germination tests.

- **In addition to the two wild species, the pollen flow may also affect other cultivated brinjal species. India has a very rich biodiversity of brinjal which is having more than 1000 germplasm. Brinjal often being a cross pollinated crop, one year study is not sufficient. As risk of gene transfer exists on a long run, it is not advisable to permit GM crops in a country which is considered as origin / secondary origin of the crop concerned. Further, there is a risk of farmers switching over to the GM crop as it happened in case of Bt cotton, unmindful of the concern for biodiversity.**

The baseline susceptibility data for at least three pests – Fruit and Shoot borer (*Leucinodes orbonalis*), Gram caterpillar/fruit borer (*Helicoverpa armigera*) and Stem borer (*Euzopheraperticella*) shall be conducted during the two season field trials. Cry1Ac protein expression levels in plant parts shall be assessed every 15 days as prescribed by the RCGM throughout the crop cycle.

The baseline susceptibility for the target insect pests viz. Fruit and Shoot borer (*Leucinodes orbonalis*), Gram caterpillar/fruit borer (*Helicoverpa armigera*) and Stem borer (*Euzophera perticella*) was established during two seasons of field trials.

The data generated indicates that the three target insect pests are sensitive and highly susceptible to the Bt protein deployed in Bt brinjal event EE-1. Despite these studies the main concern is -

- Cry1Ac protein expression levels were assessed every 30 days, instead of 15 days as prescribed.
- Data on the level of expression of Cry1Ac at fifteen days intervals is not presented. The Bt protein content at different growth stages is essential, to demonstrate that at no stage of its growth, the Cry1Ac protein levels exceed the toxic levels to useful insects, cattle and goats.

Soil impact assessment study should include tests on the total microbial counts related to Rhizosphere on the soil of Bt and normal plots and for the presence/absence of Cry1Ac protein at different depths (maximum up to one metre) in the soil at one location. The changes in soil fertility and impact on the next crop may also be recorded, as per protocol devised by the Director, IIVR Varanasi. The study shall also assess carry-over effects of residues of Bt brinjal.

Soil impact assessment study was conducted on soil samples collected from Bt brinjal large-scale trial conducted at Parbhani (Maharashtra) during 2007-08 and 2008-09 as per protocol approved by IIVR.

- The study included tests on the total microbial counts related to rhizosphere. Though the counts included bacterial population, fungal population, earthworm and Collembola, the data on the population of useful soil microbes like Pseudomonas, Micorrhizae and Trichoderma are missing. This is important since they are useful soil microbes helpful as Bio Control agents for several diseases.

Bt brinjal being a food crop, a flavour analysis of Bt and non-Bt fruits shall be undertaken at Central Food Technology Research Institute (CFTRI), Mysore/ any other NABL accredited laboratory.

CFTRI, Mysore was approached for flavor study. However, they expressed their inability to conduct study on transgenic crop product at that stage.

However, as per the recently adopted "Guidelines for safety assessments of food derived from GE plants, 2008" , such kind of studies do not form part of safety assessment. So EC-II was of the view that such studies are not required as per the internationally prescribed Codex guidelines and national guidelines prescribed by the GEAC.

- However, the committee feels that as the consumption / marketability of brinjal mainly depends on flavor also, it is suggested to consider this parameter also for analysis.

The food/feed safety assessment should include any possible foliage/shoot toxicity study in goats.

This condition was stipulated in view of the apprehensions that there were sheep deaths in Andhra Pradesh due to grazing on Bt cotton fields.

- The majority of studies were conducted in private laboratories as per "Guidelines for the safety assessment of foods derived from GE plants, 2008", which is in line with the Codex requirement.
- The main concern is that the safety tests are carried out in private labs. Despite being government accredited private labs, the doubts are still persisting on their results. Hence, more involvement of government labs and public institutes is needed to instill confidence in the people.
- These studies were conducted for a short period of 90 days ignoring the cumulative effect of continuous feeding. It is suggested to take up long term studies for >180 days.

The skin sensitization test of transgenic material in guinea pigs as laid down in the DBT guidelines shall be conducted.

The skin sensitization tests were done on guinea pigs as per the "Guidelines for safety assessment of foods derived from GE plants, 2008" mostly in private labs.

- It is suggested to carry out such tests in a reputed Govt. institutions like IVRI etc.

Additional toxicity/ allergenicity/ compositional/ nutritional studies, if any, as recommended by Director, National Institute of Nutrition (NIN), Hyderabad shall be conducted.

Director, NIN was requested to examine raw data and clarify any variations/anomalies in the toxicity and allergenicity and also indicate the need to repeat additional food safety studies keeping in view the Codex guidelines. Raw data has been examined by Director, NIN and found to be satisfactory.

- However, simple verification of the data may not give the clarity and transparency in this regard. Hence, it is desirable that the above studies with regard to Bt protein present in Bt brinjal (raw) vs. cooked or processed brinjal need to be generated by public institutes like NIN, Hyderabad and CFTRI, Mysore.

Socio-economic study of Bt brinjal

The *ex ante* assessment of socioeconomic benefits of Bt brinjal has been initiated by NCAP with the financial support of MoEF.

Sustained economic benefits of Bt brijal Vs IPM brinjal on a long run are to be confirmed in view of :

i) Loss of crop due to refugia.
ii) Additional cost of Bt brinjal hybrid seed.
iii) Anticipated additional costs on controlling the secondary pests in the light of their incidence in Bt Cotton / development of resistance by FSB as in the case of boll worms in Bt cotton.
iv) Ultimately, the benefit to the farmer by growing Bt brinjal needs to be established taking the economics of Bt brinjal vs Brinjal grown with IPM practices.

Note: *Biosafety data of Bt brinjal is taken from the GEAC website* ***www.envfor.nic.in/divisions/csurv/geac/bt_brinjal.html*** *in like 8 volumes (Comparative food safety studies-4 volumes, Environmental safety studies-2 volumes and other studies-2 volumes).*

Vice-Chancellor
Admn. Office, ANGRAU
Rajendranagar, Hyd. - 30.

VICE CHANCELLOR
A.P.HORTICULTURAL UNIVERSITY
VENKATARAMANNAGUDEM-534 101
WEST GODAVARI DISTRICT (A.P)

ANNEXURE – III A

Submissions by Scientists in India

सत्यमेव जयते

जय हिन्द

MINISTRY OF SCIENCE & TECHNOLOGY

सचिव
भारत सरकार
विज्ञान और प्रौद्योगिकी मंत्रालय
बायोटेक्नोलॉजी विभाग
ब्लाक–2, 7 वां तल, सी० जी० ओ० कम्पलेक्स
लोदी रोड, नई दिल्ली–110003

डा० एम० के० भान
Dr. M. K. Bhan

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D.O.No.SBT/5578/09

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Dear Sir,

As desired, I have carefully analysed data related to safety and efficacy of Bt. Brinjal. Sir, you are well aware that regulation of Transgenic products is event/product specific. As I do not deal with regulation and had not examined the Transgenic Brinjal documents personally, it seemed unfair to express an opinion over and above that of GEAC, without personally studying all documents and cross checking on gray areas. It took time to access all documents and query the concerned scientists. My carefully considered view is as follows:

1. Need for Bt. Brinjal

Fruit and shoot borer (FSB) is one of the major pests of brinjal, which damage the crop to the extent of 80 percent. FSB control through pesticides is difficult to achieve effectively because, once it is hatched, it has two hours time for exposure to pesticide before it enters the fruit. Pesticide application is not possible within the two hour window to control the pest. Once in the stem/fruit, FSB will be protected from pesticide contact. Even repeated sprays are not useful, and only increase the cost of cultivation. Further, repeated sprays/indiscriminate use of pesticides has lead to increasing concern among the consumers about the high pesticide residues in vegetables. Bt. brinjal with toxin protein (Cry1Ac) specific to FSB, is an effective alternative to control the pest. Bt-brinjal has the potential to solve crop failure due to FSB infestation and provide a safe solution to farmers growing hybrid varieties.

2. Safety for human health and environment

A careful examination of the submitted documents shows that the regulatory system and committees governing the release of Bt-brinjal seem to have made a critical analysis of adherence of

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strict procedural formalities to examine the risks, if any. Bio-safety assessment of Bt. Brinjal included tests of toxicity, allergenicity of pure proteins and Bt. brinjal, analysis of key components, feeding studies with fish, chicken, cows, goats and rabbits, gene transfer from Bt. brinjal to other plants, gene transfer from Bt. brinjal to other organisms, potentiality for relative weediness of Bt-brinjal, impact on non-target organisms and soil impact studies.

These studies when reviewed by GEAC indicated that Bt-brinjal is risk free and safe for humans and animals for consumption. I concur with this view of GEAC. Further, Cry1Ac is non-toxic to humans and animals as they lack the receptor sites and the Bt protein is degraded during the cooking process.

3. Impact on genetic diversity of brinjal

Adverse effect of Bt. Brinjal on the genetic diversity of brinjal is not likely for following reasons:

- Several of the wild species of brinjal are self-pollinated (over 90%); pollen grains are sticky and do not travel over long distance; role of pollinators such as birds and insects is insignificant and the species do not hybridize in nature.
- Bt. Gene, if transferred to wild species/relatives will not confer any fitness advantage to the wild species because no major insect pests have been found to be feeding on them.
- There are no reports of inter-specific hybridization between the cultivated and wild species of brinjal.
- Though cultivated and wild relatives are crossable, their diversity in nature is not decreased and many land races occur in pure-form
- Studies on the floral structure and reproductive biology of brinjal and experience in cultivating the crop for several centuries in India, do not suggest any possibility of gene flow from transgenic brinjal to normal brinjal types.
- There are no reports on weediness and aggressiveness behavior as was evidenced in field trials at Indian Institute of Vegetable Research (IIVR), Varanasi.
- There was negligible out-crossing of 1.46 to 2.7% in trials conducted in multi-locations and maximum distance traveled by pollen was 15-20 meters.

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4. Benefits of Bt-brinjal

There is a consensus among agriculture scientists about several benefits of Bt Brinjal. Bt-brinjal will help realize: i) productivity increase per unit area and marketability of brinjal; ii) improved monetary benefits to farmers; iii) reduced environmental problems due to minimal use of spurious pesticides; iv) protection and improvement of human health due to phased reduction in use of pesticides; and v) contribution to an overall improvement of rural economy.

5. Bt brinjal is an illustration of co-development and not an international product

Bt.-brinjal technology is developed by Maharastara Hybrid Seeds Company (Mahyco). Mahyco developed the event EE-I by transferring Cry1Ac obtained from Monsanto and also transferred into 8 of its own varieties (MHB 4, 9, 10, 80, 99, 11, 39 and 111). Subsequently this event was transferred into other Bt. brinjal varieties both at TNAU (Co-1, PLR-1, MDU-1 and KKM-1) and UAS, Dharwad (Manjari, Gota, Udupi, Gulla, Malapur local, Kudachi local, 112-GO and Rabkavi local) to local varieties under the ABSP-2 (Agricultural Biotechnology Support Program) funded by USAID and managed through Cornell University. Subsequently, the same mode was adopted to transfer the event to IIVR, Varanasi, University of Philippines, Los Banos, Bangladesh Agricultural Research Institute and a private seed company (East-West seed company), Bangladesh.

While Bt. Gene discovery is an international effort, product development was a national effort. This is an effective model for biotechnology for years to come until India achieves discovery capabilities on larger scale. We have only now started to invest in gene discovery, in creating people, knowledge and intellectual property. When I joined DBT, its annual budget was 200 crores, which is a departmental budget in US or Europe. Our science is picking up rapidly, we now own a number of genes, and this product experience will be very useful in future. No country can live totally on its own discovery. Indeed, innovative countries will use product development expertise to leverage global knowledge and IP.

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6. Conclusion

To the best of my ability, and as a socially responsible scientist, my conclusions are as follows:

- *Bt-brinjal is a very useful solution to control the spread of FSB damage; FSB is also a pest on other crops.*
- *Its introduction will enhance the profitability of small and medium farmers and economize the cost of cultivation of brinjal.*
- *The new product will reduce pesticide residues in brinjal other foods and environment.*
- *I believe the available evidence, as well as background technological and scientific knowledge, indicate that Bt-brinjal is safe for human and animal health and the environment.*

That biotechnology cannot be ignored for future is a view that has Prof. M.S. Swaminathan's endorsement. We started too late but our strength is growing. I believe Biotechnology has huge potential in agriculture and nutrition, even more for health. We have a competent and professional regulatory committee. We need to show faith in our scientists who participated in this assessment. Over the next few years, we will built a strong professional organization to back up our scientists.

Our Scientists and Industry will be reluctant to invest time and resources, if they believe that our decisions are based on apprehensions, they might see in it an inability to deal effectively with modern technology and the complexity it involves. In that sense, this is a historic moment. It is our great fortune, to have a leader like your goodself to guide us. I am sure, you will take the right decision.

With regards,

Yours sincerely,

MKBhan

(M.K. Bhan)

Shri Jairam Ramesh
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Comments of the ICAR on Bt-brinjal

Brinjal is the most important vegetable crop grown across the country in different seasons. One of the most serious problems in cultivation is the infestation of the shoot and fruit borer, which causes severe losses to plant and fruits resulting in the reduction of marketable yield, a serious impediment in growing of brinjal.

To manage the shoot and fruit borer, chemical as well as integrated and pest management have been recommended, but due to excessive use of chemical resistance has developed against many insecticides and as such molecules are less effective. The IPM technology, which includes growing with various border crops, clipping of borer infested plant parts and use of pesticides, reduces the incidence of the pest but the problem continued to be serious. Many farmers in their quest for controlling the shoot and fruit borer attack resorted to very high dose of pesticides. Many times the number of sprays ranged for 10-12 which not only leaves residual toxicity but have potential to cause environmental pollution.

Since resistance to shoot and fruit borer of brinjal is not available in the species, the option is to look for transgenics. Accordingly, efforts have been made to develop transgenic using Bt gene *Cry1Ac*. The Bt brinjal developed by M/s Mahyco, UAS Dharwad and TNAU, Coimbatore with *Cry IAc* gene is specific to the target pest and does not have effect on non-target organisms like beneficial insects, birds, fish and mammals including human beings. Various studies on bio-safety, environmental safety and projected socio-economics benefits were carried out by several research laboratories. Based on the reports of various expert committees the matter was thoroughly examined by the committee (GEAC), which has approved the varieties for the commercial use.

The Bt brinjal hybrid were evaluated at 48 locations and trials indicated that Cry1Ac gene provides effective protection against shoot and fruit borer. Reduced infestations and 71% yield increase was recorded. Lower insecticides costs in Bt hybrid coupled with high yield resulted in higher income.

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Bt Brinjal – Ban or Boon?

G.PADMANBAN

The Genetic Engineering Approval Committee (GEAC) cleared Bt Brinjal for commercialization on October 14, 2009. The activists are up in arms terming the approval as a shame. The government has chosen to go slow and states that it would consult the stake holders before making a decision on the release. It is not clear as to how this consultation process would help, since this process has been gone through earlier. Besides, the stake holders have taken hardened positions and would not relent. The arbiters would be the farmers. They would go for it if they can make profit, as has been the case with Bt cotton, clandestine or otherwise.

The Bt Brinjal trials have been reviewed by two expert committees, EC-I (2006) and EC-II (2009). Gilles-Eric Seralini, a French scientist and President of the Committee of Independent Research and Information on Genetic Engineering (CRIIGEN) and commissioned by Green Peace, has contributed his bit on behalf of the activists by stating that Bt Brinjal is potentially unsafe for human consumption. But, if one were to go through carefully the points raised by Seralini[1], it is in the nature of picking holes on the extensive environmental and food safety studies carried out by the developers of Bt Brinjal since 2002. The comments range from describing the Bt gene used as an unknown chimeric toxin containing Cry1Ac and Cry1Ab, whose safety remains unsubstantiated, to the use of prohibited antibiotic resistance markers and significant alteration of blood chemistry in the experimental animals used. Every parameter assessed from gene flow in non-target organisms to duration of the animal experimentation studies has been questioned, revealing a mind set to oppose anyway. It would be instructive to go through the assessment provided by the Expert Committee (EC-II)[2] , which has given a positive evaluation of the product, to each of the points raised by Seralini. First of all, the gene product is not an unknown toxin. It is 99.4% identical to cry1Ac gene and the 0.6% difference is due to replacement of one amino acid in the entire sequence, although amino acids 1 to 466 are derived from cry 1Ab and 467-1178 are derived from cry 1Ac. The antibiotic resistance markers used, npt11 and aad genes, are poorly expressed and states that in India the Brinjal crop has required 40 pesticide sprays in a season and in Bangla Desh, Brinjal crop was sprayed with pesticides 84 times in a span of 6-7 months! Bt Brinjal has been developed by Mahyco (a private company) and UAS, Dharwad/ TNAU, Coimbatore (Public Sector academic institutions) with other collaborators as well. Should we not recognize the toil of our own outstanding Agriculture Universities and a private partner, who is equally committed? The scientists involved in generating the ECII report are outstanding and internationally recognized for their contributions. Why should we ever think that they will compromise on the environmental and health safety of the nation? There is no reason for the government to delay the release of Bt Brinjal. In a couple of years one would know its success or otherwise in the field and farmers would provide the answer. A second green revolution is necessary for the country.

The government should actually use this occasion to come up with a policy framework on the commercialization of GM-crops. While, there can be no bar on any aspect of GM-crop research, commercialization needs a well deliberated policy issue. To start with Bt Brinjal, how would government ensure an affordable price for Bt seeds ? What would be the mechanism for technology advice to the farmer, year after year? What next? Would it be Bt Bhindi? Bt rice is on the horizon and is almost ready. China is ahead of us and will eventually go for Bt rice in a big way. With all the international trade and many countries going for GM-technology, what is the point in trying to put irrational obstacles without a scientific basis?

Scientists should also deliberate on the consequences of creating a Bt world. Even if the different Bt genes code for different proteins, they all seem to act through the gut receptor in the insect, although binding to different sites. What would happen if the receptor protein gets mutated? Resistance to different Bt gene products may result simultaneously. In a laboratory study it has been shown that among insects selectively bred for resistance to Cry 2Ab protein, some showed resistance to Cry 1Ac as well and the resistance could have involved the common step of activation through a protease[5]. Should we not go for genes acting through entirely different mechanisms for purposes of pyramiding? Monsanto may be far ahead of us in this game, but encouraging indigenous

Regarding the continual assessment of GM-crops in the field, it would be instructive to learn as to how the Environmental Protection Agency (EPA) in the USA undertakes such an exercise. For example, EPA undertook an exercise in 2001 to assess the performance of GM-crops in the preceding 5 years[6]. In puts were obtained in terms of human health assessment, insect resistance management, environment assessment in terms of gene flow etc. Additionally, it performs a watch dog function on even laboratory findings, which may have an implication for the field situation. There is a recent report entitled " Bt cotton in India- A status report" generated by the Asia-Pacific Cosortium on Agricultural Biotechnology (APCOAB)[7]. The status report examines all the publications on the performance of Bt cotton in India and endorses the significant increase in yield and revenue to the farmer and provides statistics for the phenomenal acceptance and adoption of this GM crop in the country. It also discusses the concerns and strategies to sustain GM-crop cultivation in future.

However, one needs a statutory body with regulatory authority and R&D capabilities to govern all aspects of GM crop cultivation in the country, once they are released for commercialization. The government can decide on the design of the institutional structure , but it would take considerable effort to put an autonomous institution in place, not just with authority, but with expertise to analyse data from the field and to generate data in the laboratory.

Finally, the institution suggested should play a major role in providing authentic and correct information to the public on GM-technology. Many unsubstantiated reports ranging from failure of germination of Bt seeds to death of goats eating Bt crop residues are engineered to appear in the press. Several months ago, I was appalled to read a report that activists had approached the Supreme Court to stop scientists from introducing genes to bring about male sterility in plants, a combiner required for plant breeding, stating that it is terminator technology! Ingo Potrykus, the discoverer of golden rice to improve Beta-carotene (Vitamin A source) content was criticized either way, first projecting that children could be poisoned by excess vitamin A and later stating that 4 kg of rice is the daily requirement for a therapeutic effect! This story of the loss of biodiversity due to introduction of a couple of foreign genes is overstated. Can any one

BT BRINJAL: 1. TECHNOLOGY AND BIOSECURITY REGULATION

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1. GENETICALLY ENGINEERED CROPS

In the year 2008, about 30 countries have approved genetically engineered (GE) crops either for commercial cultivation or for imports. Global cultivation of GE crops increased from 1.7 mill ha in 1996 to 125 mill ha in 2008, accounting for a cumulative acreage of two billion acres (800 mill ha) (James, 2008). Issues related to the impressive growth of GE crops and the diverse benefits of 13 years of their commercialization are in detailed by James (2008).

2. *BT* CROPS

Transgenic technology, involving a wide range of pesticidal genes from the universally occurring soil bacterium *Bacillus thuringiensis* (*Bt*), dominates the scenario of GE crops (the *Bt* crops). Literature on *Bt,* discovered over a 100 years ago and in use as a pesticide for some 70 years, is very vast. The reader is advised to refer to 'Transgenic *Bt* technology' (Kameswara Rao, 2009), for a referenced review of the technology and related issues.

Bt proteins are *per se* not toxic. To function as toxins *Bt* proteins require a specific set of biochemical and biological parameters which are available for different *Bt* proteins only in specific insect groups, which makes *Bt* toxins insect group specific. For example, Cry1Ac and Cry2Ab control the cotton bollworm, Cry1Ab controls corn borer, Cry3Ab controls Colorado beetle of potato and Cry3Bb controls corn rootworm. The *Bt* genes incorporated into different crops are specific to Lepidopteron (having wings covered by scales) pests on them (Glare and O'Callahan, 2000).

The following *Bt* crops are in commercial cultivation or permitted for imports in different countries (James, 2008):

***Bt* corn:** Argentina, Australia, Brazil, Canada, Chile, China, Columbia, Czech Republic, Egypt, European Union Countries, Honduras, Japan, Mexico, Netherlands, New Zealand, Philippines, Romania, Russian Federation, Singapore, South Africa, South Korea, Switzerland, Taiwan, UK, Uruguay and USA.

***Bt* cotton:** Argentina, Australia, Brazil, Burkina Faso, Canada, China, Columbia, European Union Countries, India, Indonesia, Japan, Mexico, New Zealand, Philippines, South Africa, South Korea and USA.

flower and fruit production and fruit damage drastically reduces marketability of the produce. Even after continuous and very heavy insecticide application, the SFBs affect 50 to 70 per cent of the crop yield annually, the damage starting from the nursery and carried to the next crop (Choudhary and Gaur, 2009). External application of insecticides does not much help as the pest is deep in the stem and fruit tissues. The Cry1Ac gene imparts an inbuilt systemic tolerance to the pests, particularly *Leucinodes orbonalis. Helicoverpa armigera* (American bollworm), the major pest on cotton which is controlled by Cry1Ac gene, also affects brinjal fruit. The *Bt* brinjal effectively resists both these pests resulting in diverse benefits to the farmer, consumer and the country, more particularly vastly enhanced produce recovery and the avoidable use and exposure to pesticides and their residues.

Mahyco has integrated EE1 into eight of its own brinjal hybrids (MHB 4, 9, 10, 80, 99, 11, 39, 111). The TNAU developed *Bt* brinjal varieties Co-1, PLR-1, MDU-1 and KKM-1, while the UASD developed *Bt* varieties Manjari Gota, Udupi Gulla, Malapur local, Kudachi local, 112-GO hybrids and Rabkavi local, together covering a large part of the needs of the different States, though several more *Bt* hybrids and varieties need to be developed to every suit the requirements of every brinjal growing region in India.

3.3 Private-Public Partnership

The development of *Bt* brinjal varieties constitutes a welcome private-public partnership. A similar arrangement is extended to the Indian Institute of Vegetable Research, Varanasi, University of Philippines, Los Banos, Bangladesh Agricultural Research Institute and a private seed company, East West Seeds, Bangladesh. The transfer of technology from the private to the public sector was effected through the Agricultural Biotechnology Support Project II, funded by the USAID and managed by the Cornell University.

4. EVALUATION OF GE CROPS

4.1 Biosecurity

In the context of modern agricultural biotechnology the term Biosecurity has two components: a) Biosafety, the safety of genetically engineered (GE) organisms and/or their products to humans and animals as food, feed and medicine, and b) Environmental safety, the safety of non-target organisms, soil and water. The terms biosecurity and biosafety are often used incorrectly as synonyms.

There is no risk-free technology. It was the international scientific community, not the activists, who have identified the possible biosecurity risks from the transgenic crops and devised protocols for the identification, assessment, quantification and mitigation of risk. Science has reasonable peer reviewed experimental evidence to answer biosecurity concerns.

Biosecurity issues are unfortunately often mixed up with political, economic, cultivates GE crops), and f) District Level Committees (DLCs, one for each district that develops or cultivates GE crops).

The Indian Government have issued the following documents to guide product developers and evaluators through the regulatory oversight: a) Handbook for IBSC Members (2005), b) Regulatory Frame Work for GMOs in India (2007), and c) Guidelines and Standard Operating Procedures for Confined Field Trials of Regulated, Genetically Engineered Plants (2008).

A number of public sector organizations such as the a) the Indian Council of Agricultural Research (ICAR), b) the Indian Council of Medical Research (ICMR), c) the State Agricultural Universities (SAUs), and d) the Drugs Controller General of India (DCGI) are contextually involved in biosecurity regime.

The ICAR and its institutions evaluate agronomic performance and environmental safety and recommend the crop for commercial release. The SAUs and the State Departments of Agriculture are involved in the pre- and post-release monitoring of the GE crops.

The following research institutions are contextually involved in the evaluation of GE crops: a) Indian Agricultural Research Institute, New Delhi (IARI), b) Indian Institute of Horticultural Research, Bangalore (IHRI), c) National Centre for Plant Genome Research, New Delhi (NCPGR), d) National Botanical Research Institute, Lucknow (NBRI), e) National Research Centre for Weed Science, Jabalpur (NRCWS), f) Central Rice Research Institute, Cuttack (CRRI), g) Directorate of Rice Research, Hyderabad (DRR), and h) Central Potato Research Institute, Simla (CPRI).

5. BIOSAFETY OF *BT* TRANSGENICS

Bt being a universally occurring soil bacterium, all species of plants and animals in agricultural and other situations, and those that use plants as food have been exposed to *Bt* and *Bt* proteins for centuries. *Bt* proteins are transient in the environment. The toxicity of *Bt* proteins is pest specific, dependent upon a set of biological pre-requisites. The use of *Bt* as a conventional pesticide for over 70 years has demonstrated that it is safe to the consumers and a variety of non-target organisms. Nevertheless, antitech activists raise the following safety concerns repeatedly, ignoring massive evidence on product efficacy and biosecurity of GE crops.

5.1 Toxicity

Bt proteins were shown to be harmless to vertebrates, including mammals and humans, even at high doses, by ingestion, inhalation or injection.

Bt is one of the few pesticides recommended for widespread application in North America (Glare and O'Callaghan, 2000), and was broadcast or sprayed on crops and air sprayed to control forest pests in Utah (US, 1990-1995) and Ontario (Canada, 1985-1994). Water borne *Bt* was air sprayed to control the Asian gypsy moth in Vancouver

The much publicized instance of toxicity of *Bt* corn pollen proteins to non-target organisms (Monarch butterflies; Losey *et al.,* 1999), was reinvestigated and disproved (Sears *et al.*, 2001). The performance of bumble bees was not affected in any manner by Cry 1Ab *Bt* proteins (Babendreier *et al.*, 2008). Chen *et al.*, (2008) showed that Cry1C proteins were safe to parasitoids that control pest populations in many crops, in contrast to the severe damage caused to the parasitoids by the traditional insecticides.

Reports of the death of peacocks and the death of farm animals in Andhra Pradesh and honey bee Colony Collapse Disaster in Europe and North America, deliberately attributed to the presumed toxicity of *Bt* proteins in GE crops, were shown to be due to causes other than *Bt* protein toxicity (Kameswara Rao, 2008 a,b).

6.3 Gene Flow From Transgenics

The possibility of gene flow from transgenics and the negative impact of this on other crops, biodiversity and the environment occupy a prominent position in discussions that denigrate modern agricultural biotechnology, although the experience gained from the regulatory processes of transgenic crops and their cultivation for over two decades have not indicated any serious possibilities of gene flow or its negative consequences. Gene flow depends upon the reproductive biology and breeding behaviour of the crop in question (Kameswara Rao, 2008 c,d), which the activists do not take into consideration.

6.4 Vertical Gene Flow

The essential pre-requisite for vertical gene flow is sexual reproduction between the transgenics and related plants. The ease of vertical gene flow depends upon the genetic relationships between the varieties and whether the crop is self or open pollinated, which *Bt* technology does not change. Transgenics are no more promiscuous than their isogenics. If vertical gene flow were possible between isogenics and any related varieties or species, it would be so between transgenics and related plants too.

A study, much quoted by the critics as evidence of vertical gene flow, which relates to *Bt* maize in Mexico (Quist and Chapela, 2001), was reinvestigated and disproved (Ortiz-Garcia *et al.*, 2005).

The floral structure and pollination behavior of such *Bt* crops as tomato, potato, bell pepper and brinjal does not warrant any significant threat from gene flow among these crops or their supposed relatives (Kameswara Rao, 2008c,d).

6.5 Lateral/horizontal gene flow

Lateral/horizontal gene flow involves exchange of genes between genetically unrelated organisms, a fact of evolution, but not of day-to-day occurrence. It does not involve sexual reproduction and the transferred genes can express in the same generation.

The Mahyco Research and Life Sciences Centres (MRC) conducted the following studies on *Bt* brinjal: a) MRC, Kallakal, Andhra Pradesh: substantial equivalence of *Bt* and non-*Bt* brinjals, b) MRC, Dawalwadi, Maharashtra: protein expression, effects of cooking and protein in cooked fruit and c) MRC, Ranebennur, Karnataka and Jalna, Maharashtra : pollen flow ((15 to 20 m; 1.46 to 2.7 per cent out crossing)

The following public and private sector institutions were involved in conducting various biosafety evaluations of *Bt* brinjal:

a) G. B. Pant University of Agriculture and Technology, Pantnagar: Feeding studies in lactating crossbred dairy cows;

b) Advinus Theraputic, Bangalore: Subchronic (90 days) feeding studies using New Zealand rabbits, b) Subchronic (90 days) feeding studies in Goats;

c) Intox, Pune: a) Acute oral toxicity studies in rats, b) Sub chronic oral toxicity study in Sprague Dawley rats,

d) Mucous membrane irritation test in female rabbit and d) Primary skin irritation test in rabbit;

e) Rallis India, Bangalore: Assessment of allergenicity using Brown Norway rats;

f) Central Avian Research Institute, Izatnagar: Effect on performance and health of broiler chicken;

g) Central Institute of Fisheries Education, Mumbai: Responses, as a dietary feed ingredient to common carp *(Cyprinus carpio)* on growth performances;

h) All India Coordinated Research Project on Vegetable Crops, Varanasi: Effects on non-target and beneficial insects; and

i) Indian Institute of Chemical Technology, Hyderabad: Chemical fingerprinting of *Bt* and non-*Bt* brinjal (including alkaloids).

All these studies have shown that *Bt* brinjal is functional and is as safe as non-*Bt* brinjal for human consumption and to the environment (Choudhary and Gaur, 2009).

8. ANTITECH ACTIVISM

From the time of initiation of development till commercial release, a GE crop involves over 10 years of research by over 150 scientific and technical personnel. Nearly two decades of experience in the development of *Bt* crops (including potato, tomato and bell pepper related to brinjal) and over 13 years of experience in their commercialization in nearly 30 countries has built up an enormous amount of biosecurity data that convincingly demonstrate their benefits and safety. *Bt* brinjal has been adequately tested

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BT BRINJAL: 2. AN ACTIVIST DESIGNED IMBROGLIO

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1. THE BACKGROUND

On October 15, 2009, the Genetic Engineering Approval Committee (GEAC) approved *Bt* brinjal for commercialization, considering it safe for human consumption and ready to be made available to farmers, basing on protracted product and biosecurity evaluation and its review by two Expert Committees (2007, 2009).

The activist groups who have been working hard for a ban on not just *Bt* brinjal but all genetically engineered (GE) crops in India slipped into a tizzy and demanded that the Minister for Environment and Forests (MoEF), Government of India, should reject GEAC's approval. They seem to have arranged for over '40,000 e-mails and letters' to the MoEF opposing the approval of *Bt* brinjal, which the MoEF said 'amounted to blackmailing' (The Hindu, October, 15, 2009).

The MoEF issued a Press Statement on October 15, 2009, stating that a) Comments are sought, by December 31, 2009, on the Expert Committee report placed on the Ministry's website (www.moef.gov.in), b) during January-February 2010 he would have a series of consultations with in different places with scientists, agriculture experts, farmers' organizations, consumer groups and NGOs representing all points of view, and c) the decision will be made only after the consultation process was complete and all stakeholders are satisfied that they have been heard (October 15, 2009) (http://moef.nic.in/downloads/public-information/Press_Bt%20Brinjal.pdf). The public response should be communicated to the MoEF as per the information provided towards the end of this brief.

The MoEF's decision is surprising and seems pointless for several reasons:

a) In India, *Bt* brinjal passed through extensive agronomic and biosecurity evaluation as per the mandatory provisions of the Indian Regulatory regime, during 2000-09 involving about 200 scientists and experts from over 15 public and private sector institutions.
b) *Bt* brinjal's agronomic and biosecurity evaluation dossier is on the GEAC website since November 2008 (http://www.envfor.nic.in/divisions/csurv/geac/bt_brinjal.html).
c) The First Expert Committee recommended to the GEAC to permit *Bt* brinjal for Large Scale Field Trials (July 2007). The GEAC accepted this recommendation (August 2007) and directed that the trials be conducted for two seasons under the

The activist charge sheet includes several issues, the following being more prominently repeated: GE products are toxic and allergenic, they harm non-target organisms, gene flow from transgenics eliminates related varieties/species, they become super weeds and eliminate all vegetation, they negatively impact ecology and biodiversity, there is a terminator gene in GE crops affecting the farmers' interests, etc. They attribute farmer suicides to failure of GE crops. There is vast evidence to show that none of these charges has any substance.

They cite European Union (EU) countries for their rejection of GE crops, ignoring about 30 countries that have approved them, though even in the EU imports some GE crops (for example, MON 810 corn) are permitted. They brand GE technology as foreign technology while the ideas and means of their activism themselves were imported. The bulk of the arguments sound MNC phobia and anti-Americanism.

The spread and depth of anti-tech activism costs enormous amounts of money and the Government never questioned the sources. Opposing GE technology is a matter of livelihood and not a calling for the vast majority of the activist groups who pursue someone's agenda.

The European role in anti-GE activism in India was being reported for long. Times of India (February 11, 2001) referred to reports that 'the European NGOs have funded the Indian NGOs in order to stop transgenic seeds and they are spreading plenty of disinformation.... (and) have even taken the Indian government to court' (http://www.gene.ch/genet/2001/Feb/msg00035.html).

There is vast information on the internet indicating that European funds to multinational activist groups are diverted to intervene in the policies of foreign governments and to mould public opinion in different parts of the world. For example, the Friends of Earth (FoE) produced a report entitled "Who Benefits from GM crops? - The Rise in Pesticide Use", to mislead the public that these crops 'are not good for the environment, as they are increasing pesticide use,' and that they 'do not benefit small farmers or consumers in terms of quality or price.' This and several such other misleading claims were countered by the international scientific community.

Greenpeace and FoE are 'multinational corporations registered themselves as political lobby organizations with European Union' (http://www.gmobelus.com/2009/06/24/eus-ngos-declare-they-are-lobbyists). European money seems to be spent in India to disrupt our agricultural efforts. In June 2009, Greenpeace have invaded a field trial in India. It was reported that 'Sponsored by the European Union, and funded by the government of the Netherlands, the activists struck a government-approved 1,440 sqm field trial of rice in Chinnakanjarla village of Medak district. No injuries were reported, nor any complaints lodged regarding India's territorial sovereignty' (http://www.gmobelus.com/2009/06/24/european-lobby-group-invades-indian-field-trial).

The exact origin of *Solanum melongena* is uncertain. It is not known in the wild, barring as an escape from cultivated fields. It probably originated from the African wild species *Solanum incanum*. *Solanum melongena* was first domesticated in Southeast China, and taken to the Mediterranean region during the Arab conquests in the 7th century. If brinjal was mentioned in ancient Indian literature, it only indicates that it was naturalized, having been introduced into India, a long time ago and this in itself is not an evidence of its origin in India.

Hindu tradition prohibits brinjal in food served particularly at the time of death ceremonies (the 10th to 13th day or annual ceremonies), along with several other vegetables (even chillies for that matter) which are not native to India. This is also a pointer to that brinjal is not native to India.

3.3 Centres of Diversity of brinjal

India is one of several Centres of Diversity of brinjal. There is a large number of varieties of brinjal in India, but not two or three thousands as the activists claim, probably based on a confusion between accessions in a seed collection and the actual number of varieties/hybrids. Chaudhary and Gaur (2009) listed 28 hybrids and 88 varieties of brinjal released during the past thirty years. Farmers generally habitually opt for new varieties/hybrids and discord old ones. After a time the stored seed loses its viability and seed banks become seed musea. Counting unusable collections does not help even the activist's an argument in boosting up the number of varieties.

3.4 Gene flow from *Bt* brinjal

The floral structure and pollination behavior of such *Bt* crops as tomato, potato, bell pepper and brinjal do not warrant any significant threat from gene flow among these crops (*bt* or not) or their supposed relatives (Kameswara Rao, 2008c,d). In nature, species of *Solanum* do not normally hybridize, as they are predominantly self-pollinated (90 per cent). Even when artificial hybrids are produced, the progeny are sterile. The farmers never complained of any hybrids between their variety and a neighbouring farmer's variety and they do not make any effort to protect varieties of cultivated brinjals from hybridizing among themselves or with the wild Solanums.

3.5 Rejection of GE crops by some countries

There is a serious concern that European Union countries and others would reject Indian farm exports if they contain some GE element. Exports help only the middle men and not too many farmers and certainly not the small farmer. Should our agriculture be geared to cater to the European Union and a few rich exporters or should it mind our own people?

The United States Department of Agriculture issued a missive that brinjal imported from Israel and Ghana should be free from *Leucinodes orbonalis and Helicoverpa armigera,*

4. SUPPORT *BT* BRINJAL

Consider all evidence available and if you are convinced of the efficacy and safety of *Bt* brinjal, communicate with the MoEF, in support of it. Those who would like to write to the Shree Jairam Ramesh, the MoEF, can do so by post (Minister of State (Independent charge), Ministry of Environment & Forests, Paryavaran Bhavan, CGO Complex, Lodhi Road, New Delhi - 110003, India, or by fax (+91-11-24362222) or by e-mail (mosef@nic.in, jairam@vsnl.com) or post your comments via MoEF's website (http://moef.nic.in/modules/contact-ministry/contact-ministry/) before December 31, 2009.

5. FURTHER READING

Space and time constraints prevent a lot more of information from being presented here. If you wish to know more, refer to the following, in addition to the websites indicated above:

Amman, K. 2004. The impact of agricultural biotechnology on biodiversity. A review. Botanical Garden, Berne, Switzerland.
http://www.botanischergarten.ch/Biotech-Biodiv/Report-Biodiv-Biotech12.pdf (accessed April 29, 2009).

Choudhary, B. and Gaur, K. 2009. *The development and regulation of Bt brinjal in India.* ISAAA Brief No. 38, ISAAA, Ithaca, USA.

Crawley, M. J., Brown, S. L., Hails, R. S., Kohn, D. D. and Rees, M. 2001. Transgenic crops in natural habitats. *Nature,* **409**: 682-683.

Daunay, M. C., Lester, R.N. and Ano, G. 2001. Cultivated eggplants. , In *Tropical Plant Breeding*, edited by A. CHARRIER, M. JACQUOT, S. HAMON and D. NICOLAS. Oxford University Press, Oxford. pp. 200–225.
http://www.genetics.org/cgi/content/full/161/4/1697

Daunay, M. C., LESTER, R.N., GEBHARDT, C., *et al.*, 2001. Genetic resources of eggplant (*Solanum melongena* L.) and allied species: a new challenge for molecular geneticists and eggplant breeders, pp. 251–274 in *Solanaceae V*, edited by R. G. VAN DEN BERG, G. W. BARENDSE and C. MARIANI. Nijmegen University Press, Nijmegen, The Netherlands.

Gruere, G. P., Mehta-Bhatt, P. and Sengupta, D. 2008. *Bt Cotton and farmer suicides in India: Reviewing the evidence.* Discussion paper 00808. International Food Policy Research Institute, Washington, D.C.
http://www.ifpri.org/pubs/dp/IFPRIDP00808.pdf (accessed April 29, 2009).

James, C. 2008. *Global Status of Commercialized Biotech/GM Crops:2008.* ISAAA Brief No. 39-2008, ISAAA, Ithaca, N.Y.
http://www.isaaa.org/resources/publications/briefs/39/default.html (accessed April 29, 2009).

PNAS, **98**: 11937-11942.

Wu, K-M., Lu, Y-H., Feng, H-Q., Jiang, Y-Y. and Zhao, Z. 2008. Suppression of cotton bollworm in multiple crops in China in areas with *Bt* toxin–containing cotton. *Science*, **321**:1676-1678. http://www.sciencemag.org/cgi/content/abstract/321/5896/1676 (accessed April 29, 2009).

November 9, 2009

CONCERNS ABOUT BT BRINJAL
SUMAN SAHAI

What, you may ask, is common between potatoes, tomatoes, brinjal, chilli, datura , tobacco and the deadly nightshade (belladonna) ? They all belong to a plant family called Solanaceae. The Solanaceae family contains a number of important agricultural plants as well as many psychoactive and toxic plants. Solanaeae species are rich in complex chemicals called alkaloids and contain some of the most poisonous plants known to mankind. They produce alkaloids in their roots, leaves and flowers. These alkaloids can be hallucinogens, stimulants or out right toxic. For example, when potatoes are exposed to light, a chemical called *solanin* is produced which appears as a green tinge. Green potatoes can be toxic , damage an unborn fetus and cause abortions. Other plants of this family known for their toxic qualities are belladonna, datura and tobacco.

Farmers have been working for thousands of years to domesticate wild plants like of the Solanaceae family, to make them safe for eating. Much of this exercise involved breeding out the toxins contained in the wild plants. Scientists too have used careful, selective breeding to 'clean up' crop varieties which had good qualities but contained toxins. Now through genetic engineering, brinjal, a member of this family has been genetically engineered to produce a toxin to protect itself against a particular pest. This seems to be a process working to reverse several thousand years of efforts to detoxify natural plants to make them fit for human consumption !

Genetic engineering in plants has not been mastered enough to rule out the creation of dangerous new products in the cell when genes are muddled during the insertion of new, usually foreign genes. Several cases are known when new proteins and toxins were produced in plants which were genetically engineered. For example, when GM peas were being developed by the CSIRO (Commonwealth Scientific and Industrial Research Organisation) in Australia to protect the peas from the pest pea weevil ,it was found that newly formed proteins in the GM peas repeatedly caused immunity problems and lung inflammation when fed to mice. The experiments had to be abandoned. In another case, when mice were fed the genetically engineered Flavr Savr tomato, seven out of forty experimental animals died within 14 days and the others suffered from stomach lesions.

Genetic Engineering in plants of the Solanaceae family could be dangerous since disturbing their genetic material through the process of inserting new gene constructs containing a battery of genes, including the toxin producing Bt gene, may trigger off metabolic processes that have been lying dormant. There are apprehensions that not only new toxins could develop but that old toxins that were removed by selective breeding, may reappear. Disturbing the cell metabolism (by genetically engineering) of species that are naturally genetically hardwired to produce toxins, is likely to call up old plant toxins in these species.

Testing for food safety is key in genetically engineered plants; it becomes more so with the Solanaceae family. At present biotechnology companies rely on the concept of "Substantial Equivalence" to demonstrate the safety of genetically engineered (GE) foods . In this method, the overall chemical composition of the GE food is compared to an equivalent conventional food. If there is no significant difference between the two, the GE plant is considered to be safe. The Mahyco seed company has also tested its Bt brinjal in the same way. However, Substantial Equivalence is a highly contested paradigm, favored by the biotech industry but rejected by most countries. This is because there is no mechanism in such an approach to detect unexpected or unintended changes like new toxic compounds in the cell.

Apart from the critical safety issues, there are other questions that arise with the impending release of India's first genetically engineered food crop. There is no system in place for labeling these foods. Indeed, how can one , in the Indian situation label a vegetable that will be sold from farmers fields, laden into trucks and taken to wholesale *mandis.* How will the vegetables on the vendor's cart or the corner shop be labeled as GM? The government of India recognizes the need to label GE food, and its position in the meetings of the Codex Alimentarius, has been consistently in favor of mandatory labeling. Accordingly, the Ministry of Health has drafted rules under the Prevention of Food Adulteration Act to include labeling of Genetically Engineered food and food ingredients.. But there are as yet, no mechanisms in place to label GE food, nor have any awareness programs been conducted to explain the nature of GE foods and the need for labeling them. For most consumers, especially rural consumers, GE foods are a black box and unless they are made aware of the nature of GE foods, labeling would be meaningless. Despite these big gaps in preparedness, the GEAC (Genetic Engineering Approval Committee) has approved Mahyco's Bt brinjal for commercial production.

Does this mean, that the consumer's right to informed choice about their food is about to be trashed? This right is enshrined in India's Consumer Protection Act and the GEAC approval will violate the provisions of this Act. Further, labeling is not just about pasting a colored sticker on a brinjal, it involves a rigorous process of segregation and identity preservation (IP) to keep Bt and non Bt food segregated. IP is a complex and expensive process requiring separation of a GM food (Bt brinjal) from non GM food , starting from farmers' fields, all the way to vegetable shops. Without going through this process, labeling cannot be done. Or has the GEAC planned that all brinjals cultivated in this country henceforth will be only genetically engineered ?

And what about fixing liability for damage ? There is no liability law in this country. In the event of contamination of organic brinjal with Bt brinjal, what will be the process of recall? Who will be liable to the producers of organic brinjal? There are no provisions for monitoring the long term impact of GE foods on the health of consumers. In case adverse health impacts are reported from eating Bt brinjal, who would be liable to pay compensation? How would the liability be fixed and what would be the quantum? In the absence of any kind of preparedness or safeguards, what would be the liability of the government for approving such food crops? And in the event of damage caused by Bt brinjal, will Mahyco be put in the dock ?

Commercial Cultivation of Bt Brinjal in India: Risks and Concerns

- Bt brinjal has been given approval for commercial cultivation by the GEAC
- The minister for Environment and Forests has invited comments from the public and has put up the data on Bt brinjal on his website
- Genetically Engineered (GE) food is being promoted in India but there is no system in place for food labelling.
- A law and a system for the labelling of GE food must precede the introduction of GE foods
- Labelling of GE food has to be informative and make sense to ordinary people. No process of labelling will make any sense unless the consumer understands the technology and the risks associated with it.
- Informed consumer choice is a right. Introducing Bt brinjal without a system of mandatory labelling in place violates this right.
- How will GE food be labelled in a country where food is not sold only in supermarkets?
- Labelling will require clear segregation of Bt brinjal and non-Bt brinjal at all stages from the field to the market. How is this proposed to be done?
- In the event of contamination of non Bt brinjal with Bt brinjal, what will be the process of recall? Who will be liable to producers of organic brinjal?
- In case of adverse health impact from eating a GE food, who would be liable? There is no liability law in this country.
- How would the liability be fixed and what would be the quantum?
- There are no provisions for monitoring the long term impact of GE foods on the health of consumers

- In the absence of the provisions mentioned above, what would be the liability of the government for approving such food crops?
- Because pollen flow is inevitable, does this mean that organic farming would be put at risk with the farming of GE crops?
- How will the government ensure that the native germplasm of brinjal would be safeguarded given that India is the centre of origin of brinjal?
- This plant family (Solanacae) has several natural toxins. What tests are being conducted to detect the creation of new toxins or the resurfacing of old ones. These are highly probable in a family known for its natural toxins. To this family belongs nightshade, dhatura , tobacco etc.

COMMENTS OF DR P M BHARGAVA ON THE REPORT OF THE EXPERT COMMITTEE (EC-II) ON BT BRINJAL EVENT II-I DEVELOPED BY M/S MAHYCO

I. General comments

(1) Any statement that the study was approved by RCGM/GEAC or was done according to any national or international protocol is, in a scientific evaluation, irrelevant. The only question that needs to be answered is whether the study is scientifically sound and valid. In fact, many of the comments that follow are an aspersion on the approval process adopted by our approval mechanism. We should not ignore the fact that the vast portion of GMOs (84% in 2008) in use are confined to four countries (USA, Canada, Argentina and Brazil) and that some 90 percent of the member countries of United Nations have not approved the planting of GMOs or their use as food material without labelling. For inadequacies of the U.S. system of approval of GMOs, see W. Freese & D Schubert, Safety testing and regulation of genetically engineered foods. Biotechnology and Genetic Engineering Reviews, 2004, **21**, 299-324 (96 references).

(2) The toxicity tests/biosafety tests that have been done either by Mahyco (I will, for obvious reasons, use the term Monsanto, in place of Mahyco in what follows) or by private labs or by Government labs. Examples of tests done by Monsanto are on page 1 (line 14 from bottom), page 13 (lines 1-10), page 17, pages 25-29, page 46 [Section 3.3.3(1)], page 50 (4.1). Monsanto has strong vested interests, and it has an extremely derogatory record in respect of honesty, integrity, and following the law. Examples are given in Annexure 1. Monsanto also knows very well that whatever they say would be accepted by RCGM/GEAC as we have ensured that there is no organized and reliable system with high public credibility to check on its results. In view of this, tests done by Monsanto cannot be relied upon. As regards, the tests done by private or Government laboratories, the samples were given by Monsanto. I am not aware of any foolproof record available to show that, in every case, all these samples tested were the right samples.

(3) The differences found between normal and Bt brinjal have been attributed to variation in the normal (non-Bt) product. Any statistician will tell you that if the variation in the control is so large, the number of samples in both the control and the experimental groups has to be much larger that has been used. Examples of such differences are on pages 68-71, items 4, 5, 6; and pages 74-75.

(4) Before the environmental release of Bt brinjal, we should determine if we need it. Therefore, its socio-economic survey should be done before it is released.

hundred thousand crores a year. We *can* capture, say, three quarters of the world vegetable market. All this market will be lost if we allow GM vegetables. Eighty four percent of our farmers are small or marginal farmers with a holding of less than 4 hectacres. According to Monsanto's own data, Bt brinjal pollen can travel for 30 metres and could thus easily contaminate the neighbouring non-Bt brinjal field. In course of time, we would be left with no non-Bt brinjal population even if the farmers do not want Bt Brinjal. Unlike in Europe, Britain and many other countries, we have no labelling laws. In these countries, any food product which has more than 0.9 percent of GM material, must be labelled as genetically modified. Therefore, neither will we be able to export our vegetables nor will *we* be able to exercise choice in regard to GM brinjal or non-GM brinjal. Just extend it to all vegetables and imagine the consequences. There is an ever-increasing demand everywhere, including in our country, of organically grown food which fetches the farmer better price. This market will also be lost.

(iv) Page 36: The comments on "gene transfer from brinjal to other plants" or"gene transfer from brinjal to other organisms" are totally invalid. There is an enormous amount of evidence (Annexure 4) of horizontal gene transfer across species. It is believed widely that more than 10 percent of all the genes in all living organisms are a consequence of horizontal gene transfer. Species non-specific viruses are known; they become non-specific on account of high mutation rate. A Nobel Prize was given to Joshua Lederberg for discovering the process of transduction in which viruses carry a gene from one organism to another.

(v) Page 41-42, item 3.2.4: Who did these studies on possible accumulation and persistence of Bt protein in the soil? Was it Mahyco/Monsanto? The half-life of Cry1Ac protein is reported by EC-II to be 9.3 to 40 days in soil (where ? in India?). These levels are not low. A statement that no Bt protein was detected in any of the soil samples goes against the above-mentioned half-life.

(vi) Page 43, Section 3.3.1 (toxicity and allergenicity of pure proteins): What is reported here is invalid, as pure (probably surrogate) protein and not plant extract containing the protein product in the plant was used.

(vii) Page 46 (alkaloid content): The samples given by Monsanto were not checked by IICT as regards their authenticity. The actual data does not support the statement made in the report that there was no significant difference between the alkaloid content of Bt and non-Bt brinjal.

(b) L. Zolla *et al.*, Proteomics as a complementary tool for identifying unintended side effects occurring in transgenic maize seeds as a result of genetic modification, Journal of Proteomic Research, 2008, 7, 1850-1861.

(xiv) Page 86 (Item 3): What about changes in the glycosylation pattern of other proteins? Proteomics will tell you that.

(xv) Page 86 (Item 6): Environment is of course important. But the fact is that surface properties that are genetically determined are more important. The capability of an organism is determined by its genetic make-up, while environment determines the extent to which these capabilities would be converted into abilities. Ignorance of this rule can be disastrous.

(xvi) Page 86 (Item 7): By reproductive interference, I mean reduction in the reproductive ability of animals which has been demonstrated with GM food crops. (For reference, see Annexure 3)

(xvii) Page 86 (Items 8, 9): See item (iii) above.

(xviii) Page 87 (Item 10): These techniques need to be developed *before* environmental release so that we have a method of detecting contamination at the level of 0.01 percent.

(xix) Page 87 (Item 11): Unless experiments have been done, one cannot arrive at any conclusions.

(xx) Page 88 (Item 13): Please see item (ii).

(xxi) Page 87 (Item 12): The answer given is totally inadequate and irrelevant. The question is not what X, Y or Z says should be done. The world's entire scientific wisdom does not lie with them, especially as they have vested interests. The question is what is scientifically valid and logical. What I have said should be done is so obvious! Why don't we take lessons from the process of release of drugs?

(xxii) Page 88 (Item 14): I would like to have details of studies looking at effect of Bt brinjal or Bt-anything on cattle micro-flora. The other studies referred to are not relevant. The question is not whether or not composition of the diet influences micro-flora. The question is, does the presence of the toxic Bt gene and all other possible changes in the plant (which only proteomics, transcriptomics and metabolomics will reveal) influence the microflora? All the evidence points towards the probability that the death of several thousand cattles in Warangal District over a period of two years was on account of their consuming Bt cotton plant remnants. The intestines of these animals were found shrivelled. This could be a consequence of Bt toxin having an adverse effect on the rumen microflora and thus on digestion. This clearly needs to be studied. Why is there such a reluctance to do such studies? Is the company afraid that such studies done in an unbiased way, will go against the company?

Fwd: Scientific perspectives for Bt Brinjal from CICR Nagpur Tuesday, 2 February, 2010 8:56 PM

From: "Jairam Ramesh" <jairam54@gmail.com>
To: rammoolam@yahoo.co.in

---------- Forwarded message ----------
From: **keshav kranthi** <krkranthi@gmail.com>
Date: Sun, Jan 31, 2010 at 11:48 AM
Subject: Scientific perspectives for Bt Brinjal from CICR Nagpur
To: jairam54@gmail.com, jairam@sansad.nic.in

To
Shri Jairam Ramesh
Hon'ble Minister for Environment and Forests

Respected Sir,
Greetings. Congratulations on the exemplary handling and conduct of the 'Bt-Brinjal' meeting in Nagpur. I am writing this mail on behalf of our scientists from the Central Institute for Cotton Research, Nagpur, to place before you a few scientific perspectives that we were unable to present in the meeting that was so charged with energies of all kinds.

Bt-Cotton (Background)

1. Since its discovery in 1901, the biosafety profile of *Bacillus thuringiensis* was always widely acknowledged by all scientists all over the world. It was successfully used as a biopesticide in organic farming and Integrated Pest Management (IPM) systems for more than 50 years without any concerns expressed from any quarters.

2. The crystal (cry) proteins are toxic to specific insects only and therefore have been considered for the development of GM crops.

3. Bt cotton was commercially approved in the USA in 1996 and is currently approved for cultivation in 12 countries. In India it was released in 2002. Cotton oil is used for human consumption and the residual foliage may be fed to farm animals, generally after harvest. Besides this cotton seed and de-oiled cotton seed cake is used as a high protein supplement in cattle feed for milch animals. Thus far there have been no scientifically authenticated bio-safety issues encountered anywhere.

Farmers have adopted the technology with great zeal and are happy with the outcome. The problem of bollworm is almost forgotten now thanks to Bt-cotton. As expressed by several farmers their living conditions and economy has significantly improved due to the use of Bt cotton.

'Stewardship' issues

1. Insect populations of mealybugs, mirid bugs, gall midge and safflower caterpillar, which were hitherto unknown as pests, have suddenly emerged as concerns after the introduction of Bt-cotton. This may have occurred ***due to the reduction in pesticide usage*** during the reproductive phase of the crop, which would have been otherwise normally been used on conventional cotton. Other factor that may have contributed to the sudden upsurge of these minor insect pests is that there are many ***Bt-cotton hybrids which are highly susceptible to these pests***, apart from being susceptible to leaf reddening

and wilt.

2. Bt-cotton due to high productivity requires adequate fertilizer and water inputs for higher yields and profits. The productivity is maximum in good soils. However a number of hybrids are suitable even for such sub-optimal situations in rain-fed farming conditions and marginal soils. With 619 Bt-cotton hybrids, there is confusion all round with farmers not being able to choose the Bt-hybrids that may be suitable for their soils and farming conditions. A suitable recommendation on the adaptability of specific hybrids for specific agro ecological sub zones would facilitate further productivity improvement. Lack of such recommendations have resulted in progressive problems and slight decline in productivity (560 kg lint /ha in 2007; 520 Kg lint/ha in 2008 and 512 Kg lint /ha in 2009) despite a steady increase in the area under Bt-cotton (62% in 2007, 73% in 2008 and 84% in 2009).

These issues are related to 'stewardship' of the technology and have nothing to do with biosafety aspects. The issues have been a major concern with farmers since insecticide use is gradually increasing as required for the management of these emerging new insect pests.

It is extremely important to learn from the experiences of Bt-cotton so as to ensure that the same issues related to the emergence of new pests and the unsuitability of hybrids to specific regions, do not arise in future.

Researchable issues for Bt Brinjal

1. Resistance development is a very serious concern for monophagous pests. There is a need to develop ***baseline susceptibility data of Cry toxins on the fruit and shoot borer populations*** from all the Brinjal growing states in a Government Institute Laboratory known for its expertise in resistance management. The data available thus far is only from Mahyco. There is also a need to set up a main resistance monitoring laboratory to monitor the changes in baseline susceptibility changes of the fruit borer to Cry proteins after releasing the technology.

2. Resistance Management Strategies are essentially developed based on output profiles of stochastic models which integrate toxicological, ecological, genetic and biological parameters. ***Stochastic models*** for resistance should be developed to calculate resistance risk and devise pro-active Insect Resistance Management (IRM) strategies. ***The structured refuge strategy of 5% conventional Brinjal within the ecosystems of Bt-Brinjal proposed by Mahyco is based on basic simplistic assumptions and not through defined algorithms and modeling.***

3. There is a need for a ***consolidated report on ecology, biology, genetics and population dynamics of insect pests of Brinjal*** that are available thus far. Based on the ecology, biology and population dynamics, simulation models should be developed so that appropriate strategies can be formulated to ***prevent the emergence of new pests and delay development of resistance in key pests.***

These studies can be completed within a few months and scientists of CICR who are acknowledged worldwide for their experience with resistance management, can assist to the best of our capabilities. Our papers related to the subject have mostly been published in 'Current Science' and are widely referred and cited all over the world.

We support the Bt-Brinjal technology and would like to strengthen the regulatory agencies with appropriate scientific support so that we shall be able to move towards a pesticide free world.

Thanking you
With Respectful Regards

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(जैव प्रौद्योगिकी विभाग, विज्ञान एवं प्रौद्योगिकी मंत्रालय, भारत सरकार का स्वायत्त संस्थान)
CENTRE FOR DNA FINGERPRINTING AND DIAGNOSTICS
(An autonomous institute of the Dept. of Biotechnology, Ministry of Science & Technology, Govt. of India)
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डॉ. ज. गौरीशंकर
Dr. J. Gowrishankar
निदेशक
DIRECTOR

CDFD/Dir/Gen3(2)/74
November 13, 2009

Shri Jairam Ramesh
Hon'ble Minister for Environment & Forests
Government of India
Paryavaran Bhavan
CGO Complex, Lodhi Road
New Delhi 110 003

Dear Sir,

Thank you for your reply acknowledging my letter to you dated 28.10.2009 on the Bt brinjal issue. As requested, I am giving below a summary of my views and what we should be doing now.

1. ***On Bt brinjal***: I reiterate that the Expert Committee-II (EC-II) report is an excellent, cogently reasoned, scientific document and that the GEAC's recommendation based on the report is fair. Ordinarily, I would have urged that the GOI immediately accept and implement the recommendation, but since you have now already proposed consultation in Jan-Feb 2010, I suggest that the GOI decision in favour be made as soon as possible thereafter. One could argue that the concept of "equal time" to all parties has been more than adequately met even as of now, as is clearly brought out in the EC-II report.

It is also upsetting that some distinguished critics, in interviews to the media, have stated that the GEAC decision was tainted by extraneous influences on its members. This is an instance of hitting below the belt.

2. ***In the long term***: I have recently argued (in *Current Science*, 25 June 2009) that the time may have come to disband the GEAC and RCGM mechanisms for monitoring GMOs. These Committees were created following the apprehensions that were expressed in the Asilomar Conference of 1975 when GMOs had first become technically feasible, but none of the apprehensions have materialized since and the Asilomar recommendations have been progressively watered down over the years. What now exists in India merely serves to impose a high barrier to entry of new products as well as players, because of which for example one does not envisage any competition to Mahyco Ltd on Bt brinjal for many years to come.

Contd..... 2 .....

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In the same vein, I would also argue that the EC-II report, although excellent, was unnecessary in the first place entailing waste of the time of its expert members. In other words, the burden of proof with regard to GMOs ought henceforth to be shifted, so that they are seen as "innocent until proven guilty" rather than the other way around as it is now.

Thank you,

Yours sincerely,

Gowrishankar J

[J GOWRISHANKAR]

Fwd: Views on Bt Brinjal

From: "Jairam Ramesh" <jairam54@gmail.com> Tuesday, 2 February, 2010 8:46 PM
To: rammoolam@yahoo.co.in

---------- Forwarded message ----------
From: **Dr.V.S. Dagaonkar** <vsdagaonkar@ankurseeds.com>
Date: Wed, Jan 27, 2010 at 6:19 PM
Subject: Views on Bt Brinjal
To: jairam54@gmail.com

Res. Sir,

At the outset, I profusely thank you for giving me an opportunity to present scientific views on Bt Brinjal in the consultation meet held at Nagpur. I am giving some more views in support of Bt Brinjal in addition to what I said in the meeting.

1) **Concern about Biodiversity**- We already have National Centre for Germplasm Conservation in the form of National Bureau of Plant Genetic Resources (NBPGR) and Project Directorates like Indian Institute for Vegetable Research (IIVR) and Indian Institute for Horticultural Research (IIHR) to take care of the issue. Hence there won't be any loss of biodiversity. Instead, perhaps we will be in a position to conserve and maintain Brinjal varieties that are highly susceptible to Brinjal Shoot & Fruit Borer but desirable for some other traits. In fact, Plant Breeding itself is an art of selecting genotypes that suit our requirement. The varieties that do not suit the environment themselves become extinct or go out of cultivation. Hence extinction of non- suitable germplasm and development of suitable germplasm is a continuous process and hence the concern about loss of Biodiversity is unjust. Otherwise how we would have realised the benefits of green revolution?

2. **Health Hazards from Bt** - Sir, It is well known that Bt is a soil bacterium present everywhere in the environment. We know infants when they start understanding the world, try to eat everything they find in their vicinity. They accidently consume soil but have we ever heard of infant mortality due to food poisoning because of Bt (ingested through soil)? We also know that Bt as a biopesticide is in use since sixties. Have we ever heard of death because of accidental consumption of Bt biopesticide? Most of the suicides that occur because of consumption of insecticides are becaue of chemical insecticides and never because of Bt biopesticides. Secondly, the enzyme Neomycin Phospotransferase is highly degradable enzyme and is produced in ultra low levels in plants. If resistance against the antibiotics is concerned, then if we study the pharma situation in last 20 years, then more than a dozen antibiotics have been released in the market. This is because the microbes gain resistance after some time period and hence it is required to introduce new antibiotics in the market.

3. **Fear about High Productivity and Low Economic Gains** - It is feared that because of high productivity the farmer will be at economic loss. If this is a presumption, then it may also happen that the farmer will go for reduced acreages and still fetch equal or more yields of the crop. The important fact is that with use of Bt Brinjal, he will save on account of reduced no. of pesticide sprays and labour required for pesticide application. The left over land can be utilised for other commercial crops of importance and thus can give additional economic gains. To fetch additional market prices, the farmers try to grow the crop in the off season so that the produce gets a good market price. Bt Brinjal will be the best technology for off season cultivation. This will also support our mission of food security. Afterall, we have to feed billions of mouths with the reducing arable lands. Intensive agriculture is the only solution.

Lastly, I would like to submmit that there has always been a blame on Indian scientists that they are always lagards in technology development and follow what the western world develops. This is for the first time that and Indian seed industry has developed a technology in India with Indian hands useful for the country. Negating this technology will perhaps put brakes to future biotech projects in the country and force us again to accept anything that is developed by western world for their necessities. Since the technology has been thoroughly tested on all parameters, I strongly feel that the technology should get a green signal for the Indian market. If there is anything that is required by you in this endevour, I shall always be at your service to support this noble and national cause.

I keenly look forward to positive decision on this matter.

With warm regards,

Sincerely,

Vipin S. Dagaonkar Ph.D.
Vice President (Research)
Ankur Seeds Pvt. Ltd., Nagpur
Cell +919822220107

YAHOO! INDIA MAIL Classic

Fwd:

From: "Jairam Ramesh" <jairam54@gmail.com>
To: rammoolam@yahoo.co.in
2 Files (618KB)

Wednesday, 3 February, 2010 5:09 PM

TRANSGE... BREEDIN...

---------- Forwarded message ----------
From: **Deepak Pental** <dpental@gmail.com>
Date: Tue, Jan 12, 2010 at 3:25 PM
Subject:
To: jairam54@gmail.com

No.VC/DU/2010/
January 12, 2010

Shri Jairam Ramesh
Minister of State (Independent Charge)
Environment & Forests
Government of India
New Delhi – 110 003

Dear Sir,

I am sorry for not responding to your mail for some inputs on Bt brinjal. Actually I needed to go through the reports once again and I could only do this on Sunday, the 10th. I have the following comments:

(i) The Kanamycin gene used as a marker gene for selecting transgenics *in vitro* has been used in a number of transgenics which are in the field and have been grown for almost ten years. Extensive biosafety tests have been conducted on the protein product of this gene. So far nothing untoward has been reported.

(ii) Cry genes from Bacillus thungiensis have been used in cotton and maize very extensively. Earlier, these toxins were used extensively as bacterial suspensions or crude crystal preparations to protect high value vegetable crops from insect attack. This has been going on from the turn of the last century without report of any adverse effects.

Very extensive toxicological and allergenecity tests have been conducted on these genes/ proteins and nothing untoward has been reported.

(iii) Very extensive work has been conducted on the field usage of transgenics containing Bt genes. This work led to the concept of Refugia, that is to mix susceptible with resistant transgenics so as to delay the development of resistance.

(iv) My concern is not on the safety of two genes but whether the expression of transgene is sufficient.

There are attacks on Bt brinjal (0-20 larvae on the transgenics) compared to 3.5-80 larvae on non-trangenics plants. However, sufficient information is available to show that even with low expression the incidence of insect attack gets drastically reduced.

(v) A major concern is that our own agriculture research programmes are so weak that we are getting totally dependent on Transnationals for high end solutions.

(vi) I recommend that GEAC's decision to release Bt brinjal for general cultivation be upheld. However, two realities must be understood; One - as India is a centre of origin of cultivated brinjal, transgenes can move to the wild germplasm. However, this should not unduly alarm us. Two - we will not be able to differentiate between Bt and non Bt brinjal, in other words labeling is not possible.

I send you two articles which I wrote on agricultural R&D in India. People have read these but they refuse to quote these because no one at the top wants a change. f you find time, please do read these. I am available for any briefing if you have time to spare.

With warm regards,

Yours sincerely,

Deepak Pental

Encl.: As above

****
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****

Breeding objectives and requirements for producing transgenics for major field crops of India

Anil Grover[†] and Deepak Pental*

[†]Department of Plant Molecular Biology and *Department of Genetics, University of Delhi South Campus, Benito Juarez Road, New Delhi 110 021, India

To identify crop improvement objectives in twelve important field crops (rice, wheat, maize, sorghum, pearlmillet, pigeonpea, chickpea, mungbean, cotton, potato, mustard and soybean) that are grown extensively in India, we conducted a survey amongst plant breeders, pathologists, entomologists and agronomists specializing in each of these identified crops. A questionnaire was sent to around fifteen scientists actively involved with each crop with the following queries: (1) Identification of problems with the crop at the regional level in terms of priority, (2) Identification of problems with the crop at the national level in terms of priority, (3) Which are the most extensively grown cultivars of the crop at the regional and at the national levels?, (4) What steps could be taken to raise the yield of the crop (heterosis breeding, pure-line breeding)?, Do you know of combiners that would give high heterosis in the crop?, (5) Do you know of germplasm sources that could be used for meeting some of the breeding objectives?, (6) What is your assessment of need for transgenics (a) for nutritional enhancement, (b) for resistance to biotic stresses, (c) for resistance to abiotic stresses, (d) for herbicide resistance and (e) for value addition?

A list of pests and pathogens known to affect each of the above crops as given in *Handbook of Agriculture* (Indian Council of Agricultural Research, 1997) was also sent to the specialists for help in answering question 2. The five most important problems identified by the specialists in response to the questions 1 and 2 were given scores. The foremost important problem identified was given a score of 5 followed by scores of 4, 3, 2 and 1 for problems identified in descending order of importance. For each of the breeding objectives identified by the respondents, a total score was calculated. Cumulative score for each objective was normalized to a percentage score. In Figure 1, first five problems identified for a crop are given with their scores in top five boxes and all the other problems identified by the respondents are put with a normalized cumulative score in the lowermost box (for all crops except pearlmillet). The breeding objectives identified in relation to regional needs were compared with the objectives identified at the national level and the findings are highlighted in this article. Figure 2 shows the area under cultivation and the production levels of different crops that have been dealt with in this study (except mungbean). This information is presented to highlight changes in production, area under cultivation and yield of the crops over the years.

Rice (*Oryza sativa*)

Rice is the most extensively grown crop of India and is grown in almost all parts of the country. This crop is grown under diverse agro-ecological conditions as irrigated rice, upland rice, lowland rice and deepwater rice. Objectives related to breeding for resistance to various fungal and bacterial diseases and insect pests were identified as the top priorities for rice. Rice blast (*Piricularia oryzae*), sheath blight (*Rhizoctonia solani*) and bacterial blight (*Xanthomonas oryzae*) topped the list of priorities (Figure 1 *a*). Two insect pests namely, stem borer (*Scirpophaga* sp., *Chilo* sp., *Sesamia inferens*) and brown plant hopper (*Nilaparvata lugens*) cause extensive yield losses in rice and were identified as problems that need attention (Figure 1 *a*). The respondents in general felt that germplasm for resistance to blast, bacterial leaf blight, tungro virus, stem borer, brown plant hopper, gall midge and whiteback plant hopper is available. However, resistance sources for stem borer, leaf folder, sheath blight and sheath rot were thought to be inadequate. Therefore, the development of transgenics for resistance to the last four biotic stresses needs to be given the highest priority.

Breeding for higher yield through exploitation of heterosis was also identified as a major challenge. For heterosis breeding in rice, several good combiners were identified by the respondents. However, it appears that more extensive search for parental lines with high combining ability is necessary for full exploitation of heterosis breeding. In comparison to all other crops that are included in this survey, rice scientists made most extensive suggestions for the development of transgenics. The following objectives were considered to be worth pursuing

*For correspondence. (e-mail: dpental@hotmail.com)

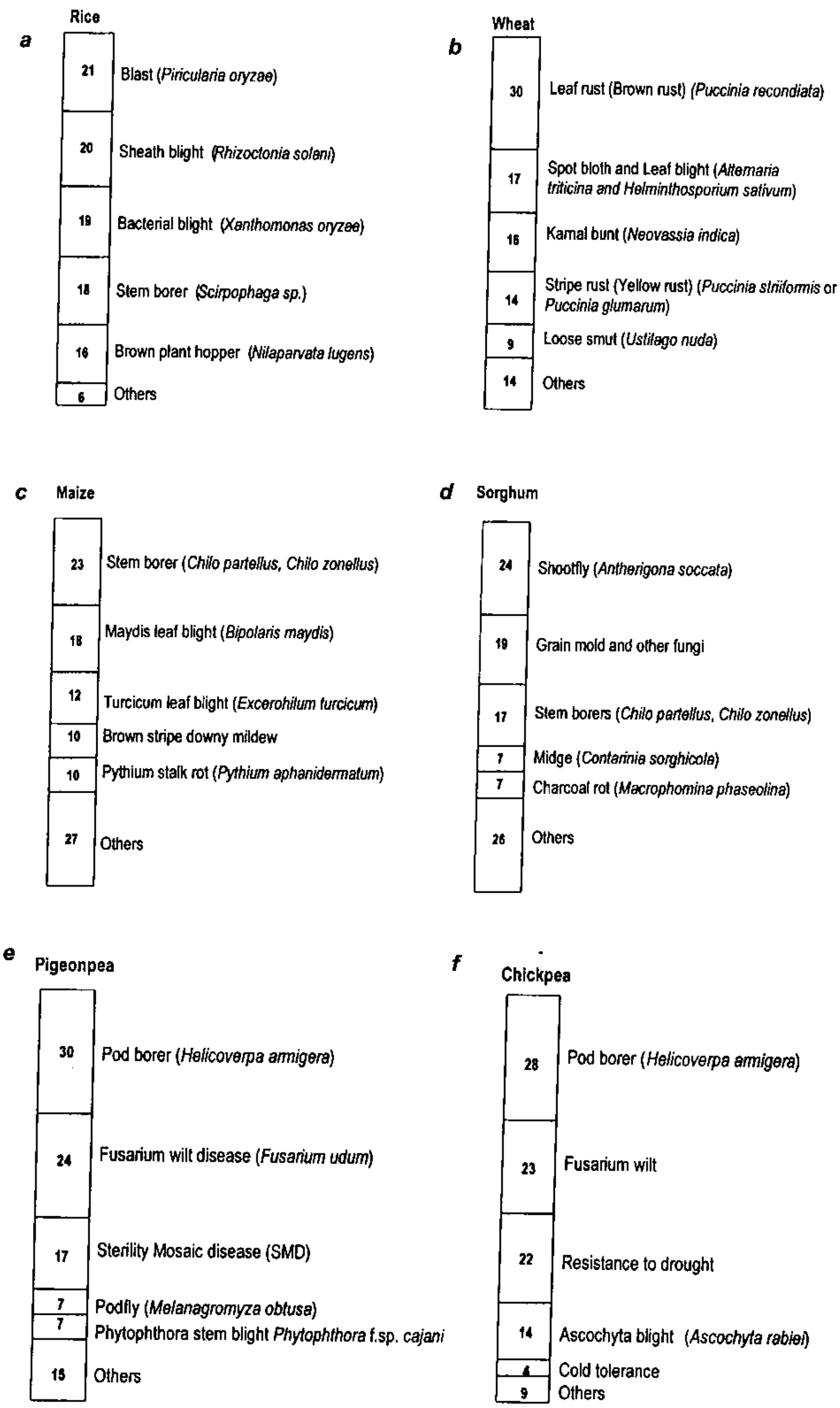
a
Rice
21
Blast (*Piricularia oryzae*)
20
Sheath blight (*Rhizoctonia solani*)
19
Bacterial blight (*Xanthomonas oryzae*)
18
Stem borer (*Scirpophaga sp.*)
16
Brown plant hopper (*Nilaparvata lugens*)
6
Others
b
Wheat
30
Leaf rust (Brown rust) (*Puccinia recondiata*)
17
Spot bloth and Leaf blight (*Alternaria triticina and Helminthosporium sativum*)
16
Karnal bunt (*Neovassia indica*)
14
Stripe rust (Yellow rust) (*Puccinia striiformis* or *Puccinia glumarum*)
9
Loose smut (*Ustilago nuda*)
14
Others
c
Maize
23
Stem borer (*Chilo partellus, Chilo zonellus*)
18
Maydis leaf blight (*Bipolaris maydis*)
12
Turcicum leaf blight (*Excerohilum turcicum*)
10
Brown stripe downy mildew
10
Pythium stalk rot (*Pythium aphanidermatum*)
27
Others
d
Sorghum
24
Shootfly (*Antherigona soccata*)
19
Grain mold and other fungi
17
Stem borers (*Chilo partellus, Chilo zonellus*)
7
Midge (*Contarinia sorghicola*)
7
Charcoal rot (*Macrophomina phaseolina*)
26
Others
e
Pigeonpea
30
Pod borer (*Helicoverpa armigera*)
24
Fusarium wilt disease (*Fusarium udum*)
17
Sterility Mosaic disease (SMD)
7
Podfly (*Melanagromyza obtusa*)
7
Phytophthora stem blight *Phytophthora* f.sp. *cajani*
15
Others
f
Chickpea
28
Pod borer (*Helicoverpa armigera*)
23
Fusarium wilt
22
Resistance to drought
14
Ascochyta blight (*Ascochyta rabiei*)
4
Cold tolerance
9
Others

Figure 1 *a–f*.

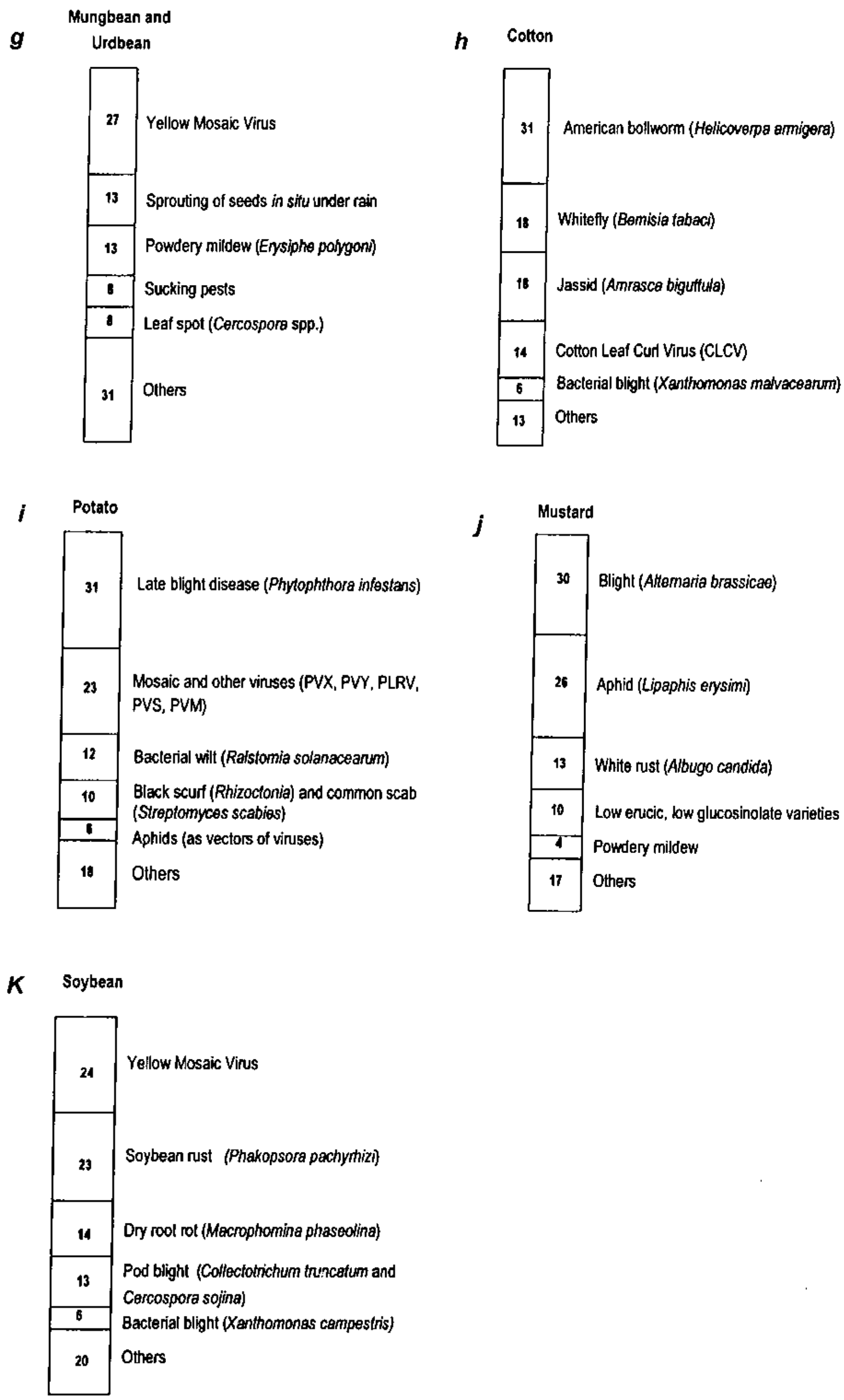

Figure 1. Normalized scores of major constraints that were identified from the survey conducted in this study. The top five problems in each crop are represented with their respective normalized scores. All other problems with a normalized cumulative score are shown in a separate box at the bottom of the histogram column for each crop. The details of problems shown in the 'Others' box are as follows: rice – sheath rot, tungro virus, etc.; wheat – stem rust, powdery mildew, earcockle, hill bunt, flag smut, etc.; maize – bacterial stalk, head smut, charcoal rot, banded leaf, sheath blight, water logging, weeds, etc.; sorghum – anthractose, smuts, downy mildew, rust, etc.; pigeonpea – water logging, resistance to drought, etc.; chickpea – *Botrytis* grey mould, bruchids on stored grain, etc.; mungbean – storage grain, bruchids, resistance to drought, etc.; cotton – pink bollworm, spotted bollworm, thrips, wilt, etc.; potato – tuber moth, brown rot, nematodes, etc.; mustard-downy mildew, non-availability of hybrids; soybean – *Perenospora* sp., stem borer, green semi-looper, etc.

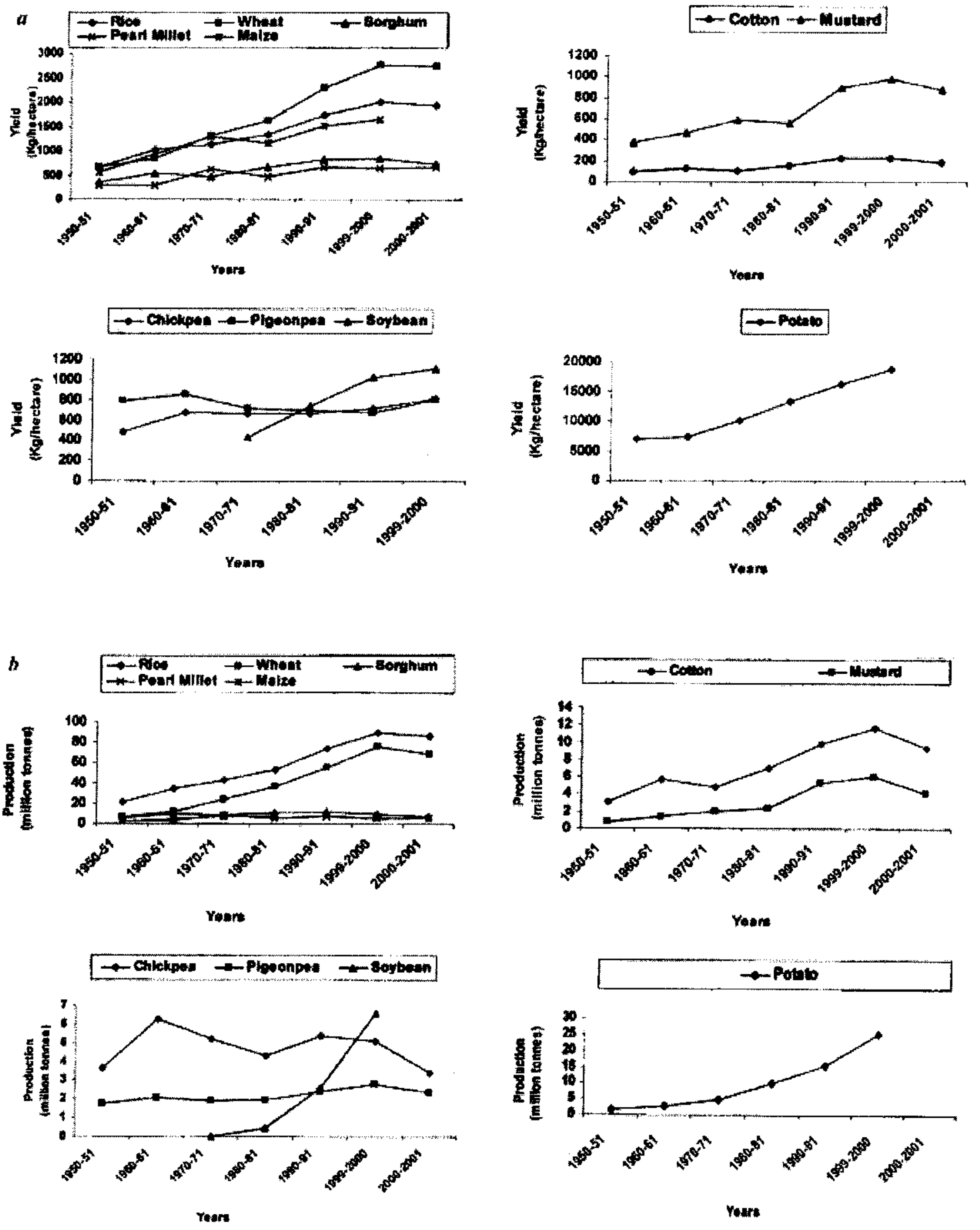
a
Rice
Wheat
Sorghum
Pearl Millet
Maize
Yield (Kg/hectare)
Years
Cotton
Mustard
Yield (Kg/hectare)
Years
Chickpea
Pigeonpea
Soybean
Yield (Kg/hectare)
Years
Potato
Yield (Kg/hectare)
Years
1950-51
1960-61
1970-71
1980-81
1990-91
1999-2000
2000-2001
b
Rice
Wheat
Sorghum
Pearl Millet
Maize
Production (million tonnes)
Years
Cotton
Mustard
Production (million tonnes)
Years
Chickpea
Pigeonpea
Soybean
Production (million tonnes)
Years
Potato
Production (million tonnes)
Years

Figure 2 *a–b*.

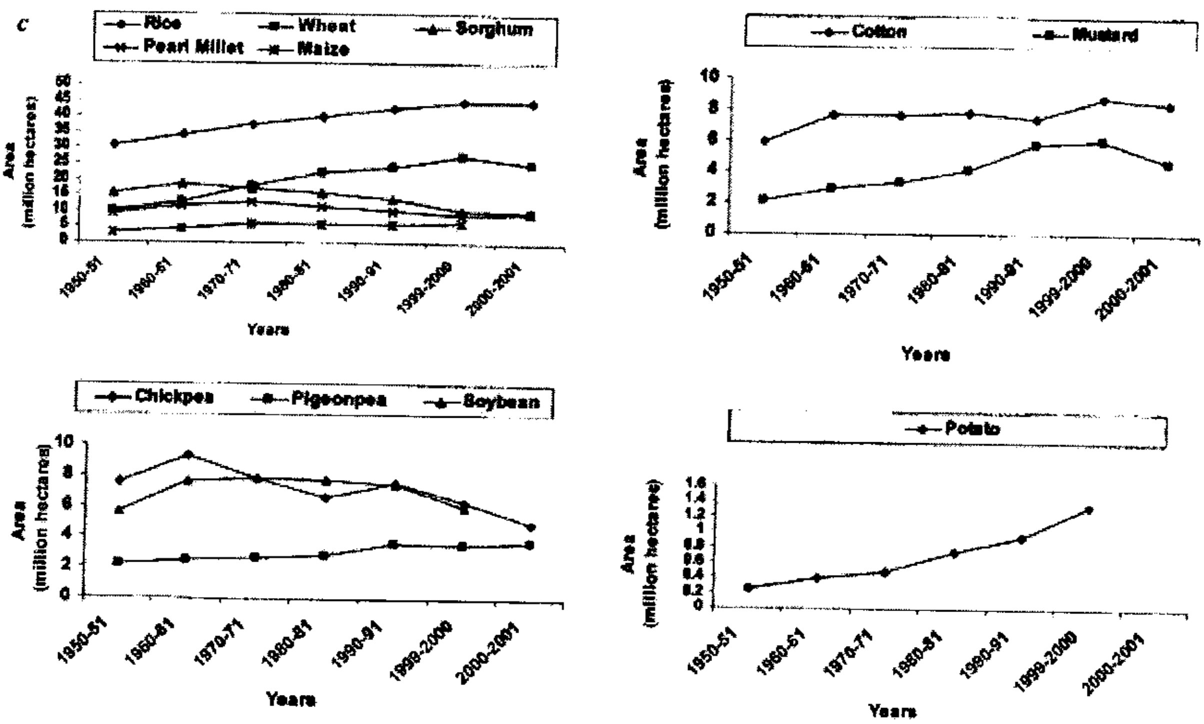

Figure 2. Current production levels and area under cultivation of twelve selected crops in India. *a*, Yield (kg/hectares); *b*, Production (million tonnes) and *c*, Area (million hectares). This figure is based on information available at web site www.agricoop.nic.in.

in this regard: (1) Development of rice with β-carotene pathway and higher iron content. (2) Transgenics for resistance to diseases and insect pests. (3) Transgenics for resistance to flooding and drought tolerance, the latter being particularly important at the grain filling stage. Cold tolerance at maturity in rainy season crop and cold tolerance in general for 'boro rice' were considered important. (4) Herbicide resistance was proposed to be particularly important for upland rice and for allowing direct seeding to replace the practice of large-scale transplantation. (5) Quality improvement by incorporation of characters related to aroma and grain length were mentioned, although it is not clear from the survey whether this needs to be accomplished through the development of transgenics or whether it can be achieved by conventional breeding.

In short, biotic stresses take the highest priority in rice breeding followed by abiotic stresses like drought and flooding. For developing resistant rice varieties for both biotic and abiotic stresses, this survey emphasized the use of transgenic technologies.

Wheat (*Triticum aestivum*)

Breeding for resistance to fungal diseases appeared as the most important overall objective in present-day wheat breeding programmes. Leaf rust (caused by *Puccinia recondita*), leaf blight (caused by *Alternaria triticina* and *Helminthosporium sativum*), Karnal bunt (caused by *Neovossia indica*), stripe rust (caused by *Puccinia gluamarum*) and loose smut (caused by *Ustilago nuda* cv. *tritici*) were identified as the relevant problems (Figure 1 *b*). Diseases such as stem rust (*Puccinia graminis*), powdery mildew (*Erysiphae graminis*), earcockle (*Anguina tritici*), hill bunt (*Tilletia foetida* and *T. caries*) and flag smut (*Urocystis tritici*) were also counted. The severity of different diseases varied in different wheat-growing regions of the country: in the most extensively cultivated areas of the North-West, leaf and stripe rusts, foliar blight and Karnal bunt emerged as the major diseases; stem rust (though some specialists felt that this is no more a problem), leaf rust and loose smut emerged predominant in the South and Central peninsular regions; hill bunt and stripe rust were considered common in hills of North India; powdery mildew appeared prevalent in Northern sub-mountainous regions and North-Eastern region appeared to have leaf rust, loose smut and foliar blight. The respondents felt that enough germplasm was available in both cultivated varieties and related wild species to breed for resistance to major diseases. However, not many sources of resistance to leaf blight were enlisted. Karnal bunt appeared an important disease and development of varieties for resistance to Karnal bunt by conventional as well as transgenic means emerged to be important considering the possibility of using surplus wheat for exports.

Pure line breeding has been, by and large, successful in wheat. Breeding for disease resistance in wheat is a major success story in India. However, since the introduction of dwarf wheat varieties in 1960s, the yield potential of wheat has not increased. A large number of respondents agreed that heterosis breeding would be useful for increasing wheat yield. However, little work appears to have been carried out on systematic identification of combiners or of heterotic pools containing divergent germplasm. In wheat, the available male sterility and restorer systems were not considered adequate and seemed to impose yield penalties. Wheat is predominantly a self-pollinated crop and in most of the commercial materials, anthers dehisce before the florets open. For hybrid seed production, adequate level of cross-pollination was considered necessary in this crop. The most critical requirement in production of hybrid wheat seeds was considered to be a stable male sterility/restorer system. However, cost-effective production of hybrid wheat seeds also appeared to require breeding for change in floral structure to develop varieties that allow reasonable cross-pollination. It was stated that such a character would have to be identified amongst cultivated varieties or in the wild relatives of wheat.

Amongst abiotic stresses, heat tolerance, particularly at the terminal stages (seed-filling stage) was considered to be an important breeding goal. Over-expression of *triticin* gene for improving lysine content was identified as another objective for transgenic research. Some respondents raised a query whether engineering of β-carotene pathway in wheat would be useful for addressing the problem of malnutrition. Although *Phalaris minor* is a very recalcitrant weed of wheat crop particularly in the highly productive regions of North-West, only four of the thirteen respondents identified development of transgenics for herbicide resistance as an important objective. The recommendation for herbicide-resistant wheat therefore appeared region-specific. It seems that such transgenics would particularly be useful for the major wheat growing areas of Punjab and Haryana. Many respondents suggested that breeding for specialty traits like bread-making quality and bakery products will allow India to compete in the international markets. These objectives can also be achieved through conventional breeding programmes.

It appears from this survey that the overall maintenance of wheat productivity depends on the incorporation of disease resistance in the existing high-yielding varieties. The breeding community, by and large, seems to feel that enough variability is available to breed for resistance by conventional pure line breeding methodologies. Yield increase can also come through new multi-floret genetic stocks that have been developed at CIMMYT (Mexico) or through heterosis breeding. Heterosis breeding will require male sterility/restorer systems and extensive combining ability studies. In comparison to rice, need for producing transgenics for meeting major breeding objectives in wheat seems to be less urgent.

Maize (*Zea mays*)

Maize is grown mostly as a rainfed crop in the Indo-Gangetic plains and parts of Southern India. Resistance to stem borer (*Chilo partellus, Sesamia inferens*) and the fungal diseases Maydis leaf blight (caused by *Bipolaris maydis* and *Cochliobolus heterostophus*) and Turcicum leaf blight (caused by *Exserohilum turcicum*) were identified as the most important breeding objectives in maize (Figure 1 *c*). The respondents felt that resistance to stem borer is only available in the wild relatives of *Zea mays* and hence would be difficult to transfer through conventional means. Development of transgenics for stem borer was therefore considered an important goal. Some germplasm resistant to Turcicum leaf blight and Maydis leaf blight were identified by the respondents but it was not clear how much of this germplasm is actually being used for plant breeding.

Maize breeding is done through the development of composites or hybrids. Development of composites is mostly in the public domain. Companies utilizing inbred lines from other countries have developed most of the hybrids that are available in the market. This hybrid maize is not useful for human consumption as it is high in starch content. The respondents felt that there is a need to develop high yielding single cross hybrids that could be used for human consumption. It was stated that male sterility/restorer system is not required in this crop for hybrid seed production as male and female flowers are separate and male florets can be readily removed.

Maize is deficient in two essential amino acids, lysine and tryptophan. Quality protein maize (QPM) high in lysine and tryptophan has already been developed by conventional breeding methodologies. Herbicide tolerance would be useful as maize, being a rainfed crop, has heavy infestation of weeds. Breeders from Punjab specifically recommended the development of herbicide-resistant composites or hybrids. Waterlogging (also referred to as excess soil moisture stress) appeared as the most critical abiotic stress that affects maize cultivation. Due to sensitivity of maize to waterlogging, this crop is not grown extensively in North-Western parts of India as an alternative to rice. As germplasm with adequate resistance to waterlogging is not known, gene discovery for resistance to waterlogging and subsequent development of transgenics were considered high priority areas. However, some specialists were of the view that there are some strains in India which are tolerant to waterlogging. Drought is also a limiting factor in maize cultivation. However, germplasm resistant to abiotic stresses has not been adequately tested under Indian conditions. The need for introducing cold tolerance in winter maize was identified. It was suggested that the germplasm for cold tolerance could come from the temperate regions of the world. In short, this survey showed that improvement of maize would require both conventional breeding and transgenic approaches. Transgenic approaches would be especially useful for dealing with the problem of stem borer, leaf blight and sensitivity to waterlogging.

Sorghum (*Sorghum vulgare*)

Sorghum (jowar) is both a grain and a forage crop. Sorghum is grown in the rainy season and also in the post-rainy season. This crop is well adapted to grow in rainfed dryland areas. Hybrids in sorghum are extensively cultivated. However, in general, land area under sorghum cultivation is shrinking (Figure 2 *c*). The post-rainy season sorghum and sorghum grown in 'Kharif' are very important for provision of fodder. The importance of sorghum as a fodder crop for dairy animals is enormous. However, the consumption of jowar grain as bread (or 'roti') has decreased.

Resistance to shootfly (caused by *Antherigona soccata*), grain mould (caused by a number of fungi), stem borer (*Chilo zonellus*), midge (*Contarinia sorghicola*) and charcoal rot (caused by *Macrophomina phaseolina*) were recognized as important problems in cultivation of sorghum (Figure 1 *d*). Some other problems identified as important in sorghum cultivation included anthracnose (caused by *Colletotrichum graminicola*), smuts (caused by *Sphacelotheca reiliana*, *S. ehrenbergii*, *S. cruenta*, *Tolyposporium ehrenbergii*), downy mildew (caused by *Sclerospora sorghi*) and rusts (caused by *Puccinia purpurea*). Some specialists felt that smuts are not a serious problem and downy mildew and rusts are highly localized problems. It was also suggested that grain mould is a problem only in 'Kharif' when the flowering and grain-set stage coincides with rainfall; shootfly is a problem only in 'Rabi' and if sowing is delayed in 'Kharif'. Some respondents felt that tolerant lines are available to grain mould and shootfly but absolute resistance is not available. The respondents were generally of the view that some germplasm is available for resistance to stem borer, shootfly, charcoal rot resistance, nutritional quality and drought resistance. However, these agronomic traits have not been transferred to good combiners. Low levels of resistance to grain mould and shootfly in early to medium maturing, high-yielding cultivars during 'Kharif' and 'Rabi' seasons were identified as major reasons for poor productivity of sorghum. Hybrids are available only for the rainy season crop in which problems of grain mould and midge are prevalent while the post-rainy season crop suffers from charcoal rot and shoot fly.

It was not clear from the survey whether lack of progress in the utilization of germplasm for breeding-resistant composites or hybrids is due to weak breeding programmes or to complications in transfer due to complex genetics of resistance factors. A number of hybrids are available for sorghum crop. However, the levels of resistance in male sterile lines to grain mould, shootfly, charcoal rot, stem borer and drought were considered inadequate. A lack of qualitatively superior disease-resistant forage sorghum hybrids was also evident in the response. Requirements of nutritional enhancement in terms of an increase in lysine content, improvement in dough quality and in protein content were identified. The respondents were of the view that incorporation of herbicide resistance into sorghum was not needed. In short, this survey revealed that major objectives for transgenic research in sorghum are to develop lines with resistance to grain mould, stem borer and shootfly.

Pearlmillet (*Pennisetum typhoides*)

Pearlmillet is a crop of dryland areas. However, the area under cultivation of this crop is on the decline as millet grains are losing to rice and wheat (Figure 2 *c*). The most important yield constraint identified in pearlmillet was susceptibility to downy mildew (*Sclerospora graminicola*) particularly in the single-cross hybrids. Ergot (*Claviceps microcephala*), smut (*Tolyposporium penicillariae*), rust (*Puccinia penniseti*), blast (*Pyricularia setarie*) and mycotoxins in the grain due to fungal infections were identified as major problems in this crop. Amongst abiotic stresses, increased drought tolerance was identified as an important goal.

It appeared that millet hybrids are more susceptible to diseases and the respondents considered incorporation of resistance into divergent combiners by backcross breeding important. To achieve high productivity in pearlmillet, respondents felt that the emphasis on heterosis breeding must continue. The improvement of parental lines of elite hybrids by backcross breeding emerged as an important goal. This survey suggested that genetic diversification of the crop via population improvement should also be emphasized to avoid problems related with narrowing down of the genetic base of the crop. In pearlmillet, hybrids can give 40–50 quintals/ha while the realized yields are in the range of 10–12 quintals/ha. Incorporating the requisite traits, amongst which moisture stress tolerance was considered as an important one, can possibly bridge this gap. It was proposed in this survey that drought-tolerant lines are available in this crop, though there are only a few lines that have been characterized for physiological basis of drought tolerance and the genetics of the trait has also not been worked out. All the respondents suggested development of transgenics for resistance to downy mildew. It was felt that sources that offer a more broad spectrum resistance (horizontal resistance) should be identified and transferred either by sexual crosses or by transgenic approach. The respondents felt that resistance to downy mildew is available and can be incorporated into heterotic combiners. For nutritional enhancement, this survey suggested that vitamin A and protein content could also be improved.

Pigeonpea (*Cajanus cajan*)

Pigeonpea is grown in the rainfed dryland areas of the country in the 'Kharif' season. It was the general feeling of the respondents that the productivity of the crop has not undergone any significant improvement in the past three decades. The most important yield constraint on pigeonpea is from the lepidopteran pest *Helicoverpa armigera*. Another significant insect pest is pod fly (*Melanagromyza obtusa*). Fusarium wilt (caused by *Fusarium udum*), Phytophthora stem blight (caused by *Phytophthora drechsleri* f. p. cajani) and sterility mosaic disease were identified as other major constraints on pigeonpea yield (Figure 1 *e*). Development of extra-early varieties and resistance to drought and waterlogging were identified as important breeding targets. This survey revealed that there were differences in regional priorities: in the Central zone, terminal drought and pod borer (in that order) are important; in the North-East sterility mosaic, wilt, pod fly and pod borer are important and in the North-West, *Phytophthora* blight, susceptibility to cold at the seed filling stage and wilt (in that order) are important. Although a large number of germplasm lines have been identified for resistance to *Fusarium* wilt, sterility mosaic and *Phytophthora* stem blight, resistance for insect pests has been only partial and germplasm with absolute resistance is not available. Some of the respondents suggested wide hybridization for developing resistance to pod borer. *Atylosia scarabaeoides* is resistant to pod borer. However, respondents felt that despite efforts in this direction, no success has been achieved.

Heterosis breeding was identified by sixteen of the eighteen respondents to be the method of choice for increasing the yield of pigeonpea. This survey showed that although combiners are known, no adequate pollination control mechanism was available in this crop. A genetic male sterility (GMS) system developed by ICRISAT (Hyderabad) had been extensively worked upon but had been found inadequate for large scale hybrid seed production as more than 50% of plants were fertile (due to distortion of expected 1 : 1 segregation ratio) and had to be rogued out after identification at the flowering stage. A CMS system has been identified in this crop under the All India Co-ordinated Research Project on pigeonpea. A few fertility restorers have also been found and experimental hybrids have been developed. However, there is an opportunity to use molecular methods for producing male sterile and restorer lines for hybrid seed production in pigeonpea.

A number of physiological traits were identified for improvement in pigeonpea, including improving the harvest index and resistance to drought and waterlogging. Although pigeonpea is essentially a rainy season crop and grows slowly at the seedling stage, only three out of eighteen respondents felt that development of transgenics for herbicide resistance is of any value. In summary, the major emphasis of all the respondents was on development of transgenics for resistance to insect pests (all the 18 respondents) and abiotic stress (15 out of 18 respondents). However, the catalogue of abiotic stresses was rather extensive – need for transgenics was felt for resistance to drought, waterlogging, salinity and thermo-insensitivity. While the importance of transgenics for pigeonpea improvement was widely accepted, it is important to consider that there is no reproducible protocol for genetic transformation of pigeonpea. It thus emerged that substantial efforts have to be put in this direction to make use of transgenic technologies for pigeonpea improvement.

Chickpea (*Cicer arietinum*)

Chickpea is a major crop of dryland rainfed agriculture in North India and its cultivation has now spread to peninsular India. The most important priority identified for chickpea breeding was to develop varieties that are resistant to *Helicoverpa armigera* (Figure 1 *f*). Breeding of chickpea for resistance to wilt (caused by *Fusarium oxysporum* f. p. *ciceri*) and blight (caused by *Ascochyta rabiei*) emerged as the other important goals. The respondents felt that *Fusarium* was a problem both in northern plains and southern regions of the country while *Aschochyta* was mostly prevalent in North.

As chickpea is a self-pollinating crop with a narrow genetic base, there is not much scope for heterosis breeding in this crop. Therefore, pure-line breeding was recognized as a method of choice for developing new chickpea varieties. Due to limited genetic variability available in this crop, the respondents did not feel that there is much hope for overall yield increase. However, stabilization breeding was considered to be of high significance in this crop. Although respondents identified germplasm for blight and wilt resistance, no information could be gained from the survey on the success achieved in the transfer of resistance to elite varieties.

Development of transgenics in chickpea for resistance to *H. armigera* was the major recommendation of all respondents. This survey also showed that despite identification of some germplasm for resistance to wilt and blight, all the respondents suggested development of transgenics for resistance to the two fungal diseases. Development of transgenics for resistance to drought and frost tolerance were also identified as important areas. Response to other goals like nutritional improvement and herbicide resistance was poor. As protocols for chickpea transformation are not optimized fully and the frequency of genetic transformation achieved so far is low, basic work on genetic transformation of chickpea was considered important before breeding objectives outlined above could be dealt with through transgenic technologies.

Mungbean and urdbean (*Vigna radiata* and *V. mungo*)

Vigna radiata and *V. mungo* are the major legume crops of India. Mungbean yellow mosaic virus (MYMV) was identified as the most critical yield-limiting problem in *Vigna* species. A physiological problem related to sprouting of seeds *in situ* under rains, powdery mildew (caused by *Erysiphe polygoni*) and leaf spot caused by *Cercospora* spp. were the major factors that were identified to limit grain yield (Figure 1 *g*). It was felt that germplasm for conferring resistance to MYMV, powdery mildew and cercospora leaf spot is available but its utilization has been mainly restricted to develop MYMV-resistant varieties which are now available for all crop growing conditions. The respondents suggested development of transgenics for addressing the problem of MYMV as the highest priority but some respondents differed as they felt that a large number of MYMV-resistant varieties are available and thus transgenics are not needed for this trait. A number of constructs have been developed for pathogen-derived resistance in mungbean and urdbean crop against MYMV. However, low genetic transformation frequencies reported in mungbean and urdbean appear to be a major impediment for developing virus-resistant transgenics. Until reproducible and highly effective transformation protocols are developed for these crops, progress will remain tardy. In general, respondents have overwhelmingly suggested breeding for resistance to insect pests and diseases by transgenic technologies as an important goal. Genetic engineering for resistance to pre-harvest sprouting was another important goal identified in this survey.

Cotton (*Gossypium hirsutum*)

Cotton is the major fibre crop of India. This crop is of great commercial importance to India as it sustains livelihood of a large number of rural people through cultivation and picking and a large workforce employed in both small scale and large industrial units. Cotton apparel is a source of export earnings for the country to the tune of 45,000 crores. The most significant constraints on the productivity of cotton were considered to be insect pests. This study showed that American bollworm (*Helicoverpa armigera*) is the most prevalent and damaging pest of cotton in India. Other lepidopteran pests like pink bollworm (*Pectinophora gossypiella*) and spotted bollworms (*Earias insulana* and *E. vitteulla*) also cause extensive damage (Figure 1 *h*). Sucking insects such as white fly (*Bemisia tabaci*) and jassids (*Amrasca biguttula biguttula*) too have a major negative impact on cotton yield. Besides insect pests, cotton crop also suffers from bacterial blight (caused by *Xanthomonas malvacearum*) and cotton leaf curl virus (CLCV; a geminivirus spread by whitefly), which has so far affected the crop only in the North-West (Rajasthan, Haryana and Punjab) but may spread to other cotton-growing areas of the country in future. This survey revealed that germplasm is available for early maturity, bacterial blight resistance and high ginning amongst *G. hirsutum*, extra long staple in *G. barbadense* and for low shedding and early maturity in *G. arboreum* lines. However, resistance to insect pests was reportedly not available in conventional types of cotton.

India was the first country in the world to deploy hybrids in cotton. Hybrid seed of cotton is produced by manual emasculation and hand pollination between good combiners. As no adequate CMS/restorer system is available in cotton, the respondents felt that it would be useful to develop male sterility/restorer system for producing hybrid seed on a large scale. Use of transgenic approaches for hybrid seed production was considered an attainable goal for improving productivity of cotton in the country. Although breeders claimed that a number of combiners for hybrid seed production have been identified, the area under hybrids has declined. Further, it appears that there is a multiplicity of hybrids in the market and only a few of these have survived over the years.

From the point of view of nutrition, a decrease in the content of gossypol in seeds was considered useful for improving the quality of cotton meal. However, it emerged that gossypol will have to be specifically reduced in the seeds as other parts of the plant reportedly require gossypol for resistance to insect pests. All the respondents identified the use of insecticidal proteins obtained from *Bacillus thuringiensis* (*Bt*) for developing cotton transgenics for resistance to lepidopteran insect pests but also cautioned that more than one insecticidal gene would be required as development of resistance to *Bt* toxins has already been shown in some insect species. Resistance to sucking insects through transgenic technologies was identified as another important target. The respondents felt that there is a need to reduce the unsaturated fatty acid content of cottonseed oil and to increase the monounsaturated fatty acid (MUFA) and polyunsaturated fatty acid (PUFA) contents. Further, increasing oil content above 25% was also considered an important goal. The present varieties have an oil content of around 16–18%. Twelve out of sixteen respondents suggested development of transgenics for herbicide resistance in cotton.

Briefly the most prominent suggestion was the development of transgenic cotton for resistance to insect pests. Oil quality was also an important objective that could be achieved through the development of transgenics. The respondents felt that transgenics for herbicide resistance and male sterility/fertility restoration could help to achieve an increase in cotton productivity. From the survey, it appeared that improvement of cotton in India required a major thrust in the area of development of transgenics.

Potato (*Solanum tuberosum*)

Potato has become an important crop in India both as a vegetable and as raw material for processed food industry. As potato is vegetatively propagated, heterosis can be fixed readily by propagating F_1s. No male sterility systems are required for potato. At the national level, resistance to late blight disease (caused by *Phytophthora infestans*) was identified as the most important breeding objective followed by mosaic disease (caused by a large number of viruses), bacterial wilt (caused by *Ralstomia solanacearum*), black scurf (caused by *Rhizoctonia solani*) and aphids (Figure 1 *i*). Aphids are more of a problem as vectors for viral transmission. In terms of severity of diseases and pests, there appeared major regional variations. In the main potato growing areas of Indo-Gangetic plains, late blight and black scurf were considered as the major problems. In the North-Western hills, late blight appeared as an important disease and in the Eastern hills both late blight and wart disease affected potato crop. In the plains of Maharashtra and Karnataka, mosaic virus and foliar necrosis were considered as the major problems. Late blight appeared to be a major problem in the Southern hills and nematodes extensively damaged the crop in the Nilgiri hills.

The response of specialists showed that many of the wild relatives of *Solanum* carry genes for resistance to the major pests and pathogens. However, as no query on the effective utilization of germplasm for improvement of crops was included in the survey, it is difficult to say how effective the wide hybridization programmes are in this respect.

Thirteen out of nineteen respondents suggested breeding for nutritional enhancement of potato. Suggestions included expression in tubers of provitamin A and increasing the content of sulphur containing amino acids. The *ama*1 gene (that encodes a seed storage protein having a balanced amino acid composition) from *Amaranthus* has been mobilized into a large number of potato varieties in India. Eighteen out of nineteen respondents suggested development of transgenics to control biotic stresses mostly fungal diseases in potato. Development of transgenics resistant to tuber moth appeared to be an important suggestion since no germplasm is available for resistance to tuber moth. Twelve of the nineteen respondents suggested development of transgenics for abiotic stresses as an important goal. Traits to be dealt with included heat tolerance, particularly to develop cultivars, which can form tubers above 20°C. However, development of transgenics for tuber formation under high temperature would require a thorough understanding of induction and development of the process at the molecular level. For value addition, it was proposed by some respondents that varieties with more than 20% dry matter and less reducing sugars should be developed.

It was proposed in this survey that yield improvement in potato could be attained by utilizing diverse genetic base available in *Solanum tuberosum* ssp. *andigena* (for biotic and abiotic stresses) through introgression breeding programmes. Crossing unrelated genetic material by a two-way hybridization approach followed by vegetative propagation was considered adequate for enhancing yield. In general, potato researchers seemed to favour use of transgenic technologies for meeting a number of breeding objectives that included development of cultivars resistant to fungal and viral diseases and high temperature. It appears that potato transgenics are specially needed for increased starch production through over expression of suitable genes, reduction of cold storage induced sweetening, production of vaccines for livestock, development of aphid-(vector) resistant cultivars, development of late blight-resistant cultivars, gene pyramiding for durable resistance to insect pests and development of temperature insensitive genotypes.

Indian mustard (*Brassica juncea*)

Indian mustard (*Brassica juncea*) is a major oilseed crop of rabi season in Northern India and is largely grown as a rainfed crop. It is predominantly a self-pollinated crop but considerable cross-pollination also occurs. There is a real possibility of development of hybrids in this crop but this potential has remained untapped. No commercial hybrids have yet been released in this crop but some field trials have been conducted on experimental hybrids based on the use of transgenic male sterile and restorer lines.

The most important breeding objective in mustard is the development of lines with resistance to *Alternaria* blight (caused predominantly by *Alternaria brassicae* and *A. brassicicola*), aphids (*Lipaphis erysimi*) and white rust (*Albugo candida*) (Figure 1 *j*). The respondents agreed in general that resistance to white rust is available within *B. juncea* germplasm but sources of resistance to *Alternaria* are not available. This survey revealed that development of transgenics for resistance to *Alternaria* would be a major breakthrough for mustard cultivation. It would be useful to consider if disease resistance conferring genes of *Arabidopsis thaliana* and/or of other alien species could be used in mustard for resistance to *Alternaria* blight. Aphids cause huge yield losses in mustard crop. It emerged that effective strategies were not available to control this pest, except to breed for early maturing cultivars at the cost of yield. More or less, all the respondents suggested exploration of transgenic technologies for developing aphid-resistant cultivars.

Improvement in oil quality by developing 'zero' erucic acid and meal quality by developing 'zero' glucosinolate cultivars (less than 30 μ moles of glucosinolate per gram of defatted meal) were identified as major breeding goals. Resistance to herbicides was not considered important in this crop. Some respondents proposed that mustard transgenics could be developed for resistance to abiotic stresses like drought, heat, cold and salinity. *Brassica* transgenics have already been developed in the country with *codA* gene and would need to be tested for resistance to different abiotic stresses at field level. Heat tolerance for early planting and at seed filling stage could also be of value and the possible role of heat shock proteins (HSPs) in this context could be examined. It was proposed that heterosis breeding could substantially increase mustard yield. A complete male sterility/restorer based on transgenic technologies has been developed both in private and public systems and could be used for developing hybrid seeds. Mustard and other *Brassica* species are highly amenable to techniques of genetic engineering. Thus, there is tremendous scope for improvement in the mustard crop by the use of transgenic technologies.

Soybean (*Glycine max*)

Soybean is an important legume crop of USA, Brazil, China and Argentina. In India, this crop is currently grown in large tracts of Madhya Pradesh and other parts of Central India during the 'Kharif' season as a rainfed crop. Soybean is also a very popular crop in the Northeastern states, particularly Nagaland, from very early times. It is an introduced crop and initially, was free of diseases. However, continuous cultivation of this crop has led to incidence of a number of diseases on the crop. In the survey, the most important problem in soybean cultivation appeared to be yellow mosaic virus (YMV) (Figure 1 *k*), a geminivirus, spread through whiteflies. Besides YMV, soybean rust (caused by *Phakopsora pachyrhizi*) was identified as an important disease and diseases such as root rot (caused by *Macrophomina phaseolina*), pod blight (caused by *Colletotrichum* sp.) and bacterial blight (caused by *Xanthomonas campestris* pr. *glycines*) were considered noteworthy. YMV is the predominant disease in Northern plains and hills but is not a threat in the major soybean growing areas of Madhya Pradesh. Availability of resistant lines would allow cultivation of soybean in place of rice in the Northern plains.

The most important recommendation in soybean was to develop transgenics that are resistant to YMV and fungal diseases. Amongst insect pests, stem fly (*Melanogromyza sojae*), stem borer (*Oberlopsis brevis*) and green semi-looper (*Chrysodeixis acuta*) were identified as major problems but exact quantification of yield losses due to these insect pests remains to be done. The respondents in general felt that lack of certified seed and poor agronomic practices are contributing in a significant way towards low yield of soybean. As a 'Kharif' crop, soybean has major problems with weed infestation. However, only three respondents proposed development of transgenics for herbicide resistance in this crop. The respondents also felt that protocols for genetic transformation of soybean need to be established in the country if transgenics for the identified breeding objectives are to be developed.

Epilogue

Two major crops namely groundnut and sugarcane could not be covered in this survey. These two crops along with some other oilseed crops like safflower, sunflower and sesame will need to be included in future assessments. It would also be useful if annual losses incurred due to lack of adequate resistance to biotic and abiotic stresses are estimated for different crops.

Finally, all the conclusions and suggestions made in this article are based on analyses of inputs that were received from different respondents and are not the personal views of the authors. It is possible that some of the points made in this write-up represent the opinions of individual contributors. We have not carried out any statistical validation of the received inputs. We only wish to add that the suggestions made in this article represent the collective wisdom of a large number of ground-workers and therefore, must be further investigated by those who direct the future of Indian biotechnology/agriculture research.

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Transgenics for productive and sustainable agriculture: Some considerations for the development of a policy framework

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Agriculture is of great importance to India. Although the overall contribution of agriculture to India's GDP is gradually declining, agriculture and its related activities continue to contribute in a significant manner to the overall growth of the Indian economy. Time to time, various thinkers have predicted catastrophic consequences of population growth[1-3]. However, predictions of widespread famines proved wrong as major breakthroughs were achieved in agricultural productivity by the deployment of dwarf wheat and rice, and slow incremental improvements were made in other major crops. The world used about 1.4 billion hectares of land for crops in 1961 and only used 1.5 billion hectares in 1998 to get twice the amount of grain and oilseeds[4]. In the absence of improvement in productivity brought about by breakthroughs in breeding varieties that are more productive and more stable, predictions of mass starvation might have come true.

The introduction of dwarf rice and wheat in India and many other developing countries brought about food self-sufficiency, at least in cereal crops. These developments in the 1960s and early 1970s have been popularly called the 'Green Revolution'. The impact of the Green Revolution, extensively studied and analysed, is generally positive. However, in the aftermath of the Green Revolution some negative impacts have become obvious. The cultivation of dwarf varieties requires high inputs, both in terms of fertilizer and irrigation. These inputs are heavily subsidized in India and elsewhere. Higher productivity in wheat and rice coupled with an assured pricing mechanism has led to an over reliance on these crops[5]. Varieties developed by the utilization of dwarfing genes have a narrow genetic base and intensive cultivation of these is leading to a build-up of pests and pathogens. In the last ten years the productivity of the two crops has plateaued while the population continues to increase, and will not stabilize till 2030. The average growth rate of the total food grain production in India during 1994–95 to 2000–2001 has been a dismal 0.8% (ref. 6).

Currently, the food situation in developed countries is very comfortable. Agriculture is heavily subsidized (the US alone provides every year around 50 billion dollar subsidy), but the amount is affordable. Food security has ceased to be a major concern. Organically-grown food has become fashionable. Some land has been reverted to forestry and food surplus is being used to cover the deficit in Asia and Sub Saharan Africa. However, in comparison, the food situation in most of the developing countries remains precarious. Around 800 million people worldwide are food-insecure[7]. In India alone, around 200 million people are undernourished[8]. Many specialists in agriculture have called for a new outlook in agricultural development. Swaminathan has called for an 'Evergreen Revolution'[9] and Conway has called for a 'Doubly Green Revolution'[10]. Many others have simply called for a movement towards more sustainable agriculture[11,12]. The thrust, at least in thinking, is towards creating agricultural systems which will be frugal in their requirement of inputs, involve diverse crop for proper crop rotation, and be based on genetically divergent cultivars within each crop. While reducing the overall exploitation of non-renewable natural resources, such systems should concomitantly provide yield enhancement and stability to feed a growing population.

The wish list of those who want a second revolution in agriculture, which is both productive and sustainable, is very long. It is pertinent to assess the possible contribution of transgenic technologies to sustainable agriculture. In July 2000, a report[13] prepared under the auspices of the Royal Society of London, the US National Academy of Sciences, the Brazilian Academy of Sciences, the Mexican Academy of Sciences, the Chinese Academy of Sciences, the Indian Science Academy and the Third World Academy of Sciences, had the following to say: 'We conclude that steps must be taken to meet the urgent need for sustainable practices in world agriculture, if the demand for an expanding world population is to be met without destroying the environment or natural resource base. In particular, GM technology, coupled with important developments in other areas, should be used to increase the production of main food staples, improve the efficiency of production, reduce the environmental impact of agriculture, and provide access to food for small-scale farmers'. In this article I will assess the requirements of

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sustainable agriculture, possible role of transgenic (GM) technologies in achieving higher productivity without compromising on sustainability, and the need to develop a policy framework both at the national and global levels for the proper utilization of transgenic technologies.

Sustainable agriculture would require efficient utilization of water resources, crop rotation and crop diversification and in-built resistance to pests and pathogens

One of the biggest challenges facing India and many other developing countries, including China is scarcity of water[11]. In most parts of India, rains are seasonal. As a consequence, ground or stored water has to be used for irrigation, industrial and domestic use. Pressure on water resources is bound to increase in the future due to population growth, urbanization, increased industrial requirement and higher living standards. To enhance the productivity of dryland agriculture, some protective irrigation will have to be provided in the areas which receive low rainfall. The water-table in many parts of India is receding and overexploitation of groundwater resources is a major threat to survival of future generations. Transgenic technologies have little to contribute towards alleviating the problems created by the overexploitation of water resources. However, if transgenic technologies can contribute towards enhancing productivity and yield stability of crops adapted to a low water requirement, the overall dependence on groundwater for irrigation will be reduced.

As discussed by Chand and Pal[5], Indian agriculture, both due to policies on grain procurement and subsidies on power and irrigation and fertilizers, is biased in favour of cultivation of wheat and rice. Rice is historically a crop of eastern India where rainfall is copious, and also of river basins in south India where irrigation has been readily available. Due to its high productivity potential, rice is now grown under irrigation in large parts of the country which traditionally grew other crops. Irrigated tracts give the highest per acre yield of rice, albeit at the expense of groundwater resources and high energy costs. Wheat is mostly grown under irrigation in north India during the winter season. Parts of north India receive some rain during winters, but wheat cultivation even in these areas is supported by six to seven irrigations. In the north, high-yielding wheat and rice varieties are grown in a continuous wheat–rice cycle, year after year[14]. In the irrigated areas of south and east, multiple crops of rice are grown on the same piece of land. This is leading to the depletion of sub-soil water and in the absence of proper rotation of crops, tremendously increasing the pressure of pests and pathogens. Over reliance on rice and wheat has also led to overproduction of these two cereal crops. Currently, the country holds around 60 million tonnes of wheat and rice in reserve[15]. Concurrently, there is a huge shortage of grain legumes and oilseeds. The more input-frugal crops are not grown in the irrigated, high-intensity agricultural areas as their overall productivity is low, while susceptibility to pests and pathogens is even higher than that of wheat and rice[16]. If we have to approach the goal of sustainable agriculture even remotely, it will require proper crop rotation which, in turn, will require proper pricing policies[5] and possibility of high yields from the replacement crops.

Perhaps the most challenging goal before Indian agriculture is to reduce the water requirement of rice and wheat while maintaining their high productivity. Variability is available in the two crops for water requirement, but most varieties that have lower levels of water requirement, such as upland varieties of rice, have low productivity. There could be three broad strategies for reducing the water requirements of the two major cereal crops: (i) development of transgenics with single or few genes[17], which may provide tolerance to abiotic stresses without compromising the overall yield; (ii) characterization and mobilization of QTLs (quantitative trait loci) for conferring resistance to abiotic stresses in the overall genetic background of high-yielding varieties; and (iii) transfer of the highly heritable traits contributing to the yield, from high-yielding materials into the overall genetic background of low-irrigation requiring genotypes.

Most traits related to abiotic stresses (such as tolerance to drought and salinity) have been shown in field-breeding experiments to be quantitative traits. However, a large number of transgenics in which single or few genes have been introduced and modifications have been made only in the quantity or timing of expression (constitutive expression instead of induced), have been shown to confer resistance to the targeted abiotic stresses[17]. If simple overexpression could have contributed to conferring resistance to biotic stresses, genetics of stress tolerance or characteristics such as less water requirement would have been simpler and Nature would have 'discovered' and utilized single gene changes for resistance to abiotic stresses, over and over again. It seems that traits like water requirement and abiotic stress tolerance are predominantly quantitative in nature. Transgenic technologies, in all probability, have little potential for reducing water requirement of crops like rice and wheat. Marker-assisted breeding could be more pertinent for addressing the issue. Most of the QTLs for resistance to abiotic stresses or traits like lower water requirement, however, cannot be so readily marked due to their low heritability. In comparison, the yield-enhancing loci, many of which have high heritability, will be more amenable to mapping, and subsequently, these traits could be mobilized into diverse genetic backgrounds, including varieties that are frugal in their requirement of water. A priori, it cannot be guaranteed that the last-mentioned approach would work. However, if such work is undertaken, it would at least allow diversification of QTLs for yield in a large number of diverse genotypes. If this approach works, as envisaged, we may have varieties with high yield and low water requirement. Tagging of QTLs related to yield and the transfer of the tagged loci would require multidisciplinary teams and a funding commitment of ten to fifteen years. Both requirements, trained manpower and long-term research backing, are currently missing in the Indian research agenda on agriculture.

Transgenic technologies can make the most profound contribution to yield stability and sustainability by developing varieties that are resistant to pests and pathogens

A survey published in this volume[16] clearly shows that a large number of field crops grown in India suffer from major pests and pathogens. A number of articles in this volume have discussed the molecular methodologies and transgenic approaches that could be used for tackling the problems posed by pests and pathogens[18–20]. Providing resistance through genetic means would reduce input costs in terms of agrochemicals and in the long run, would protect the ecosystem from accumulation of chemicals currently being used for controlling pests and pathogens.

The development of disease and pest-resistant varieties has been a major activity in plant breeding. The economic returns of this activity are very high but remain underestimated, as the lag periods between initiation of the research activity and returns are rather long, ten to fifteen years. Options available to plant breeders for developing resistant varieties can be best explained through the concept of gene pools (Figure 1). Identification of resistance within the primary gene pool and its

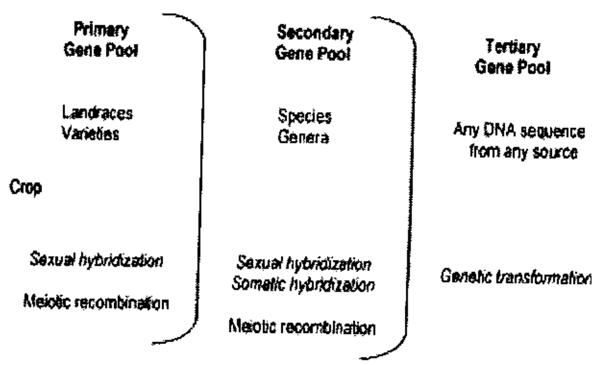

Figure 1. Concept of gene pools was given by Harlan and de Wet[60] in the pre-recombinant DNA era. In the light of the new developments, I propose a modified scheme in which besides evolutionary distance, methods of gene transfer (given in italics) are also taken into consideration. The tertiary gene pool would increasingly become the most important donor of gene sequences for the improvement of crop plants. However, the primary gene pool would remain important for pure line and heterosis breeding, and the secondary gene pool would be of value for the broadening of the genetic base of crop species.

incorporation into a high-yielding variety is the most straightforward option. However, variability within the primary gene pool for resistance has been almost exhausted. In the last twenty years the secondary gene pool, comprising species and genera related to the crop species, has provided a large number of resistance-conferring genes[21,22]. Transfer of genes from wild relatives to crop plants through hybridization suffers from many difficulties. As the evolutionary divergence increases, sexual crosses become increasingly difficult and eventually impossible. Embryo abortion is common, but can be circumvented by embryo rescue. The most excruciating difficulty in transfers is lack of chromosome pairing. If genetic exchanges do occur, the problem of linkage-drag (the gene of interest is linked to a deleterious or yield-reducing gene) could become the limiting step in successful gene introgression. Such tight linkages are difficult to break.

Techniques of molecular biology and genetic transformation have now vastly expanded the scope of plant breeding as these allow mobilization of genes from disparate, sexually incompatible genomes to crop species[23]. Most of the transgenics in the field today[24] are first generation transgenics which were developed with genes from very distant organisms, mostly prokaryotes. Being haploid organisms with small genomes, gene identification is easier in prokaryotes compared to the large-genome, diploid eukaryotic organisms. Two interesting examples of the use of genes from prokaryotes are transgenics for insect resistance in cotton and maize using insecticidal protein genes of *Bacillus thuringiensis*[18]. Conferring resistance to viral pathogens through sequences taken from the pathogen itself is another area where success has been achieved[20]. Being small, viral genomes are easy to sequence. Unfortunately, little work has been done in India on variability in the genomes of major viruses affecting crops in India. I propose that a major effort be launched on studying genomic variability in viruses causing huge economic losses on crops of high economic value. Development of effective PDR (pathogen-derived resistance) strategies will depend upon the availability of information on genomic sequences, transformation protocols and proper testing facilities. Unfortunately, research in this area in India is sluggish, below threshold and therefore inconsequential in terms of providing any benefits to the farming communities.

With the development of high throughput technologies in sequencing, it should be possible now to mine genes of high agronomic value from the near and distant relatives of crop plants and to introduce these into recipient crop varieties through the techniques of genetic transformation. The use of *R* genes for conferring resistance to crop species has been discussed in this volume[19]. Genomes of two higher plants, *Arabidopsis*[25] and rice[26–29] have already been sequenced, and information from these genomes would allow characterization of resistance-conferring genes in related plant species and genera. Many interesting direct approaches have also been taken to isolate resistance-conferring genes from resistant germplasm[30]. For example, a large number of graminaceous species which are sympatric to cultivated rice in northeast India or for that matter anywhere else and are not affected by the diseases prevalent on cultivated rice in that area may contain all the genes for conferring resistance which can be transferred to rice. Unlike in humans where lesion and susceptibility loci are important, in plants, genes from the wild relatives are going to be the most important contribution of the science of genomics. It is hoped that sequencing of the rice genome will be followed by sequencing of some of the wild relatives which have relatively small genomes for allele mining for resistance to diseases and insect pests. However, the current thought process in setting research agendas both at the national and at the Consultative Group on International Agricultural Research (CGIAR) institutes does not seem to be emphasizing this point. Given the national and international needs in agriculture, identification of resistance-conferring genes in the wild relatives of crop plants and their subsequent transfer to high-yield rice varieties through transgenic technologies should be a major thrust area for using genomics and transgenic technologies for sustainable agriculture.

If success is achieved with model crop rice, mining of alleles for resistance to diseases and pests could be taken up in crops which are well adapted to dryland agriculture, i.e. sorghum, millets, mustard, groundnut, safflower, pigeonpea, chickpea, but suffer from a large number of biotic stresses. Little involved work is being undertaken on these crops at the international level, and it would be a major challenge for the developing countries to address these problems through genomics and transgenics, by developing linkages with the CGIAR institutes and laboratories in the developed countries. For a large number of crop plants that are adapted to dryland agriculture, particularly grain legumes, transformation protocols are not available[31]. A major effort will be required to develop efficient methodologies for genetic transformation in these crops.

Transgenics for nutritional enhancement and senescence retardation can contribute to productivity without compromising sustainability

Two other important areas which have been only covered in passing in the articles in this issue are nutritional enhancement and senescence retardation. Research and development in both these areas can have a great impact on developing countries. In the area of nutritional enhancement, an oft-cited example is that of golden rice[32]. There is a lot of argument on how much of golden rice would have to be consumed to fulfil the daily requirement of vitamin A. The issue of golden rice has also been over-exploited by the transnationals to show a humane face so as to gain opportunities to deploy transgenics in developed and developing countries[33]. Nevertheless, golden rice is an interesting development which could open the way for improving nutritional standards in rice-eating cultures. In a similar way, work done in India on the introduction of balanced amino acid–protein-encoding gene *ama1*, from *Amaranthus* into potato holds promise for enhancing nutritional value of a low-protein food[34,35]. Transgenic potatoes with *ama1* genes are undergoing field trials. The results on nutritional benefits of potatoes carrying this gene are eagerly awaited. Critics of nutritional enhancement research feel that the supplementation of one vitamin in golden rice and some nutritional enhancement in potato will not be sufficient by themselves to balance the nutritional requirement. This point is appropriate, but a summary dismissal of these technologies will be, to put it mildly, myopic.

Interesting work is also being done on changing the fatty-acid composition of different oilseeds to enrich these with oil fractions which are healthier for human consumption[36]. Work is also under way to use transgenic approaches to improve the iron content in seed or the other edible parts, and also to accumulate it in a more usable form for the human digestive system to tackle a widespread problem of iron deficiency in the developing countries[8].

A major increase in production of vegetable and fruit crops will be required in the coming two decades[5] as consumption of these will increase due to improved income levels and increasing awareness about health and nutrition. Balanced food requires a fair amount of vegetables and fruit. However, these crops are highly perishable. Hence, farmers who are not well connected to big cities are reluctant to grow these crops. Farmers also have to indulge in distress sales of fruit and vegetables as, at times, there is too much produce and there is no concomitant off-take by consumers. It has been shown that senescence can be slowed by down-regulating some of the genes involved with ethylene biosynthesis[37]. There are other pathways also which can be manipulated to slow down senescence in highly perishable crops. Unfortunately, no such transgenics have been produced in India and studied for their viability. Addressing the issues of post-harvest losses and nutrition could contribute to the earnings of the small farmers and provide enhanced nutritional status to the poor without increasing the pressure on the natural resources.

Transgenic technologies can facilitate hybrid seed production in some of the major crops grown in India

Even in the high-yield crops of wheat and rice, further advances in productivity have been achieved through involved ideotype breeding (rice in China and at International Rice Research Institute (IRRI), wheat at International Maize and Wheat Improvement Centre (CIMMYT) and in rice through heterosis breeding in China and to some extent in South and South East Asia. Projections from various studies show that it will be difficult to increase the cropping area in India. Therefore, productivity enhancement even in wheat and rice would be required, despite the buffer stock availability at present[6,38–40]. In fact, it will be necessary to reduce the area under these crops while taking care of the grain needs of a still expanding population. This can be achieved through reducing losses to pests and pathogens in the two major cereal crops and also by making efforts to enhance productivity, as has been done in China for rice through ideotype breeding and through hybrids[41]. However, breeding for higher productivity in other major crops (minor cereals, legumes and oilseeds) and stabilization of yields in these crops is an absolutely essential requisite for nutritional security and agricultural sustainability. Besides the incorporation of resistance factors, it will be useful to develop technologies for heterosis breeding in crops like pigeon pea, safflower, sesame, rice and wheat. In India, hybrids have performed better than pure lines in the rainfed areas, as hybrid vigour allows plants to establish quickly under limiting conditions.

Heterosis breeding is currently a major method of developing productive materials in maize, sorghum, millet, sunflower and many of the vegetable crops. Essentially, heterosis breeding requires a stable pollination control mechanism and combiners (parents) that would give high productivity hybrids. The efficiency of hybrid seed production also depends upon the pollination behaviour of a crop. The development of hybrid seed is easy in cross-pollinated crops like maize, millet and sunflower. It is readily possible in crops which are pre-dominantly self-pollinated, but have significant levels of cross-pollination, i.e. mustard, pigeon pea, cotton and rather poor in crops like rice and wheat which tend to be mostly self-pollinated. A major impediment in hybrid seed production of rice is lack of opening of the florets for cross-pollination. For crops which are mostly self-pollinated like rice, wheat and soybean, besides the necessity of robust pollination-control mechanisms, changes will also be required through breeding in the floral structures to allow high frequency of cross-pollination for large-scale hybrid seed production. The development of combiners and the modification of breeding behaviour can be done predominantly through conventional breeding methodologies. Transgenic technologies may have little to contribute. However, in the area of pollination-control mechanisms, transgenic technologies provide a lot of scope[42]. In many crops, the genetic male sterility (GMS) systems and cytoplasm male sterility (CMS) systems have proved to be inadequate as these are either labour-intensive or impose yield penalties. Some of the CMS systems tend to become susceptible to diseases. The genetic engineering-based technologies for producing male sterile and restorer lines need to be explored for hybrid seed production in dryland crops like pigeonpea, cotton and safflower.

IPRs, as they exist in the developed countries, if extended to the developing countries will create major impediments for the proper utilization of transgenic technologies

In developed countries, much of the resistance to the deployment of transgenics stems for health and environment-related concerns. Some of these concerns are genuine, others are imaginary. The threat of IPR regimes to the effective use of transgenic technologies worldwide has been overlooked in the developed countries. However, some of the NGOs in the West, despite overall apathy to the issue due to lack of general awareness, have time and again forewarned developing countries on patents which could have a detrimental effect on their agriculture. An illustrative example is 'Terminator Technology', which has been briefly discussed in this volume[43].

In the early days of recombinant DNA technology and genetic engineering, it was felt that breakthroughs would be achieved at breakneck speed, and that their implementation could effectively occur through the well-organized global reach of the transnationals, provided trade and economic policies were effectively liberalized in the developing countries. This optimism perhaps never took into consideration social realities and also the excruciatingly slow pace of agricultural research. The latter facet has been discussed in two thorough research reports by the International Food Policy Research Institute (IFPRI)[44,45].

Unlike the development of antibiotics, chemical molecules and materials which are stand-alone commodities – promoters, vectors, genes and even varieties on their own, are grossly insufficient. It is the combinations of these elements and subsequent stacking of gene constructs in adapted varieties bred through recombination breeding that viable products useful to the farmers can be developed. New molecules can be manufactured and traded in an organized way and their production can be located in any part of the world. No special location-specific inputs are required. Agricultural developments on the other hand, are location-specific. A new variety developed in USA or in Europe may not be of any direct benefit in India. A disease resistance-conferring gene may have to be tested extensively against prevalent races of a pathogen in diverse agroclimatic conditions.

As reported by Grover and Pental[16], almost all the major crops grown in India require multiple character inputs. Important genes that are required to be introduced into each crop will run into tens, if not hundreds. Each gene sequence will require a promoter, a vector and a transformation protocol. All these components which will be necessary for the development of a transgenic for a specific character could be under independent IPR regimes. As an example, the much applauded and cited development in crop biotechnology, 'golden rice', in which provitamin A synthesis ability has been introduced into rice through transgenic technologies, incorporated intellectual property based on at least 70 patents with 32 owners[4]. Pardey and Beintema[45] rightly point out – 'as patenting becomes more prevalent, the number of separate rights needed to produce new innovation proliferates. If ownership of these rights is diffuse and uncertain, the multilateral bargaining problem can become difficult to resolve. Instead of over-exploitation of a common property with low entry cost, there is under-exploitation of a pool of intellectual property due to high costs of access – a manifestation of the so-called 'tragedy of the anticommons' which occurs when too many individuals have rights of exclusion to a common resource'.

There have been two sets of responses to IPRs in crop biotechnology. One has been extensive litigations which have cost millions of dollars. The development and commercialization of the *Bt* gene in corn and cotton illustrates this. Around 81 separate research organizations (59 private and 22 public) owned a total of 388 patents for the *Bt* gene and its use in various crops. The litigations around this technology led to settlements totalling more than US $ 175 million and, by some estimates, destroyed more than $ 1 billion of shareholder value[46]. The difficulties in negotiating the rights to use patents and the high costs of piecemeal acquisition of patent rights have encouraged the second response, takeovers and mergers of agriculture-related industries dealing with seeds, pesticides, herbicides creating behemoths that may end up monopolizing entire sets of technologies required for the production of transgenic plants[47]. Majority of the plant DNA patents are held by around 14 transnationals, the biggest stakeholders being Monsanto, Zeneca and Novartis[48]. Merger or takeover of companies and consolidation of patent rights are continuing unabated.

Most of the genetic transformation technologies, particularly the development of *Agrobacterium*-based vectors (for details see Veluthambi *et al.*[23]) were developed with the support of public funding. However, when used for specific crops, transformation protocols were granted patent protection. The generalized patents and patent protection to gene sequences, the latter being the result of millions of years of organic evolution, could become the most impeding factor in the utilization of transgenic technologies for sustainable agriculture. It can also be argued that findings on naturally-evolved gene sequences are merely discoveries and not inventions and, therefore, these do not come in the preview of patents. If the gene discoveries are through the use of complex and resource-intensive technologies, then for this reason alone, discoveries should not be termed as inventions. However, sequences that have been modified by human intervention or have been searched for in conjunction with some proprietary molecules, i.e. herbicides, could be reasonable cases for patent protection.

In the pre-recombinant DNA era, establishment of genotype–phenotype relationship was not protected by patents. A large amount of germplasm collected from all over the world, particularly from germplasm-rich developing regions of the world, was freely used by breeders in both the public and private sectors to develop resistant or high-yielding varieties or hybrids. Just as germplasm effectively resolved many problems related to crop plants and will probably provide us with the necessary genes for breeding through the use of transgenic technologies in the future, discovered genes must also be freely available for deployment in varieties to meet the requirements of different agro-climatic regions of the globe.

The Indian Plant Variety Protection Act 2002 is a creative solution to IPR-related problems

Proprietary claims started in 1980 when the US Supreme Court ruled in favour of utility patenting for life forms. In 1985, the US Board of Patent Appeals allowed patent protection for asexually, sexually or *in vitro* propagated plants. Prior to this, protection was only available for asexually propagated plants. However, the biggest assault on the free exchange of biological materials came from Bayh-Dole Act in 1980 in USA. This Act gave researchers the right to retain title to materials and products that they invented using the federal (US govt) funding. This has led to profitable privatization of biotechnologies developed at the universities and public institutions. The change was tantamount to using public money for profits through the mediation of industry. Proprietary claims, for example in the US, cover all kinds of biotechnologies which include germplasm, genes, sequences, promoters, transformation technologies, marker vectors, etc. Another landmark development was the agreement in 1994 on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as a part of the Uruguay-round of multilateral trade negotiations. TRIPS now forms a part of the legal obligations of countries that are members of the WTO. Box 1 gives the major features of TRIPS agreement on patents.

In the TRIPS agreement, plants and animals were left out of compulsions of strict patent regimes (Box 1). However, the developing countries, in which no IPR for plants exists, were required to enact a *sui generis* (one of its kind) system for the protection of new plant varieties. In response to this, the supreme law-making body of the country, the Parliament, enacted a Plant Variety Protection (PVP) Act. This has been thoroughly discussed in this issue by Sahai[43]. This author has argued for some changes in the Act to provide the farmers more rights. I believe, clauses related to germplasm usage by private companies would be tedious to implement and are self-defeating. Private industry, if it is to provide superior varieties to farmers, would need free and unhindered access to germplasm. I would urge that no attempts should be made to either dilute the PVP Act towards farmers' benefit or to further strengthen it towards breeders' interest without extensive discussions within the country. It is

Box 1. TRIPS agreement on Patents

Section 5: Patents
Article 27: Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial applications. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

a. diagnostics, therapeutic and surgical methods for the treatment of humans or animals;
b. plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

unfortunate that the Government of India has decided to implement UPOV1991 (International Union for the Protection of New Varieties of Plants) when the Parliament had cleared the PVP Act after an extensive and broad-based dialogue. It is certainly a case of bad advice to the government by the 'specialists'.

The PVP Act has taken into consideration some of the provisions of CBD (Convention on Biological Diversity). An extensive study of TRIPS related to agriculture and the contradiction between TRIPS agreement and CBD have been discussed by Watal[49]. Essentially, CBD is more sympathetic towards the rights of gene (germplasm)-rich countries of the developing world.

In developing countries (and fortunately now in developed countries also), there is an emerging consensus amongst experts with liberal leanings that overzealous patenting is not favourable to the future of world agriculture. The British government in 2001 set-up a panel of experts for 'Integrating Intellectual Property Rights and Development Policy'. The report of this Commission on Intellectual Property Rights (CIPR)[50] was published in September 2002. The main recommendations of CIPR on agriculture and genetic resources are given in Box 2. These recommendations come much closer to the PVP Act passed by the Indian Parliament[43] and clearly show more sensitivity towards the needs of agricultural research and development in the developing regions of the globe. This emerging consensus on IPR in agriculture needs to be widely disseminated and discussed. The threat to agricultural research from monopolies and the 'tragedy of anti-commons' is real and must be addressed through appropriate laws and free exchange of materials and methodologies.

The PVP Act can be used in a creative manner to allow protection for both the public and the private sectors. All crop species can be broadly grouped on the basis of their pollination mechanism into three groups: strictly out-crossing, both self-and out-crossing and strictly selfing. In India, hybrid seed is being produced and sold for a large number of cross-pollinated crops (e.g. maize, jowar, bajra, forages, etc. and for a few self-pollinated crops, (e.g. tomato). The seed industry in India has been active in the area of hybrid seed production for many years[51]. If farmers keep the seed of hybrids (F1 generation), characters will segregate in the next generation (F2) and yields would be lower. Consequently, for many vegetable crops, maize, sorghum, millet, cotton, there is an extensive market for hybrid seed and farmers repeatedly go to the seed companies for hybrids. Under the PVP Act, inbred lines and hybrids could be registered, and further protection would be available. For many self-/cross-pollinated crops, both pure line breeding and hybrids are possible. Hybrids, in general, out-yield pure line varieties. While the public system can concentrate on pure line breeding, the private sector could produce more productive materials through hybrids. Transgenes can be stacked in hybrids and there will not only be in-built protection available to hybrids but also protection by the newly-enacted PVP Act. This level of protection should provide enough incentive to private companies to invest in hybrid seeds.

Even for the self-pollinated crops like rice and wheat, hybrids are a distinct possibility. China has achieved notable success in hybrid rice. Again the private sector can be active in this area of R&D. However, for the two major cereal crops, rice and wheat, and many of the other strictly selfing legume crops like soybean and groundnut, there will be little incentive for the private sector to invest in pure-line breeding, as the farmers under the PVP Act would be able to keep their own seeds for fresh

Box 2. Recommendations of the Commission on Intellectual Property Rights* for the area of agriculture and genetic resources

- Because of the restrictions patents may place on use of seed by farmers and researchers, developing countries should generally not provide patent protection for plants and animals, as is allowed under TRIPS. Rather, they should consider different forms of *sui generis* systems for plant varieties.
- Because they are unlikely to benefit from the incentives to research offered by the patent system, but will have to bear the costs, developing countries with limited technological capacity should restrict the application of patenting in agricultural biotechnology in ways that are consistent with TRIPS. For similar reasons, they should adopt a restrictive definition of the term 'microorganism'.
- However, countries that have, or wish to develop biotechnology-related industries may wish to provide certain types of patent protection in this area. If they do so, specific exceptions to the exclusive rights, for plant breeding and research, should be established. The extent to which patent rights apply to the harvested crop also needs to be carefully examined. It is important that a clear exception to the patent right is included in legislation to allow for farmers' reuse of seed.
- The review of the relevant provisions in TRIPS which is currently taking place in the TRIPS Council, should preserve the right of countries not to grant patents for plants and animals, including genes and genetically modified plants and animals. It should also permit countries to develop *sui generis* regimes for the protection of plant varieties that suit their agricultural systems. Such regimes should permit access to the protected varieties for further research and breeding, and provide for the right of farmers to save and plant-back seed, including the possibility of informal sale and exchange.
- Because of the growing concentration in the seed industry, it is important that public sector research on agriculture, and its international component, should be strengthened and better funded. The objective should be to ensure that research is oriented to the needs of poor farmers, that public sector varieties are available to provide competition for private sector varieties, and that the world's plant genetic resource heritage is maintained. In addition, this is an area in which nations should consider the use of competition law to respond to the high level of concentration in the private sector.
- Developed and developing countries should accelerate the process of ratifying the FAO Treaty on Plant Genetic Resources for Food and Agriculture and should, in particular, implement the Treaty's provisions relating to not granting IPR protection on genetic material in the form received from gene banks protected by the Treaty. They should also implement at national level, measures to promote Farmer's Rights. These include the protection of traditional knowledge relevant to plant genetic resources; the right to participate in sharing equitably benefits arising from the utilization of plant genetic resources for food and agriculture and the rights to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources.

*The Commission on Intellectual Property Rights was set-up in May 2001 by the British government. The report was submitted in September 2002 and can be accessed on www.iprcommission.org. The members of the Commission were John Barton, Daniel Alexander, Carlos Correa, Ramesh Mashelkar, Gill Samuels and Sandy Thomas.

plantation. Consequently, the public system will have to provide breakthroughs in these crops for enhanced and stable yields through the development of new pure-line varieties or transgenics from the existing varieties.

I propose that the PVP Act, if implemented properly, will allow both the private and public sectors to contribute towards agricultural progress. The private sector can invest in hybrids, while the public sector could provide leadership in the development of pure lines.

Public-funded agricultural research in India is becoming ineffective and requires major changes in managerial practices to contribute to productive and sustainable agriculture

The major funding for biotechnology research in India has come from the government[5,52]. However, the impact of this public-funded research could have been far greater. First, India has not recognized any patents either on genes or on plants. Patents are territorial, and scientists in India can use any of the sequences or technologies described in the literature or patents. That we have failed to produce a large number of transgenics based on existing knowledge in itself shows weakness in R&D in the public sector. The Indian Council of Agricultural Research (ICAR) system as it exists presently is extensive (Table 1)[38] but unfortunately over-bureaucratized. The quantum of funding for specific projects remains below threshold. The lack of adequate trained manpower is another dampner, as new recruitments are sparse and the existing scientific staff (although large in number) is unable to cope with the new methodologies of markers, genetic transformation and gene cloning. It is ironic that many of the senior administrators in the ICAR system, both in the past and at present, have observed agricultural research at the global level, particularly in the CGIAR system; yet no effort has been made to develop multi-disciplinary teams for trait-specific breeding as has been done in the CGIAR institutes. Although there is a dedicated institute for every major crop in the ICAR system, no spectacular examples of teamwork exist. A major effort is required in searching for competent research leaders and establishment of teams that work in a time-bound and goal-specific manner. The bureaucratic strangleholds on the execution of projects must be removed if the public system is to contribute towards the development and

Table 1. Institutions under the National Agricultural Research System in India

Institution	1974	1985	Current
Indian Council of Agricultural Research			
Institutes	23	39	49
National Research Centres	–	11	30
Project Directorates	–	5	10
All-India Co-ordinated Research Projects/Network Projects	69	63	80
Central Agricultural Universities	–	–	1
Others	–	8	14
Total	92	126	184
Agricultural Unisversities	17	23	29

Source: Ref. 38.

evaluation of transgenics. If current practices are to continue, R&D in the public sector is definitely moribund.

It is of critical importance to the country that in the next two years, trait-specific programmes of crop improvement are identified and research on these is implemented jointly by Department of Biotechnology (DBT) and ICAR. Although the two departments belong to two different ministries, ways and means must be found to develop coordinated systems of research and to involve both agricultural and non-agricultural laboratories in the R&D programmes.

The current decline of CGIAR system is not in the interest of sustainable agriculture

A major threat to the use of transgenic and other new technologies for sustainable agriculture stems from the decline of the CGIAR centres. The CGIAR system grew out of the initial support by the Ford and the Rockefeller Foundation in the 1950s, to support joint venture programmes in agriculture. IRRI was established to work on rice in 1960 at Los Banos in the Philippines. CIMMYT was set-up at El Botan in Mexico in 1967. The CGIAR system at present has 16 international centres. The overall achievement of the CGIAR system and the contributions of individual centres can be readily accessed[53] and hence will not be described. However, it is pertinent to point out that the CGIAR centres have made immense contribution towards breeding materials for both developed and developing countries. Dwarf wheat and rice varieties bred at CIMMYT and IRRI have been responsible for major yield increase in the developing countries through 'Green Revolution', and these developments have been referred to extensively in this special section. However, contribution of the CGIAR centre to agriculture of the developed countries remains largely unknown. In the early 1990s, one-fifth of the total US wheat land was being sown with varieties derived wholly or in part from material developed at CIMMYT. For the California Spring wheat, this figure was estimated to be 100% (ref. 10).

It is, therefore, quite inexplicable why the overall financial support to CGIAR institutes is decreasing (Japan in 2002 has cut support to IRRI by half)[54] and why there is no attempt in global fora to make these institutions central to the themes of sustainable agriculture. The total budget of the CGIAR system has remained stagnant for the past ten years and as some new institutions have been started, budgetary support for established centres has actually declined[45]. Even centres like IRRI and CIMMYT, despite their well-recognized contributions, are at a receiving end. Many of these centres are doing contractual work with transnationals on which there would be IPR fetters at the end of the day[33].

Throughout the world, particularly in the developed countries, since the advent of recombinant DNA techniques, genetic engineering methodologies and high throughput instrumentation, expenditure on biological research has grown manifold. The CGIAR centres, either due to a design or out of a false sense of food security, are seeing their actual budgets shrink. This should be unacceptable to the world community. A major effort should be made by the Indian government, in partnership with the developing countries of Asia, Africa and Latin America, to seek in the next three years at least 20–25% annual increase in the research budgets of CGIAR institutes.

Effective use of transgenic technologies would require complete transparency in evaluation and release of genetically engineered material

It is clear from the article by James[24] that the two American continents have been most enthusiastic towards transgenic crops. China, by all accounts, is another country which has taken up R&D on transgenics as a major priority[55]. Many of the developed countries in Europe and Japan are rather lukewarm. Currently, no transgenics are being grown in these countries. Transgenics are perceived to give genetically modified food. Hence, the name GM is far more in use in the popular lexicon than the more scientific and esoteric term, transgenics. Most of the food we eat is genetically modified through selection and controlled breeding. This selection occurred throughout the human evolution, mostly in an inadvertent manner, but in the last century has been through controlled methods and elaborate selection strategies. As a consequence all food carries some genetic modification.

Transgenic research has expanded the scope of genetic modification (Figure 1) and brought higher levels of precision to breeding work. However, there are ecological fears about transgenics which should not be dismissed and require careful analysis[56–59]. One major fear is regarding the use of antibiotic resistance-conferring marker genes which are used for the *in vitro* selection of transgenics. Technologies are now available for the removal of the marker genes[23]. The other major fear is on the spread of the transgenes. It is thought that related species which are sympatric with the crop, and some of these at times invade the crop fields as weeds, may receive the transgenes and thereby become super weeds. The fear of super weeds is mostly imaginary. But increasingly, scientific work shows that transmission of transgenes from crops to closely related species is possible. In cross-pollinated species, transmission could be extensive. Also, once transgenics are put in the farmers' field, keeping the transgenic material distinct from the non-transgenic material will become impossible, given that the land holdings in India are very small and farmers tend to keep their own seed, particularly in the self-pollinated crops. Therefore, the possibility of 'GM' food getting mixed-up with 'non GM' food is real and cannot be wished away. Although research published on the movement of transgenes from transgenic corn to land races of corn in Mexico has been shown to be incorrect, once large-scale cultivation of transgenics is undertaken, the possibility of genetic exchange between land races and transgenic material exists as much as it exists for exchange between transgenic varieties and non-transgenic varieties growing in the farmers' field. The best way of avoiding genetic contamination of land races is to secure germplasm in the gene banks of the world.

As transgenic material can cross with non-transgenic varieties and also with the wild relatives, transgenic material must be put through rigorous tests for toxicity and allergenicity. Only material which pass through the most rigorous and well-established tests should be sent to the farmers' field. Fortunately, as discussed by Sharma *et al.*[52] in this volume, the Government of India is already implementing very strict and thorough evaluation criteria for transgenics. The norms for food safety should be stringent and penalties for rogue release of transgenic material should be high.

It is important that till society at large is convinced about the benefits of transgenics, all the trials on such material should be done in a transparent manner. The public system can contribute to the process by setting up trials at institutes and agricultural universities. These trials should be supported by ICAR and DBT. ICAR has the world's most extensive coordinated trial system for the release of new crop varieties. This strength must be utilized to set-up proper trials on yield potential of transgenics and to gain experience on the field behaviour of transgenic crops. The nutritional, toxicological and allergenicity tests should be conducted by ICMR institutes or by those duly certified by ICMR to carry out such tests. Trials conducted under the tutelage of the two organizations would carry more conviction with the public at large.

The current process of Institutional Biosafety Committee (IBSC), Review Committee on Genetic Manipulation (RCGM) and Genetic Engineering Approved Committee (GEAC) should be maintained (discussed by Sharma *et al.*[52] and figure 1 in that article). I propose that to improve the evaluation process, RCGM should be given the powers to receive reports from ICAR on yield and field behaviour, and Indian Council of Medical Research (ICMR) on nutrition, toxicology and allergenicity. However, this may be easier said than done. The involved organizations are under different ministries. An inter-ministerial panel with secretaries of all the concerned departments, viz. Agriculture, Health, Science and Technology, Environment could be created to reach an understanding on all the steps of evaluation and release. Special cells should be created in ICAR and ICMR to direct the process of evaluation. Results from all the studies should be hosted on the web for scrutiny by the public.

A policy framework for supporting crop breeding and concluding remarks

Development of a productive but sustainable agricultural system would require initiatives on many fronts. Transgenic technologies can contribute in a limited but significant way to the lofty goal of sustainable agriculture. This contribution, however, can be realized only if a proper policy framework is created and I propose one on the basis of arguments made in this article.

1. Transgenic technologies are not a substitute for conventional methods of plant breeding. Pure line breeding to diversify varieties and to select transgressive segregants for important traits must continue. Component breeding through marker-aided selection must be provided adequate funding. The development of heterotic pools in some of the important crops like wheat and rice has so far been given little attention. This needs to be rectified as it is essential for enhancing productivity.
2. The most important contribution of transgenic technologies will be in the areas of developing varieties resistant to pests and pathogens. A major effort should be launched to develop transgenics that contain resistance to pests and pathogens.
3. For pests, discovery of new insecticidal proteins encoding genes both from microbes and plants should be given high priority. Currently, there is no work on search for new *Bt* Cry proteins or VIPS. At least three laboratories should be given the charge of collecting new strains from different ecological regions of the country so as to identify new insecticidal proteins. Already described and new genes should be tested on the most devastating insect pests of crops grown in India. *Heliothis armigera*, that effects at least three major crops should receive high priority.
4. Variability at the molecular level needs to be studied for viral pathogens; otherwise strategies based on patho-

gen-derived resistance would be ineffective. Work on variability analysis should be initiated at the earliest.

5. Some of the major bacterial and fungal pathogens need to be more intensively studied, both for variability at the molecular levels and through differentials.
6. Participation of laboratories from India in structural and functional genomics work through international collaborations should be encouraged. India did well to participate in the international rice genome sequencing effort. Such participations should continue on sequencing genomes of model legume species and some of the important pathogens of crop plants.
7. In functional genomics, top priority should be given to identification and isolation of genes conferring resistance to pest and pathogens. India should sequence the genome of a wild relative of rice for allele mining. The choice of the wild relative should be based on genome size and resistance of the wild species to major pests and pathogens of rice. Sequencing of only transcriptionally active areas may suffice. As an alternative, chromosome addition lines with resistance can be sequenced to mine alleles present on the additional chromosome.
8. Development of transgenics for resistance to pests and pathogens would require either strong multidisciplinary groups or collaboration among laboratories specializing in genome sequencing, plant pathology, breeding and genetic transformation. Such groups can be assembled in a crop-wise manner. These groups should be developed only in a few institutes in the country, as general infrastructure in many institutes is insufficient for experimental work in genomics, genetic transformation and molecular breeding.
9. As each crop requires inputs of a number of genes, there should be a crop-wise strategy for gene stacking. Technologies for the removal of marker genes should be used so that transgenics could be protected from homology-based silencing and do not contain a surfeit of marker genes.
10. In India, transformation protocols are available only for a few crops. There is great urgency in developing routine transformation protocols for crops like pigeonpea, chickpea, safflower, mungbean and wheat. Some new and innovative approaches will have to be supported as little success has been achieved to-date with some of these crops.
11. Heterosis breeding would require development of elite heterotic pools and sterility/fertility restoration systems. Groups working in the area of developing heterotic pools will have to be assigned the task of finding and properly recording the heterotic parental lines. Such lines must be deposited with the National Bureau of Plant Genetic Resources. In many cases, data on heterosis are on a limited population size and, therefore, are not reliable.
12. Development of transgenics for reducing post-harvest losses should be given high priority. Basic work on senescence retardation will have to be supported.
13. For each crop, a thorough study needs to be undertaken on technological options that are available to meet the identified breeding goals. In areas where knowledge is not adequate or new strategies are required, basic research work should be funded.
14. A major effort needs to be made in training and retaining scientists who are competent to handle genomics and gene discovery work. Efforts should be made to attract scientists trained abroad in the key areas of genomics, gene discovery and molecular plant pathology. The recruitment of scientists through ARS should be abandoned. Scientists should be hired directly in the institutes according to the need.
15. A major initiative will be required to attract talented students to agricultural biotechnology. At the undergraduate and postgraduate levels, curricula are outdated. These need to be changed.
16. The PVP Act should be followed for the next 15 years. If any modifications are required, these should be made through proper deliberations and assessment of the long-term consequences. The PVP Act should be used creatively to encourage the private industry to invest in hybrid seeds. Patents on gene sequences as they exist in nature should be avoided.
17. India should take a lead in strengthening the CGIAR system. The CGIAR institutes can provide valuable pre-breeding material which can be used for region-specific breeding. The Indian government, to halt the decline of these institutions, could take a proactive role and increase its own contribution to the CGIAR system.
18. Seed industry could be helped by putting up trials on transgenic material through agricultural universities and the coordinated trial system of ICAR. There is sufficient expertise in the universities and ICAR institutes to do proper trials. Seed industry should be also provided germplasm without any fetters.
19. Indian fertilizer industry should be given incentives to enter the business of producing and delivering quality seed of both hybrids and pure lines to the farmers. With their strong distributional networks and ties with the farmers, the fertilizer companies may be able to bring about a rapid turnaround in the seed sector.
20. The current process of clearance through IBSC, RCGM and GEAC should continue. However, the RCGM should be given the powers to receive reports from ICAR on yield and field behaviour, and ICMR on nutrition, toxicology and allergenicity. Special cells should be created in ICAR and ICMR for organizing these studies.
21. It would be difficult to label GM and non-GM foods in India as land holdings are very small and food is

processed predominantly by the small-scale industry. Therefore, transgenics should be released after proper testing and evaluation.

22. All information on trials under RCGM should be put on websites so that the community at large is informed about the performance and the merits/demerits of the transgenic material.

The recommendations given in this article will need to be critically examined and may have to be modified and expanded upon. It is hoped that this article and the other articles in this special section will at least serve the purpose of initiating an earnest debate on how to enhance the productivity and sustainability of Indian agriculture through the judicious use of transgenic technologies.

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Brinjal – Diversity and gene flow

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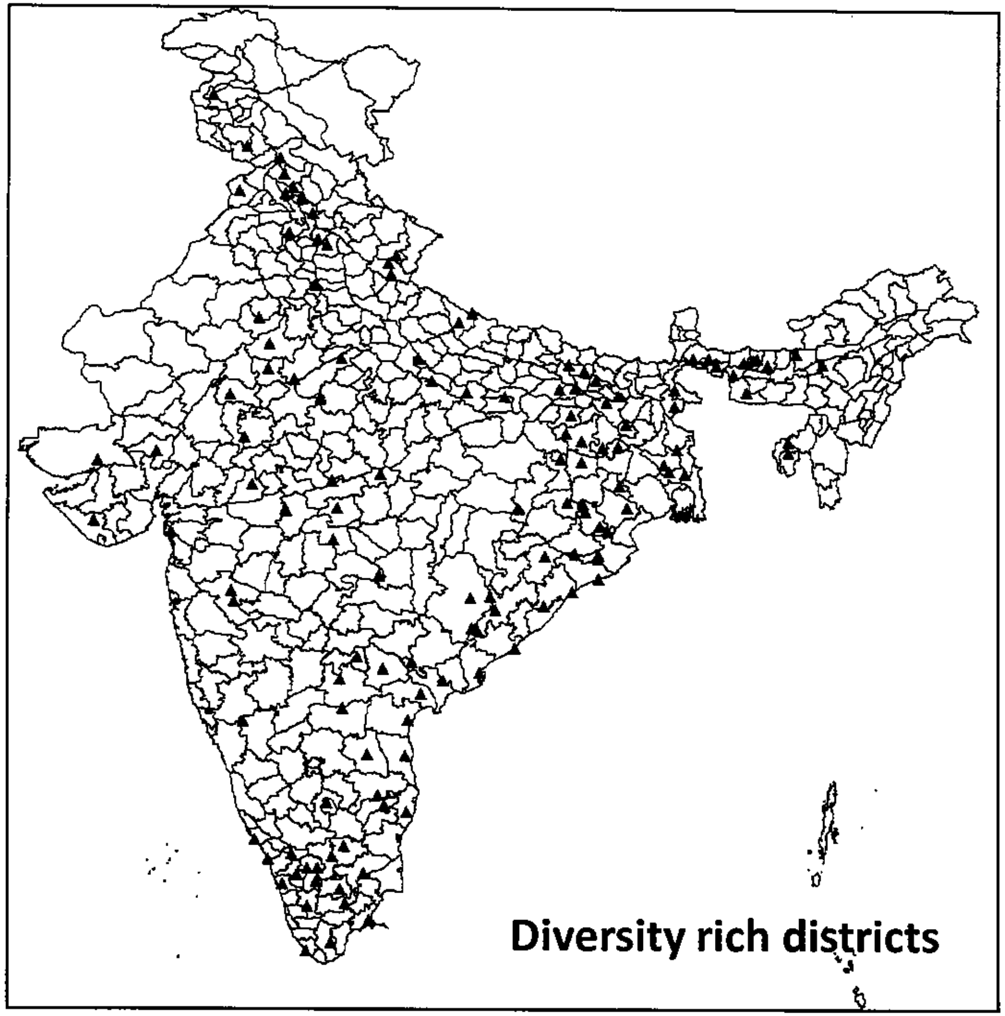
Brinjal – Diversity and Gene flow



Origin: India (Vavilov, 1928)

Period of cultivation : > 4000 years

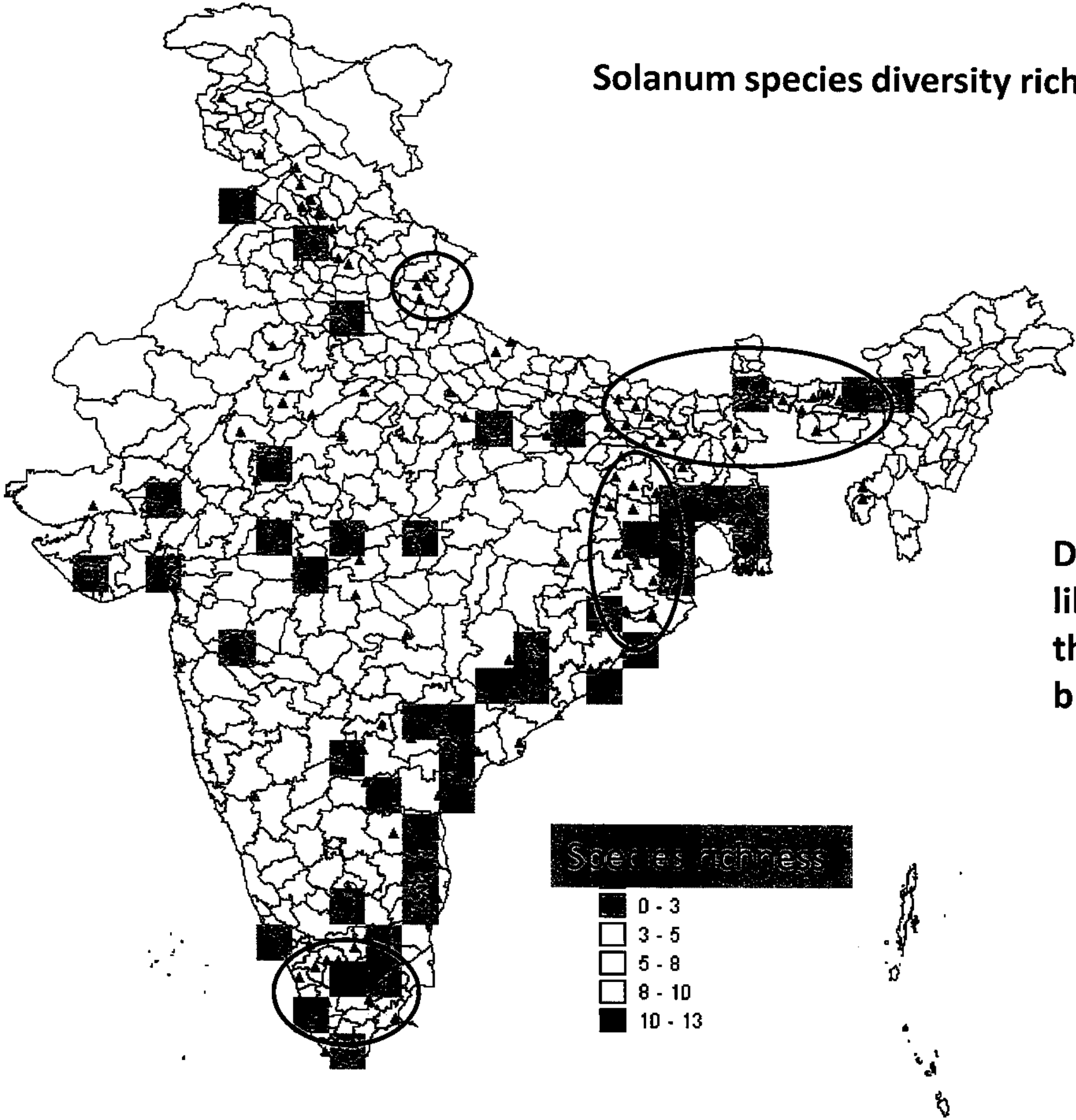
Number of non-tuberiferous species in India: 22 (*Bhaduri, 1951*)

Landraces & local cultivars: >1200

No. of collections in NGB: **3951 accs.**

No. of diversity rich districts: **134**

Solanum species diversity rich pockets in India



Diversity rich regions likely to be affected by the introduction of Bt brinjal due to gene flow.

Inter-specific crosses occur in Solanums

- Published evidence

Theoretical and Applied Genetics (1984) 67:419-426
Current Science (1966) & (1977)

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"There is no threat to wild brinjal germplasm as brinjal *S. melongena, the cultivated* variety, does not cross naturally with any of the wild relatives to produce fertile offspring".- page 15 of the document National consultations on Bt brinjal

YAHOO! MAIL INDIA Classic

Fwd: FW: Safety of BT proteins Wednesday, 3 February, 2010 9:12 PM

From: "Jairam Ramesh" <jairam54@gmail.com>
To: rammoolam@yahoo.co.in

---------- Forwarded message ----------
From: **raj bhatnagar** <rajbhatnagar@hotmail.com>
Date: Wed, Feb 3, 2010 at 6:04 PM
Subject: FW: Safety of BT proteins
To: jairam54@gmail.com

Dear Mr. Jairam

I have edited the mail I sent to Rajni Warrier to illustrate our results in simpler way. **Some relevant data for biological activity of Cry1Ac is as follows:**
The Cry1Ac BT protein degrades rapidly at pH of human gut. It degrades completely within 30 seconds, as a result it does not have enough opportunity to find partner protein to interact in the mammalian gut. Hence biological activity of Cry1Ac is not possible in human gut environment.
The region of receptor protein to which the Cry1Ac binds is different in insect- *Helicoverpa* and mammals. This region is absent in corresponding human receptor molecule.
Let me know if any further clarification is required.

Kind regards,

Raj Bhatnagar
Group Leader
Insect Resistance
ICGEB, New Delhi

From: rajbhatnagar@hotmail.com
To: warrier@nic.in
Subject: Safety of BT proteins
Date: Thu, 24 Dec 2009 06:54:06 +0000

Dear Dr. Warrier,

This is in continuation to our discussion during recent RCGM meeting and PAcific RIM meeting. As you are aware our group has been evaluating the molecular basis of lack of interaction of BT proteins with mammalian species. This theme of investigation is a consequence of several reports regarding safety of BT proteins as reported by several laboratories in India and abroad. These **results** are an outcome of extensive feed trials run by independent agencies.
Over the last couple of years our group has carefully examined all the biochemical parameters to identify the receptor molecules in insect and investigate corresponding molecules in mammals. For example ours and

several other laboratories in US, Mexico , Europe and Japan identified Aminopeptidase as receptor to Cry1Ac in Helicoverpa armigera.
Now we have gone further and evaluated uniqueness of aminopeptidase of Helicoverpa armigera against human aminopeptidase.
By several incisive techniques our results revealed that the binding domain of Amniopeptidase in Helicoverpa is unique and is absent in human aminopeptidase. Overall our results **suggest** the following
1) **The receptor to Cry1Ac bt protein**, Aminopeptidase of insect Helicoverpa is different than aminopeptidase of human in sequence and architecture.(**For a protein to mediate its effect it must recognize and bind to a receptor protein (human receptor is divergent in sequence)**
2) The pH requirement for activation of BT protein Cry1Ac is 10.0. At acidic pH Cry1Ac degerades in 30 seconds. The pH of human gut is highly acidic (**3.0**) and hence Cry1Ac cannot remain intact.
3) The Cry1Ac protein interacts with specific amino acid sequences on the aminopepetidase in Helicoverpa armigera. These sequences are absent in human aminopeptidase.
4) In addition to interacting with aminopeptidase the Cry1Ac protein also interacts with cadherin protein at the insect gut. As with aminopeptidase we have analysed the amino acid sequences of cadherin that interact with Cry1Ac. Here also we find that the stretch of amino acids is uniquely present in the cadherin of Helicoverpa armigera only. This stretch of amino acids is absent from human cadherin. The absence of these Cry1Ac recognition stretch of amino acids in human cadherin is responsible for lack of action of Cry1Ac with human cadherin.
5) Taken together our results reveal that Cry1Ac protein degrades rapidly at pH encountered in human gut and the Cry1Ac interacting receptors sequences are unique to insect and absent in human.

Best wishes,

Raj Bhatnagar
Group Leader
Insect Resistance
International Centre for Genetic Engineering and Biotechnology,
New Delhi, India

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Fwd: Independent scientist's view of Bt-brinjal

Wednesday, 3 February, 2010 9:10 PM

From: "Jairam Ramesh" <jairam54@gmail.com>
To: rammoolam@yahoo.co.in

---------- Forwarded message ----------
From: **NS Talekar** <talekar29@gmail.com>
Date: Wed, Feb 3, 2010 at 8:49 PM
Subject: Independent scientist's view of Bt-brinjal
To: jairam54@gmail.com

E-mail to: jairam54@gmail.com
From: N. S. Talekar talekar29@gmail.com
Subject: Independent scientist's view of Bt-brinjal
Date: 4 February 2010

Dear Honorable Minister,

I am writing this, as a concerned independent Indian scientist, to express my dismay that in the current nationwide debate on Bt-brinjal, views of the specialists who know the crop, insect, and the usefulness and limitation of Bt-technology are ignored first by GEAC and now by concerned political leaders, exemplified by approval of use this technology by the Minister of Agriculture. I am a graduate of University of Pune (1964), got M. S. from Indian Agricultural Research Institute, New Delhi (1966), and Ph. D. from the University of Wisconsin, USA (1973). I did research on the concerned insect, brinjal shoot and fruit borer (BSFB), for more than 10 years at the Asian Vegetable Research and Development Center (now, World Vegetable Center) in Taiwan and successfully developed and implemented a convenient, environmental-friendly integrated pest management (IPM) technology for over 5 years in India and Bangladesh until my retirement in 2005 and eventual return to India, after a professorship in China, in 2009. Currently, I am an Honorary Professor at Mahatma Phule Krishi Vidyapeeth. As a concerned Indian, that too professional scientist, three months ago, when GEAC approved the Bt-brinjal, I wrote to the Minister of Agriculture detailing him all the pros and cons of this topic and informed my conclusion that he should reject the use of Bt-brinjal in present form. But, regrettably, although not that unexpectedly, he rejected my advice.

Since your decision will make or break the use of this technology and consequences thereof, I am briefing you on the topic and urging you to reject the use of Bt-brinjal in its present form. Since your busy schedule may not permit you to have time to meet with me to brief you personally, which will be more effective, I am providing you the details behind my advice. I hope you or your staff will find time to study it before making the decision.

Farmers in parts of our country are using large amount of chemical pesticides, largely out of their lack of proper knowledge of this insect, to reduce damage by BSFB. Such practice, besides being costly, is damaging to environment and human health. So, the use of Bt-transgenic technology that will reduce pesticide use is justified. However, the manner in which the proponent of the product recommends farmers to use this technology is faulty and unscientific and would lead to disaster. If this point is not rectified, BSFB will soon become resistant to Bt-brinjal and start causing damage to Bt-brinjal similar to it does now to normal brinjal. Farmers, therefore, will lose faith in this technology and start using pesticides again, even in greater quantities, which will be damaging to environment and public health.

Like with chemical pesticides, if an insect is exposed for long time to Bt-brinjal, it will become resistant to Bt-brinjal. How soon that insect will become resistant depends on the following three biological factors:

(1) Variability in genetic makeup of the insect population: More variable the insect, greater are the chances of it becoming resistant. BSFB is genetically variable as shown by research at Tami Nadu Agricultural University, published in 2006 in a technical journal, Pest Management in Horticultural Ecosystem. Also according to data published in April 2009 issue of Agricultural Biotechnology Support Project II, a USAID-funded activity, BSFB already shows resistance to Bt-brinjal at some locations in neighboring Bangladesh, because of this very same reason; the genetic variability in BSFB population.

(2) How soon after becoming adults the insect mates to start next generation: The longer the time between insect becomes adult and mating, the lesser are chances of insect becoming resistant. This is because before mating such insect will fly away from its place and mate with genetically dissimilar population so that the progeny produced by such mating will not be resistant and Bt-crop will retain usefulness for several more seasons. This point is closely related to the 3rd point below. BSFB becomes adult (comes out of pupa in soil) starting with sunset and in most cases (about 80%) mates with insects in the close vicinity (i.e. genetically similar insect) during the same evening or the next. Progeny produced out of such mating becomes resistant much more quickly than the progeny from mating of insects from different location. To avoid this, farmers must plant appropriate area, in this case 50% or at least 33% under normal (non-Bt) brinjal mixed with Bt-brinjal, which the GEAC ought to but does not seem to recommend.

(3) How active-flying is the insect. Very active flying insect (like cotton bollworm) flies farther, before mating, and thus has far greater chances of mating insect with different genetic makeup thus reducing chances becoming resistant sooner. That is one of the reasons why, despite cultivation of Bt-cotton for nearly 10 years, the cotton bollworm has not developed resistant. The BSFB is a weak-flyer and remains around the patch of land it emerged from and mates with

insects not beyond 2-3 meters before it dies within 3-4 days. If entire field is planted to Bt-brinjal, as the committee seems to recommend, Bt-resistant insect will mate with Bt-resistant one and the progeny will be more resistant, thus reducing the utility of Bt-brinjal variety much sooner.

There are ways to overcome insect developing resistance. In cotton, they recommend planting 10-20% area under normal cotton in the vicinity of Bt-cotton field. This way the large number of susceptible insects emerging from normal cotton will mate with few potentially Bt-resistant ones from Bt-cotton and reduce chances of progeny becoming resistant, because the insects emerging from normal cotton is susceptible.

In the case of Bt-brinjal, however, I could not find, from DBT website, any specific information on how they plan to manage postponing insect becoming resistant to Bt-brinjal. Therefore, I contacted the technical advisors of the company, Mahyco-Monsanto, both of whom are professors at Cornell University, and was told of a proposal of planting only 5% area under normal brinjal in the vicinity and not mixed with Bt-brinjal, as scientifically required. This is hopelessly inadequate. Based on the points I enumerated above, one will need at least 33% area under normal brinjal planted mixed within Bt-brinjal, in order to delay BSFB developing resistance. If company's suggestion is to be followed, BSFB will become resistant far sooner and farmers will be forced to go back to their heavy pesticide use practices. This will damage the environment and farmers' confidence in biotechnology and they will be reluctant to accept such product in future. We in India need biotechnology to increase productivity of our agriculture, but the biotechnology application should be fool-proof, because most of our farmers are still not educated, at least in biology, enough. The proposed Bt-brinjal biotechnology approach is not fool-proof and I want to urge you not to approve the use of Bt-brinjal for cultivation in our country unless GEAC comes forthright on this point, and force Monsanto-Mahyco to sell premixed seeds to farmers.

(4) There is added danger to the environment in the use of Bt-brinjal technology. It has to do with contamination normal brinjal cultivated by farmers who, for various reasons, are not interested in Bt-brinjal, with genes from Bt-brinjal. This is how it will happen. Although brinjal is largely self pollinated (male and female parts of the same flower "mate" and produce fruits and seeds), there is certain percentage of cross pollination by insects such as honey bees and others. If Bt-brinjal of one farmer is planted in the vicinity (across the border) of normal brinjal of other farmers, insects will carry some pollens from flowers of Bt-brinjal and pollinate flowers of normal brinjal and pass on the Bt-genes to the next generation of crop of the innocent farmers. This should not happen and the proponents of this technology should prove that this will not happen. They can conduct a simple but very telling experiment, where Bt-brinjal and normal brinjal are planted in the vicinity, as it occurs on farmers' fields, under a medium size nylon net cage and releasing honey bee or

other pollinating insect inside the cage. Scientist can monitor the movement of genes easily by analyzing the seeds of normal brinjal. This is a simple but essential one-season experiment.

I am sorry to bother you with such a lengthy letter, but I thought it is important that as a concerned scientist, I must brief you on this topic. If my explanation here is not clear to you, I am prepared to meet with you at any time and any place in India, even at no cost to the government, if you could spare an hour's worth of time for me.

Thank you very very much for your kind attention.

Sincerely yours,

N. S. Talekar
124-B, Mahatma Society
Kothrud, Pune 411029
Tel: 99-7072-0763

bt-cotton

Inbox x

Jairam Ramesh waiting eagerly for your current science paper update dr. 7:27 AM (6 hours ago)

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Respected Sir,
Kindly find herewith a review of Bt-cotton benefits and concerns in India. The manuscript contains details of the experiences with the technology in India, and can be extended into a complete book. However I would like to highlight the following points and concerns for your kind consideration.

1. There is a need for a 'National Biosafety Institute' that can conduct all tests (biochemical, molecular, animal safety, microbial studies etc.) needed for a GM crop at a single place. The institute can conduct baseline studies and also monitoring for development of insect resistance.
2. With the state of art technologies, biosafety with GM crops is no longer a major concern, since the science of introducing single genes for protein production in the GM crops is very precise.
3. However, there have been stewardship problems in India
4. We could have harnessed the benefits in a much better manner if the number of hybrids would not have been more than 10 each for each of the 13 agro-eco sub zones in which cotton is grown.
5. Insecticide use declined initially, but is now gradually increasing on account of the emergence of minor insect pests on Bt-cotton.
6. Insect Resistance Management strategies have been recommended for GM cotton and GM Brinjal in India, but require to be refined based on good science and logistics of India Farming systems so that farmers adopt them easily.

I have no hesitation in supporting the Bt-Brinjal technology and am sure that we will improve in future based on what we learn today. Congratulations for infusing scientific energy and absolute democracy into the GM release proceedings. Thanks for this opportunity.
With Respectful Regards
Kranthi
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Bt Cotton: A Critical Appraisal

K. R. Kranthi,
Central Institute for Cotton Research Nagpur

Introduction

Cotton is an immensely important crop for the sustainable economy of India and livelihood of the Indian farming community. It contributes about 65% of the total raw fibre material needs of textile industry in India. It is cultivated in about 310-320 lakh hectares across the world and in about 100 lakh hectares in India, which accounts for 27% of the global cotton area and contributes to 20.5% of the global cotton produce, currently ranking second after China.

During the decade prior to 2002, cotton production and economy in India was in constant crisis due to insecticide resistant bollworms which were responsible for excessive use of insecticides and constant low production and stagnant productivity of 15.0 to 17.7 m bales (bale = 170 kg lint). Subsequent to 2002, after the introduction of Bt-cotton, the scenario has changed. Over the past five years there has been a significant leap in the production. India's contribution to global cotton production increased from 14% in 2002 to 20.5% in 2007. The production increased from a meagre 23 lakh bales (170 kg lint/bale) in 1947-48 to a previous record production of 176 lakh bales in 1996-97 and an all time highest record of 315 lakh bales during 2007-08. It is widely believed that the introduction of Bt cotton into India has contributed to the sudden increase of India's contribution to global cotton production, from 14% in 2002 to 20.5% in 2007. Though, India ranks second in the world in cotton production after China, even its best productivity of 560 kg/ha, places it at 24th rank in the list of 80 main cotton producing countries.

Bacillus thuringiensis and insecticidal proteins

Bacillus thuringiensis (Bt) is a gram positive soil bacterium that was discovered by Ishawata in 1901 in Japan and first used as a commercial insecticide in France in 1938. Currently there are 67 recognized subspecies of *B. thuringiensis* most of which produce spores and insecticidal proteins. Thus far more than 450 toxins have been identified and assigned to more than 59 groups of Cry toxins (Cryl to Cry59), 2 groups of cytolytic toxins (Cytl and Cyt2) and 3 groups of (vegetative insecticidal proteins) VIP toxins (VIP1 to VIP3), belonging to 196 groups have been reported to have been isolated from *Bacillus thuringiensis.*

Amongst the genes that have been deployed in insect resistant transgenic cotton, thus far, Cry1Ac is the most toxic to *H. armigera* and against a wide range of lepidopteran insect pests that include the other two bollworms the spotted bollworm *Earias vittella* & the pink bollworm, *Pectinophora gossypiella*. Bt-cotton incorporating Cry1Ac is highly toxic to the bollworms and other minor pests such as the cotton semilooper and hairy caterpillar, but not effective on the leaf eating tobacco caterpillar *Spodoptera litura.*

Cry2Ab2 (which is present in Bollgard-II) is moderately toxic to *Helicoverpa armigera,* and *Spodoptera litura.* However the expression levels of Cry2Ab2 are very high (120-180 ppm), as compared to the Cry1Ac (0.5 to 15 ppm) and therefore Bollgard-II is highly toxic to *H. armigera* and toxic to *Spodoptera litura.*

The Cry1F is not effective on *H. armigera* but the levels of expression in 'widestrike' (Dow Agrosciences) is at 10-40 ppm confer mild tolerance to *H. armigera* and fairly good toxicity to *Spodoptera litura.* The Cry1Ac belongs to the class 'Bt-delta-endotoxins' which function as oral toxins. The delta-endotoxins are ingested and the protoxins present in the crystals are proteolytically activated to trypsin resistant active core δ-endotoxin in the alkaline mid-gut. The active toxin traverses the peritrophic membrane to bind cadherin receptors present on the brush border membrane vesicles of the insect midgut. The cadherins process the toxins to smaller fragments which form homo-oligomers and bind to alkaline phosphatases and aminopeptidases before causing pores in the epithelial membrane, resulting in osmotic lysis of the cells. This results in cessation of feeding and finally causing mortality.

Import and indigenization

The development of Bt cotton in India from the transgenic cotton of Monsanto, USA, underwent a stringent regulatory process before it finally reached farmer fields. Mahyco had obtained 100g of Coker 312-Bt (Cry1Ac)-cotton seed from Monsanto USA, in 1996. The imported Bt-cotton contained three transgenes namely

1. *cry1Ac* which is insecticidal;
2. *npt-11* (neomycin phosphotranferase) which allows transformed plants to survive kanamycin and
3. *aad* (aminoglycoside adenyltransferase) which confers streptomycin tolerance to Agrobacterium.

The Coker312 Bt cotton was developed using *Agrobacterium tumefaciens* mediated transformation system. Within two years after importing the seeds Mahyco successfully incorporated the transgenes into about 40 elite Indian cotton lines in at least six generations of back crossing by accelerated breeding programme through embryo culture in Green house conditions. During this process they had conducted 58,000 bioassays and 2,65, 667 ELISA tests to continuously track down the Bt gene. The stability of Bt-gene expression and segregation in F2 progeny has been examined and was found to be stable and segregation as per Mendelian laws. Biosafety test results clearly showed that the Cry1Ac in Bt-cotton was highly safe to the environment and non-target organisms. Field trial results showed good boll retention and higher yields. Apart from the increase in yields there was a concomitant reduction in the use of insecticides due to Bt-cotton. Thus it was concluded that Bt-cotton has potential to improve the lives of cotton farmers through the provision of favourable environmental and economic consequences and subsequently released in 2002 for commercial cultivation.

Pre-release biosafety testing and agronomic evaluation of Bt-cotton in India

Import

1995 Mahyco obtained the DBT (Department of Biotechnology) permission to import 100 grams of Bt-cotton seeds containing Bt Cry 1 Ac gene. Mahyco set up its IBSC (Institutional Biosafety Committee)

1996 Mahyco imported Bt-cotton seeds of Coker 312, from Monsanto. First limited scale field trial of Bt cotton was conducted at one location.

Biosafety and Environmental studies

1997-98 Studies conducted on pollen flow, aggressiveness, allergenicity and toxicity to goats.

2000-01 Biosafety studies conducted on cows, buffaloes, chicken and fish. Pollen flow, soil persistence, gene stability, biochemical studies on proximate analysis, insect toxicity, studies on the presence of protein and gene in oil were conducted.

Multilocation testing and agronomic field evaluation

1998-2000 Multilocation field trials were conducted at 40 locations in Andhra Pradesh, Karnataka, Tamil Nadu, Haryana, Maharashtra, Madhya Pradesh, Rajasthan, Punjab and Gujarat.

2000-2002 Large scale field trials at 80 locations per zone. Advanced stage multilocation field trials conducted by ICAR

2002 Bt-cotton released for Commercial cultivation on 5th April (32nd GEAC meeting 26th March)

Bt-Cotton

Genetically modified cotton that expresses insecticidal toxin genes from the soil bacterium *Bacillus thuringiensis* is popularly called Bt-cotton and currently represents an elegant pest management tool that has now been proven world-wide as one of the most ecologically acceptable options of bollworm control. Bt cotton (event Mon-531) was first developed by Monsanto, USA through the incorporaton of *cry1Ac* gene into the cultivar Coker 312, using *Agrobacterium tumifasciens.*

It was first approved for commercial cultivation from 1996 in the US and has thus far been approved for cultivation in 13 countries. Bt cotton was released for cultivation in China, Mexico and Australia in 1997, and later in Argentina (1998), South Africa (1998), Indonesia (2001), India (2002), Colombia (2003), South Korea (2003), Brazil (2005), Burkina-Faso (2008) and Egypt (2009). Currently an estimated 14.5 m hectare area is under Bt cotton in the world. This accounts for 45% of the total global cotton area (32 m ha). Recently, Cry2Ab and Cry1F have been released in the US for commercial cultivation. Cotton transgenic plants resistant to *H. armigera* have been developed using the cowpea trypsin inhibitor gene in China. Both genes, 'Bt toxins' and 'protease inhibitors' used thus far, are extremely specific in their target range and have been conclusively demonstrated to be safe to the environment.

The Bt-cotton technology was first approved in 2002 by the GEAC for commercial cultivation in central and south Indian cotton–growing zones in India in the form of three hybrids (MECH-12, MECH-162, and MECH-184). Subsequently, the GEAC approved RCH-2 (Rasi seeds) in 2004, for cultivation in the central and southern zones. In 2005, another 16 hybrids were approved. Thus, the total reached to 20 *Bt* hybrids, with 6 for north, 12 for central and 9 for south India, thus making available the technology for entire country. Realizing the immense potential of the technology, several Indian Seed companies rushed forward as sub-licensees of the technology to acquire the rights to incorporate the *cry1Ac* gene into their own hybrids. By 2006, the total number of hybrids reached 62, with an additional approval of 38 more hybrids from 15 companies, which also included the commercial release of two new Cry1Ac based events, GFM-Cry1A of China and Event-1 of JK seeds. By 2007, an estimated total of 162 Bt-hybrids (135 Bt-hybrids, excluding brand overlap) were released for commercial cultivation. By the end of July 2008, the total number of Bt-hybrids increased to 280 and by August 2009 the number increased to 619 Bt-hybrids and one Bt-variety. The area under *Bt* cotton increased from 29 307 hectares in 2002 to an estimated 6.2 m hectares by 2007. In 2009, the area under Bt-cotton is estimated to have reached 82% of the total cotton area (10.0 m ha) in India.

Six Bt cotton events have been thus far in India for commercial cultivation. There are four Bt Cotton events expressing Cry1Ac, one event with Cry1C, and one event with Cry2Ab2. The various Genetically modified events are 1. MON531 (Cry1Ac) event of Monsanto; 2. JL Event-1 (Cry1Ac) event of JK seeds; 3. GFM Cry1A (Cry1Ac) event of China, introduced by Nath seeds India; 4. BNLA106 (Cry1Ac) event developed by NRCPB and UAS Dharwad; 5. Event 9124 (Cry1C) event developed by Metahelix, India and 6. Mon15985 (Cry2Ab2) event in Bollgard-II Monsanto.

All the Cry1Ac genes present in the four events released in India are chimeric fusion genes. The *Cry*1Ac gene in the Bollgard event 531 is a chimeric gene of 3534 bp size, with the first 1398 nucleotides (corresponding to the first 466 amino acids) of *Cry*1Ab gene and rest of the 1399-3534 nucleotides (corresponding to the 467-1178 amino acids) from the *Cry*1Ac gene. Except for one amino acid at 766 position, the *Cry*1Ac amino acid sequences are identical to that of the wild type *Cry*1Ac gene. The chimeric gene produces a protein that is 99.4% identical to that of the wild type *Cry*1Ac. The Cry1Ac genes in JK and BNLA106 are chimeric fusion genes of 1842 bp with the first 1398 nucleotides (corresponding to the first 466 amino acids) of *Cry*1Ab gene and rest of the 453 nucleotides (corresponding to 151 amino acids at 467-671 position) from the *Cry*1Ac gene. The Cry1Ac in Nath seeds is >99% identical to the Cry1Ac used in JK and BNLA106 events except that the size is smaller at 1824 bp with the first 1377 nucleotides (corresponding to the first 459 amino acids) of *Cry*1Ab gene and rest of the 453 nucleotides (corresponding to 151 amino acids at 460-664 position) from the *Cry*1Ac gene.

Weediness

Evidence was submitted to demonstrate that there is no threat of the Bt gene causing weediness characteristics through outcrossing with wild cotton relatives. Additionally data have been produced to show that pollen of Bt-cotton did not have any toxic effects on honey bees and other non-target organisms. Biochemical and toxicological tests carried out at CICR and elsewhere indicated that there was no difference in the chemical composition of the Bt and non-Bt cotton seed and seed oil.

Confirmation of absence of the terminator gene

Evidence from experiments conducted at the Delhi University indicated that all three Bt-cotton hybrids that were proposed to be released for commercial cultivation, did not contain the '*cre*' recombinase gene which is a key component of the terminator technology.

Evaluation in multilocation and large scale field trials

Prior to the commercial release of Bt cotton for cultivation in India, extensive tests were conducted by CICR to assess the strengths and weaknesses of the technology. The chronology of scientific trials preceding the ICAR evaluation was as follows. 1996: Limited field trial at one location; 1997-98: Limited field trials- 5 locations; 1998-99: Multi-centric replicated trials 40 locations; 1999-2000: Multi-centric replicated trials 11 locations and 2000-2001: Large scale field trials under farmer field conditions.

The first multi-location trials were initiated in the Kharif of 1998 and continued for 4 years. Field trial results of four years from 1998 to 2002 indicated that Bt cotton was able to resist bollworm infestations thereby resulting in good boll retention and higher yields. Apart from the increase in yields there was a concomitant reduction in the use of insecticides due to Bt-cotton. Thus it was concluded that Bt-cotton has potential to improve the lives of cotton farmers through the provision of favourable environmental and economic consequences.

The Bt-Cotton trials were carried out by ICAR under the aegis of the AICCIP (All India co-ordinated Cotton Improvement Project). The Central Institute for Cotton Research conducted field trials of Bt-cotton (Bollgard Mech-12, Bollgard MECH-162 and Bollgard MECH184) taking into cognizance all guidelines that were laid out by the GEAC/MEC and the DBT. At all sites of experimentation, the Scientists of the institute closely supervised all the trials. The field evaluation was considered to be of utmost priority in terms of being evaluated for its cost/benefit and benefit/risk analysis. The Bt-cotton trials were taken up during 2001-2002 under the AICCIP at Khandwa, Akola, Surat, Nanded, Junagarh and Nagpur of Central India and Guntur, Dharwad, Nandyal and Coimbatore of South India. The following sets of evaluation trials were carried out: Agronomy

Evaluation, Crop Improvement (Breeding) evaluation and Plant Protection evaluation (includes evaluation under sprayed and unsprayed conditions; development of IPM packages and evaluation for disease susceptibility). The ICAR appointed monitoring and evaluation teams for Bt-cotton trials carried out by AICCIP comprising of experts from Department of Biotechnology, GOI, Ministry of Agriculture, GOI, Ministry of Forest & Environment GOI, Ministry of Health, GOI, and the scientists comprising of Breeders and Entomologists from ICAR and State Agricultural Universities. Two teams were formed for evaluation of trials under Central and South zones under the chairmanship of Director, CICR, Nagpur for Central zone and Project Co-ordinator, Coimbatore for the South zone. The teams visited the trials during the grand growth period in Nov-Dec 2001, and submitted their reports. The reports appreciated planning, protocol and successful conduct of the Bt cotton field trials.

Economics of Bt-cotton cultivation in ICAR trials 2001.

Hybrid	**Yield Q/ha**	**Gross income Rs./ha**	**Insecticide cost Rs./ha**	**Net income Rs./ha**
MECH-12 Bt	11.67	21,006	1,727	16,854
MECH-12 Bt	13.67	24,606	1,413	20,768
MECH-12 Bt	14.00	25,200	1,413	21,362
Local check	8.37	15,066	2,845	12,221
National check	7.31	13,158	2,001	11,157

Two sets of replicated field trials were conducted by Mahyco during 1998-99 and 2000-01. The first set was conducted with six Bt-hybrids at 15 sites in seven states and the second set with one Bt-cotton hybrid (MECH-1) was conducted at 25 sites in nine states. Results showed that the Bt-hybrids yielded 37-40% more than the non-Bt counterparts. Bollworm larval population was 80% less on Bt-cotton as compared to the non-Bt. Spray applications were reduced by 60-70%. There was no significant difference in the populations of sucking pests (aphids, jassids, and whitefly) and beneficial predators (ladybirds, green lacewing bug, spiders)

Yields, boll retention, boll weight, ginning out turn, fibre qualities and earliness

The results clearly indicated that the Bt cotton hybrids showed higher retention of first formed bolls due to low fruiting point and boll damage. Hence, Bt cotton hybrids exhibited more balanced plant growth.

The Bt-cotton hybrids registered increased seed cotton yield over their non-Bt counterparts and check hybrids. The increase in yield over the non-Bt counterparts, zonal check and local check was of the order of 61, 47 and 15% respectively in the central zone. However, in south zone, the Bt cotton hybrids have recorded more than 100 % increased seed cotton yield over their counterpart non-Bt hybrids, zonal and National check hybrids. MECH-162 Bt with a mean seed cotton yield of 13.3 Q/ha in central zone and MECH-184 Bt with a yield of 20 Q/ha in South zone were the best Bt hybrids. MECH-184 Bt and MECH 162 Bt recorded significantly higher seed cotton yield at all locations compared to non-Bt and check hybrids. The yield superiority of these hybrids was around 5-6 Q/ha while MECH 12-Bt gave additional yield of 3-4 Q/ha compared to non-Bt and check hybrids.

MECH hybrids recorded higher boll weight than the non-Bt hybrids. MECH-12 Bt recorded highest boll weight of 5.4 g in the south zone and 4.3 g in central zone. The check hybrids, on the other hand recorded a mean boll weight ranging from 4.3 to 4.6 g in south zone and 3.6-3.7 g in central zone. MECH-12 Bt registered the highest ginning out-turn of 38.2% in south zone and 36.7% in the central zone. The check hybrids on the other hand recorded a mean ginning out turn ranging from 34.3 to 35.3% in the south zone and 33.6 to 35.1% in the central zone. Incorporation of Bt gene did not have any negative effect on any of the major fibre quality parameters. All the MECH hybrids were superior in fibre quality than the checks. MECH-184 Bt hybrid apart from high yield possessed fibre qualities and merits consideration. Subsequently a number of tests were conducted on almost all the Bt-hybrids. All studies showed that the fibre properties of Bt-hybrids were similar to their non Bt counterparts. Due to early retention of bolls in Bt cotton hybrids, the boll bursting commenced nearly 15-20 days in advance and required lesser number of pickings to complete the harvest.

Release and rapid spread of the technology in India

In 2002, The GEAC approved three Bt cotton hybrids i.e. MECH 12, MECH 162 and MECH 184 for commercial cultivation in Central & Southern cotton growing zones in India. The three hybrids were developed by Maharashtra Hybrids Seeds Company Ltd (Mahyco). Two years later the GEAC approved RCH-2 (Rasi seeds), for cultivation in Central and Southern zones. In 2005, the GEAC approved another 16 hybrids. Thus the total reached 20 Bt hybrids, with 6 for north, 12 for central and 9 for south India. By 2006, the total number of hybrids reached 58, with an additional approval of 38 more hybrids from 15 companies, (Mahyco, Rasi, Ankur, Nuziveedu, JK, Nath, Ganga Kaveri, Tulasi, Ajeet, Emergent Genetics, Vikki Agrotech, Vikram, Pravardhan, Krishidhan and Prabhat). Interestingly the recently released Bt-cotton hybrids include three different Cry1Ac events (Monsanto, China and JK seeds, India) that are the only ones commercially available in the world.

State wise Bt cotton area in India

(lakh ha)

STATE	Year						
	2002	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**
PUNJAB	0.000	0.000	0.000	0.704	2.810	5.750	4.760
HARYANA	0.000	0.000	0.000	0.107	0.420	2.790	3.800
RAJASTHAN	0.000	0.000	0.000	0.023	0.050	0.380	1.210
NORTH ZONE	**0.000**	**0.000**	**0.000**	**0.834**	**3.280**	**8.920**	**9.770**
GUJARAT	0.091	0.417	1.259	1.493	4.070	13.000	14.500
MAHARASHTRA	0.120	0.218	1.615	5.088	16.550	25.620	25.720
MADHYA PRADESH	0.014	0.133	0.861	1.362	3.020	4.710	5.140
CENTRAL ZONE	**0.225**	**0.768**	**3.735**	**7.943**	**23.640**	**43.330**	**45.360**

ANDHRA PRADESH	0.038	0.054	0.712	0.904	6.570	10.000	11.430
KARANATAKA	0.021	0.030	0.343	0.293	0.800	1.460	1.720
TAMIL NADU	0.003	0.076	0.120	0.170	0.320	0.600	0.720
SOUTH ZONE	**0.062**	**0.160**	**1.175**	**1.367**	**7.690**	**12.060**	**13.870**
TOTAL	**0.287**	**0.930**	**4.980**	**10.150**	**34.610**	**63.340**	**68.900**
Total Area	73.900	78.350	89.700	91.580	91.580	95.550	93.730
% of Total	0.388	1.187	5.552	11.083	37.792	66.290	73.616

Source : Directorate of Economics & Statistics as on 1st April, 2008.

Insecticide usage on cotton 1997-2008 (Rs crores)

Year	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**
% Bt Cotton								5	12	35	65	77
Cotton	956	854	879	839	1052	597	925	1032	649	579	733	791
Insecticides	2650	1907	2128	2052	2268	1683	2146	2455	2086	2223	2880	3228
% share	36	45	41	41	46	35	43	42	31	26	25	25

Bt hybrids exhibited higher tolerance to bollworm damage. Bambawale *et al.* (2004) reported a 50% overall reduction in the *H. armigera* larval population in Bollgard-MECH-162 compared to the non-Bt MECH-162. Their data showed that the total per cent damage to fruiting bodies, including squares and flowers, green bolls and shed reproductive parts was 65% lower in Bollgard-MECH-162 compared to non-Bt MECH-162. Further, the locule damage caused by pink bollworm was found to be 58% lesser in Bt-cotton. Udikere *et al.* (2003) also showed that the three Bt-cotton hybrids, Bollgard-MECH-12, Bollgard-MECH-162 and Bollgard-MECH-184 were able to reduce larval populations of *H. armigera* up to 40%, spotted bollworm (*Earias vittella*) up to 30-40% and pink bollworm (*Pectinophora gossypiella*) up to 60-80% in south India.

Insecticide usage data were collected from independent sources of the pesticide industry and compiled. The introduction of Bt Cotton appears to have resulted in reduction of market share of insecticides used on cotton. Bt Cotton was introduced in 2002 and the area increased to 5% in 2004, 12% in 2005, 35% in 2006, 65% in 2007 and 77% in 2008. Clearly the share of insecticides used on cotton declined from 43% in 2003 to 25% in 2008.

Effects of Bt-cotton on non-target organisms

The Cry1Ac is mainly toxic to the bollworms (cotton bollworm, pink bollworm and spotted bollworm), semiloopers and hairy caterpillars. Bt-cotton expressing Cry1Ac is absolutely non-toxic to all other non-target organisms such as beneficial insects, birds, fish, animals and human beings. Laboratory and field studies carried out in India showed that the Cry1Ac protein deployed in Bt-cotton did not have any direct effect on any of the non-target beneficial insects. Work carried out elsewhere in the world also showed similar results. Dong et al., (2003), reported only minor effects on some life table parameters in laboratory feeding studies with lacewings and predatory beetles and none with predatory bugs and spiders. There was some evidence of a reduction in numbers of predators and parasitoids which specialise on the Bt controlled bollworms, but also of increases in numbers and diversity of generalist predators such as spiders. Generally the decrease in the parasitoid and predator populations were associated with decrease in the densities of the pest populations on account of Bt-cotton. Any effects could be assigned to the decrease in prey quality – for example with stunted *Spodoptera litura* caterpillars which had fed on Bt cotton. In the field situation, partial life studies broadly confirmed this finding. There was no increase in green vegetable bug numbers, aphid or whitefly numbers on Bt cotton. **In general, such adverse effects as have been measured are very small when compared with the side effects of the spraying of conventional insecticides.**

Effects on soil microorganisms

There is concern that transgenic *Bt* crops carry genes that could have undesirable effects on natural and agro-ecosystem functions. Sarkar *et al* (2008) from IARI, New Delhi, investigated the effect of *Bt*-cotton (expressing the *Cry 1Ac* protein) on several microbial and biochemical indicators in a sandy loam soil. *Bt*-cotton (MRC-6301*Bt*) and its non-transgenic near-isoline (MRC-6301) were grown in a nethouse on a sandy clay loam soil. Soil and root samples were collected 60, 90, and 120 days after sowing. Soil from a control (no-crop) treatment was also included. Samples were analysed for microbial biomass C, N and P (MBC, MBN, MBP), total organic carbon (TOC), and several soil enzyme activities. The microbial quotient (MQ) was calculated as the ratio of MBC-to-TOC. The average of the three sampling events revealed a significant increase in MBC, MBN, MBP and MQ in the soil under *Bt*-cotton over the non-*Bt* isoline. The TOC was similar in *Bt* and non-*Bt* systems. Potential N mineralization, nitrification, nitrate reductase, and acid and alkaline phosphatase activities were all higher in the soil under *Bt*-cotton. They concluded that growth of *Bt*-cotton has a positive impact on most of the microbial and biochemical indicators, such as MBC, MBN, MBP, MQ, and a range of soil enzyme activities and **therefore cultivation of *Bt* cotton appears to be no risk to soil ecosystem functions**.

Biosafety studies with Bt cotton were conducted at CICR, Nagpur to examine the side effects on soil microflora and fauna to assess the safety of BN-BT cotton expressing *cry1Ac*. However no significant difference was observed either in the population or type of fungi associated with the rhizosphere of BN-BT and its non-BT counterpart. Similarly, soil fauna were hardened and found No activity of earthworms in Bt and Non- Bt plots. Dehydrogenase assay was done to determine the overall biological activity of the soil. The enzyme activity ranges from 17.2 to 28.4 mg / TPF / g soil /h. Treatment differences between cultivars were not significant. **The results suggest no adverse effects of Bt cultivars on the soil biological activity.**

Effects on parasitoids and Predators

Udikeri *et al* (2007), UAS, Dharwad, studied the dynamics of cotton aphids and its predator in RCH-2Bt and non-Bt cotton hybrids. Laboratory feeding experiments using Bt and non Bt cotton were carried out to study the effect of Bt fed aphids on predator indicated no difference in incubation period, longevity of grubs and adults, fecundity and aphid consumption potential indicating safety of Cry1Ac to predator through intoxicated aphid host. The Cry1Ac based Bt-cotton is mainly toxic to the bollworms (cotton bollworm, pink bollworm and spotted bollworm), semiloopers and hairy caterpillars. Bt-cotton expressing Cry1Ac was reported to be safe to all other non-target organisms such as beneficial insects, birds, fish, animals and human beings. Laboratory and field studies carried out all over the world showed that the Cry1Ac protein deployed in Bt-cotton did not have any direct effect on any of the non-target beneficial insects. Studies in India and elsewhere indicated only minor effects on some life table parameters in laboratory feeding studies with lacewings and predatory beetles and none with predatory bugs and spiders. There was some evidence of a reduction in numbers of predators and parasitoids which specialise on the Bt controlled bollworms, but also of increases in numbers and diversity of generalist predators such as spiders. Generally the decrease in the parasitoid and predator populations were associated with decrease in the densities of the pest populations on account of Bt-cotton. Unsprayed Bt cotton sustained 4 times more attack of tarnished bugs, 2.4 times more with boll weevil, 2.8 times more with stink bugs and *Spodoptera*. Due to these changes in pest complex, farmers had to spray 3-5 times on bollgard as compared to 6-8 times on non-Bt cottons. Any effects could be assigned to the decrease in prey quality – for example with stunted *Spodoptera litura* caterpillars which had fed on Bt cotton. In the field situation, partial life studies broadly confirmed this finding. There was no increase in green vegetable bug numbers, aphid or whitefly numbers on Bt cotton. In general, such adverse effects as have been measured are very small when compared with the side effects of the spraying of conventional insecticides.

Biosafety tests on animals (facilitated through CICR)

Comprehensive biosafety studies were carried out by ICAR institutions with Bt cotton. First the biosafety of Bt Cry protein on lab animals such as Rabbit, Rat and Guinea Pigs were studied to discover the side effect of Bt protein. Various studies such as primary skin irritation test on **Rabbit**, irritation to mucous membrane in **Rabbits**, acute oral toxicity study in **Rats** and skin sensitization study on **Guinea pigs.** The results showed that Bt-Cotton seeds were non-irritant to the skin of rabbits and vaginal mucus membrane. In case of acute oral toxicity study in Rats did not induce any treatment related observable toxic effects when compared with Non-Bt cottonseeds. Studies on skin sensitization revealed that the **repeated application of Bt cottonseeds did not induce dermal sensitization (allergies) to the skin of any of the guinea pigs when compared with animals applied with Non-Bt cottonseeds**.

Secondly **broiler chickens** were tested with feeding of Bt cotton seeds and its side effects. This study was conducted at ICAR's Central Avian Research Institute, Izatnagar. Methodical studies were conducted with broiler chickens and tested for the effect of Bt protein. Birds were weighed at weekly intervals to observe weight loss or gain. After 7th week of studies, 8 birds per treatment were sacrificed to study the effect of feeding CSM types on different carcass traits and development of digestive and immune organs. The results of the study revealed that the **body weight gain and feed conversion efficiency, did not differ statistically overall phases.** The protein and energy efficiencies of experimental diets fed to broiler chicken also remained statistically similar. The carcass traits (% of live weight) of broilers (blood loss, feather loss, dressed yield, eviscerated giblet, ready to cook yield and abdominal fat), cut up parts (breast, drum stick, thigh, back, neck, wings) and digestive and immune organs weights (heart, liver, gizzard, spleen, bursa) also remained statistically ($P<0.05$) similar. It is concluded that the **solvent extracted transgenic Bt cottonseed meal can be included safely with maize or soybean meal based broiler diet** up to 0-7 weeks of age.

A systematic study was conducted with Bt cotton seeds meal as a feed for **Fish Common Carp** and we tested the side effect if any in the fish food chain. This study was conducted at CIFE, Mumbai. A 60 days feeding trial was conducted on common carp fry. Bt cotton seed cake was included in the diet of common carp at 3 – level (10, 20, 30%) and compared with its non-Bt counterpart along with control group no cotton seed cake. Growth rate of Bt cotton seed cake fed group was equally comparable ($P > 0.05$) with that of control group and which and non-Bt counterpart as well. No mortality was found after feeding the Bt cotton cake, suggesting **no adverse side effect of Bt cotton seed cake and can be fed comfortably without any problem**.

Studies were also conducted on large animals such as **Cow** and **Sheep** to assess the bio-safety of BT cottonseed. A trial was conducted at Central Sheep & Wool Research Institute (ICAR), Avikanagar for 120 days by continuous feeding on Weaner lambs at a high plane of nutrition. Nutrient (OM, CP and fiber fractions) and mineral (Ca, P. Mn, Co and Zn) contents were identical in BT-cotton and non-BT cotton seeds. **The growth performance of lambs was similar on control, non- BT cotton seed and BT-cotton seed included diets**. The growing lambs consumed 168 g BT-cotton seed per day and did not have apparent adverse effect on dry matter intake, nutrient utilization and nitrogen balance. Similarly BT-cotton seed intake of 0.681 % of body weight or 19.5 % of dry matter intake did not produce deleterious effect on performance and dry matter intake, thus palatability and growth performance was not a problem for BT-cotton seed feeding in lambs even under high plane of nutrition. Rumen fermentation characteristics *viz,* pH, TVFA and NH3-N concentrations was not influenced by feeding of GNC, non- BT cotton seed or BT-cotton seed in lamb diets. Heamatological observations did not change due to BT-cotton seed feeding compared to non-BT cottonseed or GNC feeding. Interestingly feeding of BT-cotton seed increased RBC and decreased WBC in blood. Serum IgG level did not change due to BT and non-BT cotton seed feeding. Thus feeding of BT cottonseed to lambs did not alter immunity and allergen status. Internal organs weights as g per kg empty live weight (ELW) indicated precise effect of BT- cottonseed feeding on internal organ changes. The weights of kidney, spleen, pancrease, heart, lung, penis, kidney fat, cole fat, GI tract, ingest and empty GI tract were not different among BT cotton seed and non-BT cotton seed fed lambs, thus indicating that **Bt cotton was safe to the animals tested**.

A comprehensive study was conducted with Bt cotton seeds on milking cows. This study was conducted at NDRI, Karnal for four weeks. Sixteen crossbred (KS and KF) multiparous cows were adapted to test by feeding Bt cottonseed based diet. Mainly we tested the Bt Cry protein side effect and absorption in the milk. Milk yield and voluntary feed intake were recorded daily while milk samples were collected at the start of experimental feeding and thereafter at weekly intervals during the four week experimental period for the analysis of milk composition and to test for the presence of Bt protein. At the end, a blood sample from each cow was collected and plasma was separated to test for the presence of Cry 1Ac protein. Cry 1Ac protein in cottonseed, milk and blood samples was measured by ELISA method. The amount of Cry 1Ac protein in Bt cottonseed was 195.04 ng/g on fresh basis. Corresponding values in Bt concentrate mixture was 78 ng/g on fresh basis. Cows in both the groups improved their body weight during the study period and body weight gain in both groups was similar. Average milk yield during 28 days of experimental period in Non Bt (13.53 kg/day) and Bt (13.12 kg/day) groups did not vary significantly. During the experimental period the milk composition in terms of fat, protein, lactose, SNF and total solids content in Bt and Non-Bt were similar. **Cry 1Ac protein was not detected in milk samples, drawn at 0, 7, 14, 21 and 28 day of feeding the experimental diet, as well as in plasma samples drawn on day 28 from the cows fed the Bt cottonseed based ration.** Lactating dairy cows of both the groups did not show symptoms of any disease, maintained their health and performed in a similar fashion when fed Non Bt and Bt cottonseed as a source of energy and protein supplement during the four-week long experimental period. The present study results revealed that the Cry1Ac proteins were neither detected in the milk nor in blood of cows fed Bt cottonseed during the four week trial and there is no effect of Bt cottonseed containing Cry protein on milking cows. Hence, **feeding of Bt cottonseed as a source of protein and energy in the ration of crossbred cows is safe and as nutritious as Non Bt cottonseed.**

Field studies with goats fed on Bt cotton and conventional cotton

A field study was carried out at CICR, Nagpur by a team of scientists led by a senior scientist (Ph.D in animal nutrition) of the Krishi Vigyan Kendra, for two years (2007-2009) by tethering six goats in one hectare of Bt cotton and one hectare of conventional cotton. The goats were fed on the crop continuously for four months and there were no differences in any biological aspects of the two sets of animals. The biochemical and health results clearly showed that Bt cotton was safe to goats.

Pre-release apprehensions

Right from the inception of the technology there has been a sustained opposition from some of the NGO groups. The initial opposition was very speculative and confusing without any reasonable assessment of the technological strengths of Bt-cotton. Most of the criticism was also based on plain ignorance. The Karnataka Ryta Sangha conducted public demonstrations against Bt-cotton and uprooted a few Bt-cotton experimental plots in 1998 and 1999 with misleading accusations of the possible presence of the 'terminator' genes in Bt-cotton. Later several NGOs started highlighting crop failures as failure of Bt-cotton technology. Clearly crop failures resulting from either abiotic or biotic stress, were being attributed to Bt-technology. They tried to instigate the farmers to claim compensation from the company, ignoring the fact that Bt-cotton has been developed

specifically to offer protection against bollworms, not against any other adverse factors (Manjunath, 2004).

Apprehensions and misapprehensions

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There have been several problems pointed out by NGOs and farmers. Some of them are being listed below:

1. Bt-cotton was reported to have slightly enhanced jassid and thrip infestation
2. Re-emergence of *Spodoptera* spp. populations on Bt-cotton
3. Emergence of mealybugs, mirid bugs and gall midges as a problem on Bt-cotton
4. Leaf streak virus in Bt-cotton was reported in some parts of Andhra Pradesh
5. Some Bt-cotton plants harbored the cotton bollworm, *Helicoverpa armigera*
6. Pink bollworm infestation, albeit at low levels, was reported to occur on Bt-cotton
7. Low yields in Bt-cotton plots in some rainfed regions of the country
8. Sudden wilt in Bt-cotton fields

Non-toxic to non-target organisms

The Cry1Ac is mainly toxic to the bollworms (cotton bollworm, pink bollworm and spotted bollworm), semiloopers and hairy caterpillars. Bt-cotton expressing Cry1Ac is absolutely non-toxic to all other non-target organisms such as beneficial insects, birds, fish, animals and human beings. Laboratory and field studies carried out in India showed that the Cry1Ac protein deployed in Bt-cotton did not have any direct effect on any of the non-target beneficial insects. Work carried out elsewhere in the world also showed similar results. Dong et al., (2003), Liu *et al* (2004) and Guo *et al*., (2005) reported only minor effects on some life table parameters in laboratory feeding studies with lacewings and predatory beetles and none with predatory bugs and spiders. There was some evidence of a reduction in numbers of predators and parasitoids which specialise on the Bt controlled bollworms, but also of increases in numbers and diversity of generalist predators such as spiders. Generally the decrease in the parasitoid and predator populations were associated with decrease in the densities of the pest populations on account of Bt-cotton. Any effects could be assigned to the decrease in prey quality – for example with stunted *Spodoptera litura* caterpillars which had fed on Bt cotton. In the field situation, partial life studies broadly confirmed this finding. There was no increase in green vegetable bug numbers, aphid or whitefly numbers on Bt cotton. In general, such adverse effects as have been measured are very small when compared with the side effects of the spraying of conventional insecticides.

Non-toxic to sucking pests and less toxic to *Spodoptera*

Bt-cotton is not at all toxic to any of the sucking pests of cotton. Since the donor parent Coker 312 is known to be highly susceptible to sucking pests such as jassids and thrips, the hybrids showed slightly enhanced susceptibility to these pests, especially if the recurrent parent did not possess inherent resistance to the sucking pests. The Bt-cotton currently released in India is only moderately toxic to the leaf eating caterpillar *Spodoptera.* Hence farmers in some parts of the country would find *Spodoptera* on Bt-cotton. It is known that the usage of synthetic pyrethroids had significant negative impact on the populations of Spodoptera and several other miscellaneous bugs such as the mirid bugs, *Creontiodes biseratence* (Distant). The reduction of pyrethroids and several conventional insecticides on Bt-cotton were expected to result in the increase of several non-target species.

Tobacco leaf streak virus

News paper reports indicated wide spread occurrence of the tobacco leaf streak virus in some parts of Andhra Pradesh only on Bt cotton. The virus was confirmed through PCR tests conducted on infected samples, but on conventional and Bt cotton hybrids. A few Bt cotton hybrids were more susceptible to thrips which spread the virus and therefore appeared to have been severely affected.

Emergence of mealybugs, mirid bugs and gall midges as a problem on Bt-cotton

Bt-cotton is toxic to bollworms and does not control any of the sucking pests of cotton. The Bt-cotton currently released in India is only moderately toxic to the leaf eating caterpillar *Spodoptera.* Over the past seven years, coincidentally after the introduction of Bt-cotton, cotton cultivators in India have been facing new problems with insect pest management in many parts of the country, mostly presumed to be a consequence of low insecticide usage. New sucking pests have emerged as major pests causing significant economic losses. It is known that the usage of synthetic pyrethroids for bollworm control had significant negative impact on the incidental populations of *Spodoptera* spp. and several other miscellaneous bugs including the mirid bugs, *Creontiodes biseratence* (Distant), *Ragmus* sp. The reduction of pyrethroids and several conventional insecticides on Bt-cotton is presumed to have led to an enhanced infestation of several non-target species such as mirid bugs, mealy bugs, thrips and *Spodoptera litura.* Apart from the reports of enhanced disease problems such as grey mildew, leaf spots and rust, new reports of damage by safflower leaf caterpillar in Maharashtra and gall midge damage in Karnataka in cotton, were alarming.

The mealybug was detected as a new species *Phenacoccus solenopsis*, which was not known to be found on cotton in India. Because the problem is new to cotton, it appears to have sent panic signals within the scientific community. There has been a sudden increase in the use of insecticides on cotton, especially those of the extremely hazardous category, over the past two years for mealybug control. Despite insecticide use, the pest was found to spread rapidly all across India causing damage in Punjab, Haryana, Rajasthan, Gujarat and parts of Madhya Pradesh and Maharashtra and is expected to cause more damage if proper precautionary measures are not initiated.

Bollworm occurrence on Bt-cotton

Some plant parts such as the boll rind, square bracts, buds and flowers which express low levels of Cry1Ac, may sustain a small proportion of larvae that feed on them. *In-vivo* and *semi in-vivo* bioassays were conducted on intact plants and isolated plant parts. The assays indicated that a small proportion of larvae survive under field conditions and majority of these grew well on flowers and boll rind. Survival of 5-10% larvae on Bt-cotton plant parts in *semi-invivo* bioassays is not uncommon. An overall analysis revealed that the Bt-cotton technology had a capability of reducing insect pest infestations by 60-90% under field conditions. The efficacy to a large extent was dependent on the host into which Cry1Ac was introgressed. The Bt-cotton hybrid plants express a toxin called Cry1Ac in all parts of the plant. The toxin expression is highest in leaves followed by squares, bolls and flowers. The expression levels in leaves decline after 110-120 days after sowing. Therefore, Bt-cotton controls bollworms effectively at 90-100% up to 100-110 days after sowing and 70-80% of the bollworm larvae thereafter. The cotton bollworm *Helicoverpa armigera* lays majority (70-80%) of its eggs on leaves of the upper canopy and neonate larvae scrape and feed on the surface of the leaf soon after hatching and get killed. However rest of the eggs laid directly on squares, flowers and bolls can survive, depending on the levels of toxin expression in these parts. Hence, at times of high pest pressure, insecticide sprays may become necessary to protect the Bt-cotton crop. The bolls on F-1 plants contain seeds which segregate in 3:1 ratio of Bt:non-Bt. Therefore bollworm larvae may survive on the 25% non-Bt seeds in green bolls if they manage to bore into green bolls. The pink bollworm survival in Bt-cotton is mainly due to the presence of such segregating Bt-cotton seeds in the green bolls of the Bt-cotton F-1 hybrids.

Low yields and crop failure in Bt-cotton

Several news paper reports and NGO surveys have been reporting that Bt-cotton failed in many parts of the country especially in rainfed regions. Clearly there is a fair amount of confusion in

Sudden Wilt

Farmers were incorrectly associating Bt-cotton with parawilt. Parawilt was found to occur due to asphyxiation and can be more in Bt cotton plants because of higher boll retention. Farmers need to be educated that water, nutrient and soil management are extremely critical to get the best performance from Bt-cotton. Poor soils and rainfed conditions are not ideal for the performance of Bt-cotton. It needs optimum water and nutrients at a time when it holds maximum fruiting bodies including green bolls. Bt cotton does not withstand moisture and nutrient stress, especially because the boll retention capacity is much higher as compared to non-Bt varieties. Problems of wilt are generally reported commonly with Bt-cotton. It is true that wilt can be more in Bt-cotton as compared to non-Bt cotton. This is because of the high boll load in Bt-cotton crop.

1. Bt cotton suffers from extra moisture and nutrient stress, especially because the boll retention capacity is much higher as compared to non-Bt varieties.
2. Drought followed by rainfall lead to a 'hiccup' like phenomenon, in the more-thirsty Bt-cotton crop, which creates asphyxiation like condition in roots, thus leading to 'parawilt'. Parawilt is more common in shallow soils and rainfed conditions, wherein the performance of Bt-cotton falls below expectations.
3. Parawilt affected plants also suffer secondary infection from diseases. But this had nothing to do with Cry1Ac or Bt-cotton.
4. Farmers need to be educated that water, nutrient and soil management are extremely critical to get the best performance from Bt-cotton. Poor soils and rainfed conditions are not ideal for the performance of Bt-cotton. It needs optimum water and nutrients at a time when it holds maximum fruiting bodies including green bolls.
5. The soil condition must be improved by adding 25-30 tonnes of FYM before sowing. If conditions of parawilt are in the initial stages, drenching the soil around the infected plants with 1% Bavistin will ward off secondary infection and can help plants in recovery.

Illegal Bt-cotton

Bt-cotton was being sold in India for at least two years before it was approved for commercial cultivation. Navbharat-151 was one of the earliest brands of illegal Bt-cotton, that was available in Gujarat initially, but later spread to other parts of the country. The cost of illegal Bt-cotton brands was reported to be half of the regular price of Bt-cotton. Though many farmers found the illegal brands to be profitable, the studies conducted by CICR showed severe quality constraints with many brands of illegal Bt-cotton. Hence, farmers were strictly advised to avoid falling prey to 'illegal Bt cotton'. Surveys conducted by CICR showed that only 25% of the packets being sold as illegal Bt-cotton are F-1 seeds. About 30% of the packets do not contain any Bt-seeds at all. The rest of 50% is F-2, F-3 or poor quality seed mixtures. There are also problems of duplicate or fake Bt-seeds being sold as legal and genuine seeds. Wherever there is doubt, the seeds or plant parts may be tested with the Bt-detection kits developed by CICR, Nagpur. The kits are simple to use and can be used directly by farmers themselves. The kits are commercially available with CICR, Nagpur.

Bt toxin expression

The Bt-cotton technology gives 70-80% protection against bollworms. Initially in the season it gives almost 100% control of the bollworm upto 80-85 days old crop. Later in the season about 10-20% insects can survive on the crop. The Cry1Ac expression was found to be high in leaves and less in flowers and bolls. It was also found to reduce in leaves after 110 days after sowing. Therefore farmers are advised to scout for the pest and take up appropriate pest control measure. The expression of Cry1Ac through the season in Bt cotton plants was assessed by insect bioassays and ELISA (Enzyme Linked Immunosorbent Assay). The expression was high in terminal leaves, moderate in squares but slighly less in bolls. However the expression in bolls was adequate for bollworm control. Quantification of Cry1Ac expression (Kranthi, et al., 2005) in various plant parts of eight Bt-cotton hybrids was done using ELISA and bioassays throughout the cropping season during 2001-2003. Cry1Ac expression ranged at 0.01 to 19 μg/g in various parts of the plant. The highest expression was in leaves at 75 days after sowing (DAS). A decline in expression of toxin levels was observed in all the eight hybrids. The earliest decrease was in MECH-162, with toxin levels falling off to 1-2 μg/g by 85 DAS. Expression in some hybrids such as RCH-144 and MECH-184 declined only after the 120th day after sowing. The expression levels were highly variable in different plant parts. Though younger leaves expressed highest levels of the toxin, there was a lot of variability in expression. The boll rind, buds and flowers had low expression at 0.01 to 2 μg/g. On an average the Cry1Ac expression in the eight Bt-cotton hybrids was found to be adequate for bollworm protection at least until the first 100-120 days after sowing. However, some plant parts such as the boll rind, square bracts, buds and flowers which express low levels of Cry1Ac, may sustain a small proportion of larvae that feed on them. *In-vivo* and *semi in-vivo* bioassays were conducted on intact plants and isolated plant parts. The assays indicated that a small proportion of larvae survive under field conditions and majority of these grew well on flowers and boll rind. Survival of 5-10% larvae on Bt-cotton plant parts in *semi-invivo* bioassays is not uncommon. Though 2-3 fold differences in Cry1Ac levels were common between the hybrids during early phase of the crop growth, variability up to 7-fold was also observed at times. The current study showed that increasing levels of *H. armigera* survival were correlated with the toxin levels decreasing below 1.8 μg/g of the plant parts. Hence, despite the variability in toxin expression, the pest control properties are unlikely to be affected significantly at least until the crop becomes 100-115 days old, after which, the toxin levels may decline below 1.8 μg/g in some plant parts. The toxin expression in the boll-rind, square bud and ovary of flowers was clearly inadequate to confer full protection to the fruiting parts. Thus, some larvae were found to survive on fruiting structures and leaves of older Bt-cotton plants in laboratory bioassays and on the field crop (unpublished). Nevertheless, it is pertinent to mention here that these surviving larvae suffered a 49-98% weight reduction over the 7-d bioassay period. The efficacy to a large extent was dependent on the host into which Cry1Ac was introgressed. Kranthi et al., (unpublished) found that cloudy conditions were unfavourable for the toxin expression. An overall analysis revealed that the Bt-cotton technology had a capability of reducing insect pest infestations by 60-90% under field conditions.

Studies in the USA (Adamczyk & Sumerford, 2001) with 13 Bollgard® varieties showed that all varieties did not provide the same level of control despite having the same insertion event 'Monsanto-531'. Thus, the assumption that all Bt varieties express similar levels of Cry1Ac δ-endotoxin, and thus have an identical effect on the intrinsically tolerant Lepidopteran survival and development, appears to be inaccurate. The published studies on differential expression of Cry1Ac toxin among Bt-cotton plant parts and varieties in Australia (Fitt, 1998; Holt, 1998) and the USA (Sachs et al., 1998; Adamczyk et al., 2001) indicate variability of Cry1Ac expression within genotypes, plants and plant parts. Also, the terminal leaves were shown to express more Cry1Ac compared to flower structures (Adamczyk et al., 2001; Greenplate, 1999; Greenplate et al., 2000; Gore et al., 2001). Though 2-3 fold differences in Cry1Ac levels were common between the hybrids during early phase of the crop growth, variability up to 7-fold was also observed at times. The current study showed that increasing levels of *H. armigera* survival were correlated with the toxin levels decreasing below 1.8 μg/g of the plant parts. Hence, despite the variability in toxin expression, the pest control properties are unlikely to be affected significantly at least until the crop becomes 100-115 days old, after which, the toxin levels may decline below 1.8 μg/g in some plant parts. The toxin expression in the boll-rind, square bud and ovary of flowers was clearly inadequate to confer full protection to the fruiting parts. Thus, some larvae were found to survive on fruiting structures and leaves of older Bt-cotton plants in laboratory bioassays and on the field crop (unpublished). Nevertheless, it is pertinent to mention here that these surviving larvae suffered a 49-98% weight reduction over the 7-d bioassay period.

The Cry1Ac toxin levels were found to decline over the season in all the hybrids, albeit to varying degrees and at different time frames (Adamczyk and Meredith, 2004; Rochester, 2006). Studies in Australia (Finnegan et al., 1998, Olsen et al., 2005) and USA (Adamczyk & Sumerford, 2001; Adamczyk et al., 2001) also showed that the Cry1Ac toxin expression decreased consistently as the plant aged. The differential expression and decline in Cry1Ac were correlated with increased survival of *H. armigera* in Australia (Olsen & Daly, 2000) and the corn earworm, *Helicoverpa zea* in the USA (Adamczyk et al., 2001). Reduction in the levels of mRNA production, were found to be responsible for the decline in Cry1Ac expression in Bollgard Bt-cotton (Finnegan et al., 1998). Furthermore, it was shown that factors such as parental background had a stronger impact on the expression of Cry1Ac than the environment (Adamczyk & Sumerford, 2001). Studies in Australia (Olsen & Daly, 2000) demonstrated that apart from a decrease in the Cry1Ac content as the plants aged, the increase in *H. armigera* survival in late season plants was also due to the interference of condensed tannins with Cry1Ac toxicity, especially as the tannin content increased over the season.

Insect Resistance Management Strategies for Bt-cotton

After the introduction and large scale cultivation of Bt transgenic cotton it is reasonably certain that bollworms, especially the cotton bollworm, *Helicoverpa armigera,* which will respond to the intense selection pressure through a decline in its susceptibility to *cry1Ac*, the gene used frequently against it not only in cotton but also other host crops such as corn, tomato, pigeonpea, chickpea and vegetables. Hence it is important to develop strategies to retard the rate of resistance development. In India the Genetic Engineering Approval Committee (GEAC) has recommended refuge of non-Bt (5 border rows) with Bt-cotton per acrea or an area of 20% Bt cotton that can be subjected to insecticide sprays. Recently, pigeonpea has also been approved as refugia to be cultivated as border rows around Bt cotton. The current strategy of ensuring a 5-row non-Bt crop all around an acre of Bt-cotton crop, was not found to popular with farmers since it was not suitable for Indian conditions. Stochastic models (Kranthi and Kranthi, 2004) showed that though refugia is a very useful strategy under most situations, it may have only a limited influence in delaying the development of resistance in *Helicoverpa armigera* in India even if fully implemented. Globally, some research groups recommended for seed mixes with non-Bt as a preferred strategy. The arguments against seed mixes have been that they could create a halo effect wherein the susceptible larvae from non-Bt plants would migrate to Bt-cotton plants and get killed, thus depleting the susceptible reservoir. Tabashnik (1994) found that seed mixtures were preferable to pure Bt fields. Both studies agree that refugia are more successful than seed mixtures (Mallet and Porter, 1992; Tabashnik, 1994a). Kranthi and Kranthi, (2004) argued that the extent of reduction in the surviving population, which represents resistant genotypes, was the most important factor that would determine the longevity of the technology utilization.

Geographical variation in susceptibility to Cry1Ac through baseline susceptibility studies was reported for *H. armigera* (Gujar *et al.* 2000; Kranthi *et al.*, 2001; Wu *et al.*, 1999; Fakruddin *et al.*, 2003; Jalali et al., 2004) and the related species *H. virescens* and *H. zea* (Sims *et al.*, 1996). The baseline LC_{50} susceptibility values of *H. armigera* to Cry1Ac in China (Wu et al., 1999), were found to be very variable with a range from 0.091 to 9.073 µg/ml diet, whereas, the baseline LC_{50} values of 0.01 to 0.67 µg/ml reported by Kranthi et al., (2001), and 0.11 to 0.71 µg/ml by Jalali, et al. (2004), for Indian strains indicate that the Chinese *H. armigera* strains were inherently more tolerant to Cry1Ac than the Indian strains. The baseline range of EC_{50} values reported by Kranthi et al., (2001) at 0.003 to 0.008 and EC_{90} 0.009 to 0.076 µg/ml diet, published by Jalali et al. (2004), showed that the results of the bioassays on Indian *H. armigera* population were comparable even when performed independently in laboratories across the country.

The changes in variability of *H. armigera* susceptibility levels to Cry1Ac toxin from *Bacillus thuringiensis* were monitored by Kranthi (unpublished) through log dose probit assays conducted on populations collected from 53 cotton growing districts of India during the 6 year period from 2001-2007. The collections were from 10 cotton-growing districts of North India, 26 districts of Central India and 17 districts of South India. The LC_{50} (median lethal concentration) values ranged from 0.02 to 0.54 µg Cry1Ac/ml of diet in 2002 and 0.057 to 1.146 µg Cry1Ac/ml of diet in 2008. The IC_{50} values ranged from 0.003- 0.034 µg Cry1Ac/ml of diet in 2002 and 0.009 to 0.201 µg Cry 1Ac/ml of diet in 2007. The frequency of alleles conferring resistance in bollworm to Cry1Ac was estimated using the 'iso-female-F-2 screen test'. The frequency increased from an initial level of 0.0008 in 2002 to 0.00149 in 2007. The data did not indicate high levels of resistance in the populations that may be adequate for significant survival of the populations under field conditions. However, the data indicated that there was a clear decrease in the proportion of susceptible populations. For example, the proportions of populations exhibiting LC_{50} values of less than 0.1 μg Cry1Ac/ml of diet were 22-38% between 2002 and 2004, which decreased to 5-12% during 2005 to 2008. Similarly, the proportions of populations exhibiting LC_{50} values of less than 0.01 μg Cry1Ac/ml of diet, were 22-50% between 2002 and 2003, which decreased to 0-3% during 2004 to 2008. **Therefore it has been concluded that thus far bollworms have not developed resistance to Bt cotton in India.**

With the exception of the field results of Guo-Ping et al., (2007) in China wherein they confirmed that there was a small increase in the frequency of major, non-recessive resistance genes to Cry1Ac in *H. armigera* over time, resistance to Cry1Ac in field populations of any of the lepidopteran insect pests, is yet to be detected in any part of the world, despite the fact that Bt transgenic cotton was being cultivated on a large scale in the U.S, China and Australia over the past ten years. Resistance management strategies required for India will have to be specifically designed keeping the Indian farming situation and the characteristically different cotton pest profile, in mind. Unlike *H. virescens*, *H. armigera* is not a leaf feeder hence, it would be useful to regulate high toxin expressions confined to fruiting parts, throughout the fruiting phase. Moreover, to combat the innately Cry1Ac tolerant *H. armigera* individuals, it may be advisable to resort to gene pyramiding through a combination of more than one gene such that together, the combination represents a high dose.

Some of the universally proposed strategies include; use of multiple toxins, rotation of toxin genes, crop rotation, seed mixes, gene pyramiding, high or ultra high dosages, and spatial and temporal refugia. A combination of more than one or all of these tactics together may also prove beneficial in attempts to prevent or diminish the selection of rare individuals carrying resistance genes. Amongst the several strategies recommended world wide, refugia has been one of the most commonly deployed resistance management strategies. The strategy is based on the fact that if a small defined area of non-trangenic plants are cultivated in close vicinity of the toxin expressing transgenic plants, they serve as hosts of the target insect pests, a major proportion of which would be susceptible insects. These would then serve as reservoirs of the susceptible alleles and when mated with the survivors from transgenic plants would result in heterozygous progeny which would express susceptibility, especially if the resistant alleles are recessive in nature.

There have been significant changes in the IRM strategies world over. Since, Bollgard II accounted for more than 80% of the annual plantings in Australia over the past 2-3 years, the regulatory authorities of Australia have stipulated the following refugia conditions for Bollgard II. A grower with 100 ha of Bollgard II has four refuge options. 1) 10 ha unsprayed conventional cotton, 2) 5% irrigated unsprayed pigeon pea, 3) 15% irrigated unsprayed sorghum, 4) 20% irrigated unsprayed maize. The refuge field has to be within two kilometers of the Bollgard II crop. In the US, the EPA has approved a natural refuge for Bollgard II for Alabama, Arkansas, Florida, Georgia, Kansas, Kentucky, Lousiana, Missouri, Mississippi, North Carolina, Oklahoma, South Carolina, Tennesse, parts of Texas and Virginia. Thus in effect the natural refuge is operational in all the states east of Texas and in most of the counties of Texas. The natural refuge option gives growers a choice to use alternate host crops instead of conventional cotton for refuge purposes.

In light of the facts that the Cry1Ac expressed in the current Bt cotton events does not represent 'high dose' against *H. armigera* and also that the allele conferring bollworm resistance to Cry1Ac, is not extremely rare and is inherited in a semi-dominant manner, it is important to develop resistance management strategies appropriate for Indian conditions. More importantly, the strategies should be acceptable to the Indian farmer and should be compatible with the existing cropping systems and management practices. Resistance management approaches generally rely on 1. Conserving susceptibility by minimizing toxin exposure or 2. Getting rid of resistant RS and RR genotypes by using either high dose of the same toxin or by using other unrelated toxins. IRM strategies for India should focus more on the deployment of gene stacks such as the one (Cry1Ac+Cry2Ab) present in Bollgard-II, which has toxin combinations with different modes of action and different mechanisms of resistance and therefore do not show cross-resistance. Other strategies such as non-Bt cotton or pigeonpea as refugia and control of residual larvae on Bt cotton using biopesticides are useful options to delay the onset of resistance and ensure that the benefits of the technology are harnessed for the longest possible time.

Emerging challenges

Some of the emerging challenges are related to transgenic cotton and harnessing the full potential of the technology. Thus far 619 Bt cotton hybrids have been approved/recommended by the Genetic Engineering Approval Committee (GEAC) until August 2009 and 83 lakh hectares were under Bt cotton cultivation in 2009 constituting 83% of the total area. Over the past two years, cotton productivity has been declining. In 2007, the productivity was 560 kg lint/ha, which declined to 520 kg/ha in 2008 and 512 kg/ha in 2009. The emerging issues relate to the following:

Some of the emerging challenges related to cotton production are discussed below. Yields may decline for the following reasons.

1. Package of practices for each of the 619 Bt hybrids have not been developed. Spacing, fertilizer and insecticides are applied at ah-hoc basis based on farmers wisdom.

2. Progressive nutrient (Macro and Micro) depletion due to source sink relationship because of Bt-cotton after Bt-cotton hybrid cultivation. Bt-cotton hybrids utilize more nutrients to yield more. Therefore the soils are getting progressively depleted and need more nutrient refurbishment. Cotton crop is showing nutrient deficiency symptoms in many regions, especially in rainfed zones where wilt and leaf reddening problems are getting severe over the years.

3. Farmers are constantly experimenting with the available 150-200 Bt-cotton hybrids in each district. Some are good and some are unsuitable, thus improper choice of hybrids is resulting in yield losses as well as confusion.

4. The area under Bt cotton has reached above 90% in many parts of the country. Farmers are not following the recommended refugia practices. The intensive Bt cultivation and the non-compliance of refugia is likely to hasten resistance development.

5. Threats from new insect pests (mealybugs, mirid bugs, jassids, thrips, pink bollworm) and diseases (CLCuV), wilt and other foliar diseases are increasing. Many Bt-hybrids are highly susceptible to minor pests such as mealybugs, mirid bugs and several diseases, thereby facilitating proliferation of the pests and diseases, thus resulting in hot-spots and emergence of the minor pests and major pests.

6. Farmers are not following the recommended 'refugia'. With about 90% area under Bt cotton bollworms can develop resistance very soon. The concern needs to be addressed on priority before it is too late.

7. The new technology 'Roundup Ready-Flex' developed by Monsanto does not support cotton intercropping with the commonly used inter crops such as pigeonpea, soybean, maize, jowar etc., which were cultivated as part of risk aversion or sustenance. Moreover, reduction in area of inter-crops can hasten development of bollworm resistance to Bt-cotton.

8. Since 2002, every Bt-cotton seed has been treated with the highly effective insecticide 'imidacloprid'. Farmers have also been spraying this insecticide on the crop to control jassids. Jassids have developed resistance to 'imidacloprid' and therefore crop can be damaged and yields are likely to decline due to sucking pests.

9. Until 2005 100% of cotton area in north was under varieties. Now 95% area is under hybrids in Punjab and Haryana and 40% of the area is under hybrids in Rajasthan. Productivity in north Indian is likely to decline because of the

   a. Declining potential of hybrids
   b. Leaf Curl Virus problem is re-emerging due to introduction of the large number of untested hybrids in North India.
   c. High level of susceptibility to sucking pests (varieties were resistant)
   d. Problems of nutrient deficiencies and physiological disorders will start
   e. Mealybugs and miscellaneous insect problems are likely to increase

Need for a Cotton R&D Policy

India has all he potential to emerge as a world leader of cotton. India has the largest cotton area in the world with about 100 lakh hectares accounting for almost one-third of the global cotton area. It has probably the best dedicated scientific talent of the world for cotton research. With carefully planned policy on cotton research we can ensure that the emerging challenges facing cotton farming are addressed from time to time, while harnessing the full potential of our natural resources, manpower and technologies so that cotton farming becomes a sign of prosperity and India emerges as a global leader of cotton.

Following are important aspects to be considered for an action plan to enhance cotton production in India over the next decade:

1. India has the largest area in the world and ranks second in production. Recently India doubled its production from a stagnating 158 lakh bales in 2001 to 315 lakh bales in 2007.

2. **Though, India ranks second in the world in cotton production after China, even its best productivity of 560 kg/ha, places it at 24th rank in the list of 80 major cotton producing countries.**

3. **India is the only country that cultivates hybrids**, while rest of the world grows only varieties and all the 23 countries that have better productivity than India also grow only straight varieties.

4. Several countries harvest about 50-60 q/ha seed-cotton as national average in most parts of the world by cultivating straight varieties. China harvested an average 58 Q/ha in 63 lakh hectares recently. India's best thus far is 17 Q/ha as its national average, even with over 80% area under Bt hybrid cotton.

5. Almost all production constraints in India have been overcome and conditions are unlikely to get any better in the near future. Therefore possibilities of any further yield enhancement looks weak.

a. Bollworm is no longer a problem
b. Bt cotton and new effective insecticides are available
c. Bt hybrids, Bunny, Mallika, RCH-2, RCH 134, MRC-6301, MRC-6304, Tulasi-4, Brahma, JKCH 1947, Ankur 2534, Ankur 651, Ajeet-11, ACH 33, KDCHH 621, ACH 5, Eswar, Jay, Kanak etc., have good fibre traits and are high yielders.
d. The area under Bt hybrids is now about 90%
e. Area under irrigation has reached 40-42%
f. Emerging problems (mealybugs, leaf reddening, wilt, etc.,) are being effectively tackled.

Despite all the above positive factors the yields appear to have been stagnating at 300 lakh bales.

6. The new technologies (Roundup-Ready-Flex, Cry1F and vip3) expected to be introduced in the next 5-10 years are unlikely to contribute to any additional yield enhancement. No major changes in the yield enhancement or crop protection technologies are expected in the immediate near future. Drought resistance (may be commercially available by 2020). Jassid resistance (through lectin genes may be

commercially available by 2020). Leaf curl virus resistant (may be commercially available by 2015). RNAi based technologies for pest management (may be commercially available by 2020)

7. Plant population cannot be increased with hybrids. Hybrids are highly input intensive and more susceptible to pests and diseases and thus require more fertilizers and pesticides for optimum production. The cost of hybrid seed is much higher and plant growth is luxuriant and therefore does not permit high density planting.

8. High yielding elite Bt-varieties suitable for high density planting may be available only by 2015 in India.

How can the yields increase in future?

A cotton policy is needed for India to enhance and sustain cotton productivity

1. A plan to enhance the production to 1000 lakh bales
2. A plan to develop and identify varieties for specific agri-eco zones
3. A plan to allocate specific quality varieties for specific agri-eco zones
4. A plan to utilize our germplasm through MAB and Transgenics
5. A plan to discover new genes for economic traits and use them
6. A plan to gear up with new technologies such as RNAi
7. A plan to utilize our cotton and export textiles and not raw cotton
8. A plan to make cotton less labour intensive and more profitable

The following strategies are suggested for policy and management

1. Specific productivity enhancing cotton policies should be formulated separately for the 60 districts in India, which cultivate more than 50 thousand hectares each. Twenty of these districts cultivate cotton in 50-90 thousand hectares, twenty districts cultivate in 91-150 thousand hectares and twenty districts having 150-430 thousand hectares in each, with a total of 50 lakh hectares.

2. Each of the 30 Seed Companies should be encouraged to enlist district-wise hybrid suitability of their hybrids and sell only one of their best hybrids in a district

3. Import Bt-Mon-varieties from Mexico and non-Bt from Mali for Vidharba for immediate testing under closer spacing. The varieties have superior fibre traits and yield up to 15-30 Q/ha under identical conditions and latitude as that of Vidharba.

4. Ensure seed purity of hybrids and varieties, especially the Bt-hybrid seeds.

5. Introduction of Cry1C (2009), RR-Flex (2011), Wide-strike Cry1Ac+Cry1F (2012) and Bollgard-III (2015) to enhance diversity of genes and ensure sustainability.

6. Permit Bt-cotton commercial hybrids only if they are resistant to jassids and major diseases of the zone. About 90% of the current Bt-hybrids are susceptible to jassids, whiteflies and mealybugs. Therefore insecticide usage in cotton appears to have increased from Rs 640 crores in 2006 to Rs 800 crores in 2008.

7. Introduction of new insecticides for sucking pest control. Jassids and whiteflies are showing high level of resistance to almost all the recommended insecticides.

8. Intensify Biological control (inundative and inoculative releases of *Aenasius, Promuscedia* and *Cryptolaemus* spp.) and IPM especially for the emerging pests and diseases, especially for the management of mealybugs and mired bugs.

9. Dissemination of the Insecticide Resistance Management Strategies for sucking pests and Cry toxin resistance management in bollworms that have been developed by ICAR. The strategies should be implemented immediately in Gujarat to delay any possible further resistance development.

10. Mandatory spray on Bt-cotton with Spinosad or Acephate+HaNPV+SlNPV at 120-140 DAS to reduce the residual resistant bollworm population on Bt-cotton so as to delay bollworm resistance development to Bt-cotton.

11. Increase irrigation facilities and drip irrigation in Vidharba region of Maharashtra either through the PM relief fund or Rashtriya Krishi Vikas Yojana.

12. Encourage pre-mosoon sowing systems where-ever possible in Central India. Intensify Water harvesting and Integrated Nutrient Management in at least the 20 main cotton districts that cultivate cotton in more than 1.5 lakh hectares.

13. Intensify extension efforts to educate farmers on the appropriate effects and potential of GM technologies in cotton and biosafety related issues.

14. Investment should be made to develop spinning technologies that are suitable for the desi cottons of 16-20 mm and 18 g/tex, so that the low-input costing, high yielding desi cotton varieties can be promoted and utilized.

15. Organic cotton can be cultivated in Gujarat and Karnataka using *G. herbaceum* varieties which occupy about 5-6 lakh hectares.

The following strategies are suggested for research and Development

1. Develop compact Bt varieties suitable for >116,000 plants per hectare instead of the current 10,000 per hectare density of Bt-cotton hybrids. Cotton genotypes are characterized by extremely precise photoperiod and thermal requirement for optimal performance. Therefore it would be most appropriate to identify individual highest yielding genotypes for extremely specific geographical zones that have a common photo and thermal profile across the season.

2. Develop Bt-cotton (with CLCuV Res and whitefly Res in north) using the public sector varieties already identified as jassid resistant, drought resistant, compact genotypes with good boll size.

3. Convert Surabhi, DCH-32 and other elite ELS varieties with Bt on priority. Twenty best high yielding varieties (*G. hirsutum* and *G. arboreum*) possessing superior fibre quality traits (spinnable at 40-50 counts) should be converted to Bt cotton and tested through district-wise multilocation trials again in major agro-ecological zones under narrow spacing (plant population of at least 100,000 per hectare) and appropriate nutrient management. Highest yielding varieties of specific agro-ecological zones should be identified and certified seed should be made available for only those locations. *G. hirsutum* varieties, MCU 5 (29 mm), Surabhi (29 mm), LH 1556 (27 mm), Abhadita (27 mm), MCU 12 (27 mm), LRA 5166 (27 mm), LRK 516 (27 mm), Sahana (27 mm), Rajat (26 mm), Sumangala (26 mm), DHY 286 (26 mm), HS 6 (25 mm), F 846 (24 mm), RST 9 (24 mm), B1007 (24 mm), Khandwa 2 (24 mm), *G. arboreum* varieties PA 183 (27 mm), PA 255 (28 mm), PA 402 (28 MM), Sarvottam (24), and *G. herbaceum* varieties, G Cot 21 (24 mm), G Cot 17 (23 mm), Jawahar Tapti (24 mm) and RG 8 (19 mm) can be subjected for the multilocation testing again after converting them to Bt cotton varieties. Varieties with zero monopodia that are suitable for closer spacing should be identified.

4. Introduce Bt-RG-8, LD 327and RG-18 in north India, AKA 8401 and Sarvottam in central India for higher yields of non-spinnable cotton.

5. Identify and utilize new genes for RNAi based pest control for GM cotton.

6. Use Marker Assisted Breeding for quality improvement using the existing molecular markers available in public domain. High yielding elite germplasm lines (250-300 g/plant), which are inferior in only one or two of the desirable fibre traits and elite varieties should be chosen for marker assisted accelerated back-cross breeding method using high yielding lines as donor parents possessing the desirable trait.

7. Cotton planters should be developed for adjustable spacing. Small scale machine pickers should be developed.

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The concern of **Indian Systems of Medicine**, i.e., **Siddha Ayurvedha and Unani** about **BT Brinjal**

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Introduction

Indian systems of Medicine are widely using Brinjal in its medicinal uses. The Functionalities and therapeutic benefits about Brinjal had been in the Traditional texts of Siddha and Ayurvedha in the name of ***Vazhuthunangkai***. CSIR, in its Wealth of India publications, clearly mentioned that, ***vazhuthunangkai*** is a synonym ***(Malayalam)*** for Solanum melongena

There are two major varieties, ie. Solanum melongena and Solanum indicum are in the pharmaceutical applications in traditional medicine.

In southern part of India, especially Solanum melongena *(Brinjal-Kaththirikkai)* has been used as a substitute for Solanum indicum.

Brinjal in Siddha and Ayurvedha medicine

In Siddha, Dasamoola chooranam one of the major traditional medicine widely used by Siddha physicians.In that herbal powder, dried raw brinjal whole plant is used as one major ingredient.

The roots of brinjal are used for making traditional herbal oil to heal vitiligo and dried roots were used in many traditional and folk medicines.

In Ayurvedha,Charaka introduced brhati or kathirikkai in his fourth chapter in sophakna gana. It is tikta Katu rasa, ushna veerya, rooksha guna, kapha vata reduces in nature. Basically vayu akasa bootha, is present in kathirikkai. The bootha combination is very important.

- Dasamoola is one among the major siddha and ayurvedhic preperations. The brinjal plant is used in this drug one among the ten major ingredient.
- Brinjal is present in dhanwantra kashayam, dhanwantra tailam.
- Brinjal is present in the Dasamoola panchakadadi kashayam of sahasarayogam.
- Dhanwantram is mentioned in astanga hrdaya in shareera sthanam
- Dasamoola panchakoladi kashayam is mentioned in sahasarayogam.
- Dasamoolarishtam is mentioned by Sharangadhara samhita. There are more than 100 recipes which contains dasamoola. These are all the few examples.
- Indukantham kashayam also another example where dried brinjal whole plant is used.
- Dasamoola haritaki told in astanga hrdaya, sopha chikitsa is another example.
- Dasamoola rasayanam told in sahasara yoga for cough is another example.
- Dasamoola katuthrayam kashayam told in sahasarayogam for respiratory diseases is another example

In chooranam and asavam preparation the whole plant of brinjal is used as raw. Only in arishtams, it is used as aqous decoction in the process.

1. Loss of Synergy in BT Brinjal

The alkaloidal comparison between Solanum melongena and BT S.Melongena, done by Indian Institute of Chemical Technology, Hyderabad, shows significant differences. But in the conclusion of that didn't appreciate the variation and neglected the significant changes, which can affect the entire synergy of the plant.

Sl number	Alkaloid	WILD BRINJAL-FRUIT MeOH extract	BT BRINJAL FRUIT-MeOH extract
1	SOLASONINE	100 mg	140
2.	SOLAMARGINE	90 mg	68

Sl number	Alkaloid	WILD BRINJAL-root	BT BRINJAL root
1	Total alkaloid	0.428	0.169

The basic units in the biogenesis of the true alkaloids are amino acids. It is obvious that alkaloids are the secondary metabolites of the plant. Any change in that quantity is definitely because of the stress to plant, which can be from outside environment or from inside metabolism. The change estimated in the study (ref: table-1) shows definitely the imbalance the synergy. If the synergy of the Brinjal plant molecules were disturbed the ***nutritional, functional and therapeutic*** outcome will definitely vary. Undesirable outcome can happen immediately or cumulatively. **It is really unfortunate that these cumulative effects were not studied elsewhere yet.**

Another major apprehension is, in BT Brinjal, by disturbing the cell metabolism (by genetic engineering) that are naturally genetically hardwired to produce toxins, is likely to call up old plant toxins in these species. **This valid hypothesis totally neglected and this could certainly affect the synergy of the plant.**

2. Insufficient studies on cooked BT Brinjal

Studies on cooked BT Brinjal are half baked and insufficient. They had done in the four categories viz. Shallow roasted, fried, deep fried and steamed.

The investigator neglected the real cooking methods practiced in India. **The cooking methods of India didn't have any standard operating procedures.** It varies depending on the culture and the available types. Indian culinary with brinjal largely varies because of its diversified uses. In south India very commonly they cook brinjal with tamarind juice and fried with Sesame oil. But the studies carried out and submitted in GEAC was cooking with groundnut oil only. **As per Prof. Gopal of NIN inference, the amino acid and vitamins will be preserved when it**

cooked with tamarind juice like acidic media (ref: pages 33-34,chapter 4, effect of processing in nutritive values, title: Nutritive values of Indian foods published by NIN,ICMR,Hydrabad).

In that case what will happen to CRYA1C when BTB is cooked with tamarind or other acidic medium? These studies weren't done so far. The stuffs used in brinjal also varies according to cultural, geographical and heritage variations. While cooking BT Brinjal, the changes that happen in the co-stuffs were also not done, as it is very much essential.

According to ISM, the patterns of cooking and final ingredients added after cooking are very important. There is a traditional method of seasoning called ***thalisam*** it is used to nullify the toxic effect happened during cooking/processing of food. ***Tridoda samapporutkal-eight spices used for traditional seasoning*** are used in that process. Every Indian women cooks brinjal and finally they add various spices/herbs at the end of the cooking. There is no study done what will happen to the seasoning process, if BTB used.

In nutshell, the cooked BT Brinjal study is totally insufficient. We shouldn't allow or accept

Raw Brinjal in Indian systems of Medicine

The investigators and inventors of BTB assumed as if nobody uses Raw Brinjal.

Indian systems of medicine use raw brinjal in various applications. Eg: Dhasamoola chooranam-**Siddha;** Dasamoola asava-in **Ayurvedha**

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FIG. 118 — SOLANUM KHASIANUM — FLOWERING AND FRUITING BRANCH

distinctly recurved. Leaves are large, with deltoid or ovate lobes and flowers are white or pale-yellow. The plant grows wild in the Khasi and Jaintia hills of Assam, N.E.F.A., Sikkim, West Bengal, Orissa, the upper Gangetic plains and the Nilgiris, ascending to an altitude of 1,600 m. (Maiti, *J. Bombay nat. Hist. Soc.*, 1965, **62**, 324; Kumar & Dayal, *Indian For.*, 1968, **94**, 186; *Indian Sci. Abstr.*, 1967, **3**, 200).

S. khasianum has recently come into prominence as a rich source of solasodine. Fruit of the plant is reported to be a richer source of the steroidal alkaloid than leaves of *S. aviculare* (q.v.), used in some countries for the production of solasodine. A survey carried out by the Botanical Survey of India has shown that the mature fruits of *S. khasianum* var. *chatterjeeanum*, collected from the Nilgiris, contain 5·4 per cent solasodine on dry weight basis. The solasodine content in fruits collected from different areas varies; thus, fruits collected from Cherrapunji (Assam) contain 3·2 per cent; those from Subansiri Frontier Division (N.E.F.A.) and Khasi and Jaintia hills, 2·1 and 2·02 per cent respectively. Fruits of plants grown in Bombay are reported to yield 2·6 per cent solasodine (Maiti *et al.*, *Curr. Sci.*, 1964, **33**, 730; Maiti & Mookherjea, *Rep. bot. Surv. India*, 1968; Saini *et al.*, *Indian J. Pl. Physiol.*, 1965, **8**, 103; Information from Dr. Y. K. Hamied, CIPLA, Bombay).

The concentration of solasonine is maximum in mature fruits when the colour changes from green to yellow (55–60 days after fruitset). Immature fruits and over-ripe fruits contain very small quantities of alkaloid. The fleshy cover and washed seeds, which form about 60 per cent of the whole fruit, do not contain any alkaloid. The alkaloid is concentrated in the mucilage surrounding the seeds. Leaves contain 0·69 per cent total alkaloids. A new glycoalkaloid, solakhasianin, containing galactose and rhamnose as sugar components, has been reported. Fruit contains diosgenin (Maiti & Mookherjea, *Rep. bot. Surv. India*, 1968; Saini, *Curr. Sci.*, 1966, **35**, 600).

Alcoholic extracts of the plant have been tested for biological activity. They affect the contraction of the isolated ileum of guinea-pig and also influence the central nervous system (Dhar *et al.*, *Indian J. exp. Biol.*, 1968, **6**, 232).

S. melongena Linn. EGGPLANT, BRINJAL

D.E.P., VI(3), 258; C.P., 1026; Fl. Br. Ind., IV, 235; Kirt. & Basu, Pl. 676.

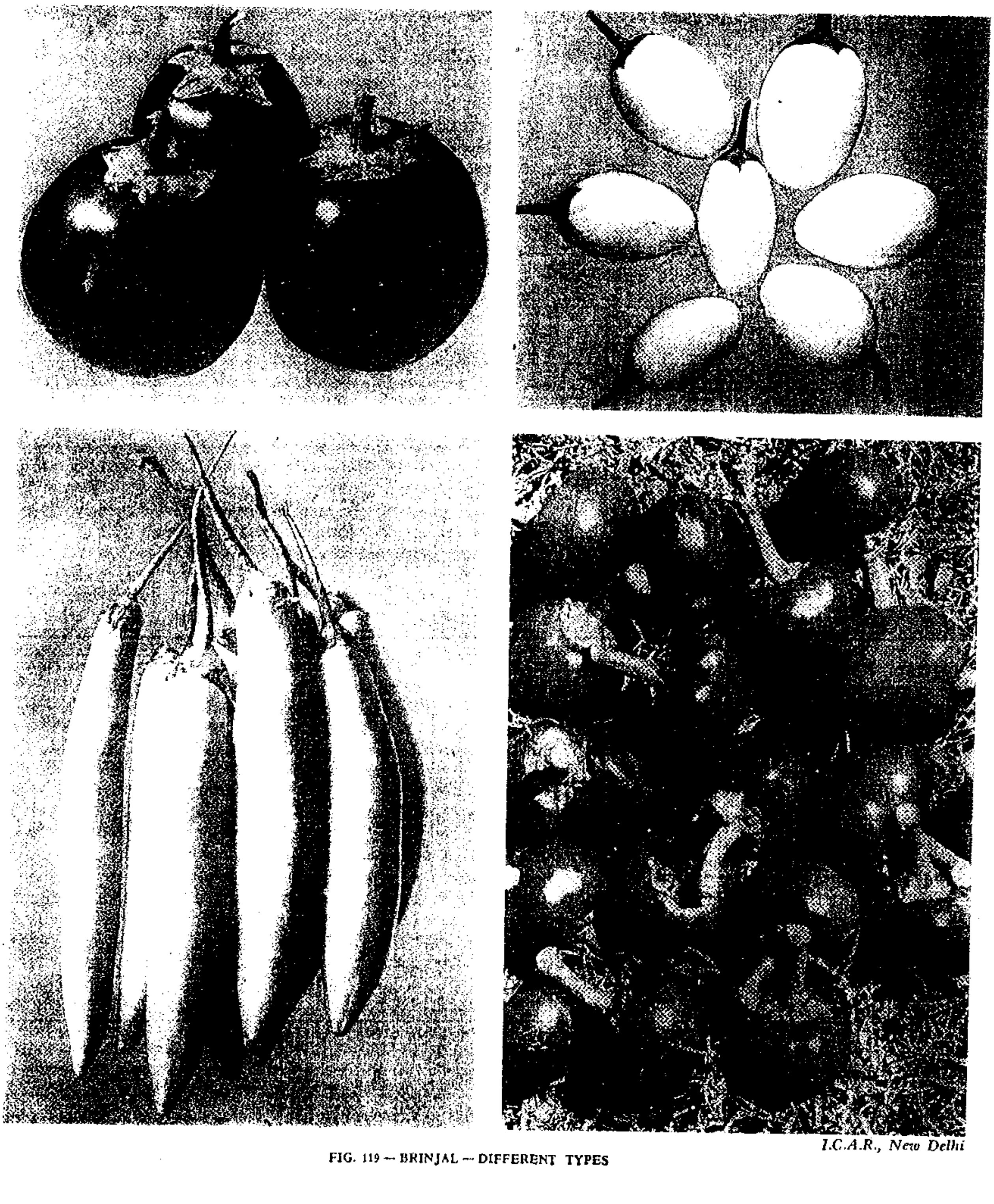
SANS. — *Vartaku vatigama, vatigana, bhantaki, jukutam, hingoli*; HINDI — *Baingan, bhanta, badanjan*; BENG. — *Begun, kuli-begun, bartaku, mahoti hinpoli*; MAR. — *Vangi*; GUJ. — *Ringni, vengni, vantak*; TEL. — *Chirivanga, vangachettu* (plant), *niruvanga, mettavangu, eruvanga, vankaya*; TAM. — *Kathirikai, vankaya*; KAN. — *Badanekayi, dodda badane*; MAL. — *Vazhuthana*; ORIYA — *Baigun*.

KASHMIR — *Vangun*; PUNJAB — *Baingan, vataun*; ASSAM — *Jati bengani*.

A herbaceous prickly or sometimes unarmed perennial 0·6–2·4 m. tall, cultivated throughout India as an annual for its edible fruit. Leaves ovate, sinuate or lobed; flowers blue, in small clusters of 2–5; berries large, ellipsoid or elongate in various shades of white, yellow or dark-purple, 2·5–25 cm. long, glabrous, with thick calyx; seeds many, discoid.

It is difficult to fix the ancestry of cultivated eggplants, but hybrid-vigour and continuous selection must have played an important role in the evolution and development of the various cultivated types of *S. melongena* which bear large edible fruits and are adapted to a wide range of climatic conditions.

The genus *Solanum* is predominantly Central and South American and most of the species originated there, but the brinjal plant is probably a native of South Asia. Some authors have suggested that it is a native of Africa and even Arabia. Vavilov is of the opinion that its centre of origin is the Indo-Burmese region. From the study of ancient records it appears that the plant is native to India and was first cultivated in this country; later, its cultivation spread through Iran to Egypt and other North African countries and to Turkey and the Balkans. In China, its cultivation has been known for the last 1,500 years. The origin of *S. melongena* in the Indo-



I.C.A.R., New Delhi

FIG. 119 — BRINJAL — DIFFERENT TYPES

Burmese region with a large number of types distributed all over the world suggests a parallel evolution of the various types of cultivated eggplants (Bailey, 1949, 869; Sampson, *Kew Bull. Addl Ser.*, XII, 1936, 159; Bailey, 1947, III, 3182; Haines, IV, 613; Purewal, *Farm Bull.*, No. 36, 1957, 55; Vavilov, 24, 27; Bhaduri, *Indian J. Genet.*, 1951, **11**, 75).

There are four main botanical varieties : (i) var. *incanum* (Linn.) Kuntze syn. *S. incanum* Linn., *S. coagulans* Forsk; (ii) var. *melongena* syn. *S. melongena* var. *esculenta* Nees; (iii) var. *depressum* Bailey; and (iv) var. *serpentinum* (Desf.) Bailey syn. *S. serpentinum* Desf. Of these, var. *incanum* bears bitter, usually non-edible fruit but the other three varieties and their hybrids are cultivated and bear different types of edible fruits.

S. melongena Linn. var. *incanum* is a medium-sized, prickly, perennial shrub with blue flowers and yellow ovoid or globose berries. Var. *melongena* includes the COMMON EGGPLANT with large, pendent, ovoid, oblong or obovoid berries, 5–30 cm. long, shining, purple, white, yellowish or striped. Var. *depressum*, DWARF EGGPLANT, is a small and straggling plant with pyriform to ovoid 10–12 cm. long, purple fruits. The fruits of var. *serpentinum* are greatly elongated, up to 30 cm. long, and 2·5 cm. in diam. and are curled at the end (Mansfeld, 393; Bailey, 1949, 869).

Commercial types of eggplant are based on the colour and shape of fruits which may be oval, globose, pear-shaped, or even cylindrical. As already mentioned, the colour of fruits ranges from white to deep-purple or almost black and there are regional preferences for colour. Purple brinjals are most esteemed in the northern parts of the country, while the long and green types are preferred in Bihar and Mysore, and the round and green in Orissa. Yellow, brown, and white brinjals are comparatively less popular [Harbhajan Singh, *Indian Hort.*, 1961–62, **6**(2), 23; Singh & Sikka, *Indian Fmg, N.S.*, 1955–56, **5**(2), 18].

The commercial type, *Banaras Giant*, with light-green fruit from Ramnagar near Varanasi, is much liked for roasting; *Panipat Round* has large round fruits; *Wynaad Giant*, though with small fruits, is a wilt-resistant type; *Batia* or *Sarhandi* of the Punjab, with long and black fruits, leads the rest; and *Long Green* with purple splash, available in December in Calcutta market, has the shape of miniature bottle-gourds. Types which produce fruits in clusters include *Nurki*, bearing deep-purple, elongated fruits; *Mysore Green*, with green fruits, from Mysore; and *Guttivankaya* (*Guttivanga*) from Andhra Pradesh and Tamil Nadu.

Hybrids are more vigorous and high-yielding. In some types, such as *Pusa Purple*, seeds remain immature even in mature fruits; such fruits are preferred. The types of brinjals cultivated in different States are given in Table 2 and the characteristics of some important types are given in Table 3 [Pal & Singh, *Indian Fmg*, 1949, **10**, 378; Choudhury, *Indian Hort.*, 1965–66, **10**(2), 56].

TABLE 2 — TYPES OF BRINJALS CULTIVATED IN DIFFERENT STATES

Andhra Pradesh	East Godavari (H. 131); Guttivankaya (Guttivanga), Pithapuram Long; Pusa Purple Cluster
Bihar	Muktakeshi SM 17; ST 1; ST 2
Delhi	Banaras Giant; Black Beauty; Manjri Gota; Nurki Long; Pusa Anmol; Pusa Kranti; Pusa Purple Long; Pusa Purple Round; Surti Gota, Pb. 8
Himachal Pradesh	Black Beauty; Nurki Long; Solan Selection; Pusa Purple Cluster
Madhya Pradesh	Nurki Long; Nurki Round; ST 2 (Pink); ST 2 (White); Skyaround
Maharashtra & Gujarat	American Purple No. 88-22-23; Manjri Gota No. 28-IS; Surti Gota No. 24-IS
Mysore	Mysore Green
Punjab & Haryana	Nurki Long; Pb. 8; Pb. 34; Pusa Purple Cluster; Panipat Round, Batia
Tamil Nadu	Gudiyatham (S.H. 68); Guttivankaya (Guttivanga); Surti Gota (H. 427); SM 62; Wynaad Giant, Pusa Purple Cluster (in South India)
Uttar Pradesh	Black Beauty; Kalianpur T_1, T_2, T_3 and T_4; Muktakeshi; Banaras Giant; Pusa Purple Long; Pusa Purple Round; Nurki Long
West Bengal	Krishnanagar Green Long; Krishnanagar Purple Round

CULTIVATION

Brinjal is a warm season crop and is very susceptible to frost, late round types being less susceptible to frost than the early long ones. It is grown almost throughout the year in the plains but on the hills it is grown only during the summer, the crop extending up to September. Deep, fine, rich loam (pH $\not> 6$) with proper drainage is most suitable. In clayey soils the plants remain stunted and bear small fruits. The growth is luxuriant in the soils rich in organic manure and the plants bear more fruits. The field for transplanting the seedlings should be well-manured with organic manure and ploughed 4–5 times before transplanting (Chauhan, 349–50).

Manuring—A good crop of brinjals at Delhi needs about 80–110 kg. each of nitrogen and phosphorus and 55 kg. of potash per hectare. At the time of field preparation about 40–50 tonnes of well-rotten farmyard manure or sludge may be added, together with 400 kg. of superphosphate, 200 kg. of ammonium sulphate, and 100 kg. of potassium sulphate or nitrate of potash. Another top-dressing, with half the quantity of ammonium sulphate and potassium sulphate may be given after about six weeks. In Tamil Nadu, application of chemical manure consisting of 100 kg. nitrogen, 50 kg phosphorus and 30 kg. potash/ha. was found to give excellent results. All fertilizers were applied as basal dressing except nitrogen, of which 50 per cent was applied as basal dose and the remaining after 45 days of transplanting. There are reports that in some areas

TABLE 3 — CHARACTERISTICS OF IMPORTANT COMMERCIAL TYPES OF BRINJALS UNDER CULTIVATION*

Type	State or region	Characteristics
American Purple No. 88-22-23	Maharashtra	A selection from an American Round Purple; tall- and quick-growing; leaves large, spineless; fruits lose lustre and wither on plant if not irrigated; fruits big, purple or violet, lustrous, turning dirty yellow on ripening, c. 500 g. each, watery, shrinks the next day after harvest; yield c. 20 qt./ha.; seeds dirty yellow, c. 205 weigh to a gramme
Banaras Giant	East Uttar Pradesh, Delhi	Fruits round, big-sized, light-green; roasting-quality much liked
Black Beauty	Himachal Pradesh, Uttar Pradesh, Delhi	Plants tall, mature in 80 days; fruits round, jet-black, tender, retain colour during transit; heavy yielder
Gudiyatham (S.H. 68)	Tamil Nadu	Plants erect, moderately branching; fruits ovate, medium, purple with green streaks; yield 80-100 qt./ha. Fairly resistant to shoot- and fruit-borer
Guttivankaya (Guttivanga)	Andhra Pradesh, Tamil Nadu	Fruits 2-5 in clusters; a useful character for increasing the yield; dark-purple; round types usually in autumn and winter; long types in summer and rainy season; long types yield more but round ones considered superior and costly; round types less affected by frost; resistant to shoot- and fruit-borer
Kalianpur T-1	Uttar Pradesh	Plants tall, early; fruits long, purple
T-2	Uttar Pradesh	Plants tall, late; fruits long, purple
T-3	Uttar Pradesh	Plants tall, early; fruits round, purple
T-4	Uttar Pradesh	Plants tall, late; fruits round, purple
Krishnanagar Green Long	West Bengal	Crop ready for harvest in 75-80 days after transplanting; recommended for growing during winter; fruits long, 25 cm.×30 cm., green, fleshy, with scanty seeds; yield 25-38 qt./ha.; best when fried
Krishnanagar Purple Round	West Bengal	Crop ready for harvest in 75-80 days after transplanting; well suited for winter; fruits round or slightly ovoid, large-sized, dark-purple, fleshy, scanty-seeded; yield 25-30 qt./ha.
Manjri Gota No. 28-IS	Maharashtra	A selection from local bulk Manjri; comparatively dwarf, spiny; resistant to wilt and little-leaf virus; yield of fruit, 7-15% more than the local; leaves smaller; fruits small to medium, pinkish or rosy with white strips, turn golden-yellow on ripening, c. 160 g. each; taste good; keeps well for 4-5 days; yield 18-20 qt./ha.; seed golden yellow; c. 238 seeds weigh to a gramme
Muktakeshi	Uttar Pradesh, Bihar	Fruits nearly cylindrical, bulging at the base and tapering towards the stem-end, dark-purple
Mysore Green	Mysore	Fruits long, green, in clusters
Nurki Long	Uttar Pradesh, Delhi, Himachal Pradesh, Punjab, Madhya Pradesh	Fruits elongated, deep-purple, in clusters
Pb. 8	Punjab, Haryana, Delhi	A selection from Black Beauty, suited for winter; early, prolific type; fruits round or oval, purple, medium-sized
Pb. 34	Punjab	A selection from Sirhandi, suited for summer; fruits long, purple
Pusa Anmol	Delhi	A hybrid from Pusa Purple Long × Hyderpur; fruits long to oblong, deep-purple, very attractive; yield 10-15% higher, early yield; 80-100% more yield than Pusa Purple Long
Pusa Purple Cluster	Himachal Pradesh, Punjab, South India	A selection from Nurki, suitable for all areas; plants tall, erect, with purplish leaves and stems; fruits 10-12 cm. long, 6-9 in clusters, deep-purple
Pusa Kranti	Delhi	A high-yielding selection from Pusa Purple Long × Wynaad Giant, suitable for all regions; fruits oblong, deep-purple, glossy
Pusa Purple Long	Northern Plains and hills; also suited to southern climate	A selection from mixed Batia; 45-60 cm. high, spineless, very early type; prolific bearer; April-July for transplanting, best being June-July, ratooning can be done; useful during spring and early summer; ready for harvesting in 100-110 days; grows on any soil, best being heavy, loamy soils; resistant to shoot-borer; fruits long to oblong, 20 cm.×25 cm., slender, shining, deep-purple, turn dull-yellow when mature; high-yielding
Pusa Purple Round	Northern Plains and hills	A spineless, 45 cm. high, sturdy type, suitable for autumnal-winter crop and for all areas; transplanting only in July; more resistant to root-knot nematode than Pusa Purple Long, fruits round, purple, attractive, c. 500 g. each, 8-10 fruits during season per plant, turn yellow when mature; highly resistant to little-leaf virus

TABLE 3 — CHARACTERISTICS OF IMPORTANT COMMERCIAL TYPES OF BRINJALS UNDER CULTIVATION—Contd

Type	State or region	Characteristics
SM 17	Bihar	A selection from local type from Samastipur (North Bihar), semi-spreading, very tall, spineless; considerably drought-resistant; fruits long, green, av. 27 cm. x 20 cm., uniformly slender, clustered, fleshy, c. 1 kg. each; a good yielder; excellent taste and quality
(Cluster White) SM 62	Tamil Nadu	Duration 165 days; harvested 80 days after sowing, continuing for 85 days more; cultivated in 3 seasons for 3 crops; yield 12,000–15,000 kg./ha.; fruits medium in size, white, in clusters
Skyaround	Madhya Pradesh	Fruits pink
Solan Selectio..	Himachal Pradesh	Plants upright, mature in 78 days; fruits long, thin, deep-purple to black, in bunches, tender, tasty; prolific type
ST 1 (also known as *Collegia Began*)	Bihar	A selection from Muktakeshi; spreading, spineless or with weak spines at maturity; fruits long, bulging, deep-violet, av. 20 cm. x 14 cm., fleshy, solitary, yield 11–22 qt./ha.; delicious on cooking; seeds bold, whitish-buff-coloured
ST 2	Bihar	A mutant from ST 1; semi-spreading, spineless, differs from ST 1 in possessing long and more or less uniformly slender fruits, av. 26 cm. x 7·6 cm.; less fleshy, clustered; yield 14,700–35,180 kg./ha.; seeds smaller than S.T. 1, buff-coloured
Pink } White }	Madhya Pradesh	
Surti Gota No. 24-IS	Maharashtra, Gujarat, Tamil Nadu	A selection from bulk from Surat (Gujarat); tall-growing; leaves broad, spineless; fruits slightly long, medium-sized, blackish-purple, slightly lustrous, turn dirty yellow on ripening, watery, less tasty, c. 300 g. each, yield 20 qt./ha., more than the local; seeds dirty yellow, c. 220 weigh to a gramme, bearing capacity not affected on storing as in American Purple No. 88–22–23 and Manjri Gota No. 28-IS; tolerant to wilt and little-leaf virus
Wynaad Giant	South India	A wilt-resistant type; fruits round, medium-sized, purple, some locals of the size of pingpong-ball

* Kolhe, *Poona agric. Coll. Mag.*, 1961–62, **52**, 17; Harbhajan Singh & Sikka, *Indian Fmg, N.S.*, 1955–56, **5**(2), 18; Chauhan, 351–53; Juneja & Upadhayaya, *Himachal Hort.*, 1961–62, **2** & **3**, 239; Srinivasan & Basheer, *Indian Fmg, N.S.*, 1961–62, **11**(8), 19; Harbhajan Singh, *Indian Hort.*, 1961–62, **6**(2), 23; Reddi & Subrahmanyam, *Andhra agric. J.*, 1954, **1**, 230; Bhan, *Indian Hort.*, 1965–66, **10**(2), 68; Choudhury, ibid., 1965–66, **10**(2), 56; Nandpuri, ibid., 1965–66, **10**(2), 70; Jotwani, *Indian J. Ent.*, 1961, **23**, 153; Richharia & Roy, *Indian J. Hort.*, 1944, **2**, 39; *Madras agric. J.*, 1968, **55**, 100; Choudhuri, 46; Mehta, *Inf. Leafl.*, Indian Coun. Agric. Res., No. 96, 1958; Singh, *Farm Bull., Punjab agric. Univ., Ludhiana*, No. 24, 1969.

brinjal shows little response to phosphorus and potash separately and a combination of N, P and K fertilizers in the ratio of 67·2, 67·2 and 112 kg./ha. respectively was considered essential for obtaining good yields (Chauhan, 351; Kamalanathan *et al.*, *Madras agric. J.*, 1969, **56**, 214; Sundaram *et al.*, ibid., 1969, **56**, 581).

Seeds are very light and 500–750 g. of seeds are required to raise seedlings sufficient to transplant over a hectare of land. Seeds germinate well at a temperature of 25° and in 4–6 weeks the seedlings are ready for transplanting, when they are about 15 cm. tall. The germinating percentage is 75–80. For obtaining brinjals during March–May, the seeds are sown in the nursery in November and the seedlings are transplanted in the field from the end of December to early January; for fruits during June–August, the seeds are sown in April and transplanted in May; and for fruits during September to January the seeds are sown in the middle of June and the seedlings transplanted about a month later. During June–July, both the long and the round types are sown, while during December–January only the round types are generally planted; the types with slender and long fruits are usually sown during February–March (Chauhan, 350; Purewal, loc. cit.).

Generally, the transplanting of the long-fruited types is done at a spacing of 60 cm. x 45 cm. and of round-fruited ones, 75 cm. x 60 cm. Timely irrigation is very important for high yields. Irrigation may be done every third or fourth day during summer, and after 12–15 days during winter. Regular irrigation keeps the soil moist during frosty days. Hoeing should be done to check the weeds, taking care not to damage the roots. The operation may be fairly deep in the young crop, but it should be shallow as the plants develop. The most serious weed in the brinjal fields is *Orobanche* sp., which is an angiospermic root-parasite. Spraying the soil with Crag herbicide I before the emergence of parasite controls the infestation without injuring the crop [Choudhry, *Indian Fmg, N.S.*, 1962–63, **12**(6), 39; Chauhan, 350, 354].

Diseases and Pests

Fungal diseases — About 20 diseases caused by various fungi have been reported to damage the crop. In several cases the fungal infection is carried through seed. A serious leaf-blight and fruit-rot is caused by *Phomopsis vexans* Sacc. & Syd. in western India. Once established, the disease causes complete rotting of fruit. This blight can be controlled by hot water treatment of seeds.

Damping-off of seedlings is caused in nurseries by *Rhizoctonia (Corticium) solani* Kuhn and *Pythium aphanidermatum* (Eds.) Fitz. Several fungicides like Cerenox are effective in controlling the disease. A blight caused by *Myrothecium roridum* Tode ex Fr. is a serious disease of brinjal crop in Orissa. It kills seedlings in 2–3 weeks. *Phytophthora parasitica* Dast., *P. palmivora* Butler and *P. colocasiae* Rac. cause brown, watersoaked patches on stems and fruits. In heavily infested fields, the organisms can be destroyed by thorough desiccation of surface-soil. Two species of *Alternaria*, viz. *A. tenuis* Nees and *A. melongenae* Rang. & Samb. and *Cercospora* spp. are the cause of leaf spot in brinjals. The spots spread from the leaves to fruits and render the latter unfit for consumption. Spraying the plants with 1 per cent Bordeaux mixture or Fortalan controls the disease. Other important diseases of brinjal are root- and foot-rot (*Rhizoctonia solani* Kuhn and *Fusarium* spp.) and sclerotial disease (*Sclerotium* and *Pellicularia* spp.). Treatment of seeds with Captan (2 g./kg. of seed) gives good results. Seeds from infected fruits should be avoided. Sclerotial disease can be controlled by destroying the affected plants [Butler, Bisby & Vasudeva, 446; Pawar & Patel, *Indian Phytopath.*, 1957, **10**, 115; Nema & Mahmud, *Nagpur agric. Coll. Mag.*, 1950, **25**(1–2), 3; Mahmud, *Sci. & Cult.*, 1952–53, **18**, 149; Rangaswami & Sambandam, *Indian J. agric. Sci.*, 1961, **31**, 160; Kapoor & Hingorani, ibid., 1958, **28**, 109; Padmanabhan, *et al.*, *Madras agric. J.*, 1963, **50**, 109; *Hort. Abstr.*, 1949, **19**, 394].

Fruits, after harvest, are subject to rotting due to the infection by various fungi like *Alternaria tenuis* Nees, *Curvularia lunata* (Wakker) Boed., *Fusarium solani* (Mart.) Appel & Wollen., and *F. roseum* Link (Srivastava *et al.*, *Proc. nat. Acad. Sci. India*, 1964, **34B**, 342).

Virus diseases — Two virus diseases have been reported to infect the brinjal crop. Of these, *brinjal-mosaic* is found to occur on winter as well as summer crops. The leaves show mild mosaic mottling of light yellow and green areas. The affected plants bear smaller leaves and fewer fruits. The other virus disease is the *little-leaf virus*. It is more frequently observed than the former and infects the summer- and rainy-season crops. It is transmitted by a jassid, *Eutettix phycitis* Dist. and is characterized by reduction in leaf size and formation of tufts of very small leaves in the axils of leaves. In severe cases, the plants assume a peculiar appearance of a dense assemblage of closely crowded, small-sized leaves. Such plants do not bear any fruit. The disease spreads more rapidly when the weather is dry. Some success in checking the spread of the disease is achieved by roguing the affected plants. Spraying of the plants with 0·2 per cent Guesarol (wettable DDT 50%) and dusting with 5 per cent BHC dust 2–3 times, at fortnightly intervals, is also useful (Chattopadhyay & Das, *Bull. bot. Soc. Beng.*, 1955, **9**, 42; Capoor & Sharma, *Proc. Indian Sci. Congr.*, pt III, 1961, 498; *Mem. Dep. Agric. Madras*, No. 36, 1954, 1158).

Root pests — The plant is susceptible to damage by the root knot nematode (*Meloidogyne javanica* Treub. & Chitwood) and eelworms (*Heterodera* spp.) both in the nursery and in the field. The nematode causes swellings on the roots. Although such plants are not killed, they fail to bear fruits. Fumigation of nematode-infested soil with fumigants like DD fumigant, ethylene dibromide and carbon tetrachloride before planting or sowing can prevent the infestation. Some brinjal varieties are resistant to nematodes [Reddy & Gupta, *Indian Hort.*, 1966–67, **11**(2), 32; Birat, *Sci. & Cult.*, 1966, **32**, 192; Rao & Rao, *Andhra agric. J.*, 1955, **2**, 76; Srivastava & Bachcha Singh, *Labdev J. Sci. & Technol.*, 1965, **3**, 264].

Shoot and fruit pests — Of the numerous pests which attack brinjal crop, the brinjal-beetle (*Epilachna* spp.), fruit- and shoot-borer (*Leucinodes orbonalis* Guen.), and the stem-borer (*Euzophera perticella* Rag.) are the most destructive pests. Caterpillars of *L. orbonalis* and the budworm (*Pthorimoea blapsigona* M.) bore into the shoots and fruits of brinjal plants, causing considerable loss. Fruits are attacked through the calyx during the early stages and the pest leaves no visible sign of infestation; the large holes on fruits are usually the exit holes of caterpillars. Calcium arsenate spray or dust is quite effective in controlling both these pests. Spraying of the plants with Endrin, Lindane and Sevin (methyl naphthyl carbamate) 3–4 weeks after transplanting helps in checking the infestation of *L. orbonalis*. Some borer-resistant varieties are said to have been evolved at Coimbatore [Wlth India — Raw Materials, V, 195; *Farmer*, 1962, **13**(10), 27; Reddy & Gupta, *Indian Hort.*, 1966–67, **11**(2), 32; *Mem. Dep. Agric. Madras*, No. 36, 1954, 943; Balasubramanian, *Agric. Coll. Mag.*, *Annamalai Univ.*, No. 6, 1965–66, 50; Srinivasan & Gowder, ibid., 1958–59, **3**(2), 7; Srinivasan & Gowder, *Indian J. agric. Sci.*, 1959, **29**, 71; Srinivasan & Basheer, *Indian Fmg, N.S.*, 1961–62, **11**(8), 19; David, *Madras agric. J.*, 1963, **50**, 103; Singh, *Labdev J. Sci. & Technol.*, 1967, **5**, 269; Crop Pests and how to fight them, 86].

Leaf pests — Caterpillars of the brinjal leaf-roller (*Eublemma olivaceae* M.) lodge themselves in the folds of the leaves and feed on the green matter. The affected leaves wither and dry up. If the infestation is also accompanied by that of brinjal stem- and fruit-borer (*Leucinodes orbonalis*), spraying of the plants with Carbaryl wettable powder is useful. For the control of *Eublemma*, two sprayings of 0·25 per cent wettable DDT powder after an interval of 20 days have been recommended [Jotwani & Sarup, *Indian J. Ent.*, 1963, **25**, 275; Srivastava, *Indian Fmg, N.S.*, 1966–67, **16**(2), 17].

The *bhendi*-jassid (*Empoasca devastans* Dist.) infests also the brinjal-crop. The adults and the nymphs suck the leaf-sap and the affected plants remain stunted. DDT 5 per cent dust or 0·1 per cent spray gives good control of the jassid. The infestation of mealy bug (*Centrococcus insolitus* G.) is acute in brinjal fields during rainy season.

Therapeutic benefits

Application of Basudin (0·1%) helps in eradicating this pest. Aphids (*Aphis faboe* and *A. gossypii* Glover) are serious pests and are usually accompanied by the mealy bug. Both the insects drain off the leaf-sap, causing white patches on the leaves. If the infestation of *A. gossypii* is very high, the plant appears as if dusted with white powder. A tiny predator-beetle (*Hyperapsis maindroni* Sic.) has been reported to feed on both these pests and may, thus, prove useful for their biological control [Chatterjee, *Curr. Sci.*, 1954, **23**, 133; *Mem. Dep. Agric. Madras*, No. 36, 1954, 943; Reddy & Gupta, *Indian Hort.*, 1966–67, **11**(2), 32; Banerjee & Basu, *Hort. Abstr.*, 1956, **26**, 570; Balasubramanian, *Agric. Coll. Mag.*, *Annamalai Univ.*, No. 6, 1965–66, 50; Reddy, *Indian Fmg, N.S.*, 1963–64, **13**(4), 35; Rizvi & Khurana, *Sci. & Cult.*, 1970, **36**, 49].

Lace-wing bug or the brinjal tingid (*Urentius echinus* Dist.) is one of the most destructive pests of brinjal crops. The adults and nymphs suck sap from leaves and cause yellowish spots which together with the black, scale-like excreta of the insects impart a characteristic mottled appearance to both the leaf surfaces. Wettable DDT powder (0·025–0·05%) is recommended for its control (Bhandari & Sohi, *Punjab hort. J.*, 1962, **2**, 44; Rao & Rao, *Andhra agric. J.*, 1955, **2**, 76; Rao *et al.*, ibid., 1954, **1**, 312; Jotwani *et al.*, *Indian J. Hort.*, 1961, **18**, 81).

The brinjal-beetle (*Epilachna vigintioctopunctata* F.) is an important leaf-eating pest. The adults are hemispherical in shape and pale red in colour with a number of black spots. The adults as well as the grubs scrape and feed on the leaves, causing appreciable damage. Spraying of the plants with DDT or Endrin (0·2%) at fortnightly intervals prevents serious damage to the crop. The vegetable-mite (*Tetranychus telarius* Linn.) is gradually becoming a serious pest in West Bengal. Malathion, Thiodan and Trithion reduce mite population [Srinivasan & Narayanaswamy, *Indian Fmg, N.S.*, 1960–61, **10**(11), 13; Pawar, ibid., 1963–64, **13**(10), 25; David, ibid., 1964–65, **14**(9), 35; Rao & Rao, *Andhra agric. J.*, 1955, **2**, 76; *Biol. Abstr.*, 1966, **47**, 3781].

Harvesting — Fruits are harvested when they are still immature, possessing a bright glossy appearance, before the flesh becomes tough and the seeds begin to harden. They tend to shrink rather quickly, hence they are harvested in the afternoon and sprinkled with water till they are sent for marketing. They are severed from the plant by shears or knives. The fleshy calyx and a short piece of the peduncle are left attached to the fruit. Fruits of round variety are usually heavy and should be handled with care [Singh & Sikka, loc. cit.; Purewal, loc. cit.].

Yield — The yield of fruits generally varies from 9·5 to 13 tonnes/ha., depending on the type and sowing season; yields up to 35 tonnes/ha. have, however, been reported. The size of fruit may be increased to some extent by spraying the plants with growth regulators like 2,4-D, NAA, NOA, IAA, and IBA. The sprays reduce blossom-drop and tend to give seedless fruit [Chauhan, 354; Muthukrishnan & Srinivasan, *Indian J. Hort.*, 1963, **20**, 150; Muthukrishnan & Srinivasan, *S. Indian Hort.*, 1966, **14**, 68; Muthukrishnan, *Madras agric. J.*, 1958, **45**, 157; *Biol. Abstr.*, 1968, **49**, 5261; Mukherji & Roy, *World Crops*, 1966, **18**(3), 34].

Storage — The fruits can be stored for 1–2 days in summer and 3–4 days in winter, provided they are stored in shade and kept moist. At 9–10° and 85–90 per cent R.H., the fruits can be stored for about four weeks. Small fruits are not suited for long storage and tender fruits suffer low temperature injury. Prepackaging of brinjals in adequately ventilated polyethylene bags (100 gauge) increases the shelf-life of fruits from 3–4 days under ordinary conditions in winter to 8–9 days at 22–26° and 40–70 per cent R.H., and up to 30–32 days at 8–10° and 85–90 per cent R.H. Treating brinjals with wax emulsion containing suitable fungicides also extends the shelf-life by 30–40 per cent. The treatment consists of dipping fruits for about a minute in freshly prepared 3 per cent aqueous fungicidal wax emulsion [Kripal Singh *et al.*, *Indian J. Hort.*, 1952, **9**(3), 16; Viraktamath *et al.*, *Food Sci.*, 1963, **12**, 326; *Bull. cent. Fd technol. Res. Inst., Mysore*, 1953–54, **3**, 10; Agnihotri *et al.*, *Indian Agriculturist*, 1963, **7**, 72].

Fresh brinjals are consumed as a vegetable by both the rich and the poor. On account of lack of organization and orderly marketing of fresh vegetables, there is considerable amount of confusion as to the quality and prices of brinjals sold. Therefore, to provide a basis for orderly marketing of vegetables and at the same time to enable the consumer to identify the quality in relation to price, a standard IS : 2776–1964, has been formulated by the ISI. There are three grades of brinjals, viz. super, fancy, and commercial.

Utilization and Composition

Besides being esteemed as a vegetable, brinjals are consumed in a variety of ways. Roasted in hot ashes, mashed and seasoned with salt, onion, chillies, and lime juice or curds and mustard oil, they are made into *bharta*, a preparation relished all over India. The brinjals may also be pickled. Sliced fruits are sometimes dried in the sun and stored.

The value of brinjals is enhanced as a vegetable during autumn when other vegetables are scarce. They are eaten when approaching ripeness and are a fairly good source of calcium, phosphorus, iron and vitamin B [Burkill, II, 2045; Singh & Sikka, loc. cit.; Brown, 1946, III, 319].

Roots of brinjal plants are credited in the indigenous medicine as antiasthmatic and general stimulant. In Guiana, their juice is employed to cure otitis and toothache. Roots are pounded and applied to ulcers in the nose (Kirt. & Basu, III, 1758; Brown, 1946, III, 321).

Leaves are said to possess sialagogue and narcotic properties and are used in cholera, bronchitis, dysuria and asthma. Brinjals are recommended in liver complaints.

The seeds are used as a stimulant but are apt to lead to dyspepsia and constipation (Kirt. & Basu, III, 1758; Chauhan, 349).

Brinjal is reported to stimulate the intrahepatic metabolism of cholesterol. Both leaf and fruit, fresh or dry, produce a marked drop in blood cholesterol level. The decholesterolizing action is attributed to the presence of magnesium and potassium salts in the plant tissues. Experimental results, however, have not been confirmed by clinical trials. Aqueous extracts of fruit inhibit choline esterase activity of human plasma. Extracts of the plant inhibit the growth of several types of bacteria; the pulp of the fruit is more effective than the juice. Dried fruit is reported to contain a goitrogenic principle (Watt & Breyer-Brandwijk, 995; *Nutr. Abstr. Rev.*, 1961, **31**, 433).

Analysis of the edible portion of fruit (all except stalk and calyx) gave the following values : moisture, 92·7; protein, 1·4; fat, 0·3; minerals, 0·3; fibre, 1·3; and other carbohydrates, 4·0 g./100 g. The mineral constituents present are (mg./100 g. edible matter) : Ca, 18; Mg, 16; P, 47 (phytin P, 3); Fe, 0·9 (ionisable Fe, 0·8); Na, 3; K, 200; Cu, 0·17; S, 44; and Cl, 52; small quantities of manganese (2·4 mg./100 g.) and iodine (7 μg./kg.) are reported to be present. The vitamins present are : vitamin A, 124 I.U.; thiamine, 0·04 mg.; riboflavin, 0·11 mg.; nicotinic acid, 0·9 mg.; vitamin C, 12 mg.; and choline, 52 mg./100 g. of edible matter (Nutritive Value of Indian Foods, 61, 97, 127; Rudra, *J. Indian chem. Soc.*, 1939, **16**, 131; Iodine Content of Foods, 76).

Brinjal contains 14–19 per cent protein (dry wt. basis) of high biological value (71%) and digestibility coefficient (75%). It contains the following essential amino acids (g./g. of N) : arginine, 0·21; histidine, 0·11; lysine, 0·10; tryptophan, 0·06; phenylalanine, 0·27; methionine, 0·06; threonine, 0·23; leucine, 0·39; isoleucine, 0·32; and valine, 0·37. The protein is relatively poor in lysine, tryptophan, methionine and isoleucine. The free amino acids present are mainly aspartic acid, γ-aminobutyric acid and pipecolic acid; lysine, methionine, leucine and a few other amino acids are present in traces. The sugars present in brinjal are sucrose, glucose and fructose (Nutritive Value of Indian Foods, 146, 149; Kuppuswamy *et al.*, 112; Rao *et al.*, *J. sci. industr. Res.*, 1956, **15C**, 39).

Although not a rich source of vitamin B_2, brinjals contain a higher percentage of the vitamin than many other vegetables. Toasting is reported to raise the nicotinic acid content at the expense of trigonelline which is present in it; 66–69 per cent of trigonelline is converted to nicotinic acid during toasting. The vitamin C content of the fruit varies according to variety; values as high as 24·2 mg./100 g. have been reported, but the usual value lies within the range of 4–12 mg./100 g. Leaves contain more vitamin C than in the fruits. Analysis of the plant from Pakistan gave the following values for vitamin C (mg./100 g.) : leaves, 52·38–104·70; stems, 22·85–28·23; fruit, 10·85–20·10; and flowers, 25·40. Brinjals with dark-purple skin contain more vitamin C than those with white skin. The vitamin C content of the vegetable is seriously affected by canning, and canned brinjals contain negligible quantities of the vitamin (*Chem. Abstr.*, 1935, **29**, 845; 1968, **68**, 38187; Mishra, *Sci. & Cult.*, 1966, **32**, 545; Shah *et al.*, *Pakist. J. sci. Res.*, 1962, **14**, 4; Qudrat-I-Khuda *et al.*, *Pakist. J. sci. industr. Res.*, 1962, **5**, 232; Sawant & Magar, *J. sci. industr. Res.*, 1958, **17A**, 144).

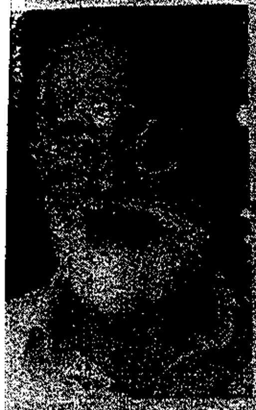
The fatty oil extracted from seeds is rich in linoleic acid. The oil (yield, 21·2%) has the following characteristics : $n^{25°}$, 1·4689; iod. val., 108·8; and sap. val., 296·7. It contains : saturated acids, 20·7; monoenes as oleic acid, 30·0; and dienes as linoleic acid, 49·3%. Analysis of a sample of oil from seeds of *S. melongena* var. *melongena* grown in Japan gave the following values : yield of oil, 19·83%; $d_{4°}^{30°}$, 0·9232; $n_D^{14°}$, 1·4754; acid val., 5·65; sap. val., 180·3; iod. val., 126·2; and unsapon. matter, 3·84%; the fatty acids present are myristic, palmitic, stearic, arachidic, oleic and linoleic acids (Atal *et al.*, *Indian J. Pharm.*, 1964, **26**, 163; *J. Amer. Oil Chem. Soc.*, 1959, **36**, 185).

The main pigment of fruit is an anthocyanin, a delphinidin-3-bioside named nasunin, $C_{21}H_{31}O_{17}Cl$; monohydroxy lycopene, lycoxanthin ($C_{40}H_{56}O$), is also present (McIlroy, 57; Deuel, I, 548).

The bitter principle present in leaves of the plant and in fruit peel is reported to be solasonine. Arginine glycoside, composed of 1 mole each of arginine and glucose, has been isolated from the aqueous extracts of the plant (*Chem. Abstr.*, 1960, **54**, 22871; 1965, **62**, 10821; 1966, **65**, 4543).

The edible portion of fruit is reported to contain 11 per cent pectins (dry wt. basis); oxalic acid, trigonelline ($C_7H_7O_2N$) and β-amino-4-ethyl-glyoxaline are present. Among the phenolic compounds present are chlorogenic acid, neochlorogenic acid, scopoletin and caffeic acid. Chlorogenic acid is widely distributed in the plant; the highest amount is present in fruit cells, and the embryo is devoid of it; roots contain very little. Other substances reported to be present in the fruit are 5-nucleotides, 5-hydroxy tryptamine and traces of hydrocyanic acid (Kertesz, 301; Kaul & Verma, *Indian J. med. Res.*, 1967, **55**, 274; Sinha *et al.*, ibid., 1961, **49**, 681; Henry, 671; *Chem. Abstr.*, 1963, **58**, 12856; 1959, **53**, 4435; 1948, **42**, 4648; 1965, **63**, 4868; Watt & Breyer-Brandwijk, 1145; Oke, *Exp. Agric.*, 1965, **1**, 125).

Two polyphenolases differing in substrate specificity have been identified in the eggplant; both oxidize catechol to its o-quinone. One of them oxidizes the anthocyanin, nasunin (opt. *p*H 6·5), the reaction being stimulated by chlorogenic acid, which presumably acts as a hydrogen donor; the reaction is partially inhibited by ascorbic acid. The second polyphenolase (opt. *p*H 5·0) is less active against the anthocyanin, but it readily oxidizes chlorogenic acid (Sakamura *et al.*, *J. Fd Sci.*, 1966, **31**, 317; *Chem. Abstr.*, 1963, **58**, 12856; 1965, **63**, 3543; Kenkare & Sohonie, *Curr. Sci.*, 1951, **20**, 268).



Prof. R. Vasudevan Nair

Medicinal plants

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Prof. R. Vasudevan Nair retired as Head of the Department of Botany, from Govt. Victoria College, Palakkad, in 1989. Since then he has been working as Botanist for **The Arya Vaidya Pharmacy (Coimbatore) Limited**. He is also President of Centre for Indian Medical Heritage, Kanjikode, Palakkad. He is a field botanist of recognition and has several publications in national and international journals to his credit. He is acclaimed as one of the hundred best botanical illustrators of the world. He has already published three books on medicinal plants. The present book is an attempt to expose the nomenclature confusion still prevailing in the field of Indian System of medicine.

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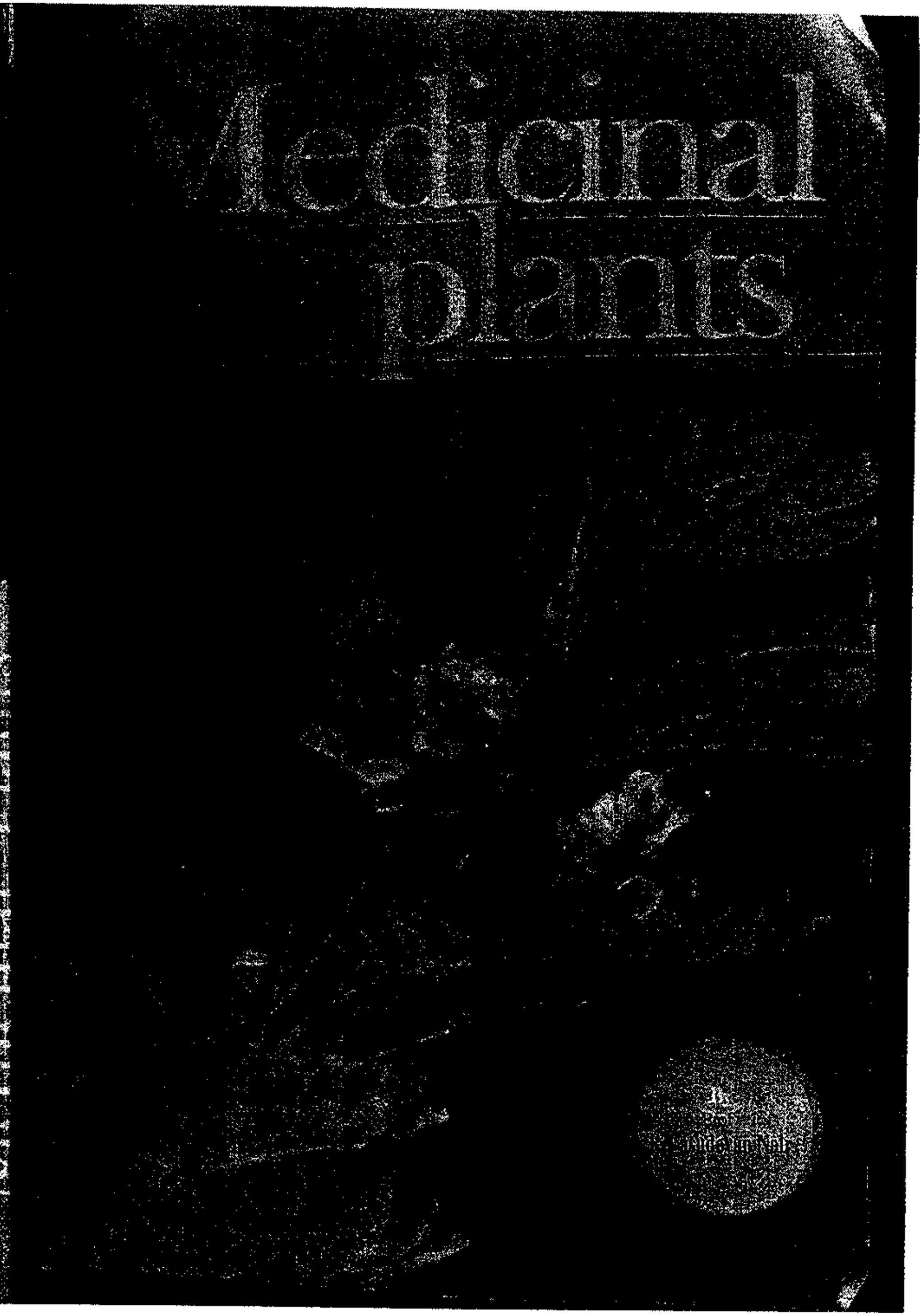
Medicinal Plants

Prof. R. Vasudevan Nair



SOLANACEAE

472. **SOLANUM NIGRUM Linn.**

Black nighshade

Sanskrit - Kakamachi,Kakini (19)

Malayalam - Manathakkali

Hindi - Makoi,Gurkamai

Tamil - Manathakkali,Milaguthakkali

473. **SOLANUM FEROX Linn**

Sanskrit - Garbhada,Svetakantakari (13)

Malayalam - Aanachunda,Vellttuvazhuthana

Hindi - x

Tamil - Aanaichundai

474. **SOLANUM VOILECEUM Ortega**

(S.Indicum linn.)

Sanskrit - Brahati,Kantakin

Malayalam - Puttarichunda,Cheruchunda,Cheruvazhutana

Hindi - Barhanta

Tamil - Karimulli,Cheruvalutanai

475. **SOLANUM VIRGINIANUM Linn.**

(S.xanthocarpum Sch. & wendl.)

(S.surattense Burm.f.)

Sanskrit - Brahati,Kantakari,Bhantaki

Malayalam - Kantakari,Kantakarivazhutana

Hindi - Katai,Kateli

Tamil - Kantankathiri

The above two species are to be the 'brahatidvayam' mentioned in ancient texts.These plants are not available in required quantities.So physicians make use of other species of the genus.'Kantakari' is treated as a separate drug by physicians in Keralam.

476. **SOLANUM CAPSICOIDES All.**

(S.aculiatissimum Jacq.)

Malayalam - Velutta Kantakari

Confusion prevails about the botanical identity of the drugs known as brahatidvayam.Moreover physicians fail to differentiate between what are locally called 'chunda' and 'vazhuthana'.Some physicians consider 'karutha chunda','putharichunda' and 'cheruvazhutana' as one and the same drug and equate them which **Solanum violaceum Ortega.Similarly,**

'Velutha chunda'.'Velvazhutana' and '**Solanum melongena**' are all treated as one.

477. **SOLANUM MELONGENA Linn.**

Brinjal,Egg plant.

Sanskrit - Vartaki,Bhantaki,Vanagana

Malayalam - Vazhutana

Hindi - Badujan,Bhanta

Tamil - Valuthalai,Kathiri

Being a widely cultivated plant this plant is developed several varieties, with different forms of fruit.

A.**SOLANUM MELONGENA**(L) var. **insanum**(L) prain

Perhaps this is to be called 'cheruvazhutana'

B.**SOLANUM MELONGENA**(L.) var. **Incanum**

This form is known as 'punniahachunde'.

Recent studies have shown that **S.melongena** is highly variable and recognition of varieties is of little significance.

478. **SOLANUM TUBEROSUM Linn.**

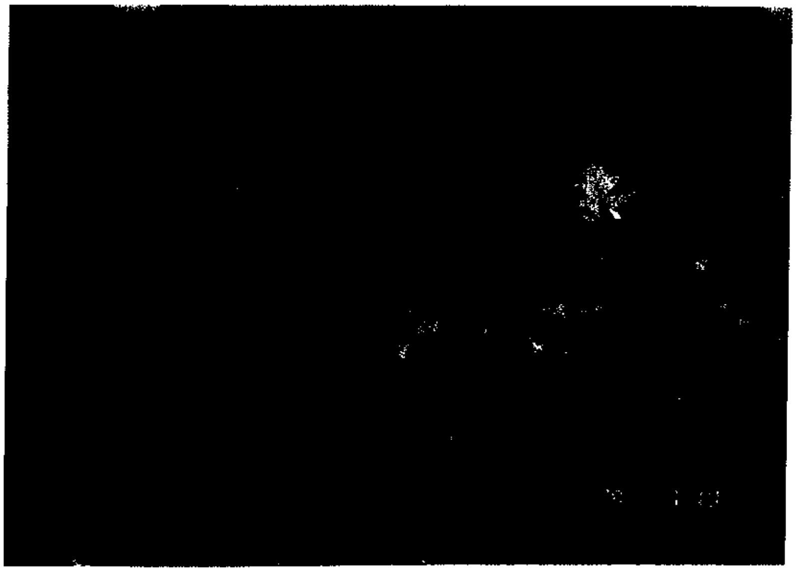
Potato

Sanskrit - Golkanda

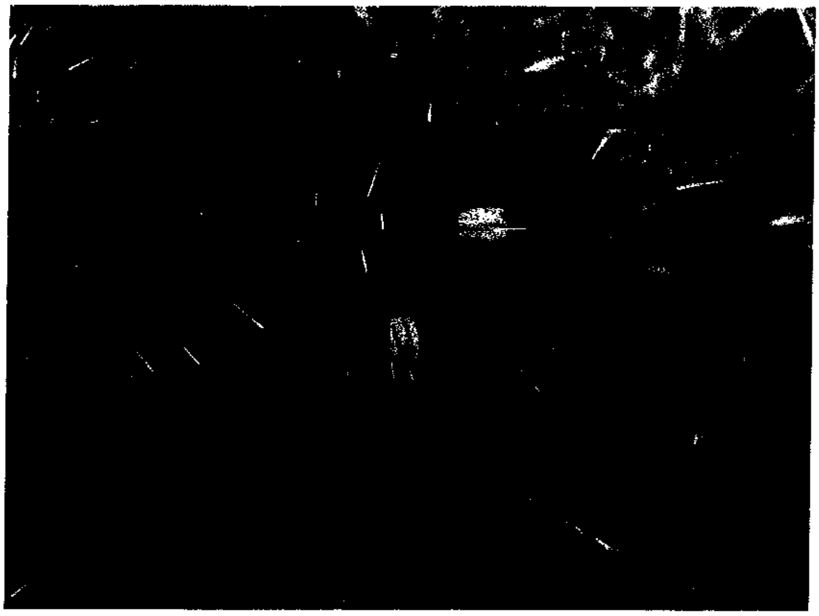
Malayalam - Urulakkizhangu

Hindi - Alu

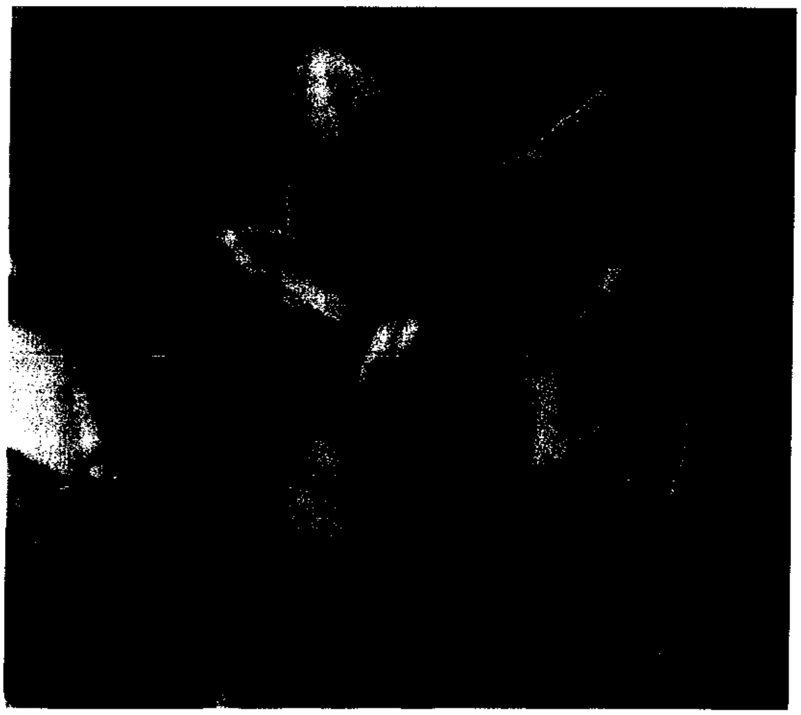
Tamil - Urulakkizhangu



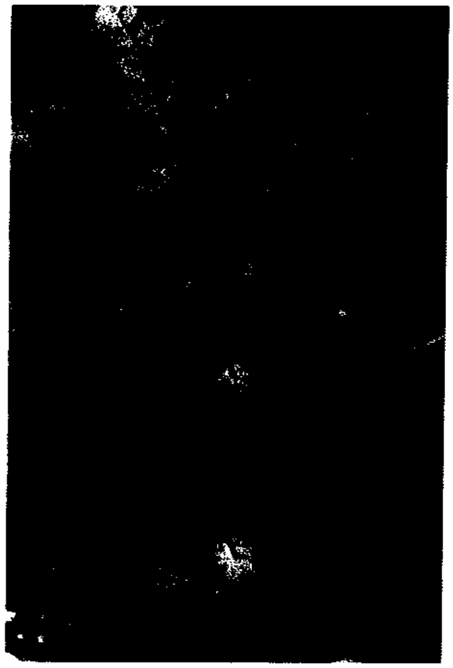
Solanum _ indicum1 (1)



Solanum _ Xanthocarpum.2



Solanum indicum (1)



Solanum _ Xanthocarpum (1)

Solanum indicum 4(1)

Solanum _ Xanthocarpum (1).1

HEALTH HAZARDS RELATED TO GENETICALLY MODIFIED FOOD WITH REFERENCE TO BT BRINJAL

Submitted by

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Introduction:

There are at least 65 documented adverse health effects related to direct consumption/ environmental exposure to GM food as well as so called "non-food" crops. ***What is even more scary and dangerous is what is 'yet unknown'*** and would reveal itself in foreseeable and distant future as some effects have been observed to manifest themselves after 3rd or 4th generation among experimental animals fed GM foods like GM corn/ soya etc.

It is a scientific fact that existing GM process is at best unpredictable. The resultant new species created **CANNOT BE RECALLED**, even if detected to be harmful subsequently, unlike some agrochemicals recalled (eg DDT, Endosulphan) when found toxic after release for use by farmers.

In the whole process of BT Brinjal approval, the public health perspectives have been overlooked. The negative impacts on medicinal aspects of use of Brinjal in Ayurveda and Sidhdha and the importance of preserving the herbal kingdom and the concerns of AYUSH are totally neglected.

There is non-cognizance of existing information on Health hazards associated with Bt Brinjal and GM food. Based on existing knowledge and clinical experience, the Adverse Health Effects of Bt Toxin &/or Genetic Engineering process as well as related issues can be grouped in the following categories:-

A. Adverse Effects of Genetically Modified Bt Food

1. **Damage to fertility and reproductive health**. Serious reduction in size of litter, growth and age of offspring, inability to conceive by offspring , manifesting itself after 2-3 generations.

2. **Multi-organ damage,** notably to Liver, Kidneys, heart, adrenal glands, spleen intestine and haemotopoietic systems (organs related to detoxification of food/ poisons).

3. **Immune reactions and allergies**. All BT Proteins are foreign and different proteins and several studies were shown that they provoke immunological reactions such as respiratory allergy like Asthma and Skin allergies.

4. **Malnutrition**-15% less calorie uptake was noted in the Mahyco studies itself

5. **Causation/ initiation of Cancers.**

6. **Unpredictable Mutations**/ distortion of Cellular structure.

7. **Detection of Antibiotic Resistant Marker genes in human/ animal gut bacteria,** portending disastrous consequences e.g. Kanamycin resistant gene detected in gut bacteria in GM feeding trials can seriously jeopardize National Tuberculosis Control Programme due to grave pre-existing problem of Multi-Drug-Resistant(MDR) and Extreme-Drug-Resistant(XDR) Tuberculosis in India as well as other parts of the world.

8. **Large scale deaths of cattle/ goats/ sheep** grazing on Bt Cotton fields in Andhra Pradesh. Post-mortem examinations revealed multi-organ damage

B. Variety of Adverse Effects Due to GM Food in General

1. Change in Cell structure and Function:

   GM food caused significant modifications in the nuclei (irregularly shaped nuclei) in the Liver cells of GM fed mice. The modifications observed in pancreatic acinar cell nuclei of GM-fed mice could be related to the reduction in digestive enzyme synthesis and secretion and can influence the pancreatic metabolism in mouse.

2. Several animal studies indicate serious health risks associated with GM food consumption including infertility, immune dysregulation, accelerated aging, dysregulation of genes associated with cholesterol synthesis, insulin regulation, cell signalling, and protein formation, and changes in the liver, kidney, spleen and gastrointestinal system. **There is more than a casual association between GM foods and adverse health effects.** Animal studies also show altered structure and function of the liver, including altered lipid and carbohydrate metabolism as well as cellular changes that could lead to accelerated aging and possibly lead to the accumulation of reactive oxygen species (ROS). One study, done by Kroghsbo et al., has shown that rats fed transgenic Bt rice trended to a dose related response for Bt specific IgA. Also, because of the mounting data, it is biologically plausible for Genetically Modified Foods to cause adverse health effects in humans.

C. Catastrophic consequences on Ayurveda and Siddha as under-

- *Loss of Synergy in BT Brinjal* - The alkaloidal comparison between Solanum melongena and BT S.Melongena, done by Indian Institute of Chemical Technology, Hyderabad, shows significant differences. But in the conclusion of that didn't appreciate the variation and neglected the significant changes, which can affect the entire synergy of the plant.
- *Raw Brinjal in Indian systems of Medicine*-The investigators and inventors of BTB assumed as if nobody uses Raw Brinjal. Indian systems of medicine use raw brinjal in various applications. Major Eg: Dhasamoola chooranam- **Siddha**; Dasamoola asava-in **Ayurvedha**
- Out crossing-the most precious heritage herb of India, e.g. Bt Brinjal (Solanum melongena) trans-gene material likely to escape in open field cultivation, can distort medicinal properties of medicinal plants of "Solanum" species/ even some varieties of Brinjal itself used in Ayurvedic medicines. Same applies to accidental/ unintended contamination of non-target species of plants having medicinal properties, thereby loss of genetic heritage of precious plants of India.

D. Methodological Inadequacies in the Study Design

Several international experts have pointed out serious inadequacies with the methodology and study design in the toxicological study for BT Brinjal conducted by Mahyco.

Experts have observed that "the interpretation of results sponsored by Mahyco is not scientifically acceptable" and hence consumption of BT Brinjal can not be considered safe.

The first independent, critical analysis of the data generated by the company had been done by Prof Eric-Gilles Seralini who is the President of the Scientific Council of the Committee for Independent Research and Information on Genetic Engineering (CRIIGEN) and who had been in the French GMO Regulatory Commission. He has concluded, "the two main organs of detoxification, liver and kidney, have been disturbed in this study"

E. Health Risks for Pregnant Women and babies

- GM fed female rats died within 3 weeks as compared to 10% death rate among the natural soyafed control group.

- GM fed babies were smaller and later had problems getting pregnant.
- GM soya fed male rats showed changes in the colour of their testicles from normal pink to dark blue.
- GM soya fed mice had altered young sperm
- GM fed parent mice had significant changes in the DNA of their embryos
- GM corn fed mice had fewer babies which were also smaller than normal as per Austrian Government study.

- Certain GM corn varieties fed pigs in US became sterile, their number was in thousands
- Since the DNA parts of Transgenes have been found in the foetal tissue, concerns about Teratogenic effect on unborn foetus exist.

F. Antibiotic Resistance

The use of Antibiotic Resistance Marker(ARM) using Kanamycin here could be linked with the emergence of antibiotic resistance. There is real possibility of gene transfer into the existing virus, bacteria in the gut or in the soil etc. more so if the horizontal gene transfer occurs in existing pathogenic bacteria. With mere 0.9% GDP being spent on health and 80% health expenditure out of pocket, and public health crisis well known, potential public health risk of emergence of antibiotic resistance must be avoided specially since Kanamycin is a second line anti TB drug and we have over 10 million people affected with TB and drug resistance is a growing public health concern.

Increase in Food Related diseases and infectious diseases is already being seen.

G. No Independent unbiased research

- Absence of independent institution, labs, long term studies where testing can be done and correlation established eg. cancers, infertility, offspring mortality, etc.

- With the use of GM crops, pesticide usage has not decreased, since the transgenic crops carry genes to produce endotoxin against specific pests or be herbicide resistant to a specific herbicide

- Emergence of resistance to pesticide is known and is associated with their initial decreased but later increased use.

Public health impact studies would need to capture the collective impact of adverse health impact of GM as well as pesticide.

Ref: Ben brook Charles (Nov 2009) Impacts of Genetically Engineered Crops on Pesticide Use in the United States: The First Thirteen Years.

H. NO LIABILITY AND COMPENSATION MECHANISM IN PLACE

Health hazards when they occur are usually denied. Even if acknowledged who will legally held accountable for the health hazards if found to be severe and widespread.

- The Bt Brinjal patent owners, seed owners commercially promoting potentially risky product in the market
- Research and scientific bodies involved in the Biosafety studies of Bt Brinjal calling it safe
- The committees that give clearance – alleging safety
- Seed sellers unaware of the risks
- Policy makers permitting potentially hazardous products, when options of use of precautionary Principle or promotion of non GM non pesticide chemical free agriculture is possible and desirable in view of the increasing food linked public health problems irreversibility and unpredictability involved.

J. Potential for misuse of Intellectual Property Rights on the Bt gene

Percy Schmiezer's case related to Roundup Ready contamination of his canola crop is a warning, as to what powerful corporations can do, to wipe out those unwilling to become part of the market. Since with natural pollinators, like wind, birds, butterflies, insects, pollination genetic contamination will take place, more so since the distances between fields separating GM and non GM crops is very little because of the small land holdings.

Percy Schmiezer was sued by Monsanto for violating their patent right even though he denied having used GM seeds. His 50 years collection of non GM seeds was confiscated.
Ref: Vandana Shiva: "Stolen Harvest: The Hijacking of the Global Food Supply"(2000)

This "substantial equivalence Doctrine reflects total contradictions" 'double standards' 'intellectual dishonesty' as it considers GM foods as natural foods when it comes to the need for conduction of rigorous Biosafety studies, alleging SAFETY. While granting exclusive Intellectual Patent Rights to the GMO seeds considering them 'unique' and different from ordinary seeds. The proliferation of the GM products by Monsanto, DOW Cheminals, DUPONT etc. has followed which would have never been possible had the required biosafety studies and post marketing surveillance been undertaken.

K. **Recommendation by American Academy of Environmental Medicine**

The American Academy of Environmental Medicine after reviewing the literature, has noted that GM foods have not been properly tested for human consumption, and because there is ample evidence of probable harm, it recommends the public to avoid GM foods when possible and asks the members to provide educational materials concerning GM foods and health risks. It has also asks for a moratorium on GM food and implementation of immediate long term independent safety testing and labelling of GM foods, which is necessary for the health and safety of consumers.[23]

In view of the above and in the interest of the Health of the people and animals of India, and in view of the PRECAUTIONARY PRINCIPLES laid down in the United Nations Commission on Environment and Development (UNCED Treaty/Rio Declaration 1992), the following action seems necessary:

1. Immediate moratorium of at least 7-10 years be imposed on all open field trials and/ or release of GM crops (both Food and so called Non-food crops) including Bt Brinjal.

2. Strict regulation of surreptitious release of GM seeds brought into the country on any pretext or by any mode.

3. Establishment of independent, credible testing facilities in the country within the period of moratorium, to incorporate the mandatory safety protocols suggested by Biotechnology

4. Mandatory review of Bt Brinjal bio-safety data submitted by M/S Mahyco by independent experts. Full Environmental Impact Assessment should be conducted as against mere 90 day trial/ other perfunctory lab tests carried out to claim fitness for release. Data should be in public domain.

5. Ministry of Health formal clearance should be mandatory for release of any Genetically Modified food/ drug/ other crops as the National Environment, Commerce and Agriculture policy cannot be at cross-purposes with human / veterinary health. Dept. of AYUSH must be a stake holder in the approval process.

6. Re-orientation of policies to promote sustainable, ecologically safe, indigenous crop protection technologies like IPM, NPM etc. Success model of organic farming of sustainable agriculture on 20 Lakh Acres in Andhra Pradesh should be replicated in all agrarian states.

7. It is submitted that doctors are not against the science of Biotechnology wherein benefits like cost-effective production of monoclonal antibodies, rare blood factors, vaccines, pharmaceutical products as human insulin, gene therapy etc exist, and which essentially does not require uncontrolled open-field release with consequences on ecology, biodiversity, health or food.

BRIEF META-ANALYSIS OF CURRENT SCIENTIFIC LITERATURE REGARDING BIOSAFETY OF GENETICALLY MODIFIED CROPS

A. Recent studies about Adverse Effects of Transgenic Bt foods:

There have been a series of scientific reports indicating side effects of transgenic Bt corn or potatoes on the animals.

1. In July 2008, Austrian researchers found that feeding rats a diet containing the transgenic corn NK603 x MON810 affected the reproduction of mice that was **detected in 3rd and 4th generation** in the reproductive assessment by continuous breeding (RACB) study design. Some effects on the kidneys were also observed.[1]

2. In November, 2008, Italian researchers concluded that "the consumption of Bt MON810 maize ... induced alteration in intestinal and peripheral immune response of weaning and old mice."[2]

3. In December 2009, Joël Spiroux de Vendômois et al., studied the rats with feeds of three main commercialized genetically modified (GM) maize (NK 603, MON 810, MON 863), which are present in food and feed in the world. They observed that it causes hepato-renal toxicity. Other effects were also noticed in the heart, adrenal glands, spleen and haematopoietic system.[3]

4. Mice fed potatoes engineered to produce the Bt toxin developed abnormal and damaged cells, as well as proliferative cell growth in the lower part of their small intestines (ileum).[4]

Based on above, transgenic Bt food cannot be considered "safe" when some studies have shown adverse effects on 3rd generation at the earliest and that too by Reproductive Assessment by Continuous Breeding (RACB) study design. The toxicological studies done by Mahyco do not include studies beyond 90 days of exposure. Multi-generational studies appear necessary to establish safety of Bt foods.

B. Adverse Effects Due to GM Food in General

Certain studies have shown that the GM food can change the cell structure itself as follows:

1. Researchers studied effect of feeding GM soybean on mice and found out that it caused significant modifications in the nuclei (irregularly shaped nuclei) in the hepatocytes of GM fed mice.[5]

2. Scientists studied pancreatic acinar cell nuclei on the mice fed on genetically Modified soybean. The modifications observed in pancreatic acinar cell nuclei of GM-fed mice could be related to the reduction in digestive enzyme synthesis and secretion and can influence the pancreatic metabolism in mouse.[6]

3. Several animal studies indicate serious health risks associated with GM food consumption including infertility, immune dysregulation, accelerated aging, dysregulation of genes associated with cholesterol synthesis, insulin regulation, cell signalling, and protein formation, and changes in the liver, kidney, spleen and gastrointestinal system. **There is more than a casual association between GM foods and adverse health effects.** Animal studies also show altered structure and function of the liver, including altered lipid and carbohydrate metabolism as well as cellular changes that could lead to accelerated aging and possibly lead to the accumulation of reactive oxygen species (ROS). One study, done by Kroghsbo et al., has shown that rats fed transgenic Bt rice trended to a dose related response for Bt specific IgA. Also, because of the mounting data, it is biologically plausible for Genetically Modified Foods to cause adverse health effects in humans.[23]

C. Increase in Allergic reactions

Allergic reactions occur when the immune system interprets something as foreign, different, and offensive, and reacts accordingly. All GM foods, by definition, have something foreign and different. Several studies show that they provoke reactions as under:

1. Rats fed Monsanto's GM corn had a significant increase in blood cells related to the immune system.[7]

2. GM potatoes caused the immune system of rats to respond more slowly.[8]

3. GM peas provoked an inflammatory response in mice, suggesting that it might cause deadly allergic reactions in people.[9]

4. Scientists have demonstrated high immunogenicity of Cry1A proteins administered by intragastric route and cautioned the use of transgenic plants for human consumption.[10]

5. There have been reports of allergic reactions to Bt spray. The reaction was severe enough to cause hospitalisation in some of the cases.[11,12,13]

6. Bt toxin might also trigger reactions by skin contact. In 2005, a medical team reported that hundreds of agricultural workers in India are developing allergic symptoms when exposed to Bt cotton, but not when exposed to natural varieties.[14]

Although, there may be many causes, it might be difficult to identify whether GM foods were triggering allergic responses in the population. **Since our country does not conduct regular studies or keep careful records, we need to do allergic studies in great detail before GM food is permitted for human consumption.**

D. GMOs are inherently unpredictable

It has been scientifically proved beyond doubt that genes are not carriers of a single trait. The effect of every gene is determined by the total situation in the cell. Therefore, the transfer of a single gene can not yield intended results and is inevitably unpredictable.

Insertion of transgene can lead to mutation, deletion and alterations of the genomic structure. All this can change RNA, protein, enzymes and other countless natural products in the organism as under:

The gene of soybean glycinin was transferred into potatoes with the aim to increase their protein content. However, the improvements in protein content or amino acid profile were minimal. In fact, the total protein content of the GM potatoes after the gene transfer became significantly less than that of the control line. Even more unfortunately, the contents of some vitamins were reduced while the amounts of both solanine and chaconine increased in the GM lines. In this light the claimed substantial equivalence of the GM and parent lines was not supported by the published results.[15]

As some of the changes are unpredictable and it is only possible to compare the known properties and constituents of GM and conventional plants. It is not possible to analyze unknown components as these are not looked for.

Scientists have opined that just chemical analysis of macro/micronutrients and known toxins is at best inadequate and, at worst, dangerous. More sophisticated analytical methods need to be devised, such as mRNA fingerprinting, proteomics, secondary metabolite profiling and other profiling techniques.
Presently India does not make these analyses mandatory, although it is practicable to do so.

E. Horizontal Gene Transfer

The issue of Horizontal Gene Transfer (HGT) is important.

There is evidence that relatively long fragments of DNA survive for extended periods after ingestion. DNA may be detected in the faeces, the intestinal wall, peripheral white blood cells, liver, spleen and kidney, and the foreign DNA may be found integrated in the recipient genome. When pregnant animals were fed foreign DNA, fragments may be traced to small cell clusters in foetuses and newborns.[16]

In pigs fed GM and non-GM corn, transgene and gene fragments were detected in the lower gastrointestinal tract (rectal and cecal).[17] In chicks fed GM corn, antibiotic resistance marker gene was found in their stomach.[18] The transgene for a Bt corn line (the full length of the coding portion for Cry1AB) was found in-tact in sheep rumen (the first compartment of a ruminant animal's stomach). The authors concluded, "DNA in maize grains persists for a significant time and may, therefore, provide a source of transforming DNA (i.e. Horizontal gene transfer) in the rumen.[19]

The transfer of marker gene can lead to many undesirable consequences not even thought of. There is a possibility of resistance to antibiotic Kanamycin due to HGT. Kanamycin is currently used in many infectious diseases and is a second line treatment for tuberculosis (TB). Drug resistant TB is a major public health problem in India. What will happen if we lose an important second line drug?

F. Studying Effects of GM Food on par with Pharmaceuticals, Monitoring and Regulation Issues

In view of the above unpredictability of GM foods it is contended that GM Foods, including Bt Brinjal need to be treated on par with medicines – for approval and regulatory purposes. At a genetic level there is no difference between a genetically modified food and medicine. Therefore the same level of precautions which are taken for pharmaceuticals need to be taken for GM Foods and Bt Brinjal in this instance.

Trials on three mammalian species – the norm for GM foods – need to be done before human trials first to establish safety of the food followed by .Phase 1, 2, 3 and 4 (post-marketing surveillance studies) trials on human beings.

Post-marketing trials – or monitoring for adverse effects – is going to be really difficult, if not impossible. India's record of adverse drug reaction monitoring of drugs is next to nothing. Pharmaco-vigilance exists in name only. Indeed, that puts in doubt any viability and effectiveness of any regulatory mechanism for Bt Brinjals and GM foods in general, considering also the impossibility of labelling in a diverse market in a country that exists at several levels of poverty and illiteracy at the same time.

With possibility of lateral contamination of Bt genes within and across species, damage across populations and markets is going to be practically irreversible – a fact complicated by absence of gene and seed banks of varieties of non-GM foods. Lateral contamination also effectively destroys choice for the consumer who does not want to consume Bt Brinjal.

Pharmaceuticals are consumed mostly at times of disease by affected sections of populations. It has been difficult to ensure sale only on prescription across the 400,000 retail pharmacy outlets in India leading possibly to all kinds of drug resistance problems and adverse drug reactions. Bt Brinjals and GM vegetables would be consumed by entire populations across the country, especially in the absence of clear choice. Our governance, adverse drug reaction monitoring and regulatory problems in pharma have barely been solved, if at all – how do we expect to solve the same for an item of daily consumption like brinjals across populations, in the event of monitoring adverse effects of Bt Brinjal.

G. Methodological Inadequacies in the Study Design (Bio-safety data of Bt Brinjal submitted by M/s Mahyco)

Several international experts have pointed out serious inadequacies with the methodology and study design in the toxicological study for Bt Brinjal conducted by Mahyco.

Experts have observed that "the interpretation of results sponsored by Mahyco is not scientifically acceptable" and hence consumption of Bt Brinjal can not be considered safe.[20,21]

The first independent, critical analysis of the data generated by the company had been done by Prof Eric-Gilles Seralini who is the President of the Scientific Council of the Committee for Independent Research and Information on Genetic Engineering (CRIIGEN) and who had been in the French GMO Regulatory Commission. He has concluded, "the two main organs of detoxification, liver and kidney, have been disturbed in this study"[22]

Serious inadequacies in the study design itself and all the studies claiming safety of the product either done or sponsored by the same company put a serious doubt on the claimed bio-safety of the Bt Brinjal.

H. On Acceptance of Data Submitted by M/s Mahyco

The response of the EC 2 is that this is in line with the "practices for data generation are in line with the national and international norms followed in case of other products such as pharmaceuticals."

These so-called practices in the pharmaceutical sector have been questioned for the last 10 years. The experience of Merck's hiding unfavourable data with respect to Rofecoxib (subsequently withdrawn by the company and/or banned in several countries), the selective publication of data including an entire fake journal by, again, Merck, the almost complete absence of published data on unsuccessful clinical trials, etc.– these and several others have been routinely questioned.

[1) Hopewell S, Loudon K, Clarke MJ, Oxman AD, Dickersin K. Publication bias in clinical trials due to statistical significance or direction of trial results. Cochrane Database of Systematic Reviews 2009, Issue 1. Art. No.: MR000006. DOI: 10.1002/14651858.MR000006.pub3. 2) See for instance: Erick H Turner, Annette M Matthews, Eftihia Linardatos, Robert A Tell, Robert Rosenthal. "Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy." *The New England Journal of Medicine*. Boston: Jan 17, 2008. Vol. 358, Iss. 3; pg. 252.]

I. Conflict of Interest - at Several Levels

According to the website http://www.indiagminfo.org/ , the following are the undesirable facts undermining the objectivity of approval process of the Expert Committee which recommended Bt Brinjal for clearance (EC2 or Expert Committee II):

- Indication of external pressure on the Chairperson and members of GEAC.
- Some sitting members have vigilance cases pending against them.

- Some members have been part of the development process of Bt Brinjal/ associated with the consortium of developers, hence direct conflict of interest.
- Some members happened to be reviewing their own institutions' data for approval.
- Some members did not submit any inputs to EC2

This represents a huge conflict of interest and compromises the recommendations of the report. Attempt to conceal the data from public domain is also indicated.

J. Recommendation by American Academy of Environmental Medicine

The American Academy of Environmental Medicine after reviewing the literature, has noted that GM foods have not been properly tested for human consumption, and because there is ample evidence of probable harm, it recommends the public to avoid GM foods when possible and asks the members to provide educational materials concerning GM foods and health risks. It has also asks for a moratorium on GM food and implementation of immediate long term independent safety testing and labelling of GM foods, which is necessary for the health and safety of consumers.[23]

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February 8, 2010

To,
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Respected Honourable Minister Shri Jairam Ramesh

Sub: ABLE supports India's First Locally Developed Agri Biotech Product – Bt Brinjal

ABLE (Association of Biotechnology Led Enterprises) is an association of the leading biotech companies in India and is a collective face of the Indian Biotech industry. It is a forum that generates a symbiotic interface between the industry, the government, academic and research bodies, and domestic and international investors.

ABLE aims at accelerating the pace of biotechnology in India by enabling strategic alliances between researchers, the Government and the global biotech industry.

The Special Interest Group on Agricultural Biotechnology (SIGAB) in ABLE is a team that is specifically taking up the matters related to agricultural biotechnology.

At the outset we would like to mention that ABLE supports the approval and the launch of India's first locally developed (developed by Mahyco) agri biotech seed product – BT brinjal, for the benefit of Indian farmers and consumers. ABLE clearly realizes that lack of correct information is the cause of all the negative publicity around this subject

India is the world's second largest producer of brinjal and it is one of India's foremost vegetable sources of protein. Brinjal is applied with the highest quantity of pesticides (worth about Rs.600cr) in India.The need for safer brinjals with lower insecticide MRL's is clear, however not expressed by consumers due to lack of information. In view of providing safe food to the citizens at large and making agriculture more sustainable at the farmer level, we believe that Bt brinjal should be approved.

Our Prime Minister has stated, *"Our agricultural productivity still ranks far below the best in the world."* That Technology is the only way forward is a globally understood and accepted fact, Biotechnology can help us in this endeavour to feed our growing population.

India has a large body of world-class scientists, the world's second largest agriculture acres and a billion plus growing population. Indian scientists can lead the way in safely meeting our country's food and health needs by improving the productivity and farming efficiency of brinjal and other India-centric crops.

What India has done in info tech (IT), we have outdone with agri biotech in cotton. It is estimated that in 2008 an estimated Rs.40,000cr of economic benefit was delevered to the Indian economy due to Bt cotton. Through partnership, Indian biotech and seed companies, farmers and Central and State Governments have delivered a tremendous success for India with biotech cotton. Using agri biotech, India became the world's second largest cotton producer and exporter, ahead of the USA and only behind China – with Indian seeds and competitive technologies! We are very sure a similar record can be created with Bt brinjal which can deliver 100% higher yields and 60% reduction in pesticide for the farmer.

India has now taken centre-stage in the world affairs and we need no longer be followers of other Nations. It is time to show the world that India's time has come. Bt Brinjal need not be at a disadvantage because it is the first vegetable crop coming up for GM Approval in the world.

The soci-economic impact of transgenic insect resistance technology has been well documents and there are 100's of thousands of success stories of farmers in India. It is unfortunate that the good news has not reached the public at large, who are currently totally unaware of how their food is produced.

BT Brinjal has been researched for over nine years and has been created by Indian company – Mahyco (with US company – Monsanto's protein), in full compliance with Indian regulatory guidelines to ensure its safety. BT Brinjal is the most rigorously tested vegetable with 25 environmental and bio-safety studies supervised by independent and Government agencies. Bt, in the form of spores, has been used as an insecticide by organic and other forms of farming for over a hundred years. Bt spores are very commonly recommended in organic farming. In comparison to many of the chemical pesticides, this protein hardly leaves a trace in the environment, as it is completely degraded in a few hours when exposed to solar radiation. By far this is the safest and the oldest insecticidal protein used by mankind, known for its specificity and environmentally safe aspects.

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With BT brinjal, consumers can benefit from healthier vegetables without loads of insecticides far above the MRL and also free from insect damage. BT brinjal is compositionally identical to other brinjals in every respect, with the additional BT protein. The Fruit & Shoot Borer (FSB) pest causes 50-70% damage to the brinjal crop, costing the nation approx. Rs. 1,000 crores yield loss per annum.

Farmers spray 25-80 rounds of pesticides on brinjal each season to control FSB pest infestation. Of the 15 recommended insecticides for brinjal more than half, or eight, are prescribed only for FSB. On average, 4.6 kg of active ingredient of insecticide are sprayed per hectare of brinjal per season at a cost of Rs 12,000 per hectare. Brinjal pesticides represent the highest quantity of pesticide applied to any vegetable in India with the exception of chilli at 5.13 kg and okra at 3.71 kg of active ingredient per hectare respectively.

With BT Brinjal's in built pest protection against the FSB pest, in conjunction with good farming practices, farmers can get improved productivity (100%), save money by using less insecticide usage (60%), and earn higher income. With BT Brinjal, the overall marketable yield is expected to rise by over 100% over conventional hybrids, and 150% over conventional varieties. This will provide the farmer more land to be able to grow others crops that could support the food and nutrition requirement of his family, which is exactly what one hopes to do with modern techuology.

In addition to BT Brinjal, 45 private sector companies, 37 research institutions and 24 universities in India are conducting agri biotech R&D in approx. 30 crops in biotech traits in the areas of insect-tolerance, fungal-, bacterial, viral diseases; drought-tolerance; nutrition enhancement (amino acids, protein, carotene); salinity and alkalinity etc. The Government of India Dept. of Biotech (DBT) Budget for R&D and Capacity Building is approx. Rs. 2,450 crores for 2009-10. This should assure our fellow citizens of the need and benefits of biotech.

You already know that agri biotech products are studied much more extensively than any other plant product in the world, and provide equal or greater assurance of safety of these products compared to conventional plant varieties.

Since 1996, plant biotechnology products have been cultivated and imported in 55 countries with no adverse reports. It is interesting to note that 90% or 12.3 million small and resource-poor farmers in developing countries have benefited from the innovations in agri biotechnology products.

GM foods have been safely cultivated and consumed across the world – tomato (China), papaya (USA, China), corn and soyabean (16 countries), and squash and zucchini (USA). China recently approved BT rice cultivation.

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The UN WHO, Food and Agricultural Organization (FAO), European Food Safety Authority (EFSA), UK's Royal Academy of Sciences, French Academy of Medicine, British Medical Association all concluded that Bt crops are as safe as their non Bt counterparts. 25 Nobel Prize recipients and over 3400 prominent scientists have expressed their support for agri biotech as a "powerful and safe" way to improve agriculture and the environment.

Central and State Government policies must encourage research-driven Indian biotech companies to apply agri biotech innovation to increase yields in key crops.

Since the complexity of successful product development and potential for consumer and farmer benefits are both immense, decisions on new biotech products must be based on science, not politics.

Sir, Nobel Laureate Norman Borlaugh who passed away recently was a great supporter of agricultural biotechnology and the role it could play in enhancing the productivity of land. He played a crucial role in the Green Revolution that benefited India tremendously. It will be a fitting tribute to him as well as the Indian scientific community if India enters the GM food crops space with the approval of Bt brinjal.

ABLE supports the Genetic Engineering Approval Committee's (GEAC) finding Bt brinjal is safe for consumption, produces higher yields and has greater resistance to FSB pests, and is environment-friendly. ABLE supports GEAC decision for commercial release of Bt brinjal, and request speedy approval by the Ministry of Environment and Forests (MoEF)

Yours sincerely,
For Association of Biotech-Led Enterprises (ABLE)

V.R.Kaundinya
Chairman of the SIGAB

Encl : List of ABLE members
: China GM info report

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List of ABLE Member Companies

Animal Biotech (Bangalore) Pvt Ltd.
AR-Ex Laboratories Pvt Ltd
AstraZeneca India Pvt. Ltd.
Aurigene Discovery Technologies Ltd
Advinus Therapeutics Pvt Ltd
Asiatic Clinical Research Pvt Ltd
Accutest Research Laboratories (I) Ltd
Aurigene Biosciences Pvt Ltd
Aptuit Laurus Pvt Ltd
Alexandria Real Estate Management(India)Pvt Ltd
Advanta India Ltd
Anthem Biosciences Pvt Ltd
Atharva Lifesciences Consulting Pvt Ltd
Bangalore Genei Pvt Ltd.
Becton Dickinson India Private Limited
Bharat Biotech International Ltd
Bharat Serums and Vaccines Limited
Bhat Bio Tech India (P) Ltd
Bigtec Private Limited
Bio Rad Laboratories (India) Private Limited
Bioserve Clinical Research Pvt Ltd
Biogenomics Ltd
Biogen Idec Biotech India Pvt Ltd
Biomedical Consulting India Pvt Ltd
Bayer Biosciences Pvt Ltd
BASF India Ltd
Camson Biotechnologies Ltd
Clinigene International Pvt Ltd
ClinTec (India) International Pvt Ltd
Chiron Panacea Vaccines Pvt Ltd
Customised Technologies (P)Ltd
Connexios Life Sciences (P)Ltd
Devgen Seeds and Crop Technology
Dow AgroSciences India Pvt Ltd
Evolva Biotech Pvt Ltd
Enzene Biosciences Pvt LTd
GangaGen Biotechnologies Ltd.
GE Healthcare
Indus Biotech Pvt Ltd
Indus Biotherapeutics Ltd
Indus BioPharmaceuticals Ltd
International Panaacea Ltd
Jubilant Biosys Pvt Ltd
JK Agri Genetics Ltd
Kaypeeyes Biotech Pvt Ltd
Kilpest India Ltd
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MAHYCO
Ecron AcuNova Ltd
Metahelix Life Sciences Pvt Ltd
Millipore (India) Pvt Ltd
Molecular Connections Pvt Ltd
Monsanto Research Centre
Max Neeman Medical International Ltd
Natural Remedies Pvt Ltd.
Novo Nordisk India Pvt LtdNutracryst Therapeutics Pvt Ltd
Ocimum Biosolutions Ltd
Priya Chemicals
Premas Biotech Pvt Ltd
Polyclone Bioservices Pvt Ltd
PHI Seeds Ltd
Quintiles India
ReaMetrix India Pvt Ltd
Research Support International Ltd
Rossari Biotech India
Richcore Life Sciences Pvt Ltd
Shantha Biotechnics Pvt Ltd
Strand Life Sciences Pvt Ltd
Syngene International Pvt Ltd
SK Marine Technologies(India)Pvt Ltd
Syngenta INDIA Ltd
VARDA Biotech (P) Ltd
Vitro Sciences Technologies Pvt Ltd
Voran Consulting Pvtr Ltd
XCyton Diagnostics Ltd
Zilo Technologies Pvt Ltd
BioSpectrum
NASSCOM
ASSOCHAM
Ernst & Young Pvt Ltd
PricewaterhouseCoopers Pvt Ltd
Nath Biogene (I) Ltd
Serum Institute of India Ltd
Biocon
Avesthagen Ltd
Indian Immunologicals Ltd
Tata Consultancy Services Ltd
Panacea Biotec Ltd
Sartorius Stedim India Pvt Ltd
Biozeen / Bangalore Biotech Labs Pvt Ltd
Sun Microsystems India Pvt Ltd

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Xinhua's China Economic Information Service

[redacted]

GM food unsafe? No evidence yet: Chinese experts

8 February 2010
01:47
Xinhua's China Economic Information Service

BEIJING, Feb. 5 (Xinhua) -- Chinese food and agricultural experts said no evidence has proven genetically modified crops are unsafe for people and the environment.

Huang Dafang, director of Biotechnology Research Institute under the Chinese Academy of Agricultural Sciences, said Friday that the genetically-modified crops are of great significance to the sustainable development of agriculture and China's competitiveness in global arena.

"It could help increase the output to ease the food supply strain caused by the shrinkage of farmland," Huang said.

"We are technically advantageous in hybrid rice planting. The genetically-modified technology could ensure China's superiority in food production."

China, a populous country with 1.3 billion people, has put the food security on high agenda in its national development planning.

China's central authorities issued a document on Jan. 31, which calls for pushing forward the industrialization of genetically-modified crops on the basis of scientific appraisal and management in accordance with law.

However, people are concerned with the safety of genetically-modified food.

Wu Yongning, a food safety specialist with the Chinese Center for Disease Control and Prevention, said current studies have not proved genetically modified food harmful to human health.

Wu said that genetically-modified food have to pass scrupulous testing in order to get on shelves, including laboratory and field studies, toxicity and allergy tests.

Besides, health administrations will establish a system to monitor and report adverse effects, said Wu.

"I am not ruling out all possible risks, but those risks of genetically-modified food are no greater than that of traditional ones, given the heavy use of pesticide in growing traditional food," he said.

The State Council of China introduced a regulation in 2001 to ensure the safety of genetically-modified food, with strict provisions on its research, test, production and marketing.

Huang Dafang said the genetically-modified food are less vulnerable to insects and diseases, and as a result, fewer pesticide is needed in growing them, which is safer to human beings and the environment.

According to the International Service for the Acquisition of Agri-biotech Applications (ISAAA), about 224,000 tons of pesticide was saved during the decade between 1996 to 2005 thanks to the expansion of genetically-modified planting.

Besides, the reduced workload to pesticide the crops can help ease the labor shortage in China's countryside resulted from large population of migrant workers, said Huang.

III - A

To: Mr Jairam Ramesh, Hon. Union Minister for Science & Technology

Respected Sir,

I was present at the Bt brinjal public hearing at Bengaluru on Feb 6th from the beginning till conclusion, but could not speak due to obvious reasons. Therefore, I am expressing my opinion below for your kind information and consideration. Attached please find my brief background for your kind reference.

Bt Brinjal: Not a threat to native varieties and safety

One of the major concerns expressed by those opposing Bt brinjal was that it is going to displace native varieties and also that it does not match some of the indigenous varieties in respect of flavour, taste, yield potential, medicinal qualities, local preferences, etc. Some opponents went to the extent of demanding a ban on the importation of 'foreign varieties such as Bt brinjal' as there is no need for it as we are self-sufficient with 'desi' varieties. Such statements clearly showed that there is a misconception about Bt technology not only among some farmers and politicians which is somewhat understandable, but also among some scientists who have not updated themselves precisely with the latest technologies which is very disappointing.

Bt is only a trait, not a variety:

1. The Bt gene, cry 1Ac, incorporated in brinjal plants confers only an insecticidal trait to control Fruit-and-Shoot Borer (FSB) which is a highly destructive pest of all varieties and hybrids. The cry protein is highly specific to insects belonging to the order Lepidoptera (moths and butterfly group) and has no adverse effect on humans, animals or environment.

2. Bt confers only an insecticidal trait; it is not a variety by itself.

3. The Bt gene has been introduced into brinjal varieties or hybrids that have already been developed and are under commercial cultivation. The purpose is to control FSB which does not spare any variety.

4. Since the Bt gene is introduced into prevailing varieties, there is no question of 'Bt brinjal' either adding or replacing any variety as alleged by some.

5. By its presence in the plant, the Bt gene empowers the plant - be it a native variety or hybrid - to protect itself from FSB throughout its life.

6. The action of Bt protein is limited to control of FSB and it has no other influence on the plant. It has been proved that Bt brinjal is 'Substantially Equivalent' to its non-Bt counter part in all respects. Thus, Bt strengthens a native variety or hybrid without any compromise on its other distinctive features such as taste, favour, yield, genetic vigour, medicinal quality, etc.

Beneficial and Safe:

7. The Fruit-and-Shoot Borer is an internal feeder and leads a concealed larval life. It has been responsible for 50 to 70% marketable fruit losses inspite of repeated application of chemical insecticides costing about Rs.6,000/- per acre during a crop season. Trials conducted with Bt brinjal have shown that it can effectively control FSB resulting in better harvest with drastic reduction (80%) in the use of chemical insecticides.

8. The Bt gene, cry1Ac, that has been deployed in Bt brinjal, is almost similar to the one in Bt cotton that had earlier undergone extensive tests and has been under commercial cultivation on million of acres year after year since its regulatory approval in the USA and other countries since 1996 and in India since 2002. Bt cotton has not caused any scientifically proven adverse effects on humans, animals or environment. On the other hand, it has already been cultivated on more than 80% of 9.4 million hectares of cotton area and accepted by over 70% of the 7.5 lakh cotton farmers in India who readily acknowledge that it has brought substantial social and economic benefits. The same is expected from Bt brinjal and the true farmers are eagerly waiting for it.

The opponents may try to suppress or hide facts for vested interests, but cannot change them!

Unacceptable behaviour by Mr H D Deve Gowda and Prof U R Anantha Murhty:

We can understand that out of respect, you have so graciously accommodated these two surprise guests on the dais when the meeting was in progress. Instead of being neutral observers like you, it was unfortunate that both Mr Deve Gowda and Prof Anantha Murhty chose to make 'patriotic statement' that we should protect our 'desi' varieties and not allow 'imported Bt brinjal' at any cost and openly declared that they are with the opposition. This betrayed their lack of undertaking of the Bt technology and sensitivity of the meeting,, but came as a big boost to antis who cheered them. We really felt let down as there were no such prominent persons on the dais to clarify that Bt only a trait, not an imported variety meant for replacing any 'desi' varieties as explained above.

I request you to consider the points that I have mentioned above while taking your decision on Bt brinjal. I hope I will get an opportunity to interact with you in the near future.

With regard,

-Dr. T. M. Manjunath
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III . A

Dear Hon. Minister Mr.Jairam Ramesh,

I am the Regional in charge of College of Agriculture and Life Sciences, Cornell University led research programs in the South Asian region. I am also the in charge of the Agriculture Biotechnology Support Project (ABSPII) that has consummated and supported the Bt Brinjal partnership for the development and delivery of Bt eggplant in India, Bangladesh, Philippines with some scientific support emanating from US as well. I was participating in some of the public consultation you have held in various cities (Hyderabad and Bangalore). My association in leading ABSPII has been since the beginning in 2002.

I would like to submit to you the following:

1. The effort of the Public sector in India supported by Department of Biotechnology and Indian Council of Agriculture Research is commendable in development and validation of the Bt eggplant. When we stepped in to form this consortium, Mahyco was about two years ahead of the public sector in their transgenic material development, but TNAU and Dharwad eventually got their transgenic lines ready for validation almost at the same time as Mahyco, clearly indicating that Indian Public Research bodies can rise to the scientific challenges if motivated and supported with encouragement. The role of Ministry of Environment in encouraging these public partners itself is highly commendable.

2. I was also proud as an Indian to see this product being developed in India, from point zero to final validation of the bio safety and agronomical safety assessment without any external help. As one who has put together the licensing agreement between Public partners in India, Philippines and Bangladesh on the one hand and Mahyco on the other hand, I can clearly indicate that the role Monsanto is no where there, either as royalty collector or stipulator of terms. Mahyco acquired this gene from Monsanto during the 90s and the public sector have full freedom to deliver the product to the farmers without any benefit sharing for the technology and without any contribution to the licensing of the technology. However, TNAU and Dharwad have assumed full stewardship responsibility in taking care to engage in responsible dissemination of the technology. Association of University Technology Managers of USA (AUTM), has identified the efforts of Indian public sector in this project as one of the 25 global efforts that can create a "BETTER WORLD". The efforts present at the World Food Prize Forum recognized publicly the effort of the Indian Public sector as a tribute to the Late. Normal Borlaug in in introduction of the Bt eggplant, on the day when GEAC reviewed the dossier. The ABSPII model is being studied by several developing country consortiums to forge sustainable public efforts with private enterprise support.

3. I was proud as an Indian to see the other countries such as Philippines and Bangladesh finding the Indian dossier thorough and exhaustive and adopting the Indian findings as relevant for their own decision making process. The Indian dossier was thoroughly studied by Philippines Biosafety Authority and also the Bangladesh Bio safety Authority (Since Bangladesh did not have full capacity to study this, they had to engage some global experts to fully understand the comprehensiveness of the dossier). Today, Philippines and Bangladesh public partners are in advanced stage of final agronomical studies, which we hope they would complete and be ready for the respective governments to consider

approval of de-regulation in their countries before the end of the current calendar year. Philippines earlier approved Bt corn based on the dossier approved by FDA and this is the second food product in Philippines where in the Biosafety committee took a decision to allow University of Philippines, Los B not to independently conduct bio safety dossier as they were satisfied with Indian dossier. In a way this is the first agronomic gift from India to rest of the Southern world to improve their own food safety.

4. You have highlighted in the Bangalore consultation your agony in public sector not engaging in outreach. This is certainly a significant weakness in this effort of the public sector to engage in this ambitious global effort. While DBT and ICAR have supported in product development, the universities have very little resource to engage in outreach efforts at the gross root level. The two universities have spent considerable time educating their governments (though Tamilnadu was successful in this effort, the Dharwad is still struggling to engage their own government to appreciate their effort). However, reaching consumers and reaching farmers is a sustained effort requiring resources, faculty time commitment and creation and engagement of a structured outreach wing within the university.

As the College of Agriculture in Cornell engaged extensively during the 90's in spreading unbiased science based information to the public at large and to the farmers when the GM crops were in their serious phase of adoption, we realized how productive role the research organizations can play in helping farmers and consumers make informed decisions by understanding simple facts of good science. The Land Grant Universities collectively played a key role in helping common man in USA understand how technology can help to improve the safety of the food intake. This sustained outreach effort continued for ten long years. Even now, there are continuous efforts going on to mitigate public concerns and to educate farmers. This is certainly absent today and you have rightly observed this in the Bangalore consultation. I fully agree that a massive effort of outreach is essential for agriculture biotechnology to be accepted in this country. All the more, when Greenpeace and other professional NGOs pump in millions of Euros in their effort to create concerns in the minds of farmers and consumers. I think the only way to engage in this outreach process is to encourage Universities to gear their extension departments to spread meaningful, simple scientific facts to the benefit of the farmers and consumers. ABSPII partners have approached DBT, ICAR and would be glad to seek the support of the MOEF in engaging in this process. Should the Bt eggplant find its approval, this will be pre-requisite for the successful introduction of the science as it would help consumers and farmers make "informed decisions".

5. I also find that due to low level of engagement by many State Agriculture Universities in less progressive States, they themselves are staying behind in understanding of the basic science of genetic manipulation and some of the mixed signals that come out from some of the Universities is due to their own lack of engagement in the learning, consultation and disseminating process. It is true that science and innovation is today confined to few of the State Agriculture Universities and this itself creates a sense of self-denial among other universities. I was quite concerned to see the A. P. Agriculture University Vice Chancellor has conveyed to AP Government not to encourage the introduction without even

interacting with ICAR evaluators or the TNAU and Dharwad to try to understand the basic facts in this development process.

6. Your efforts to hold these consultation is commendable. To me, this has been an eye opener to see how the gap exists in our country between those who have been privileged to gain some knowledge and those who are in need of the application of such knowledge. The effort to bridge is going to be enormous and I am delighted that you have embarked a mission to accomplish this. We are committed to provide all efforts in this regard and work with national partners to make this process a success.

With best wishes and regards,

Vijayaraghavan (Vijay). (from Hyderabad).
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III A

Union Minister for State for Environment and Forests (i/c)
Government of India
New Delhi

Dear Mr. Ramesh,

I held up my no. placard for close to two hours to draw your attention to let me speak in the time allocated for "scientists" and also in other time slots. As I was with my two little boys, I was unable to do more to draw your attention.

I am a Statitician (Game Theorist) who has worked in statistical clinics In the Univ. of Minnesota on issues relating to testing agricultural products. I have subsequently worked with Indian Statitistical Institute (Blore), Indian Institute of Management (Blore) and Gallup.

I hope a statistician's opinion of the kind of analysis undertaken by Mahyco in promoting Bt Brinjal would be assistance to you in formulating your final decision. Here are some quick comments. In case you need a detailed critique of the statistical analysis claimed as the basis of approval by GEAC of Bt Brinjal, please let me know and I will offer my help free of cost - to ensure that our country is not subordinated by bad statistical analysis.

Note:

The statistics of the report "Biosafety Data of Bt. Brinjal containing cryAc (EE1) event developed by M/s Maharashtra Hybrid Seeds Company Limited" beginning from the design of experiments to analysis and interpretation of results is seriously flawed. It has been done in an extremely incompetent manner, without proper scientific rigour, nor application of mind, and thus must be rejected as invalid. Evidently, the DBT regulations which Mahyco claims to adhere to are also seriously flawed and must come in for a complete overhaul.

Some points to consider are as follows:

- In good statistics, any sample should be representative of the population under consideration. According to th University of Agricultural Sciences, Bangalore, there are 10 agroclimatic zones in Karnataka alone. In Mayco's field trials, there were only a maximum of 11 locations - clearly not representative of the country's agroclimatic zones.

- The pollen flow study was done only in two locations, again not representative of the country's agroclimatic zones.

- The pollen flow study was conducted over only two seasons, again not representative of seasonal variations in climatic conditions.

- India has a population of over a billion, but was represented in Mayco's toxicity study by only 12 rats, 6male. and 6 female!!! Any sane person would find this totally unacceptable.

- Moreover, Mayco's claim that healthy rats which are 90 - 110 days of age are equivalent to 21 - 25 years of healthy human age is plain stupid. And even if it were so, this would mean that children, teenagers, older adults and the elderly, not to mention the sick and invalid did not even get a chance to be represented by rats!

- In fact, out of twelve rats, a few did get diarrhoea during the 90 days, but this was conveniently attributed to ear infections.

- Good statisticians know that with small sample sizes, the power of the test is also small, that is, if there is no significant observed difference between the control and test group, we can not automatically accept the null hypothesis of no difference. For a sample of size 12 the probability of not detecting deleterious effects is close to 40%!

- For the skin irritation test, only three rabbits 'represented' the country!

There are hundreds of such inadequacies in the report, making it invalid, unscientific trash.

Yours Sincerely,

Dr. Lakshmi Nilakantan

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III A

From:
S. Parasuraman
Director
Tata Institute of Social Sciences
Mumbai

To
Shri. JAIRAM RAMESH
Hon. Minister of Environment & Forests
Government of India
New Delhi

Dear Mr. Ramesh

Greetings!

The Ministry of Environment and Forests constituted a Bt Brinjal Technical Review Committee in early 2007 with following objectives:

1. To evaluate comments received from various stakeholders vis-à-vis the biosafety data generated by the Company and available scientific/technical data/literature from studies conducted by various national and international institutions.
2. Suggest additional studies (if any) to be conducted).
3. To evaluate the adequacy of the protocol proposed for LST and recommend additional safeguards (if any).
4. Recommend protocol for socio-economic studies.
5. Any other recommendations on related aspects.

I was one of the members of the technical review committee. I reviewed about 5000 pages of documents and submitted my report (attached to this mail). A number of issues emerged from my analysis of the documents reviewed. That included:

1. Approval for the large scale trials **must not be granted** as existing information about the safety, need and impacts of Bt brinjal, in particular, and transgenic crops, in general, is not adequate. In keeping with the National Environment Policy 2006, the Precautionary Principle must be adopted with respect to taking decisions about transgenic crops.
2. The Precautionary Principle must be adopted when there is:
   - Doubt about the cause end effect connection,
   - Doubt about the probability estimates,
   - Doubt about the risk assessment,
   - Doubt about cumulative consequences and long term, and/or
   - Doubt about whether restrictive and management measures are working as expected
3. All the biosafety/other studies conducted by or for MAHYCO must be made public in their complete form – the entire report, and not just the summaries.
4. These studies must be peer-reviewed and subject to evaluation by external experts.
5. The regulator, in consultation with NGOs, must appoint a non-interested third party expert to conduct independent studies on Bt brinjal.

6. The clarifications to the feedback provided by NGOs on the studies conducted must be shared with the agencies that posed the queries so that the validity of MAHYCO's responses can be evaluated.
7. There is a need to evaluate whether there is actually any ground level requirement for Bt brinjal at all, particularly given the fact that several farmers' groups have strongly protested the introduction of the same.
8. If the above need is established without doubt, then long term studies that adhere to the highest ethical standards must be conducted to assess biosafety, social and economic impacts, environmental impacts, and human health impacts.
9. With respect to socio-economic studies, the first step would be to undertake an indepth analysis of the experiences with Bt cotton. This study must be conducted by an independent agency chosen in consultation with NGOs.
10. Following this, then a comprehensive, large scale impact assessment study needs to be conducted. This study can be developed and conducted by a coalition of academic institutions and NGOs. This study needs to address the at least following concerns:

- Risk of negative effects on environment and health:
  a) What are the possible negative consequences?
  b) What is the probability that these negative consequences occur?

- Is it reasonable to say there is a need, by demand, in one way or another, for the product?

- Is it reasonable to say the product can solve, or contribute to solve, a problem for the society?

- Is it reasonable to say it is considerably better than corresponding products already on the market?

- Is it reasonable to say that other alternatives are better than the product regarding solving, or contribute to solve, the actual problem for the society?

- Does it contribute in making new employment opportunities?

- Does it contribute in making problems for existing production that otherwise should have been preserved?

- Does it contribute in making problems for existing production in other countries?

- Is approval/prohibition of the product, its production and use, trade and marketing, in accordance with the general public normative opinions and values?

- Is the product and its production in conflict with ideals of solidarity and equality between humans, especial taking into account susceptible or weak groups in the society?

- Are the product and its production in conflict with the intrinsic values of animal species?

- Does the production imply any unnecessary suffering for animals?

- Does the production imply that any barriers between species is exceeded in ways that are distinctively different from what usually happens when breeding, or in the wild, and that it is considered incompatible with the value and importance of separate species?

11. The socio-economic impact study must include a careful comparative analysis of the costs of production of Bt brinjal, of potential markets and market values, and of the possibility of its commercial release enhancing existing societal/global inequalities.

12. There should also be an assessment of ecological, affordable and farmer controlled alternatives available to Bt brinjal.

13. Any decision about the approval of large scale trials or commercial release of Bt brinjal must be contingent on a nation wide consultation of farmers' groups and environmental groups.

The Technical Committee reviewed my report and recognised the importance of points 10 to 13 and constituted a sub-committee to undertake a detailed study on the experiences with the existing varieties of Brinjal and feed that to further decision making on Bt Brinjal. Members of the committee included:

- Dr. Mathura Rai, Director, Vegetable Research Institute, Varanasi
- Prof. M. N. Murthy, Director, Institute of Economic Growth, Delhi
- Prof. S. Parasuraman, Director, Tata Institute of Social Sciences, Mumbai.

The Sub-committee met in Varanasi on 6th October 2007 and developed Terms of Reference and methodology for the study. This study was to be done by institutions of Indian Council of Social Science Research (ICSSR Institutions) with funding from the Government of India (certainly not from MAHYCO). But the study was never commissioned nor done. It is important that basic studies on Brinjal and issues related to Bt Brinjal must be done by independent agencies and informed decision made based on the knowledge base.

I request you to provide time to carry out basic socio-economic and technical studies by independent institutions before giving approval to Bt Brinjal.

With regards,
S. Parasuraman
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Tel: 022 2552 5200 (o) / 9223214951

Observations on submissions
Large Scale Field Trials of Bt Brinjal
By
S. Parasuraman
Member, Technical Review Committee for Bt Brinjal

1. Terms of Reference of Committee

1. To evaluate comments received from various stakeholders vis-à-vis the biosafety data generated by the Company and available scientific/technical data/literature from studies conducted by various national and international institutions.
2. Suggest additional studies (if any) to be conducted).
3. To evaluate the adequacy of the protocol proposed for LST and recommend additional safeguards (if any).
4. Recommend protocol for socio-economic studies.
5. Any other recommendations on related aspects.

2. Potential benefits of Bt brinjal

1. Increase in yield due to lowered incidence of fruit and shoot borer.
2. Decreased use of external pesticides/insecticides. This has health and environmental benefits, and is also supposed to reduce production costs.

3. Questioning the validity of MAHYCO's submissions

- Most of the biosafety studies were done by MAHYCO.

- The studies done by the 'independent' institutes seem to have been sponsored by MAHYCO. It is certain that MAHYCO sponsored at least six studies (conducted by Intox Labs and Rallis India), and it is likely that MAHYCO sponsored the others too.

- None of these studies are published or peer-reviewed.

- There seems to be a very distinct possibility that the study results were reproduced from elsewhere. In the summary[1] of a study on acute toxicity of Bt brinjals in rats put up on the GEAC website for public comment, it is reported that the one control group of rats was fed on non-transgenic ***cotton***[2]!!! When this gaffe was highlighted by an NGO, MAHYCO defended itself saying that this was a **typographical** error!! It is difficult to accept that the transformation of *brinjal* to *cotton* can be attributed to a typing mistake.

- Another giveaway is found in MAHYCO's clarifications to the NGO comments (Document 3, page 43). In what was meant to be removed while editing, the person answering a question regarding baseline susceptibility levels of the pest, has within

[1] , http://www.envfor.nic.in/divisions/csurv/geac/brinjal_part-I.pdf
[2] The control group ought to have been fed with non-transgenic *brinjal.*

parentheses included the following line - "Pl (sic) check and ensure that MIC 95 values[3] are consistent with other replies already field (sic) with GEAC" - Why the value provided by the person answering the question might be even remotely different from or inconsistent with that provided to the GEAC if they were the results of the same study is unclear. Is MAHYCO making up test result values to suit the situation??!

- Some of the studies published in journals provided in support of MAHYCO's arguments were conducted by employees of Monsanto[4]. One of the studies was funded by USAID[5], another important promoter of the Bt brinjal project in India. Yet another was partly funded by Monsanto.[6] Another study was labeled as an advertisement as per US legislation as the authors paid the journal page charges to publish it[7].

4. At the outset

- It is very telling that among all the NGO and other civil society submissions, only one group has argued in favour of Bt brinjal, and this happens to be a group that is involved in GE (Genetic Engineering) technology. Every other organization – environmental groups, women's groups, farmers' groups, consumer groups – none of which have a vested, commercial interest in Bt brinjal, have expressed very strong reservations about the project, and have urged that the approval for the large scale trials not be given.

- The summary document provided by MAHYCO states that the full reports of the biosafety studies are provided as separate attachments (Attachments 1 – 17). However these attachments have not been provided. The full reports have not been made public as well. Further, the attachments that go with the submissions of the Centre for Sustainable Agriculture are also missing.

- No long-term studies[8] have been conducted. It is well established that several types of damage to the natural environment and human health occur only over an extended period of time with sustained exposure to the toxin, or a combination of them. It is also established that adverse consequences can accumulate without any external symptom till a certain point of no return is reached, in which the entire system collapses – ecosystems exhibit Prigoginian self-organization, as recognized by complex systems theory. A classic example is that of the development of the hole in the ozone layer. Therefore, what must be recognized is that the various acute and sub-chronic studies conducted to assess biosafety are highly inadequate and are not conclusive at all. There does not exist any substantive and definitive information/data about the long-term, chronic and cumulative impacts of GE brinjal, in particular and GE crops, in general, whether it is to do with food safety, effect on ecosystems, contamination, pollen flow etc. This cannot be overlooked.

[3] These refer to the level of toxin required for control of the target pest.
[4] Head et al, 2002; Betz et al, 2000; Sims et al 1996
[5] Krishna and Qaim, no date.
[6] Hossain et al, 2004.
[7] Hoffmann et al, 1988
[8] The sub-chronic studies are of the longest duration (except for the agronomic trials); they are of ninety days length.

- The above characteristic of natural ecosystems demands that the Precautionary Principle be followed with respect to decisions about transgenic organisms.

- The Green Revolution showed how even the most scientifically validated procedures can be unpredictable and have disastrous consequences over the long-term. Therefore, introducing another high-tech procedure into Indian agriculture which could have unpredictable consequences,[9] where there is minimal need for the same, seems unwise.

- Only the protocols and summaries of the biosafety studies have been made public. These summaries do not include the statistical data from which the results were inferred. Therefore, an informed evaluation of the studies by the public is not possible. Data from the agronomic trials also have not been statistically analysed.

- There is an on-going Supreme Court case on biosafety and the introduction of genetically engineered organisms. The interim verdict of 22 September 2006 has imposed a ban on all field trials of GE crops.

5. Socio-economic Considerations

a) Need for Bt brinjal

- MAHYCO has not provided any data to substantiate their claim that production of brinjal in the Indian subcontinent (among other regions) has been 'seriously affected' by the 'steady increase in insect pest infestation, especially the fruit and shoot borer (FSB)'
- If anything, field reality indicates that market availability of brinjal is more than adequate, and in fact, any increase in yield could result in a drop in prices, thus affecting farmers adversely.

b) Production Costs and Patenting

- Organic, Integrated Pest Management (IPM) and No Pesticide Management (NPM) techniques of farming have been dismissed by MAHYCO as being too expensive. However, no data comparing production costs of Bt brinjal and of IPM/NPM/organic brinjal has been given. There is thus no guarantee that Bt brinjal will not be as expensive or perhaps more expensive than these techniques.
- Further, if the farmer chooses to follow organic or NPM techniques of pest control, then these would control the FSB as well, thus negating the need for Bt brinjal.
- Farmers will not be able to save or exchange seeds. They will have to buy seeds every season (these seeds are expected to cost 5 times as much as non-transgenic brinjal) therefore increasing their financial investments.
- Farmers in India historically have developed varieties of brinjal and have saved and exchanged seeds according to their needs. The introduction of patented Bt brinjal will threaten farmers' seed sovereignty and put them at the mercy of seed companies from which they will have to buy seeds every season.

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[9] Especially when there are inherently safe techniques already available. GE technology is similar to nuclear technology.

- It is also likely that Bt brinjal seeds are accessible only to economically stable farmers, thus increasing the gap between the classes.
- No data has been provided on the actual costs of Bt brinjal production, along with comparative figures (non-bt, organic and NPM).

c) Labour Issues

- In a country like India where unemployment is rampant, it is socially more equitable to promote labor intensive techniques like organic farming and NPM rather than high technology solutions like transgenic crops.

d) Experiences with Bt cotton

- There are reports that farmers in Andhra Pradesh have incurred severe financial losses because of the exorbitant prices of the Bt cotton seeds along with crop failure. The AP government had to promulgate an order forcing Monsanto-MAHYCO to reduce prices by more than half after they refused to compensate farmers for crop losses.

e) Export markets

- Bt brinjal will not be acceptable to several countries, including many members of the European Union, as it is genetically engineered, and as it has genes that code for antibiotic resistance.
- The danger of contamination is also likely to damage export markets of other crops as well.

f) Socio economic studies submitted by MAHYCO

- The study done by Mark Chong involved the presentation of the risks and benefits of Bt brinjal to farmers, who were then asked to respond to questions relating to their risk perception. The study states upfront that that the farmers were generally unaware of transgenic crops. The reading out of risks and benefits is far too theoretical and removed from ground reality. 10 farmers who were inter viewed were present at a MAHYCO organized farmer's day. Through all the interviews, a MAHYCO representative was present. Since the sampling was non-random (convenience sampling!!), the choice of farmers could have been influenced by the MAHYCO representative. The scenario read out was just five minutes long; it was completely hypothetical, and not experience based; therefore the perception of economic benefits was also completely hypothetical, based on the scenario. Concepts like resistance, contamination etc, may have not been understood by 'uneducated' farmers in the five-minute scenario. The study anyway compared only moral risks versus economic benefits – role of morality in risk assessment, a very narrow theme in the debate over GM. The scenario presented was also very sketchy – it just dealt with environmental impacts in general; nothing about damage to human health, gene transfer etc. Therefore, the study is not an adequate assessment of the impacts of Bt brinjal and farmers' preferences.

- Krishna and Qaim's study was sponsored by USAID, a principal promoter of Bt Brinjal in India. Data from MAHYCO field trials was used in analysis. The study just looks at 'Willingness to Pay' (WTP) and concludes that the farmer would be willing to pay 4 times to amount paid for conventional brinjal; it adds that when the public sector produced seeds are released, WTP will reduce by 35%, thus requiring reduction of private sector prices to prevent loss of market space, but yet, potential for profit-making exists. In the study, only the benefits of Bt technology– higher yields and lower pesticide costs – were presented to the farmers, and dichotomous answer choices were given, not open-ended questions.

6. Environmental Issues

a) Effect on non-target organisms

- Non-pest lepidopterans could be affected by the Bt toxin (Cry1Ac). It has been documented that the monarch butterfly has been affected adversely by transgenic (genetically engineered) corn. While MAHYCO maintains that other studies have questioned this finding, they have not produced any paper relating to these studies. Further, while it may true that no endangered lepidopteran species exist currently in India, there is not guarantee that the proliferation of the Bt gene and Bt brinjal will not lead to the endangerment of the species currently not endangered.
- The toxin may be transferred to organisms that feed on pests that have ingested the Bt protein. Bioaccumulation cannot be ruled out, with the concentration of the toxin increasing as it moves higher up the food chain. Thus the entire ecosystem can be affected.
- There are studies that show that the Bt toxin has adverse long-term effects on beneficial organisms like earthworms.
- The death of 1600 sheep in AP after consumption of Bt brinjal stalks has yet to be resolved. The feeding tests by MAHYCO on goats, cattle, chicken and fish do not simulate real life conditions where the animals may feed on any part of the plant (not just the fruit), and may also consume it in larger quantities[10] than those studied in the lab tests.

b) Gene transfer

- The potential for uncontrolled transfer of the gene exists as brinjal is a cross-pollinating plant and several wild varieties of the same exist in India.
- Small farmers are not likely to follow the conditions regarding the buffer zone to prevent cross-pollination as this would have economic consequences. Lack of farmer literacy is also likely to make the adoption of the necessary biosafety measures less probable.
- MAHYCO has not established that cross-pollination will *not* occur; they just contend, without providing any data, that the chances of the same are low. This is not consistent with the fact that brinjal could have a potential cross-pollination rate of up to 48%.
- Cross-pollination and transfer of the gene could have two consequences – a) loss of biodiversity of the brinjal plant as the hybrid with the cry1Ac gene could have an evolutionary advantage b) aggressive growth of the hybrid (likely if the crossing takes place with a wild variety)
- Transfer of the nptII and aad genes that are also inserted in the Bt brinjal plant to bacteria in the soil or in the human gut could result in making these bacteria resistant to streptomycin, kanamycin and neomycin, antibiotics that are widely used in India. While this danger is dismissed on the grounds that the *probability* of such transfer is minimal, what must also be considered are the *consequences* of such transfer in India where these drugs are used widely, with streptomycin being used to treat TB. Therefore, an assessment of the risks must engage

[10] Especially when there is market wastage.

with the scale of the disaster if such a transfer occurs, and not merely with the probability of the transfer.

- The fact that these genes are derived from other bacteria make them more capable of transferring than genes found naturally in plants. Therefore studying plant models to predict potential of transgenic gene transfer is not very valid.
- The risk to biodiversity of brinjal varieties because of gene transfer is all the more higher as India is the Centre of Origin of the brinjal plant. No other country in the world has permitted the release of a GE crop if it is the centre of origin of that crop. The Cartagena Biosafety Protocol to which India is a signatory requires extra caution to be taken when impact assessments of GE crops in their Centre of Origin are made.
- The effects/potential for gene transfer to other organisms (plant or animal) cannot be determined with the short-term studies conducted by MAHYCO.
- The likelihood of gene transfer is enhanced by the fact that these genes are specially designed to cross species barriers.

c) Contamination of brinjal population with the Bt gene

- Despite the efforts at containment, the experience of Bt cotton has showed that widespread contamination is almost certain in the case of Bt brinjal as well.
- Bt brinjal seeds could spread in an unchecked manner.
- With respect to Bt cotton, the situation is such that it is no longer possible to tell with certainty (unless tested) where a particular crop has Bt plants or not. This contamination can be directly attributed to the failure of the regulatory system, which was unable to check the spread of unauthorized transgenic cotton seeds.
- This contamination could have serious consequences as it has now become impossible to trace the location and effects of the Bt gene in the cotton plant; Bt cotton is spread all over.
- It is only almost too certain that a repeat of this situation if likely with Bt brinjal.
- It must be noted that contamination or gene transfer is IRREVERSIBLE.

d) Degradation of the Bt protein (cry1Ac) in soil

- The study was done by MAHYCO
- Another independent study[11] published in a journal that was used to counter the NGO contention that the Bt protein could indeed persist in the soil only shows that Bt toxin does not persist in high amounts in the soil but low amounts may persist for several weeks or months.
- The Bt toxin is purportedly toxic only to lepidopterans. Brinjal is susceptible to several other pests, all of which would have to be controlled by other techniques – insecticides/organic/IPM/NPM.
- The above fact implies that there could be in effect no real reduction in use of pesticides.
- The question of if whether there will be an increase in other pests if there is overall reduction in pesticide use also remains unanswered.

[11] Palm et al (1996) Persistence in soil of transgenic plant produced Bacillus thuringiensis var.kurstaki delta-endotoxin, *Canadian Journal of Microbiology*, 1258-1262

e) Development of resistance to Bt toxin

- It is admitted by MAHYCO that resistance of the target pest to the Bt toxin can only be delayed.
- Reliance on a single gene for pest management is believed to lead to greater resistance in the target pest.
- This requires adoption of stringent resistance management strategies such as creation of a non-Bt refuge, regular resistance and base-line susceptibility[12] monitoring etc.
- The creation of refuges has economic implications for small farmers.
- Monitoring is recognized to be problematic in India where the regulatory system is not adequate[13]. Monitoring and regulation systems have failed in the case of Bt cotton in India.

f) Human health

- The concept of 'substantial equivalence' introduced by the WHO (1991) has been used to assess the food safety of Bt brinjal. However, since then, further academic work has led to the recognition of the fact that application of 'substantial equivalence' is not adequate to assess food safety as it takes into account only molecular composition, and not structural variance.
- The fact that external Bt formulations have been used safely as pesticides over the last few years has been used by MAHYCO to infer that Bt brinjal would be safe too. However, this inference ignores the fact that these external formulations degrade relatively quickly due to ultraviolet activity and lose most toxic activity within two weeks. They can also be washed off before consumption. In the transgenic brinjal, however, the Bt toxin is produced be nearly every cell of the plant for its entire life.
- Brinjal is the first vegetable crop (widely consumed by humans) that is being subject to genetic engineering. Hitherto, all GE crops have been mostly produced by animal feed or for highly processed, low-consumption items like oil.
- Ayurvedic doctors have expressed their concern over the introduction of Bt brinjal and the effect it could have in ayurvedic formulations with brinjal.
- Several developed countries have banned GE food crops, and foreign food companies have provided commitments that they will not use GE ingredients in their products.
- The Bt toxin in its natural state is supposed to be non-toxic to human beings as the human gut does not have the receptors required for their binding. However, experiences with GE peas have showed that the introduced protein, though safely consumed in their natural state in beans, exhibited allergenic properties in peas[14].
- The effects of genes inserted by unnatural methods are extremely variable.
- One of the toxicity tests reports that the limiting dose of 5000 mg/kg body weight does not cause any toxicity in rats. If the limiting dose is the upper limit, and doses above it could be toxic, then this implies that consumption of a medium size brinjal by a 50 Kg human being could be hazardous!
- Another test reports that the no-observed-adverse -effect-level (NOAEL) of Bt brinjal in rats is more than 1000 mg/kg body weight. This implies that a person weighing 50 kg a day eating a quarter of a brinjal a day may be at the risk of being in danger!

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[12] Of FSB larvae to the toxin

[13] In all fields, not just GE organisms.

[14] Prescott et al (2005) Transgenic Expression of Bean alpha-amylase Inhibitor in Peas Results in Altered Structure and Immunogenicity, *Journal of Agricultural Food Chemistry*, 9023 - 9030

- The above two examples reiterate the need to have the biosafety tests conducted and evaluated thoroughly by independent experts without any **financial interests** in transgenic crops.

7. Validity of the biosafety study protocols

- The protocols of the various studies – for instance, with respect to pollen flow, toxicity, allergic potential – are questioned by independent observers on scientific grounds. For instance, the concept of substantial equivalence is considered by many scientists to be an inadequate measure of biosafety[15]; none of the protocols estimate inter-generational hazards, pollen flow studies[16] were done at only two locations whereas it is well known that pollen flow varies with local conditions like wind, insect lead and activity etc.
- MAHYCO's only defense was that these protocols were approved the regulatory body. This hardly addresses the concern that these protocols are faulty/ inadequate.
- It is also unclear whether MAHYCO has provided responses to the concerns raised by NGOs, and whether these responses have been evaluated by the NGOs. Providing clarifications to the committee members alone is not adequate, and these responses must be given to the agency that posed the concerns so that they can interpret and evaluate the same.
- All the studies were short-term, and most adverse consequences like multi-generational effects, reproductive health effects etc. cannot be determined with these.

8. Ethical issues

- The conduct of several animal studies, most of which involved extreme pain to the experimental animals and *all* of which involved termination of the experimental animals for post-mortem studies, is highly questionable on ethical grounds especially when *none* of them offer any *conclusive* evidence about the biosafety of Bt brinjal.
- None of the studies was long term, and further, it is being increasingly recognized that animal models cannot be conclusively extrapolated to human beings. This throws further shadow on the conduct of these experiments, which can be likened to the Nazi experiments on Jewish prisoners in concentration camps (all conducted in the name of science, and for the advancement of medicine and human health).

9. Other issues

- The lack of an adequate regulatory system, and the high possibility of contamination is going to lead to a situation in which the GE status of the crop is going to be indeterminate. Labeling of GE products will be difficult to enforce. It will be impossible to ascertain if any particular product has a constituent that is of GE origin – for instance, the GE status of maize in cornflakes, or if cotton in a shirt! Consumer choice, therefore, would be seriously affected.
- It is not clear who has liability if anything goes wrong. The Bt cotton debacle is yet unresolved.
- The increasing acceptance and recognition of organic and NPM techniques in the Indian agricultural sector has been completely ignored by the promoters of Bt brinjal, despite

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[15] It does not examine the structural variance of the same protein in different organisms, and this structural variance could cause allergies and immunological reactions.

[16] To estimate likelihood of cross pollination.

exhortations by farmers' groups to conduct comparative studies between these techniques and transgenic crops.

10. Other studies/submissions

- A researcher from the **Salk Institute** has submitted a letter expressing strong reservations about the introduction of Bt brinjal.
- The Health and Family Welfare Secretary has requested the GEAC to examine whether there are any economic or technical justifications for the introduction of a transgenic crop before sanctioning the same. This request has come in the context of concerns raised over the introduction of Bt brinjal in India.
- The fine print of the study[17] submitted by MAHYCO to substantiate their contention that the Btk toxin does not persist in the soil actually reveals that the Bt toxin does not persist in high amounts in the soil but low amounts may persist for several weeks or months. It is added that 'the persistence of the Btk toxin may be of concern if any nontarget organisms are affected at low dosages or if repeated use of Btk-producing plants causes an accumulation of the toxin'. This contradicts MAHYCO's contention that no Bt toxin persists!
- Another study[18] submitted to support MAHYCO's argument that no gene transfer to intestinal microflora occurs in the human gut also reveals a different picture when the fine print is scanned. This study says that three of the seven ileostomists studied showed evidence of low-frequency gene transfer from GM soya to microflora in the small bowel before their involvement in the experiment. Their only conclusion was that this transfer did not occur during the experiment, not that transfer did not or will not occur at all.

11. Proposed Large Scale Trials

- The protocols for the large scale trials does not detail the acreage, the location etc.
- The protocols state that only company officials or government nominees will be allowed access to the trial plots and records. This is highly problematic as it does not allow for independent monitoring.
- MAHYCO is requesting permission for commercial seed production even before the trials are over and GEAC approval for commercial release is granted. Further, it requests permission to use farmers' fields for seed production. This poses immense threats with respect to contamination. Withdrawing/destroying the seeds in the case GEAC does not grant approval will be next to impossible, and therefore, permission for seed production should not be granted at this juncture.

12. Recommendations

1. Approval for the large scale trials **must not be granted** as existing information about the safety, need and impacts of Bt brinjal, in particular, and transgenic crops, in general, is not adequate. In keeping with the National Environment Policy 2006, the Precautionary Principle must be adopted with respect to taking decisions about transgenic crops.

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[17] Palm et al (1996) Persistence in soil of transgenic plant produced Bacillus thuringiensis var.kurstaki delta-endotoxin, *Canadian Journal of Microbiology*, 1258-1262

[18] Netherwood et al (2004) Assessing the survival of transgenic plant DNA in the human gastrointestinal tract, *Nature Biotechnology*, Vol. 22, No. 2, 204 - 209

2. The Precautionary Principle must be adopted when there is:
   - Doubt about the cause end effect connection,
   - Doubt about the probability estimates,
   - Doubt about the risk assessment,
   - Doubt about cumulative consequences and long term, and/or
   - Doubt about whether restrictive and management measures are working as expected
3. All the biosafety/other studies conducted by or for MAHYCO must be made public in their complete form – the entire report, and not just the summaries.
4. These studies must be peer-reviewed and subject to evaluation by external experts.
5. The regulator, in consultation with NGOs, must appoint a non-interested third party expert to conduct independent studies on Bt brinjal.
6. The clarifications to the feedback provided by NGOs on the studies conducted must be shared with the agencies that posed the queries so that the validity of MAHYCO's responses can be evaluated.
7. There is a need to evaluate whether there is actually any ground level requirement for Bt brinjal at all, particularly given the fact that several farmers' groups have strongly protested the introduction of the same.
8. If the above need is established without doubt, then long term studies that adhere to the highest ethical standards must be conducted to assess biosafety, social and economic impacts, environmental impacts, and human health impacts.
9. With respect to socio-economic studies, the first step would be to undertake an indepth analysis of the experiences with Bt cotton. This study must be conducted by an independent agency chosen in consultation with NGOs.
10. Following this, then a comprehensive, large scale impact assessment study needs to be conducted. This study can be developed and conducted by a coalition of academic institutions and NGOs. This study needs to address the at least following concerns:

- Risk of negative effects on environment and health:
  a) What are the possible negative consequences?
  b) What is the probability that these negative consequences occur?

- Is it reasonable to say there is a need, by demand, in one way or another, for the product?

- Is it reasonable to say the product can solve, or contribute to solve, a problem for the society?

- Is it reasonable to say it is considerably better than corresponding products already on the market?

- Is it reasonable to say that other alternatives are better than the product regarding solving, or contribute to solve, the actual problem for the society?

- Does it contribute in making new employment opportunities?

- Does it contribute in making problems for existing production that otherwise should have been preserved?

- Does it contribute in making problems for existing production in other countries?

- Is approval/prohibition of the product, its production and use, trade and marketing, in accordance with the general public normative opinions and values?

- Is the product and its production in conflict with ideals of solidarity and equality between humans, especial taking into account susceptible or weak groups in the society?

- Are the product and its production in conflict with the intrinsic values of animal species?

- Does the production imply any unnecessary suffering for animals?

- Does the production imply that any barriers between species is exceeded in ways that are distinctively different from what usually happens when breeding, or in the wild, and that it is considered incompatible with the value and importance of separate species?

11. The socio-economic impact study must include a careful comparative analysis of the costs of production of Bt brinjal, of potential markets and market values, and of the possibility of its commercial release enhancing existing societal/global inequalities.

12. There should also be an assessment of ecological, affordable and farmer controlled alternatives available to Bt brinjal.

13. Any decision about the approval of large scale trials or commercial release of Bt brinjal must be contingent on a nation wide consultation of farmers' groups and environmental groups.

YAHOO! INDIA MAIL Classic

Fw: bt-brinjal Tuesday, 9 February, 2010 10:28 AM

From: "Jairam Ramesh" <mosef@nic.in>
To: rammoolam@yahoo.co.in

----- Original Message -----
From: Director, CDFD
To: Jairam Ramesh
Sent: Friday, November 13, 2009 3:39 PM
Subject: Re: bt-brinjal

CDFD/Dir/Gen3(2)
November 13, 2009

Shri Jairam Ramesh
Hon'ble Minister for Environment & Forests
Government of India
Paryavaran Bhavan
CGO Complex, Lodhi Road
New Delhi 110 003
E-mail: mosef@nic.in

Dear Sir,

Thank you for your reply acknowledging my letter to you dated 28.10.2009 on the Bt brinjal issue. As requested, I am giving below a summary of my views and what we should be doing now.

1. ***On Bt brinjal:*** I reiterate that the Expert Committee-II (EC-II) report is an excellent, cogently reasoned, scientific document and that the GEAC's recommendation based on the report is fair. Ordinarily, I would have urged that the GOI immediately accept and implement the recommendation, but since you have now already proposed consultations in Jan-Feb 2010, I suggest that the GOI decision in favour be made as soon as possible thereafter. One could argue that the concept of "equal time" to all parties has been more than adequately met even as of now, as is clearly brought out in the EC-II report.

It is also upsetting that some distinguished critics, in interviews to the media, have stated that the GEAC decision was tainted by extraneous influences on its members. This is an instance of hitting below the belt.

2. ***In the long term:*** I have recently argued (in *Current Science*, 25 June 2009) that the time may have come to disband the GEAC and RCGM mechanisms for monitoring GMOs. These Committees were created following the apprehensions that were expressed in the Asilomar Conference of 1975 when GMOs had first become technically feasible, but none of the apprehensions have materialized since and the

Asilomar recommendations have been progressively watered down over the years. What now exists in India merely serves to impose a high barrier to entry of new products as well as players, because of which for example one does not envisage any competition to Mahyco Ltd on Bt brinjal for many years to come.

In the same vein, I would also argue that the EC-II report, although excellent, was unnecessary in the first place entailing waste of the time of its expert members. In other words, the burden of proof with regard to GMOs ought henceforth to be shifted, so that they are seen as "innocent until proven guilty" rather than the other way around as it is now.

Thank you,

Yours sincerely,

[J GOWRISHANKAR]

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****

On Fri, Nov 6, 2009 at 9:04 PM, jairam ramesh <mosef@nic.in> wrote:

many thanks for communicating with me on bt-brinjal dr. gowrishankar.

may i request you to please send me a note summarising your views and on what we should be doing now in light of the expert committee report (that is available on www.moef.gov.in).

many thanks.

jairam ramesh

सी.डी.एफ.डी. **CDFD**

डी एन ए फिंगरप्रिंटिंग एवं निदान केन्द्र
(जैव प्रौद्योगिकी विभाग, विज्ञान एवं प्रौद्योगिकी मंत्रालय, भारत सरकार का स्वायत्त संस्थान)
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22nd January, 2010

Shri Jairam Ramesh
Hon'ble Minister for Environment & Forests
Government of India
Paryavaran Bhavan
CGO Complex, Lodhi Road
New Delhi – 110 003

Dear Sir,

Sub:- GEAC approval for *Bt Brinjal* – Regarding.

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In connection with the approval of *Bt Brinjal* by the Review Committee on Genetic Manipulation (RCGM) and the Genetic Engineering Advisory Council (GEAC) for the field release, and as I understand that you are presently engaged in public consultation in different parts of the country, I have the following comments to make:

Every modern development, whether it is automobile or antibiotic or nuclear power has its own potential risks and benefits. The man in his quest for better quality life has been exercising prudence to choose the one where benefit outweighs risks. In the case of *Bt Brinjal* 'benefits' are shown to outweigh the "unknown" risks such as effect on non-target organisms, mutations in the gut receptors that render the pest insect resistant to *Bt toxins*, allergenicity of Cry proteins in humans etc. These 'risks' are blown out of proportion by the doubting Thomases who appear to have straight jacketed notions that the food safety and environmental issues are compromised by the scientists, regulators and administrators. I do not mean that the scientists should be allowed to blow their trumpets without close scrutiny by the stake holders and tax payers of the country. At the same time, a small proportion of people with preconceived ideas should not be allowed to prevent the flow of scientific benefits to the society at large. It is like killing the baby before it is being born! This way we will be doing great disservice to the society. The scientific literature is replete with examples of gene transfer from bacteria/virus/pathogens to their hosts (including humans) and vice versa. Such 'transferred' heterologous genes have remained integral part of the genome and are quite often subjected to Darwinian selection. What about the crop improvement programme being pursued by man from the time he embarked upon intensive agriculture? Many genes have been incorporated for specific traits through classical breeding protocols to the present day 'elite' varieties which have occupied the major part of the cultivated area driving many land races/traditional varieties to the confines of germplasm. Then why transgenics with a couple of heterologous genes are held in such a suspicion of "unproven" hazards!

Of course, once introduced to the cultivation scene, the *Bt Brinjal* should be monitored closely for transgene stability, transgene expression, seed purity etc. so that farmers are not taken for a ride. Otherwise, in my opinion, caught in the cobweb of ill-defined debates, we continue to deprive the millions of people in this part of the world of the application of fruits of science. In case of *Bt Brinjal,* for that matter all GMOs remain guilty before being proven to be innocent (although proven to be innocent!).

Thanking you,

Yours faithfully,

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Prof. M S Swaminathan
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Personal

MSS/RM/
4 February 2010

Hon'ble Shri Jairam Ramesh
Union Minister for Environment and Forests
Paryavaran Bhavan
New Delhi
Email: jairam54@gmail.com

Dear Jairam,

Sub: Bt Brinjal

I am glad you had wide ranging consultations, and something useful should emerge from such unprecedented churning of minds and experience. Both benefits and risks are now well known. There are unquestionable benefits in the short term, but also potential risks to human health and our brinjal heritage in the long term. What is the way forward?

1. **Conserve India's genetic heritage in brinjal:**

My post-graduate thesis at IARI in 1949 was on Brinjal and non-tuber bearing **Solanum** species. I have studied our rich genetic wealth in this wonderful crop. What will be the long term impact of numerous local strains being replaced with one or two varieties with Cry1Ac gene from Monsanto? I suggest that during 2010, ICAR (the National Bureau of Plant Genetic Resources) along with Dr Anil Gupta of the Indian Institute of Management, Ahmedabad (he maintains a national data base on indigenous knowledge and farmers' innovations) should both collect, catalogue and conserve the existing genetic variability in brinjal. Such a collection must be carefully preserved, before we permit the extinction of the gifts of thousands of years of natural evolution and human selection.

2. **Assess the chronic effects of consumption of Bt Brinjal:**

The second step which needs to be taken is to ask the National Institute of Nutrition, Hyderabad, and the Central Food Technology Research Institute, Mysore to undertake a careful study of the **chronic effects** of Bt brinjal on human health. This is analogous to the studies carried out on the impact of tobacco smoking on the incidence of lung cancer in humanbeings.

It will be in national interest to complete these two steps before a decision on the release of Bt brinjal for commercial cultivation and human consumption is taken.

With warm personal regards,

Yours sincerely,

M S Swaminathan

Tamil Nadu Science Forum (TNSF)
245, Avvai Shanmugam Salai, Gopalapuram, Chennai - 86

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8 Feb 2010

To
Mr. Jairam Ramesh
The Minister of State for Environment and Forests
Govt of India

The Tamil Nadu Science Forum urges the Minister of State for Environment and Forests and the government not go ahead with grant of approval for commercialization of Bt brinjal.

There should be a moratorium on the release of Bt brinjal because:

1. Precautionary principle should apply considering our lack of knowledge of gene dynamics and protein interactions in the ecosystem and the availability of alternate integrated pest management methods that are sustainable and effective.
2. Steps need to be taken to preserve the biodiversity of brinjal.
3. The tests carried out are inadequate and have not explored medium and long term effects.
4. The procedures followed are non transparent.
5. Conflict of interest exists in the testing process since Mahyco was involved.
6. Measures to safeguard both farmers and consumers against the predatory policies of agribusiness MNCs needed, including price, certification and quality regulations.
7. Any new seed technology should be made available to farmers through the public sector at affordable prices.

Moreover, for the time being there should be moratorium on the release of GM foods, till the above related issues are sorted out.

Krishnaswamy
State President TNSF

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Copy of what i sent to other ID Inbox x

Dr. M. Mahadevappa to me   show details 10:07 AM (3 hours ago)   Reply

Respected Sir,

I do not whether the ID to which I sent my views yesterday is the right one. So I am copying the same matter to this ID. Please excuse me for the inconvenience if any.

To

Sri Jairam Rameshji
Hon Minister for Environment & Forests
GOI, New Delhi

Respected sir,

The unprecedented, rationalistic and historic process of Public Consultations undertaken by your kind self on the issue of commercial release of Bt brinjal in India is appreciated by one and all. I am one of them. But I felt this opportunity could have been better utilised by all, had there been seriousness among some participants.

I am allergic to shouting. Hence I could not make my points clear on 6th. My points are attached in only one page pin pointedly. Please go through and oblige. I will meet you on 10 -11 Feb for different purpose - to invite you to the International conference to be held in Mysore on March 12.

Bt brinjal- Some wrong beliefs due to misinformation

- **GM crops have terminator gene:** *This is not true. Such a gene is still in conceptual stage.*
- **Bt brinjal seeds can be produced and sold only by multinational companies:** *This is untrue. Farmers can be trained to produce their own seeds of Bt brinjal varieties developed by universities. Public organisations will soon come out with their hybrids and private companies will have no claim on seeds of such hybrids.*
- **The traditional varieties will be contaminated and biodiversity disturbed:** *Thisis untrue. Pollination pattern will not change because of addition of a gene. Several varieties have been existing for centuries without disturbing the identity and any new brinjal variety will only be added as accession to the existing germplasm.*
- **Testing is inadequate:** *If this is the reason, a focussed scientific effort needs to be made on fast track to take up tests with definite time frame and concluded. A competent committee should decide this. Delaying their release for reasons which are not scientific is denying farmer the benefit of advanced technology.*
- **Bt contaminates soil:** *Bt is present in soil in natural course even without Bt brinjal. No harm.*
- **No American brinjals, we want only locals:** *All the present recommended ones are locals only but with addition of a gene.*
- **If there has to be a ban on multinationals handling seed business with alternate system, it is welcome. This is possible if concerted effort and adequate support is provided to public organisations.**
- **Bt is only a gene. Most people who particited in the meeting on Feb 6, think some forign variety is being introduced to replace native varities which is wrong. The Bt gene is inserted to native varieties.Other trait of the native varities are intact.**

Conclusion

Can we feed millions of people without an efficient and modern agriculture? At this crucial juncture where we need to produce more food to feed, biotechnology holds a promise. If some more tests are necessary, this can be done on fast track. It is to be realized by concerned that Public institutes should be supported to develop GM crops even before private sectors do it and farmerse trained for seed production and to minimize dependence on seed companies. **We have models prepared by our NGO in Karnataka in 21 districts with GOI and GOK support. It is unfair to deny the innocent farmer the benefit of modern science and technology.**

With respectful regards,

Dr. M. Mahadevappa

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Reply Forward

<u>ANNEXURE – III B</u>

Submissions by Scientists from outside India

GM aubergine in India and conflictual scientific hypotheses for its evaluation - An answer to GEAC report - January 2010

by Prof. G.E. Seralini, University of Caen, Risk Pole CNRS, Institute of Biology, CRIIGEN and ENSSER.

Main points and references

This comment was published in Nature News, November 2009, after the paper « Bt brinjal put on ice ».

Few aubergines varieties have been genetically modified to synthesize a mutated insecticide toxin (16-17 mg/kg) from a chimeric Cry1Ab-Cry1Ac transgenic sequence. There are also two antibiotic resistance marker genes. The process of authorization is debated in India, including in the Supreme Court. In order to study possible health risks, due to a new metabolism, or to the insecticide, it is necessary to evaluate the longest toxicological tests performed with blood analyses in mammals [1]. These are subchronic tests 90 day-long with goats, rabbits, and rats. A first debate is about the possible occurrence of unintended effects on a long term not visible in 90 days. The second debate is about the interpretation of statistical significant differences in the blood and physiological parameters within 90 days between animals eating the GM aubergine and those fed with its closest isogenic variety, used as control. Other various reference groups are added not demonstrated to eat aubergine-based diets of the same composition in the experiments. Among other signs, for instance in goats eating GM, bilirubin and prothrombin time as well as alkaline phosphatase are modified. The two first parameters were also changed in rabbits but also albumin, lactose dehydrogenase, alanine and aspartate aminotransferases... The liver weights were reached among other criteria in GM fed rats.

Similar cases were discussed for three GM maize producing other insecticides or that tolerate the main herbicide Roundup [2-5]. These clear significant differences in the raw data could be a reflect of natural variations for Mahyco company patenting the aubergine [1,5]. On the other hand another interpretation is that it cannot be excluded that these are first signs of hepatorenal toxicities varying according to the sex or nonlinearly to the dose of GM [6]. The only scientific issue is to repeat and prolong these toxicological tests before feeding with GM aubergine billions of people and animals.

1. http://www.envfor.nic.in/divisions/csurv/geac/bt_brinjal.html Raw Mahyco's data (November 2008).
2. Séralini GE, 5. Seralini GE, Cellier D, Spiroux de Vendomois J. New analysis of a rat feeding study with a genetically modified maize reveals signs of hepatorenal toxicity. Arch Environ Contam Toxicol. 2007; 52: 596-602.
3. Doull J, Gaylor D, Greim HA, et al. Report of an expert panel on the reanalysis by Séralini et al. (2007) of a 90-day study conducted by Monsanto in support of the safety of a

genetically modified corn variety (MON 863). Food Chem Toxicol. 2007; 45:2073-2085.
4. Séralini GE, Spiroux de Vendômois J, Cellier D, et al. How subchronic and chronic health effects can be neglected for GMOs, pesticides or chemicals. Int J Biol Sci. 2009; 5: 438-43.
5. Spiroux de Vendômois J, Roullier F, Cellier D, Séralini GE. A comparison of the effects of three GM corn varieties on mammalian health. Int J Biol Sci. 2009; 5: 706-721.
6. Maharashtra Hybrid Seeds Company Ltd.(Mahyco), Mumbai et al. Report of EC-II on Bt brinjal. Submitted to GEAC, october 2009.
7. Séralini GE. Report for the Supreme Court (January 2009). http://www.criigen.org/brinjal

Conclusion of the summary: ***The risk on human and mammalian health is too high for authorities to take the decision to commercialize this GM brinjal.***

Developments
This is a detailed answer to the Mahyco EC-II report submitted to GEAC in October 2009.

Background

Mahyco is explaining in its original file for Bt brinjal deposited to the Indian government that Bt brinjal was developed to produce a new insecticide toxin (16-17 mg/kg). This will not avoid all insecticides spread on the plant since this genetic engineering technique is supposed to produce a specific insecticide, toxic for some species of insects only. Thus, any claimed advantage of this should compare scientifically the toxicity for environment and health of this toxin in Bt brinjal in comparison to the toxicity of the insecticides really avoided (with scientific observations, and not claimed to be avoided) in similar length studies. For instance, the toxicity of most insecticides is known with the help of six month to two years long tests requested by the international regulation processes, which is unfortunately maximally three months for GMOs and associated insecticides including this Bt brinjal. In addition, since the technology could add additional metabolic changes, not visible by the study of the Bt brinjal chemical composition which is not enough detailed, the whole Bt brinjal should only be used in toxicological valid studies in comparison to its closest isogenic control in order to study the effect of the GM transformation and not irrelevant parameters.

Mahyco explains in Toxicity and Allergenicity studies vol. 1 p.32 on 142 that the toxin produced is a chimeric one containing Cry1Ab and Cry1Ac sequences, plus a change on Cry1Ac subsequence. Moreover, this toxin nor its cDNA have been fully sequenced after insertion in Bt brinjal. **CONSEQUENTLY, THIS TOXIN IS NOT EXACTLY CRY1Ac AND SHOULD BE REASSESSED PROPERLY, THIS IS CRUCIAL.**

The first point submitted to GEAC in the EC-II report is thus wrong (it is not exactly the same Cry1Ac gene!).

The other marker genes described in the Background section, such as the antibiotic resistance gene, are unnecessary and should be removed instead of discussing risks or lack of risks without scientific proofs.

A decision of a committee is not, in any case, a proof of innocuity. The longest toxicological tests in each species should be instead analysed in details. This was performed and clearly reveals numerous side effects showed in the raw data from Mahyco, and not their abstracts. These have been detailed in my first report (January 2009) in comparison to the animals receiving in their diets the best isogenic controls. Other comparisons are irrelevant to study only and precisely the effect of the genetic transformation.

Moreover, any release in the environment will result in an inevitable dissemination that can also be called a genetic pollution, as shown in Europe. This will force the establishment of thresholds of contamination for labelling. No method is described for assays of Bt brinjal in Indian environment and labelling. **The mixture of seeds in the seed containers, machines and factories will be superior to any cross-pollination and thus can pollute any kind of food or feed. The isolation distance of 300m will be useless in this regard. In United States, a sterile GM maize containing a vaccine for pigs has contaminated 500.000 tons of soya because some was remaining in the silo.**

Details and comments

On pages 7/8. It is surprising that Mahyco committee details the insecticides normally sprayed on Bt brinjal, thus indicating its concern on pesticide toxicity and environmental impacts, without studying on a longer term than 90 days on mammals the new pesticide synthesized at high levels by the Bt brinjal.

One could also compare this spray of pesticides with its economy in organic agriculture.

On page 12. It is also indicated that the acute oral toxicity studies began for this file in 2003, one year after pollen flow studies! Is this a responsible behaviour from a big company constructing a toxin-producing plant? Moreover, these are really short term studies on a few days, the 3 month-long studies (still really short) on rats only came in 2005, 3 years after field releases with inevitable contaminations ! And then, nothing longer for toxicity studies!! **We will have in 2010, 10 years after conception, a big hole in health assessment non compensated by any serious study more than 3 month-long with very large field releases ! All the rest of the file is somewhat theoretical on health and environmental assessment on humans and mammals.** Such as the genetic modification characterization if it is not obtained after re-sequencing in many Bt brinjal varieties to study the stability and real nature of the construct, together with the surrounding sequences that were interrupted.

On page 29. In consequence, it is obvious that there is a profound disagreement with Mahyco's conclusion stating that no other safety studies are required. Chronic toxicity studies 2 years-long on rat (studying the risks during the whole lifespan) are thus necessary before giving these kinds of possible toxic aubergines to mammals and humans during their entire life.

On page 33. There is the proof that to demonstrate genetic stability Mahyco did not sequence the insert and flanking regions in multiple Bt brinjal varieties, this is not in the list of the experiments performed. Thus these experiments are highly insufficient, for instance to see if different toxins are in fact produced by the GM plants.

On page 36. It should be underlined that there is no need of gene transfer to other plants or other organisms that could arise, to create a genetic contamination by mixing of seeds and harvests, in real life.

On page 37. The presumed specificity of modified Cry1Ac toxin produced by Bt brinjal towards lepidopteran insects and not harmful to any other non target species including mammals and humans is a legend, not documented by any serious scientific experimental reference. The ecotoxicological experiments summarized are pretty short in regard to possible impacts on biodiversity and not published nor peer reviewed.

On page 40. The soil is considered today as a blackbox concerning microflora in particular. The limited number of studies listed does not allow to conclude that there is no impact on soil with Bt brinjal. For instance, it is underlined that no Cry1Ac Bt toxin is found in the soil. This is almost impossible since roots exsudate this kind of toxin. Thus the specificity and sensitivity of the assays performed, not indicated, should be tripled checked before any conclusion. In particular, it is possible that the method performed only measures natural Bt toxin and not the artificially modified chimeric Cry1Ab-Cry1Ac toxin produced at high levels by the GM brinjal.

On page 43, toxicity and allergenicity, or digestive studies. These studies were not conducted with the real chimeric modified toxin produced and extracted from the plant, and are thus invalid.

On page 44, nptII studies. This antibiotic resistance marker is useless for food and feed and should be avoided in order to remove these limited and incomplete studies of risks associated to this gene and corresponding protein.

On page 45. The 90 day studies in rats do reveal significant findings that are very surprisingly not discussed (see my Report on January 2009)!!

On page 46. The compositional analysis do reveal some differences (see also my previous Report) and are insufficient to see pesticide residues for instance, and other toxic compounds.

On page 47-48. Studies on animals did reveal significant findings in the first Mahyco file that are not even discussed here. This is a very important problem for Mahyco's credibility and honesty. See previous Reports.

On page 55. EC II admits that the insecticide toxin issued from the inserted chimeric Bt gene is different, even a little, from the toxin tested in some of their studies. This gives power to our argument. Every serious scientist in the field knows that only one amino-acid difference in a protein can cause a genetic disease, a change in stability or toxicity, like for the prion in Bovine Spongiform Encephalopathy. Thus the corresponding experiments and reasoning of Mahyco are invalid. Moreover, the proof of re-sequencing the gene after insertion in 3 GM brinjals cultivated from different sources in three different places (because wild mutations are always possible) is not given at all.

The fact that antibiotic resistance marker genes have been already used in other GM plants is not a proof of the necessity neither a proof of lack of toxicity (see references 2, 4, 5 on page 1 of this Report). **There is not AT ALL history of safe use with traceability of this kind of antibiotic resistance -useless- marker genes in GM for two decades. This is not true. Where is the epidemiological scientific reference? Numerous people are deceasing all over the world from antibiotic resistance.**

On page 58. The limits of quantification and detection of the ELISA test in food and feed are usually dependent on the matrix which is not precised. Moreover, it is given for the Cry1Ac toxin and not for the modified toxin purified and produced from the plant. These limits of assays are thus non valid, implying that there is no proof of lack of presence and / or lack of toxicity of the toxin or its metabolites in food and feed.

This applies for the following studies cited in the EC-II Report.

On the issue 8 on the necessity of long-term studies - The arguments raised by EC-II are not acceptable for the following reasons:

- The international guidelines are still in construction and do not even request 90 day tests on 3 mammals nor traceability; thus the point argued does not mean that it is scientifically serious. A number of products have been forbidden after being authorized because they were found toxic, even if their authorization process has followed to some extent some guidelines.
- The Cry1Ac toxin is not the one produced by Bt brinjal (see above).
- It has not been proved AT ALL safe on mammals on long-term.
- There are millions of chronic diseases in people from unknown origin that could be attributed to GM toxins because of lack of traceability in food / feed.
- We hope to have a lifespan more than 25 years!!
- The modified Cry1Ac extracted from Bt brinjal has not been studied, nor demonstrated as degraded in digestive fluids.
- Other metabolic changes could arise in Bt brinjal due to the genetic modification itself that could not be assessed with a toxin alone, and this must also be assessed on a chronic point of view with the whole food / feed.

On page 59, issue 9. The significant effects are found by Mahyco, but presented only in raw data (ref 1, p.1 of this file) and not in their abstracts! There are between parameters of animals and their proper controls fed with the closest isogenic line. These differences have been already detailed in my Report (January 2009).

- These are statistically significant according to Mahyco raw data.
- The normal physiological range is not a validated well defined concept; it thus should correspond to the proper controls in their experiments.
- The biochemical data are very often disrupted before histopathological changes.
- The transient changes within 90 days could well be signs of a progressive settling of a chronic pathology like a cancer, their transient recovery by organ reactions / transient defenses do not mean that there is no sign of pathology AT ALL !
- Then there is a lie: of course significant changes listed in my first Report are in raw Mahyco's data, the Committee assessing this dossier is urged please to check carefully.

On page 60. The impact on organic farming will be great because of inevitable contaminations if the Bt brinjal is covered by one or several patents, and without careful traceability and insurances in India.

On page 63, point 6. The Bt cotton has not been approved for extensive human and animal consumption. A toxin can be folded and glycosylated or modified differently in a different plant.

On page 64, points 14-16. It is completely wrong: there are significant differences in the raw data in comparison to closest controls, and this gives a holistic view of hepatorenal toxicity that necessitates chronic toxicity studies, by contrast to what is said in point 15. Point 16 is wrong and has already been discussed: there is no history of use with this modified insecticide, different from Cry1Ac, and even Cry1Ac has not been authorized for consumption in mammals. Thus it was never proven as safe (where is the experimental reference on human cells for instance?)

Table answering to my points, p. 69-70... See detailed answers in Annexes of this document. Each time there is a clear significant difference with the closest isogenic control for a parameter in the raw data, Mahyco either concludes that it is « in the range of biological variations », « variations are expected in dynamic biological systems » or « variations were considered as incidental and not related to Bt brinjal treatment ». All that means nothing is not scientifically and medically serious at all and hides the truth. There is no point to make such experiments to conclude like that every time! What do they expect in mammals for pesticide-like effects within three months? That the rats explode or develop a burning cancer? Without measuring specific markers like cytochrome P450, steroids or other hormones, it is very hard to be sure within three months, and any sign of toxicity in comparison to controls should be taken very seriously, and not as a joke: « variations in dynamic system » ! The tests should be prolonged up to two years for chronic entire life studies for rodents in particular, because the health of billions of people and animals is in the game for their entire life!

The fact that an observation was not seen in the other sex (end p. 72) is a reason to find it not biologically relevant for Mahyco!! This is completely wrong! (Seralini et al., 2009, cited in page 1).

On p. 81. Of course the pollen flow depends on the size of the field; this has been concluded by all environmental studies in Europe.

In fact, all Mahyco arguments for the underlined points are empirical and not acceptable. The author maintains his remarks and a contradictory independent expertise is highly necessary in front of the raw data. The laxity of Mahyco's interpretations will be put in the light.

CONCLUSIONS / RECOMMENDATIONS. Because of the above arguments the EC-II report and the commercialization of the Bt brinjal are unacceptable in their present forms, This Bt brinjal release in the environment includes major risks. It is not serious to give to billions of people and animals for their entire life a food / feed that has not been tested more than 3 months with blood analyses. We do not know the long term consequences of the genetic modification itself nor the effects of the modified insecticide toxin produced at very high levels. Moreover there were clear signs of hepatorenal toxicities, among other effects, shown within 90 days by significant differences in Mahyco's toxicological subchronic tests in mammals: goats, rats and rabbits. These are not clear proofs because the tests are too short, but preoccupying enough to forbid Bt brinjal release at this stage.

ANNEXES
ANALYSIS OF DETAILED ANSWERS OF MAHYCO TO MY REPORT, p 66-84 of GEAC report

1/ My name is Prof Seralini and I am from the University of Caen, Mahyco has made two mistakes in this first sentence. This tells long about the precisions of the answers.

First of all numerous criticisms that I have raised in my report of January 2009 have not been answered in GEAC report (for instance the signatures of the research files to be valid, but also a lot of scientific points). The major point is that it could be criminal and a scientific nonsense to wait for final proofs of chronic toxicity within three month tests in mammals. Accordingly, there is absolutely no scientific reference for proven safe chronic consumption for any GMO, nor for Bt brinjal. GMOs are not labeled nor traced in America, no epidemiological serious study can thus be available; and the numerous chronic dietary pathologies observed there may be attributable to any or several food and feed contaminants.

Details answering to annotated remarks in the Table:

Seralini: Bt brinjal has been modified to produce an unknown chimeric insecticide toxin containing Cry1Ab and Cry1Ac modified sequences. In the toxicity tests on target and non-target insects, this chimeric toxin has not been used but instead, an improper Cry1Ac toxin was used because this control was easier. This could also make these tests not valid.

GEAC point in favour of Mahyco : The *cry1Ac* gene inserted in Bt brinjal event EE-1 has been constructed by combining the first 1398 nucleotides of the *cry1Ab* gene (corresponding to amino acids 1 to 466) (Fischhoff *et. al.*, 1987) with nucleotides number 1399 to 3534 of the *cry1Ac* gene (corresponding to amino acids 467 to 1178). The resultant protein encoded by this gene is 99.4% identical to native Cry1Ac from *Bacillus thuringiensis* sub sp. *kurstaki*. This difference of 0.6% is attributed to the difference in presence of one amino acid at position 766 i.e. serine in place of leucine.

S: This has not been proven by resequencing three different brinjal samples after growth in the plant. The transgene described is well chimeric, it was maybe the genetic construction used but several research articles have shown (Bertheau Y.'s group; Buiatti's group...) that commercialized GMOs have mutated sequences during or after insertion in the plant. Moreover, only one amino-acid change in a protein may have a folding and a pathological incidence, like in pathogenic prion or several genetic diseases. The experiences made with the recombinant protein not extracted from the Bt brinjal are thus invalid, because they were made with an improper protein out of a chimeric Cry1Ab-Cry1Ac gene which only resembles to a mutated Cry1AC, this is recognized by Mahyco.

G: The molecular characterization studies (Western blot) have confirmed that Cry1Ac protein expressed in EE-1 brinjal is equivalent to native *B.t.k* Cry1Ac as also Bollgard cotton event 531 already approved in India.

S: Every scientist in molecular and cellular biology knows that a Western blot is not sufficient at all to characterize a protein, anyway this figure is not shown in the file precisely enough, and the protein from Bt cotton has not been assessed for long term consumption.

G: The EC-II concluded that the argument that this protein is unknown is incorrect as detailed characterization has been undertaken. The issue has been raised on the presumptions that the inserted construct is going to produce unknown chimeric protein. Based on the scientific facts, it is evident that large chunk of gene is cry*1Ac* and the expressed protein is also the same as per the experiments shown. Hence the control is appropriate.

S: "Large chunk of gene" is not an entire gene! You are potentially feeding billions of meals with that improperly characterized protein! According to my previous arguments, this is still completely wrong. There are no scientific data of sequencing the transgene appropriately inside the plant, and Mahyco already admits a difference anyway.

2. S: Two unnecessary antibiotic marker genes, called NPTII (neomycin phosphotransferase II) and aad (coding resistance to streptomycin or spectinomycin) have been used in Bt brinjal. Antibiotic resistance is recognized to be a major health problem and the commercialization of such a food should be forbidden.

G: Antibiotic resistance markers have been extensively used in the production of GM plants. The health issues related to antibiotic marker genes have already been addressed by numerous peer reviewed publications and studies as well as reviews by regulatory authorities worldwide such as US FDA, Health Canada, EFSA, FSANZ etc. Though, the antibiotic resistance genes produce enzymes that can degrade antibiotics, it has been well researched and proven that the enzymes from these genes are produced at such low levels that is absolutely ineffective on the antibiotic. Numerous studies have also been carried out on the fate of antibiotic resistance marker from GE plants in digestives tracts. It has been well established that the probability of transfer of transgenic from GM plant material to bacteria (including that normally inhabit stomach and intestine) is unlikely because of a series of well established barriers. All the above is supported by experimental evidence.

The EC-II concluded that the two genes used in Bt brinjal Event EE1 i.e *npt II* and *aad* genes have already been accepted for use by regulatory authorities around the world, such as USA, EU, Australia, Philippines etc and that the crops containing the same have a history of safe use for more than a decade.

S: The facts are 1/ these genes are useless to be added in all cells of a genetically engineered food or feedstuffs, 2/ millions of people are deceased or sick or had amputations because of capture of antibiotic resistance genes in the environment; they did develop antibiotic resistant infections, 3./ all the experimental evidence non referenced above is not in the real life. These genes should be removed before commercialization; this is also the recommendation from European Union.

3. S: Cooked forms of Bt brinjal are supposed not to contain Cry1Ac although the specificity and sensitivity of the assay does not form a part of the dossier. Thus this cannot be accepted as proof that the Bt toxin is not present in cooked Bt brinjal.

G: All cooked forms of Bt brinjal have been tested using ELISA for the presence of the Bt protein, which is an established and accepted method for testing the presence of the protein. The ELISA kit is based on a monoclonal antibody which specifically recognizes Cry1Ac/Cry1Ab antigen only. It will not detect any other Bt protein. The Cry1Ac ELISA plate is highly specific for Cry1Ac residues and Cry1Ab residues in plant extracts. It has a sensitivity of below 1%, i.e. the plate can detect presence of Cry1Ac. The limit of quantification (LOQ) is 0.625 ng/ml and limit of detection (LOD) is 0.046 ng/ml. Further it has been demonstrated that Cry1Ac protein is heat labile and thus is not expected to be present in any cooked form of the brinjal. Thus ELISA results have confirmed the same.

S: This is a convincing answer. However, undetectable secondary metabolites of Cry1Ac or disruptions of metabolism due to Cry1Ac justify completely toxicity experiments with cooked Bt brinjal or food/feed from it.

G: The EC-II was of the view that no additional information regarding toxicity and allergenicity needs to be generated as the Bt proteins have a history of safe use since last more than one century, starting from whole bacteria to purified proteins.

S: Not at all, there is no authorization for adding Bt in food as an ingredient in the world, nor serious chronic toxicity study with a Bt protein in food. And if that was for a Bt protein, that does not exclude effects with this new mutated toxin in Bt brinjal.

3bis S: It is also expected that cooking degrades at least in part the Bt toxin. However there is no information on toxicity and allergenicity of the resulting products.

G: Bt protein behaves like any other protein during the cooking process. Further it breaks down into common amino acids in the digestive system, which are part of the normal diet and are neither toxic nor allergic. The Cry1Ac protein has been extensively tested internationally in various digestive assays and found to be safe.

The EC-II was of the view that no additional information regarding toxicity and allergenicity needs to be generated.

S: To think that every protein is degraded in individual amino acids in the digestive tract is scientifically wrong. There is always a part non digested and smaller undegraded peptides, every physician and person looking at his feces knows that. Once again, the experiments with the improper Cry1Ac protein, as it was admitted by Mahyco's answer above, are not valid for this purpose, unless laxity is admitted. We are not in an approximate proof of a research but in common life potentially feeding billions of humans and animals!!

4. S: Studies for toxicity assessment and nutritional effects in mammals have been limited to a maximum of 90 days period or less, which is not adequate and there is a need for long term studies for assessment of chronic effects.

G: Safety assessment of a GM food crop requires an integrated stepwise and case by case approach. The evaluation of possible toxicity and allergenicity of gene products as well as consideration of the nutritional aspects is undertaken in a comprehensive manner through a multitude of tests. As per FAO/ WHO expert consultations and Codex principles, toxicity studies up to a 90 day repeat exposure study are sufficient to indicate the safety of the GM crops. Similarly, the guidelines have been provided for assessment of allergenicity and comparison of nutritional aspects. The studies undertaken in Bt brinjal comply with the international guidelines as well as ICMR Guidelines accepted by GEAC.

S: The scientific history has been written first believing that the planet earth was flat. Who can believe that a new genetically engineered fruit producing an uncharacterized insecticide may be given to millions of beings without being tested more than three months on rats?

G: The EC-II concluded that no long term studies are required because of the following reasons:

- The Cry1Ac protein inserted into Bt brinjal event EE-1 has been extensively studied for its safety. It has been well established that the Cry1Ac protein cannot cause any toxic effect in mammals because of lack of highly specific receptors and alkaline environment in the gut of mammals.

S: Arguments already have proven wrong above.

- **G:** Cry1Ac protein has a history of safe use for human and animal consumption as GM crops such as Bt maize and Bt potato containing Cry proteins including Cry1Ac protein have been consumed by millions of people without any adverse effects.

- **S:** Arguments already proven wrong above.

- **G:** It has been reported that 90 -110 days of age (mating age) of rats is considered equivalent to 21-25 years age of humans (Laboratory Animals in the Study of Nutrition' in LAIS Centre News- No - 30, 1993).

S: We hope that people will not be living only 25 years anyway, thus it is crucial to prolong the tests; moreover this is a too much approximate calculation. Developing small animals (from gestation to 2 months) should be used also, babies being more sensitive than adults.

- **G:** Cry1Ac protein has shown to be rapidly degraded (in 30 seconds) in simulated digestive fluids and thus is not detectable even in the short term studies.

S: This experiment has not been done with the good protein (see above) which is not the exact Cry1Ac in Bt brinjal, moreover it could be processed differently in the plant than the recombinant protein used in these experiments.

4 Sub-chronic feeding study in Goats

a-S : There was significantly lower hay consumption in Bt group in week 11 in comparison to non

Bt group. The authors of the experiment do not conclude anything problematic from this.

a-G: Inter-animal variability and intra-animal variability at different time intervals in the feed/hay consumption is commonly observed in the feeding experiments. Such differences are expected in dynamic biological systems but such differences should be checked only if they are statistically significantly different. In the present study, there is variability in the feeding pattern of animals at different intervals of time e.g. hay consumption of Bt brinjal treated group males during week 11 was reflected due to decreased consumption in only one male goat. This particular animal has shown similar variability in the hay consumption as seen in the goats with normal diet without brinjal as well as with non Bt brinjal. As the differences were not of any statistical significance, the decreased hay consumption of Bt brinjal treated males during week 11, was considered as incidental and not related to Bt brinjal treatment.

S: The difference pointed out IS statistically significant according to the original Mahyco's file. The authors of the experiment could explain that 1/ It is only due to one animal. 2/ It is not biologically significant. If 1/ is true, that means that there is a crucial lack in the protocol of the experiment taking a dramatically insufficient number of goats, and thus no conclusion can be driven out of this invalid experiment. 2/ There is no proof at all in the experiment that it is not of biological relevance. Any sign of toxicity should be considered since these are dramatically short experiments insufficient to study chronic toxicity. If all statistical signs are neglected one after the other on an arbitrary subjective basis, there is no point at all to undertake such experiments. More investigations are needed.

G : The EC-II opined that it is inappropriate to quote insignificant observations out of context as many such observations seen at one time point do not persist at the next time point or not observed in the other sex.

S: Sorry, but to wait for a persistent sign of toxicity in both sexes is wrong (Seralini et al., 2009), since carcinogenesis or endocrine disruption for instance is settling by waves and sex-differentiated.

b-S: The feeding trial consisting of six male and six female but on page 323 it has been stated that the trial consisted of 6 male and 3 females.

b-G: The phrase reads as 12 animals (6 males and 3 females).
The EC-II noted that this is clearly a typo graphical error. The entire dossier provides data on all six males and six females.

S: Admitted, but not very serious for a commercial file. Proofread please next time.

c-S: The prothrombin time as well as total bilirubin was significantly higher in the GM-fed males at termination, and alkaline phosphatase was significantly lower.

c-G: As regards the prothrombin formation time, the values in the pre treated male goats as well as Bt brinjal treated animals were within the physiological ranges. These marginal changes in the Bt are a normal variation and of no statistical significance. Although some differences were noted in the total bilirubin, AST and ALT values in control Non -Bt brinjal and Bt brinjal treated groups in comparison with the Normal diet without brinjal but even the higher total bilirubin values were within the physiological control range. Additionally, there were no alterations in the hepatic parameters or histopathology of the liver. Therefore these changes were considered as normal variation and not related to Bt brinjal treatment.

S: We are speaking about the statistical differences that I cited, that are not by definition within the physiological variations a priori, otherwise there is no point to do this experiment. The authors of the experiment are confused between significant statistical differences, they always say that these are within physiological variations whatever these are, without demonstration, and they affirm that there is no biological significance. This point clearly cannot be assessed during 90 days only, since any sign of toxicity should be taken into account in this context. Correlations with other parameters may exist or not at the first beginning of a pathology, and if it is the case it may be an indication, but the contrary cannot be BY ANY MEANS a proof of safety. Theoretical reasoning and parameters taken into account are not clear. Histopathological changes cannot be assessed by the referee and the counter-expertise, and thus are not valid to cite.

G: The EC-II noted that no statistically significant changes have been observed in the parameters mentioned and the values are within the normal physiological ranges. Further significant changes given only at a single time point and not given at the end of the study are considered to be transient changes. These changes are also not associated with any histopathological changes and therefore do not warrant any attention.

S: Again, sorry, but transient significant changes within the first 90 days (this is the case) may be signs for settling of a chronic pathology. Who is a medical doctor contradicting that within GEAC or in the world? Who could sign in GEAC that he has examined organs and histopathological slides of this experiment? For any histopathologist a sign may warrant attention. The last sentence reveals, I am sorry, a crucial laxity.

d-S: Growth curve in Bt fed -males are below the others from week 7. They gain a lot less weight. The feed consumption is lot less, even 25% less (week 5) only for this transgenic fed group. This is important although not clearly reported in the summary and obviously significant after curves observation. This appears to be a sex dependent effect like for endocrine diseases. Bt brinjal as an animal feed, or human food that it will be mostly, cannot be considered as safe with such results.

d-G: Barring the intra-animal variability, there is no statistical significance difference obtained in the feed consumption, body weight and body weight gains and the hay consumption (except for the incidence of decrease hay consumption in males during week 11) of Bt brinjal treated group and the Non - Bt brinjal treated group and Normal diet group. The scale used in the growth curves very small, even a subtle change is seen with magnification.

S: Some statistical changes are effectively revealed by Mahyco in the original file.

G: The EC-II noted that the test product findings need to be compared with the concurrent control and/or normal control findings, baseline control data/historical control data and published references wherever applicable and in this study, the generally accepted procedures have been duly complied with.

S: Sorry, but the historical control data do not mean anything in this experiment. In science to raise a conclusion the treated animals should be first compared with the appropriate controls in the experiment, these having similar living conditions and closely related diets, except for the GMO. Once again, it is wrong within 90 days to search for a final proof of toxicity to stop Bt brinjal, we are preoccupied by any sign of toxicity that warrant attention, and then we need to ask for further investigations since billions of lifes will be concerned.

5 Sub-chronic feeding study in rabbits

a-S: There was a reduction of consumption at week 6 in the male Bt group in comparison to non Bt, the GM fed males consumed less in general, in the female group at week 11 (due to one animal, but the groups are too limited in numbers of animals unfortunately to calculate a real statistical significance) as if the Bt brinjals were less palatable. The females consumed less Bt brinjal.

a-G: The data related to food consumption demonstrates that the average food consumption in the Bt brinjal and Non -Bt brinjal treatment group- males were 95 and 104 grams/rabbit/day, respectively. The decrease is very marginal (9 grams) and such variations are expected in dynamic biological systems.

S: A new light is shed with parallel signs occurring in goats, this is preoccupying.

G: In respect of variations reported in the sub-chronic feed study in rabbits (5 a to c), the EC-II opined that in general toxicology and in safety testing, the results are compared between test and control groups. If differences do occur which is but expected in dynamic biological systems such differences should be checked for:

i. Are they statistically significantly different.

S: Yes, we noticed only these ones admitted by Mahyco with the proper closest isogenic controls.

G: ii. If yes, are the values or data in the normal physiological range.

S: This is too subjective to be taken into account since it was not defined a priori. The other controls eating other kind of diets not substantially equivalent but richer or poorer in vitamins, ions, minerals, proteins, amino acids, lipids, sugars... do not represent the physiological range but other treatments.
Thus we cannot answer to that in the protocol or from the back of a head.

G: iii. If there are more than one dose group then one should look for dose dependent changes in the parameters.

S: Absolutely not, sorry, it is completely and scientifically wrong, since endocrine disruption, carcinogenesis, or immune answers for instance are not linear within two doses chosen a priori, which is the case in this protocol.

G: iv. Even if there are significant differences and they are in physiological range then one should correlate biochemical and haematological data with histopathological changes.

S: If this is possible OK, otherwise one should compare the patterns occurring in all mammalian models, which are preoccupying here. Moreover, if there is no correlation at all, never forget that in science and medicine the first signs of any pathology are not correlated, but there can be wild sporadic disruptions of variable parameters. Once again, it is wrong to search for a final proof of chronic toxicity within 90 days; we are just looking for the first signs of a possible chronic pathology, because billions of people are potentially concerned with such a diet during their entire life.

G: v. If there are significant differences and they are outside physiological ranges and they are associated with parallel histological changes e.g. elevation of AST, ALT with liver cell necrosis or changes in haematological parameters with corroborative changes in bone marrow. Then it is assumed that the test material could result in cellular changes. Significant changes given only at a single time point and not given at the end of the study are considered to be transient changes.

S: Of course transient changes should be taken into account and not a priori neglected just because they are transient, it could be an heavy medical mistake to consider that there is nothing to see, without following the experiment after 90 days and during 2 years, like for any chronic search of a side effect for a drug in a laboratory mammal.

G: In view of the above, the EC-II concluded that the findings of the study are in order and the variations observed are not attributable to Bt treatment.

S: There is no reason to conclude that sorry, as explained above. We conclude that there is no proof of toxicity, but possible signs of the beginning of a chronic pathology, and that the experiments should be prolonged in mammals before giving this very new insecticide-producing plant in billions of meals.

b-S: There was at interim blood sampling an increase in albumin and total bilirubin in GM fed males versus adequate controls, and of total bilirubin and lactose dehydrogenase in GM fed females; at terminal blood sampling again a significant increase of total bilirubin in males and females GM fed, increases in hepatic markers alanine and aspartate aminotransferases and sodium levels in GM fed males, a decrease of glucose levels in GM fed females. The authors of the study claim all the above differences as incidental and not treatment related, with no scientifically acceptable reasons.

b-G: The changes in the total bilirubin were normal variations in biological systems. All the values were within the normal ranges and do not signify any organ pathology and hence were considered as incidental and not related to Bt brinjal treatment.

S: All these are very preoccupying changes which are statistically significant changes according to Mahyco (between GM-fed animals and appropriate controls). The reasoning exposed in the previous paragraph is not understandable a priori for all the reasons already explained in a detailed manner by the referee.

c-S: The platelet count was significantly reduced during the experiment as well as mean corpuscular haemoglobin concentration in the blood of Bt fed males in comparison to their controls, an increase in haematocrit value; prothrombin time was increased in females.

c-G: The minor variations in various blood parameters are physiological changes which are observed even in the Normal diet treatment and the Non-Bt brinjal treatment and hence considered as not related to the Bt brinjal treatment. Further the testing lab as well as experts have re-examined the data and informed that all the figures are within the normal ranges (e.g. the normal range of platelet count is between 1,00,000 to 5,00,000).

S: The statistical changes first count between GM-fed animals and their closest controls. This should be considered in relation to disruption of similar parameters in the other mammalian model. The normal range has not to be decided a posteriori independently of experimental conditions, strand, etc... Otherwise there is no need to put controls in the protocol!

6. Feeding study in (lactating, crossbred) cows:

a-S: It has been claimed that Bt toxin is not detected in blood but there was only a short description of the method of detection and its limits and efficiency as well as repeatability were not indicated.

a.-G: The method of detection that has been used is ELISA based on a monoclonal antibody which specifically recognizes Cry1Ac/Cry1Ab antigen only. It will not detect any other Bt protein. It has a sensitivity of below 1%. The limit of Quantification (LOQ) is 0.0625 ng/ml and Limit of Detection (LOD) is 0.046ng/ml.

S: OK, good, but other direct an indirect metabolites are not proven to be detected by this method.

G: The EC-II noted that the test has been standardized by M/s Mahyco and the required information has been provided.

S: OK, but not for the question just mentioned above.

b-S: More milk production (14.3%) by GM fed cows, almost as if they were treated by a light hormone, in 42 days.

b-G: The data clearly indicates that there was no significant difference in weekly yield and feed intake between the cows fed transgenic and non -transgenic brinjal fruits.

S: The power of the statistical method is too bad to detect such changes with such limited number of animals, thus the conclusion is maintained.

G: The EC-II reiterated that insignificant changes have been unnecessarily highlighted.

S: Sorry for GEAC, the necessity is to reveal any sign of problem within a so short period, overall when a committee is legally responsible for giving advices to the government giving authorizations for this product in billions of meals. To my mind, the composition of the GEAC committee is too scientifically light, as well as from a medical point of view, to be maintained as such.

c-S: The ash content of the milk varied significantly for Bt brinjal - fed cows between the second and fourth week, by the end of the experiment they had significantly more roughage dry matter intake (10.5%).

c-G: The variations in ash content in milk in different weeks were also there in cows fed with non-transgenic brinjal fruits.

S: No, we speak about statistical differences with appropriate controls. Look again the results.

G: The EC-II noted that all the values of ash content were within the normal range in both the groups.

S: No, there were statistically different with appropriate controls. Look please!!

d-S: It cannot be concluded from this experiment that there are no metabolic changes after Bt brinjal consumption in lactating cows and thus this feed cannot be considered as safe.

d-G: There was no significant difference between the cows fed transgenic and non-transgenic brinjal fruits and differences in weekly yield and feed intake.

S: Yes there were statistical changes with appropriate controls admitted by Mahyco. Anybody can take the time to check in the raw data.

G: The results of the study clearly demonstrated that consumption of Bt brinjal by cows did not result in any metabolic changes and showed no adverse effects.

S: This is wrong, sorry. Discussed above.

7. Sub-chronic oral toxicity study in (Sprague Dawley) Rats:

a-S: The first experiment of 14 days with rats allowed to the company to test two doses of Bt brinjal is a badly designed experiment from a scientific point of view, increasing control animals by 2 in regard to treated rats. This was unexplained.

a-G: All protocols were designed as per the guidelines issued by DBT and approved by RCGM. Two controls (non-Bt counterpart and commercial Brinjal) were used in the study to demonstrate that there were no differences between non-Bt hybrid developed by the applicant and commercially available Brinjal.

S: In any serious scientific experiment, if GMO potential toxicity is really studied, only this parameter should be changed first. A mixture of substantially equivalent commercial brinjals could have been given in controls, but the number of studied animals should be the same in GM and non GM-fed rats by the end to avoid statistical problems and bad power of discrimination of any effect!

G: (a-b-c) The EC-II noted that increasing control animals in no way affect the scientific credibility of the experiments. The reviewer has unnecessarily tried to correlate common and incidental observations to the effect of Bt brinjal which is very unfortunate and indicates lack of familiarity with the subject.

S: The reviewer has more than 20 years familiarity with carcinogenesis experiments, or toxin effects in vivo in rats, more than 10 years familiarity in assessing commercial files of GMOs as an expert for governments. More than 10 research papers assessing GMO residues toxicity and several books published in major editors on this subject are also in his CV. How many GEAC members have similar experience?

G: For example circling observed due to internal ear infection is a common observation in all rodents in cages and has taken place in both Bt and non Bt group. However, the same has been highlighted only in case of Bt group to mislead the readers about safety of Bt brinjal. Regarding the minor difference in clinical parameters, the EC-II reiterated its observations cited earlier (refer Point 5).

S: The referee didn't speak about that, sorry, read again.

b-S: Circling disorder and diarrhea were noticed only in the Bt brinjal group, males and females.

b-G: Circling was observed in one rat from non-Bt brinjal control group and one rat from Bt brinjal group. This is due to internal ear infection which is commonly noticed rodents housed in cages. This does not affect normal living of rats. Hence it is not related to Bt treatment Diarrhoea seen in only one female and two males out of ten animals in each group of rats, for only four days out of 90 days of study is an incidental observation and not related to treatment.

S: This conclusion is somewhat arbitrary, no further analysis has been performed. An impact on the immune system of a treatment may always render the animals more sensitive to infections. No cytology analysis was available, which is a common analysis when animals are sick in an OCDE standard test.

c-S: Moreover liver weight and relative liver to body weight ratio decreased in the dose range study in females, by 13% apparently significantly. Bt brinjal cannot be considered safe for rats considering these results. For the rats fed with Bt brinjal water consumption was 8-21% more than the non Bt brinjal group for some periods. The significance of this claimed to be null. However, all the scientific committees consulted agree with companies that statistical significant differences have been reported during 90 day studies between control and treated rats with different GMOs on numerous parameters, including blood composition and detoxification organs such as kidneys.

c-G: Minor differences in clinical parameters of Bt brinjal fed animals have been quoted out of context as such variations are fairly common in biological systems. Many observations seen at one time point do not persist at the next time point or not observed in the other sex or not significant against the non-Bt brinjal.

S: 13% of liver weight significant difference, for instance, in comparison to appropriate controls, is not minor at all, but the sign of a mammalian physiology that could have heavy nutritional problems within a so short period. Biological systems should be assessed in comparing in this case GM-fed rats to their closest appropriate controls. Otherwise think about this question: what could be considered as preoccupying for GEAC? Significant differences only at one point out of two in an experiment should be considered as a potential problem to be explored, otherwise a laxist interpretation may lead to a criminal attitude towards billions of people (these tests last 90 days only!). Sorry, but to avoid to consider an effect because it is only in one sex is stupid, non scientific, and criminal also. Numerous hormonal imbalances begin in one sex first, numerous cancers are sex-dependant, and not only for breast or gonads, but liver and kidney are biochemically sexually differentiated (Seralini et al., 2009).

8. Primary skin irritation tests on (New Zealand white) rabbits:

S: Three rabbits only were treated with Bt brinjal on a total of 12; this is not serious at all.

G: In the study, the Bt treatment was compared with three sets of controls, which does not in any way affect the results obtained with Bt treatment. The study was conducted in 2004 as per the "Guidelines for toxicity and allergenicity evaluation of Transgenic Plants", 1998.

S: Sorry, three rabbits only were treated with Bt brinjal on a total of 12; this is not serious at all. To test immune problems seriously in a whole human situation? Revise your physiology.

G: The EC-II concluded that since the non allergenicity of Bt protein has been demonstrated through a series of studies using pure protein...
S: It was proven above that the "purified protein" was not the toxin in the Bt brinjal. This argument is invalid.

G: ...this study is not much relevant and not required as per the new Guidelines for safety assessment of foods derived from GE plants, 2008 adopted by GEAC.

S: This is not correct, as indicated.

9. S: Mucous membrane irritation test and measurement of allergenicity in young adult Brown Norway rats are very limited tests to assess allergenicity for a whole population, a serum bank to assess antibodies potentially reacting with Bt brinjal residues could have been an alternative.

G: Allergenicity assessment is undertaken using a weight of evidence approach based on FAO/WHO Consultation on Biotechnology and Food Safety. Internationally accepted methods such as the source of gene, heat stability, pepsin digestion, amino acid homology testing using bioinformatics have been used in allergenicity assessment of Cry1Ac protein in Bt brinjal.

S: Cry1Ac as such is not present in Bt brinjal, the modified Cry1Ac toxin in Bt brinjal may have reactivity. This was not tested, it is a severe lack in this Mahyco's and GEAC assessment.

G: In addition, allergenicity tests in young adult Brown Norway rats were undertaken as per the regulatory requirements stipulated as per the "Guidelines for toxicity and allergenicity evaluation of Transgenic Plants", 1998.

S: Three animals only are ridiculous in comparison to the goal of immune safety testing that should be reached.

G: The EC-II concluded that the allergenicity assessment of Bt brinjal event EE-1 has been done as per the internationally accepted Codex guidelines. Further, the requirement for testing in young adult brown Norway rats is not mandatory in India as per the newly adopted Guidelines for safety assessment of foods derived from genetically engineered plants, 2008. This requirement has been dispensed with as there are no validated animal models for allergenicity assessment of GM foods.

S: A screening of a patient's serum bank as been proposed by numerous authors in this case; the development of specific allergy tests in humans is also possible for medical doctors.

10. GM brinjal consumption by birds (Feeding study in broiler chickens):

a-S: 40 unsexed chickens received 5% Bt brinjal in their diet, 40 others, 10%, and 200 received different non GM diets. This was not a good design to detect any unintended GM effect in these conditions. In particular 10% is too low a percentage to clearly see unintended effects.

a-G: The experimental design consisted seven dietary treatments with two levels (5 and 10%) each of Bt, non Bt parental and a commercial brinjal along with a corn soya control treatment. Each diet was fed ad libitum to five replicated groups of eight unsexed chicks in both the grown phases i.e. starting 0 to 3 weeks and finishing 4 to 6 weeks phases following completely randomized design. The experimental design is a widely accepted design and many research papers have been published in international journals with the similar design.

S: But still what I have said is exact and several moratoriums have been put in the world; moreover no country has grown nor tested Bt brinjal; moreover other GMOs proofs of safety are widely discussed and generally found insufficient all over the world. These papers have been invalidated by numerous scientists in the world.

G: The test diets contained 5 or 10% brinjal meal in dried powder form as part of total daily diet that for 42 days (starting from 1 day -old to 42nd day) ad libitum without any interruption in between. The 10 g dried brinjal meal in 100g of feed is equivalent to 67 grams of fresh brinjal for a broiler of about 1000g body weight. Hence, these levels of inclusions are much higher than generally consumed by human being.

S: Not within 42 days at all for chronic safety testing, this is the main point of this written debate.

G: (a-b) The EC-II opined that broiler chicken is the representative model and the experimental design is in conformity with the accepted guidelines. The EC-II was of the view that the reviewer has unnecessarily' chosen to highlight insignificant issues. All the six groups have lower and insignificant differences compared to the control group.

S: GEAC always opines Mahyco's assessments in this file, thank you, we all know that. The answer is not relevant, Mahyco's one was better.

b-S: Moreover there is only one species of bird studied for a limited period of time.

b-G: Poultry birds especially broiler chickens are used as model animals for bio-safety studies because of faster growth rate. Also since the broiler chickens are more vulnerable to any toxic / anti-nutritional factor (s) present in feed/feedstuffs they serve as good model animals. S ix weeks (0-42 days) experimental period, when rate of growth is maximum, is sufficient to exhibit the toxicity of any substance, if any. Being rapid growth, 37 times of initial body weight, in the present context, in 42 day old broiler chickens were the most suited birds for conducting this experiment.

S: For environmental assessment concerning non-target species of birds, if bird biodiversity is a concern in India, this is insufficient, sorry.

c-S: The feed intake for GM-fed broilers (10% Bt -brinjal) was 10% lower than in the corresponding control (10% non Bt brinjal in the diet) at different weeks (21-35 days of age) and then higher, the implication of this is a differential metabolism between both groups but the experimental report did not calculate the statistical significance of this difference. The blood glucose was also significantly different in the Bt groups.

c-G: The feed intake for GM-fed broilers was compared statistically week -wise and phase-wise. The mean values did not differ statistically/significantly either when analysed on weekly basis or on phase basis. The blood glucose was also significantly different in the Bt group in comparison to control diet, which was also evident in all the treatments fed brinjal from any source. Therefore, it is the characteristic of brinjal as a whole, not for Bt brinjal alone.

S: The other brinjals are not demonstrated chemically equivalent at all to the Bt brinjal and its control, they may contain less water or more sugars, thus this scientific reasoning is invalid in this case.

G: (c-d) As regards the intra-animal variability in the results, the EC-II reiterated that such differences are expected in dynamic biological system. The EC-II further reiterated its observations in Point 5.

S: If such statistical differences are expected from this design, that means that GEAC opines that potential toxicity signs may be evidenced, since there is no point to consider that all significant results are obtained just by chance only, in a well powerful design of a statistical study. And if this was possible, the contrary also. In order to decide, drastically wrong scientific assessments should be avoided such as: a statistically significant effect has to be present in both sexes to be a clinical sign of a potential chronic pathology, or should be linear to the dose between two doses chosen a priori to be assessed, or the effect has to be outside of the range of any other diet, not chemically equivalent, but containing other brinjals. All these reasonings have been used by error by Mahyco. Sorry to repeat again, but Mahyco finally always uses these arguments at the final points of each experiment of this debate, that GEAC repeats, and that are fully wrong for the all scientific serious community.

d-S: The authors of the experiment write that there is no significant difference due to Bt brinjal consumption by chickens, but these differences lead instead to the conclusion that the Bt brinjal cannot be considered as safe according to this experiment.

d-G: The reviewers have interpreted the results based on the observations and statistical analyses. All the response criteria, related to growth and welfare evaluated in this study were not affected by feeding the brinjal of any source. Neither the heterophile to lymphocyte ratio nor the yield of visceral and immune organs, humoral and cell mediated immune response were affected with Bt brinjal. Hence, the conclusions drawn were based on scientific observations, rather than mere assumptions.

S: There is no other thing for counter-expertise than the raw data of this experiment and Mahyco's statistical analysis. The counter-expertise has been base on pathological / endocrinological interpretation of these data. Going to the raw data, the confidence has been lost with the criteria of interpretation used by Mahyco. All the statistical data between Bt brinjal fed groups and closest appropriate control are confirmed by Mahyco in the raw data, whatever the comments are.

11. Feeding studies on common carps:

a-S: There were numerous unnecessary non-transgenic control groups masking the significant effects between the two closest groups, Bt and non Bt. There were only 6 pools of 60 fishes (360) receiving Bt brinjal in the feed on a total of 24 pools, i.e. 1440 fishes, instead of having two main groups. This disproportion can mask a lot of significant effects if only a small group is compared with all the others.

a-G: The four groups of brinjal used in feeding trial for common carp were taken for better results to actually compare with each other. Secondly, the numbers of fishes per pool were enough (60/pool) for statistical analysis with two replicates (60 + 60 =120) for each test concentration (15%, 30% and 45%) of four groups of brinjal used totalizing 360 fishes for each brinjal feeding trial. Thus, there was no harm to undertake the comparative study of Bt and Non-Bt with other groups of same type of brinjal available in the market. This was taken up for the comparative studies without adversely affecting the objectives.

S: OK, but the point above is not answered. There were two many different non Bt brinjal groups that can mask the results. Instead, Mahyco should have made two equivalent groups in numbers (720), one fed with Bt brinjal, the other fed with a mixture of commercial brinjals equilibrated to be substantially equivalent to the first group (except for the GM character and toxin), in order to assess the effects of several brinjals in comparison.

G: The EC-II opined that the objection of disproportionate sample sizes between treatment group and control group is very unfortunate and unscientific.

S: <u>Thank you, then this experiment is invalid and the effects of Bt brinjal release in the environment is at best unknown because there are no valid studies on aquatic life, and any brinjal cultivation will put Bt brinjal residues in contact with surface waters and finally with aquatic life. A moratorium should be pronounced immediately for Bt brinjal release in the environment. At worse, statistical</u>

signs are real signs of chronic pathology and this Bt brinjal release should be forbidden.

G: Comparison was made with Bt-brinjal group with non-Bt brinjal group, local variety and with a group that does not contain any brinjal. This means the Bt group is compared with three times its size. This is very robust and logical, since data in each group is provided separately with its own statistics reported. No pooling of the control group was done to mask the observations as claimed. Further growth was similar in all the groups, which nullify the possibility of any apprehension regarding the comparison between Bt and non-Bt brinjal.

S: The pooling was not done in the calculations, but in the statistical comparisons and the interpretations, when any significant effect was in the range of any other non chemically equivalent diet, it was considered as null. This is wrong, since a diet with more or less lipids, salts or sugars may induce pathologies as worse as some GM effects.

b-S: Average feed conversion and efficiency ratios were significantly higher in the Bt group versus closest control, at 45% brinjal in the diet. No safety can be concluded.

b-G: The Feed Conversion Ratio (FCR) and Feed Efficiency Ratio (FER) ranged between 2.8 + 0.02 to 3.3 + 0.10 and 0.35 + 0.02 to 0.30 + 0.02 respectively in all the feeding trials of four groups of brinjal. Furthermore, FCR and FER in the Bt group versus the closest control, at 45% brinjal in the diet were recorded as 3.1+0.2 & 3.3+0.10 and 0.32+0.03, 0.30+0.02 respectively which clearly demonstrate that there is no significant difference in feed conversion and efficiency among them.

S: Crude values never demonstrate a significant difference or not, sorry. Again this is a crucial mathematical and interpretation error. The "nose opinion" cannot replace the statistical calculations done by Mahyco itself.

G: The only significant difference with respect FCR found at 45% level of feeding is unusually higher for fish. This difference might have been caused due to erroneous recording of feed intake data for the Bt brinjal fed group at 45% level. This can be explained as:

$$\text{FCR} = \frac{\text{Feed intake}}{\text{Weight gain}}$$

The weight gain was similar in all the groups as explained earlier (table 9). Hence FCR value will only increase if feed intake value increases. Feed intake value is calculated after collecting the refusal. If something is leached out into water then it is not estimated. There is maximum possibility of overlooking this factor, which otherwise gives a wrong impression of higher feed intake. Inclusion of 45% brinjal in a pelleted feed may definitely change the texture of the feed leading to leaching of the dry matter. The water stability of that diet was beyond the scope of the study.

S: Thus Mahyco recognizes at best an important mistake in the data recording. This experiment should be considered as invalid and the underlined conclusion above is confirmed.

G: The EC-II opined that these minor differences are in no way linked with the safety issues.

S: There is no scientific reason to decide that a priori. Science does not function with such a priori authority decisions.

12. LIMITED TESTS OF BT BRINJAL ON SOME SOIL MICROFLORA:

A-S: Limited environmental studies of Bt brinjal risks have been performed on an extremely little part of soil microflora, collembolan, nematodes and earthworms. It is almost impossible through a few species measurements to get a whole view of a complicated ecosystem, moreover varying a lot from place to place in India. In addition, statistical tests that have been chosen appear to be limited, grossly inadequate as we have demonstrated in other studies (Séralini et al., Arch. Env. Contam. Tox. 52, 596 -602, 2007). There are some severe limitations to the studies performed or that can be performed:

- Culture media used do not allow for sure all bacteria and fungi to be measured.
- Not all groups of invertebrates or insects have been taken into account.
- Bt brinjal was cultivated only during 5 months before testing soil fertility, but most effects can appear after long term cultivations with pesticides treatments.
- New Bt insecticide present in the soil due to GM brinjal and produced by it may be partially linked to particles and be released after rain or environmental changes, this has not been assessed either.
- Significant differences have been observed in colembolla and earthworms populations between Bt and non Bt real control fields. Two additional controls mask the effects, by the end of the experiment (120 or 150 days), these don't have to be persistent to be of biological relevance since evolutions and reactions may exist in these complicated ecosystems that could alter in a long-term soil life and fertility.
- Mortality of beings is often an insufficient parameter measured, reproduction capacity or physiological parameters are more pertinent for non-acute but chronic effects.

a-G: The soil microflora studies and effects on Collembola, nematodes and earthworms in Bt brinjal field plots have been carried out in almost every growing season since 2003 over at least 50 locations in India and not a single instance of reduced soil fertility has been reported. The studies have been repeated in large scale trials conducted by IIVR as per the directive of GEAC. These studies demonstrated that Bt brinjal does not have any significance effects on soil microflora both fungi and bacteria and soil invertebrates such as earthworm, collembola and nematodes. No Cry1Ac protein was detected in any of the soil samples of Bt brinjal field plots.

S: It is not Cry1Ac which is in Bt brinjal but a modified form of Cry1Ac, this was admitted by Mahyco above. Moreover, the scientific hypothesis that all the toxicity is due to the toxin is a limited one, the genetic modification may have induced unknown metabolic changes either.

G: The EC-II opined that it is not possible to culture many soil fungi and bacteria and indicator species measured provide a framework for evaluation of soil effects. It was concluded that sufficient soil impact analysis has been undertaken by M/s Mahyco and IIVR. Therefore, hypothetical "evolutions and reactions" are not a justification for invalidating the studies conducted. Further the Bt cotton expressing the same gene is being grown extensively in the country since 2002. Bt cotton and Bt corn containing the same gene are being grown in more than 20 countries worldwide and no adverse reports have been reported.

S: Same answer, the toxin may not be the only reason for toxicity. Moreover a crucial debate is open on the environmental effects of Bt cotton in India that should be scientifically investigated for a Court with external experts to decide.

13. Bt TOXICITY TESTS FOR NON TARGET INSECTS

a-S: Effects on honey bees (7 days) or larvae survivals were considered non significant at 20 ppm of Bt (NOEL: chosen as the No Observable Effect Level). Ladybird beetles, or green lacewing larvae, also beneficial insects, gave similar results for the company after 30 days. Unfortunately these tests are not relevant since they have been conducted with Cry1Ac which is not the insecticide produced by the Bt brinjal at all. As anyone can see, they are also very limited in time and doses.

a-G: The results reported by the applicant are comparable and relevant as they are tested with the protein that has been demonstrated to be biochemically and functionally similar to the one produced in Bt brinjal event EE-1 through a series of tests.

S: No, it is a mutated modified Cry1Ac, this was admitted by Mahyco at the beginning of this written debate.

G: The effects on honeybees, ladybird beetles or green lacewing are tested by adding the Cry1Ac protein at doses lethal to target insect pests and represent the direct effects, if any. The dose of 20 ppm is around 338 fold higher than the dose of 0.059 ppm required to kill the target insect or stop its growth.

S: This is why the chronic real effects have not been assessed at all in these very limited tests.

G: The EC-II was of the view that the ecotoxicology tests for non-target insects have been always carried out using bacterially produced proteins as it is extremely difficult to extract the required protein from the plant material.

S: GEAC should not carry on his shoulders the technical problems of Mahyco to help them. If Mahyco is a potent serious biotechnological company, it is possible to extract a modified toxin produce in such important levels in the brinjal (16-17 mg/kg).

G: The study reports submitted by the applicant have been reviewed and accepted by regulatory authorities in many countries viz. United States Environment Protection Agency, Canadian Food Inspection Agency, Office of Gene Technology Regulator, Australia, European Food Safety Agency, etc.

S: This is not a proof. These organisms have not published their analyses in peer-reviewed scientific journals. Bt brinjal has not been cultivated at large scales in any of these countries (www.isaaa.org) and no scientific observation has been made.

b-S: Field trials are an inadequate basis to assess impacts on the agrosystem:

- Studies of long term effects are lacking,
- Studies on beneficial insects (e.g. natural enemies of target pests), as well as studies of

abundance of secondary pests (which would have to be sprayed with insecticides) are lacking.

- Indirect effects (e.g. does the Bt toxin affect organisms that eat the target insect) are important in this regard.
- No laboratory studies have been performed to evaluate other lepidoptera insects.

b-G: The field trials are well accepted methods for evaluating the impact on agro system. Extensive field trials have been conducted on Bt brinjal event EE1 over a period of five years at multiple locations representing different agro-climatic conditions. During these field trials the non-target insects (includes moths and butterflies) and beneficial insects have been recorded throughout the crop growth period. A total of 17 non-target and beneficial insect species are being recorded in these field trials comprising of insects from orders Lepidoptera, Coleoptera, Thysanoptera, Homoptera and Diptera, besides spiders (Arachnida).

S: Congratulations. All the crude data are not reported in the file.

G: As regards long term effects, the reduction in insecticide use in a Bt crop will enhance the survival and reproduction of predators and parasitoids in an agroecosystem, which was already reported in several studies from Australia, China and the USA (Head et al . 2005, Chen et al., 2007). Laboratory studies have been performed to evaluate the impact on other lepidopteran insect as well and reported in the literature (Mendelsohn et al., 2003).

S: Once again, the scientific hypothesis that says that all possible side effects should be due to the modified insecticide toxin or to the reduction (unmeasured either in the raw data, by the way) in chemical insecticides is wrong.

G: The EC-II concluded that data generated during field trials coupled with laboratory and greenhouse evaluation and information on the biology of brinjal is adequate to assess the impact of Bt brinjal event EE1 on agro systems.

S: GEAC always finds that Mahyco assessment is sufficient by authoritarian decision, we all know that.

c-S: The harmful increase in secondary pests takes place after many years. Brinjal has also many insect pests (for example, sucking pests like whiteflies) that will not be controlled by this Bt toxin, and may increase over time. Thus will in turn increase chemical insecticide use compared to initial years of Bt brinjal use. This situation is difficult to predict, and would require monitoring after commercialization.

c-G: In the Bt resistance management program, the sustainability of efficacy of currently available insecticides will be considered, as Bt crops are part of holistic IPM program in a crop.

S: Thank you to agree with my point. Could these raw data (that should also have been measured during the important field trials of course) be given to the Court for counter-expertise, before any decision is taken.

G: The EC-II opined that appropriate post release monitoring mechanisms and IRM strategies would address this issue.

S: So everybody agrees with that, and that the pre-monitoring raw data should be given (Full nature of chemical insecticides – and fungicides, herbicides? - removed or added from controls, quantities released each year on controls, and on Bt brinjal fields).

14. Bt toxicity tests for target insects:

a-S: The toxicity of Bt toxin Cry1Ac to the larvae of a target fruit and shoot borer lepidopteran insect, Leucinodes orbonalis Gwen has been evaluated by the company. The Cry1Ac was from a commercial formulation and not purified from the Bt brinjal (surrogate protein), thus modifications of the protein in amino acids, structure and post-transcriptional modifications such as potential glycosylations have not been taken into account, limiting the significance of the results.

a-G: The objective of the test is to study bio efficacy of the Cry1Ac protein on target fruit and shoot borer. Both commercial Cry1Ac protein and lypholized Bt brinjal powder have been found to be effective against fruit and shoot borer. The use of commercial Cry1Ac protein does not in any way limit the significance of the results as the protein produced is the same as present in Bt brinjal event EE-1.

S: Not at all, we have already admitted that a lot of times, this is a too much gross scientific approximation. If this could be tentatively admitted in a research paper, it cannot be in a real life for billions of individuals eating that.

G: The EC-II concluded that the insect bioassays for bio efficacy against fruit and shoot borer have been undertaken as per the protocols approved by regulatory agencies. Further, the results of insect bioassays have been confirmed in field trials conducted in more than 50 locations across various agroclimatic zones in the country.

S: This does not answer to the scientific problems previously raised.

b-S: Some lyophilized transgenic fruit powder was also used in bioassays but these lasted only 7 days. There were 12-14 fold variations in the results. The Bt protein was significantly toxic in this regard; this was the goal of the GM brinjal on this insect.

b-G: Bioassays have been done for seven days to demonstrate a dose response with Bt brinjal powder which is comparable to artificial diet bioassays. In an artificial diet bioassay, one can hold the diet with no bacterial and viral infections to a maximum of 8-10 days. The 12-14 fold variation presented in the results is a natural response observed in insect populations.

S: Thus the samples are insufficient to have good statistical results.

15. Pollen flow studies:

a-S: Cross pollination or pollen flow is a very small part of contamination possible by GM plants.

Thus, pollen flow study alone has little impact on environmental risk assessment of dissemination per se because:

1) First, the seeds can be contaminated during the production when bought or taken by agricultural workers,
2) The transportation and spreading of seeds for cultures is not full closed and cannot be restricted temporally to a particular designed field,
3) The cultivation can imply the sharing of workers or tools or even machines that bring contamination of pollen or seeds from one field to another,
4) The insects, birds, other animals such as rodents or mammals will bring fruits or parts of flowers or fruits from one place to another,
5) The harvest is made by tools that are shared and may mix the productions at low levels,
6) The storage is made in places that cannot be always fully dedicated to GM or non GM plants,
7) The markets or transformation factories or cookers may mix the fruits or seeds.

a-G: Pollen flow is a natural phenomenon in plants, which cannot be controlled and thus its impact needs to be evaluated. Issues related to dissemination mentioned by the reviewer are external factors, several of which can be controlled and the extent to which this aspect needs to be monitored is a trade related issue and not a part of environmental risk assessment.

S: All these points become finally a huge part of environmental risks, thank you to agree with that. Thus, the monitoring plans to address these issues should be given, and reviewed, and tested also, in order to see if there are credible ways to prevent these risks.

G: The EC–II concluded that the pollen flow studies for four years as well as other environmental safety studies provide enough evidence of the safety of Bt brinjal to the environment. Other issues raised by the reviewer are hypothetical and out of the scope of the environmental risk assessment.

S: All the other issues raised by the reviewer are very pragmatic and real, happened for other files in the States of America or in Europe, and are of concern for 150 countries having signed the Carthagena protocol, these are considered as part of environmental risks. The fact that GEAC does not consider these risks means that the Indian government should claim a moratorium on commercial Bt brinjal release immediately and built another Committee with agronomic experience to assess that. This was already carefully studied by European authorities.

b-S: The sampling procedures are crude and limited and do not take into account the form and size of the field and the environment.

b-G: The sampling procedures are as per the standard practices and approved by RCGM and IIVR.

S: Numerous scientific studies since 2000 have proven that these pollen flows vary a lot with the size, the environment, and the form of the fields. These raw data should be included in the experiments.

c-S: A maximum of 50 meters from the source has been studied for dissemination, this is not

significant in comparison to the well known wave's effects of pollen disseminations depending on the wind blowing and insects, and this has been demonstrated for several pollens (maize, oilseed rape...). Thus the assessment was incomplete and not extensive. Pollen flow rates depend on a number of factors not addressed by the applicants. For example, in addition to proximity of fields, the relative size of brinjal fields can influence the rate and level of pollen contamination. Small conventional (non-GMO) brinjal fields planted near large Bt brinjal fields will have higher rates of contamination than large conventional brinjal fields in otherwise similar situations. Therefore, smaller conventional brinjal farmers may be at greater risk of higher levels of contamination than larger farmers.
Further, the applicant did not consider that levels of contamination may be additive over time if a farmer saves non-GMO brinjal seed, and if neighbouring Bt brinjal farmers continue to plant Bt brinjal. If more than one brinjal crop is planted in a year, this would accelerate this trend.

c-G: In the pollen flow studies conducted initially, the distance of 50 metres was used, but the studies were repeated as per the recommendations EC-I and conditions stipulated by GEAC up to 300 metres the pollen flow was observed only up to 30 metres. Dissemination of pollen is dependent on wind blowing and insects, but most importantly it is crop specific and depends on the reproductive biology of that particular crop. Keeping in mind the size, pollen production, morphology and viability as well as environmental factors, pollen flow studies are designed. In no way, the results obtained in maize, oilseed etc. can be compared with brinjal. Size of field or repeated cultivation has no effect on the pollen flow.

S: Of course it has, if the pollen flow is taken in the wide sense, i.e. contamination with pollen over time, and not only release of pollen during the culture. And even that is dependent on the field size, environment (wind, rivers, specific animals transporting...), etc... As explained.

d-S: The analysis of pollen flow also neglects other very important routes of contamination (e.g. by mixing seeds). Based on data from other countries on other genetically engineered crops, it seems likely that routes of contamination such as seed mixing are important. For example, in the U.S., levels (concentration) and rates (percent of the total crop) of contamination of soybean, a crop with low out-crossing rates similar to brinjal, were as high as for crops like corn that outcross at much higher rates. Since out-crossing occurs by pollen flow, these data suggest that other means of contamination are likely to be important ("A Growing Concern", Union of Concerned Scientists, 2004, http://www.ucsusa.org /assets/documents /food_and_ agriculture /seedreport_fullreport.pdf).

d-G: The concerns regarding seed mixing are trade related issues and not a part of environmental risk assessment.

S: These should be assessed anyway because these create concerns in environmental risks assessments anyway, and monitoring plans should be given before any commercial releases.

e-S: Gene flow to wild weedy relatives may result in environmental harm. This important route of possible environmental harm is widely recognized, but apparently not considered by the applicant. Gene flow from Bt brinjal in India may occur with the sexually compatible wild weedy relative Solanum insanum. Another sexually compatible relative, and the progenitor species of brinjal, S. incanum, probably also occurs in India. Gene flow from GMO crops has occurred from a large scale field trial of creeping bentgrass (Agrostis stolonifera) in the U.S., and from commercialized canola in Canada – in both cases involving a gene for glyphosate herbicide tolerance. Transfer of the modified Cry1 gene to these wild relatives may lead to harm to Lepidoptera or other non-target organisms that feed on these wild plants or the wild plants may become weedier due to suppression of herbivorous insects that may help keep their growth in check. Whether these possibilities occur depends on a number of factors that have not been tested by the applicant. For example, it must be determined whether these wild species grow in areas where brinjal is cultivated, which would allow gene flow to occur. Harm from such gene flow can only be determined through appropriate tests such as determining which organisms feed on these wild species, and whether they are sensitive to the Bt toxin. It should be noted that GM crops containing a Bt gene have not been commercialized in proximity to wild relatives anywhere in the world. Finally, gene flow to wild relatives may in some cases lead to reduce genetic diversity of the wild species. This is especially true for wild relative that grow near the crop, and occurs through the phenomenon of gene swamping when the crop is more numerous than the wild relative.

e-G: The crossability of different species of brinjal in India has been studied and reviewed by Rao, 1979. It has been reported that there is no natural crossing among cultivated and wild species of brinjal including S. incanum and S. insanum.

S: Please use more recent references with modern and more precise technologies of assessment.

G: Under forced crossing situations, even if crossing was possible, the viability and subsequent development of stable crosses have not been successful. Particularly in case of S. incanum, the crossability studies have been repeated by Indian Institute of Vegetable Research. It has been indicated that there was very limited crossing when S. incanum was used as female parent, whereas in the earlier study (2007-08), no crosses could be obtained. It can be concluded that gene flow from S. melongena to wild relatives of brinjal is not possible under natural conditions.

S: The science under this very important affirmation is really too light, these crossing have a lot of chances to occur in real life with several relatives.

f-S: It is recognized that brinjal wild relatives may provide important pest resistance genes for brinjal diseases and insects, as well as other desirable traits. The possible reduction of such diversity could have negative implications for further improvement of the brinjal crop, and should therefore be carefully considered.

f-G: Genetic improvement by conventional plant breeding has not been successful due to the lack of resistance to FSB in brinjal germplasm. Some wild Solanum species showed high levels of resistance, but it has proved to be impossible to incorporate the genes for resistance from wild species into commercial cultivars due to breeding incompatibilities (Dhankhar et al., 1982).

S: This does not answer the question at all that remains an entire real problem, sorry. <u>The above answer from Mahyco and GEAC even shows that the conservation of brinjal biodiversity is crucial as indicated, and thus should be preserved by an interdiction of Bt brinjal release.</u>

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January 15, 2010

The Hon. Jairam Ramesh,
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Ministry of Environment & Forests
Government of India
Paryavaran Bhawan, CGO Complex
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New Delhi 110 003
INDIA

Re: Bt-brinjal

Dear Minister Ramesh,

Thank you for the opportunity to comment on the risk assessment of Bt brinjal for commercial use in India. I commend the ministry for delaying a final regulatory decision about Bt brinjal pending further review. I am a senior scientist for the science-based NGO, Union of Concerned Scientists in the United States, and a plant pathologist whose research included genetic engineering. I also worked for the U.S. Environmental Protection Agency, where I assessed the safety of genetically engineered crops and microorganisms, and served as an advisor to the U.S. Food and Drug Administration concerning the regulation of genetically engineered organisms. I am therefore qualified to review risk assessments of genetically engineered crops.

The purposes of this letter are to: address serious flaws in the EC-II report (*Report of the Expert Committee on Bt Brinjal Event EE-1*) on gene flow risks from Bt brinjal, and recommend steps necessary to correct the flaws and engender public confidence in the ministry's review. I do not consider here the potential for gene flow to reduce the genetic diversity of wild brinal relatives, nor the possible loss of genetically diverse and valuable Indian varieties (landraces) due to the adoption of Bt brinjal.

Based on my preliminary evaluation of the EC-II report, I find that its assessment of the risks of gene flow and possibility that, if gene flow occurred, environmental harm may result, is both flawed and incomplete. The conclusion of no risk is therefore invalid or at best premature. Several steps should be taken by the ministry to produce a valid risk assessment that reassures the public that the risks of genetically engineered crops are taken seriously.

Flaws in the EC-II risk assessment

Gene flow

The EC II report fails to adequately address gene flow in two major respects: the likelihood, first, that mating between brinjal and its wild relatives would occur in the environment, and second, that such matings would produce viable progeny.

I made several points and recommendations concerning gene flow risks in a previous paper (*Comments on Possible Consequences of Gene Flow from Bt Brinjal to Brinjal Wild Relatives in India, and the Inadequacy of the Current Risk Assessment*, April 15, 2009, attached, referred to here as "previous comments") that has since been considered by the EC-II. My previous comments discussed environmental risk from gene flow, the potential for gene flow from Bt brinjal to related wild plant species, and an outline of the tests needed to determine risk from gene flow. The points made in my previous comments are based on scientific literature and expert consultation on gene flow and brinjal. These comments remain relevant to my assessment of the EC-II report.

At the time that I wrote my previous comments, the only assessments of gene flow from Bt brinjal evaluated by GEAC were several studies on pollination distances between brinjal plants. Such studies are typically done to determine adequate separation distances between genetically engineered crop fields and non-engineered plants to reduce the likelihood of gene flow during experimental field trials of engineered crops. This is not adequate for determining gene flow risk for commercialized crops because, as discussed at length by the U.S. National Research Council,[1] current containment methods—such as separation distances between the engineered crop and wild plants—generally cannot prevent gene flow after an engineered crop has been commercialized. This is why the other aspects of gene flow risk—outlined in my previous comments—need to be evaluated. None of these other aspects of gene flow risk were previously considered by the GEAC.

Recently, several additional studies concerning gene flow have been made public. These studies have been evaluated by the EC-II (page 56 of the EC-II report), which concluded that the concerns raised in my previous comments have been addressed, and no significant gene flow risk exists from Bt brinjal in India. Unfortunately, I have not had adequate time to thoroughly review these new studies, and my comments here must therefore be considered preliminary.

The following comments on the flawed gene flow assessment are based on my earlier comments and my preliminary assessment of the new studies. First, several of the new studies on the GEAC web site seem to show that mating between brinjal and at least one wild relative, *Solanum incanum*, can produce viable progeny. This suggests that such hybrids may also occur naturally through gene flow[2], and therefore contradicts the assessment of the EC-II. Because the successful production of viable progeny from mating between brinjal and *S. incanum* was accomplished without using extraordinary measures—that is, without highly artificial methods such as embryo rescue or protoplast fusion—these experiments suggest that viable crosses may occur in nature.

The artificial pollination of wild relatives of brinjal mentioned by EC-II appears to consist of hand-pollination methods that, while increasing the frequency of cross pollination, does not alter the fact that brinjal has been shown to cross pollinate without human assistance. Scientific literature and discussion with scientists who study brinjal and wild relatives that I cited in my previous comments, indicate that brinjal can successfully mate with *S. incanum* in the environment, and that their progeny are fertile.

It is therefore unclear why the EC-II concludes that gene flow cannot occur under natural conditions. This conclusion appears to be based on a single paper from 1979 by Rao, and observations that hybridization has not been reported. Differences between qualified scientists, on this or any issue, need to be resolved openly, rather than ignored—as seems to be the case in the EC-II report.

Although Rao's paper was useful for its time, reliance on a paper that predates more sensitive modern methods of determining gene flow in the wild—especially when more recent work contradicts this paper—is not adequate support for the unequivocal conclusions of the EC-II. More sensitive molecular methods, especially starting in the 1980s and 1990s, well after the Rao

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[1] National Research Council, 2004, *Biological Confinement of Genetically Engineered Organisms*; National Academies Press, Washington, DC.
[2] Ellstrand, N. 2003. *Dangerous Liaisons: When Cultivated Plants Mate with their Wild Relatives*. Johns Hopkins University Press, Baltimore, MD. See for example p. 59.

paper, have often shown that gene flow occurs in the wild in other species, despite earlier belief that gene flow to wild relatives was not common.[3]

Undocumented observations, mentioned by EC-II, also cannot substitute for careful experimental analyses. Hybrids may not always be observed or be distinct enough to be noticed in the field.

The EC II has also not adequately considered gene flow to *S. insanum*. Perhaps this is because some classify *S. insanum* as a subspecies of brinjal rather than a separate species. But even if that is the case, the ability of *S. insanum* to survive and spread on its own in non-agricultural environments strongly suggests that it should be evaluated. This is especially so because it has been reported to be a weed of brinjal, and is often found near brinjal fields which would allow gene flow to occur.

Evaluation of the Possibility that the Bt Gene could Spread in Wild Brinjal Relatives, and Cause Harm

Insects that feed on weeds and other wild plants may reduce the fitness of those plants and possibly their ability to compete and spread in the environment. Conversely, the plants may spread more aggressively in the environment if these insects are prevented from feeding on the plants. If this occurs, these plants may displace other plants species or become more aggressive weeds.

The EC-II improperly concluded that insects that can be controlled by the Bt gene are not prevalent on wild relatives of brinjal, and therefore gene flow would not increase weediness or other environmental harm. In addition, the report failed to adequately assess potential selective advantage whether or not insects turned out to be prevalent.

The report provides no support for the assertion that Bt-susceptible insect pests are not prevalent (not defined by the EC-II) on brinjal wild relatives—in particular *S. incanum* and *S. insanum*. No scientific references are provided, for example, that survey the insect pests found on brinjal wild relatives. Furthermore, I could find no research by the developers of Bt brinjal on this issue. Perhaps there are no data or existing data have not been disclosed. Lack of disclosure of whatever sources or information that the EC-II relied upon to conclude that insects are not prevalent on brinjal wild relatives is also contrary to accepted scientific practice because it does not allow review of the data—which is a fundamental tenant of sound science.

Prevalence of insects often varies considerably over time and at different locations, so there needs to be a number of such observations to determine prevalence over time and space. And even if not prevalent, a selective advantage favoring gene flow may still occur. This usually must be determined by careful experimentation, as has been done in other cases,[4] rather than by simple observation. Population genetic theory shows that even low positive selection advantage which may occur with low or variable presence of insects, will lead to the spread of a gene over time.[5]

Recommendations

Given the shortcomings of the risk assessment, I offer four recommendations below, which, if followed, would substantially strengthen the EC-II report and improve the public's confidence in the ministry's oversight of GMO crops.

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[3] Ellstrand, N. 2003. *Dangerous Liaisons*, see for example chapter 7.

[4] See, for example, Snow AA et al. 2003. A Bt transgene reduces herbivory and enhances fecundity in wild sunflowers. *Ecological Applications*, Vol.13:279-186.

[5] See, for example, Haygood et al. 2004. Population genetics of transgene containment. *Ecology Letters*, Vol. 7, Issue 3, pages 213-220. These authors use moderate selection in their equations. Lower selection—for example as may occur from low prevalence of insects—would produce similar gene flow results, only more slowly.

First, to produce a valid assessment of gene flow risks, additional testing should be performed along the lines that I recommended in the last section of my previous comments. The details of those tests would need to be determined.

Second, if there is any basis for the EC-II conclusion that insect pests are not prevalent on brinjal wild relatives, and that insects that feed upon wild brinjal relatives—prevalent of not—do not increase the fitness of those plants, those data should be made public.

Third, I recommend that your Ministry consult with independent, internationally respected scientists who are experts on gene flow or brinjal and its wild relatives. Gene flow experts include Allison Snow at the Ohio State University, Norman Ellstrand at the University of California at Riverside, and Paul Gepts at the University of California at Davis. These scientists have been advisors to U.S. regulators of GMO crops and other governments and have served on U.S. National Academy of Sciences panels evaluating gene flow issues. Experts on brinjal and its wild relatives include, for example, Dr. Marie-Christine Daunay of INRA in France and Dr. J. L. Karihaloo at the CGIAR in New Dehli.

Finally, the Ministry should allow additional time for non-government scientists to thoroughly evaluate the new data recently added to the Ministry web site. You have taken admirable steps toward making the risk assessment of Bt brinjal a more transparent process that, if completed, could provide the public with improved confidence in the conclusions of the Ministry. Truncating this process, on the other hand, could have the opposite effect. The issue of Bt brinjal is sufficiently important that a reasonable postponement of a final decision in the interest of safety and confidence in the evaluation process is warranted.

Respectfully yours,

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Comments on Possible Consequences of Gene Flow from *Bt* Brinjal to Brinjal Wild Relatives in India, and the Inadequacy of the Current Risk Assessment

- Doug Gurian-Sherman, Ph.D, April15, 2009[1,2]

Summary

One important way that genetically engineered (GE) crops may cause environmental harm is through gene flow, which typically occurs when pollen from the GE crop fertilizes either non-GE crop plants, or wild relatives of the crop. In this evaluation, I discuss potential risks to the environment caused by gene flow from *Bt* brinjal to brinjal wild relatives. I also evaluate how Mahyco has addressed this risk, and make some suggestions about how to better determine the gene flow risks from *Bt* brinjal. The conclusions and recommendations in my evaluation are based on existing data on gene flow in the scientific literature, as well as the regulatory and legal record concerning gene flow from GE crops in the United States.

Mahyco presents no data that I am aware of that assesses the risks of gene flow from *Bt* brinjal to wild relatives. The company presents limited data on gene flow distances, which cannot substitute for a risk assessment of potential harm from gene flow, and is wholly inadequate to predict gene flow if *Bt* brinjal were to be commercialized or grown in field trials in areas where wild brinjal relatives are found.

Several wild relatives of brinjal are found in India and have been shown to be sexually compatible with brinjal. And it appears that at least one wild relative grows in or near brinjal fields. Further, methods to prevent gene flow from crops to wild relatives currently do not exist (there are some methods that can slow this process in some crops). Gene flow from *Bt* brinjal to wild relatives, if commercialized, would therefore be virtually certain. Whether the *Bt* gene becomes a permanent part of the environment in India would then depend on the properties of the gene in the wild plants–something that cannot be predicted without performing tests. No such tests have been performed according to the records available to me.[3]

Harm from gene flow may occur in several ways, but not all gene flow is harmful. If permanent gene flow were to occur, possible harm to the environment can only be imperfectly predicted, and this can only be accomplished by conducting additional tests. These or similar tests have also apparently not been performed.

Because of the high possibility of gene flow from *Bt* brinjal to wild related species, and because India is a center for domestication and genetic diversity of brinjal, I believe that environmental risks due to gene flow from *Bt* brinjal should be seriously considered and evaluated. The only reasonable way to do this is through an understanding

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[1] The author has written this evaluation under his own auspices, rather than as a part of any organization.

[2] I would like to acknowledge invaluable background information and publications from Dr. Marie-Christine Daunay, INRA, France. I also thank Dr. J. Karihaloo for his kind responses to my inquiries about brinjal wild relatives. It must be noted however, that the willingness of Drs. Daunay and Karihaloo to supply information does not constitute an endorsement of the views expressed in this paper.

[3] The records that I have examined include: "Field evaluation of Bt brinjal in limited field trials during growing season 2002-03,", apparently submitted by Mahyco to GEAC; "Development of Fruit and Shoot Borer Tolerant Brinjal" submitted to the GEAC by Mahyco in 2006. I have also briefly examined other documents submitted to GEAC by Mahyco on toxicology and effects on non-target organisms.

of the biology of wild relatives and their interactions with the environment, and scientific studies including safety tests. Some examples of such studies are outlined at the end of these comments. Because, apparently, none of these studies have been performed, I conclude that the risk assessment of *Bt* brinjal is seriously incomplete, and conclusions about environmental safety are not adequately supported.

Evidence that gene flow from genetically engineered crops may be harmful

The possibility of harm from gene flow has been widely recognized by many scientists.[4] In the United States, this recognition has been a major factor in regulatory action restricting the commercialization of GE crops with wild relatives. For example, concern about gene flow from GE creeping bentgrass (an important turf grass) to several wild relatives growing in the United States resulted in the U.S. Department of Agriculture (USDA) submitting GE creeping bentgrass to its highest regulatory evaluation—an environmental impact statement (EIS)–under the National Environmental Protection Act. Requiring an EIS had not occurred, I believe, for any other GE crop until that time (this evaluation has been ongoing for several years, and has yet to be completed). Recently, a U.S. Federal Court ruled against the USDA on its regulatory handling of GE creeping bentgrass, largely because of the possibility of gene flow. However, these actions may have been too late to prevent gene flow, which occurred prior to the EIS or court order. The transgene escaped from a large field trial and now appears to be established in the environment.[5]

The geographic restriction of *Bt* cotton cultivation in the United States also demonstrates recognition of the importance of gene flow by U.S. regulatory agencies. The U.S. Environmental Protection Agency (USEPA) prohibits the cultivation of commercial *Bt* cotton in several parts of the southern United States, Hawaii and several Caribbean islands because of the presence in those areas of wild cotton relatives and the possibility that gene flow could cause environmental harm.

The scientific community has also weighted in on the issues of gene flow. The U.S. National Academy of Sciences (NAS 2002) severely criticized the USDA for not adequately assessing possible harm from gene flow of virus-resistance transgenes from GE squash to a wild relative,[6] and in response USDA supported several studies to retroactively determine whether gene flow could harm the environment. The subsequent studies suggest that these genes may not be harmful in this case. It should be noted that the possibility of harm from gene flow to wild squash was acknowledged and evaluated by USDA prior to commercialization, so the concern by the NAS was that the USDA did not do a thorough assessment. It is not enough to merely acknowledge the possibility of gene flow and to argue that a particular transgene will not cause harm. The regulators

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[4] Ellstrand N, 2003, "*Dangerous Liaisons? When Cultivated Plants Mate with Their Wild Relatives,*" The Johns Hopkins University Press, Baltimore, MD; Snow A.A. et al., 1997, Commercialization of transgenic crops: potential ecological risks, *BioScience* vol. 47:86-96; National Research Council, 2004, "*Biological Confinement of Genetically Engineered Organisms,*" National Academies Press, Washington, D.C.

[5] Reichman, J.R. et al., 2006, Establishment of transgenic herbicide-resistant creeping bentgrass (*Agrostis stolonifera* L.) in nonagronomic habitats, *Molecular Ecology* vol. 15: 4243-4255

[6] National Research Council, 2002, "*Environmental Effects of Transgenic Plants: the Scope and Adequacy of Regulation,*" National Academies Press, Washington, DC

must also have adequate data to demonstrate that gene flow either will not occur, or not be harmful if it does.

More recently, the prevention of gene flow to a wild relative of sugar beets was an important part of the regulatory assessment of GE sugar beets by USDA. There is a wild weedy relative of sugar beets in California, and therefore seed production (where flowering is involved and therefore potential gene flow) of GE sugar beets is not allowed in California.

These and other examples, and the scientific literature, establish that gene flow is considered to be one of the most important environmental issues concerning GE crops.

It should also be noted that for the examples discussed above, the United States is not a center of domestication or genetic diversity for any of the crops. However, India is a center of domestication and diversity for brinjal, and this adds additional concern.[7] This is because centers of domestication usually have particularly high genetic diversity of the crop and wild relatives (which can serve as important sources of genes used in conventional breeding of many vitally important traits, from pest resistance to drought tolerance). This diversity may be harmed by gene flow.

It should also be noted that gene flow to a wild relative will not necessarily cause harm (unless the mere permanent presence of the transgene in the environment is considered to be harmful). However, the only way to determine whether gene flow may cause harm is to perform appropriate tests.

<u>What has been done to determine whether gene flow to wild brinjal relatives may occur, and whether this may be harmful?</u>

Given the widespread concern about gene flow, it is remarkable that there appears to be no assessment of possible harm from gene flow from *Bt* brinjal to wild brinjal relatives in India. The safety record available to me, apparently submitted to GEAC, includes no gene flow safety data.

A few experiments were performed to examine gene flow distances. But this is wholly inadequate, because it is now clearly understood that after commercialization (and possibly also during field trials) gene flow *will* occur if there are wild relatives in the vicinity of the GE crop (whether this becomes permanent depends on the interactions of the transgene with the wild relative and the environment). As noted by the U.S. National Academy of Sciences, currently available technology cannot prevent gene flow from occurring if wild relatives are present.[8] And since the wild relative *S. insanum*, and possibly *S. incanum*, is found in or near brinjal fields in India, gene flow is a virtual certainty.

It is known that sexually compatible wild relatives of brinjal occur in India. For example, "India: Country Report to the FAO International Technical Conference on Plant Genetic Resources," Leipzig, 1996, notes the presence (page 9) of the sexually compatible wild relatives *S. insanum* and *S. incanum* in India. Dr. J. Karihaloo, an international brinjal expert with the CGIAR, confirmed that *S. insanum* is distributed throughout India, can be found growing in or near brinjal fields as an occasional weed,

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[7] see, for example, "India: Country Report to the FAO International Technical Conference on Plant Genetic Resources," Leipzig 1996

[8] National Research Council, 2004, op. cit.

and can cross with brinjal to form fertile hybrids, while *S. incanum* may be restricted to Southern Indian scrub forests.[9] Therefore, *Bt* gene flow is likely to *S. insanum*, and may also occur if brinjal fields are located near scrub forests where *S. incanum* is found. Several other species may also be recipients of gene flow, although this is less clear. Several published papers also establish the sexual compatibility of wild species, and in fact Mahyco itself confirms this.[10]

The only data on gene flow appears to be some studies that suggest gene flow occurs up to 15 meters.[11] However, gene flow distances are highly dependant on a number of factors such as the size of the experimental plot, presence of pollinators, weather conditions, etc., and tend to be highly variable. Limited tests of the kind done by Mahyco are therefore highly unreliable for accurately predicting gene flow distances.[12] And given that gene flow for brinjal may occur through pollinating insects, and many of these are known to pollinate flowers over a distance of several kilometers, the limited data for brinjal gene flow from Mahyco probably greatly underestimate gene flow distances. These data are wholly inadequate to assess gene flow from multiple large field test plots or commercialized *Bt* brinjal.

A clear example of the failure of these kinds of gene flow distance predictions was the proposed isolation distance to separate GE creeping bentgrass from wild relatives in the United States. This isolation distance was initially set at 900 feet. Subsequent studies by USEPA scientists indicated that gene flow actually occurred at distances of at least 21 km from a large field trial.[13] This and many other examples show that limited experiments to determine adequate isolation distances (as done by Mahyco) should be viewed with a very high degree of skepticism.[14]

If the *Bt* gene makes a wild crop relative more able to survive and reproduce than the wild relative without the transgene (in genetics terms, makes the wild relative more fit), then population genetic theory clearly shows that the gene will probably spread through the wild-relative population and become common in it and a permanent part of the environment.[15] When this occurs, it becomes virtually impossible to eradicate the gene from the natural environment, and therefore, if it is harmful, that harm is highly likely to become a permanent feature of the environment where the wild plants grow.

Once gene flow has occurred and the gene has become established in the wild relative population, harm can occur in several ways, depending on the properties of the gene, the recipient wild relative, and the environment. If the wild relative containing the transgene is more competitive toward other plant species than without the gene, it will develop larger populations and to some extent replace other plants in the environment. If the wild relative is an agricultural weed, then it may become a more serious weed causing

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[9] J. Karihaloo, personal email communication with D. Gurian-Sherman, February 11, 2007

[10] see "Development of Fruit and Shoot Borer Tolerant Brinjal" submitted to the GEAC by Mahyco in 2006

[11] "Development of Fruit and Shoot Borer Tolerant Brinjal," op. cit.

[12] Gurian-Sherman, D., 2006, Contaminating the Wild? *Gene Flow from Experimental Field Trials of Genetically Engineered Crops to Related Wild Plants*, Center for Food Safety, Washington, DC; Ellstrand N, 2003, "*Dangerous Liaisons?* op. cit.

[13] Watrud L et al, 2004, Evidence for landscape-level, pollenmediated gene flow from genetically modified creeping bentgrass with CP4 EPSPS as a marker, *Proceedings of the National Academy of Sciences USA* 101(40):14,533-14,538

[14] Gurian-Sherman, D., 2006, Contaminating the Wild? op. cit.

[15] National Research Council, 2004, op. cit.; Ellstrand N, 2003, "*Dangerous Liaisons?* op. cit.

greater crop losses. An important wild relative of *Bt* brinjal that can be the recipient of the *Bt* gene is *S. insanum*. This plant is widely dispersed in India and may be found in and near brinjal fields as an occasional weed, and therefore should be evaluated for its weed potential if it received a *Bt* gene.

The *Bt* gene may make wild brinjal relatives become more aggressive weeds by reducing damage from insects that are susceptible to the *Bt* toxin, especially moth larvae of various species. Preliminary data suggesting this kind of effect was reported in a peer-reviewed paper showing that a weedy wild relative of sunflowers that contained the *Bt* gene survived and produced more progeny than the normal wild sunflowers without the *Bt* gene.[16] This research suggests that if gene flow occurred from the *Bt* sunflower crop to wild sunflower relatives, the gene would spread through the wild population, and possibly cause environmental harm, such as by making the wild sunflowers more aggressive weeds (*Bt* sunflower has not been approved or commercialized in the United States). Unfortunately, the company that owns the *Bt* gene forbade any further research using their *Bt* gene, so we still do not know how much harm wild *Bt* sunflowers could cause. Whether a similar situation may occur with *Bt* brinjal can only be determined by performing the proper tests.

Another way that gene flow may cause environmental harm is if the toxin kills organisms that use the wild brinjal relatives as a food source. This is most likely to occur with moths and butterflies, but may also occur with other organisms.[17] For example, laboratory studies have shown that *Bt* toxins may harm a number of different insect species.[18] A recent scientific review, for example, pointed out that some species of moths or butterflies are highly dependent on wild sunflowers as a food source, and if they are killed or harmed by the *Bt* gene, those species could face serious problems if the gene spread through the wild sunflower populations.[19] Again, whether this may be the case with wild brinjal relatives in India can only be determined by the appropriate tests.

Gene flow may also reduce the genetic diversity of wild crop relatives, and these wild relatives may be sources of genes that could be important for improving brinjal. There are several known instances of loss of genetic diversity by wild relatives due to large amounts of gene flow from the nearby crop (known examples are non-GE, but could also happen with GE).[20] A gene that confers a powerful selective advantage (as *Bt* may) might exacerbate such effects.

What should be done?

It is clear that gene flow (at least the initial stages that lead to hybridization) from brinjal to wild relatives in India is likely to occur, at least to *S. insanum*, and possibly also

[16] Snow AA et al., 2003, A Bt transgene reduces herbivory and enhances fecundity in wild sunflowers, *Ecological Applications* vol.13:279-186
[17] It should be noted that while some moths are important agricultural pests, many are important plant pollinators.
[18] Lövei, G.L. and S. Arpaia, 2004, The impact of transgenic plants on natural enemies: a critical review of laboratory studies, *Entomologia Experimentalis et Applicata* vol. 114: 1–14
[19] Pilson D. and Prendeville H.R., 2004, Ecological effects of transgenic crops and the escape of transgenes into wild populations, *Annual Review of Ecology Evolution and Systematics* vol. 35:149-174
[20] Ellstrand N, 2003, "*Dangerous Liaisons?* op. cit.

to *S. incanum*. It is also clear from the literature and scientific consensus that gene flow may cause environmental harm. Therefore, the possibility of the *Bt* gene entering wild brinjal relatives and causing harm should be taken seriously. What should therefore be done to determine if permanent gene flow may occur and whether it would cause harm?

It is beyond my intention to suggest a detailed testing regime that should be carried out to determine whether *Bt* brinjal could cause environmental harm, but a few brief examples may illustrate the kinds of studies that could be done, have been done in the United States, or have been suggested by scientists.

First, better data could be gathered as to the frequency of gene flow to *S. insanum* and *S. incanum*, and the fertility and fitness of hybrids between them and brinjal. The fitness of the gene in the wild relative itself should also be determined. The main focus for *S. insanum* should probably be on fitness determinations, because the data already available suggest that gene flow to this relative is probably inevitable (although more data on gene flow would also be useful). Fitness determinations would give an idea of the likelihood of the gene spreading through wild relative populations (this was done in the U.S., belatedly, for a squash wild relative concerning possible gene flow of virus resistance genes). For *S. incanum*, it appears that more data are needed to determine whether it occurs in areas where brinjal is planted. If so, the fitness of *Bt* brinjal:*S. incanum* hybrids, and *S incanum* containing the *Bt* gene, should be determined.

Second, if the *Bt* gene increases the fitness of wild relatives, it should be determined if this increases the competitiveness of those relatives compared to other plants that grow with it, and also if *Bt* enhances the weediness of the wild relative.

Third, it should be determined whether wild relatives are important food sources for insects that feed on it, especially moths and butterflies. This was done in the United States after it was found that the *Bt* gene may harm the highly valued monarch butterfly (in that case it was found that the most widely commercialized varieties of *Bt* corn probably are not harmful to monarchs in the wild, but another type that had more toxin in its pollen, could probably have caused harm if it had been more widely grown).[21] If the wild brinjal relatives are important food sources, those insect species that rely on brinjal should be tested for susceptibility to the *Bt* toxin.

These tests, broadly speaking, are noted mainly to highlight the glaring lack of any tests in the submissions of Mahyco, as far as I can ascertain. It would be, in my opinion, a major oversight on the part of the GEAC to allow the commercialization of *Bt* brinjal, or large-scale field trials, without better understanding the implications of gene flow.

Sincerely,
Doug Gurian-Sherman, Ph.D.

[21] Stanley-Horn D.E. et al.,2001, Assessing the impact of Cry1Ab-expressing corn pollen on monarch butterfly larvae in field studies, *Proceedings of the National Academy of Sciences USA* vol. 98: 11,931–11,936

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The Hon. Jairam Ramesh,
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Paryavaran Bhawan, CGO Complex
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New Delhi 110 003
INDIA

January 29, 2010

Re: Bt-brinjal

Dear Minister Ramesh,

Thank you for your ongoing assessment of the risks and benefits of Bt brinjal in India.

I have attached several recent papers and reports by our organization evaluating some of the proposed benefits of genetically engineered (GE) crops. The first short paper, "Agricultural Practices and Carbon Sequestration," considers the value of no-till, a practice associated with herbicide-tolerant GE crops, as a means of reducing carbon dioxide. The industry has claimed that GE crops benefit the environment by promoting no-till, but the most recent science calls into question the value of no-till for carbon sequestration. It is also likely that GE is not needed in many cases to practice no-till, as was shown by the U.S. Department of Agriculture (http://www.ers.usda.gov/publications/aer810/aer810.pdf , pages 28 and 29), and contrary to industry assertions based on weak data.

The other two reports help assess how well GE is living up to its promise after 20 years of research and commercialization. The risks and benefits from particular GE crops will vary considerably, and these papers do not specifically address Bt brinjal in India. Nonetheless, they provide part of a conceptual framework for considering the benefits GE, and especially how well GE stacks up against other agricultural methods and technologies.

My experience has been that the purported benefits of genetically engineered crops are usually determined against a limited set of current agricultural practices that do not adequately represent the range of available technologies. In the case of Bt brinjal, claims have been made about the efficacy of some current alternatives—in particular sprayed insecticides. However, it appears that other possible, sustainable alternatives have not been adequately considered. These may include long crop rotations and cover crops, among others. For example, while stem borers are often a problem on conventionally-grown corn in the U.S., organic farmers typically produce yields comparable to those of farmers using Bt corn, but without engineered Bt or insecticides. Generally, in the U.S., advanced organic and low-external-input methods have been shown in the peer-reviewed science literature to produce crop yields comparable to the best industrial methods (see "Failure to Yield" pages 12, column 1, and 27—29). These results have also been supported by studies sponsored by the U.N. and other international institutions.

The report "Failure to Yield" evaluates the contribution of GE to increasing crop productivity in the U.S. since the inception of the technology. It evaluates the main two GE crops—Bt corn and herbicide-tolerant soybeans. The report found that GE crops have contributed only marginally to improved productivity in the U.S. For example, only about 3 to 4 percent of the 28 percent increase in corn yield over the past 13 years comes from the Bt trait.

Although the report does not evaluate GE crops in developing countries, it has the advantage of comparing GE to other advanced technologies and methods used in the U.S., and therefore is a robust test of the performance of GE against a range of methods.

The recent report, "No Sure Fix," evaluates the ability of GE crops to reduce the serious issue of nitrogen pollution from crop fertilizer—which also contributes to climate change. Although breeding and other techniques like precision agriculture have improved nitrogen efficiency in crops, GE has yet to do so.

Together these reports caution that the often exaggerated claims of the GE industry must be carefully tested, making sure that the contribution of the engineered gene is properly evaluated, and that proper and varied standards of comparison are used to determine benefits from GE.

Respectfully yours,

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Senior Scientist
Union of Concerned Scientists, USA

Union of Concerned Scientists

Agricultural Practices and Carbon Sequestration

FACT SHEET

OCTOBER 1, 2009

One of agriculture's major opportunities to help mitigate the effects of climate-warming gases lies in management of soil to increase organic content, thereby removing carbon from the atmosphere. Many scientists are conducting studies to determine which agricultural practices will in fact sequester carbon. Recent studies, summarized below, demonstrate that a number of biological, soil-based practices employed in integrated systems have great potential to sequester carbon. In contrast, recent studies suggest that no-till, a form of conservation tillage, has environmental benefits such as reducing soil erosion, but may not sequester more carbon than conventional tillage (plowing).

Integrated soil-based practices

The most promising systems for carbon sequestration in soil combine crop rotation and low or no inputs of pesticides, herbicides, and industrial fertilizers. Long-term studies done by the Rodale Institute and others suggest that such systems build (not simply conserve) significant quantities of soil organic carbon through a variety of mechanisms such as enhanced abundance of mycorrhizal fungi. Several studies, including some done over long periods of time, have compared carbon accumulation in organic (plowed) and conventional (plowed) systems[1] and demonstrate that organic systems sequester more carbon than conventional chemical-intensive systems.

In a head-to-head comparison between conventional no-till and organic plowed systems, organic plowed systems sequestered more carbon even though the sampling was restricted to shallow soil, where no-till tends to show carbon accumulation.[2] Although more studies are needed, there are good reasons to believe that organic systems would do at least as well as conventional systems deeper in the soil. Current organic systems typically employ plowing to control weeds, and conventional plowed systems generally sequester more carbon at greater soil depths than no-till (discussed below).[3]

Systems that use crop rotations and green and animal manure have shown higher biodiversity by foregoing chemical pesticides, supplying more diverse habitats,[4] and reducing nitrogen pollution. Systems that integrate livestock and crops, employ perennial pastures, and adopt many of the practices used in organic production (e.g., long crop rotations, leguminous crops and cover crops, manure produced by livestock as fertilizer) also have shown potential for improved greenhouse gas balance, reduced pollution, and higher profitability. Further research on these promising approaches will help optimize their benefits and determine their applicability across geographic regions.

In summary, available data suggest that organic and near-organic farming systems achieve greater carbon sequestration and other benefits compared with conventional systems. Further work, supported by adequate research funding, is needed to realize the promise of these biologically sophisticated production systems.

No-till practices

Scientific evidence accumulated over the last two years has called into question the long-held view that no-till practices result in significant accumulations of carbon in the soil. The most important of these reports are

- Baker, J.M., et al. 2007. Tillage and soil carbon sequestration—What do we really know? *Agriculture, Ecosystems and Environment* 118:1–5.

This landmark review of the scientific literature found that no-till fields sequestered no more carbon than plowed fields. Most previous studies measured carbon sequestration only down to about 30 cm. For example, a review often used to support no-till as a means to sequester soil carbon cited 140 studies, none of which measured soil carbon below 30 cm.[5] However, the roots of crops—which deposit carbon in the soil—often grow much deeper. In a review paper cited in Baker et al. that examined carbon changes to soil depths greater than 30 cm, most (35 of 51) of the studies found no significant difference in carbon sequestration between plowing and no-till. In fact, on average, the no-till systems may have lost some carbon over the period of the experiments. In summary, no-till tends to show increased carbon at shallow depths where crop residues are found, but at greater depths plowed soils typically sequester more carbon.

- Blanco-Canqui, H., and R. Lal. 2008. No-tillage and soil-profile carbon sequestration: An on-farm assessment. *Soil Science Society of America Journal* 72:693–701.

This research compared soil carbon between plowed fields and fields managed with no-till practices for up to 30 years on actual farms (as opposed to controlled field tests) in three eastern states, using paired sites on each farm. Most of the sites showed no statistical differences between no-till and plowed fields in soil carbon accumulation when carbon from the entire soil profile (including depths below 30 cm) was measured. Three of the 11 sites had greater soil carbon accumulation in the plowed fields than in the no-till fields. The paper also reviewed 16 studies from around the world that examined carbon sequestration at soil depths greater than 30 cm and found similar results.

- Poirier, V., et al. 2009. Interactive effects of tillage and mineral fertilization on soil carbon profiles. *Soil Science Society of America Journal* 73:255–261.

This study of sites in Quebec, Canada, over a period of three years also found that the amount of sequestered carbon did not differ between no-till and plowing. These authors also found higher carbon accumulation from no-till only where the top several centimeters of soil were measured. When the measurements included the entire soil profile, the higher carbon accumulation in plowed fields at lower depths compensated for the lower amount of carbon near the soil surface. Different fertilization rates did not alter these results.

Summary of the science

The current scientific literature does not support favoring no-till over plowing for carbon sequestration. The emerging consensus from numerous studies and reviews is that under a variety of environmental conditions no-till sequesters no more carbon than plowing. The apparent advantage for no-till in previous studies of carbon sequestration was an artifact of sampling carbon only near the soil surface.

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[1] Drinkwater, L., et al. 1998. Legume-based cropping systems have reduced carbon and nitrogen losses. *Nature* 396:262–265; Pimentel, D. 2005. Environmental, energetic and economic comparisons of organic and conventional farming systems. *BioScience* 55:573–582; Marriott, E.E., and M.M. Wander. 2006. Total and labile soil organic matter in organic and conventional farming systems. *Soil Society of America Journal* 70: 950–959.

[2] Teasdale, J.R. 2007. Potential long-term benefits of no-tillage and organic cropping systems for grain production and soil improvement. *Agronomy Journal* 99:1297–1305.

[3] Baker, J.M., et al. 2007. Tillage and soil carbon sequestration—What do we really know? *Agriculture, Ecosystems and Environment* 118:1–5.

[4] Gabriel, D., et al. 2006. Beta diversity at different special scales: Plant communities in organic and conventional agriculture. *Ecological Applications* 16:2011–2021.

[5] West, T.O., and W.M. Post. 2002. Soil organic carbon sequestration rates by tillage and crop rotation: A global data analysis. *Soil Science Society of America Journal* 66:1930–1946.

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7 December 2009

The Honorable Shri Jairam Ramesh
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Sub: Approval of *Bt* brinjal for commercial cultivation in India

Dear Honorable Minister:

As an agricultural law professor who teaches, writes, and speaks about agricultural biotechnology and policy, I have followed the development and GEAC approval of *Bt* brinjal closely since the year 2000.

I support the GEAC decision and the commercial cultivation of *Bt* brinjal for several reasons:

• The GEAC has taken careful and extraordinary steps to evaluate *Bt* brinjal. GEAC has done what the law and regulations of India mandated it to do and has rendered a judgement of approval. GEAC, as an administrative agency of the State of India, deserves the support of the Government.

• Indian scientists have been heavily involved in both the development and the evaluation of *Bt* brinjal. These Indian scientists support the GEAC decision. Indian scientists have the world class ability to improve the agricultural productivity of Indian agriculture, if they see that their work to develop seeds through modern plant breeding will be validated for commercial release.

• Studies by a number of research social scientists have concluded that the positive agronomic, environmental, and economic benefits for the Indian farmers of brinjal will be very large. The poor resource farmers particularly will benefit the most. In addition. Indian consumers will benefit by having higher quality produce at a reduced cost. Consumer benefits too will be very large. Poverty at both the farm level and the consumer level will be reduced by access to high quality, lower cost products from modern plant breeding.

I support the GEAC decision for another reason. I have worked in India and I admire the dynamism and dedication of Indian scientists. By failing to approve the commercial cultivation of *Bt* brinjal, India runs the very strong risk of discouraging agricultural research and development. Moreover, a failure to approve *Bt* brinjal may also put India at a distinctly competitive disadvantage in comparison to China where Chinese authorities have recently approved transgenic low-phytase maize and transgenic rice. India needs and deserves agricultural research and development from its scientists to reduce poverty and to remain competitive. But they cannot provide that research and development if their efforts are thwarted.

Sincerely yours,

Drew L. Kershen (e-mail signature)

Drew L. Kershen
Earl Sneed Centennial Professor of Law

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December 18, 2009

Dr. Robin Schoen, Director
Board on Agriculture and Natural Resources
The National Academies (National Research Council)
500 5th Street, NW
Washington, DC 20001

Dear Dr. Schoen,

We are writing in response to the request you received from Jairam Ramesh, Minister of Environment and Forests for the Government of India, about information needed to approve Bt brinjal (eggplant) for commercial release. We reviewed the "Report of the Expert Committee (EC-II) on Bt brinjal event EE-1," and we focused on possible environmental effects related to gene flow - the dispersal of transgenes from the crop to recipient populations. As you know, we have both published many peer-reviewed scientific articles on related topics, including serving on Committees that created reports for the US National Academy of Sciences/National Research Council.

Worldwide, it is standard practice for governmental regulatory agencies to require information about the extent to which a transgenic crop will cross-pollinate with its wild or weedy relatives. Knowledge about gene flow is primarily needed to evaluate whether the Bt transgene could unintentionally enter populations of wild or weedy relatives of the crop, where it might have unwanted effects on their weediness or could become harmful to non-target, lepidopteran insects that feed on wild or weedy relatives. Also, more broadly, various stakeholders have an interest in knowing whether transgenes are likely to spread from crop-to-crop, crop-to-weeds, and crop-to-wild relatives, especially where landraces and wild or weedy relatives represent valued germplasm for future crop breeding.

Here, we focus on whether the Report of the Expert Committee (EC-II) adequately examined the extent of gene flow from Bt brinjal to its wild and weedy relatives. Cultivated brinjal has large, bee-pollinated flowers and occurs near sexually compatible wild or weedy relatives (Report of the EC-II). Although the report and its supporting documents include a great deal of useful information, we identified the following major shortcomings, each of which is discussed as an Appendix in this letter.

1. We found insufficient evidence for whether cultivated brinjal (*Solanum melongena*), including local landraces, has given or can give rise to volunteer or feral populations.

2. We found insufficient evidence for this statement on p. 56: "It has been reported that there is no natural crossing among cultivated and wild species of brinjal including *S. incanum* and *S. insanum* (Rao, 1979)."

3. We found insufficient evidence that wild or weedy relatives of brinjal would not obtain a fitness benefit from a Bt gene should gene flow occur.

We recognize that the decision about whether to release Bt brinjal in India will depend on assessing expected risks, benefits, and societal priorities for various stakeholders. We appreciate the opportunity to evaluate these documents in terms of their scientific rigor, and we would be glad to answer any questions that you or the Minister's office may have on these issues.

Sincerely,

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APPENDIX - Explanation of Points 1-3:

1. Insufficient evidence for whether cultivated brinjal (*Solanum melongena*), including local landraces, has given or can give rise to volunteer or feral populations.

The report does not explain whether *S. melongena* occurs as volunteer or feral populations that are recently derived from crop plants. This is a complicated question and may not be fully answered by previous studies. Working in southern India, Deb (1989) noted that "feral forms are sometimes found."

Recommendation: Further clarification is needed as to whether some cultivars of brinjal, including landraces, may persist as volunteer or feral populations. If this occurs, the Bt transgene may be able to disperse *via* modern or landrace cultivars that revert to a weedy phenotype and give rise to weedy populations with the Bt transgene.

2. Insufficient evidence for this statement on p. 56: "It has been reported that there is no natural crossing among cultivated and wild species of brinjal including *S. incanum* and *S. insanum* (Rao, 1979)".

This statement refers to a book chapter by N. Narasimha Rao (1979), but we did not find support for "no natural crossing" in the chapter. Rao (1979) carried out crossability studies with cultivated *S. melongena* and its close relatives, *S. insanum* and *S. incanum*. Rao (1979) listed *S. insanum* as *S. melongena* variety *insanum*, while *S. incanum* was listed as a separate species.

Three lines of evidence suggest that cultivated *S. melongena*, weedy *S. melongena* var. *insanum*, and "wild" *S. incanum* from India should be considered as a single inter-breeding species: 1) crossability, 2) extremely similar genetic profiles based on allozymes and RAPD markers, and 3) overlapping morphological variation among wild, weedy, and cultivated forms (Deb 1989; Karihaloo and Gottlieb 1995; Karihaloo et al. 1995). Lester and Hasan (1991a) consider Deb's (1989) *S. incanum* and *S. melongena* var. *insanum* to be "weedy varieties or primitive landraces of *S. melongena*". After observing many wild/weedy *Solanum* populations in Kerala, Tamil Nadu, and Karnataka in southern India, Deb (1989) found continuous variation in prickliness, hairiness, branching, floral, and fruit traits, leading him to conclude that "*S. incanum* and *S. insanum* are now found synonymous."

Rao (1979) and other investigators found that *S. melongena*, *S. melongena* var. *insanum*, and *S. incanum* can be crossed to produce fertile offspring. This is also supported in the Report of the Expert Committee (EC-II), which cites unpublished studies by the Indian Institute for Vegetable Research (IIVR) showing that crosses with *S. incanum* were more successful when the cultivar was used as a maternal parent than as a pollen donor. Some investigators have been able to cross plants from these taxa more easily than others (e.g., see Rao 1979; Kalihoo and Gottlieb 1995). Even when early-generation hybrids are only partially fertile, studies of other species with inferior hybrids demonstrate that genes from crops can persist in wild or weedy populations (e.g., Ellstrand 2003, Campbell et al. 2007).

Viswanathan (1975) found a putative hybrid between *S. melongena* and *S. incanum* growing along a roadside in Kerala, India. However, to rigorously determine whether natural crossing to wild or weedy relatives occurs under field conditions, crop-specific genetic markers are needed, such as transgenes, isozymes, or DNA markers known as RAPDs, ISSRs, or SSRs. We were not able to find empirical studies that tested for natural crossing from brinjal using genetic markers. Rao (1979) stated that "natural hybridization, even between similar and sympatric species, is impossible or rare in this section of *Solanum*," but he did not provide any evidence for this regarding *S. incanum* or *S. melongena* var. *insanum*.

Recommendation - The Report of the Expert Committee (EC-II) described field experiments documenting crop-to-crop gene flow from a source area to crop plants that were at least 30 metres away. Similar experiments with recipient populations of wild and weedy relatives are needed to support the statement that "there is no natural crossing among cultivated and wild species of brinjal including *S. incanum* and *S. insanum*." To include relevant genetic diversity, these studies should use recently collected wild and weedy genotypes (not older accessions) from a range of habitats and geographic areas in India (e.g., see Karihaloo and Gottlieb 1995). The presence of local bees (*Bombus, Xylocopa* spp.) that use "buzz-pollination" to collect pollen should be monitored, along with overlap in the crop and wild/weedy plants' flowering times. Field experiments with currently available lines of Bt brinjal would be relatively easy to carry out.

3. Insufficient evidence that wild relatives of brinjal (*Solanum melongena*) would not obtain a fitness benefit from a Bt gene should gene flow occur.

We were not able to find any recent studies or previous publications to support the following statement from p. 56 of the Report of the Expert Committee (EC-II): "FSB is a lepidopteran pest that prefers only brinjal and cry1Ac provides protection only against FSB and other lepidopteran pests. Since no lepidopteran pests are prevalent on *Solanum* wild species, the matter of fitness advantage does not arise."

Recommendation: Because gene flow from the crop cannot be ruled out at this time, field surveys should be carried out to determine whether FSB (fruit and shoot borer, *Leucinodes orbonalis*) or other lepidopteran larvae feed on wild and weedy relatives of brinjal. For example, Cohen et al. (2008) provide a sampling design for this type of study. If lepidopteran larvae are present at any stage of the life cycle, further studies should be carried out to determine whether a Bt transgene could enhance the survival or fecundity of wild/weedy plants under a variety of field conditions, thereby providing a fitness advantage (e.g., Snow et al. 2003). If this is the case, the Bt trangene is likely become more common in wild or weedy populations that hybridize with the crop. Further studies could be carried out to evaluate whether the fitness advantage is strong enough to result in more problematic weed populations, whether the expected ubiquity of Bt toxins in wild or weedy populations could have unwanted effects on non-target lepidopteran insects, and whether the rapid spread of the Bt transgene (and linked crop genes) would negatively affect genetic diversity in wild relatives to a greater extent than ongoing gene flow from non-transgenic eggplant.

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Review of Data Package Submitted in Support of Commercial Approval of Bt Brinjal in India. Prepared for Minister of Environment and Forests, Government of India

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Introduction

I have reviewed the data package (Volumes 1 through 8) posted on the GEAC website for Mahyco's Bt Brinjal. Here I present the key findings of my review, which includes an overview of the data package and a more in-depth review of the Insect Resistance Management (IRM) plan and supporting data.

The data package presented provides a comprehensive set of environmental and toxicological safety data that together both complement and reinforce existing data on the environmental safety of Cry1Ac protein from *Bacillus thuringiensis* and of GM food and feed derived from crops engineered to produce this protein. The benefits of Bt brinjal are compelling. Bt brinjal has the potential to provide clear economic, environmental, and human health benefits to producers and the agricultural environment. While conventional brinjal production requires the frequent application of insecticides to manage the brinjal fruit and shoot borer (BFSB), the proposed Bt brinjal should eliminate this need. This in turn would reduce the cost of raising a brinjal crop, reduce the exposure of growers and their families to potentially harmful insecticides, and reduce the presence of broad spectrum synthetic insecticides in the agricultural environment. This will serve to protect natural populations of beneficial and other non-target organisms and promote the use of other integrated pest management practices. Preservation of natural enemies is expected to help in managing pests other than the target Lepidoptera, including leafhoppers, whiteflies, thrips, and mites As has been seen with Bt cotton in India, the associated cost savings and environmental and health benefits to growers will drive grower adoption of the technology and improve the broader agricultural environment and economy.

These same benefits have been clearly established from the experience of other crops producing Bt proteins in other parts of the world, especially Bt maize in Canada, the United States of America, Argentina, Brazil, Colombia, Philippines and Bt cotton in the United States of America, Brazil, Australia, China and India. Bt crop technology has seen one of the fastest adoption rates of new agricultural technology globally (James 2009).

Food and Feed Safety

The food and feed safety of the introduced proteins and the genetic material necessary for their production has previously been clearly established. Cry1Ac has a long history of safe use, both as a microbial spray and when produced in genetically modified plants, and there are abundant data on food and feed safety. The data presented do not contradict this prior knowledge. The antibiotic resistance marker gene *npt*II has also previously been used as a marker for currently approved and commercialized crops with no documented evidence of negative impacts. Antibiotic resistance marker genes have been shown to have no propensity to "jump" to pathogenic bacteria to impart antibiotic resistance.

There are two areas where the insert characterization could be extended. First, Mahyco have not presented an open reading frame analysis of the site of insert that would provide additional assurance that a native gene was not interrupted by the genetic insertion, or that an unexpected novel protein might be produced. Second, while the submission includes the statement that the *aad* gene, inserted to enable selection of *Agrobacterium* cells that contain the T-DNA of interest, is not expressed in eukaryotic cells as it is controlled by a prokaryotic promoter, additional justification for this claim would be helpful.

However, the comprehensive animal toxicity, allergenicity and feeding studies conducted in multiple species provide copious evidence that the Bt brinjal lines tested are as safe and nutritious as conventional brinjal. This conclusion can be drawn based on acute, chronic, and subchronic exposure regimes using mammals, birds and fish. Feeding studies with Bt brinjal are useful for detecting either direct deleterious effects of the inserted genes or unintended changes to the plants during the transformation process that could be dangerous. The genetic transformation process used allows the introduced DNA to be integrated randomly in the plants' genome, each genetic transformation event represents a unique opportunity to interrupt one (or more) native genes, or to create novel open reading frames. Feeding studies to evaluate the safety of food and feed should be conducted on the event of commercial interest. It is unclear from the descriptions of these studies whether the event used in the trials was the same as the one intended for commercialization. However, there have been no verified instances of a GM plant developed using the technology used for Bt brinjal causing adverse effects in feeding studies. Such studies are therefore best regarded as supplementary, but not necessary, in establishing food and feed safety, given that the safety of the inserted proteins has been proven.

As with the feeding studies, it is not clear that the protein expression studies were conducted using the Bt brinjal event of commercial interest. There is expected to be dramatic differences among events in Bt protein levels, so a full characterization of the commercial event should include this information. That said, since Cry1Ac has no known effects on organisms other than a subset of Lepidoptera, there is no safety concern whatever the Cry1Ac levels are in the crop.

I am unclear what to conclude from the segregation analysis since both the BC1 and BC2F1 produced more than expected Bt-positive plants, and when added together, the ratio is marginally significantly different from 1:1 (chisq, $p = 0.07$). In any case, there is abundant evidence that the Brinjal is non-toxic, wholesome, and does not pose environmental risks, regardless of the number of inserts.

Environmental Safety

Cry1Ac has been well-established environmental safety profile. Bt cotton lines producing this protein has been shown in many studies to have no unexpected non-target effects. Similarly, Bt corn lines producing similar insecticidal proteins have been shown to not have unexpected negative effects on non-target organisms. Cry1 proteins are known to only be active against a subset of Lepidoptera species, and when expressed by Bt plants, only those Lepidoptera feeding on those plants, or on pollen deposited on nearby plants, are exposed. Since such species feeding on the crop are considered pests, only lepidopteran species that may encounter Bt brinjal pollen deposited on other plants warrant specific consideration. Mahyco have conducted this analysis and found that there are no listed endangered lepidopteran species that may be exposed to the Cry1Ac protein produced by Bt brinjal.

The field studies with Bt brinjal presented by Mahyco provide additional evidence that cultivation of this crop will not have adverse effects on non-target organisms, including insects and soil biota. Indeed, reductions in insecticide sprays that this crop enables is likely to result in improvements in the diversity and abundance of beneficial organisms in the crop production systems. It should be noted that the field trials are in small plots, which can reduce the potential to detect effects on mobile organisms that can move among plots. Small scale trials have also been criticized for having insufficient power to detect subtle effects. However, within the context of heterogeneous and dynamic agricultural ecosystems, subtle effects on the environment would be swamped by the more dramatic effects caused by other agricultural practices such as weeding, cultivation, water and fertilizer inputs, and especially other pest management practices including crop rotation, varietal selection, manipulation of planting and harvesting dates, and insecticide applications. Furthermore, it has been demonstrated that when planted on commercial scales crops producing Bt proteins do not have measurable direct effects on organisms outside of the targeted order, and only expected indirect effects on specialist parasitioids (due to dramatic reduction in host availability) have been detected.

Brinjal is not known to be a significant weed in agricultural environments. The insertion of the *cry1*Ac gene is not expected to alter the weediness or invasiveness of brinjal unless the affected pest species, BFSB, is an important factor in limiting the natural populations of brinjal. Mahyco have presented data showing that Bt brinjal is no different in germination rates. Other reproductive parameters, such as flower production and seed set, could also be measured in this context, and such studies should be conducted on the event of commercial interest to ensure that unintended event-specific changes in physiology would be detected. However, as stated above, since the phenotypic difference between Bt and conventional brinjal is simply the production of Cry1Ac insecticidal protein and no pleiotropic changes have been observed, changes in reproductive biology are not reasonably predicted unless BFSB plays a major role in limiting reproductive capacity of brinjal in natural habitats.

Similarly, Mahyco have presented data showing that outcrossing is very limited in agricultural settings, so the *cry*1Ac gene is unlikely to spread and become established in wild populations of brinjal or its sexually compatible relatives. Even when outcrossing does occur, the consequence of this is likely to be insignificant since the production of Cry1Ac has been shown to have no ecological or human safety effects other than direct effects on susceptible lepidopteran (pest or other) species. Therefore, potential effects of outcrossing only on endangered lepidopteran species that feed on wild brinjal or its sexually compatible relatives and that occur in the area of proposed Bt brinjal cultivation warrant consideration. Mahyco have conducted this analysis and found that there are no listed endangered lepidopteran species that may be exposed to the Cry1Ac protein produced by Bt brinjal.

Durability – management of the potential for pest adaptation

As with any pest control tactic, there is a possibility of pest adaptation to the Cry1Ac protein produced by Bt brinjal should Bt brinjal be cultivated across large areas. The evolution of resistance to Bt proteins has been documented in laboratory and field populations of several insect species. This potential for resistance evolution however should not be a reason to prevent commercial use of the product. The consequences of deploying the product and resistance evolving need to be compared with the consequences of not deploying the product at all. The consequences of resistance in this case would be only to reduce the utility of Cry1Ac for control of BFSB in the affected area. The same protein would continue to be efficacious against other pests and and against BFSB in other areas. Cry1Ac-resistant BFSB could still be controlled with conventional or alternative transgenic crop tactics. Logically, the negative consequences of resistance are smaller and temporally delayed compared with the immediate negative consequences of failure to allow cultivation (e.g. continued use of synthetic insecticides, continued degradation of non-target insect populations, continued human and environmental exposure to insecticides, continued financial losses due to both the pest and the costs of insecticide applications).

Judicious use of the crop and appropriate management and stewardship approaches can prevent or delay the onset of resistance and therefore preserve the durability of the benefits that can be derived from this product. In developing a resistance management plan, one must consider multiple factors, including the potential intensity of selection pressure, the potential genetics of resistance, the potential adoption of the pest control tactic, and the practicality of any resistance management practices. The use of refuges has become established as a standard approach to resistance management for Bt crops, both diluting selection pressure and providing susceptible insects to mate with any resistant insects surviving in the Bt crop. The tactic is especially effective if the progeny of such matings, which would be heterozygous for resistance alleles, are largely controlled by the Bt crop. In this way the Bt crop actually removes a large portion of resistance alleles from the pest population.

The proposed resistance management plan consists of a 5% non-Bt brinjal refuge to be planted at edge of each Bt brinjal field. The key questions that are addressed in the plan are the adequacy of the refuge size, the effectiveness of the refuge placement, and the practicality of the separate refuge approach.

Refuge size

The theoretically-appropriate refuge size for a Bt crop depends on several factors: the time horizon (insect generations) over which resistance delay is intended; the level of control expected of heterozygous insects; the background frequency of resistance alleles in unselected populations; and the abundance of "natural refuge" composed of non-Bt hosts of the pest population. Prior to deployment of the crops, and especially prior to finding resistant insects, there is little information available about these factors.

The level of control of heterozygous insects is unknown in the absence of resistant insects. However, extremely high levels of control of susceptible insects (high doses) suggest that heterozygous insects will also be well controlled, especially if resistance is receptor mediated. Receptor-mediated resistance is the most likely mechanism for an insecticidal protein that causes very high levels of mortality of susceptible insects. Mahyco claim that no BFSB have been observed to complete development on Bt brinjal. However, data to substantiate this claim are rather weak. Efficacy results suggest feeding damage is reduced by > 80%, but it is not clear how this translates into insect survival. Additional studies to measure insect survival and adult emergence would be helpful to substantiate this claim.

The background frequency of resistance alleles appears to be rare based both on the observation that no BFSB have been observed to complete development on Bt brinjal and on the baseline susceptibility data. On-going research should aim to provide greater resolution around this, perhaps by observing insect survival and adult emergence in commercial fields.

The host range of BFSB beyond brinjal is not known, and therefore is presumably limited. Until the host range is better characterized, an insect resistance management plan should therefore rely on non-Bt brinjal as the major source of refuge from resistance selection.

The genetics of resistance are unknown, but based on characteristics of other insects with high levels of resistance to Bt proteins, it is reasonable to expect that resistance would be receptor mediated and controlled by one or more major alleles. The observations of high levels of susceptibility to Cry1Ac in BFSB and of consistent control in field studies suggest that indeed resistance is rare and that a high level of resistance would be needed to overcome the Bt protein in Bt brinjal. However, I am unclear whether the protein expression studies, and the BFSB susceptibility inferred from them, were conducted on the event of commercial interest. Conclusions relating to efficacy and dose are not easily extrapolated among different events due to expected differences in Bt protein expression levels. The statement "MIC95 is an accurate parameter to predict the fate of neonate caterpillars feeding on Bt brinjal plant" (page 6 of the protein quantitation report-K'04 and page 6 of the K'05 report) should be backed up with event-specific data.

The predicted ratio of susceptible to resistant moths emerging from the brinjal area when a 5% refuge is used is based on these assumptions, which appear to be reasonable. While a larger refuge may be a more cautious approach to resistance management, in the early years of Bt brinjal commercialization, it is likely that non-Bt brinjal (and wild relatives) will serve to augment the refuge and reduce selection pressure. Therefore a 5% refuge seems to be appropriate as long as there are clear information triggers that would lead to adoption of a larger refuge and a clear mechanism to communicate such a change.

Refuge placement
Provision of the non-Bt refuge Brinjal in close proximity to the Bt brinjal crop is important to ensure that any resistant insects emerging from the Bt area are able to mate with the plentiful susceptible insects expected to emerge from the refuge. Placement of the refuge at the edges of the brinjal field also serves to "intercept" resistant adults that may be dispersing out to of the field. This arrangement has the added benefit of providing a barrier hindering Bt pollen movement out of the field. While larger growers can benefit from more flexibility in refuge placement (e.g. maize producers in the United States are permitted to plant some refuges up to ~1km from the Bt field), such benefits are unlikely to apply to small hectare farms or when refuge sizes are small.

Practical implementation of refuge requirements
Non-Bt refuges are regarded by growers as costly or inconvenient as they are not able to derive the full financial opportunity of planting Bt varieties. Some growers may therefore be reluctant to purchase and plant non-Bt refuge seed. The proposed plan helps address these concerns by providing the refuge seed along with the Bt seed. In addition the plan allows for an individual producer to plant up to 95% of their brinjal acreage to Bt varieties, and therefore will suffer little economic loss at the farm scale, instead realizing the economic benefit from the 95% of their brinjal crop that is protected by Cry1Ac. Education efforts need to address not just what the refuge recommendations are, but why they are important for the producer. With a strong education program, growers should be able to plant the necessary refuge and therefore realize the benefits of Bt technology for the long term. However, it needs to be expected that a portion of the growers will not follow the refuge recommendations for all their fields, and the IRM plan needs to be sufficiently conservative to account for this. Since in the early years of introduction only a portion of the brinjal produced will produce Cry1Ac, there will be a significant natural refuge in addition to the 5% structured refuge which will provide the necessary conservativeness.

Recommendation
The 5% refuge supplied as a separate seed packet appears to be a good starting point for a resistance management program for Bt brinjal. If field relevant resistance (ie. such that homozygotes are able to complete development on Bt brinjal) is not very rare or very recessive, a larger refuge may be warranted as adoption of the technology exceeds 50%.

The biology of the pest, with minimal movement of larvae among plants, lends itself well to provision of the refuge as a seed mix rather than a separate package. The IRM document suggests that growers may not accept seed mixes because visible damage to refuge plants could look like the product is not working as it should. However, growers should not be led to expect that the crop, even if 100% Bt brinjal, will be damage-free. Low levels of damage to Bt brinjal are observed in field tests, and pests other than BFSB are not controlled by Cry1Ac. Therefore growers should expect to see some pest damage to Bt brinjal and the addition of a small percentage of non-Bt plants is not likely to significantly alter the perception. That the efficacy of Bt brinjal is superior to insecticides, it seems likely that growers would embrace the technology even if a small percentage of plants were unprotected against BFSB. Mahyco should evaluate the grower acceptability of such an approach, which would guarantee that the refuge is planted, improve the ease of implementation of the IRM recommendations, and ensure that every Bt brinjal crop has includes a suitable non-Bt refuge.

On-going research is warranted to investigate the validity of some of the assumptions of the IRM plan, and such research should be accomplished during commercialization but before adoption of the technology becomes widespread. Criteria for judging the validity of the IRM program should be assessed and a mechanism developed for making any changes to the program that such research may reveal are warranted. Field research in commercial plots should validate the claim that no BFSB have been observed to complete development on Bt brinjal which would serve to both verify the "high dose" and rareness of resistance alleles. Attempts to isolate and characterize resistance alleles should also be considered as the results of such efforts can aid in refining IRM plans as well as developing new Bt brinjal products. Validating the assumption that heterozygotes will be susceptible to Bt brinjal would be particularly helpful in providing assurance of the long-term viability of the IRM program. Finally, it will be helpful to improve the knowledge of the availability and suitability of other crop and non-crop host plants to serve as natural refuges.

As with any stewardship program, monitoring should be conducted to evaluate the effectiveness and on-going need for the stewardship program. Monitoring efforts should encompass both the crop (how much is deployed, levels of refuge implementation) and the insect (changes in sensitivity to Cry1Ac protein and/or changes in performance on Bt brinjal in commercial fields).

Results of research and monitoring programs should be used to evaluate the continuation of the IRM program. Ideally at the same time the monitoring program is being developed triggers should be identified that would change the IRM requirements. For example, if resistance alleles are found to be more frequent than 1 in 500, an increase in refuge size may be warranted. Or if grower implementation of refuges is low, alternative means of deploying the refuge, including a seed mix, may be warranted. Alternatively, if the research indicates that the resistance potential is lower than assumed (e.g. due to high fitness costs associated with resistance, or to the presence of significant natural refuge), refuge requirements could be relaxed or eliminated.

Future development of GM Brinjal
Cry1Ac-producing Bt brinjal should not be seen as a silver bullet to managing lepidopteran pests in brinjal. The potential for resistance to evolve, and the inherent difficulties in anticipating and appropriately implementing proactive IRM measures, mean that research should continue to develop new Bt brinjal varieties that are able to further delay or overcome such resistance. Diversity of active ingredients brought about by developing Bt brinjal events that produce alternative Bt proteins, and especially pyramided events that produce more than one Bt protein active against the same pests, will serve to increase and extend the benefits of the technology while requiring less proactive resistance management. Creating a political and regulatory environment that encourages continued development is an important step towards the development of such alternative products.

Conclusions

The data presented on Bt brinjal demonstrate that, as with other Bt crops, the crop does not pose unreasonable adverse risks to the environment or to human and animal health. Cultivation of such a product would have many benefits to brinjal producer, including economic, environmental, and human health benefits compared with cultivation of conventional brinjal. Careful implementation of resistance management strategies will ensure that the benefits are sustainable for the long term.

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Mr. Jairam Ramesh
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Re: Bt-brinjal Part One

Dear Minister Ramesh

It is my pleasure to respond to your request of 7 November 2009 for my views on the Monsanto-Mahyco application to approve open cultivation of Bt-brinjal for use as food. As you know, I was one of a number of independent scientists who read and critiqued the scientific information provided by the developer in its case to demonstrate that the genetically engineered Bt-brinjal posed no safety concerns for human health or the environment. I came to the conclusion that the molecular data, and some related analyses, were too poorly conducted to make a definitive claim that this product is safe.

Since that time, the official Indian advisory body, GEAC, has ruled that the science provided by the company does satisfy them that Bt-brinjal is safe. I have only just learned, however, that new evidence in support of the claim of safety has become available. All or some of this evidence was gathered after the dossier was made publicly available in August of 2008. The new data was posted for viewing only days ago. I have been unable to review the new data to determine if they adequately address the concerns I raised previously. To do so properly, I will need additional time. Considering the volume of new data posted, I hope that you will extend your period of review until March of 2010.

Therefore, if you would permit me, I would prefer to respond to your request in two parts. In this letter, I will describe how I came to my present views on agriculture and my involvement in assessing other genetically engineered crops and the outcome of those assessments. This I believe to be important information because it is related to how I prioritise my assessment of the testing of Bt-brinjal, which will be the focus of my next letter.

Traits such as Bt (insect tolerance in general) and HT (herbicide tolerance in general, often RR for roundup ready) suit particular agroecosystems and philosophies of industrial agriculture. That is perhaps why, even according to industry figures, 67% of all commercialised genetically engineered crops are grown in only 2 countries, the United States and Argentina, and 80% in just 3 countries including Brazil. India, which the industry describes as a GE megacountry, produces only 6% of the world's GE crops and only uses 4% of its agricultural land for GE. The industry figures are contested and may overstate the amount of GE produced outside of the US and Argentina, making the concentration of GE crops in just a few agroecosystems even more telling.

As I discuss in my book *Hope not Hype*, only two countries on this planet have gambled with GE on more than 35% of their agricultural land. Those two countries are Argentina and Paraguay (and decidedly *not* the United States). They have over two-thirds of their agricultural land in GE production. Alongside the change to GE production has been an increase in "food insecurity" and "very low food security" as measured by the UN Food and Agriculture Organisation (see Box 7.2 of *Hope not Hype*).

Since India's only genetically engineered crop at this time is cotton, it is worth considering how GE cotton varieties in the US, where they have been in production the longest, are doing. Interestingly, the latest studies do not vindicate the claim that the crops are reliably increasing yield or financial returns (this is discussed and fully referenced in detail in Chapter 5 of *Hope not Hype*). The latest research shows that over time profits follow yield, but there is no consistent yield increase with GE cotton. There is year-to-year variation, with good yield years promoted by those who sell GE cotton seeds.

There are many reasons beyond safety to consider whether GE crops are the right kind of biotechnology for your country. These were considered methodically and holistically by the single largest research exercise on global agriculture in history conducted with funding from multiple UN agencies and the World Bank. This report, published in January as *Agriculture at a Crossroads*, was produced under the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD). It involved around 400 researchers and twice the number of peer-reviewers. Built on the IPCC model, it underwent two rounds of open international peer-review and was ratified overwhelmingly at the intergovernmental plenary in April 2008.

The "IAASTD report" came to the conclusion that 'business as usual' will inevitably result in food and fuel needs exceeding global ability to meet them. However, this isn't a food shortage problem. The problem historically and presently is caused by social barriers and because of the model of agriculture for which most GE products are designed. In fact, more GE is more 'business as usual'. Some hunger in the future will probably be due to production limitations, but again mainly because of conspicuous consumption in wealthy countries, loss of land and fertility in both developed and developing countries (because of use of fossil-fuel dependent fertilizers), and poor policy decisions on water and biomass use. Unless the problem of "feeding the world" is considered holistically, inappropriate technologies that are not sustainable will be proposed as stop-gap solutions and that would not address the major causes of shortage.

I was a lead author on Chapter 6 of the global report, and of the biotechnology section of the Synthesis Report. This latter role was why I was invited to represent the authors at the intergovernmental plenary at which the report was adopted. In addition to that role, I have been a biotechnology advisor to multiple government agencies in New Zealand, and agencies of the US and Norwegian governments. I am listed by the United Nations as a biosafety expert and serve on the Ad Hoc Technical Experts Group to the Secretariat of the Convention on Biodiversity. I publish in the international peer-reviewed literature including such journals as *Science, Nature, Nature Biotechnology* and *Trends in Biotechnology* and have an active laboratory with three PhD students (with more on the way), a postdoctoral scholar and an honours student.

I am also the director of a research centre that voluntarily participates in the consultation in our country over the use of GE crops as human food. Our food regulator, Food Standards Australia New Zealand, is the competent authority for both Australia and New Zealand. They invite opinion, particularly scientific opinion, on applications for amending our food code to include GE crops on a case by case basis. I have reviewed three applications in great detail, and four applications to date. Two applications for which I submitted comments were withdrawn by the applicant (both ostensibly for commercial reasons, but there are reasons to doubt that, at least for the second application).

Both applications that were ultimately withdrawn were from Monsanto. The first was for a modified wheat plant in 2004.The most recent withdrawal was of Monsanto's high lysine maize LY038. This is the most interesting case. My colleagues and I found over a hundred scientific flaws in the data. Nonetheless, the application was approved in several jurisdictions, including Australia/New Zealand, despite these problems. However, many of those flaws, and the most significant ones, were not considered permissible by many European countries or the European Food Safety Authority (EFSA), which refused to approve the maize unless the key problems with the scientific dossier were addressed with new experiments and the results still supported approval. Instead of investing the small increment of money necessary to produce this science, Monsanto instead stopped all commercial development of LY038. Since we estimate that Monsanto had by this time invested nearly US$1 billion in development, marketing and processing facilities, and by its own admission expected that this product would produce a revenue stream of US$1 billion/year, a few hundred thousand dollars of new scientific tests was to us an unlikely reason for withdrawing the product.

I relate this story for two reasons. The first is to let you know that I am not naïve to what it takes to make a quality dossier for an application to approve a GE plant and determine that it is safe for human health and the environment. I have been doing this analysis for some time, and been found to be in agreement at least with some competent authorities. Strikingly, the major defect in the LY038 dossier was the use of the wrong comparator. They used another GE variety against Codex Alimentarius and EU rules. Some jurisdictions went to great lengths to excuse this fundamental flaw, but others held their ground. I could not find the comparator even mentioned in the brinjal safety studies that I took special note of, much less a sense that the studies consistently used the appropriate comparator.

Second is to say that while India can have whatever standards it wishes for deciding on GE foods, other countries may close the door if proper and thorough safety testing has not been done. The LY038 application is instructive here. The Bt-brinjal dossier I viewed in August 2008 is, in my opinion, nowhere near the sophistication and quality of the LY038 dossier, and that dossier was still unacceptable to Europe. Many of the Bt-brinjal experiments, at least as described, would not satisfy Codex Alimentarius guidelines as applied by careful regulators. Does India want a reputation for low standards in food? Does it want to put its exports at risk? If the answers to these questions are 'no', then I would encourage you to set the standard with Bt-brinjal that you would like the industry to meet now and in the future for any GE crop.

It is easier for industry to meet high government standards communicated clearly at the start than it is for government to raise industry standards later.

It is for me a serious error to assume that those with an interest in product development can also be biosafety scientists. The extensive network of funding for research for the purposes of advancing commercial agendas includes many in academia, so it is no longer valid to simply choose researchers from universities and call them independent. A truly world-leading strategy would be to maintain a distance between the regulator and the technology, and to certainly remove any consideration of trade from the regulator's brief. India could achieve this by supporting independent laboratories and researchers committed to public and environmental safety at both the basic research level and in review of technological applications. As we are witnessing by the accumulation of research results from a small and widely spread independent research community, the truth ultimately comes out. The challenge will be for political leaders such as yourself to ensure that the truth comes out before any undetected harms of new technologies.

With best wishes,

Prof. Jack Heinemann
24 November 2009

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Mr. Jairam Ramesh
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Government of India

Re: Bt-brinjal Part Two (of two)

Dear Minister Ramesh

It is my pleasure to respond to your request of 7 November 2009 for my views on the Mahyco et al. application to approve open cultivation of Bt-brinjal for use as food. As you know, I was one of a number of independent scientists who read and critiqued the scientific information provided by the developers in their case to demonstrate that the genetically engineered Bt-brinjal posed no safety concerns for human health or the environment. I came to the conclusion that the molecular data, and some related analyses, were too poorly conducted to make a definitive claim that this product is safe.

Since that time, the official Indian advisory body, the Genetic Engineering Approval Committee (GEAC), has ruled that the science provided by the company does satisfy them that Bt-brinjal is safe. Later I learned that new information had been released in November of this year. This put additional stress on my ability to meet your request of information by 31 December. I have done everything I could to meet the deadline regardless, but I ask your indulgence to submit more information in the future should I have overlooked something due to the short time available to review the new information.

As promised on 24 November, this is the second part of my response. In this letter, I will review selected criticisms formed in August 2008 when I reviewed the scientific information available at the time, and indicate how these have been addressed by the developers or GEAC.

Summary of analysis of dossier from Mahyco et al. in support of their claims of safety of fruit and shoot borer tolerant brinjal

I previously provided a review of selected topics within Mahyco's dossier. This was referred to in the "Report of the Expert Committee (EC-II) on BT Brinjal Event EE-1" (EC-II) of 8 October 2009 as item 17 "comments by Prof. Jack A. Heinemann".

GEAC considered my comments, as I understand, through the report of the expert committee. However, several significant issues remain either not addressed, misunderstood or incorrectly addressed.

1. Insertions

A proper safety assessment includes a molecular (genomic) level profile of the modified plant. In my original report I said that Mahyco had not eliminated the possibility that there is more than one insertion of recombinant DNA and that all insertions are not free of vector "backbone" DNA. Such confirmatory experiments are relatively inexpensive and the methods so common that they are taught in some high schools, so there should be absolutely no reason to fail on this first step of a safety assessment.

GEAC has summarised the insert data, but to my knowledge has not based this summary on any updated evidence. The following are reasons why GEAC cannot conclude from Mahyco's data that there is a single insert and no additional inserts of unexpected size or sequence composition.

A. The Southern blot analysis is fundamentally flawed and incapable of finding unexpected inserts.
    a. The probe is described as "cry1Ac probe" or "Bt" probe (p. 34)[1], presumably meaning the *cry1Ac* transgene and the probe was presumably appropriately sequence modified to reflect changes introduced by the developers[2]. ECII also refers to a single probe called "Bt" in section 3.1.4. Since the probe is specific to only this part of pMON10518, the blot is inappropriate for establishing that there are no other inserts and no backbone DNA from pMON10518. This is the scientific equivalent of using a microscope to track asteroids.

[1] Page numbers are from document called Toxicology and allergenicity studies vol. 1.
[2] "Both regions of the cry1Ac gene were genetically modified for increased plant expression using a strategy comparable to that described by Perlak..." (p. 33).

Later in ECII, GEAC asserts that Mahyco has used "the entire pMON10518 plasmid as a probe, as well as the nptII gene and 7S terminator-right border regions as probes. No additional bands were detected using these probes, indicating that there are no additional fragments from the construct at other locations in the genome." *However, I could not find these data either in the materials release in 2008 or in late 2009. Where are these data? In addition, the GEAC summary does not address the important point that there are no sensitivity parameters upon which to build confidence that any unexpected or unanticipated insertions would be detected (see below). The conclusions of GEAC on this point are based on the strength of a negative result (non-detection), which could have multiple causes besides the absence of additional inserts.*

b. As recommended by Codex Alimentarius, Mahyco should disclose all details that are necessary to establish the sensitivity of their analyses. Therefore, the size of the probe and the stringency of the wash procedure should be reported. All probes should be shown on the plasmid map. Partial fragments of transgenes or genomic DNA interspersed into transgenes have been detected as fragments as small as 15 bp[3]. Mahyco would have to show that all its probes would have detected such small insertions at the sensitivity of 0.5 copies per diploid genome in order to establish with reasonable certainty that the negative result was meaningful.

   It is impossible to determine the sensitivity of the methods used to attempt to detect unexpected or unanticipated additional inserts from the documents provided.

Note that Codex makes specific recommendations on molecular characterization: The sensitivity of all analytical methods should be documented (p. 11). Codex, (2003). Codex Work on Foods Derived from Biotechnology. CAC/GL 45-2003.

c. The sensitivity of genomic profiling methods (e.g. Southern blotting) for surveying insertions of partial transgenes should be at least to the standard of

3 https://bat.genok.org/bat/?sp=html/practical_assessment/ch2_DNA_to_insert/molecular_characterization/southern_blots.html

published studies[4]. A combination of FISH, fiber-FISH and Southern analysis are used to increase detection of unanticipated or unintended inserts, whereas Mahyco has only used Southern and PCR. These other published studies found that even to their much higher standard, they failed to detect all insertions initially. They found for example that "[t]ransgenic oat line 3830...was previously characterized with FISH, fiber-FISH, and Southern analyses and shown to have a single major transgene locus estimated to be ca. 15 kb in length. However, when T1 progeny of line 3830 were analyzed by Southern blot hybridizations with longer exposure times and more genomic DNA per lane compared to these previous analyses, two additional minor transgene loci were detected" (Makarevitch et al. 2003). Their work emphasizes how vulnerable analyses are to arbitrary exposure times, probe sizes and wash stringency.

d. The PCR data does not substitute for the required Southern data because small fragments cannot be expected to insert in the correct order or proximity to primers for easy amplification[5].

e. The Southern blot provided as evidence (p. 46) is below acceptable standard for other reasons as well. A light band of the same size can be seen in control lanes and in the lanes with DNA taken from transgenic plants. This result can arise from sloppy handling and loading of samples. It can also result from contamination of control lines, and thus the use of controls that are also GM plants. Since we do not know the sensitivity of the probes, the possibility that the control lines carry a single simple insert cannot be ruled out with this data. In addition, larger bands are seen to hybridize and these could have secondary inserts to which the probe binds. The only way to resolve these possibilities is to clone and sequence all visible bands.

f. Mahyco should meet the dual standard of demonstrating comprehensive coverage in their search for pMON10518 DNA (which the list of probes does not) and demonstrating appropriate sensitivity to small inserts (which the data do not).

References

Makarevitch, I., Svitashev, S.K. & Somers, D.A. (2003). Complete sequence analysis of transgene loci from plants transformed via microprojectile bombardment. Plant Mol. Biol. 52, 421-432.

[4] https://bat.genok.org/bat/?sp=html/practical_assessment/ch2_DNA_to_insert/example.html

B. Mahyco previously argued incorrectly that there could be no vector sequences transferred and did not to my knowledge provide any evidence of having verified their assumption. GEAC has not addressed this criticism.

The claim by Mahyco was that during Ti plasmid-mediated DNA transfer from *Agrobacterium tumefaciens* to plants, only the T-DNA is transferred. These claims begin on page 32 (section 3.3). This view is clearly wrong. First, the expectation is inconsistent with the biochemical process (Waters and Guiney, 1993). Second, at least since the mid-1990s it has been known that the "long transfer – the collinear transfer of DNA past the traditional left border – is a common phenomenon" (Wenck et al., 1997).

"In this study, we report the surprising result that approximately 75% of the transgenic plants that we generated using Agrobacterium-mediated T-DNA transfer contained binary vector 'backbone' sequences integrated into the plant genome. We obtained these data using both DNA blot and PCR analyses of the DNA of these transgenic plants" (Kononov et al., 1997, emphasis added).

Outdated views such as those expressed by Mahyco derive from previous experiments that were not designed to detect backbone transfers. *"Usually, transfer of only the non-T-DNA sequences to the plant would remain undetected because: (1) there is no selection for the transfer of such sequences; and (2) scientists generally have not looked for the transfer of these sequences"* (Kononov et al., 1997, emphasis added). Mahyco continues this tradition. The amount of DNA that can transfer can be many times the length of the T-DNA region: *"extremely long regions of DNA (greater than 200 kbp) can transfer to and integrate into the genome of plants"* (Kononov et al., 1997, emphasis added). More troubling, short backbone sequences can transfer and be difficult to detect. *"In many instances, vector 'backbone' regions of a binary vector are smaller than what is conventionally termed the 'T-DNA' region"* (Kononov et al., 1997, emphasis added).

These scientific facts invalidate additional claims made by Mahyco, notably that "The border sequence itself is not entirely transferred during the T-DNA insertion in the plant genome. This means that the inserted DNA is no longer functional T-DNA, i.e., once integrated into the plant genomic DNA, it can not be remobilized into the genome of another plant even if acted upon by vir genes again" (p. 32). Note that Mahyco has rested

[5] https://bat.genok.org/bat/?sp=html/practical_assessment/ch2_DNA_to_insert/example.html

its understanding of the T-DNA transfer process on references that are 1992 or older, and clearly no longer apply.

Mahyco also makes the claim that the disarmed Ti plasmid "does not transfer to the plant cells but remains in the Agrobacterium" (p. 32). The Ti plasmid is a conjugative plasmid. It has been known since the 1980s that conjugative plasmids transfer to eukaryotes including plants. At some frequency, the Ti plasmid itself may transfer to the plants (Buchanan-Wollaston et al., 1987, Ferguson and Heinemann, 2002, Heinemann, 1991). It is Mahyco's burden to demonstrate with proper molecular analyses that this did not happen. No data are presented by Mahyco to establish the absence of Ti DNA, *and this is not denied by GEAC.*

Finally, there is no indication of a left border on the pMON10518 map (p. 40) or on the list of genetic elements (Table 3.2, p.48). If the left border is indeed missing, then the entire plasmid will transfer.

GEAC should be aware of these facts and should have, in my view, required the company to properly demonstrate that no unanticipated or unexpected additional inserts exist. India has several reasons to be concerned by the possibility that additional sequences exist. First, there is the biological rationale for characterizing all inserts as part of proper hazard identification. Second, all inserts constitute new "events", and events may be patented. This second reason has important trade implications. If sequences common in backbones are described as the intellectual property of others in importing countries, then India may lose its control of domestically-produced brinjal.

In its review of the molecular characterization (ECII section III), GEAC fails to indicate that it is aware of the deficiencies in Mahyco's experiments, and commits its own errors of logic. For example, GEAC asserts: "*Agrobacterium*-mediated transformation has been used for the development of numerous biotech crops grown around the world for the past two decades, and has a proven track (*sic*) from a biosafety standpoint."

GEAC is wrong to associate its views on the safety of some commercialized products with the conclusion that the method of development has a history of safe use. There are a limited number of commercialized products derived from *Agrobacterium*-mediated transformation and these products are considered safe by competent authorities in some countries based on both a pre-market assessment and their use in structured agricultural systems. The number of products being used is still very small and does not warrant an endorsement of the safety of a particular procedure. For example, considering the number and the kinds of products based on nuclear fission (from bombs to power plants) it could be asserted that in the context in which products of nuclear fission are deployed these products have a safe track record. This does not mean that every nuclear fission reaction is inherently safe and by extension every bomb or powerplant in every context is inherently safe just because it is based on nuclear fission.

References

Buchanan-Wollaston, V., Passiatore, J. E. and Cannon, F. (1987). The mob and oriT mobilization functions of a bacterial plasmid promote its transfer to plants. Nature 328, 172-175.

Ferguson, G. C. and Heinemann, J. A. (2002). Recent history of trans-kingdom conjugation. In Horizontal Gene Transfer, M. Syvanen, and C. I. Kado, eds. (London and San Diego, Academic Press), pp. 3-17.

Heinemann, J. A. (1991). Genetics of gene transfer between species. Trends Genet. 7, 181-185.

Kononov, M. E., Bassuner, B. and Gelvin, S. B. (1997). Integration of T-DNA binary vector 'backbone' sequences into the tobacco genome: evidence for multiple complex patterns of integration. Pl. J. 11, 945-957.

Waters, V. L. and Guiney, D. G. (1993). Processes at the nick region link conjugation, T-DNA transfer and rolling circle replication. Mol. Microbiol. 9, 1123-1130.

Wenck, A., Czakó, M., Kanevski, I. and Marton, L. (1997). Frequeunt collinear long transfer of DNA inclusive of the whole binary vector during Agrobacterium-mediated transformation. Pl. Mol. Biol. 34, 913-922.

2. Expression: Novel RNA and Proteins

As indicated in my previous submission, Mayhco has not provided information on potential novel RNAs and proteins produced in the six possible open reading frames created by the EE-I event or by undetected secondary insertions. In fact, Mahyco has provided no information whatsoever on novel RNAs. This is a significant omission. Moreover, since Mahyco uses the nos3′ terminator in its construct it has an added obligation to look for novel RNAs. The nos3′ is not an efficient terminator in eukaryotes, leading to read-through, longer mRNA molecules and potential fusion proteins.

According to Codex (p. 14, paragraph 32), "Information should be provided on any expressed substances in the recombinant-DNA plant; this should include: the gene product(s) (e.g. a protein or an untranslated RNA); the gene product(s)' function…".

Codex, (2003). Codex Work on Foods Derived from Biotechnology. CAC/GL 45-2003.

In response to my previous submission, GEAC (ECII) has commented that "the insertion sites from Bt brinjal event EE-1 was isolated and sequenced. The 3' end of the *cry1Ac* gene was examined and found to have the expected stop codon, followed by the 7S terminator and right border. Genomic flanking sequence examined on either side of the insertion showed no significant matches [to] any sequence in GenBank, and does not encode any open reading frames in all six frames. This suggests that no novel RNAs or proteins were generated as a result of the EE-1 insertion."

A. This response is based on assumption, not evidence. Moreover, the assumptions are not reliable.

   a. I indicated in my previous submission that the presence of stop codons and terminator sequences are not sufficient to prove the absence of unintended or unanticipated RNA and protein products.

   For example, Mahyco has used the nos3′ terminator adjacent to the nptII gene. The nos3′ is not an efficient terminator in eukaryotes, leading to read-through, longer mRNA molecules and potential fusion proteins (Rang et al., 2005).

   Researchers first reported this in a transgenic soybean called 40-3-2. Interestingly, 40-3-2 is a Monsanto product and Monsanto is presumably the source of pMON10581. Even more troubling, "the read-through transcript [in 40-3-2] was processed in four different RNA-variants" (Rang et al., 2005). The variants might arise from splicing pathways or other pathways that are not predicted from Genbank DNA sequences.

   A significant concern raised by the authors about the variant RNA molecules in 40-3-2, if they arise through a splicing mechanism, was that the nos sequence itself harbors a splice site. "The cis regulatory regions that initiate and mediate splicing are located within the removed region of spliced transcripts. If this is also true for the mechanisms mediating posttranscriptional processing of the described variants, it seems reasonable to assume that the transcribed nos terminator region might be responsible for processing the RNA. *Since the nos terminator was and still is commonly used as regulatory region in the production of genetically modified crops, read-through products and RNA variants could also be expressed in these plants*" (Rang et al., 2005, emphasis added). Since nos is also used in Bt binjal, these established research findings require that it be evaluated for variant RNA species arising from the inserted DNA.

This research has been extended by others generalizing to other genetically engineered plants based upon Monsanto-derived vectors and transgenes.

> The experiments showed the synthesis, due to the known loss of the NOS terminator, of fusion RNA variants coding for putative CRY fusion protein showing 2 or 18 putative additional aminoacids, composed of the 3′ end of truncated cry1A(b) gene and the putative HECT 3′ sequences transcribed in antisense orientation. Different transcripts showed a series of deletions some of which in common to all observed RNAs...In silico translation of putative fusion RNAs did not show significant identities with known protein domains...Taken together, our data, while suggesting the insertion of the transgenic sequence in a putative HECT gene, *show the transcription of new fusion RNAs, a result similar to that obtained by Rang and et al. (2005) in Roundup Ready Soybean 40-3-2* (p. 280 Rosati, A. et al., 2008, emphasis added).

Note that these novel variants were not predicted from Genbank analyses of open reading frames. This is emerging as a general theme in molecular biology and cannot be ignored by the industry or the regulator. In addition to transcriptome changes, there are unpredicted changes in the proteome. For example:

> A comparison of a commercial maize variety carrying the MON810 event [from Monsanto] and its isogenic relatives (Zolla, L. et al., 2008) indicates both that unanticipated changes occur as a result of the engineering process and that these can be more carefully characterized using profiling techniques that are not common in the scientific dossiers provided to regulators (Heinemann, J.A., 2007).
>
> The commercial line (33P67) was confirmed by Southern blotting to have a single insert (Zolla, L. et al., 2008). The subsequent analysis was on the proteome,

comparing seeds of the commercial line and the seeds of its immediate F1 generation (33P67F1) with the seeds of the isogenic comparator (33P66) and the seeds of its immediate F1 generation (33P66F1). These comparisons allowed the researchers to measure variability in the proteome that was caused by the environment (33P66 vs. 33P66F1 and 33P67 vs. 33P67F1), effects caused only by the engineering process (33P66F1 vs. 33P67F1), and the combined effects of environment and engineering (33P66 vs. 33P67).

Approximately 100 of the identifiable proteins varied either quantitatively (increases or decreases but protein in both) or qualitatively (protein present only in one) in the comparison of the seeds from the conventional line and the seeds it produced (33P66F1). Similar numbers of statistically significant changes were observed in the seeds of the transgenic 33P67 and its F1 progeny (78 changes). This is the effect of breeding and the environment on proteome changes because the tested seeds (33P66 and 33P67) came from plants grown in different environments. Comparisons between 33P66 and 33P67 reveal the combination of differences in environment and effects of the genetic engineering process. There were 27 statistically significant proteome differences between the conventional and transgenic seeds.

This illustrates that only thorough scientific testing, and not assumption-based reasoning of the kind used in the ECII, can properly be used for risk assessment.

References[6]

Heinemann, J.A. (2007). Letter to the Editor. Environ Plann Law J 24, 157-160.
Zolla, L., Rinalducci, S., Antonioli, P. & Righetti, P. G. (2008). Proteomics as a complementary tool for identifying unintended side effects occurring in transgenic maize seeds as a result of genetic modifications. J Proteome Res 7, 1850-61.

Regardless of whether the variant RNAs arise from a cryptic splice site within nos or through other processing pathways, all novel RNA species in Bt binjal must be reported for a proper safety assessment. GEAC should be adhering to the full extend of Codex Alimentarius guidelines, and not picking and choosing which standards to enforce and which to excuse.

6 https://bat.genok.org/bat/?sp=html/practical_assessment/ch2_DNA_to_insert/breeding_trees_equivalence.html

References

Rang, A., Linke, B. & Jansen, B. (2005). Detection of RNA variants transcribedfrom the transgene in Roundup Ready soybean. Eur. Food Res. Technol. 220, 438–443.

Rosati, A., Bogani, P., Santarlasci, A. & Buiatti, M. (2008). Characterisation of 3' transgene insertion site and derived mRNAs in MON810 YieldGard maize. Plant Mol. Biol. 67, 271-81.

b. The failure to adequately assess the kinds of novel RNAs produced at the site of insertion is compounded by the very real possibility that there exist additional uncharacterized and unanticipated insertions, each of which could be responsible for generating unknown and unanticipated novel RNA and proteins. Two kinds of experiments would put this question to rest:

   i. proper and full profiling of the genome by a combination of techniques (done properly, as discussed above); and

   ii. transcriptome[7], proteome and metabolome[8] profiling:

> Non-targeted, analytical approaches at the gene, transcript, protein and metabolite levels are the methods-of-choice for investigating the physiology of the GM plants as comprehensively as possible, thus increasing the chances of detecting unintended effects.
>
> Rischer, H. & Oksman-Caldentey, K.-M. (2006). Unintended effects in genetically modified crops: revealed by metabolomics? Trends Biotechnol. 24, 102-104.

Disappointingly, GEAC (ECII) dismissed Dr. P.M. Bhargava's previous recommendation for profiling for the following reasons:

- the techniques are expensive and have "little value"; and
- they are not validated.

These assertions are not based on evidence and are not in my opinion—and that of other biosafety experts—correct[9]. In fact, even Mahyco's

[7] https://bat.genok.org/bat/?sp=html/topic_guides/ch1_basics/profiling_hazards/molecular_methods/transcriptome_techniques/main.html

[8] https://bat.genok.org/bat/?sp=html/topic_guides/ch1_basics/profiling_hazards/molecular_methods/proteome_techniques/main.html

collaborator, Monsanto, has demonstrated its ability to perform such profiling.

> For example: "[T]his method [2D gel electrophoresis] could be used to interrogate proteome alterations such as a novel protein, fusion protein, or any other change that affects molecular mass, isoelectric point, and/or quantity of a protein" (p. 2154).
>
> Monsanto study published under Ruebelt, M. C., Leimgruber, N. K., Lipp, M., Reynolds, T. L., Nemeth, M. A., Astwood, J. D., Engel, K. H. & Jany, K. D. (2006). Application of two-dimensional gel electrophoresis to interrogate alterations in the proteome of genetically modified crops. 1. Assessing analytical validation. J. Agric. Food Chem. 54, 2154-2161.

- GEAC and all other regulators do accept profiling evidence. Southern blotting (done properly) to determine if unanticipated or unintended additional insertions were made during transformation is a profiling of the genome. This procedure has not been "validated", but is ubiquitously accepted.
- Mahyco's collaborator, Monsanto, can and does profile both transcriptomes and proteomes. These procedures have not been cost prohibitive for the industry, are rapidly becoming less expensive and do provide useful information. For example:

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[9] see quote above by Rischer et al. and https://bat.genok.org/bat/?sp=html/topic_guides/ch1_basics/profiling_hazards/main.html

Transcriptome

Monsanto researchers conducted a survey of small RNAs found in soybean seeds, corn kernels, and rice grains (Ivashuta, S.I. et al., 2008). Although this survey was incomplete, it represents the largest such survey that I am aware of to date. These RNAs were ≤30 nucleotides long. The RNA molecules isolated from rice were sequenced using high throughput 454 procedures, for a total of 285,864 unique and sequenced RNA molecules.

The researchers were able to quantify the amount of RNA in size range of ≤30 nucleotides for mature soybean and corn seeds. Soybean had approximately 0.70 g of small RNA/gram of tissue, and corn and rice reportedly had similar amounts.

This study demonstrates that it is within the capacity of developers to perform profiling experiments for the purpose of hazard identification. The number of small RNAs reported in this study would likely exceed the number of anticipated and unintended small RNAs generated as a result of the engineering process and insertions, and thus the exercise would be even simpler when applied to the GMO.

References: Monsanto study published under Ivashuta, S.I., Petrick, J.S., Heisel, S.E., Zhang, Y., Guo, L., Reynolds, T. L., Rice, J.F., Allen, E. & Roberts, J.K. (2009). Endogenous small RNAs in grain: semi-quantification and sequence homology to human and animal genes. Food Chem Toxicol 47:353-360.

Proteome

This study demonstrated that 2DE [2D gel electrophoresis] can be utilized to reliably analyze the seed proteome of transgenic *A. thaliana* (p. 2176).

Quote from a Monsanto publication under Ruebelt, M. C., Lipp, M., Reynolds, T. L., Schmuke, J. J., Astwood, J. D., DellaPenna, D., Engel, K. H. & Jany, K. D. (2006). Application of two-dimensional gel electrophoresis to interrogate alterations in the proteome of gentically modified crops. 3. Assessing unintended effects. J. Agric. Food Chem. 54, 2169-2177.

3. Comparator[10]

All scientific studies that form part of a safety evaluation must involve a comparator. The comparator must be appropriate and used consistently. The purpose of the comparator is to provide the standard baseline for all measurements, and be the single common element in all experiments using material grown in multiple locations and years. It is impossible to determine if either of these rules were followed in the dossier for Bt brinjal.

The Minister is or should be aware that failure to adhere to these simple scientific rules has resulted in withdrawal of other commercial products. Monsanto's dossier for LY038 and LY038 x MON810, two GM corn varieties, also failed to follow these rules. Despite LY038 being approved by several jurisdictions, both Food Standards Australia New Zealand (FSANZ) and EFSA required Monsanto to redo crucial experiments because Monsanto did not use the proper comparator. While some revised experiments were submitted to FSANZ and LY038 was ultimately approved by them, in early 2009 EFSA required other experiments to be redone. Despite an estimated US$1 billion investment in LY038 and its derivatives' marketing, processing and development, Monsanto instead chose to withdraw the product from further evaluation by EFSA and discontinued all plans for commercial production. This story illustrates the critical importance of the comparator to all the scientific findings. Getting this wrong can kill the product in other jurisdictions and for good reason: using different and/or inappropriate comparators in the many different experiments takes away the ability to identify true hazards and assess them.

The comparator is defined by Codex Alimentarius as the conventional counterpart derived from the non-GM parent.

[It] is recognized that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts.

Codex, (2003). Codex Work on Foods Derived from Biotechnology. CAC/GL 45-2003.
Codex, (2008). Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA animals. CAC/GL 68-2008.

[10] https://bat.genok.org/bat/?sp=html/topic_guides/ch2_dna_to_insert/breeding_trees.html

EFSA requires that:

> The appropriate comparators have all traits in common except for the newly introduced ones.
>
> EFSA (2008). Safety and nutritional assessment of GM plants and derived food and feed: The role of animal feeding trials. Food Chem. Toxicol. 46, S2-S70.
>
> In the case of vegetatively propagated crops, comparative analyses should include the non-genetically modified isogenic variety used to generate the transgenic lines. In the case of crops that reproduce sexually, comparators would include appropriate information required in applications for GM plants and/or derived food and feed non-GM lines of comparable genetic background.
>
> EFSA, (2006). Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed. EFSA J. 99, 1-100.

While Codex and EFSA do not preclude the use of control lines in addition to the proper comparator, these additional lines should not substitute for the comparator.

What was the comparator for Bt brinjal? Was it the non-GM parent, closely related (e.g. ≥50%)? Was a single comparator consistently used in all molecular, toxicological, immunological, feeding and compositional studies? I could find little or no information on the comparator in any experiment that I reviewed. The GEAC report (ECII) mentions the comparator zero times. GEAC does mention the "conventional counterpart", but does not indicate that this was a single closely related parent used consistently in all experiments, nor does GEAC provide any details on the genotype or history of this conventional counterpart. Hence, I have low confidence that the simple, but critical, scientific practice of using the same and the appropriate comparator has been followed.

In my opinion, the dossier and the subsequent GEAC analysis (ECII) fail to meet fundamental and even routine hazard assessment standards for molecular characterization. Since this is the starting point of any risk assessment, the downstream effects on the analysis can be significant. Many of the analyses that were undertaken seem to have been half-efforts, with shortcuts taken and then retrospectively justified using non-validated or incorrect assumptions. If indeed Bt brinjal is safe for human consumption, safe for environmental release, and the right technology for India's food security and trading future, then the certainty of this can be demonstrated using existing, affordable and effective scientific analyses.

I urge the Minister to insist on the proper standards being met so that he can be sure that the product matches the claims. A checklist of tests is provided by the Biosafety Assessment Tool (https://bat.genok.org/bat/) which is freely available to all. This checklist allows a careful regulator to assure the Minister that the science has been done to high and appropriate standards and that the guidelines set by Codex Alimentarius and competent food safety agencies have been fully addressed by the data.

With best wishes,

Prof. Jack Heinemann
30 December 2009

Scientific Review of Materials Available to Expert Committee II on Bt Brinjal Event EE-1

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I have not reviewed the responses of the Committee or the applicant to criticisms from the public because I was not given those documents as a part of this review. In this review, I consider uncertainty and incompleteness. I find considerable uncertainty and some incompleteness. These are sufficient to lead me to question the adequacy of the environmental risk assessment, but they are not sufficient to allow me to conclude that the environmental risk assessment is erroneous. My specific comments follow.

Stressor Identification

For GM plants, stressor identification typically involves: (1) specification of the GM plant; (2) specification of the inserted transgene(s); and (3) specification of the gene products of the transgene and expression levels. In the dossier, (1) is done appropriately, (2) remains uncertain and incomplete, and (3) is incomplete.

Inserted transgene

(A) Number of inserts. The file identifies one insert. There are three sources of uncertainty that may affect risk. Two may increase risk and one may increase or decrease risk. Uncertainty arises because the size of the DIG-labeled Bt probe is not specified. If it is large, it may not detect independently inserted fragments; if it is small, it may not detect independently inserted fragments not associated with the probe. Uncertainty also arises because probes for other parts of the plasmid are not searched for. Although these other parts are normally not expected to be expressed because they have bacterial promoters, if fragments are inserted to create a new open reading frame that is associated with a plant promoter, they may be expressed. The third source of uncertainty is associated with the breeding program. Although the file makes it clear that the transformed plant is back-crossed to elite brinjal germplasm, it is not clear how many backcross generations were done. Each backcross generation reduces the probability that an additional integration event is retained into the final brinjal product. With 2 linkage groups, about 7 backcross generations are necessary to eliminate all but the chromosome with the transgene with 99% probability. Seven BC generations would also eliminate all but 0.8% (on average) of the genetic material associated with the transgene. Thus, the more backcross generations, the less likely an undetected integration event is retained in the final brinjal product. Because the number of backcross generations is not specified for each of the Bt binjal products, it is uncertain how well the inserted transgene has been characterized.

(B) Sequence of the inserted transgene. Under the assumption that there is only one transgene inserted into the Bt brinjal varieties proposed, as asserted by the file, the sequence of the inserted transgene was not reported. This sequence is typically required by regulatory authorities around the world. Although the sequence of the Bt gene, and all of the marker genes was provided, this is the sequence of the plasmid, not the sequence of the inserted gene. There are typically differences between the two. The sequence of the inserted transgene is necessary to substantiate the logic behind the reasoning that the marker genes pose no risk, and that the Cry1Ac protein is virtually identical to other Cry1Ac proteins that have been studied previously.

(C) Flanking regions. While there are limitations on the extent of genetic (DNA) analysis that can be done on brinjal because the entire genome has not yet been sequenced, there remain several significant and important elements that were not done. Typically an inserted transgene will be flanked by a mixture of plasmid and plant DNA, which is further flanked by only plant DNA of the original chromosome. Sequencing through the mixed flanking regions to the plant flanking regions is now routinely required by many regulatory authorities around the world. The flanking sequences are needed to determine if there are inadvertently created open reading frames and to determine if a functioning plant gene was interrupted by the insertion event. Lacking the full brinjal sequence, it is not possible to determine unambiguously if a plant gene was interrupted, but because of the high correspondence with the tomato genome, the flanking region sequences can be blasted again the tomato genome until such time that the brinjal sequence is available.

Expression
Expression levels of Cry1Ac are provided, but results for some important plant parts are not reported (e.g., pollen, flora tissue, roots). These data are necessary to interpret some of the non-target experiments.

Risks/ Adverse Effects Associated with Gene Flow and Consequences

There remains considerable uncertainty in the assessment of the effects of gene flow. The uncertainties are oriented around (1) are there any significant sources of genetic diversity potentially at risk from gene flow; (2) what are the expected and worst-case levels of gene flow.

Potential Consequences
Although the uncertainty associated with the evolutionary origin of brinjal is clarified by two somewhat contradictory expositions in the file, a key issue that is not clarified is whether there is valuable genetic diversity in India for either brinjal (land races, cultivars, dooryard plants, feral populations, etc.) or related plant species (land races, cultivars, dooryard plants, feral populations, etc.).

Level of gene flow
(A) To other brinjal. The file reports published outcrossing estimates of 0.2-48% for brinjal in various environments. These data would suggest that a reasonable worst-case estimate might have been 48% and an expected level of outcrossing might be somewhere between the extremes. The file also reports a very low measured rate of outcrossing in one (or two?) experiments involving some of the Bt brinjal varieties (vol.5). This level is probably close to 1% or less (the

actual value is not reported). The file does not justify why the experimentally measured rates are more representative than the published rates. The experimental rates might be low because:

a) The flowering times of the Bt brinjal and the surrounding non-Bt brinjal were not coincident. Relevant data to determine the degree of coincidence are not provided in the file.

b) The location of the honeybee colonies at the corners of the Bt brinjal plot may enable bees to take very short inter-plant movements to harvest sufficient pollen and/or nectar, thereby underestimating the degree of outcrossing (most inter-plant movements would be among Bt brinjal plants or among non-Bt brinjal plants rather than between Bt and non-Bt brinjal plants. By positioning the colonies farther away, bees would have to move farther to find the plot, and then might be more likely to move more frequently between Bt and non-Bt plants.

c) Slight differences in flower morphology between the Bt and non-Bt brinjal might lead bees to specialize foraging on one of the other (but not both), leading to underestimated levels of outcrossing (and gene flow).

Even if the experimental data have no obvious biases, it remains problematic that the measured rates are so low compared to the published rates.

(B) To other *Solanum* species. The file contains contradictory evaluations of the possibility of crossing with other *Solanum* species. Both the literature and the file focus on *Solanum incanum*. In Vol 1, page 25, the file states that hybrids between *S. melongena* and *S. incanum* can be produced, yet later, the file states that risks associated with such hybrids need not be evaluated because they do not occur. The level of gene flow to *S. incanum* should have been assessed.

Weediness

The assessment of weediness is overly simplistic and should rely more on available information about the weediness of non-Bt brinjal. The aggressiveness study is insufficient to assess weediness.

Aggressiveness. There is uncertainty with the negative results from the aggressiveness test (vol. 5). Because there is no information about the level of seed deposition, it is not possible to know if the negative results are due to the lack of aggressiveness of brinjal or because of the lack of seed deposition. Citation of other related results might help distinguish the hypotheses. For example, if brinjal can volunteer significantly, then the results from the aggressiveness study are probably misleading. However, if other studies on the weediness of brinjal have shown that brinjal is not weedy, this mitigates in favor of a determination of safety with respect to the risk of weediness.

Risks/ Adverse Effects on Other Species

Problem formulation

The main potential risks of a Bt crop to other species are: (A) increased secondary pests, either through direct enhancement or through the reduction of natural enemy controls; (B) reduction in soil quality or health, adversely affecting crop production in either the short or long term; (C) reduced value of non-crop economic activities (such as honey production or wild food harvesting); (D) reduced cultural value by affecting a cultural icon or a species of cultural significance (e.g., Monarch butterfly in the United States); (E) increased conservation concern, such as an adverse effect on an endangered species; (F) reduced environmental quality through an effect on an ecosystem service such as pollination; (G) increased human disease via environmental change. For Bt brinjal, (G) is unlikely, so a good risk assessment will focus on (A) through (F), allocating effort to address the most important issues with the greatest effort.

The risk assessment bases a tremendous amount of its analysis on the specificity hypothesis expressed in volume 1, page 38. There are several weaknesses to this hypothesis that renders it shaky grounds on which to base the entire assessment.

Here are a few of the problems. The assessment states: "More importantly, non-target insects lack receptors for the proteins on the surface of their gut cells." The evidence that all non-target species lack receptors for Cry1Ac on the midgut epithelium is actually quite poor. The number of studies are few enough that the statement should be "non-target insects probably lack receptors for the proteins on the surface of their gut cells." In addition, the assessment states "The Cry1Ac protein expressed in Bt brinjal shows strict host-range sensitivity for lepidopteran insects and has no deleterious effects on non-target organisms." It is true that the published literature on Cry1Ac has revealed fewer effects than the published literature on Cry1Ab, a closely related protein, but the "strict host-range specificity" must be considered a hypothesis and "has no deleterious effects" is an overstatement. For example, host range studies of Cry1Ac are based on relatively few taxa. What this means is that we know the Cry1Ac **is** toxic to a range of Lepidoptera (although not all of them, and even some closely related species have widely varying sensitivity), but we do not know that it is **not** toxic to all other insects.

The consequence is that the assessment should not rely on toxin specificity as a key pillar to its argument. It can use the specificity hypothesis as evidence in a weight of evidence argument, but in the present assessment it does not do this. A further consequence is that a major component of the risk assessment is much more uncertain than the present file indicates.

The following species were tested in the laboratory using toxicology tests.

Apis mellifera adults Yes
Apis mellifera larvae Yes
**Nasonia vitripennis* No Vol 1, page 86, exposure method not provided max 20ppm
**Hippodamia convergens* No Vol 1, page 87, exposure method not provided max 20ppm
**Folsomia candida* No Vol 1, page 88, max 200ppm
**Xenylla grisea* Hypogastruridae No Vol 1, page 88, max 200ppm
?Green lacewing (species not specified) Vol 1, page 88, exposure method not provided max 20ppm
**Bombus impatiens* No Reported results from literature (India is a center of *Bombus* biological diversity)

Of these species, only *A. mellifera* occurs in brinjal fields in India, and could be of economic significance itself. These two tests are useful for the environmental risk assessment. The species identity of the green lacewing was never mentioned in the file, so its relevance cannot be determined. All other species with a * must be considered surrogate species. Although the surrogate species approach remains widely used for pesticide testing, it has been severely criticized as unreliable since the late 1980s. Thus, while these tests fulfill the letter of the regulations, they do not fulfill the intent of the regulatory approach, and therefore they are not very helpful. Moreover, it was not clear what adverse environmental effects these studies were designed to assess (A-F), so it is not clear what inferences were intended to be drawn from the studies. Finally, the file did not contain any of the experimental details for these studies, so it was not possible to assess independently the reliability of the summarized results.

I did not review the following studies:

Carp *Cyprinus carpio* oral toxicity
Rat Oral toxicity acute; sub-chronic
Goat sub-chronic oral toxicity
Rabbit Skin and mucous membrane irritant; subchronic oral
Chicken oral, Growth, nutrient utilization and blood parameters
Dairy cow oral toxicity

These studies typically support the food and feed safety evaluation and are rarely considered a part of the environmental assessment.

The file focuses considerable attention on potential adverse effects (A) and (B). (A) "increased secondary pests, either through direct enhancement or through the reduction of natural enemy controls," is addressed primarily through the field experiments, which are discussed below.

(B) "reduction in soil quality or health, adversely affecting crop production in either the short or long term," is addressed through the soils experiments. These experiments focus on the following response variables:

Total culturable bacteria
Total culturable fungi
Total nematodes
Total collembola
Total earthworms

There is some uncertainty associated with interpreting the results of this study. First, it is not clear how the response variables relate directly to soil quality associated with brinjal production in India. The responses are those used primarily in maize in the temperate zone, and India should provide some justification for how they relate to the Indian conditions. Second, the collection of the soil samples may be questionable. The rhizosphere is typically considered the be a couple of centimeters from the plant roots, and a common way to collect rhizosphere soil is to dig up the root system, shake off the loose soil, and collect soil that is still adhering to the root mass. By taking soil from as far away as 20 cm from the plant stem, the investigators may have included a substantial amount of non-rhizosphere soil, which would dilute their results. This is an alternative explanation for the observed results. Thus, the true meaning of the results is uncertain. Finally, it is essential to know species identification as much as possible, especially for the collembolan and earthworms. This is because community responses may mask important species responses.

(E) "increased conservation concern, such as an adverse effect on an endangered species," is addressed in one paragraph in vol 1. The assessment is based on the following: "There are no listed endangered species of Lepidoptera in India that will be exposed to the Cry1Ac protein produced in Bt brinjal. The Cry1Ac protein is contained within the tissues of the Bt brinjal plant; therefore only insects that feed on brinjal will be exposed to the Cry1Ac protein." It would be more useful and a better environmental risk assessment to list all known endangered species that live near brinjal fields and then provide reasons for why each may not be at risk.

There is little consideration given to (C) reduced value of non-crop economic activities (such as honey production or wild food harvesting), (D) reduced cultural value by affecting a cultural icon or a species of cultural significance (e.g., Monarch butterfly in the United States), or (F) reduced environmental quality through an effect on an ecosystem service such as pollination. The honey bee studies might be construed to address (C), and the dairy cow study might address (D), but neither study is explicit in intent.

Overall, the problem formulation could be improved substantially. This will probably not take a considerable amount of time.

Field experiments
The most useful non-target study was the series of field studies conducted at 19 sites. These studies address potential risk (A) increased secondary pests, either through direct enhancement or through the reduction of natural enemy controls. As indicated in vol. 1, The following species and groups of species were studied:

Aphids *(Aphis gossypii)*
Leafhoppers (*Amrasca devastans*)
Thrips (*Thrips* sp. and *Frankliniella schultzii)*
White fly (*Bemisia tabaci*)
Mites (*Tetranychus* sp.)
*Root grub (*Holotrichia* sp.) One site only
**Epilachna* beetle (*E. duodecastigma* and *E. vigintioctopunctata*) 3 sites
*Grey Weevil (*Myllocerus* sp.) 5sites
**Eublemma olivacea* Eggplant leafroller one site only
**Helicoverpa armigera*, not seen at any site.
Beneficial insects (*Chrysopa* sp., Coccinellids, spiders, Syrphids, predaceous bugs, *Mantis religiosa*)
*Little leaf wilt YesMaharastra Solapur 30% ND one site only 2004 more in Bt at Coimatore 2005
**Fusarium* wilt, *Verticillium* wilt, Phomopsis blight, Bacterial wilt Wilt observed at Kolar 2005 ND

Sufficient data were obtained for all of the species without a * for reliable inference. The other species and groups of species with a * appeared too infrequently to allow reliable inference. For the better studied species, there was no indication that Bt brinjal will suffer secondary pest problems. However, there was one observation on more Little leaf wilt in Bt brinjal at Coimatore during 2005 that might indicate future troubles and would merit careful attention during the commercialization of Bt brinjal.

The result of the field experiments also show that the other pests or brinjal vary considerably geographically. This implies that India will need a geographically extensive extension service that is prepared to provide timely information about new demands for pest control as Bt brinjal is commercialized. Without this support, many of the potential benefits of Bt brinjal will likely be lost soon after commercialization.

As indicated previously, it is essential that these data are collected and presented at the species level. Thus, the actual effects on thrips and beneficial insects must be considered uncertain.

Resistance Risk in Target Species

Dose

The Bt brinjal tested against the target species, Leucinodes orbonalis (Guenee) [Lepidoptera: Crambidae] are all low dose. This is demonstrated by the results from the field experiment, summarized in the table below for larval density.

Site	Larval population on Bt-brinjal/ larval population on similar non-Bt brinjal	
Ranebennur-2002	9%	12%
Jalna-2002	15%	15%
Jalandhar-2004	9%	
Bhopal-2004	6%	
Ahmednagar-2004	11%	
Solapur-2004	62%	
Pune-2004	55%	
Dharwad-2004	43%	
Kurnool-2004	27%	
Tumkur-2004	26%	
Dharmapuri-2004	16%	
Akola-2005	17%	
Coimbatore-2005	13%	
Dindigal-2005	3%	
Kolar-2005	57%	
Kamal-2005	57%	
Jaipur-2005	62%	

For all sites, the level of control of Bt brinjal is economically meaningful, but not great enough to result in >99% mortality of all susceptible pests, which is one of the recognized standards for defining high dose. In no case are the values <1% in the table. This means that IRM will be essential. Resistance evolution is likely to be faster in low dose Bt plants than high dose ones, and the early experience with Bt crops worldwide supports (but does not prove) this concern.

Consequently, India should be vigilant in implementing effective IRM, including a sensitive method for monitoring the evolution of resistance. Due to lack of time, I am unable to provide more details on this, but the ideas expressed in the file are a good first step in the process, but need to be developed more.

USDA

United States Department of Agriculture
Research, Education and Economics
Agricultural Research Service

January 17, 2010

Robin Schoen, Director
Board on Agriculture and Natural Resources
National Research Council
National Academies of the United States
Washington, DC

Dear Robin,

Thanks for the opportunity to comment on the Bt Brinjal package for India. I have read the "Report of the Expert Committee (EC-II) on Bt Brinjal Event EE-1" and the supporting documents. In general, I believe the EC-II report provides an excellent summary of the Bt brinjal studies and the recommendations they make are strongly supported by these materials. I will limit my comments to areas of my expertise, which includes 15 years working with Bt crop insect resistance management (IRM) and nine years considering possible non-target organism effects of Bt crops. I have been a Research Entomologist with the USDA-ARS, Corn Insects and Crop Genetics Research Unit in Ames, Iowa for 17 years and I am an USDA Collaborator, Assistant Professor in the Department of Entomology at Iowa State University. I have had the opportunity to serve on several Environmental Protection Agency (EPA) Science Advisory Panels (SAP) related to genetically-engineered (GE) crops for both IRM and non-target evaluations.

European corn borer (ECB), *Ostrinia nubilalis*, is the primary insect that I have studied, which is closely related to the most important insect pest of brinjal, the fruit and shoot borer (FSB), *Leucinodes orbonailis*. Both of these insects are boring insects which makes pest control problematic because insecticides are not effective once the insects tunnel into the plants. Thus, brinjal often is sprayed with chemical insecticides 80 times or more during a 6-7 month cropping season. On average India farmers spend Rs. 4800 per acre to control this pest, and even then a large amount of the fruit is damaged. The introduction of Bt brinjal to India would reduce considerably the number of chemical insecticide applications and decrease environmental and human exposure to these broad spectrum insecticides.

When entomologists in the U.S. started working with Bt maize the ECB control was remarkable; at that point, we knew that ECB pest management had been revolutionized. This was when we started to work with other maize entomologists, modelers and the Environmental Protection Agency (EPA) to develop an insect resistance management strategy. Currently this strategy involves high dose and structured refuge, which means the Bt dose is sufficiently high to kill all insects with one copy of a resistance gene (i.e., heterozygous individuals) and there are ample susceptible insects nearby to mate with rare resistant insects (the intent is to dilute resistance genes). The IRM strategy proposed for Bt brinjal is high dose with a 5 percent structured refuge.

Studies were conducted in India during the 2004 and 2005 growing seasons (Vol. 8) to determine if 5 Bt brinjal hybrids expressed high dose amounts of Cry1Ac throughout the growing season in various tissues (leaf, shoot, stem, flower, fruit and root). The expression levels of Cry1Ac (tested with ELISA) appear to be sufficiently high throughout the growing season to qualify as high dose for FSB. The registrants made a convincing argument that a 5 percent refuge on non-Bt brinjal should provide greater than a 500:1 ratio of susceptible to resistant insects, which is the current IRM recommendation.

The registrants also have demonstrated with baseline monitoring (29 populations) that susceptibility is widespread throughout India for FSB (Vol. 7). As with the European corn borer, variation in susceptibly occurs, but the levels detected for FSB across India are not a cause for concern. The main point that the baseline surveys show is that resistant FSB are rare, a precondition for the high-dose refuge IRM strategy. The resistance monitoring and remedial action plans that are outlined are robust and should be sufficient (Vol.8). The intent to reevaluate IRM each year is an excellent idea because this will allow the registrants to estimate farmer refuge compliance and to assess problems if they should arise. The registrants note that a pyramid approach (two proteins with different modes of action) is an alternative IRM strategy. When feasible, the registrants should consider pursing two toxins for brinjal because pyramids are very effective at delaying insect resistance.

Regarding the non-target studies, the submission package is very thorough (Vol. 6). They note that Cry1A toxins are highly specific to Lepidoptera because the toxins are only effective when they bind to specific midgut receptors, which leads to the formation of pores in the gut lining, septicemia and death of the insect. A "lock and key" analogy can be used to explain this specificity. In this case the toxin is the key and the specific midgut receptor is the lock. If the lock and key do not match then toxicity does not occur. To take this analogy a step further, most organisms (e.g., birds, fish and mammals) do not have these gut receptors so in effect they do not even have the lock, which is where toxin binding occurs. Thus it is not surprising that most non-target studies find no detrimental effects with Cry toxins.

The Cry1Ac protein that was used in these studies was purified from an engineered bacterial strain. This is a standard procedure that is commonly used because extracting Cry proteins from plants is very inefficient and sometimes results in deactivated protein. Proper bridging experiments demonstrated the protein used in the experiments was similar to that produced by the Bt brinjal event EE-1. The representative arthropod species that were tested include parasitic hymenoptera (*Nasonia vitripennis*), honey bee larvae and adults (*Apis mellifera*), bumble bee (*Bombus impatiens*), ladybird beetle (*Hipppodamia convergens*), green lacewing larvae (*Chrysopa carnea*), collembola (*Folsamia candida* and *Xenylla grisea*). For each species the "no observed effect level"

(NOEL) was lower than the estimated LC_{50}. The maximum nominal Cry1Ac concentration tested was 20 ppm for all of the species except collembola that had a higher nominal concentration of 200 ppm (Vol. 1). Not surprisingly several other non-target organisms were not affected by the Cry1Ac protein during feeding studies that lasted at least 90 days, including carp, chickens and (impressively) five mammals: rats, mice, rabbits, cows and goats (Vols. 3 and 4).

Similarly no effects were found with soil microflora including bacteria, fungi, nematodes, earthworms and collembola with extensive testing that was conducted at multiple locations in India in 2004 and 2005 (Vol. 5). The half-life of theCry1Ac protein is 9-40 days depending on soil types, which means Cry1Ac protein does not accumulate in soils. Fast degradation reduces exposure and further reduces the potential for harm to non-target soil organisms.

The multiple field studies (Vol. 6) further support the safety of Cry1Ac protein as there was no evidence that the five tested Bt brinjal hybrids had adverse effects on non-target arthropod pests (leafhoppers, whiteflies, thrips and mites) or beneficial arthropods (lacewing, ladybird beetles and spiders) when compared with their non-Bt counterpart hybrids.

A final note, the registrants state that Bt brinjal could become a major component of integrated pest management (IPM) for brinjal. Reduced use of chemical insecticides would increase populations of predacious and parasitic insects and would help control FSB and other pests of brinjal. They also recognize that Bt plants are not "silver bullets" and should be incorporated into an overall IPM program. This is a wise approach that should allow Indian farmers to produce brinjal in a more sustainable way.

Please let me know if you have further questions.

Sincerely,

Richard L. Hellmich

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January 7, 2010

Mr. Jairam Ramesh
Minister of Environment and Forests
Government of India
(Sent by e-mail to Rahul Bojja,
Private Secretary to the Minister
rahulbojja@gmail.com)

Dear Mr. Ramesh,

In late November, I was contacted by Robin Schoen, Director of the Board on Agriculture and Natural Resources of the National Research Council of the National Academies of the United States. She informed me that you were interested in linking with a network of experts to provide help assessing studies submitted for the regulatory approval of Bt brinjal in India. Specifically, she mentioned that you were interested in studies on gene flow, nontarget effects, and food safety, among other issues. I am aware that India's Genetic Approval Committee (GEAC) has examined these same studies and recommended the environmental release of Bt brinjal and submitted the Expert Committee-II Report on Bt Brinjal Event EE-1 for your approval. I am also aware of the tremendous pressure that those opposed to this technology have continued to exert on the Indian regulatory system. As you suggested in your October 15, 2009 press release, I hope that your office will base its decision on science and the public good for India.

As for my qualifications in assessing the studies on Bt brinjal, I am a Professor of Entomology at Cornell University where I have been for 31 years. My primary areas of expertise are insect ecology, applied entomology and integrated pest management (IPM) of insect affecting vegetables. Within these areas, I specialize in biological control, biotechnology, insecticide resistance and insect movement patterns. In the last decade, I have served on several panels of the United States Department of Agriculture studying insecticide resistance management (IRM) and potential effects of Bt plants on non-target organisms (NTOs). In 2008, I was a co-editor of the first comprehensive book on genetically engineered insect-resistant crops, and also wrote two chapters in the book. The book, *Integration of Insect-Resistant Genetically Modified Crops within IPM Programs*, received endorsements by Norman Borlaug, the 1970 Nobel Peace Prize Laureate, and Thomas Lumpkin, the Director General of the International Maize and Wheat Improvement Center, CIMMYT. The 19 chapters cover topics ranging from IRM and NTOs to global regulatory systems and economic, environmental and social considerations in the adoption of Bt plants. Additionally, I have published extensively on tests our laboratory has conducted over the last 20 years on IRM strategies for Bt plants and the potential of Bt proteins to affect NTOs. The Entomological Society of America has honored me with their two highest awards for applied entomology, the Award for Integrated Pest Management (1995) and the Recognition Award for Research (2005). In 2007 I received Cornell's College of Agriculture and Life Sciences Award for Applied Research. My complete CV can be seen at http://www.nysaes.cornell.edu/ent/faculty/shelton/index.html. Finally, I have also travelled extensively in India over the last decade and am keenly aware of the Bt brinjal program.

In the following pages are my comments on specific reports I was asked to examine.

If you have other questions, please do not hesitate to contact me directly.

Sincerely,

Tony Shelton

A. M. Shelton
Professor of Entomology
Professor and Associate Director of International Agriculture

Comments on Bt Brinjal Documents Submitted to the Indian Regulatory Authorities
A. M. Shelton

Vol. 5. Effects of transgenic brinjal expressing *Bacillus thuringiensis cry1Ac* gene on soil microflora, nematodes, collembola and earthworms.

The summary statement in this report is not surprising: "These findings indicated that transgenic brijal expressing the *cry1Ac* gene does not have any adverse effect on the microflora, nematodes, collembola and earthworms in the soil". These studies were conducted in 2004-5 in multiple locations in India. In my opinion, the experimental design was appropriate, the data were properly analyzed and the conclusions are sound. There is nothing in the 37 figures or 3 tables to suggest that Bt brijal expressing Cry1Ac is harmful to soil microflora, nematodes, collembola and earthworms. This is not surprising since the literature also confirms the lack of harm of Bt proteins to soil biota.

In an *Annual Review of Entomology* article (O'Callaghan et al. 2005), the authors conducted a comprehensive analysis of studies that examined the impacts of Bt plants on soil biota. This included studying the persistence of transgene-derived proteins in the soil and potential effects on earthworms, isopods, microarthropods, nematodes, protozoa and soil and plant associated microorganisms (e.g. rhizosphere bacteria important in plant growth). Many of these organisms are key indicators of soil health and play a vital role in the breakdown and recycling of crop residues. As O'Callaghan et al. (2005) state, testing the effect of GM plants on non-target soil organisms and processes is beset with difficulties because of the heterogeneity of the soil environment, the complexities of the soil communities and the aggregation and movement patterns of soil flora and fauna. Despite these problems, from their analysis of the published studies they concluded, "Bt plants appear to have little impact on soil biota such as earthworms, collembolans and the general soil microflora". This conclusion relates specifically to Bt proteins such as those that have been extensively studied (e.g. Cry1Ac) and are expressed in plants such as Bt brinjal.

While most of the studies to date have examined effects on biomass, diversity or composition of soil biota, a limited number of studies have taken a different approach and looked at soil processes, such as plant litter decomposition. Caution is warranted when examining some of these studies since changes in plant characterization can result from the process of genetic manipulation or tissue culturing, rather than from the presence of the transgene-derived protein. When done with the proper controls (i.e. isolines), these studies have indicated no significant differences in decomposition between Bt and non-Bt plants.

While additional studies can always be undertaken, I believe the data from the studies conducted on Bt brinjal are sound and do not suggest a risk to soil biota from cultivation of Bt brinjal. Furthermore, it is important to realize that many cultural practices (e.g. plowing) and many synthetic (e.g. organophosphate) and organic (e.g. sulfur) pesticides are far more damaging to the soil biota than Bt plants.

Vol. 5. Assessment of pollen flow from Bt brinjal.

Although I am familiar with several pollen flow studies and their role in environmental risk assessment, my major interest in this area is the potential effect pollen flow may have on plant-insect interactions. Therefore, I will limit my comments to more general issues about the phenomenon of pollen flow and what it means. The literature suggests that pollen transfer between *S. melongena* and other wild species of *Solanum* is possible, although likely at a very low rate. However, if pollen from Bt brinjal is transferred to a wild species such as *S. insanum* or *S. integrifolium*, the important question is whether this transfer would provide any fitness advantage to the wild species. I am not aware of any studies that have indicated that these weedy species are limited in productivity or spread because of any lepidopteran species that feeds on them and that would be susceptible to Cry1Ac, if it were expressed in these wild species. Typically, wild *Solanum* species would be kept in check by a complex of organisms (various arthropods and pathogens) as well as environmental conditions. Furthermore, brinjal is largely self-pollinated and, according to the literature, its pollen can only flow a relatively short distance (15-20 m). Additionally, studies have indicated that when interspecific hybrids are created, they have strong fitness disadvantages. Therefore, any deleterious consequences on insect-plant interactions arising from Bt brinjal pollen flow appear remote.

Vol. 6. The field evaluation of transgenic Bt brinjal lines with *cry1Ac* gene to shoot and fruit borer, *Leucinodes orbonalis* 2002-3.

The procedures followed in 2002-3 were standard and included 2 Bt lines, 1 non-Bt counterpart and 1 standard variety grown in a randomized complete block design (RCB). The plot size (6 x 4.5 m), number of replicates and two locations were reasonable and the sampling methods appear appropriate.

The results indicate that both Bt brinjal lines were effective at controlling EFSB and reducing its damage. It is not clear why there were some differences in some species of sucking insects between the treatments since many studies have shown that Cry1Ac is not effective against sucking insects. Differences are likely due to other factors such as plant quality. While observations suggested there were no differences in populations of natural enemies, this was a minor part of the study and its conclusions are limited by plot size since natural enemies move freely between plots. Other data showing the lack of toxicity of Cry1Ac proteins strongly reinforce this observation and I list some of these studies toward the end of this document.

Vol. 6. Performance of Bt brinjal hybrids incorporating *Cry1Ac* gene during replicated research field trials in India, 2004.

This study was an expansion of the previous study and constituted 5 Bt brinjal lines and 3 checks with 5 replications grown in a RCB design in 11 areas. As in the previous study, Bt brinjal harbored fewer EFSB and sustained less injury and there were no differences in populations of natural enemies. As contrasted with 2002-3 studies, no differences in sucking insect populations were observed, which is what would be expected with this protein. It was unfortunate that populations of *H. armigera* were negligible at the locations as this information would have been useful for this sporadic pest (*H. armigera* is susceptible to Cry1Ac when expressed in cotton). However, it does confirm that EFSB is the chief pest of eggplant and that Bt eggplant can provide control.

Vol. 6. Performance of Bt brinjal hybrids incorporating *Cry1Ac* gene during replicated research field trials in India, 2005.

This study utilized 3 Bt brinjal hybrids and their non-Bt counterparts and checks grown in a RCB design with 5 replicates in 6 locations. As in previous trials, populations of EFSB were lower in the Bt plants and damage was much reduced. No differences were seen in populations of sucking insects or beneficial insects. Bt brinjal required fewer insecticide sprays and lower insecticide costs. Reductions in insecticide use have been confirmed in studies with other Bt crops including cotton, maize and rice (Romeis et al. 2008).

Vol. 7. Baseline susceptibility of *Leucinodes obonalis* populations to the cry1Ac protein.

A total of 29 populations of EFSB were collected across India in 2004-5 and the F1 generation of each population was assayed for susceptibility to cry1Ac. In this survey of 29 populations, MVP II was used. This commercial product contains about 20% by weight of cry1Ac and is routinely used to test susceptibility to Cry1Ac and represents a good substitute for the actual protein expressed by the plant because it is readily available and is a standardized product. Previous studies have shown that if an insect is susceptible to MVP II, then it will be susceptible to Cry1Ac when expressed in a plant. Bridging studies to relate the two proteins can be performed. The other assay method used in these studies involved incorporating powder from Bt brinjal fruit and testing it against a laboratory population. With these 2 methods, MVP II or the powder was incorporated into a semi-synthetic diet. For both experiments, various concentrations of Cry1Ac were evaluated to obtain 0 - 100% mortality. These procedures are standard. The endpoints of the test were either mortality or molt inhibition. Again, these procedures are routine and appear to have been performed well in the tests on EFSB.

The results show some variability across populations, but this is expected. For the 29 populations collected in 2004-5, the 12-fold variation in the LC_{50} values was not unusual. The highest value was 0.095 ppm. The variation in the molting inhibition concentration (MIC_{50}) was higher. The variability of the MIC was far less (14-fold) when the MIC_{95} was used and these values ranged from 0.01 to 0.138 ppm.

The assay using the Bt brinjal powder worked extremely well and shows a LC_{50} value of 0.13% powder in diet. For monitoring baseline susceptibility and potential changes in susceptibility over time, either the MVP II or Bt brinjal powder could be used, but it would be far easier to use the former.

Overall, these studies appear to have been conducted well and provide very useful information as a baseline for susceptibility. In the future it would be useful to determine a diagnostic dose (DD) for monitoring susceptibility across populations, such as has been done for >10 years with populations of European corn borer in the US. A DD allows one to monitor far more populations and has proven to be essential for resistance management monitoring. Other monitoring methods are also useful, but have their own limitations (Shelton and Zhao 2009).

Vol. 8. Quantification of Cry1Ac insect control protein in tissues of 5 Mahyco brinjal hybrids field-tested in the 2004 growing season.

In this study, the plants were grown in the field and each of the 5 hybrids was replicated 5 times and the leaf, shoot, stem, flower, fruit and root tissues were examined at 30, 60, 90, 120, 150 and 180 days after transplanting. The examination was done using standard ELISA tests and the results appear to be sound. While there was considerable variation in the expression levels in different plant parts and at different times, the expression levels in the above ground plant parts appear adequate for control of the EFSB over the growth of the plant and this is the most important conclusion. Control should especially be effective against the small first instar EFSB because they are much more susceptible to the toxin. The MIC_{95} was stated to be 0.059 ppm, which was far less than the amount found in any of the plant parts over time. This suggest that the plants are "high expressing", as defined by EPA (US EPA 2000).

Vol. 8. Quantification of Cry1Ac insect control protein in tissues of 3 Mahyco brinjal hybrids field-tested in the 2005 growing season.

This test was done in a similar fashion to the 2004 test and the results are in the same ballpark. Again, the expression levels of Cry1Ac in all above ground plant parts were far greater than the MIC_{95} of 0.059 ppm.

Vol. 8. Resistance management strategies for Bt brinjal.

The evolution of resistance to Bt plants depends on several factors. From the insect side, it depends on the genetic basis of resistance, the initial frequency of resistant alleles in the population and the fitness of resistant individuals (Bates et al. 2005, Shelton and Zhao 2009). Unfortunately, these are not known prior to the release of the plants and the evolution of resistance. However, an F_2 screen (Andow and Alstad 1999) was proposed to assess the frequency of resistant alleles in the population. While the F_2 is an interesting concept, it has severe problems. For example, to examine the accuracy of the F_2 screen Zhao et al. (2002) created a synthetic population of diamondback moth with a known resistance allele frequency and then used the F_2 to determine whether it could estimate resistance allele frequency in this population. Neither the use of a diagnostic diet assay nor a Bt plant expressing Cry1Ac provided an accurate assessment of the true resistance allele frequency. This study documented a major problem with the F_2 screen. Other methods for assessing resistance allele frequency have also proven to be problematic (Shelton and Zhao 2009). Lack of knowledge about resistance allele frequency, the genetic basis of resistance and any fitness costs of resistance inhibits an IRM program, whether it be for Bt plants or conventional foliar insecticides. The best that can be done is to devise an IRM strategy within the context of an overall pest management program for the crop. This strategy should include other practices such as conservation of natural enemies that can help maintain pest populations at lower levels. Many studies have shown that Bt plants are excellent at conserving natural enemies within the crop (Naranjo 2009).

The best strategy for delaying the onset of resistance is to have a crop expressing the Bt protein at a high enough level that it will kill heterozygotes (the heterozygotes are the major source of resistant alleles prior to the evolution of resistance) combined with a refuge that can produce susceptible individuals (Bates et al. 2005, Shelton and Zhao 2009). This is the strategy required by the US EPA (US EPA 2000) and it has worked extremely well. The data on Bt eggplant suggests that its expression is high enough to kill heterozygotes.

When the report of the IRM strategy for Bt eggplant was written in 2005, there were no cases of field-evolved resistance to Bt plants. Now there are 2 documented cases of insects that have evolved resistance to Bt plants, the fall armyworm to Bt maize in Puerto Rico and the African stem borer to Bt maize in South Africa (Tabashnik et al. 2009). [A third example, the cotton bollworm, has been put forward by Tabashnik et al. (2009), but there is considerable debate about this since the insect was not highly susceptible to Cry1Ab to begin with, high levels of damage have not been observed, and the person whose data were analyzed by Tabashnik et al. (2009) does not concur with their conclusions.]. Having only 2 documented cases of resistance to Bt plants since their initial deployment in 1996 is remarkable and far exceeds the time for insects to develop resistance to conventional insecticides (Bates et al. 2005). However, it also warns us that it is important to be vigilant and that an IRM strategy is needed for EFSB. What has been proposed in this document seems reasonable.

The baseline monitoring, resistance monitoring and checking to ensure that the tissues from Bt binjal control the insect are very sound and should be implemented. The type (structured refuge) and size (5%) of the refuge are discussed in the document and appear to be sound. This is especially true in the early phases of the deployment of Bt brinjal when a considerable amount of non-Bt brinjal will act as an unstructured refuge in the areas where Bt brinjal is grown. Thus, the stated recommendation that "the refuge strategy will be reviewed annually to take into consideration farmer compliance, alternate or non-Bt brinjal plantings and Bt adoption rates" is logical and wise.

In the example provided in the document, there are 19,000 Bt plants per ha, 8 fruit per plant, 3 larvae per plant and 15 pickings. This would result in 6.8 million EFSB larvae exposed to the Bt protein. If the initial resistance allele frequency is 0.001 (a reasonable estimation) and resistance is completely recessive, this means that only 6.8 resistant individuals (i.e. individuals homozygous for resistant alleles) would arise from the 19,000 Bt plants. On the other hand, the 1,000 non-Bt plants per ha would generate 359,940 homozygous susceptible individuals per ha. In this case, the ratio of homozygous susceptible individuals to homozygous resistant individuals is 4,386:1 which far exceeds the ratio recommended by the US EPA (500:1). Again, however, it must be emphasized that this IRM strategy should be monitored for its effectiveness and changed, if necessary, as more information is obtained.

The remedial action plan (item 5) is well thought out, and the encouragement of using other complementary IPM strategies (item 6) and developing a strong educational program (item 7) is essential for successful long-term deployment of Bt brinjal. The document also contains the appropriate statement that as more information is developed the IRM program for Bt brinjal will be "further developed and refined". This strategy of adjusting an IRM program as additional knowledge has been developed has served the US EPA well.

One recommendation I will make for the IRM strategy is that companies should be encouraged to introduce dual Bt brinjal into the market as soon as possible because such plants will delay the evolution of resistance for an even longer period (Zhao et al. 2003). My statement should not be taken as a recommendation that single Bt gene brinjal should not be deployed until dual Bt plants are available. Worldwide, wherever Bt maize and cotton were first introduced, they were single Bt gene plants. They are now being replaced by dual Bt gene plants as they become available.

Other volumes provided.

I did not see anything alarming or out of line regarding the Bt allergenicity or feeding studies. Similar studies were conducted in the US before cry1Ac cotton was commercialized. There is a long history of the safety of Bt proteins, especially the Cry1A proteins such as Cry1Ac. All credible reports indicate Cry1A is far safer to humans and the environment than alternative insecticides. Because the data in these reports indicates that the use of Bt eggplant will reduce the use of more hazardous insecticides, there is strong justification for their commercialization in India.

Non-target organism studies contained in Vol. 1

Section 6.2 of Vol. 1 deals with effects of Bt brinjal on non-target organisms. I found nothing in this section that I would disagree with about the lack of toxicity of Cry1Ac to any non-lepidopteran (=caterpillar) organisms. Cry1Ac has been studied extensively for its range of activity (e.g. US EPA 2000) and has a long history of safety when used in a foliar spray. Furthermore, there have been extensive studies showing lack of harm to non-target beneficial arthropods by Cry1Ac when it is used as purified toxin or expressed in plants (Romeis et al. 2006). Although a recent report by Lovei et al. (2009) has suggested Bt proteins may have negative effects on some predators and parasitoids, this was refuted by an extensive analysis of the data (Wolfenbarger et al. 2008, Duan et al. 2009, Naranjo 2009, Shelton et al. 2009a, Shelton et al. 2009b). Studies conducted by Chen et al. (2008) have shown that a Cry1 protein is far safer to a parasitoid than several types of insecticides commonly used in India for control of such pests as the EFSB.

Other considerations for Bt brinjal

Plants that are resistant to a pest should be the foundation of an effective management program. Unfortunately, there are no wild species of brinjal that are resistant to its main insect pest in India, the EFSB. Engineering a plant to express a safe protein that is toxic only to caterpillars should be the foundation for an environmentally safe management program, and this is now possible with Bt brinjal. According to the literature, brinjal is widely grown by 1.4 million Indian farmers who are generally resource poor. Despite spraying an average of 40 or more times to control the EFSB, growers still incur substantial losses. Such heavy insecticide use is not only costly to the farmers, but is hazardous to farmers, consumers and the environment. The documents contained in the regulatory package indicate that there is 80% less spraying on Bt brinjal compared to non-Bt brinjal. This reduction in harmful insecticide use is in line with what has been experienced with Bt cotton in many areas. Worldwide, Brookes and Barfoot (2008) estimated that between 1996 and 2006 the deployment of Bt cotton reduced the volume of insecticide active ingredient applied by 128.4 million kg (a 22.9% reduction), and reduced the environmental impact by 24.6% [as determined by the environmental impact quotient (EIQ), which integrates the various environmental impacts of individual pesticides into a single "field value per hectare" (Kovach et al.1992). One should expect similar dramatic environmental benefits with Bt brinjal.

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COMMENTS AND VIEWS ON BT BRINJAL

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Dear Mr. Bojja:

Being the ABSPII Regional Coordinator for Southeast Asia and the PI for the Bt eggplant work in the Philippines, I have followed with keen interest the Bt brinjal product and regulatory file development in India. As you may know, the work in the Philippines uses the same Bt brinjal Mahyco EE-1 event used in India. Our work in the Philippines has been progressing well and has generated local data on the Mahyco event. It is in this context that I share with you my humble views and comments on the matter at hand for Bt brinjal in India:

First of all, allow me to congratulate the Government of India for upholding the importance of science, transparency and public participation in its decision-making process. The adherence to the scientific process is obvious from the rigorous and comprehensive scientific studies conducted to ensure that Bt brinjal poses no significant risk to the environment and human health. To the best of my knowledge, the Bt brinjal safety package has done far more studies particularly on the food safety aspect than what has been required of GM crops in other countries. The decision to place the entire biosafety package of Bt brinjal online is noteworthy and unprecedented. By placing the biosafety package under scrutiny of the various stakeholders concerned with safety of Bt brinjal, the GOI has demonstrated utmost respect and sensitivity for the views of all stakeholders. But all debates must come to an end and decisions have to me made. It is my humble opinion that the GOI thru the Ministry and its regulatory institutions have completed its legal and moral task of assessing and debating all issues raised to the fullest. The time to act has come.

With regard to the regulatory dossier of Bt brinjal, I find the regulatory dossier for Bt brinjal is comprehensive, of high scientific quality. It has been vetted by no less than two committees of Experts established by the Ministry. Although limited in scope, we believe that our own experiences in Bt brinjal event EE-1 under Philippine conditions lends support to the findings in India. The Bt brinjal's efficacy against the target insect pest and safety to non-target organisms have been proven by the many (reproducible) field trials conducted by Mahyco and validated in field trials by its public partners in India. The data we generated in the Philippines on the efficacy of Bt eggplant event EE-1 supported the findings in India. Mahyco eggplant event EE-1 transferred in local (Philippines) genotypes of eggplant controlled effectively the local populations of eggplant and shoot borer but did not harm to non-target organisms. Our controlled laboratory tests showed 96-100% mortality of the target insect. At very high insect infestation, Bt eggplant in the Philippines showed less than 10% damage compared to its non-Bt counterpart.

In approving the development and market release of Bt corn, the Philippines considered relevant regulatory safety data generated outside the country provided that the studies were done under very rigorous and high scientific standards. When necessary, local data were generated to supplement and validate the secondary data submitted. The same policies and guidelines have been implemented in our Bt eggplant work. For example, the data on molecular characterization, pollen flow studies and field trials generated by Mahyco were submitted and considered favorably by our regulators. This enabled us to obtain the approval to import from India the initial materials and allowed us to proceed with our backcrossing work (contained GH trial and confined field trial). As our eggplant product development progressed, we validated the genetic stability of Mahyco event EE-1 under Philippine conditions for three generations. We used the same protocol for molecular techniques (event-specific PCR, genestrip test and quantitative ELISA) provided by Mahyco and used in India.

The Philippines has been one of the mega biotech countries in the world since 2004. We are the first country in Asia to approve a food/feed biotech crop (Bt maize). This is made possible by our progressive and forward looking regulatory policies and implementation guidelines. In approving the first market release of Bt corn, relevant feed /food safety data of high scientific quality but generated in other countries were considered by the regulators in granting market approval. To date, there has been no recorded incidence in the Philippines (or anywhere in the world) of substantiated ill effects on Bt corn on human health and the environment. Following this line of policy, we have submitted the India feed/food safety data, particularly the toxicology and allergenicity package provided by Mahyco and posted in your Ministry's website as part of our application for the multi-location trials, the penultimate step to market release in the Philippines. We supplemented the data with results of our own study on compositional analysis. Our findings support the results in India, wherein the composition of Bt eggplants containing Mahyco EE-1 did not differ from its non-Bt counterpart; furthermore, that Bt eggplant compositional traits all fall within the range of values for non-Bt eggplants currently sold in local markets.

Our regulators are fully aware that the Bt brinjal in India has undergone rigorous scientific assessment and declared safe by the regulatory institutions (RCGM and GEAC) in India. Barring any change in policy, we are optimistic that our application for multi-location trial and eventual market release of Bt eggplants developed in the Philippines will be approved, taking into consideration the regulatory data, (particularly the food/feed safety package) generated in India and the actions taken by India's regulatory bodies.

In view of the above, I wish to indicate my humble support for the market release of Bt brinjal primarily on scientific merits (Bt brinjal has been proven effective and safe) but also because of its potential to help improve the lives particularly of small farmers and consumers not only in India but in other parts of the world. India's decision on this very important issue could also show the way to bring sanity and harmony to the whole issue of regulation of GM crops in particular and GM technology in general.

In closing, please convey to the Hon. Minister all my best wishes. I wish for him to have the wisdom and the political will to give Bt brinjal a chance to contribute to changing people's lives like what the Green Revolution and Bt cotton did to India.

University of Nebraska Lincoln

FOOD ALLERGY RESEARCH AND RESOURCE PROGRAM
DEPARTMENT OF FOOD SCIENCE AND TECHNOLOGY

18 January, 2010

GEAC, Gov. of India

Review of the Report of the Expert Committee (EC-II) on Bt Brinjal Event EE-1 Developed by: Maharashtra Hybrid Seed Company Ltd.

My comments will be restricted to the areas of human and animal food and feed safety.

My expertise relative to the safety assessment of genetically modified (GM) crops is primarily in the area of the allergenicity assessment of genetically modified crops, but also includes some experience in considering potential toxicity of such plants. My PhD was in Dairy Science at the Ohio State University (USA) and my dissertation research was cloning and sequencing a cDNA clone of bovine lactoferrin. That was followed by postdoctoral training and employment as a research associate in immunology at the Veterinary School at Cornell University (USA) and the Division of Pulmonary Medicine at the University of Michigan (USA). I was employed for seven years as a project manager for the allergenicity assessment of genetically modified (GM) crops at Monsanto Company in St. Louis, MO, USA. I was involved in the safety assessment of Bollgard cotton and Bollgard II for registration in India and have been studying and working with Indian scientists regarding guidelines on the allergenicity assessment for GM crops (1998 and 2008). In 2004 I joined the Department of Food Science and Technology at the University of Nebraska-Lincoln as a Research Professor. My research is primarily on identification of food allergens and evaluation of food safety of new processed food products and GM varieties and am a principle author on a number of papers related to the safety assessment. I also manage the AllergenOnline.org database which was developed primarily for identifying food proteins that might pose a risk of allergy due to prior sensitization of some individuals, or might pose a risk due to significant amino acid sequence similarity to known allergens. I have participated as a faculty member in a number of training courses and workshops on the safety assessment of GM crops in India between 2006 and 2007. I hosted/trained two Indian scientists in specific evaluation for the allergenicity assessment of GM crops who were sponsored by the USDA-FAS Borlaug program during 2008 and seven international scientists funded by the Gates foundation during 2009.

Background of Bt Brinjal Review.

I have based on my review of a number of available reports on the Indian government websites as well as on ISAAA. The review included the EC-II review as well as the original Mahyco sponsored studies.

The DNA construct introduced into Brinjal appears to be the same as inserted in Bollgard I cotton with Bacillus thuringiensis *cry1ac* as the insecticidal gene, *nptII* and *aad* as marker genes. The Cry1Ac protein and NPTII protein should be expressed in tissues of Bt Brinjal, but the AAD protein would not be expressed as it is under a bacterial promoter. Thus the

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safety assessment should include evaluation of the potential allergenicity and toxicity of the Cry1Ac and NPTII proteins only. Development of the product occurred in 2000 and in general the safety assessment seems to follow recommended guidelines from India and the international regulatory community.

I believe it is important to recognize that development and evaluation of this product spans two sets of different regulatory guidelines between 1998 and 2008. Thus there may be some confusion for some people in terms of which guidelines to follow. From my perspective, the 2008 guidelines are consistent with international guidelines (Codex Alimentarius 2003) and the tests and evaluation steps are more relevant to predicting food allergy for human consumption and animal safety for agriculturally important animals. But it does seem there are additional studies to consider in terms of relevance due to the overlapping regulatory documents.

REVIEW: Report on Bt Brinjal ECII (as well as Mahyco documents).

2.2 Compliance with the "Revised Guidelines for Research in Transgenic Plants & Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts, 1998".

. Specific steps in the assessment included

- Acute oral toxicity test of Bt brinjal expressing *cry1Ac* gene in rats.
- Sub chronic (90 days) oral toxicity test of Bt brinjal expressing *cry1Ac*
- gene in rats.
- Primary skin irritation test of Bt brinjal expressing *cry1Ac* gene in rabbit
- Mucus membrane irritation test of Bt brinjal expressing *cry1Ac* gene in
- female rabbit
- Sub chronic (90 days) oral feeding study of Bt brinjal expressing
- *cry1Ac* gene in rabbits and goats
- Feeding studies in chicken, fish and lactating cow.

[Although most of these, except the acute oral gavage, and possibly the 90 day rat study, would not be done under Codex Alimentarius guidelines the results of the studies did not demonstrate any potential reason to be concerned about safety. RE Goodman]:

Table 2.2: Status of Compliance.

Row f. It is reasonable to ask for expression levels of the GM protein (Cry 1 Ac). This information is important to help understand efficacy as well as possible consumer exposure levels. Based on information provided, they developer measured Cry 1 levels in seven hybrid lines generated from the transgenic event grown at multiple locations, which provides considerable characterization of the expected production crop materials

Row h. Fruit flavor. The CFTRI lab was not in a position to perform the requested taste panel tests of brinjal fruits. As concluded by the GEAC panel, this requirement was not based on issues of food safety, rather is one of consumer choice. It seems that the requirement was not scientifically justified for food safety. Thus failure to provide this data does not compromise the GEAC evaluation.

Row i. Goat toxicity study. As indicated by the committee, goats and other large animals are not used in predictive food or feed safety studies by regulators in other countries. Toxicity studies in goats might be performed in the event that a clearly defined scientific hypothesis specific to ruminants, however clearly not as a general screen for food or feed toxicity. Thus it was scientifically reasonable for the Government of India to drop this requirement when the 2008 guidelines were developed and adopted.

Row j. Guinea pig skin sensitization. The safety assessment guidelines are directed at evaluating the safety of food and feed. There is no scientific justification for doing a dermal sensitization test for food safety as it has not been validated to predict food or feed safety and as indicated, was dropped from the 2008 guidelines on that basis.

Data more relevant to the 2008 ICMR Guidelines, summarized in Table 2.3. Further, summaries in the review describe information relevant to the food and feed safety assessment and do not raise issues of potential risk.

Overall assessment Food and Feed Safety Assessment (3.3)

- Expression. Cry1Ac was verified to be present from 5 to 47 ppm in different tissues of the hybrids of brinjal that were tested. This is a low expressing protein, which is NOT typical of allergenic food proteins.
- The sequences of Cry1Ac and NTPII lack any relevant identity matches to known allergens or toxins.
- Assessment of in vitro digestive fate of Cry1Ac and NPTII, digested in less than 30 seconds. Many food allergens are stable in pepsin, thus this data demonstrates no significant increased risk. [Note: this work was from studies performed by Monsanto for Bollgard Cotton as the proteins are identical.]
- Acute oral toxicity of Cry1Ac on albino mice. No evidence of toxicity.
- Acute oral toxicity of NPTII on albino mice. No evidence of toxicity.
- 90 day subchronic rat oral feeding toxicity. No evidence of toxicity.

[Data seems quite appropriate and results show no reason for concern regarding safety. Further, the US FDA, EPA and EU regulators have accepted similar data for evaluation of Cry1Ac and NPTII proteins as well as the entire gene cassette (*cry1ac, nptii and aad*) and have concluded there are no scientifically reasonable risks of food allergy or toxicity associated with these proteins. RE Goodman]

Additional reported studies:

- Allergenicity in Brown Norway rats. Although this type of study was performed also for Bt cotton (Bollgard 1 and Bollgard 2) there is no evidence that the assay predicts human food allergy. Further, no animal model has been shown to be predictive for assessing potential food allergy for humans. Thus this study neither adds to, or subtracts from the basic conclusion that there is no evidence of allergenicity associated with Cry 1 Ac or NPTII.
- The skin irritation and vaginal irritation / allergenicity and irritation tests were performed and no differences were found between the transgenic and non-transgenic lines. However, these tests are not valid, nor necessary for assessing human food safety.

[Other data that is useful for evaluating overall food quality for Bt brinjal: Proximate analysis of the transgenic brinjal fruits, no statistically significant differences were found. No significant differences were found in alkaloid content (solamargine and solasonine) between Bt and non-GM brinjal samples. Feeding studies in rabbits, chickens, fish, goats and cows demonstrated no significant differences in feed quality. However, those studies are also not essential to evaluate feed safety. RE Goodman].

BT brinjal cooking and protein estimation. The brinjal samples were cooked, then tested for immunologically detectable protein. None was measured after cooking. [While this is interesting, it is not proof of safety or hazard. It is simply a measure of either protein aggregation or unfolding (thus antibody failed to bind.). There is no correlation with this kind of data and food safety. It is irrelevant, except to understand detection limits with the particular antibody/test. There is no need to evaluate an alternative. The test is not relevant for food safety, RE Goodman.]

Based on the data review of the EC-II, there are no concerns of potential risk/hazard of allergenicity or toxicity from Bt Brinjal, compared to non-GM brinjal. Based on tests and evaluation, that is the proper and scientifically valid conclusion that should be drawn. No data have been presented that suggest a need for concern regarding food safety of this GM event.[RE Goodman]

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Additional Considerations, issues raised by NGOs.
I reviewed the information considered by the EC-II regarding many comments from NGOs and individuals questions/statements. I believe the EC-II panel seemed to have performed a scientifically valid, in depth review of the comments and come to the correct conclusions.

Issue 1: The one amino acid difference in the Bt brinjal Cry1Ac compared to native kurstaki Cry1Ac is not expected to have any relevant difference. In fact, the sequence incorporated in the brinjal has been the subject of safety tests, and there is no evidence of mammalian toxicity or allergenicity.

Issue 2: ARM genes. The NPTII gene/protein has been judged safe by the US and EU regulators. There are no field applications of antibiotics that would provide selection pressure that would be altered by the presence of this protein in the Bt brinjal, and expression is too low to make a difference in selection pressure. Further, there is abundant data that demonstrates a lack of reasonable proof the gene could be transferred to microbes.

The AAD gene is not expressed in the Bt brinjal and there is no concern with ARM issues relative to the presence of the gene in the plant.

Food/Feed Safety.
Issue 6: Cooking. It is true that the data from the dossier does not prove that Cry1Ac is not present in cooked brinjal. However, there is no evidence that the presence of Cry1Ac in brinjal posses a risk / hazard for consumers. The acute studies are negative, there is no evidence of toxicity or allergenicity. Thus the presence is irrelevant. The presence or absence of the protein in food is irrelevant UNLESS there is proof of risk. Since that is lacking, this particular study is irrelevant to food / feed safety.

Issue 7. There is NO evidence that Cry1Ac (or NPTII) pose any risk to mammalian consumers or vertebrate (bird or fish). Thus it is not relevant whether cooking breaks down these GM proteins as there is no risk. In fact most proteins are not broken down by cooking, so the tests and questions are irrelevant and illogical unless a given protein was demonstrated to pose a risk. In that case, heat inactivation would be relevant to food safety.

Issue 8: Limited (90 day) studies on food safety. The suggestion that food safety studies should be of longer than 90 day duration is ludicrous. There is no evidence that this reviewer is aware of that suggests there are dietary proteins that only show risk/hazard beyond 90 days of feeding. In fact, essentially all toxic proteins are acutely toxic. That means less than 30 days. There is no evidence that Cry1Ac or NPTII are toxic period.

Issue 9. Variation in observations...during toxicity studies (acute mouse, 90 day rat studies) have been ignored. Note that there are always some differences in results in toxicity or any other comparative study such as a feeding trial. Even statistically significant differences are not uncommon. The question is whether they are relevant in terms of likely biological outcomes. Neither the commenter nor the study report for Bt brinjal have identified any specific findings or areas of concern that would reasonably considered scientifically or biologically relevant to the health of consumers or animals. As discussed by the EC-II report, one rat in Bt brinjal, and one in non-Bt brinjal had similar behaviors and diarrhea, apparently associated with ear infections, which are not uncommon in rat colonies. Also minor differences in liver weight, water consumption and other parameters, that are not consistent with treatment or control groups across most animals and most time points are common and not of concern.

The commenter states that an insufficient number of animals were used in the skin irritation and mucous membrane studies. However, these requirements under the 1998 Indian Guidelines have been dropped in the 2008 Guidelines and there are no similar tests in Codex, the European, Japanese, US or Canadian requirements for food safety as these animal model tests have not been demonstrated to be relevant to food safety tests. Thus, it would not be scientifically justified to ask for further similar tests.

Regarding maximum chicken feeding rates of brinjal meal, it is essential to obtain healthy, appropriate diets for animals. The common concentrates feed to chickens are crop materials high in protein such as soybean meal. Other common ingredients include corn meal, wheat and other grains. There is not a published history of feeding high concentrations (amounts) of brinjal (or eggplant) to chickens for any extended length of time. The diets of comparison groups must be equal in key ingredients including total protein and carbohydrate (and isocaloric), but the amino acid composition is also important, as well as micronutrients balanced. The initial metabolizability study with 20% and 40% brinjal as diets for chickens compared to reference diet demonstrated reduced nutritional value, and thus the value of 10% dry brinjal as a maximum component was a reasonable choice. The diets were balanced by adjusting other components of the diet to provide approximately equal fiber, energy, protein, lipid and micronutrients. It is also important to recognize that brinjal is not a typical or likely source of nutrition for broilers at the level of incorporation of greater than 10% (if even that). Soybean, cottonseed meal and other commodity crop materials are typically used as by-products (of vegetable oil production for instance). The high protein content of those materials are good sources for animal nutrition and rather than wasting by product, they are used in animal feed. In contrast, brinjal is consumed as whole, cooked fruit by humans. There are no by-products that would be residuals and thus the only use forseen for brinjal in chicken feed would be surplus fruit. There are no studies that have demonstrated previously that this is likely to be an economical source for poultry production. Thus the studies are more simply to demonstrate a lack of unexpected negative impact from incidental feeding of chickens the brinjal. Based on the nutritional composition of brinjal, it could be used primarily as a substitute for corn (maize) and only slightly reducing the soybean in the diet. If the rate of incorporation of brinjal was increased further, other ingredients would have to be raised to ensure a balanced diet as amino acid analysis demonstrated that the lysine, methionin/cysteine, arginine and phenylalanine would need to be increased. In terms of performance of Bt brinjal compared to non-Bt brinjal control and commercial brinjal controls, the 10% incorporation groups had very slightly lower body weight gains compared to reference and 5% incorporation diets, but that was true regardless of the types of brinjal. Thus there was no evidence that Bt brinjal had an unacceptable negative impact on production in the broiler chickens.

Further comments by Dr. Serilini suggesting inadequacy of testing in feeding trials (such as a need for additional species of birds) are not scientifically rational or justified. Fruits of brinjal are not commonly consumed by birds or by rabbits. Similarly regarding feeding studies with lactating dairy cows, there are no published studies demonstrating that brinjal is a nutritionally sound feed stock for cattle (or goats). There were not data to evaluate appropriate feeding levels and that had to be evaluated on an experimental basis. Brinjal does not appear to be a common feed stock for ruminants in practice in India, the EU or US. Thus the utility of such tests should be questioned. In all likelihood there is a positive impact in farmer acceptance of GM crops from results of studies that demonstrate whether or not the occasional introduction of the GM crop material (such as brinjal) into the diet of chickens or cows would have a negative impact on health or productivity. The data presented here do not show any differences between Bt brinjal and non-Bt brinjal. Thus there should not be a concern for producers or consumers.

Consideration of comments by Dr. P.M. Bhargava. Dr. Bhargava provided a laundry list of studies that might be considered for requirement prior to release of Bt brinjal for commercial production. From a general philosophical perspective we could argue and say that it would be nice to perform such studies on every new variety or hybrid of every food commodity crop, and every farming practice, including the use of various herbicides, insecticides and fungicides. But in considering his suggestions we should demand scientific rationale for each of the tests. Performance of the listed studies would be economically and practically impossible. And what benefit would derived from such studies? Would we have a safer food supply? Or does scientific evidence support the current safety assessment (ICMR, 2008; Codex Alimentarius 2003) and environmental evaluations required by the government of India?

In order for the studies recommended by Dr. Bhargava to be useful, we would need validated methods, baseline data, an understanding of the root cause of most variation and acceptance limits for the thousands of measurements that would be made (e.g., from studies of metabolites, GI microflora, RNA transcripts, proteomes). We do know some things about variation of these markers with respect to natural variation such as that caused by growing the crop in different field plots, different geographies, different years, for a very limited set of crop varieties. The variation is large and many differences are seemingly random. We already know that there are many different genetic backgrounds of all of the food crops. We know that the interaction of the different gene pools, along with the tremendous variation in environmental factors means that the variation in expressed metabolites, proteins and RNA are almost limitless. But we also know a great deal about the characteristics of some of the brinjal varieties that make them desirable fruits for consumption. However, we do not know the normal variation of expression of more than 99% of the genes/proteins or accumulation of metabolites. How many genes and how much variation is required to produce the purple vs. the white or greenish brinjal? Round vs. long, tubular brinjal? Large vs.small? Some varieties look the same, but are genetically adapted to growing under different environmental conditions (heat, light, moisture, disease resistance). How did we achieve such great variation in the varieties of brinjal that are commonly and safely consumed in India? As biologists we know that there have been thousands of mutations, changes in DNA that are uncharacterized except for the phenotype of the varieties. Those have been recombined through direct and intentional breeding by farmers and horticulturalists, but primarily by undirected random breeding by bees or by other pollinators. The same can be said of soybean, rice, onions, peppers and so forth. Almost all of the changes that could be measured represent small changes, with no consequence to safety or even nutrition. But over long selection times or evolution there are dramatic shifts in the genetics of the plant that can have important consequences. The larger genetic group of plants (family Solanaceae) includes tomato, eggplant, potato and pepper, all important edible crops. The same family includes many relatives of each of these species, which are inedible due to production of toxins (e.g. many "nightshade" species or due to lack of nutritional or food-quality properties. Measures recommended by Dr. Bhargava comparing tomato to potato or nightshade or just different varieties of tomato would certainly reveal a huge set of diverse comparisons, but only of few of the thousands of measures would be related to the toxins or other unacceptable characteristics. If one made the same measures within the between members of the same food species, such as tomato, there would also be thousands of significant differences that could be measured. But tomatoes are edible, not poisonous. Within a reasonable level of consumption, they are nutritious. The only significant health risk is that there are a very small number of people who have food allergy to tomatoes. The allergies are caused by a very small number of proteins (lipid transfer proteins, pathogenesis family 5 and 10 proteins and possibly profilin). Those proteins hardly differ across the many varieties of tomatoes except for a few possible amino acid substitutions. More than 99% of people can consume tomatoes safely. Only those allergic to tomatoes are at risk and that is because of one or more of a few specific proteins, not the thousands of other differences in protein isoforms, expression levels or differences in thousands of metabolites. If the government of India were to require tests and evaluation of measures similar to those suggested by Dr. Bhargava for every new plant variety or hybrid you would likely never have a new variety of tomato and those produced by pollination by bees would have to be discarded as they are of un-tested genetic mixtures. While Dr. Bhargava and a number of others who have recommended extensive additional tests undoubtedly intend to help protect the consuming public, the result of the adding the many, extensive tests they recommend simply blocks the possibility of introducing any genetically modified variety (and possibly new varieties introduced through hybridization, if applied fairly).

Instead I submit that it is much more predictive and relevant to concentrate on the measures and tests already outlined in the ICMR Guidelines of the Government of India. Evaluating the newly expressed protein(s) for evidence of toxicity and allergenicity as outlined in the guidelines. In addition, evaluate the common characteristics of this type of plant (expression of specific nutrients and anti-nutrients). Evaluation of agronomic characteristics of the edible crop material, as well as reasonable environmental impacts of the transgenic plant provide good data on unintended effects. In some cases whole animal feeding studies are warranted, such as broiler chicken or dairy cow. But in some cases those studies are not relevant if the edible portion of the plant would not be feed to the test species under normal circumstances.

OVERALL CONCLUSION [by RE Goodman]:
Based on my review of the Bt brinjal regulatory studies (from Mahyco) and data reviews (EC-II), it seems there should be no additional safety concerns about the Cry 1 Ac Bt brinjal event(s) developed by Mahyco in terms of food or feed safety. The current data package has adequately addressed scientifically justified questions and no results indicate an increased risk of toxicity, allergenicity or any unintended substantial difference in nutritional quality.

Dear Mr. Ramesh:

I suppose you can recall our acquaintance in early 2001 and 2002, when we first met at the fog bound Delhi airport waiting to catch our flights one wintery morning, and later on when we had breakfast together in Washington, DC at a time when I was a visiting research scholar at the International Food Policy Research Institute (IFPRI). Since then, I worked on the golden rice and the rice genome project for synegnta in Basel, Switzerland and have been an international biosafgeyt consultant retraining biotech regulators around the world. I recently concluded a year long stint as a Senior Research Scholar at the Science, Technology and Environmental Policy (STEP) program at the Woodrow Wilson School of International and Public Affairs at the Princeton University. Before that, I was a GM crops regulator at USDA for almost 15 years and presided over the commercialization of dozens of GM crops in the USA in collaboration with US-EPA and US-FDA. I am an author of thousands of biosafety reviews and environmental impact assessments of GM crops in North America with a majority of them being Bt crops.

I have been observing the development of GM crops technology in India for as long as it has been going on. In the mid 90s, I helped your ministry to publish the first set of biotech rules under EPA to govern GM crops in a gazette in late 90s. I have trained and advised many members of the GEAC in the years past. I have closely studied the development of Bt brinjal for over six years, and have looked into all objections by the anti-GM lobby of India. I have rigorously studied the two expert committees responses to those concerns and their recommendations. I want to assure you that GEAC has done a very competent job of considering all issues and factors before basing their decision on scientific facts and empirical evidence. A good regulator is supposed to do exactly that. Politicking and campaigning for or against has no place in making a scientific decision. Science cannot be decided by a shouting brigade.

As someone who has approved Bt crops in the USA for almost a decade and a half, I have to tell you that GEAC's final decision on Bt brijal is based on sound science that is there for anyone to verify. there is overwhelming scientific evidence and endorsements for Bt crops from scientific bodies around the world, which is what I urge you to consider, and nothing else when you finally bless that file. GEAC and your ministry can stand up and defend your decision anywhere in the world. Moreover, India's' poor farmers and Indian agriculture will benefit immensely from Bt brinjal. I appeal to you to not to be cowed down by the false propaganda of the anti-GM establishment who are playing politics to deny benefits of modern biotechnology to the poor third world country farmers through an orchestrated global campaign. You should only consider the interests of the nation and the science that supports the GEAC decision to give your final approval. For sure, you will be attacked by the anti-GM lobby when you approve it, but you should not be bothered by it as they will have no scientific credibility. I also urge you to consult with Drs. MS Swaminthan and Gurdev Khush, the two leading lights of modern agriculture to seek their opinions.

All well meaning and learned scientists will applaud your decision when you approve Bt brinjal. India is a flash point for the developing world, and everyone in Asia major will

Dear Mr. Bojja,

I have looked at the data provided in the studies on Bt Brinjal located at http://moef.gov.in/divisions/csurv/geac/bt_brinjal.html. My comments are as follows:

1. Regarding food safety studies, the feeding tests conducted with Bt Brinjal--in particular those that used the Bt Brinjal itself as the test substance--far exceed the recommendations of Codex Alimentarius (CAC/GL 45-2003). Usually, unless agronomic data and compositional analysis indicate lack of substantial equivalence, feeding studies would not be required. In the future, I would recommend more careful consideration of the need for the whole food feeding studies of the type submitted in this dossier.

2. With respect to the environmental studies, A significant amount of data has been submitted, and based on my study of these data, the Bt Brinjal has been demonstrated to be safe for the environment. These studies add to the already considerable base of data on Cry proteins and particularly Cry1Ac, confirming the environmental safety of these proteins. I also recommend that in the future, the results of the studies done by Mahyco be used to guide the requirements imposed on other applicants. For example, the study on soil microflora corroborates the information obtained repeatedly on other Bt crops, confirming that Cry proteins have no effect on rhizosphere fungi. Indeed, this lack of effect could have been predicted because of the known specific mode of action of the Cry proteins. In my opinion, studies of this type should not be required except for expressed proteins that are expected to have an effect on some component of soil microflora.

The Bt Brinjal has passed all hurdles necessary for regulatory approval in India, and has been determined by GEAC to be safe for commercial production. I support this decision and hope that the Minister will grant final approval.

Sincerely,

Dr. Hector Quemada PhD
Crop Technology Consulting, INC
Kalamazoo, MI, USA.
& Adjunct professor of Biology at Calvin College, Grand Rapids, M

SALK INSTITUTE
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November 18, 2009

Mr Jairam Ramesh
Hon'ble Minister of Environment and Forests
Government of India
425 Paryavaran Bhavan
CGO Complex, Lodhi Road
New Delhi 110003, India

Email: jairam@vsnl.com

Dear Mr. Jayaram Ramesh:

My name is Dr. David Schubert. I have a PhD in immunology and am a professor at the Salk Institute for Biological Studies in San Diego, California. The Salk Institute is considered one of the best medical research institutes in the world. I am writing this text because of my concern about the introduction of brinjal genetically modified with bacterial Bt toxin into the food supply of India. There are several reasons that the introduction of this genetically engineered (GE) food plant should not be allowed. They include:

1) The lack of need. Brinjal is not a crop threatened by an overwhelming insect infestation.
2) Environmental risk. Brinjal is native to India and the GE genes will unquestionably contaminate the native population.
3) Higher costs. The purchase of seeds on an annual basis as opposed to saving seed from year to year will increase costs at all levels of the food chain.
4) Social and political dependence. Once a foreign company controls the seed market of any single food plant, seed for more GE plants will follow, and the company will have tremendous power over both the farmers, which constitute a major segment of the Indian population, as well as the political process. This has clearly happened in the United States (US), where Monsanto is a major financial supporter of both political parties, and therefore has political appointees who dictate both national and international agricultural policy.
5) Finally, GE brinjal expressing Bt protein poses a serious health risk to those who consume it. This is the issue that I wish to address. First, however, I would like to debunk some myths that are used by the proponents of GE brinjal to claim that it is safe.

Bt cotton (I will use the term Bt throughout to mean a family of Cry 1 insecticidal endotoxins produced by the bacterium Bacillus thuringiensis) is grown in India, and it is claimed that there have been no serious human health problems due to its cultivation. This statement is irrelevant since cotton is not consumed by people, but as you must be aware there is very good evidence that the consumption of Bt cotton plants by farm animals leads to serious health problems and sometimes death. Bt maize is grown in the US and it is claimed that because there has been no documented Bt maize-associated disease, Bt brinjal is therefore safe to eat. This conclusion is invalid for several reasons.

First, only a small fraction of the Bt maize produced in the US is eaten directly. The vast majority in used as animal food and to make oil, high fructose syrup, and ethanol, none of which would contain the Bt protein. The maize containing the Bt protein that is consumed is largely in the form of highly processed corn chips and related snack foods that are not major components of the diet. In contrast, the Bt protein in brinjal will be directly consumed in massive quantities because the vegetable is a significant component of the Indian diet. In addition, it will be prepared in an infinite number of ways, leading to potential chemical changes in the protein causing unknown toxicology and immunogenicity. Cooking can readily change the structure and antigenicity of a protein. Did the feeding studies done with Bt brinjal include cooked product?

Second, it is logically false to claim that because there is no evidence of illness following the introduction of a GE product, therefore the product is safe to eat. In fact, perhaps my major concern with the introduction of any GE food is that even if it did cause an illness, it would not be detected because of the lack of epidemiological studies and the technical limitations for detecting such an illness. For example, to detect an epidemic of a disease, an incidence of at least of two fold above the background rate of the disease is required. Therefore, if Bt brinjal were to cause a disease like Parkinson's, which has an incidence of about 20 new cases per year per 100,000 people, then in India 200,000 new cases per year would have to be diagnosed and tabulated in order to identify a significant increase, and there would still be no way to associate the disease directly with a Bt crop. In addition, many environmentally caused diseases take many decades of exposure to develop symptoms. Clearly, once Bt brinjal is commercially released, there will be no way to monitor adverse health effects caused by the product.

There are at least four mechanisms by which the introduction of the Bt toxin gene into the Brinjal genome can cause harm. These include (1) the random insertion of the Bt gene into the plant DNA and the resulting unintended consequences[1], (2) alterations in crop metabolism by the Bt protein that results in new, equally unintended and potentially toxic products, (3) the direct toxicity of the Bt protein, and (4) an immune response elicited by the Bt protein. There are scientifically documented examples of all four toxic mechanisms for Bt crops.

An example of the first is the discovery of unintended alterations in the synthesis of nine known carcinogens caused by the GE modification of tobacco, a crop in the same plant family as brinjal[2]. An example of the second is the abnormally high levels of the fiber molecule lignin produced in Bt maize[3]. This trait was discovered because of dramatic changes in the stiffness of the corn stalk. Since multiple strains of Bt maize have this trait, it is most likely that increased lignin production is associated with the expression of the Bt protein itself, not due to mutations caused by the GE process itself (item one above)[4]. Importantly, the synthetic route to lignin in plants is shared with that of rotenone, a plant metabolite known to cause Parkinson's-like disease in animals. It is very likely that there are many other unintentional changes in Bt crops, and a few more have recently been documented[5].

The toxicity and immunological hazards of the Bt protein are discussed in more detail below. It should be emphasized that the majority of this material has been published in peer-reviewed journals and reproduced in more than one laboratory, therefore ruling out the possibility of an individual investigator's bias.

Allergies are complex responses of the immune system to foreign substances and vary widely between individuals in an unpredictable manner. Bt toxins have long been used as insecticidal sprays on a variety of crops, but the spray is a less toxic form of the protein than that made by GE plants. The spray consists of spores of the Bt toxin that must be activated in the gut of the insect. In contrast, Bt toxin in brinjal is a highly activated form of the Bt protein that does not require modification in the insect gut to become toxic. It is therefore much more potent than that used is sprays. Despite this major difference in Bt form and activity, and even though the spray is not ingested by farm workers, there is solid evidence that the Bt proteins elicit a strong immune response in some workers after a few months exposure, and it is likely that many more workers are affected, but associate their allergic response with the spray and decide to work elsewhere[6]. Since Bt proteins have amino acid sequence homology with known allergens, allergic reactions in some individuals are not unexpected[7,8]. Most importantly, it should be emphasized that the concentration and amount of Bt toxin protein that people will eat in Bt brinjal will be thousands of times higher than the exposure levels of farm workers.

In support of the human data, when animals are exposed to Bt toxins, the toxin also acts as a potent immunogen, eliciting responses from both the blood and gut-based immune systems[9-11]. Based upon these data, the US Environmental Protection Agency (EPA) recommended extensive safety testing of Bt crops for this trait[12], but due to the lack of required safety testing for GE food crops in the US, this was never done[4]. Although I am sure that you are aware of this fact, it should be restated that the US agencies that allowed the introduction of Bt food crops did not require any demonstration that the GE food was safe for human consumption.

Additional animal studies have shown that Bt toxins directly cause tissue damage. For example, Fares and El-Sayed demonstrated that feeding mice Bt potatoes caused the appearance of structurally abnormal cells in the gut[13]. Other studies reported histopathological changes in the kidney and liver of rats feed Bt corn[14], and changes in urea and protein levels in the urine of rats fed Bt rice[15]. While there was no extreme pathology in any of these studies, they were all short term (up to 90 days) and done with healthy animals. The outcome may be quite different if the Bt protein is consumed by infirm, under nourished, aged, or very young individuals, for the body responds quite differently in individuals compromised by any of these conditions, and all groups will be eating Bt brinjal. As far as I know none of the safety testing of Bt brinjal has taken this fact into account.

Since a significant fraction of any population falls within one or more of these categories, it is difficult to believe that the regulatory authorities could overlook this problem. To emphasize this point, it has recently been shown that the immune response to feeding very young and very old mice Bt maize is different from that of the non-GE maize fed control groups. Most interestingly, the immune responses were also very different in the young and old age groups[16]. These very robust data clearly demonstrate how difficult it is to extrapolate negative data from short term feeding studies in healthy adult animals to real world situations. They also further emphasize the need for extreme caution before the irreversible introduction Bt brinjal into the food chain.

The above citations clearly show that the family of Bt proteins can act as allergens in animals and some individuals. Most importantly for the health of the Indian population, if the introduction of Bt brinjal is allowed, an enormous number of individuals are going to consume amounts of Bt toxin that are thousands of times higher than anytime previously in the short history of this GE technology. This population is extremely heterogeneous in genetic makeup, age, and also with respect to underlying health. It is the genetics and health status of the individual that determines his or her response to foreign proteins such as Bt toxin. Less healthy individuals are much more prone to negative immune reactions. Since the ability of Bt toxin to cause an allergic response in some individuals is unambiguous, it is virtually certain that within the vast Indian population a large number of people eating Bt brinjal are going to be or will become allergic to this foreign protein; this number cannot be predicted and some of the immune responses will likely be severe, causing anaphylaxis and possibly fatalities. Since there will be no way of tracking these adverse reactions within the population, and since once Bt brinjal is commercially grown, its genetic presence within a major calorie source for the Indian population is irreversible, a simple decision has to be made. Is the negligible benefit of Bt brinjal worth the clear risk? My conclusion is that it is not worth the risk and that it would be a profound disservice to India if Bt brinjal were allowed to enter her food supply.

Respectfully,

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GENETICALLY MODIFIED CROPS: INDEPENDENT SCIENTISTS WRITE TO THE PRIME MINISTER OF INDIA WITH REFERENCE TO THE PMO LETTER OF JULY 2009 TO DR A RAMADOSS WHICH IS SCIENTIFICALLY UNTENABLE

Note: This sign-on letter is prompted by the communication, authored in July, 2009, by Mr Prithviraj Chauhan, written in his capacity at that time as Minister of State in the Prime Minister's Office. This letter entitled "Concern on Introduction of Genetically Engineered Crops and Food" was an official response to a letter from Dr A Ramadoss, addressed to Prime Minister Dr Manmohan Singh (full letter attached), dated 2nd February 2009, when he held the portfolio as India's Minister of Health.

In its opening paragraph it says: *"the various issues raised in your letter have been examined carefully and by applying the best scientific evidence available today"*. However, the signatories to this letter wish to respectfully bring to the attention of Prime Minister Dr Manmohan Singh, numerous factual and scientific errors within the Chauhan letter. From the content of this letter and its phraseology, it is apparent that much of it was excerpted directly from promotional materials of the agricultural biotechnology industry, in particular the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), an organisation that at best can be described as pseudo-scientific, funded primarily by Monsanto and other biotechnology multinational companies and whose purpose is to promote and facilitate the commercial introduction of genetically modified (GM) crops in the developing world. Inaccurate information has led to erroneous policy on GM crops and Bt brinjal in particular. Therefore, in the context of the current debate on the introduction in India of its first major GM food crop, Bt brinjal, to be grown on a commercial scale, we strongly urge the Prime Minister to consider the factual and authoritative scientific content of this letter.

We hope that this letter will help to bring the true facts of GM crops into the open to enable an informed discussion on their unique risks to food security, farming systems and bio-safety impacts which are ultimately irreversible. We urge the Prime Minister, for the sake of the safety of the Indian people, and the welfare of Indian farmers, to re-address the official position on GM crops. The global community needs India to lead in the matter of exemplary regulation of these crops.

We highlight some of the many major inaccuracies found in the Chauhan letter in italicized quotes, followed by our comments with numbers in parentheses indicating items in the list of supporting **References.**

i. *"With the rapid progress in advanced biology, biotech crops have been developed with the help of genetic engineering tools to possess special characteristics that make them better. ----also known as Genetically Modified (GM) or Genetically Engineered (GE) crops. The most common traits deployed in biotech crops so far include insect resistance, herbicide tolerance, virus resistance and improved product quality.*

This statement broadly oversteps the facts and is in fact erroneous.

- More than 95% of all GM crops are engineered to either synthesise an insecticide (Bt toxin) or to tolerate a broad spectrum herbicide (e.g. Roundup, Liberty) or both.
- **Despite many years of research, no GM crop is currently "*deployed*" with "*improved product quality*" as is claimed.**
- **To date there are only four major commercialised GM crops** (soya, maize/corn, cotton, canola/oilseed rape) most of which (soya, corn, canola) are used primarily as animal feed. All were commercialised in the late 90's. Since then, no other commercially viable GM crop application has made it to market, especially due to farmers not accepting other GM crops (such as wheat, potatoes, and rice) for negative economic reasons (lack of buyers, loss of export markets).
- **GM crops have not been widely accepted around the world.** 95% of all GM food crops are grown in only 5 countries: the US, Canada, Australia, Argentina, and Brazil. If you include fibre crops (cotton) India and China would be included. Only one GM crop is approved for cultivation within the European Union,

MON810 corn, which has been banned by several member states invoking documented health and especially environmental risks.

- Only two minor food crops have been released in the USA (squash, papaya) and one in Mexico (squash), which are engineered in an attempt to make them virus resistant. The outcome has been a mixed blessing; GM squash is resistant to some viruses but renders it more susceptible to attack by beetles (1).

ii. *"It is expected that development of crops with tolerance to drought and salinity, improved nitrogen use efficiency, enhanced yield, quality and nutritional properties coupled with existing traits will be technically feasible in the near future and be a real value addition in India. From a technological perspective, what is feasible tomorrow is even more promising but scientists and Indian Industry need a predicable regulatory and social environment. At the national level, it will make agriculture more efficient and competitive to meet the challenges of hunger, poverty, malnutrition and food security in tomorrow's world (Global Knowledge Centre on Crop Biotechnology, 2008)"*

These "promises" taken verbatim from ISAAA industry promotional material do not match either scientific fact or reality.

- *"tolerance to drought and salinity, improved nitrogen use efficiency, enhanced yield, quality and nutritional properties"* are hypothetical claims which have been made by industry for 15 years. Despite vast sums invested in research they have failed to deliver on these promises. The listed traits are genetically complex. The basic problem is that GM as employed in agriculture is conceptually flawed, crude, imprecise and poorly controlled technology (2-4), that is incapable of generating plants that contain the required multiple, co-ordinately regulated genes that work in an integrated way to respond to environmental challenges.
- Contrastingly, crop varieties already exist that are tolerant to drought or salinity, or have improved nitrogen use efficiency either naturally or specifically bred by conventional methods, and augmented in some cases by modern non-GM biotechnology gene mapping ("marker assisted selection"; MAS). For example a novel upland rice variety, Birsa Vikas Dhan 111 (PY 84), has recently been released in Jharkhand bred using backcrossing augmented with MAS with selection for multiple traits for improved root growth and performance under drought conditions (5). These methods are sustainable and safer approaches to crop improvement, less expensive and give significantly higher returns on investment. A fundamental redirection is required in agricultural investment in these areas.
- GM has failed to produce crops with improved nitrogen use efficiency whereas conventional breeding and improved farming methods have made significant improvements in this area (6).

iii. *"The most compelling case for biotechnology and more specifically biotech crops, is their capability to contribute to increasing crop productivity, conserving biodiversity, reducing the environmental footprint of agriculture, mitigating climate change and reducing greenhouse gases, increasing stability of productivity and production, the improvement of economic, health and social benefits, the cost-effective production of renewable resource-based biofuels and thus provide significant and important multiple and mutual benefits to producers, consumers and global society."*

These claims again are a reiteration of industry promotional material and have no basis in science or the empirical evidence relating to the performance of GM crops.

- **Productivity—GM has not increased yield potential.** Yields from GM crops to date have been no better and in the case of GM soya have been consistently lower. A 2009 report reviewing more than 20 academic studies clearly shows that the cultivation of GM herbicide-tolerant soybeans has not increased yields. Insect-resistant corn, meanwhile, has at best only improved yields marginally. This report found that increase in yields for both crops over the last 13 years was due to traditional breeding or improvements in agricultural practices (7).

- **Conserving biodiversity**—In South America, GM soy has been instrumental in speeding destruction of the Amazon rainforest (8)
- **Reducing the environmental footprint of agriculture**—GM crops have led to vast increases in pesticide use, not decreases and therefore reduction of agricultural pollution cannot be claimed (9).
- **Mitigating climate change**—No-till agriculture using herbicide-tolerant GM seeds does not reduce greenhouse gas emissions. Contrastingly, the high soil carbon sequestration within organic matter inherently produced by agro-ecological farming methods markedly reduces greenhouse gas emissions (10).
- **Climate change** brings sudden, extreme, and unpredictable changes in weather, which requires that a cropping system be flexible, resilient and as genetically diverse as possible. GM technology offers just the opposite.
- **Stability of productivity and production**—is much lower with many of the GM crops commercialised today. Herbicide tolerant GM soya is far more sensitive to heat or drought stress than conventional soya (11,12).
- **Improvement of economic, health and social benefits**—consistently, introduction of GM crops is linked to loss of markets and degradation of rural communities (13-17), and evidence continues to mount regarding the health hazards of GM crops (for example see refs 18-25).
- **Biofuels**—Reports from the World Bank and the United Nations Food and Agriculture Organisation have identified the biofuels boom—not lack of GM foods—as the main cause of the current food crisis (26,27).
- **The IAASTD** report* concludes that GM crops do not increase yield, have little to offer global agriculture and food security and the challenges of poverty, hunger and climate change. Instead it recommends applying low-input agro-ecological farming practices, whose use in the developing world has produced dramatic increases in yields and food security (28). [*The single largest research exercise on global agriculture in history, which was conducted with funding from multiple UN agencies and the World Bank. This report, published as *Agriculture at a Crossroads*, was produced under the auspices of the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD). It involved around 400 scientists and twice that number of peer-reviewers. It underwent two rounds of open international peer-review and was ratified overwhelmingly at the intergovernmental plenary in April 2008, including by India.]

iv. *"The concerns conveyed by you that the technology may induce instability in genetic level and have adverse health impact is not supported by scientific evidence".*

This is a scientifically indefensible statement because:

- GM transformation can produce novel biochemical processes that are unpredictable and for which there is no natural history to assume are safe (2-4).
- The GM transformation process is highly mutagenic leading to disruptions to host plant genetic structure and function, which in turn leads to disturbances in the biochemistry of the plant. This can lead to novel toxin and allergen production as well as reduced/altered nutritional quality (2-4).
- It is not a question of *if* there are disturbances to gene function and biochemistry but to what degree they will be present within any given GM plant. For example, the levels of more than 40 proteins are altered significantly in the commercialised GM MON810 corn compared to equivalent non-GM corn, which included production of a new allergenic protein (3).
- Numerous animal feeding studies demonstrate negative health impacts of GM feed on kidney, liver, gut, blood cells, blood biochemistry and the immune system (for example see refs 18-25).
- Of greatest concern is that studies show negative health effects with GM crops that have already been approved and which have been grown commercially for 10-13 years (18-25). **This highlights the inadequacy of the original criteria and set of data on the basis of which marketing approval was and is still being granted.**

  Note: MON810 has since been banned by many EU countries including France and Germany.

v. *"Biotech or GM crops are approved for environmental clearance/commercial release by regulatory authorities after passing through various regulatory stages starting from IBSC-MEC, RCGM and GEAC. The three-tier system is in the hands of the best scientists, technologists, agricultural and environmental experts in the country.... The regulatory system is adequate, reliable, efficient and transparent.... These SOPs are consistent with best international practices".*

This position oversteps the mark and is technically inaccurate as highlighted above and as further evidenced below:

- India's Regulators do not require independent bio-safety tests, but uncritically accept as evidence of safety, research conducted by the company who is applying for commercial clearance of the product. This raises serious questions regarding impartiality and conflicts of interest, which are clearly justified, based on published evidence of bias in the research conducted by industry that is contrary to accepted normal scientific conduct (29).
- GM food compositional analysis is superficial and the minimum required to establish "substantial equivalence", a scientifically conceptually flawed parameter that is virtually meaningless with respect to determining health risk (30).
- Experimental design used by the applicant is flawed, almost invariably containing irrelevant "control" non-GM comparator crop varieties, which serve to mask rather than to isolate and reveal the effect of the GM transformation process (20,24).
- The biological testing required is not adequate to detect either acute or chronic toxic effects of GM foods. At best, only 90-day feeding studies are required by the government's SOPs without an obligatory requirement for toxicological and histological evaluation. In order to assess medium and long-term (life-long) health impacts it is necessary to conduct lifetime and multigenerational feeding studies. Only these will reliably determine fertility and chronic health impacts, which is essential because it is the intension that people will be eating GM foods for their whole lifetime (24).
- Experimental data is invariably not made publically available for independent scientific scrutiny under the pretext of commercial confidentiality. This has required court action (both in Europe and India) in order to obtain the information needed to assess the quality of the research submitted by industry to be scrutinised by authoritative bio-safety experts. Such independent re-evaluation of submitted industry data has repeatedly found that this research and its interpretation thereof to be flawed, inadequate, biased and thus misleading (20,24,25).
- **All of the above points are directly relevant to the current safety dossier of Bt brinjal and imply that the Indian government's current requirements for GM food safety assessment are inadequate and need to be augmented.**

vi. *"Given that the discovery and use of Bt has completed hundred years in 2002 and Bt technology has a long history of safety, proven efficacy and benefits, Bt brinjal promises to be of great value to Indian farmers. It may be noted that those who stand to gain from wide use of pesticides, often provide misleading information for commercial interests. The GM food assessed and approved through rigorous science based regulatory process has been endorsed by Nobel laureates and leading global scientists".*

This statement ignores research showing:

- Bt toxin is a proven potent immunogen raising justifiable concerns that it can give rise to allergic reactions (31,32).
- Animals fed diets containing Bt corn have shown signs of direct toxicity (20-25).
- Independent re-evaluation of Monsanto's own research on their Bt corn crops shows negative health effects even in short-term (90-day) animal feeding studies (20,25).
- The Mahyco-Monsanto dossier of the raw experimental data of animal feeding studies with Bt brinjal shows highly statistically significant negative signs of toxicity on the functioning of multiple organ systems such as liver, kidney, blood and pancreas in all animals tested (especially rats, rabbits and goats). It is very important to note that these adverse effects were observed after only at most, a 90-day feeding time, which raises serious concerns about the safety of consuming this product over an entire lifetime. Long-term (at

least 2-year) animal feeding studies were not done and are stated as not required by the apex Regulator, contrary to the science, which requires these studies to detect chronic slow-onset toxicity and cancer.

- **There is therefore, no scientific justification for the safety claim of Bt brinjal by India's regulators, which are based on an uncritical acceptance of the interpretation of the data submitted by Mahyco-Monsanto. This has been heavily criticised by eminent scientists of international standing.**

vi. *"Biotech crops are environmentally friendly and have contributed significantly to reducing the emission of greenhouse gases from agricultural practice".*

These claims again simply quote material from industry promotional material, which as noted above is not supported by data in published peer review scientific journals:

- GM crops are designed to be used in conjunction with synthetic pesticides and fertilisers, which are manufactured from oil and natural gas.
- GM crops do not reduce greenhouse gas emissions.
- Recent data from the US Department of Agriculture has shown a vast increase in herbicide use since the introduction of GM crops tolerant to the application of these agrochemicals (9).
- **Therefore, the introduction of GM crops has exacerbated rather than reduced agriculture's carbon footprint and is clearly unsustainable.**

Alternative proven technologies that can reduce the amount of fossil fuel used in farming already exist. This includes methods for reducing fertiliser applications, selecting farm machinery appropriate for each task, managing soil for conservation, limiting irrigation and agro-ecological farming techniques.

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The inadequacy of GM Brinjal food safety studies.

A reply to the ECII report.

Dr Judy Carman BSc (Hons) PhD MPH MPHAA

February 2010

Introduction

The Institute of Health and Environmental Research Inc. (IHER) is a not-for-profit research institute with an interest in genetically modified (GM) organisms, particularly those destined for food. Its directors hold the following degrees: ordinary degrees in Medicine, Science and Agriculture, Honours Degrees in Agricultural Science and Organic Chemistry, a Master of Public Health, and PhDs in Plant Genetics and Medicine. The Directors have training and expertise in plant science, agriculture, medicine, chemistry, biochemistry, nutrition, animal feeding studies, epidemiology and biostatistics. IHER has received funding from the government of Western Australia to conduct one of the first long-term, independent animal feeding studies ever done into the safety of GM crops measuring human health end-points. IHER receives no funding from biotechnology interests and hence is completely independent of them.

Dr Judy Carman BSc (Hons) PhD MPH MPHAA is a Director of IHER and the author of this document. She:

- Has a science degree, an Honours degree in organic chemistry, a PhD in medicine in the field of metabolic regulation and nutritional biochemistry, specialising in animal feeding studies, and a Master of Public Health specialising in epidemiology and biostatistics.
- Worked in the fields of human nutrition (including at the CSIRO), infectious diseases including HIV/AIDS, national injury surveillance and analysing data from Divisions of General Practice.
- Was the Senior Epidemiologist in the Communicable Disease Control Branch of the South Australian Department of Health, investigating outbreaks of disease in the state including food-borne, mosquito-borne (eg Ross River Virus), zoonotic and pneumonia from *Legionella*. She was Acting Head of the Branch at times.
- Taught at an agricultural college and two Australian universities to the level of Senior Lecturer.
- Was Assistant Director and Senior Lecturer, Research Centre for Injury Studies (RCIS), Flinders University of SA, incorporating the National Injury Surveillance Unit (NISU) of the Australian Institute of Health and Welfare (AIHW).
- Held a number of positions in the Public Health Association of Australia (PHAA), including being spokesperson on GM foods and convening two national food conferences for the PHAA.
- Has analysed various State and Federal government disease, general practitioner, hospitalization and death surveillance systems, and has written several official State and Federal government reports from these systems, on eg cancer, communicable diseases and various injuries.
- Has advised or been consultant for parliamentarians, government and non-government organisations and industry bodies on various matters.
- Was consultant on GM foods to the Hon. Kim Chance, Minister for Agriculture and Food in Western Australia.
- Has presented to the New Zealand Royal Commission into Genetic Modification.

Dr Carman wrote a submission in January 2009 titled "A review of Mahyco's GM brinjal food safety studies" on behalf of IHER, concentrating on the food safety evaluation done by Mahyco as reported in Chapter 7 of Volume 1 of their submission. Dr Carman's submission criticised the quality of the research that Mahyco submitted to the Indian government to support Mahyco's assertion that GM brinjal was safe to eat. An expert committee (ECII) was then convened to review the material that IHER and others had submitted. It wrote a report ("the ECII report"). IHER is now writing a response to that report, particularly the assertion on page 91 of that report that all the issues that Dr Carman had raised have been addressed. This is not the case. The issues that Dr Carman raised have not been addressed.

Submission

This submission will reiterate the original points by given by Dr Carman in her original submission in January 2009 and will describe how the ECII committee has NOT addressed those points.

Compositional comparisons

IHER's original submission

One of the greatest concerns about the process of genetic engineering is that the actual process of inserting the gene may cause the plant to up-regulate or down-regulate the normal genetic expression of the plant and hence to produce more of something harmful to human health, or less of something beneficial to human health. An associated concern is that the insertion process may cause the plant to produce a novel substance for that plant. There are certainly examples of all of these effects appearing as a result of genetic engineering. Yet, the compositional analyses presented to the Indian Government by Mahyco do not assess these known likelihoods.

For example, the compositional comparisons concentrate on measuring moisture, protein, oil, ash, carbohydrates, calories for fruit tissue, nitrogen, ash and crude fibre. These are extremely crude measures of the nutritional components of brinjal. A full protein analysis would have gone some way to determine if the plant was producing more, or less, of something it normally produces, or a completely new substance. Yet it was not done.

Moreover, according to page 104 of Mahyco's document, a sample size of only three Bt brinjal and three non-BT brinjal were used to determine the differences in composition between the GM and non-GM brinjal. This is woefully inadequate to determine compositional differences between two crops. The composition of the two crops (the 'clinical' difference) would have to be profoundly different to be able to be picked up as a statistical difference using such a tiny sample size. Also, the only real way of comparing the composition in this manner is to grow the GM and non-GM parent brinjal from which the GM brinjal was developed, side-by-side in the same field, under the same conditions of soil type, fertilizer, herbicides, insecticides, water, sunshine, etc. and then to use samples from these plants in the comparison studies. Only then can any differences between the GM and non-

GM crops be determined to be due to the genetic insert and not due to confounders such as soil type, fertilizer, herbicides, insecticides, water, sunshine, etc. Yet Mahyco do not describe if their samples were obtained in this manner or not.

The analyses presented also do not take into account compositional differences found under different growing conditions in different areas of India. For example, no work seems to have been done on whether the concentration of harmful components of Bt brinjal increase under different climatic conditions, eg heat or water stress. In order to do this, the comparative growing study described above, where GM and non-GM parent brinjal are grown in the same field under identical conditions, would need to be repeated in various places in India under different climatic and soil conditions. These do not appear to have been done.

In addition, as woefully inadequate as simple amino acid and fatty acid profiles are, even these do not appear to have been done by Mahyco. (Amino acids are the building blocks of proteins, while fatty acids are the components of fats.)

Moreover, information about the chemical composition and alkaloid content measurements did not provide the following standard and required statistical information: the mean and standard deviation of each group, the nature of the statistical test done and the p-value resulting from the statistical test. Furthermore, the analysis of alkaloid content in GM brinjal does not even provide information as to how many brinjal were tested in each group. For the Cry1Ac protein estimation in brinjal after cooking, no cooking temperatures or samples sizes were given. Mahyco also appears not to have undertaken any studies to determine if the GM DNA in GM brinjal can degrade upon cooking.

GM crops are deemed to be substantially equivalent to non-GM crops until they fail some type of substantial equivalence test. Yet no decision has been made as to what this test should be; how compositionally different a GM crop needs to be from a non-GM crop to be regarded as different. To elaborate, if there had been a decision made that a GM crop is judged to be compositionally different if say 10% of its amino acids are statistically significantly different when fruit from 50 different brinjal plants are measured, or that a full protein analysis needs to be done and the GM brinjal needs to have all proteins within 10% of the levels present in non-GM brinjal, then there would be a clear hurdle that GM brinjal would need to clear to be deemed to be substantially equivalent. But there is no such hurdle. Instead, there is a bland statement by the producers of GM brinjal that their crop is substantially equivalent without even describing the scientific criteria they have used to determine substantial equivalence or any pass/fail level they may have within these criteria.

Many of the errors described constitute errors of research methodology which can only be corrected by conducting appropriately-planned and executed research. Until this work is done, it cannot be stated that the composition of Bt brinjal is similar to ordinary brinjal.

In summary, the information submitted by Mahyco is completely inadequate to determine if the composition of Bt brinjal is similar or different to ordinary brinjal. Moreover, the information presented do not meet accepted scientific standards of reporting.

How the ECII committee has not addressed these concerns

Mahyco does not appear to have provided any new information for the committee to assess. For example, a full protein analysis does not appear to have been done, extra data do not appear to have been provided to increase the woefully inadequate sample sizes, the quality of the statistical reporting remains woefully inadequate and there still appears to be no definition as to what constitutes "substantial equivalence", so it appears that almost anything can still can pass the "test".

As a result, the points in IHER's original submission have not been addressed and IHER's concerns remain.

Allergy assessments

IHER's original submission

To determine allergenicity of the Bt brinjal, Mahyco first did a paper-based analysis. It artificially split the GM protein that it expected to be produced (not any unexpected proteins) into smaller segments and compared the segments to certain data bases of known allergens. It should be remembered that not all allergens are known, even in peanuts, and that, even for the known allergens, not all are represented in these databases.

Mahyco also reported a skin irritation test on rabbits and a mucous membrane test using vaginal tissue in rabbits on pages 113-116 of volume 1. For both studies, only three female rabbits were used for each treatment group and the animals followed for only 72 hours after exposure. The studies cannot be regarded as allergy tests as the test substance was only applied once. Allergies generally require repeated exposure to a substance before an allergy can be developed. Then, the more often the exposure, the worse the allergic reaction tends to get. Although clinical signs of matters such as toxicity and skin reaction were measured in this test, there is no description as to exactly what these involved and what would constitute an adverse finding. Moreover, no matter what measurements were taken, calculations indicate that even if all rabbits treated with the GM material showed a severe adverse clinical effect compared to no rabbits suffering this effect in the non-GM-treated rabbits, the appropriate statistical test would be completely unable to find statistical significance due to the small number of animals used.

The methodology of the allergy study undertaken in Brown Norway rats does not meet the standards of allergy testing employed by other researchers that **have** found allergic reactions due to consumption of GM crops[1] and the full results were not given in the text.

How the ECII committee has not addressed these concerns

Mahyco does not appear to have provided any new information for the committee to assess. It remains that the allergy studies are woefully inadequate (this includes the sample sizes) and the studies do not meet international peer-review standards.

As a result, the points in IHER's original submission have not been addressed and IHER's concerns remain.

Reproductive studies

IHER's original submission

Mahyco did not provide any reproductive studies and it therefore appears not to have done any, even though adverse reproductive effects have been found from eating other GM crops[2,3]. These results strongly indicate that reproductive studies should be required before any GM crop could be assessed as safe to eat.

How the ECII committee has not addressed these concerns

It appears that Mahyco has still not done any reproductive studies. As a result, the points in IHER's original submission have not been addressed and IHER's concerns remain.

Digestive studies

IHER's original submission

Digestive studies used an *in vitro* (in glass) method of determining how quickly the protein that is expected to be produced will break down in the intestine. No data appear to have been given for the digestibility of GM DNA. Such studies are notorious for providing false assurances about the digestibility of GM DNA and proteins. For example, such studies often use unrealistically high levels of stomach acid and digestive enzymes. The level of acid in a human stomach moves towards neutral once food enters it. The only real way to determine how quickly GM DNA and protein are digested is to do experiments in animals or humans. Several of these *in vivo* studies have shown that GM DNA can and does survive digestion and can be found in tissues of the body. A recent study in Italy found that GM DNA present in the feed of cows could even be found in milk on supermarket shelves[4].

How the ECII committee has not addressed these concerns

It appears that Mahyco has still not supplied these data nor done any *in vivo* digestibility studies. As a result, the points in IHER's original submission have not been addressed and IHER's concerns remain.

Acute toxicity studies on animals

IHER's original submission

The results of these studies cannot be used to determine the safety of GM brinjal, as described below.

Acute toxicology test on mice

This test was not done using the GM proteins as expressed in the GM plant that people will be eating. Instead, Mahyco used proteins that were produced by GM bacteria that were engineered to produce the GM proteins. Mahyco appears not to have determined if the proteins are exactly similar in structure and function as those found in the plant, even though it is known that the expression of the same DNA in different organisms can produce proteins with different physiological effects[1]. Moreover, the study on the Cry1Ac protein used only 10 mice per group, a seriously insufficient number to determine the true clinical outcomes of these mice, while the number of mice used to test the NPTII protein is not given. It appears that body weight and food consumption were the only real measurements taken for the Cry1Ac protein study because, while tissue samples were taken, they appear to only have been kept and not analysed. Furthermore, while pathological changes were seen in the 'gross necroscopy' in some mice, neither the nature of the necroscopy nor the nature of the changes were described. Nor were the nature of the statistical tests, the means, standard deviations and p-values of the analyses given.

Oral toxicity study on rats

This study used only 5 male and female rats per group, which is an completely inadequate number to determine the true toxicological effects of GM brinjal on these rats. To give just one example of how inadequate this is, the concentration of a key liver function enzyme in the blood, AST, gives a measure of the health of the liver. Male rats fed GM brinjal had a concentration of AST that was 48% and 63% higher than feeding rats non-GM brinjal. Yet, this clinically significant finding was not found to be statistically significant. Calculations indicate that adding just a single extra rat to each group to bring the number of rats to a still tiny 6 per group, would have made this difference statistically significant, which would in turn have indicated that feeding GM brinjal to male rats could cause liver damage.

It appears that only one dose per rat was given and then the rats were followed for only 14 days. Food consumption, and only some haematology and biochemistry measurements were taken. It is normal to take 18-20 clinical biochemical measurements on blood from animals and humans to determine health. Yet only eight standard biochemical results are shown in the tables associated with this study. Only overwhelmingly adverse effects could be picked up this way using this number of animals for this time period and the study is simply inadequate to predict the effect of feeding this GM crop to 1.15 billion Indians for generations. Moreover, the company rarely reports the nature of the tests undertaken, the means, standard deviations, statistical tests undertaken or the p-values of the statistical analyses.

How the ECII committee has not addressed these concerns

Mahyco does not appear to have provided any new information for the committee to assess. That is, the actual "new" protein that actually appears in the GM brinjal is still not the protein that has been assessed for safety in these oral toxicity studies. A different protein was assessed. Then assumptions were made that this surrogate protein was sufficiently similar to the protein that the plant actually makes, even though other studies have shown that such assumptions are wrong. Moreover, extra data do not appear to have been provided to increase the woefully inadequate sample sizes and the quality of the statistical reporting remains woefully inadequate. Furthermore, the full suite of biochemical tests still appear not to have been done. These other biochemical tests are important to determine the safety of the GM brinjal. Why were they not done, or if they were done, why were they not provided?

As a result, the points in IHER's original submission have not been addressed and IHER's concerns remain.

Animal feeding studies

IHER's original submission

Several animal feeding studies are presented in an effort to show that Bt brinjal is safe to eat. They include studies on fish, chickens, goats, rabbits, cows and rats. Most of these species are most unusual to use for human health studies, and many of the measurements taken on these animals are also unusual measures of human health. For example, chickens and fish are not even mammals. Chickens fly, lay eggs and do not suckle their offspring, swallow stones and grit to help grind their food, do not have human-like lungs or digestive systems and have kidneys that do not even produce urine. As chickens are clearly very different from humans, they therefore cannot be used as a model for human health. Using fish is worse. Besides the obvious differences in physiology involving things such as scales, lungs (humans cannot breathe underwater), and kidneys (fish kidneys do not produce urine), they are not even warm-blooded animals. Many of these studies use death as an end-point. Death is not a measure of health. Most people know people who are alive but not healthy because they have serious illnesses such as cancer, diabetes, heart disease, liver disease or infectious diseases. Realistically, these studies are more useful to reassure primary producers that if they feed their fish, chickens, goats, rabbits and cows the GM brinjal, their animals will grow large enough and survive for long enough for the animal to get a good price at market. Further evidence for this is given by the emphasis on measures such as death rate, weight gain, growth rates, feed conversion ratios, milk production and carcass yield in these studies.

Furthermore, there was no full description of the diets fed to the animals in any of these studies. There was no list of the macro-nutrients used such as carbohydrate, fat, protein (and the components of these, such as the nature of the amount and type of saturated and unsaturated fats and which plants or animals they came from). Nor were the micro-nutrients given, such as the levels of the various vitamins and minerals in the diet. Nor was there a full description as to the source of the components of the diet such as which grains were used and in what proportions. So there is no understanding as to the nutritional adequacy of the diets. Furthermore, there is no understanding as to whether the diets were heat-treated before they were fed and how much heat may have been used. Heat can destroy proteins and anti-nutrients which might otherwise affect health. In addition, it does not appear that the various diets were analysed for other GM ingredients. Corn and particularly soy are often ingredients in laboratory diets and soy is certainly present in the fish and cow diets used by Mahyco. Much of the soy produced in the world comes from the US and South America and much of this is GM. The presence of GM products such as GM soy is therefore a confounder in these studies and needs to be measured. It is possible that any effects due to eating GM brinjal could be swamped by the effects of animals eating GM soy.

The number of animals used in each of these experiments is also too small to be able to find statistical significance for anything but overwhelming clinical findings. Often there are only five or six animals per group. To use a simple example of how inadequate this is, if the death rate is compared between two groups and six animals are used in each of those groups, two thirds (67%) of animals have to die in one group and nil in the other before a statistical difference can be found. If only five animals are used per group, the situation becomes even worse. Now 80% of animals have to die in one group and nil in the other before statistical significance can be found. There is also no statement as to whether the animals used were inbred or outbred animals. The use of outbred animals generally requires more animals in each dietary group for most measures to obtain statistical significance compared to using inbred animals. It is unlikely that Mahyco could source inbred laboratory fish, chickens, goats or cows.

While Mahyco's studies often report that measurements such as clinical chemistry were taken on blood, the results are rarely given. And even when they are given, it is unlikely that statistical significance could be found, given the low number of animals in each group. Organs may be weighed and perhaps expressed as a percentage of the body weight, but a diseased organ can weigh much the same as a healthy one. Histology, where the organ is sectioned, stained and looked at under a microscope is the appropriate method of determining if an organ is healthy. Yet this seems to have been rarely done.

The only real health study that could be used by Mahyco to support its application for safety is a single rat study, which is why the company submitted the raw data associated with this study to the Indian government. In this instance, 10 rats per gender were used, the highest number of animals per group in any experiment. Again, studying this number of rats for only a few weeks is clearly woefully inadequate to determine the long-term health effects of 1.15 billion Indians eating GM brinjal for generations. An example of the inadequacy of the study's statistical power to find anything is shown by considering two matters. First, calculations indicate that if the number of female rats per group was increased to just 13, the 67% higher white blood cell count in the GM brinjal-fed group compared to a non-GM-fed group could reach statistical significance. Second, if the number of rats were increased to just 16 per group, GM brinjal could be found to cause a significant difference (increase) in AST in blood. This result supports the previous finding from the rat toxicological study where if 6 rats per group had been used, male rats could have been found to have a significantly higher level of this liver enzyme. Put together, the results of the two rat experiments indicate that if more animals had been used, male rats may have been shown to have evidence of liver damage from eating GM brinjal.

The raw data of this study indicate that the rats were highly variable at the beginning of the study. The body weights of some groups varied by as much as 31% **within** a group at the start of the study. This is an unusually high amount of within-group variability for body weight, and with a sample size of only 10 per group, could have masked any between-group effects. Essentially, statistics is about finding a signal amongst the noise. If there is too much noise, the signal cannot be found even if it is strongly present. Having this much variability within each group adds noise, making it very hard to find any signal.

The blood biochemistry and haematology data are also quite limited. For example, it is normal to take 18-20 biochemical measurement in blood to determine the health of an animal.

This study takes only seven.

Moreover, while Mahyco presented a lot of raw data for some studies, with its interpretation of that data, it left-out most of the data that would be required in a peer-reviewed scientific journal for most of its studies and when data was actually given, Mahyco often omitted a key part of the analysis, such as the actual statistical results, eg p-values. That is, Mahyco omitted much of the results of the research from the report. It is also clear that the researchers were not blinded as to which group was fed GM and which was fed non-GM diets, which could bias the results. Moreover, the environmental conditions under which the animals were kept appear to be unusually variable and the GM status of the feed was determined using an inaccurate protein method instead of a far more accurate DNA method.

It appears that none of these studies has been published in a peer-reviewed scientific journal. This may be because the studies were not of a sufficient standard to be published.

How the ECII committee has not addressed these concerns

Mahyco does not appear to have provided any new information for the committee to assess. It remains that the animal models used are inadequate to assess safety. For example, chicken and fish are physiologically seriously different from humans and simply cannot be used to assess human health. It also remains that death is not a suitable measure of health. There is still a lack of information about the diet, including the micro- and macro-nutrients, and a lack of GM DNA analysis of the GM and non-GM feed (particularly for other GM crops in the feed).

Moreover, extra data do not appear to have been provided to increase the woefully inadequate sample sizes (number of animals per group), there is unacceptable variability in starting body weights, and the quality of the statistical reporting remains woefully inadequate. Furthermore, full biochemistry, haematology and histology measurements still appear not to have been done, even though they are crucial to determine the safety of the GM brinjal. Why were they not done, or if they were done, why were they not provided?

As a result, the points in IHER's original submission have not been addressed and IHER's concerns remain.

Summary

The original IHER assessment remains. That is, while it appears the Mahyco has conducted a number of studies to show that Bt brinjal is safe to eat, in fact none of the studies are of any real use, for the following main reasons:

1. The type of studies undertaken are insufficient to be able to determine if GM brinjal is safe to eat. For example, there have been no reproductive studies and the studies that have been done often use animals and/or measurements that are inappropriate or insufficient measures of human health.
2. Of those studies undertaken, the methodology and results are often insufficiently reported to be able to determine what the studies were actually measuring or how

various variables were measured. Included in this, the statistical results have not been reported to a suitable standard. For example, means, standard deviations, and p-values, which would be required for any peer-reviewed scientific journal, are usually omitted.

3. The sample sizes are insufficient to be able to find statistical difference for many measurements even if real clinical differences are occurring between groups. Indeed, much of the research presented by Mahyco could be regarded as being burdened with Type II error. This type of statistical error occurs when sample sizes are so low that the study cannot realistically be expected to find a difference between groups of animals even if clinical differences are occurring. So, when Mahyco finds no statistical difference between the composition of GM brinjal compared to non-GM brinjal, or measurements on GM-fed animals compared to non-GM-fed animals, and touts this as showing that GM brinjal will not cause harm to those that eat it, they are likely to be wrong. The lack of statistical significance is much more likely to be simply due to testing too few samples (for composition) and too few animals (for health effects).

Consequently, the studies presented by Mahyco cannot be used to show that GM brinjal is safe to eat, particularly when population health issues are taken into account. That is, if this GM brinjal comes into the Indian food supply, then every Indian will be eating it, resulting in 1.15 billion Indians exposed to the GM brinjal. Some of those exposed will be children or the elderly. Some of those exposed will already be ill with cancer, autoimmune problems, heart disease, diabetes, or infectious diseases such as tuberculosis or HIV. In addition, Indians will have no choice in whether they eat it or not, given the lack of labelling of GM crops in India. Moreover, India appears not to have a suitable surveillance system established to determine if GM brinjal causes illness after release, and no mechanism to recall the brinjal if it does cause illness or worsens existing illnesses.

Because of the number of people exposed, if GM brinjal is later found to cause illness, it could cause significant economic and social problems for India. For example, if only 1 in 1,000 of exposed people later gets ill, or has an underlying illness made worse, then 1.15 million Indians would be ill and requiring treatment. This would result in a huge cost to the Indian government and community. It is therefore important to ensure that the safety assessment of GM brinal is sound and thoroughly covers all the major concerns of toxicology, allergy, and reproductive health. The studies presented by Mahyco are simply inadequate to determine these matters. Moreover, the assertion by the ECII committee that long-term studies are only needed if toxic effects are observed in shorter studies is not only scientifically wrong, but simply dangerous. IHER recommends long-term feeding studies by people who are independent of Mahyco and other vested interests to truly determine if GM brinjal is safe to eat.

Repeated experience with tobacco, asbestos and pharmaceutical companies has taught scientists and governments to be very wary of research results generated by companies who wish to make money from their products, and that independent research is always required to determine the truth about the safety of these products. Yet the government is unable to consider independent research because no such research has been done. IHER recommends that the Indian government should not release GM brinjal until such independent studies have been done. As one of the few bodies with the expertise and experience in the area, IHER would be happy to assist the Indian government to establish its own independent studies to settle the issue of safety.

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Fw: bt-brinjal Tuesday, 9 February, 2010 10:28 AM

From: "Jairam Ramesh" <mosef@nic.in>

To: rammoolam@yahoo.co.in

----- Original Message -----
From: Gurdev Khush
To: 'jairam ramesh'
Sent: Saturday, November 14, 2009 2:56 AM
Subject: RE: bt-brinjal

My dear Jairam Jee,

I see there is lot of controversy regarding Bt Brinjal.So naturally you have to make a decision considering all the viewpoints. I hope however, you will give more weight to the science based arguments and data rather than fear mongering polemics .There is overwhelming scientific data proving Bt protein is not toxic to human beings and other mammels.Moreover, Bt protein is denatured upon cooking. Bt corn is planted on millions of hetare every year and Bt grains are used as live stock feed and are component of at least 12 human food items. There is not a single report of adverse effects of Bt protein on human health. Since there are are no closely related wild plants or weeds with witch Bt brinjal can cross there is no problem of gene transfer. So it is environmentally benign. Actually it would contibute to environmental sustainaibility and human health through reduced use of insecticides.

I know you have lot of interest in India- China relations.I enjoyed reading your interestng book CHINDIA. So the present unfortunate border controvery must be disheartening to you. Before the border hostilities between China and India in 1961 Chinese premier Chu-in-Li made an offer that China would recognise the defacto border in eastern sector eg. Macmohan line provided India recognizes Chinse control on the western sector eg.Akai Chin. Unfortunately prevailing environt did not favor acceptance of this offer. Now Chinese have firm control of Akai Chin and are still making claims on Arunchal Pradesh. Recently I saw an huge wall map of China at Stanford University showing Arunachal as Chinese territory.Unfortunate indeed.

Warmest regards.

Gurdev

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Tel.: (530)-750-2440

-----Original Message-----
From: mosef@nic.in [mailto:mosef@nic.in]
Sent: Friday, November 06, 2009 8:29 PM
To: gurdev@khush.org
Cc: rahulbojja@gmail.com
Subject: bt-brinjal

what are your views on and advice regarding bt-brinjal, dr. khush? the expert committee report is on www.moef.gov.in

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7 December 2009

The Honorable Shri Jairam Ramesh
Minister for Environment and Forests
Paryavaran Bhavan
CGO Complex
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sent by e-mail to mosef@nic.in and jairam@vsnl.com

Sub: Approval of *Bt* brinjal for commercial cultivation in India

Dear Honorable Minister:

As an agricultural law professor who teaches, writes, and speaks about agricultural biotechnology and policy, I have followed the development and GEAC approval of *Bt* brinjal closely since the year 2000.

I support the GEAC decision and the commercial cultivation of *Bt* brinjal for several reasons:

• The GEAC has taken careful and extraordinary steps to evaluate *Bt* brinjal. GEAC has done what the law and regulations of India mandated it to do and has rendered a judgement of approval. GEAC, as an administrative agency of the State of India, deserves the support of the Government.

• Indian scientists have been heavily involved in both the development and the evaluation of *Bt* brinjal. These Indian scientists support the GEAC decision. Indian scientists have the world class ability to improve the agricultural productivity of Indian agriculture, if they see that their work to develop seeds through modern plant breeding will be validated for commercial release.

• Studies by a number of research social scientists have concluded that the positive agronomic, environmental, and economic benefits for the Indian farmers of brinjal will be very large. The poor resource farmers particularly will benefit the most. In addition. Indian consumers will benefit by having higher quality produce at a reduced cost. Consumer benefits too will be very large. Poverty at both the farm level and the consumer level will be reduced by access to high quality, lower cost products from modern plant breeding.

I support the GEAC decision for another reason. I have worked in India and I admire the dynamism and dedication of Indian scientists. By failing to approve the commercial cultivation of *Bt* brinjal, India runs the very strong risk of discouraging agricultural research and development. Moreover, a failure to approve *Bt* brinjal may also put India at a distinctly competitive disadvantage in comparison to China where Chinese authorities have recently approved transgenic low-phytase maize and transgenic rice. India needs and deserves agricultural research and development from its scientists to reduce poverty and to remain competitive. But they cannot provide that research and development if their efforts are thwarted.

Sincerely yours,

Drew L. Kershen (e-mail signature)

Drew L. Kershen
Earl Sneed Centennial Professor of Law

*Bt*Brinjal: A Scientific Evaluation

Kedar Narayan, PhD. 06-February-2010

The possibility of introducing a genetically modified (GM) variety of eggplant (brinjal) as a food crop in India has raised complex questions regarding its ecological, economic, and health impact, amongst other issues. In this brief, I detail specific scientific aspects of the *Bt*Brinjal debate; I have analysed current scientific literature in the field and I include salient points to be considered in the final analysis.

Note: The analysis presented is based on peer-reviewed efficacy or toxicology studies of similar *Bt* crops, such as cotton, corn and maize (data from *Bt*Brinjal have not been made available).

RECOMMENDATIONS: Large-scale planting of *Bt*Brinjal should NOT proceed until a tiered program is implemented which addresses the following points:

1. **Detailed laboratory tests over the life time of small mammals.**
2. **Controlled in-field studies of Horizontal Gene Transfer**
3. **Controlled in-field studies of generation of resistant mutants.**

ANALYSIS:

1a. Toxicity issues with GM food crops have been raised and studied repeatedly; the scientific consensus is that, being a naturally derived protein, the ***Bt (Bacillus thuringiensis)* toxin has less of a deleterious impact than conventional (chemical) insecticides** - however, there have been reports of exceptions[1,2]. Also, ecological imbalances on account of population control of the targeted insect by *Bt* would likely be no more than if the insect was targeted by chemical insecticides.

1b. **Toxicity studies in rodents show conflicting results;** a study of *Bt*Corn toxicity by the developer of the Bt technology suggested minimal or no impact on laboratory-raised rodents over 90 days[3]. However, this has been strenuously contested by an independent group[4], which calls into question both the design as well as the statistical evaluation of the animal experiments.

→The differences in kidney and liver physiology in treated rodents suggest possible complications with toxin storage/excretion; this should be further investigated. Additionally, 90 days is an insufficient period of time to detect sub-chronic and chronic health issues; a longer trial period (ideally, at least over the life time of the rodent) and comprehensive physiological measurements are warranted.

2a. **Horizontal Gene Transfer (HGT) is a naturally occurring biological phenomenon** reported across a large variety of species[5], and by itself, is not a concern; in fact, this form of gene flow is often central to the evolution of many ecosystems.

2b. **The presence of GM genes does not increase the rates of HGT**[6]. However, a small increase in hygromycin resistant bacteria has been reported recently in laboratory infected plants[7]; therefore, an in-field study, where such co-infections are possible, must be conducted.

→ HGT to higher organisms is extremely limited; however, gene transfer to viruses may occur. While the possibility of co-infections and transfer is low, a long-term in-field study may be conducted to rule out "rogue" HGTs for this specific combination of *Bt* and host (brinjal)

3a. **The generation of mutant insect strains that are resistant to *Bt* toxin is highly likely.** The lethality of the *Bt* toxin is a strong selective pressure, i.e. an insect with a random occurrence of a resistance gene to the *Bt* toxin will survive and breed, eventually generating a toxin-resistant population. **Mutant insects that have gained the ability to resist the toxic effects of *Bt* have already been reported in other GM crop fields.** The first report of resistance to the *Bt* toxin Cry1Ac in the cotton pest Heliothis virescens was made 4 years after the introduction of the GM crop[8].

→ It is likely that Bt resistant strains will develop in the case of Bt-brinjal in the near future, necessitating further genetic interventions and/or at least a partial reversion to a chemical based pest-control paradigm.

CONCLUSIONS: From a scientific standpoint, based on publicly accessible evidence, it is my opinion that Bt-brinjal cannot be introduced safely without further laboratory, glasshouse, and in-field testing. From a social and economic perspective, the impact of GM crops is far-reaching, and beyond the scope of this brief.

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2. Zangerl AR et al, proc Acad Natl Sci (2001)
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4. De Vendemois JS et al, Int J Biol Sci (2009)
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6. Keese P, Environ Biosafety Res (2008)
7. Kim YT et al, J Microbiol (2009)
8. Gahan LJ et al, Science (2001)

Kedar Narayan, Ph. D.

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Currently, Research Fellow, National Institute of Health, working on HIV/AIDS

ANNEXURE IV

Submissions by civil society groups/research institutes and concerned individuals

Response to EC –II

Response to the Honorable Minister's call seeking public response to EC II of the GEAC with regard to the decision on Bt brinjal, from Sreedevi Lakshmikutty, 2103 Phoenix Towers, Lower Parel , Mumbai .

I have lived and studied in the United States and had the privilege of working with small farmers and local food issues in the US state of Kentucky, one of the farming states, and experienced the sorrow of watching the demise of small farming due to noxious and strangulating corporate control. My experiences in the US with regard to GM food, the corporate control over agriculture, and corporate hegemony in food retailing was a scary experience. The absolute helplessness that we felt as consumers and the fear among small farmers and the inability and fear to speak up against food issues due to their food libel laws[1] was truly something I do not want to see in our country. That is one of the primary reasons that I am following the Bt brinjal issue seriously since I returned two years back

The Bt cotton decision in India and the imminent Bt brinjal decision will only succeed in taking us closer to that devastating reality of US small farmers and their population, who are facing increasing hunger on one hand and an unprecedented obesity epidemic on the other! A good beginning to address the issue would be to do an **independent** review about the Bt cotton situation, now, six years after its approval and analyze that before taking any decision on Bt brinjal.

My response is categorized into three sections

1. General objections to the reductionist and one-dimensional approach in accepting GMOs without taking into account social, economic, ecological and cultural aspects and ignoring the experiences of countries like the US and Argentina with regard to widespread use of GMO crops.
2. Issues with GEAC decision-making and conflict of interest, lack of transparency and disregard for independent opinion and total disregard for the voice of the Supreme Court appointee.
3. Specific objections to some areas of EC-II, I am a social scientist and a reasonably aware consumer, therefore my analysis focuses on the glaring omissions and the socio-economic aspects, however that does not mean that there are no concerns regarding the scientific part of the report.

General and fundamental objections to the way GMOs are being introduced and the faulty premises based on which the decision is being forced on us.

1. The whole decision regarding GM crops and Bt brinjal was and is based on a reductionist view of science being the solution to higher productivity disregarding the bad experience with pesticides. The fundamental questions of who decides on this solution, how was it arrived at? Who does it benefit? These and many other such questions have not been examined at all. The decision on whether we need

[1] http://en.wikipedia.org/wiki/Food_libel_laws

GM crops at all should have been debated at a much broader and wider level rather than have a few multinational companies arrive in India with their technology, buy stakes in Indian companies and then sell it to our decision-makers, this is not the way a democracy should function.

2. Middendorf and others have elucidated this in their article titled "New agricultural biotechnologies: the struggle for choice"[2] . The article talks about this conundrum and also details about how the Scandinavian countries engage in public debate before any major policy decisions like these are taken. I quote, "***A key principle of these efforts is that society must democratically define its priorities; only then should it ask how technologies might help to achieve those goals. This challenges the common assumption in science policy of a positive, linear relationship between scientific advance and social progress. Another guiding principle is that since all citizens experience the effects of science and technology, and since citizens ordinarily expect to have a voice in decisions that will affect the way they live their daily lives, they should be involved in deciding the direction of science and technology policy.***"

3. If GM seeds are so beneficial a technology why is that it has not been publicly debated, why have farmers not been part of the whole decision making process, where are the consumers and citizens in this process? Why is it all behind closed doors and all about trade secrets of companies[3] rather than about public concerns, farmer issues, health issues and ecological and other impacts?

4. United States , the model we seem to be emulating, has a situation of unseemly corporate control over the all branches of agriculture related business with less than 10 companies controlling more than 50% of market share for pesticides, seeds, grains, meat, poultry and of course a single company Monsanto controlling a shocking 90% of all genetically modified traits[4]. Let us not forget that Bt brinjal is Monsanto technology and the technology fees on the sale of every packet of Bt brinjal seeds will add to its bottom line. Adopting this mode of agriculture will leave us a legacy very similar to that of the US (with disastrous results); small farming in the US is almost decimated. We are already seeing this control in Bt cotton in India.

5. GM technology is being sold and pushed as a panacea against hunger and to increase productivity, then why is that the United States, Argentina –the biggest adopters of GM crops- experiencing unprecedented hunger? At the last count 49 million Americans are hungry, almost 14.6% of the population[5].

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[2] http://findarticles.com/p/articles/mi_m1132/is_n3_v50/ai_21031835/

[3] GEAC response to the RTI commissioner when test data of Bt brinjal sought through RTI- http://www.financialexpress.com/news/make-bt-brinjal-data-public-cic/242771/

[4] http://www.desmoinesregister.com/article/20091214/BUSINESS01/912140321/1001/NEWS/Seed-deals-show-clout-Monsanto-wields-over-U.S.-supply

[5] http://obamafoodorama.blogspot.com/2009/11/unsettling-wake-up-call-for-america.html

6. Why trust Monsanto[6] – the most dreaded, feared and distrusted agri-business corporation- with our food and seed security? It is almost single handedly responsible for the soybean devastation of Argentina and the US small farmer crisis. This company produces more PCBs, defoliants, herbicides, dangerous chemicals, and drugs than any other company and has a track record of not paying damages for the harm caused and has enormous lobbying power with the US government. Are we so desperate or so naïve to believe them or are our farmers so dispensable?

7. Today due to recession, food scares and food contamination incidents homestead gardening in the US is seeing resurgence and along with it awareness about the stranglehold of Monsanto over vegetable seeds, they own the largest vegetable seller in the US –Seminis. People are realizing that due to monopoly control the number of varieties of seeds in the market is steadily being reduced by the company (as part of business decision) –biodiversity falling prey to business greed! Slowly this is dawning on the Americans after a decade and slow grassroots movement is growing to boycott Monsanto seeds by homestead gardeners. All the more reason for Monsanto to enter Indian vegetable seed market!

8. Today we are being sold Bt technology in the name of reducing pesticide use, with the companies sounding very holy about making food less poisonous, if so why are these same seed companies selling us so many toxic pesticides? It is a fact that in the **top ten** agrochemical and seed companies, **four companies (Monsanto, DuPont, Syngenta & Bayer)** are in both lists[7]; this shows the level of nexus between the two industries.

9. How is it that we can accept GMO technology (unpredictable, irreversible) without independent testing and market it without labeling in the name of "substantial equivalence" while the company selling it earns thousands of crores a year in technology fees by patenting the GMO to be a " substantial transformation" ?

10. Seed sovereignty of the farmers, how is it that by inserting an alien gene into a plant it becomes the sole property of the company which pays for it and the farmer rights and natural evolution which has contributed in the last 10,000 years become alienated? If we are all about property rights and patents, isn't the fundamental right over a food crop that of the traditional farmer, who has nurtured it and brought it to the current stage over 1000s of years?

11. A technology cannot and should not stand on its own; it should be juxtaposed within the social, ethical, moral and economic stand points of the society it is introduced into, which is something that has clearly not happened in the case of the introduction of GMOs into India!

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[6] http://topdocumentaryfilms.com/the-world-according-to-monsanto/
[7] http://www.etcgroup.org/upload/publication/707/01/etc_won_report_final_color.pdf

Issues with GEAC decision-making and conflict of interest, lack of transparency and disregard for independent opinion and total disregard for the voice of the Supreme Court appointee

1. There has been no independent testing of Bt brinjal and all testing has been commissioned and all data has been from the promoter company, which in itself makes the whole decision suspect for me as a consumer. Time and again we have had corporates claim that something is safe (pesticides, trans-fats, DDT, high fructose corn syrup, various prescription drugs in the market and so on) and then years later go back on it with impunity without paying damages for the harm caused in the interim. There is nothing in the approval process of Bt brinjal which provides me confidence to believe that this will not happen!

2. The unseemly conflict of interest within the GEAC is galling and unacceptable and all the more unpalatable is the fact that the government sees nothing wrong in crop developers sitting in GEAC and reviewing their own work. This conflict of interest has been detailed in the CNN-IBN report[8] and report from Down to Earth [9] magazine. Conflict of interest in the GEAC has been a recurring affair with CD Mayee[10] the previous chair and many members also being members of industry sponsored bodies while functioning as regulators. In addition the head of the EC-II has said that he was under tremendous pressure to approve Bt brinjal. All this makes the decision invalid.An independent regulator has to be INDEPENDENT; otherwise we as the public can't accept their decisions in full faith. For this alone in principle I oppose this EC-II report!

3. The constitution of GEAC is very lopsided with the heavy presence of bio-technologists (to review the technology they themselves work on) with hardly any farmers, consumers, social scientists, ecologists being part of the decision making. GMOs are not merely about inserting a gene into a plant it is much more fundamental decision about changing our.way of faming and eating with far reaching impact. It is a decision which affects every member of the public, as we all eat, and thereby the need for as broad based a decision making body as possible.

4. The Supreme Court has nominated Dr.Pushpa Bhargava to the GEAC to be our representative, his scientific and academic credentials places him amongst the best of the best in the world. However we find that his opinions, suggestions and questions have been blithely ignored by GEAC. This is not an acceptable situation, where the respected scientist who represents us and takes up concerns in public interest is not listened to. Dr.Bhargava's interviews and articles in the media post the approval of Bt brinjal by GEAC clearly states that he was not

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[8] http://ibnlive.in.com/news/controversy-continues-over-bt-brinjal-approval/106190-3.html & http://ibnlive.in.com/news/bt-brinjal-tests-inadequate-how-safe-is-it/106477-3.html
[9] http://www.downtoearth.org.in/full6.asp?foldername=20091231&filename=news&sec_id=4&sid=3
[10] http://www.tehelka.com/story_main37.asp?filename=Ne160208uneven.asp

happy with the process, he is dissatisfied with the amount of due diligence done and he believes that the decision was pre-mediated and not impartial.

5. It is deeply distressing and suspicious that the report when analyzing the conclusions of independent scientists seems to be brushing off every concern raised by them with a trivial " not applicable" , "not relevant " kind of replies and at places is even disrespectful of these scientists and tries to discredit them. This only diminishes the value of the EC-II report and questions its credibility and impartiality rather than of the scientist!

6. .From beginning to end the process looks like the GEAC wants to approve this product and it is only RTI queries or civil society outcry which compelled them to do some due diligence –totally contrary to what is expected of an "independent regulatory body". As the name suggests GEAC seems to be put together only to approve GMOs after some cursory discussions rather than regulating GMOs. One of its major failings is to treat GMOs merely as a technology rather than a fundamental issue! ECII report is a prime example for this reductionist approach.

7. The EC-II seems to have met just twice in the 10 month period to supposedly review, evaluate and discuss voluminous findings and prepares a 105 page report on their comments and to approve Bt brinjal based on all this, this seems too short a timeframe to have done a thorough job!

8. It would be pertinent to know where the EC-II document (a 105 page power point presentation) was prepared. Is it by the EC-II members? Or with external help? As per the document the author of that ppt or the name of the user of the computer is "Vibha", clearly not the name of an EC-II member (hopefully an office staff?). In the interest of transparency it would be relevant to know who prepared the report.

Specific objections to some areas of ECII

1. My objections to EC II begin with basic premise, what was decided as the terms of reference for the expert committee were blatantly changed as is evident from the two texts below. This prima facie makes the EC-II invalid as the terms have been narrowed and reduced to merely reviewing rather than evaluating for adequacy of bio safety and toxicity!

   Below is the text from GEAC meeting minutes of January 14th [11]

   After detailed deliberations, the Committee decided to set up a Sub-committee comprising of representatives from the Ministry of Health and Family Welfare, NIN, ICMR, CFTRI, CCMB, IIVR, NDRI,
   CFIE, MoEF DBT, TNAU and UAS Dharwad with the following terms of reference:
   - to review the adequacy of the biosafety data on Bt brinjal
   - to review the adequacy of the toxicity and allergenicity protocols

[11] http://www.envfor.nic.in/divisions/csurv/geac/decision-jan-91.pdf

- to suggest further studies, if any, based on the review of the international practices in biosafety assessment and representations received by the GEAC.
- based on such reviews make suitable recommendations for consideration of the GEAC.

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Below is the text from EC –II report

The terms of reference of the EC-II are:

- *to review the findings of the data generated during the large scale trials;*
- *to review the bio safety data of Bt brinjal in light of the available scientific evidence, reports from international/national experts and representations from NGOs and other stakeholders;*
- *to make appropriate recommendations for consideration of the GEAC based on the above review.*

2. *As Bt brinjal plants have an inbuilt mechanism of protection against targeted pests, the protein produced by the plants does not get washed away nor is destroyed by sunlight unlike externally applied pesticides.(page 11 of EC-II)*

This is a significant problem as Bt toxin is a known allergen and there have been cases of people exposed to even the Bt sprays being affected, and people carry Bt in their tissues,. In addition the "Journal of Pesticide reform" fact sheet states that, "researchers know so little about the ecology and genetic stability of Bt that the potential ecological effects of these transgenic organisms are impossible to predict with certainty"[12]. In this context the above statement in the EC-II is abundant cause for worry.

3. As per point (i) in table 2.2 in page 23 of the report regarding the *"Status of Compliance to the conditions in the permit letter issued by GEAC"* there was a stipulation that "food/*feed safety assessment should include any possible foliage/shoot toxicity study in goats. This condition was stipulated in view of the apprehensions that there were sheep deaths in Andhra Pradesh due to grazing on Bt cotton fields."*

GEAC decided to dispense with it based on (RCGM recommendation) for trivial reasons including that sheep deaths were unsubstantiated, and that goat feeding studies are not part of the protocol. As far as I understand the EC-II **was constituted to address these and many other concerns raised by people** and scientists from different parts of the world and if these concerns are brushed aside blithely, then the EC-II has not done its job and has only tried to put together a document to lead up to their already pre-decided conclusions. The sheep deaths are not unsubstantiated, they were confirmed by the AP government (which had even put up cautionary notices to farmers)and the GEAC can't ignore what a state government has publicly acknowledged and declared and refuse to do further assessments. This is a recurring pattern seen in the report -to discount anything that doesn't suit the authors of the report!

[12] Journal of pesticide reform/fall 1994 vol 14, No 3

4. As per point (j) of table 2.2 in page 23 of the report regarding the *"Status of Compliance to the conditions in the permit letter issued by GEAC"* there was a requirement for skin sensitization test.

Here again based on RCGM recommendations this has been waived stating it ahs no relevance as "bt toxin has been found to be safe in feeding studies". This is a genuine concern as Bt allergy has been reported in the bt cotton areas among the cotton farmer and cotton picking workers. Bt allergies have been reported from different parts of the world and cases are well documented. When that is the situation to ignore this in the case of Bt brinjal is irresponsible and unacceptable.

5. As per point (l) page 24 in table 2.2 it has been mentioned that socio-economic assessment of bt brinjal ***has been initiated.***, clearly it is no where near completion.

It belies logic how a technology which is unpredictable and irreversible can be unleashed on people without doing the basic due diligence regarding its socio-economic benefits. Also let us not assume and start with a bias, the study should be about the "socio-economic impacts". It is a known fact that the sub-committee constituted in the first instance (to do socio-economic evaluation) had raised serious concerns, to which GEAC had made no response. After that a unilateral decision seems to have been taken to re-assign the study to NCAP. In this context it is required in the interests of transparency to inform us what the concerns raised by the first committee were, and why a different committee was chosen. In addition a full socio-economic impact report should be obtained and analyzed before any decision is taken regarding commercial cultivation of Bt brinjal

6. The EC-II mentions in page 28 that "*the Bt protein is neither known to be allergenic nor has sequence homology with any known allergen*"

The same as in response to point (2) Bt toxin is a known allergen and there have been cases of people exposed to even the Bt sprays being affected, and people carry Bt in their tissues,. In addition the "Journal of Pesticide reform" fact sheet states that, "researchers know so little about the ecology and genetic stability of Bt that the potential ecological effects of these transgenic organisms are impossible to predict with certainty"[13]. In this context the above unsubstantiated statement in the EC-II is not acceptable.

7. As per point 3.2.1 in page 36 EC-II has discussed the implication of pollen flow/out crossing to neighbouring non Bt brinjal fields and states that, " *the members opined that in view of the relatively short distance that the pollen could travel, it is evident that the isolation distance or differences in planting time can help in minimizing the potential for any unwanted out crossing of transgenic brinjal to the conventional brinjal varieties, as may be required in cases of seed production (breeders, foundation or certified seeds), organic farming etc. Further, the EC-II opined that*

[13] Journal of pesticide reform/fall 1994 ol 14, No 3

even if there is a very small influx of pollen originating from Bt brinjal varieties, it is not of any consequence, as the Bt protein has been extensively tested for its safety to the environment and food/feed and thus pollen transfer to other cultivated brinjal would not pose any safety risk."

There are many issues with this conclusion of the EC-II, they suggest difference in planting time to "minimize out crossing" which means (1) they cant be sure that there will not be out-crossing (2) in another response they say that the non-Bt farmer has to maintain the isolation distance and (3) there is no onus on the GM crop grower to do it as per GEAC (4) if there is contamination who is liable? Will the farmer whose fields are contaminated be compensated? (5) How will a non-Bt or organic brinjal farmer know if any of his neighbours are cultivating Bt brinjal? (6) whether bt is safe or not the organic farmer will lose his certification if his fields are contaminated, what is the remedy for that? And (7) and why should non-Bt farmers have to take additional responsibility for all these risks?
This goes against the farmers fundamental right to have his crops uncontaminated and to be able to grow food safely and in makes it more expensive and maybe unviable for organic farmers to continue their farming activity.

8. As per sub section v in section 3.3.3 in page 49 it says that all analysis has been done in cooked brinjals.

This is not acceptable as a consumer to me as I would be constantly worried if I have cooked it enough and **would not consume a vegetable** which has a toxin within and has been tested only in the cooked form. The toxicity and other tests for Bt brinjal should be conducted on raw brinjals as well to ensure what the impact of it is on human health. In the current situation if my child bites into a Bt brinjal I might want to rush to a doctor!

9. Section 5.4 issue 10 in page 60 of the report is very dismissive of organic farming and its proponents and its ability to grow brinjal and the EC-II suggests that, "*the section of farmers who have a preference for organic farming can do so by following established agronomic practices such as maintaining isolation distance, differences in flowering time etc. for preventing cross contamination and ensuring identity preservation for organic produce. As described earlier, the rate of cross pollination from one field to other is quite low, and the frequency of such occurrence decreases with increasing distance from pollen source."*

It is preposterous that the EC-II imposes the burden of isolation distance, different planting time etc on organic farmers, whereas it is the Bt farmers "who are supposedly going to have economic benefits" out of this crop and clearly they are the ones who are using a genetically modified variety. (1) How is this acceptable in terms of equity? (2) It violates the rights of organic farmers (3) The EC-II is going beyond its mandate by instructing what organic farmers should do to avoid contamination while the onus should be clearly on the Bt farmers on the well established " polluter pays" principle. (4) this is also an indicator of the pro-Bt leanings of the EC-II (5) and preserving bio-diversity, maintaining identity preservation should not the unpaid job of the organic farmer, it is a national responsibility and the EC-II should take that into account while they approve

GM crops (6) here clearly the responsibility to maintain distance, different planting time and avoiding contamination SHOULD in all fairness be the responsibility of the BT farmer.

10. In section 5.4 issue 15 (a) and (d) on page 80/82 the EC –II states in response to the concern raised regarding contamination through cross-pollination and other physical means of contaminations during physical transfer, transportation, due to sharing of workers and tools between Bt and non-Bt farms, during storage etc. The EC-II has responded thus to this concern, "*Pollen flow is a natural phenomenon in plants, which cannot be controlled and thus its impact needs to be evaluated. Issues related to dissemination mentioned by the reviewer are external factors, several of which can be controlled and the extent to which this aspect needs to be monitored is a trade related issue and not a part of environmental risk assessment. The EC–II concluded that the pollen flow studies for four years as well as other environmental safety studies provide enough evidence of the safety of Bt brinjal to the environment. Other issues raised by the reviewer are hypothetical and out of the scope of the environmental risk assessment*"

This response raises many issues (1) the decision on Bt brinjal is not a scientific silo where a few scientists sit together and decide on what is good for the whole nation, it has to be a holistic approach (that's why we need people from all segments in GEAC) and has to take into account all aspects before final go ahead is given and (2) considering the response of EC-II , this reason alone is sufficient to hold the decision pending while as aspects of the approval are analyzed. (3) Here again the EC-II is silent on whose responsibility is it to monitor and control these factors, and considering that Indian agriculture is small holder based and considerable sharing happens at all levels how are these risks going to be mitigated? Obviously we all agree that we can't afford to discover these problems after Bt brinjal has been released into the environment. The other methods of contamination are not "hypothetical" as disingenuously stated by EC- II, because the world over there has numerous cases of contamination (some of them infamous like the Starlink corn, the Bayer rice case etc) and the source and method of contamination is debatable!

Conclusion:

I have taken this effort to go through the report and express my views in the hope that comments from the public will be read, evaluated and taken seriously in this decision making process.

Please acknowledge receipt

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1st February 2010

The Hon'ble Jairam Ramesh,
Minister of State (Independent Charge)
Ministry of Environment & Forests
Government of India
Paryavaran Bhavan, CGO Complex
Lodhi Road
New Delhi 110 003

Dear Shri Jairam Ramesh

OVERVIEW

This submission is a response to your invitation to submit a document on safety testing of GM crops in India, and Bt brinjal in particular. It is based on the record of the scientific evidence submitted to the Supreme Court (SC) of India as well as appropriate documents submitted to you in the Bt brinjal review process. The evidence includes statements from independent, world renowned scientists who are neither pro nor anti- GM. They state what they find, independent of links to GM pressure groups on either side. The extensive network of funding research for the purposes of advancing commercial agendas of the agbiotech Industry includes many in academia, so it is no longer valid to simply choose researchers from universities and call them independent. We therefore, need to sift carefully. The FBAE (Foundation for Biotechnology Awareness and Education) is a case in point, which has sent a 21 point submission to the Ministry, strongly backing the decision of the Regulator on Bt brinjal. The report is not available on the Ministry website. A distinctly industry-linked foundation, the GEAC has relied in the past on CK Rao its Founder, to support their scientifically inaccurate claims regarding Bt brinjal with regard to gene flow, contamination and India's importance as a centre of origin and immense diversity of brinjal (SC January 2007). Its excerpt dated 30th January 2010 is similarly inaccurate. (1)

The regulation and risk assessment of GM crops must address two questions: First, what is the degree of enforcement and commitment to keeping India safe; and second, what is required to regulate this hazardous technology before the environmental release of any GMO. The record shows that our regulatory process is a sham, geared to the approval and promotion of GM crops in agriculture and mired in a deep conflict of interest at every stage of regulation. The statements of Sharad Pawar (Minister, Agriculture) & Prithviraj Chauhan, (Minister, Science & Technology), supporting the GEAC approval of Bt brinjal for commercial planting and GM crops as a policy objective, demonstrate unambiguously, the serious disinformation that has beset our leaders in Government.[1] The arguments they rely on have no scientific basis and are factually

[1] Prithviraj Chauhan letter from the PMO to A Ramadoss in July 2009

incorrect. Unless rectified, the harm to India will be irreversible and irreparable and of many orders of magnitude on multiple dimensions. Therefore, the precautionary principle must be urgently applied and a moratorium announced.

The evidence on these matters is irrefutable and extensive, recorded in approximately 45 volumes of submissions over 5 years since the PIL was filed. While every regulatory lapse in the case of GM crops is serious, because of the risk of contamination, perhaps the most serious of lapses *known* to us is the illegal and rampant farming of HT (herbicide tolerant) cotton in Gujarat for four successive seasons (2). The only reaction thus far has been an "anguish" expressed. We petition the establishment of independent, transparent, stringent and scientifically rigorous bio-safety protocols working with civil society and until then a moratorium. India must aim for truly exemplary safety-testing protocols for GMOs that will inspire confidence in her citizens, not derision and distrust as at present, following the Bt brinjal approval by the Regulator. That process should have required a thorough and transparent review of the experience of 6 years of Bt cotton working in conjunction with civil society and farming groups. Thereafter, regulation must be grounded in three pre-requisites which are absent and have not been applied to Bt brinjal: (a) As a starting point, the question that needs to be asked is whether we need a particular GM crop. For this, the correct comparisons with alternative agriculture practices need to be made and evaluated against the particular GM crop for a legitimate comparison. These are modern organic systems and low external input methods. They may not be mono-crop cultures using external inputs of chemical fertilizers and insecticidal sprays. Yet, this is the false approach to a proper comparative model adopted by our Regulators and now to justify the approval of Bt brinjal, claiming heavy pest damage by the fruit and shoot borer of up to 60%. Have they forgotten that IPM is a part of the country's stated national agriculture policy? The evidence is that it is effective; (b) sceptical approach to GMOs recognising them to be intrinsically hazardous and requiring a process of hazard identification, as opposed to a prior stance that GMOs are safe. This is the case at present, justified by the scientifically discredited theory of SE (substantial equivalence); and (c) The central tenet of requiring a distance between the Regulator that has the mandate for approvals of GM crops on the one hand, and the risk assessment protocols along with their processes, procedures, independent test labs. and independent analyses. It is quite simply not valid to approve any GM crop for field testing leave alone commercialisation, without these three pre-requisites in place. They are not in place.

We have the Regulators' astonishing raison detre for the commercialisation of Bt brinjal: it is based on the (a) proven safety of the Bt gene; (b) higher intrinsic yields and also performance yields because of its efficacy against the bollworm pest and no resistance developing. These are claims that do not stand the scrutiny of science or the experience on the ground by our farmers. India is unlikely to buck the trend in other countries simply because the Regulators and Monsanto demand it! At best in India, current performance yields show mixed results (3). We have reports of declining yields because of insect resistance to the Bt toxin and insect shifts (examples, Gujarat, Punjab in 2007). The introduction of Bollgard II, a stacked gene bears mute testimony to this fact of resistance, mute because Monsanto and the GEAC, RCGM specifically deny resistance. It is a teasing observation that according to figures of the Cotton Corporation of India, Madhya Pradesh (MP) shows that *pre Bt cotton*, yield in MP of Non GM cotton was higher than after the introduction of Bt cotton; in fact MP's non-GM cotton yield (pre-introduction of Bt cotton) compares well to Bt cotton yields of most other States including Gujarat and in some years were higher. It would be a wise decision of the government to undertake rigorous analyses State by State, of agronomic and economic gains/losses in an independent and transparent process of enquiry as outlined above. The Iowa study confirmed that over half of farmers planting herbicide-tolerant GM soya did so because they believed that it gave them higher yields compared to conventional varieties. However, when the university analysed the harvest results of the farms concerned they found the opposite was true despite the belief of the farmers to the contrary (it is in fact now recognised that genetic modification has actually reduced the yield potential of GM soya by inadvertently disturbing other aspects of the plant's functioning). *It may be noted that there is no intrinsic yield gain with any GM crop.* In its 2002 report, the pro-GM USDA ((United States Department for Agriculture) says:

"currently available GM crops do not increase the yield potential... In fact, yield may even decrease if the varieties used to carry the herbicide tolerant or insect-resistant genes are not the highest yielding cultivars" ---" *Perhaps the biggest issue raised by these results is how to explain the rapid adoption of GE crops when farm financial impacts appear to be mixed or even negative."* USDA

As for the presumed safety of the Bt gene, it has to be said that our Regulators have gone out on a limb to support the agbiotech Industry, principally Monsanto. No Bt crop till date has been approved safe for human consumption by the US FDA. On the other hand, a search of the scientific literature on the Bt gene shows plenty of evidence of harm (Pusztai 4). It is important to note that Bt cotton in any case is *primarily* an animal feed, and for this reason as well, has not undergone adequate safety testing anywhere. (Bt cottonseed oil is a food item).

My submission follows as a formatted Word file attachment. You will also be sent a copy of the Written Submission to the SC of April 2009. This is essentially a compilation of numerous submissions.

Aruna Rodrigues
Sunray Harvesters

THE EC II REPORT & THE TEST CASE OF Bt BRINJAL
REGULATION, RISK ASSESSMENT AND HAZARD IDENTIFICATION OF GM CROPS IN INDIA

(Based on scientific evidence submitted to the Supreme Court of India)

1. Background to the process that led to the approval of Bt brinjal

In August 2008, following a protracted 18 month process under a PIL in the SC in the matter of GM crops, including 'Notice' of Contempt of Court, the apex Regulator, the GEAC put Monsanto's Biosafety Dossier on the Ministry's website in August 2008. Four scientists, internationally recognised for their expertise in their respective disciplines, responded to a request by lead petitioner Aruna Rodrigues, and critiqued the data. These were:

- Seralini and Carman: Analyses of Animal Feeding Studies
- Doug Gurian-Sherman: Gene Flow analyses
- Jack Heinemann Molecular Characterisation of the inserted gene and Cry1Ac toxin mode of action and non-target effects.

In January 2009, the GEAC appointed the Bt brinjal Expert Committee II (EC II) to assess these 4 reports (ref. 91st Meeting of the GEAC, 14th January 2009), as well as numerous responses from Indian scientists, farmers and civil society members, objecting to the findings in the dossier and the haste with which the EC II had arrived at its recommendation to commercialise Bt brinjal.
On 8th October 2009, the EC II submitted its findings to the GEAC overriding every objection without exception, and recommended the commercial release of Bt brinjal.
On the 14th October, a bare 5 days later and in a process recorded as hasty, the GEAC formally accepted the EC II recommendations.
On the 15th October, Shri Jairam Ramesh, the Minister, Environment & Forests intervened to stop the commercial release of Bt brinjal and instituted the present process of review[1] under which scientists and the public were encouraged to respond to the EC II report in writing and in a series of public consultations nationwide.

2. The EC II Report: It claims the proven safety of the Bt gene & of following comprehensive bio-safety guidelines for the safety assessment of Bt brinjal

The EC II claims and the Regulator concurs, that Bt Cotton is a conspicuous success, having given India very significant yield increases in cotton in the six years of its commercialisation; that farmers are not stupid or they would not grow Bt cotton. <u>They claim the proven safety of the Bt gene.</u> This claim is based on regulatory assessment of its safety in the US and Europe and also, empirical evidence from the commercial cultivation of Bt food crops, corn, soy and cotton for more than a decade, without hazardous health or environmental impacts. In India, it has also

[1] Jairam Ramesh Press release dated 15th October '09

proven safe since no adverse effects have been reported. The reported incidences of animal deaths due to toxic reactions from grazing in Bt cotton fields having been investigated thoroughly, are unfounded. Bt cotton therefore, is a suitable template for the commercial introduction of Bt brinjal as the first GM vegetable worldwide and in India. The EC II Report further claims repeatedly, and in Section VI in its Conclusions and Recommendations, that the protocols followed for the safety assessment of Bt brinjal are based on the 'ICMR Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2008'. It also claims that its protocols are in line with Codex and 'international guidelines'. It states that its approval is based on Monsanto having satisfied these collective guidelines comprehensively and especially the ICMR guidelines. Bt brinjal is therefore, declared safe for ingestion and does not pose a threat for human and animal health. It is also safe for environmental release. It is worth noting that every criticism against Monsanto's Dossier was rejected on the basis that the ICMR guidelines were been adhered to and are adequate. Scientists, including agricultural scientists, civil society and farmers have made their own replies to the EC II Report, directly to the Minister. These include Seralini, Heinemann and Gurian-Sherman, who first responded to Monsanto's safety dossier.

3. Regulatory guidelines and gaps in risk assessment protocols of Bt brinjal

I wish to highlight the major gaps in the protocols for risk assessment and hazard identification of Bt brinjal, false claims and faulty procedures that were allowed without hindrance. These have also been a major theme of the Supreme Court (SC) submissions in August through to October 2008, (5) after the Dossier was published and therefore, are not new. The suggested risk assessment protocols for GM crops are based on extensive evidence to the SC by many scientists, principal among them being, Dave Schubert, Pusztai, Heinemann, Gurian-Sherman, Cummins, Seralini, R Mann, Freeze. The evidence also references the US NAS (National Academy of Science), Codex (FAO-WHO) and the Cartagena Biodiversity Protocol (CBD). Additionally, Dr Pushpa Bhargava who was appointed as an 'invitee' to the GEAC meetings on the Order of the SC to observe their decision-making process, has provided a critical evaluation of what is required before a GMO can be given environmental clearance. His comprehensive listing of around 29 criteria and tests has the support of 20 independent academic scientists and that support is on record. None of this has had any impact on the Regulators or the subsequent committee that was formed, the Bt brinjal EC II. The Bt brinjal safety dossier is woefully deficient in procedure and scientific rigour. It's acceptance by the Regulators is unsurprising, as it is the culmination of a long list of serious irregularities in safety measures during thousands of field trials over the last several years of virtually, India's entire range of vegetables, oilseeds and grains. It is also the culmination of the rejection of any and every problem brought to the notice of the Regulator: animal mortality following toxic effects from grazing in harvested Bt cotton fields, allergies, human and animal and finally, the rejection of all peer reviewed studies by independent scientists that demonstrate that the Bt gene shows direct toxic effects on rats fed a diet of Bt corn or GM soy. All this collectively points to a comprehensive lack of intent to regulate under a mandate of bio-safety first and the EPA (Environment Protection Act). Thus, if the ICMR guidelines did not require some protocol or test, that was considered sufficient reason not to do it. The ICMR guidelines don't require a great deal in the matter of risk assessment. They are scandalously minimal guidelines which fail India abysmally. It has suited the

Regulators to have Monsanto adhere to these minimal standards. The whole sorry cover-up is documented in a letter to the Director General (DG) ICMR (6).
The main points are:

i. **The need for a comprehensive review of Bt cotton and Post-market monitoring:** Given that Bt cotton is being claimed as a legitimate template for the introduction of Bt brinjal as the first in line of many Bt food crops, the long-standing demand by farmers and civil society groups of the government, for a comprehensive review of Bt cotton assumes great importance. The Regulators' claims of safety, yield increase, no pest resistance to the Bt toxin, harvest successes, reduced insecticide use; no detrimental environmental impacts including on soil, economic benefits to the farmer, are strongly contested and with proof (Andhra Pradesh, (AP) Vidharbha (Maharashtra), Punjab, Gujarat, MP). It would also be unusual for India to buck the trend in terms of yield and performance when compared to other countries (ref. Failure to Yield: UCS), or resistance and insecticide use. Insect shifts are documented, so also disastrous farm economics in Vidharbha and other States, crops failures, documented human allergies and toxic effects in animals dying from grazing in Bt cotton fields. In India, our highest yielding hybrids have been used by Monsanto for conversion to transgenic Bt cotton. Furthermore, Post-Market Monitoring of Bt cotton in line with Codex, Pusztai, Bardocz, has never been contemplated. India is the largest organic producer of cotton in the world. There is contamination of organic farms, seeds and cotton, and this must be expected, (because no refuges can be observed in our small farm holdings, among other glaring examples of regulatory failure), of Non-GM seeds being systematically withdrawn from the market, rigged reports and bribes in AP as well as illegal Bt cotton in Orissa and the startling fact of illegal HT cotton in Gujarat, which has not yet been approved anywhere in India, for the 4th year in succession. Despite a SC order for validated protocols for contamination of an LOD (limit of detection) to at least 0.01%, testing for contamination by the GEAC is conspicuously absent. We have no certified labs capable of testing to these LODs. Finally, it is well documented that transgenes can rearrange over time. And, "-- *if they are present in a tandem array, uneven crossover will eventually result in one line gaining a transgene(s) and another line losing a transgene(s). In this case, the line that loses a transgene will likely suffer a drop in the expression level of Cry1Ac protein, to the point that it may become ineffective. The line that gains a transgene will likely express much more of the protein, making many of the previous safety tests on the original line irrelevant* (Prof. David Williams)[1]. Therefore, considering these facts, the absence as a first priority, of an independent and comprehensive review of Bt cotton and post-market monitoring, invalidates the decision to even consider any other Bt crop for field testing leave aside the commercialisation of Bt brinjal.

ii. **The first pre-requisite step in criteria of assessment-- is the particular transgenic crop required?** The correct comparisons of agricultural models are essential. What is required is a systematic, in-depth investigation of Bt brinjal yields in alternative agro-biotechnologies, in partnership with farmers and civil society. Given the complexity of this task, which in any case should have been a historic focus with the government, this first and most crucial step was not carried out with Bt brinjal. A growing body of peer reviewed literature is witness to the potential of modern organic or near organic farming, (a sophisticated mix of modern

[1] Ref. D Williams submission to Jairam Ramesh dated 10th January 2010

science and older practices that have been shown to work and be sustainable), and IMP, NPM and MAS (marker assisted selection). Poor farmers on bad land are not practicing modern organic: they don't have the ability to do so in many cases under current circumstances. It must be clearly understood that currently, no GM crop is engineered to increase yield (Gurian, UCS; 'Failure to Yield'); and the IAASTD[1] (the definitive report on a road map for agriculture for the next 50 years), concludes that GM crops do not increase yield. It does not see a role for GM crops to contribute to sustainable food production and global food security, the challenges of poverty, hunger and climate change (CC). Instead it recommends applying low-input agro-ecological farming practices, whose use in the developing world has produced dramatic increases in yields and food security.

iii. **CC:** The emerging consensus from numerous studies and reviews is that under a variety of environmental conditions No-Till sequesters no more carbon than ploughing. The apparent advantage of no-till in previous studies of carbon sequestration was an artifice of sampling carbon only near the soil surface (7). 'No Sure Fix' (8) evaluates the ability of GE crops to reduce the serious issue of nitrogen pollution from crop fertilizer, which also contributes to climate change. Although breeding and other techniques like precision agriculture have improved nitrogen efficiency in crops, GE has yet to do so. These reports caution that the exaggerated claims of the GE Industry, supported by our Regulator, must be carefully scrutinised, to ensure that the contribution of the engineered gene is properly evaluated (Bt brinjal), and that proper and varied standards of comparison are used to determine benefits from GE. There is already sufficient genetic variety for NUE (nutrition use efficiency) traits in crops, and probably in close relatives of important crops, for traditional breeding to build on its successful track record and develop more efficient varieties. Other methods such as the use of cover crops and precision farming can also improve NUE and reduce nitrogen pollution substantially. (Gurian-Sherman) (8).

iv. **The Monsanto Dossier** has been generated entirely by Monsanto with no regulatory oversight. This invalidates the safety dossier. This lack of oversight is exemplified by the fact that the GEAC, the apex Regulator didn't even know that the Bt brinjal Event EE1 encodes for a chimeric (Cry1 Ac and Cry1 Ab) or fusion gene. Did they read the dossier? Under pressure, the admission finally came in the EC II Report (pg 57-58). The Report dismisses its importance by stating that this amounts to just a single amino acid difference, which is insignificant. In fact, the difference is 7 amino acids. The following additional points regarding the failure to observe elementary rules of regulatory procedure underscore why the Monsanto's bio-safety dossier (henceforth called, the 'Dossier') must be rejected: (a) as a starting point, reference materials were not certified. This raises the question, what was safety tested? (b) The 'comparator' crop was not verified and/or disclosed. This kind of research smacks of cover-up and fraud and it would not be the first time. The major defect in the LY038 dossier was the use of the *wrong comparator.* Monsanto used another GE variety against Codex Alimentarius and EU rules (Heinemann submission); (c) government labs are not internationally accredited; (d) after more than a decade of thousands of field trials, the Regulator has not thought it necessary to set up independent and autonomous laboratories, certified to internationally accredited standards, capable of conducting the studies that are

[1] IAASTD:The single largest research exercise on global agriculture in history, which was conducted with funding from multiple UN agencies and the World Bank. This report, published as *Agriculture at a Crossroads*, was produced under the auspices of the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD). It involved around 400 scientists and twice that number of peer-reviewers.

required for safety testing and risk assessment. We cannot even test to an LOD (limit of detection) of 0.01% which is routinely possible in labs outside India. Yet we have a SC Order to test to at least this level.

v. **Substantial Equivalence** (SE)[1] as the regulatory norm as guided by the ICMR which claims it is following Codex, but in fact does the opposite.
vi. Long term animal feeding studies for chronic toxicity are not required in the ICMR guidelines and therefore, their rejection for Bt brinjal is justified on this basis[2]
vii. Cry 1 Ac has a history of safe use
viii. The use of surrogate proteins is accepted
ix. Event-based regulation is the regulatory norm
x. The Bt toxin only has effect on alkaline gut systems
xi. Profiling techniques for non-targeted effects are rejected

> *The EC –II noted that the technologies such as transcriptomics (transcript profiling), proteomics (protein profiling) and metabolomics (metabolite profiling) involve long drawn expensive procedures with little value, and therefore not recommended for safety* assessment of GM crops. These technologies are research tools and have not been validated for use in evaluation of GM crops."

Critique
There are very few established protocols internationally to determine the human health impacts of GE foods. These are generally piecemeal and fragmented. In the US it also *voluntary* because GE foods are given GRAS status (Generally Recognised As Safe). GRAS allows the US regulators to assume a prior stance of safety for GM crops (vinegar has GRAS status); consequently, GM crops released on to the market do not require the FDA to approve them as safe for human consumption. India is a faithful adherent of the US system and this fact is now very clear from the test case of Bt brinjal. Bt brinjal dossier is the first of its kind, the only attempt thus far, of safety-testing any crop. In India, the Regulators apply the principle of SE (substantial equivalence) and the EC II Report and the GEAC similarly, take a position of prior safety in approaches to safety testing. This is clear from the EC II report. The claim of compliance with Codex is simply not true in this matter and many others (see foot note 2 below).

The methods of rigorous bio-safety risk assessment in their time-scale are by definition, long term, to uncover the potential harmful changes in *GE proteins* in foods as a result of the transformation process. These include testing procedures for chronic toxicity. Yet, the EC II Report and the Regulators are on record dismissing both, scientific methods of risk assessment and long term multi-generational animal feeding studies because they will take too long. The question must be asked: too long for whom? The reasons that underlie the need to first, safety test GMOs and second, define the methods to be employed in their rigorous testing, form the very core of how this technology is to be addressed and regulated. "Unintended effects" are

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[1] ICMR Pg 3 paras 1 & 2: Para 1 (Codex) is at variance with para 2. The ICMR quotes Codex in para 2 in part and stops short of the full text as follows: *"The safety assessment of foods derived from GE plants in these guidelines is based on the evaluation of these foods relative to their conventional counterparts that have a history of safe use. This takes into account both intended and unintended effects"*. Codex on the other hand continues: *"It is recognised that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts"*.

[2] ICMR guidelines pg 10: *"the use of toxicology studies are not considered necessary where the substance or a closely related substance has been consumed safely at equivalent intakes or where the new substance in not present in the food"*.

inherent to the process of genetic engineering. In addition, leading independent scientists (Schubert, Pusztai, Gurian Sherman, Heinemann, Cummins, Mann, and Seralini, among others) have addressed these concerns of safety testing and Regulation and have provided affidavits in evidence to the SC. And Dr Bhargava's list of safety tests that are required to be conducted for the safe release of a GMO, are grounded in that consensus of how the unique risks of GMOs are to be addressed for public and environmental safety. (Enclosed: A List of 29 tests or criteria).

The Safety of the Bt Gene?

Dr Arpad Pusztai[1] has put together the significant research findings on the Bt transgene and has said in his statement to the SC that there is plenty of evidence of its harm, "*leading to various immunity problems*". On the contrary, "*there is no scientific basis for claiming that Bt crops are "proven safe to eat"*.

Mon 863, Mon 810 Bt corns: Pusztai (Mon863) and Seralini (mon863 & M0n 810) examined the raw data of Monsanto's own dossiers of their 90 day rat feeding studies and reported significant direct toxic effects on liver and kidney weight etc. The findings of Mon 810, which is the only GM product allowed for cultivation in Europe, resulted in bans in France (the country with the second largest acreage under cultivation of this GM corn) and Germany. It is significant that these bans came 10 years after the approval of Mon 810 by EFSA (European Food Safety Authority). Several other European countries have banned GM crops including Switzerland.

Prof. Dave Schubert:[2] *"It is argued by the GM producers that crops (mostly maize) containing the Bt gene have been eaten for 10 years (true) and therefore proven safe (not true), and that putting the same Bt gene into another crop means that it will also be safe to eat (absolutely not true).*

"The reason for the concern about the ability of GE plants to produce toxins, carcinogens, and compounds that cause birth defects (teratogens) is the result of the uncontrolled events that occur in the steps required to make a GE plant. Therefore the GM process itself is highly mutagenic and can cause the plants to make chemicals that they normally do not make ---with completely unpredictable consequences; the claims made about the precision, specificity and safety of plant genetic engineering have no scientific basis.

The potential negative impact on nutritional content and the increase in dangerous metabolites (chemicals) are the major hazards associated with highly mutagenic plant GM techniques. Although it is widely recognized that the breeding of some crops can produce varieties with harmful characteristics, millennia of experience have identified these crops, and breeders test new cultivars for known harmful compounds, such as alkaloids in potatoes (Korpan et al., 2004), (Ewen and Pusztai, 1999). In contrast, unintended consequences caused by GM techniques opens far wider possibilities of producing novel, toxic or mutagenic compounds in all sorts of crops. Unlike animals, plants accumulate thousands of nonessential small molecules ---- estimates are that they can make between 90,000 and 200,000 unique chemicals with up to 5,000 in one species-- Many of these are known to be HIGHLY TOXIC, CAUSE CANCER, AND CAUSE DISEASES LIKE PARKINSON'S.

[1] Annexure G20 Written Submission (April 2009)(cross ref: vol. XXXVII) -2007

[2] Annexure G 21 Written Submission " " "

There are many examples of unpredictable alterations in chemical metabolism in transgenic organisms. In a yeast strain genetically engineered to increase sugar fermentation, the GM event caused the unintended accumulation of a highly toxic and mutagenic compound. Another well-documented example of unintended effects is the alteration of lignin in Bt corn hybrids derived from Monsanto's MON810 and Syngenta's Bt11 plants, as well as glyphosate-tolerant soybeans. --- Both groups of plants have elevated levels of lignin, an abundant non-digestible woody component that makes the plants less nutritious for animal feed. ---COMPONENTS OF THIS SAME BIOCHEMICAL PATHWAY ALSO PRODUCE BOTH COMPOUNDS THAT HAVE A HIGH NUTRITIONAL VALUE AND ROTENONE, A PLANT-PRODUCED INSECTICIDE THAT CAUSES PARKINSON DISEASE IN ANIMALS. Because of the unique nature of plant enzymes, it is impossible to predict the products made or lost by plants during the GM process. Without the proper safety testing of the specific GM crop, which has not been properly done (with Brinjal), there is the very real possibility that the GM food will cause great harm to human health --- Of utmost importance is the fact that Brinjal in India is one of the major sources of calories for its population, while the Bt corn in the US and elsewhere is mostly used for animal food and its consumption as food is extremely small, less than a percent of total calorie intake.

There are no mandatory, safety testing procedures in the US. Therefore there is no scientific basis for claiming that Bt crops are "proven safe to eat". --It may take many years before any symptoms of a disease arising from a GM product appear. In the absence of strong epidemiology or clinical trials, any health problem associated with an illness caused by a transgenic food is going to be very difficult, if not impossible, to detect unless it is a disease that is unique or normally very rare.

The critical issue is that any new GE food crop be properly tested for safety in carefully controlled studies with open public access to all of the data, before it is allowed for environmental release in field trials. (This has not been done with GM Brinjal and the crop should not be planted). ONCE A CROP IS EXTENSIVELY PLANTED THE CONSEQUENCES ARE IRREVERSIBLE BECAUSE THERE IS NO WAY THAT THE GENETIC MATERIAL FROM THESE CROPS CAN BE CONTAINED.

Testing for Chronic Toxicity: It is beyond comprehension how the EC II report, the GEAC and the ICMR guidelines, dismiss the need to test for chronic toxicity, which by definition is only apparent in the long term. Its absence from the safety protocols for Bt brinjal was justified on the grounds that no negative health effects were apparent in the 90 day rat-feeding studies. Even supposing this were so, and both Seralini and Carman refute these claims firmly, the clear requirement to carry out long term studies for effects only detectable in the long term is self evident. Scientists affirm that GM foods must be tested in multi-generational, life time, animal feeding studies to detect slow growing cancers and other long term health effects of GM foods. Furthermore, recent studies demonstrate that these methods are bringing just such health problems to light (Austrian Government, Nov. 2008, Finamore et al. 2008, Malatesta et al. 2008; Kilic & Akay, 2008).

The use of surrogate proteins in testing: The Use of surrogate proteins in testing as opposed to using actual plant protein is justified in the EC II Report and by the GEAC on the grounds that it is very difficult to generate enough plant material. The GEAC in their counter affidavit to the SC in 2008 also contended that a "protein is a protein".

"Probably the Petitioners and the experts advising them have chosen to overlook the fact that Bt Cry proteins are produced in nanogram and microgram quantities and one cannot harvest sufficient protein"(GEAC, Counter Affidavit, 2008).

In testing paradigms, *"the use of surrogate proteins is a serious mistake since plants and bacteria are very likely to produce different proteins EVEN WHEN TRANSFORMED WITH THE SAME GENE. Testing a bacterial protein should not substitute for testing plant-expressed proteins ---- " --- "even if precisely the same foreign DNA is expressed in bacteria and plant, the TWO ORGANISMS WHICH ARE KINGDOMS APART IN BIOLOGICAL TERMS, process proteins differently. For instance bacteria are NOT known to add sugar molecules to proteins, while plants do. Glycosylation patterns influence the immune response to proteins --- Other secondary modification will certainly occur ---Immunological differences between plant-produced and bacterial surrogate proteins could have serious medical consequences". "Given the use of bacterially produced proteins as the norm for testing, one cannot avoid the conclusion that the plant-produced proteins we actually eat are virtually untested".* (Freeze –Schubert, 2004 (9))

The case of Tryptophan: *"An underappreciated fact of biology is that very small amounts of a compound can have profound effects in biological systems. Plant metabolism can produce toxic products, but while these have been selected against in our food supply during the 10,000 years of crop development or eliminated through food processing before consumption, they may be unintentionally re-introduced by modern technology. A good example is the health disaster caused by tryptophan in the guise of a dietary supplement. In 1989, more than 1,500 people contracted a rare disease, eosinophilia myalgia syndrome (EMS), at least 37 died. The epidemic was traced to the L-tryptophan producer, which had recently modified its production procedures. The purity of the toxic preparations was greater than 99%. However, a comparison of high-performance LIQUID CHROMATOGRAPHY PROFILES between toxic and nontoxic lots revealed several case-associated minor contaminants. Although it was believed at the time that a tryptophan metabolite was the cause of the EMS outbreak, there was NO EXPLANATION AS TO HOW A VERY MINOR CONTAMINANT (LESS THAN 0.01% BY WEIGHT) COULD CAUSE A FATAL DYSREGULATION OF THE IMMUNE SYSTEM. These data show that minute amounts of a compound contaminating a dietary supplement can be lethal and that chemical modifications of common, small molecules such as AMINO ACIDS* (proteins) *can lead to biologically active derivatives".*[1]

"Protein is a protein"! The fact is that allergenicity testing is now written-in to regulatory rules, internationally, including in India no matter how porous those rules are, or how badly executed. This principle of testing is therefore, clear acceptance by Regulators of the fact that proteins modified as a result of the GE process lead to unintended effects and potential allergenicity problems. The claim is extraordinary.

Dr Jack Heinemann Clarifies with Regard to Surrogate Proteins[2]: The bacterial protein differs from *"the proteins produced from transgenes when they are inserted into a plant genome, --- because the intermediates in the expression of these genes and the final products can differ*

[1] Annexure G23 Written Submission – cross ref Vol. 46: The problem with Nutritionally Enhanced Plants

[2] Annexure G24 " Statement to Lead Petitioner, 25th Sept. 2008: cross ref R 8

between the two organisms. THIS IS A FACT THAT HAS BEEN KNOWN FOR MANY DECADES AND IS BEYOND QUESTION".

- **i.** *"In the first stage of gene expression, different mRNA molecules can be produced from the same DNA sequence because of alternative promoter starts---". "---Some of these reactions are not known to occur in bacteria and many occur in a species-specific way---Since this type of processing is so far only known to occur in plants, it is not possible to conclude that the proteins produced in surrogate bacteria represent the full family of proteins that may be produced from trangenes in plants".*
- **ii.** Transcription does not stop at the terminator and thus creates an mRNA that codes for a fusion protein or a protein with additional amino acids (and is therefore fundamentally different from that produced in bacteria). "*This has been demonstrated in the commercial soy bean and is expected to occur in others".*
- **iii.** *"In addition to differences in the primary structure of the protein are differences in the post-translational modifications (PTM) of the protein. The frequency and type of post-translational modifications in bacteria and in plants is completely different and therefore, again, the full equivalence of the family of isoforms of a protein produced in a GM plant cannot be generally assumed to be similar to that produced in a surrogate bacterium*
- **iv.** *This is relevant to a GMO assessment BECAUSE THE PROTEIN OF INTEREST MAY NOT HAVE IMMUNOGENIC OR TOXIC PROPERTIES IN THE DONOR BUT DOES SO WHEN EXPRESSED IN THE RECIPIENT. Also, the same protein can exist in hundreds to thousands of different isoforms in the same cell at the same time, but not each form may exist at the same CONCENTRATION. Thus, detecting different forms can be very difficult. ----IT WOULD BE INCORRECT TO ASSERT THAT THE STUDIES CONDUCTED BY COMPANIES ARE CAPABLE OF DETECTING ALL POSSIBLE PROTEIN ISOFORMS".*

"*A concrete example of the pitfalls inherent in using surrogate sources comes from an even less extreme comparison, the expression of a protein from beans in GM peas.(*Amylase in Pea from Bean' 10*) The protein when sourced from beans has no known or demonstrated immunogenic potential in humans. However, when the same gene was expressed as a transgene in GM peas, it was found to cause an immunological reaction in a test animal (Prescott et al., 2005). This differing immunoreactivity was attributed to pea-specific PTM (post-translational modifications). These researchers concluded that "transgenic expression of non-native proteins in plants may lead to the synthesis of structural variants possessing altered immunogenicity"" (Prescott et al., 2005).*
"The references I provide here indicate that it is possible to secure proteins made from transgenes in plants for biochemical analysis. It certainly may be difficult and costly to produce enough protein for studies, but that difficulty and cost is a challenge that the developer should have incorporated into his or her decision making before deciding that a particular transgene was a commercially viable prospect. It should not be used subsequently to excuse sub-standard safety testing".

The peer-reviewed 'Pea' study in Australia titled, 'Amylase in Pea from Bean' was only discovered by RESEARCH TECHNIQUES, AND LONG-TERM ANIMAL FEEDING STUDIES, NOT CONDUCTED ANYWHERE FOR A GM PRODUCT. The Australian study used MALDI-TOF (Matrix

Assisted Laser Desorbsion-Time of Flight, combined with Mass Spectography, a sophisticated and precise procedure that has occasionally been used by companies to get the sequence of the protein but not in regulatory test procedures. In the study, it determined the chemical composition of the protein, that it was altered in subtle ways in pea (glycosylation) compared to the beans that the gene originally came from. Then, a strain of mice called Balb-c was used to see if the altered protein causes altered immune response. These mice had been used for this purpose before by independent scientists, but their use has not been required by any regulatory agency. The mice showed strong reaction to the altered protein. It is important to note that the protein in the original organism (common beans) was not immunogenic, and harmless when cooked.

"However, in the case of Prescott et al., (the pea-bean study referred to), the adverse reaction was a surprise and only found by active and proper testing of the protein when produced in the GM plant. The adverse reaction was not detected when the protein was sourced from bean or subsequently when sourced from another transgenic source, a GM chickpea (Prescott and Hogan, 2006). If they had used GM chickpea as a surrogate source of the protein, then perhaps any commercial aspirations would not have been discontinued. THIS PATTERN OF RESULTS DEMONSTRATES CLEARLY THAT ONLY PROTEIN SOURCED FROM THE GM PLANT OF INTEREST WILL ANSWER QUESTIONS ABOUT ALLERGENICITY AND POSSIBLY TOXICOLOGY" (HEINEMANN).

Alkaline Gut System: This claim by the Regulator is based on a discredited model of the action of Cry toxicity. It would seem that this is the basis for their rejection of claims of toxic effects in non-target organisms. It appears they cannot be moved despite the evidence to the contrary

Jack Heinemann[1]: The long-accepted version of Cry toxicity is not the actual mechanism. Thus, the range of organisms that will find Cry toxic may not be predicted from knowledge based on toxicity screening of the Cry proteins alone. The toxin is necessary but not sufficient for killing. It appears that the Cry toxins permeabilize the gut epithelium and this creates an opportunity for commensal bacteria to cause septicaemia. In the context of *cry*-expressing (Bt) plants, there is the possibility of exposing a vast new array of gut ecosystems, because the variety of insects and the variety of microbes inhabiting them is very large. The new model of how Cry toxins kill raises issues of uncertainty surrounding effects on non-target animals. As Mahyco does not cite the literature on the new model, it is unlikely that their thinking and therefore their experimental design was influenced by the latest research on Cry toxin activities. Since current understanding of how insects die after ingesting Cry proteins differs from Mahyco's expressed understanding, there are safety concerns that they have not addressed.

Seralini and the Codex: Seralini states that GM crops must be tested like chemical pesticides. The codex similarly speaks in terms of *"accumulation of pesticide residues, altered metabolites, -- toxic metabolites, contaminants or other substances which may be relevant to human health. The safety assessment should take this potential for accumulation into account"*. Paragraph 46 of the Codex states: "*Some recombinant-DNA plants may have been modified in a manner that could result in new or altered levels of various metabolites in the food. ---Safety assessment of such plants requires investigation of residue and metabolite levels in the food and assessment of any alterations in nutrient profile-----*".

[1] Heinemann critique of Monsanto's dossier

Finally, like Dr Pusztai, Prof Schubert, Gurian-Sherman and David William, & the Codex concludes that safety assessment is an *evolving science* which must be reviewed in the light of new scientific information that *"calls into question the conclusions of the original safety assessment: --- as scientific knowledge and technology evolves, other methods and tools may be considered ----"* [1]

The FAO-WHO also recommends consideration of post market surveillance, in analogy with the final phase of drug testing, to capture allergic responses that may be missed with pre-market testing (FAO-WHO, 2001).

Dr. Arpad Pusztai and Susan Bardocz: In 'GMO in Animal Nutrition: Potential Benefits and Risks', [2] Dr. Arpad Pusztai and Susan Bardocz have taken the protocols further. They have reviewed previously published animal studies and have examined them critically in the light of a suggested but always evolving test protocol in which the *"safety of GM crops is established from the effects of GM ingredients on the physiology, pathohistology, immunology and bacterial flora of the gastrointestinal tract of young animals and the metabolic consequences of these effects"*. --- *"More sophisticated analytical methods need to be devised, such as mRNA fingerprinting, proteomics, secondary metabolite profiling and other profiling techniques. However, and most importantly, there is an urgent need to develop comprehensive toxicological /physiological /nutritional methods which will EQUALLY BE APPLICABLE, to scientifically examine the veracity of the claimed benefits of genetic manipulation and screen for its unintended and potentially deleterious consequences for human/animal health. THE CENTER OF THIS EFFORT SHOULD BE THE PHYSIOLOGY OF THE ALIMENTARY CANAL,* (DIGESTIVE SYSTEM) *SINCE THIS IS THE FIRST CONTACT POINT OF EXPOSURE TO ANY FOOD/FEED INCLUDING THOSE WHICH HAVE BEEN GENETICALLY MODIFIED, TO ESTABLISH IN SCIENTIFIC TERMS THE SHORT AND LONG TERM CONSEQUENCES OF THE EXPOSURE"*.

The National Academy of Science[3]: *"The present state of knowledge requires that approaches for assessing the occurrence and significance of unintended health effects encompass BOTH TARGETED AND PROFILING APPROACHES, using a range of toxicological, metabolic, and epidemiological sciences. Encompassing BOTH of these approaches exploits what is known and increases the ability to prevent and assess unsuspected consequences. Developing improved techniques that enable toxicological evaluations of whole foods and complex mixtures, including: microarray analysis, proteomics, and- metabolomics.*

Profiling Techniques (non-target approaches for unintended effects): (Profiling techniques search for any changes in the full range of proteins, RNA or DNA): The EC II Report and the Regulators dismiss the relevance of these techniques and for cost reasons as well. None of the following profiling techniques have been carried out:

Transcriptomics (all novel RNAs): (The complete set of RNA transcripts produced by the genome at any one time). The transcriptome is dynamic and changes under different circumstances due to different patterns of gene expression.

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1 SC Submission: Annexure S10 of Volume VIII.

2 SC Submbission: Annexure S9 of Volume VIII

3 Safety of Genetically Engineered Foods: Health Effects: NAS.

Codex 2003 pg. 14,& 39, *"Information should be provided on any expressed substances in the recombinant-DNA plant; this should include: the gene product(s) (e.g. a protein or an untranslated RNA); the gene product(s)' function..."*.

Proteomics (The study of the proteins that are expressed at a particular time, ie under particular conditions, in a cell or cell type (tissue): This is now standard in dossiers and the absence of these data is unacceptable The most obvious profiling technique is 2 dimensional gel-electrophoresis (2DGE) (Heinemann). The effectiveness of 2DGE for profiling has been demonstrated in a series of investigations using GM Arabidopsis plants (e.g. Ruebelt, M.C. et al., 2006). Rubeld is a Monsanto scientist who in 2007 produced three papers on Arabidopsis (a mustard) where he did a complete proteomics profile. There was less than 3% difference with the comparative non-Gm line. They were able to investigate every single change. It took them a year.

Codex stipulates that limits of detection and sensitivity assays must be disclosed.

Microarray Analysis and-Metabolomics: (Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects: NAS). **Microarray** a method used for transcriptome profiling: **metabolomics** or metabolic profiling, the measurement and analyses of metabolites, such as sugars and fats, in the cells of organisms at specific times and under specific conditions. The field of metabolomics overlaps with biology, chemistry, mathematics, and computer science.

The Regulators have not adhered to the full extent of Codex Alimentarius guidelines, instead picking and choosing which standards to enforce and which to excuse. They have also ignored the NAS for assessing unintended effects, also ignored evolving approaches to testing and post market monitoring. The ICMR minimal guidelines are an irrelevancy and dangerous for India as a standard for risk assessment of GM crops and for the approval of Bt brinjal.

Respondents are right in saying that proteomic data would cost *"enormously in both time and money"(*Rejoinder Affidavit, pg 27*),* that the profile of the transcriptome, proteome and metabolome will vary with tissue, age, time and environment. But that is also WHY it should be done. If harm arises only in one tissue and ONLY AT ONE TIME DURING DEVELOPMENT, then that harm should be identified. IT ISN'T THE PUBLIC THAT HAS CREATED THE POTENTIAL FOR THAT HARM NOR HAVE THEY CREATED THE COMPLEXITY OF BIOLOGICAL ORGANISMS THAT MAKES IT POSSIBLE FOR SUCH HARMS TO BE HARD TO DETECT (source of analyses Jack Heinemann).

The correspondence of the above core methods in the risk assessment of GMOs with Dr Bhargava's guidelines is manifestly clear (ref App.1)

Summary: In summary the core testing procedures to be combined with standard crop testing procedures, to determine if a new GE product falls within the accepted norm of safety of current food crops, are:

a. The Ames test for mutagenicity
b. Genomic Profiling Techniques:
c. Molecular analysis of the gene insertion sites and transformation-induced mutations
d. Extended multigenerational and life-time animal feeding studies for carcinogenic, reproductive, and other adverse effects
e. Allergenicity testing

f. Gene flow, testing on non-target organisms, soil micro-organisms
g. Post market surveillance, both health and the environment
h. Evolving guidelines

It is admitted by the Regulator and In the EC II report that many of these core tests have not been done for Bt brinjal, because they are felt to be unnecessary. In their absence, as well as the serious procedural lapses, lack of independent testing and oversight, Bt brinjal may not be approved for field trials leave alone for commercial planting.

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DR. BHARGAVA'S LIST OF TESTS THAT MUST BE CARRIED OUT BEFORE A GMO IS RELEASED INTO THE ENVIRONMENT

TESTS PRESENTLY NOT DONE FOR ANY GMO	TESTS PRESENTLY NOT DONE FOR ANY GMO
• DNA fingerprinting and proteomics analysis and full characterization, both structurally and functionally, of the differences between the GMO and the parent organism • The total sequence of the transgene-flanking regions and the transgene, and identification of the site(s) of integration of the transgene in the GMO • Changes in the glycosylation pattern • Determination of any selective increase in transcription and translation, thus including a study of the transcriptome • Changes in the relative concentration of major and important intracellular metabolites • Changes in surface properties that may affect normal interaction between species, and with the environment, studied through scanning electron microscope and atomic force microscope • Reproduction interference • Gene flow • Dispersal into areas where positive harm could be done (as happened with water hyacinth and parthenium) • Development (if not already available) of a technique to determine with accuracy 0.01 percent contamination with GMO or its product • In the case of GM food material, possible interaction with commonly used drugs, especially probiotics • Acute toxicity studies with native **(not "surrogate")** protein, GM seeds and other GM plant material that is normally ingested by animals, including cattle. These studies should be done both on experimental lab animals and on farm animals such as goat, sheep and cows)	• Chronic toxicity studies (including carcinogenicity) as above • Effect on cattle GI microflora • Effect on soil micronutrients in every region concerned (rain-fed, irrigated, semi-arid, etc.) where GMO is likely to be released or find its way • Development of resistance to the trait that is introduced • Increasing requirements for refuge crops, if any. • Increase in susceptibility to pests and infectious agents other than those that may be expected to be killed by the transgene. • Comparison of the growth characteristics of the GMO and the parent organism. • Emergence of new dangers, for example of super weeds, following prolonged use of herbicide-resistant GM crops. • Effect on the population density of non-susceptible pests, following at least five successive plantations – for example in the case of GM Bt plants. • Automated karyotyping and gross chromosomal analysis. • If the GMO is a plant, its biomass productivity in comparison to the parent. • Comparison of inputs required for optimal growth of the GMO in comparison to the parent organism. • Impact on ecology in controlled field trials (for example, on population of bees, and other useful insects). This would require total mapping of insects and other living species in every region where the GMO is intended to be released, over a substantial period of time.

TESTS CLAIMED TO BE DONE BUT AS GOOD AS NOT HAVING BEEN DONE
• Stability of the transgene product in the whole organism and/or parts thereof, under various conditions of storage or handling (e.g. cooking in case of an edible GMO) • Efficacy on useful insects. • Effect on microflora of the soil • Allergenicity

Note: The Actual Tests to be done will depend on the nature of the GMO to be released. Some tests are particularly important if the GMO is a Food Crop.

Shri Jairam Ramesh
Minister, Environment and Forests
Ministry of Environment and Forests
New Delhi

December 1st 2009

Dear Shri Jairam Ramesh,

Sub: NO proof of safety established by the Indian Regulators of Bt cotton of Cry 1 AC protein regarding its impact on Animals that have grazed on /fed Bt Cotton:

Animals grazing in fields or being fed Bt cottonseed cake demonstrate potential and serious health problems. The potential for harm to humans from Bt brinjal, containing the same protein, and in the absence of any meaningful investigation of Bt cotton, is a risk that cannot be taken.

Submission to the honourable Minister, with a request to grant time to make a personal presentation of the case.

I wish to draw your attention to **Section V, Issue 8, pp 58-59 of the "Report of the Expert Committee (EC-II) on Bt Brinjal event EE-1", wherein the committee refutes the need to conduct long-term studies for assessment of chronic toxicity and nutritional impact on mammals.**

i) The committee dismisses the above concern raised by eminent national and international scientists, citing instead extensive studies purported to have proved its safety, a history of safe use for human and animal that have consumed GM crops containing Cry1Ac protein, and that chronic toxicity studies are warranted only if any toxic effects are observed in acute or sub-chronic studies, which were not. They also state that the Cry1Ac protein has shown to be rapidly degraded (in 30 seconds) in simulated digestive fluids and thus is not detectable even in the short term studies (Section VI, point 11, pp 63).

ii) The Expert Committee Report in **table 2.2, point (i), on page 23**, records an additional condition stipulated by GEAC that *the food/feed safety assessment should include any possible foliage/shoot toxicity study on goats.* This condition was stipulated in view of the reports of sheep deaths in Andhra Pradesh due to grazing on Bt cotton fields. ***However the GEAC subsequently reversed its decision and decided to dispense with the additional risk assessment test requirement on the grounds that***

a) the reports of sheep deaths due to Bt cotton were unsubstantiated, and
b) that the newly adopted "Guidelines for the safety assessment of foods derived from GE plants , 2008", do not require any food and feed safety assessment using goats as the model.

i) I strongly contest the Expert Committee's observations that Bt cotton has been proven safe for animals, which I wish to present before you based on the experiences of my organisation **Anthra- an organisation of women veterinary scientists**, which has been researching the impact of Bt cotton on livestock since the last 5-6 years.

ii) I draw your attention to how consistent and cumulative exposure to the Bt toxin has elicited a possible toxic / allergenic response in sheep, goats, cattle and buffalo populations in Andhra Pradesh and other states in India. Animals began to exhibit morbidity and mortality after continuous and cumulative exposure to Bt cotton (leaves, bolls, seeds, seed-cake), over successive years, with first reports of ill-health occurring in 2004-05, about 2 years after the commercial release of Bt cotton in India.

ii) I would also like to alert you to the total failure and inability of our existing public research institutions and National Regulatory Bodies (GEAC), to investigate/ test/ rigorously examine, prove or disprove these field observations, preferring to dismiss the reports as "unsubstantiated", "exaggerated, and unscientific", refusing to conduct a single field-based study and instead placing the onus of "proof" on shepherds, farmers and civil society groups who have reported the problem.

The argument that the latest guidelines do not require the suggested new risk assessments tests and hence have been dispensed with, negate and ignore the field realities where "non-target organisms" have been affected by the Bt toxin. On the contrary, these unique field experiences and observations, urgently invite new and additional specific regulatory and risk assessment protocols.

I confidently assert that the issues of safety are completely unresolved, evident as follows:

1) Field reports of toxic / allergenic reactions of animals exposed to Bt toxin in Bt cotton in Andhra Pradesh and other states: 2005-2009 and the complete failure of Public Research and Regulatory Bodies to investigate the same.

Between 2005 and 2009 Anthra has been closely investigating the reported morbidity and mortality observed in sheep and goat flocks, which have been grazed on harvested Bt cotton crop in Andhra Pradesh.

In the first 3 years, symptoms reported by shepherds, were confounded by the concurrent incidence of other contagious diseases such as peste-du petits ruminants (PPR) and blue tongue.

By 2008-09, due to in-situ presence of our veterinary scientists who continuously monitored the village flocks, which we ensured were vaccinated against all other possible preventable contagious diseases, we were able to narrow down and be precise about the specific morbidity exhibited by animals that grazed on harvested Bt cotton.

Morbidity selectively manifests itself symptomatically in animals by the 3rd of 4th day of consuming the Bt cotton as *nasal discharge, cough, respiratory distress, and occasional bloody urine and the absence of fever.* Mortality occurs in some animals, especially if untreated, not all animals.

Our field observations point towards a clear cumulative effect of the toxin on morbidity and mortality, with successive years of exposure/ grazing on the Bt cotton, eliciting what appears to be an allergenic immune response.

In Haryana, there is a strong correlation between feeding Bt cotton seeds and cotton seed cake to milch animals, and drop in milk yield and several reproductive disorders such as prolapse of uterus, premature birth of calves, increase in the incidence of abortions and decrease in conception rate. **These symptoms of reduced fertility correspond to results of reduced fertility in rats that were fed Bt Maize over four generations (*Velimerov, A et al., 2008*).**

2) Post mortem samples – Research institutes admit inability to test for Bt toxin; histo-pathological reports demonstrate lesions similar to those observed in rats fed on Bt maize (corn).

Tissue samples collected from post-mortems done on dead sheep and goat which died after grazing on Bt cotton, were sent to top research institutions of the country such as the Indian Veterinary Research Institute (IVRI) in 2008, with specific request that these be tested for Bt toxin. ***The IVRI reported their inability to test for Bt toxin (see annexure 1)***

Histo-pathological lesions in the kidney, liver and intestines of the post-mortemed sheep/goat, are similar to those recorded in Monsanto's own dossier of Mon 863, (Bt corn) of 90-day rat feeding studies, subsequently revealed by Pusztai on behalf of the German government and later, confirmed also by Seralini et al (2007) after many statistical studies (annexure 2.) The Company's hidden raw data were released in the public domain through a German Appeal Court decision (2005). Other studies by different researchers with rats fed Bt corn also revealed hepato-renal toxicity, and damage to liver and kidneys. (Kilic and Akay, 2008, Velimerov, A et al., 2008).

3) Deceptive "proof" of safety: serious scientific lapses in the investigation of animal morbidity

The so-called reports of safety, which GEAC has cited in its 82nd committee meeting, in January 2008, as having been received from the IVRI and Animal Husbandry department, AP (AHD), as evidence of "conclusive proof of safety", which my organisation subsequently obtained through RTI, **un-ambiguously points to deception and serious scientific lapses.**

To illustrate: the IVRI when requested for its report of safety, responded stating that "*no studies have been done by them and that the Animal Nutrition Department of IVRI has not submitted any reports to the GEAC*"! (Annexure 3)

The GEAC's dossier of safety which they sent us, when we filed under RTI, included copies of 4 letters—one from the AHD, one from the IVRI, one from the Sri Venkateshwara Veterinary University (SVVU), AP and one from a Joint Director (AHD) of a district which never reported any sheep deaths. *Three of the four letters clearly state the need for further bio-safety studies.* (Annexure 4)

A subsequent RTI to IVRI, quoting their letter to the GEAC where they mention having conducted a Bt cotton feeding study on goats, resulted in IVRI sending copies of research protocol and methodology to test for HCN, glyphosate, alkaloids, nitrites and nitrates! They also sent a report of toxicity assessment of feeding Bt cottonseeds to rats; but no studies on goats, which is what I had specifically asked for! (Annexure 5)

Please note that there appears to be direct factual conflict between the letters from IVRI contained in annexure 3, annexure 4 and 5. One of these is simply not truthful. It is clear that the GEAC has based its conclusions regarding Bt cotton on untruthful statements by government agencies. We strongly object to the GEAC using the same untruthful "evidence" to justify the safety of Bt brinjal.

4) A safe toxin? Conflicting claims of "safe and tolerable levels of Bt toxin"

The other "proof of evidence of safety of Bt toxin", sent to us by the GEAC, is a letter sent to the GEAC by the Director, Animal Husbandry Department (AHD), Andhra Pradesh, dated May 2007 (ref: No 3531/Epid/2006.dated 9/5/2007), wherein the director reports that (annexure 6)

" *The Bt protein levels detected in the samples of Bt cotton bolls and leaves sent for analysis was recorded as 5 µ/gm. This level is within the tolerable range which is said to be "5-10 µ/gm".*

This information was provided to the Director, AHD from the Department of Agriculture Bio-technology, Agriculture University, ANGRAU, AP, which had tested samples of Bt cotton plant (bolls and leaves), which were sent to them in connection with reports of death in sheep after grazing on Bt cotton in 2006.(ref: letter roc no: 14627/Epid/2006/, dated 20/9/2006).

5-10 µ/gm is equivalent to ***5-10 ppm***

The Bt protein content (of Bt brinjal) reported in the Expert Committees Report (**point 3.1.5**) describes the level of Bt protein (Cry1Ac protein) found in different parts of the crop to vary **between 5 to 47 ppm** in shoots and fruits.

For the sake of argument, if we are to go by the earlier submission of all institutions concerned (Agriculture university, cited by Animal Husbandry Department, cited by GEAC) that the reports of Bt toxin (Cry 1 AC protein) are safe and tolerable if they are between 5-10 ppm then it follows that the levels detected in Bt brinjal reported in the biosafety studies and Expert Committee Report, are not tolerable, as it is way above the supposed tolerable levels, which are cited as being safe for sheep!

This raises serious questions on supposed "tolerable" and safe levels of Bt toxin in plants. Who has decided on this supposed safe level for Bt toxin? What is the scientific evidence for safety? How can there be a safe level of "toxin" with a food product, when the very definition of a "toxin" indicates a poison, or something that is harmful?

The GEAC consistently referred to these Bt protein levels (as cited above) as proof of safety of Bt protein to animals, and the "evidence" that death in animals was due to Nitrate/ Nitrite / organophosphates/other diseases.

If the GEAC says the Bt protein is Cry1AC, then by their own admission, the level is not tolerable in Brinjal. If they admit the protein in Bt cotton and Bt brinjal are different, then the whole Bt Brinjal report is wrong because Mahyco is treating the chimeric protein as if it were Cry1AC, which is re-iterated by the Expert Committee in their report.

5) Deception/Cover-up by the GEAC: Absence of a rigorous protocol to test for the presence or absence of Bt toxin / Bt antibodies in sick animals/ dead animals results in its automatic omission from reported results. This has been presented as evidence of proof of safety.

It is a serious matter that in the name of scientific enquiry, we have instead, clear evidence of deception and fraud on the part of all the regulatory bodies in India, to pass off the non-testing of a toxin, and hence its "non- detection", as evidence of proof of safety.

What we have is (a) No tests to assess immune responses to the Bt toxin/ presence of Bt toxin, but (b) nevertheless, the unfounded claim of a "negative result of having not detected Bt toxin" which is passed off as proof of safety. It is scientifically untenable that without performing any tests, its absence is cited as evidence that the toxin is safe.

This circular argument of "safety" is the basis on which the GEAC claims that reports of animal deaths are "unsubstantiated", and reversed its decision to carry out further risk assessment tests on goats, as cited earlier in this letter (page1).

6) Bt toxin detected in rumen liquor and liver malfunctions detected in sheep fed on Bt cotton: 2007 study by State Veterinary University, Andhra Pradesh

In 2007, the Sri Venkateshwara Veterinary University, Andhra Pradesh initiated a season-long study on Bt cotton and sheep (annexure 7). ***The investigations were able to detect the presence of Bt toxin in the rumen liquor of the sheep, indicating that Bt insecticide is not really digested by the sheep (annexure 7, Table 6).***

This seriously contradicts the Expert Committees report (Section VI, point 11, pp 63) that *". Cry1Ac protein has shown to be rapidly degraded (in 30 seconds) in simulated digestive fluids and thus is not detectable even in the short term studies."*
The Expert Committee in their report makes the above statement without any supporting scientific peer reviewed reference. We need to know the scientific evidence in the literature for this statement.

There are other aspects in the Universities study findings that warrant further investigation, no matter that they have been dismissed as unimportant by the department, which conducted the research:

i) The presence of higher toxic heavy metals in Bt plants (842.25 ppm of lead in Bt cotton as compared to 134.62 ppm of lead in non-Bt cotton after 45 days), which is 6.25 times higher after 45 days, as compared to the non-Bt cotton.

ii) The liver marker AST which is known to increase after hepato-cellular injury, as the author of the experiment indicates, is increased in the protocol by 37% in Bt treated sheep in comparison to the untreated group of sheep fed on regular cotton, by the second month.

Then, C. (2009) in a recent article, reviewed published peer-reviewed literature, which showed that several extrinsic factors (such as enzymes, environmental stress, non-pathogenic microorganisms and infectious disease) and synergisms can impact the efficacy and selectivity of Bt toxins. The author concludes that risk assessment of genetically engineered plants should put into question the general assumption of a high selectivity and a linear dose-response relationship in the toxicity of Bt protein. Efficacy and selectivity can be influenced by synergism, which can provoke unexpected and undesired effects in non-target organisms. These findings suggest that systematic research be promoted on synergism between Bt toxin and potential extrinsic factors that could impact the spectrum of susceptible organisms.

It is evident from the above that there is much to worry about. There are obvious lies and a host of contradictions within the "safety" parameters being presented to us citizens.

Most worrying is that there is total failure and reluctance on the part of any public research institution to respond to problems, and carry out rigorous investigations. No formal regulatory guidelines and protocols exist which can respond to these emerging field conditions.

In our experience with animals, every institute that claimed the safety of the Bt Cotton plant absolved themselves of any responsibility towards conducting stringent and rigorous scientific research, to examine the field realities. The official cover-up and fraud are unacceptable and must be investigated. The implications for India are as serious as it can get.

I request you to kindly grant me personal time, to present this documentation in line with your commitment in your press release on consulting with a range of stakeholders before the government takes a final decision on granting permission for the commercial cultivation of Bt Brinjal.

Yours sincerely

Sagari R Ramdas

Sagari R Ramdas
Director, Anthra

Encl: Annexure 1- Report from IVRI regarding inability to test for Bt toxin
Annexure 2: Seralini's Paper
Annexure 3: RTI obtained from IVRI- stating that Animal Nutrition Dept has conducted no studies on Bt cotton
Annexure 4: RTI obtained from GEAC- their submission of "proof of safety of Bt cotton"
Annexure 5: RTI from IVRI – "protocols for testing HCN, et. al"
Annexure 6: Letter from Dept AHD, AP to Dept of Agriculture summarising tests conducted on Bt cotton and safety of toxins.
Annexure 7: "Studies on the toxicity of Bt cotton plants incorporated in the feed of small ruminants". Project Report. Sri Venkateshara Veterinary University, Tirupati
Annexure 8: Bt cotton and livestock. Paper presented by Dr Sagari R Ramdas, July 2009

cc: Dr Ranjini Warrier, Member Secretary, GEAC, MOEF

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Department Of Pharmacology & Toxicology, College Of Veterinary Science; Rajendranagar, Hyderabad-30.

CENTRE OF SOCIAL MEDICINE & COMMUNITY HEALTH
SCHOOL OF SOCIAL SCIENCES
JAWAHARLAL NEHRU UNIVERSITY
NEW DELHI - 110 067

November 18, 2009

To

Mr.Jairam Ramesh,
Union Minister for Environment
Ministry of Environment & Forests
CGO Complex, Lodhi Road
New Delhi-110003.

Dear Mr.Jairam Ramesh,

The faculty of the Centre of Social Medicine and Community Health, Jawaharlal Nehru University, would like to congratulate you for bringing the matter of the introduction of Bt Brinjals in the country for public discussion.

The Genetic Engineering Approval Committee (GEAC) met on October 14th 2009 to discuss the Report of the Bt Brinjal Expert Committee and take a final decision on the environmental release/commercial cultivation of Bt Brinjal in India. Reports suggest that the GEAC has decided to approve the environmental release of Bt Brinjal from Monsanto/Mahyco in India which would for all purposes permit the use of transgenic and Genetically Modified Organisms (GMOs) and products for edible purposes.

As public health workers, we are seriously troubled with this move. While we feel hunger is a public health issue that needs profound policy commitment that it does not obtain, this does not imply that the introduction of a genetically modified vegetable is a priority.

Our concerns stem from several factors:

1. First of all, **this is entirely unnecessary from a public health perspective**, indeed undesirable. The argument that Bt brinjals would not require pesticides is dissembling. There are other, better, pest management methods that we need to utilize.

2. We believe that there are **serious issues of safety that are not yet addressed through long term studies**. There is some data that these crops could be allergy- inducing, and indeed that they might be mutagenic. It is for these reasons that the European Union has decided to ban genetically modified food crops.

3. There are **serious methodological flaws** in the studies that have been carried out, not to mention ethical ones.

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4. There are **profound conflict of interest issues** involved in the studies carried out in India. The companies that stand to gain by the introduction of these crops into the market were the sponsors of the studies. This is entirely unacceptable.

5. There has not been adequate assessment of the ecological consequences of the introduction of this food crop. These concerns regarding the **health and environmental risks associated with GM crops are too serious to be disregarded.**

6. We do not have a retailing structure that allows appropriate labeling should this be introduced as safe so that people who wish to might not purchase them.

7. Finally, we believe that **increasing the role (and control) of multinationals in our agrarian economy is undesirable.**

In short, this policy move is entirely unnecessary, has not been transparent and is potentially injurious to public health. We believe there should be a moratorium on such technologies till their safety both to human beings and the environment is proven.

Best wishes,

Mohan Rao

Dr.Mohan Rao
Professor, and Chair
Centre of Social Medicine and Community Health
Jawaharlal Nehru University
New Delhi 110067

From: Rt Hon Michael Meacher MP

020 7219 6461
020 7219 5945 (Fax)

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HOUSE OF COMMONS

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www.epolitix.com/EN/MPWebsites/Michael+Meacher/
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Mr Jairam Ramesh
Minister for the Environment & Forests
Government of India

PS

10 November 2009

Dear Mr Ramesh,

GM Crops

Greetings! I understand that Indian regulators have cleared Bt Brinjal, the first such GM food crop ever in the world, for commercial cultivation and that the Government of India would now take a decision on this GMO, based on extensive consultations that you intend to organise all over the country. I congratulate you on this democratic exercise that you wish to undertake on this important decision. I also saw some earlier reports where you had expressed your views against GM foods - this is indeed a welcome stance, since this is an unpredictable and imprecise technology, even though the industry would like us all to believe otherwise.

As you may be aware, some argue that GMOs as an issue cost me my job as a Minister here in the UK! Over a period of intense engagement on the issue and getting to learn from various experts and stakeholders all the various facets, I have come to the firm conclusion that this technology is not as precise and desirable, as it is made out to be. Further, the solutions for the hunger crisis lie elsewhere (and GM crops may not have a solution to offer but could only exacerbate the situation for many poor producers and others) and this is increasingly becoming clearer for many of us. To me, the best option seems to be great caution with regard to the technology. This is more so where pest management and other solutions for small-holder farmers can be established through alternative, ecological, sustainable technologies, as experiences within India seem to be showcasing.

If India approves Bt Brinjal, the takeover of farming in your country and other countries by seed giants like Monsanto would be near-complete and that is exactly what these corporations are seeking. Bt Brinjal would open the floodgates to many other GM crops and to me, it seems very unwise that pests across crops over millions of acres should be sought to be controlled with the Bt gene-monocultures. In a country which has a vibrant tradition of farmers' knowledge over their production processes and resources as its greatest asset, depending on an unsustainable and unpredictable technology to provide any lasting solutions seems unwise.

Unless long term and comprehensive assessment is taken up, and that too vis-à-vis alternative options are available, and unless liability, redress and remediation regimes are put into place along with labelling systems to ensure informed choices, I urge you not to allow the Bt Brinjal to be tested on Indian people.

Best wishes,

Yours sincerely,

Michael Meacher

Rt Hon Michael Meacher MP
(UK Minister for the Environment 1997 to 2003)

CONSORTIUM OF INDIAN FARMERS ASSOCIATIONS (CIFA

President
Basawaraj Tambake
Secretary General
P. Chengal Reddy

Chief Patron
Dr. K. Raghuvansh Prasad Singh, M
Former Union Minister for Rural Development
Government of India

"Food security first - Farmers welfare must"

December 2, 2009

Hon. Shri Prithvirajji Chavan
Minister for Science and Technology
Government of India.
New Delhi.

Sub : Consortium of Indian Farmers Association (CIFA), New Delhi - 6th National Farmers Convention 2009 – Demands for advance technology for the improvement of Indian Agriculture, request for initiating necessary action.

Respected Sir,

Consortium of Indian Farmers Association (CIFA), New Delhi, conducted 6th National Farmers Conclave on 2nd and 3rd December, 2009. We the farmers and agriculture scientists across the country have met to discuss the glaring problems and the hardship we are facing because of natural calamities, costly inputs, reducing yields, government policies. Our problems are further aggravated by the negative role being played by certain institutions to keep us deprived of recently invented technologies. We would like to draw your attention on following points:

1. **India has the largest acreage under cotton cultivation (about 10 million ha), however our yields are still lower as compared to the global productivity. This is mainly because of large acreages under rainfed area, scarcity of labour, pest infestation, lack of mechanization. The productivity in cotton has atleast improved from 315 kg/ha to 550 kg/ha since the launch of biotechnologically derived pest resistant varieties. (Bt cotton). All cotton growing farmers in India have welcomed this decision of the Government.**

   Out of the above concerns, we can atleast resolve the labour problem by biotechnologically developed **weedicide resistant** cotton. We have been given to understand that worldwide this technology is being used in many more crops like soybean, maize, canola besides cotton.

   Considering the fruits being enjoyed by our farmer friends in the other part of world by this technology, we demand that the same should be made available with immediate effect to us.

2. **We feel that, though our country is known for providing information technology to the whole world, the Indian farmer is being kept away with new technologies related to meteorological data.**

   As we farmers are highly dependent on rainfall, we demand that meteorology information (weather forecast, rainfall forecast) should be made mandatory in all print and electronic

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14/12/09

media. We also demand that block wise information should be forecasted and made available on a regular basis.

3. **Impetus to be given to slow moving research.**

   Increased public-private partnership, reduced time in transferring technology from lab to land, need based research and involvement of progressive farmers in decision making and finalization of research projects to cater the technologies for local conditions.

4. **Time bound regulatory approvals for genetically improved crops**

   Farmers will be benefited at large if the time required for regulatory process is reduced to maximum three years. The biotechnological research in crops like rice, soybean, maize, pulses and vegetables have entered the regulatory system in the country. We demand that these technologies, once found suitable, should be made available to us in the given time frame.

After the success of Bt cotton in India, the farmers are awaiting for one more biotechnologically improved crop Brinjal. Bt brinjal has been released by GEAC after thorough discussion on Expert Committee reports. Brinjal is grown on 5.5 lakh ha and require very high number of pesticide sprays (25-50) which are done biweekly. These pesticide sprays to control the fruit and shoot borer, increases the cost of cultivation to us, health losses to us, our labours and to the consumers.

The Bt technology, which has been introduced in brinjal, will not only save the crop from dreaded pest, but also reduce cultivation cost and will have a positive impact on our health.

Based on the biosafety studies conducted at various public and private premier institutes, the scientific group comprising of the experts, which are virtually the supreme authority in their respective field, have already approved Bt brinjal as safe for environmental release. So, now we demand the release of Bt brinjal for commercial cultivation with immediate effect.

We request your kindself to intervene with the concerned ministries and make sure our demands are aforesaid immediately.

Thanking you,

Sincerely yours,

P. Ch

P. Chengal Reddy
Secretary General

cc: Sh. Vijay Sharma, Secretary, Ministry of Environment & Fore[st]
Paryavaran Bhawan, New Delhi.

Dr. Anbumani Ramadoss
M.B.B.S.
Member of Parliament
(Rajyasabha-Tamilnadu)

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CHENNAI - 600 028

Respected Sir,

19.10.2009

This is about Bt Brinjal, which if approved would be the first ever genetically modified food crop for India and the first ever such GM vegetable anywhere in the world with the toxic Bt gene in it. As you might be aware, the apex regulatory body Genetic Engineering Approval Committee (GEAC) under the Ministry of Environment & Forests has given an environmental clearance to this transgenic vegetable in its meeting on October 14th 2009.

Bt Brinjal in India: This Bt Brinjal has been developed in India by M/S Mahyco, the Indian partner of the world's largest seed company, Monsanto, headquartered in the USA. Mahyco created this new organism, Bt Brinjal, with a bacterial gene inserted into Brinjal so that a new toxin is produced inside the plant, which is toxic to certain pests that feed on the crop (fruit and shoot borer).

India is the Centre of Origin/Diversity for Brinjal: India, with its absence of any policy framework guiding the development of GM crops, allowed this Bt Brinjal development even though we are the Centre of Origin/Diversity of Brinjal. No GM crop has been allowed to be cultivated in any region of the world which is the Centre of Origin/Diversity of that crop. However, India is unwisely moving ahead with the commercial release processes for this Bt Brinjal. There are more than 2500 varieties of Brinjal in this country. This rich diversity which is humankind's heritage will be jeopardized irreversibly with the entry of Bt Brinjal, if it is allowed.

GM & Health impacts: Further, GM foods are known to cause various health effects like allergies, damage to organs like kidneys and liver, effects on immune system etc., and Bt Brinjal can be no exception. The Indian regulatory regime does not require independent research to be taken up before a GM food is allowed and all the research with regard to biosafety of this Bt Brinjal was either done or commissioned by the crop developer. No long term studies have been undertaken either.

Dr. P.M.Bhargava, the nominee of the supreme court in the GEAC and a eminent Molecular biologist himself, has asked for the development of an protocol to ascertain that no alternatives exist for Bt Brinjal, while suggesting a set of other tests to be conducted on Bt Brinjal (that have not been conducted on Bt Brinjal so far), *including extensive DNA fingerprinting and proteomics analysis, reproductive interference, interaction with commonly used drugs like probiotics, effects on human, animal GI microflora and chronic toxicity studies.*

Post this decision on the committee, he has expressed his disappointment at the hasty decision of the committee and the manner in which the committee had arrived at its decision.

Agrarian crisis in India and GM: Many analysts point out that the current agrarian crisis in India shows that farmers have been pushed into 'treadmill' technologies and are entrapped into these unsustainable technologies which are expensive, erode productive resources, leave toxic impacts on people and other life forms and make farming unviable. GM is no solution and in fact, it will make things worse for farmers and consumers.

Log -1366587

Dr. Anbumani Ramadoss
Member of Parliament M.B.B.S.
(Rajyasabha-Tamilnadu)

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Need assessment for Bt Brinjal: Bt Brinjal has not been assessed for its very need. No one can claim that it is to address food security concerns, for instance. It is not clear why we need Bt Brinjal when safer, affordable, sustainable and farmer-controlled alternatives exist for pest management. These ecological solutions have to be extended to farmers all over the country.

Consumer choices violated: If Bt Brinjal is approved, consumer choices will be violated forever. They will have no way of knowing whether the Brinjal that they are consuming is GM or not since all brinjals will look the same in the market. This will be a violation of their right to know, right to safe food and right to informed choices with regard to food.

The Food safety and standards authority which has started functioning since 2008 is still however to bring in rules regarding labelling and penalising contamination.

State governments' authority over their agriculture: Given that state governments have an authority over Agriculture and Health (state subjects) and given that states like Kerala and Orissa do not want such crops to be introduced, the Government of India should not be taking any steps that violates this constitutional authority vested with state governments.

The Indian regulators and their decision on Bt Brinjal: Reports indicate that the regulatory processes adopted including the Expert Committee's constitution, its mandate and its processes are questionable.

Adequate discussions have not been conducted on the issue of safety and socio economic issues by this expert committee The Ministry of Health and Family Welfare and the Food Safety and Standards Authority in this committee had not taken the issue seriously which pertain to the health safety of India.

The impact of Bt Brinal on the efficacy and pharmacology of the Brinjal varieties which are used in the traditional medicinal system of Siddha and Ayurveda needs to be assessed. These medicinal systems are our wealth and Heritage and if Bt Brinjal affects the pharmacology of these medicinal preparations then, it is should not be allowed.

The GEAC is reported to have taken only some hours from the time of circulating the Expert Committee report to its decision clearing Bt Brinjal for release.

There is clear reason to believe that the report based on which the GEAC gave its clearance is fraught with questions and decision-making based on this is unacceptable.

Dr. Anbumani Ramadoss
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Member of Parliament
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At this juncture, India could do well to remember that more and more regions across the world are actively prohibiting GM crops and are declaring themselves GE-Free as more experiences of GM crops unfold around the world and more studies emerge.

Given all the above, while I was the Union Minister for Health & Family Welfare, I had opposed the entry of GM foods in the country, keeping the interests of farmers and consumers in mind.

Even as the Minister for Environment & Forests is taking a view on Bt Brinjal, going through reports and plans to hold a consultative process in the first couple of months in 2010, it is desirable that the UPA government take a precautionary approach in this matter and put a moratorium on all GM crop environmental releases for at least ten years until all pending issues are resolved and questions answered.

With warm regards,

Yours,

19/10/09

(Dr.Anbumani Ramadoss)

To

Dr.Manmohan Singh,
Prime Minister of India.
New Delhi.

Shri Jairam Ramesh 18-1-2010
Minister for Environment and Forests
Govt of India. New Delhi

National Consultation on Bt Brinjal at Ahmedabad on 19-1-2010

Name : Smt Dilnavaz S Variava
Age : 66 years
Address : 2401 Crescent heights, Dr V M Naik Marg, Mumbai 400 036 email dsvariava@gmail.com

Occupation : Management Consultant. Over 35 years of professional and voluntary work on environmental, agricultural and rural development issues, as follows :

ENVIRONMENT : Chief Exec of WWF-India from 1973 to 76.

BNHS Exec Committee member for 30 years (1979-2009) and Vice Pres for 15 years.

IUCN Education Commission member and Consultant to Protected Areas Commission

Member, GOI Committees: National Com. for Environmental Planning & Co-ordn.

The National Conservation Strategy Committee, the National Board for Wildlife and its Steering Committee, Planning Com Expert group on Hill Area Development.

Co–author, Management of National Parks & Sanctuaries in India. Pub. by IIPA

Hon Co-ordinator, Save Silent Valley Committee, Mumbai.

AGRICULTURE : Chair, Working Group on the Ecological Foundations for Sustainable Agriculture,

Govt. of Maharashtra Expert Committee on 25 Year Action Plan for Agriculture.

A Founder of Agrivision Coalition. Over 200 NGOs and individual representatives.

Mg. Trustee, Sahayak Trust, doing rural education in Pune Dist and Vidarbha.

President, Saraswati Educ Society, running schools in Nasik Dist for rural children.

Chair, Organic Farming and Rural Dev.Com , Rotary Club of Bombay (2005-08)

Views and Opinions about Bt Brinjal in India

ENVIRONMENTAL IMPACTS:

1. The complexity and inter-relatedness of species within ecosystems is such that the prediction of impacts from human interventions cannot be made with certainty, nor can the time frame within which the impact will escalate be predicted. The precautionary principle is therefore paramount in giving clearance to any major or widespread intervention.
2. Historical evidence is abundantly available of the unintended impact on valuable natural ecosystems from planned or unplanned introduction of exotic species . Despite its best efforts the Forest Dept has been unable to eradicate even the relatively limited introduction of highly visible species such as lantana, parthenium (congress grass) and prosopis juliflora from even the limited and invaluable areas of national parks and sanctuaries. There are virtually no forest areas – including our national parks and sanctuaries – which are free of agriculture both inside their boundaries and around their boundaries.

3. While Bacillus thuringiensis is a naturally occurring bacterium, and pesticide manufacturers had used this justification for the preparation of various 'benign' pesticide formulations, its ill effects have become increasingly visible. These ill effects will be magnified manifold as the Bt gene is inserted into seeds which will be widely distributed across the country.
4. The impact of Bt documented in different parts of the world and briefly collated by Swadener in the Journal of Pesticide Reform v.14, n.3 Fall 94 indicates the ill effects that had manifested in respect of impacts on wild species by Bt pesticide sprayings. (See annexure1) The impact on wild species from the insertion of the Bt gene is likely to be as great or greater than from spraying as seed is distributed over far larger areas and since the toxicity of Bt manifests in every part of the plant ie root, stem, leaf, flower etc.
5. These negative impacts as documented in various countries can be substantiated from a list of studies that can be provided if required by you. The impacts include the following:
    a. Non target beneficial insects ie those that control agricultural pests or help in pollination are themselves destroyed, as has been found with bees and lacewings elsewhere.
    b. Ecosystems are disrupted as a variety of insects are killed by the Bt toxin, and the populations of other species which feed on them, such as birds, fish, amphibia, small mammals etc, are also destroyed.
    c. Bees and other pollinators can carry the genes to wild species, with unpredictable effects.
    d. Soil bacteria in agricultural fields have already shown the negative impact of Bt cotton and other crops in various parts of the world as Bt toxin is exuded from the roots into the rhizosphere, where it binds to soil particles and is protected from degradation, killing beneficial bacteria. The foundation of all ecosystems are the soil bacteria and microfauna. Though out of sight, they should certainly not be out of mind.
    e. Resistance to Bt by insect pests has been known to develop in relatively short periods, making the whole purpose of the genetic modification meaningless if the species it is meant to target becomes immune to the effect of the toxin, thereby necessitating the spraying of pesticides which was the sole justification of the insertion of the Bt gene in the first place. Studies have shown that in the case of Bt cotton, resistance by the bollworm manifests after a few years. The US Environment Protection Agency is recommending farmers should plant upto 40% non-GM crops in order to create refugia for non resistant insect pests. In India, with such small holdings, the whole concept of refugia becomes difficult to implement once a farmer has decided on Bt crops.
    f. The experience from all parts of the world from China to Australia, and including India, is that after the introduction of Bt seeds, there has been an emergence of severe infestations of secondary pests such as jassids, mirids, thrips - and even new pests like giant mealy bugs – all of which necessitate sprayings of as much pesticides, or more, than before the use of Bt seeds.
    g. The abnormal occurrences of sheep deaths, and livestock abortions, as reported in Andhra Pradesh and Maharashtra after feeding on Bt cotton residues has been brushed aside unconvincingly. Studies in different areas have shown deaths as high as 25% of the population of sheep grazing exclusively in Bt cotton fields.This has serious implications for possible impacts on other species, both domestic and wild, which will feed on any part of Bt brinjal.
    h. Aquatic insects have also been affected by Bt treatments and this, in turn, can have long term impacts on fish, amphibia and other parts of the food chain.

i. A drastic loss of Agrodiversity is the first consequence of corporate giants promoting GM seeds, as their commercial interests require that the agro-input distribution network and agricultural universities phase out local varieties.
j. India has been widely accepted as the Centre of Origin of brinjal, which is now being assiduously undermined by Monsanto and its licencees. In any event, India is undoubtedly a leading Centre of Diversity with about 2500 varieties of brinjal. It is a serious blow, and not done, to introduce a GM crop in its Centre of Origin/Diversity.

Conclusion on Environmental Impacts : The introduction of GM seeds will inevitably impact wild ecosystems in ways that will be more insidious and fatal to wild species than the earlier accidental and limited introductions of exotics. The removal of these impacts will be well nigh impossible due to the speed and range of spread of GM agriculture as promoted by seed companies. Ministry of Environment clearance to such technology would be a clear breach of its mandate for "conservation of the country's natural resources including its lakes and rivers, its biodiversity, forests and wildlife, ensuring the welfare of animals, and the prevention and abatement of pollution."

HUMAN IMPACTS

Since the Ministry's mandate states that "While implementing these policies and programmes, the Ministry is guided by the principle of sustainable development and enhancement of human well-being" let us see whether Bt Brinjal will enhance human well being - or the opposite.

Since over 60% of India's population is engaged in agriculture, the impact of Bt brinjal on Indian farmers is the first consideration.

1. Over 60 % of farmers are in rainfed areas and 80% are small and marginal farmers
2. Successive studies in Maharashtra have concluded that indebtedness arising from high input cost agriculture was a major cause of farmer suicides. (eg Reports by Tata Institute of Social Studies (TISS) by the international Institute of Science in Society (SiS) and by our Working Group which was part of the Govt of Maharashtra's Expert Committee for an Agriculture Action Plan)
3. The incidence of farmer suicides is highest in Vidharba, which also has the highest adoption of Bt cotton. Although direct correlations are difficult to establish, the rate of farmer suicides has increased after the adoption of Bt cotton – which requires high doses of fertilizers and assured water availability.
4. Farmers are dependent on agents of fertiliser and pesticide companies for advice on seeds and crop care. A false perception of prosperity is being created in the minds of the cultivators that prompt them to take serious risks in terms of fertiliser-based cropping pattern. (from NABARD report summary of TISS findings).
5. Even a 6% increase in GM crop production would lead to a doubling of chemical fertilizer consumption, as attributed to the Chair of India's Agricultural Scientists Recruitment Board. The huge adverse impact on farmer indebtedness, and fiscal subsidies, is clear.
6. The use of pesticides, after the initial 2 to 7 years, have been found in various reports and studies, to equal or be higher than before Bt was introduced, eg due to the rise of sucking pests and pests developing resistance. The emergence of new insect pests has been recorded by enotomologists after the introduction of Bt cotton. The same companies that supply Bt cotton and Bt Brinjal are major manufacturers of pesticides.

7. The introduction of Bt cotton has led to the disappearance of thousands of hardy traditional varieties as Bt seed companies have ensured that non Bt seed is squeezed out of the market , and seed distributors have in any case found the high margins of high cost seeds which require heavy inputs of chemical fertilizers more profitable. The Govt machinery has also contributed to promoting Bt seed and stopping supply of other seed.
8. The loss of agrodiveristy is not only an unacceptable loss of choice to be inflicted upon the poorest sections of society, but also has major consequences in terms of availability of disease resitant gene pools. In the case of rice, a rice famine was prevented when a primitive cultivar from near the Silent Valley in Kerala was the only variety that could supply the necessary gene for the attack by the brown plant hopper in different parts of the world. Eventually the control of germ plasm will move from traditional farmers into the hands of corporate agro-input providers leading to a serious threat to national food security and to food security for those who cannot afford high input cost agriculture.
9. Farmers in Maharashtra, and the families of suicide victims, have reported to independent persons their anguish at the highly misleading statements of yields by suppliers of Bt seeds, which induced them into debt, leading to suicide. Cotton farmers have been left with virtually no choice of non Bt seed after the introduction of Bt cotton, and are now abandoning cotton and moving to soya in large numbers.
10. The depletion of soil bacteria has been documented which will progressively lead to deterioration of soil health, fertility and productivity.
11. The occurrence of the devastating attack of red wilt or 'lalya' and consequent drop in cotton yield has been attributed to the depletion of micronutrients and soil moisture in Bt cotton cultivation, accentuated by the simultaneous fuition of bolls which puts sudden drain of soil nutrients.
12. There is every reason to believe that the introduction of Bt Brinjal will have the same highly adverse effects on soil quality, energy and water resource consumption, farmer indebtedness, loss of agrodiversity and farmer choice, loss of national self reliance and food security. This has been seen by some State Govts, and they have already conveyed their objections.
13. About 30% of India's brinjal cultivation is in Bengal, where over 90% are small and marginal farmers. I understand that the Chief Minister of Bengal has already expressed to you his opposition to the introduction of Bt Brinjal due to its impact on agriculture and biodiversity. The main brinjal pest is the Fruit and Shoot Borer. There are a large number of ecologically sound and low cost systems for controlling this pest . This information should be widely disseminated. (See www.takingroots.in) The introduction of a GM food to control this single pest in a crop of which there is abundant supply and which is not central to India's food security is literally a case of unwarranted over-kill.
14. The impact on human health will emerge with time, as it has in the case of pesticides and tobacco smoking , where also large corporates were able to stall for years the disclosure of truth by slapping huge law suits for damages on independent NGOs and individuals who tried to expose the truth to the public. Exactly these tactics have been adopted by Monsanto and other harmful agro-input providers. I will not go into the exact nature of currently assessed health impacts as there will be others more competent to do so.

NECESSITY FOR Bt BRINJAL INTRODUCTION AND ALTERNATIVES

With the above adverse impacts, and State Govts also opposing the introduction of GM crops and Bt Brinjal, the hand of the Minsitry of Environment is strengthened in fulfilling its mandate to reject the introduction of Bt Brinjal which is detrimental to the environment. The burden of proof must be on the propnents of Bt Brinjal to prove that such overwhelming "principle of sustainable development and enhancement of human well-being" is involved that the Ministry is ignoring its primary mandate and obligation to the people of India to clear a product that is clearly potentially disastrous for ecosystems and wildlife conservation, for agro and bio-diversity, and for the health of consumers. The precautionary principle must apply in all domains prior to release of Bt brinjal or any other transgenic crop, and more so in the case of food crops it is necessary to proceed on the basis of utmost care prior to release and not proceed on the basis of substantial equivalence.

Is the introduction of Bt Brinjal an overwhelming necessity for human well being and sustainable development. The Chief Minister of the largest brinjal producing state has clearly said that it is not. So also the Chief Ministers of Kerala, Uttaranchal, Sikkim etc. have opposed GM.

As the Chair of the Govt of Maharashtra's Working Group on The Ecological Foundations for Sustainable Agriculture constituted as part of its High Level Expert Committee for 25 Year Action Plan for Agriculture in Maharashtra, the conditions in Vidharba were studied by our Committee. It emerged clearly that amongst the reasons for severe indebtedness leading to farmer suicides was the promotion of agriculture based on high input costs, leading to high debt and high risk in the event of failure of rains. This has also been found by the Tata Institute of Social Studies (TISS) in its report to the Bombay High Court on farmer suicides.

Our findings, and also those of TISS, were that organic farming needs to be promoted as it depends on labour and skills and does not require debt, it is invariably based on multi-cropping reducing thereby the risks of failure of a single crop, it invariably has some food crop components thereby assuring some food security to the family, it increases soil moisture and reduces water requirement, above all it enhances rather than depletes soil fertility – making its productivity sustainable.

There are no known cases of farmer suicides amongst organic farmers in Vidharbha even as the chemical and Bt seed farmers set national records for suicides. In a study by Dharamitra with 400 farmers , the net incomes of organic farmers who were taught good sustainable agriculture practices were as much as 85% higher and within 3 years the yields were comparable or higher. The work in Andhra Pradesh by CSA the Centre for Sustainable Agriculture , is even more dramatic and heart warming. More than 3 lkah farmers in 18 out of 23 districts of Andhra Pradesh have discarded intensive chemical farming systems, said NO to Bt and other GM seeds and covered over 14 lakh hectares with ecoliogically sound and economically viable sustainable agriculture in areas which reflect the typical conditions of small and marginal farmers in rain fed areas.

IAASTD report of 4 years of investigation by more than 400 scientists from over 60 nations ,(a unique collaboration of the World Bank, FAO, UNDP, UNEP, WHO and representatives of governments, civil society, private sector and scientific institutions) indicates that GM crops are highly controversial and will not play a substantial role in addressing the challenges of climate change, loss of biodiversity, hunger and poverty. Instead, small-scale farmers and agro-ecological methods are the way forward; with indigenous and local knowledge playing as important a role as formal science.

In fact, organic farming and sustainable agricultural practices are based on highly scientific principles even though the proponents themselves may not be able to couch their knowledge in conventional scientific terms. They are based on accurate observations and interpretations of highly complex inter-relationships and what is needed is a partnership between agricultural scientists and practitioners of sustainable agriculture to systematically document in scientifically acceptable terms the path to agricultural prosperity . The corporate interests have , on the other hand, used questionable science to promote their own interests and, unfortunately, co-opted large parts of the scientific establishment in this process. There are however landmark scientific studies in India and abroad which have documented the sustainably high yields that can be achieved without the unacceptable ill effects of genetic engineering at its current stage of development.

As Minister for Environment this is a finding which I am sure you will welcome, for it promotes the conservation of wildlife, it spells the survival of biodiversity and agrodiversity, it gives enough reason to refuse to release a technology which is wholly un-necessary and harmful to humans and environment and where lakhs of farmers have demonstrated that far better options exist. In fact unleashing Bt foods will destroy a huge potential advantage that India has to be a supplier of the high value organic produce that western countries are hankering for, and are willing to buy at highly remunerative prices, apart from providing nutritious food and income security to the Indian farmer, which must be the paramount concern of any responsible democratic government

I would like to end by expressing my appreciation of the process of consultation that you have initiated and trust that you will be able to play a historic role in halting the release of this wholly unnecessary and potentially dangerous transgenic crop.

Thanking you

Sincerely

D S Variava

BHARAT KRISHAK SAMAJ

(Farmer's Forum, India)

President: Ram Niwas Mirdha
Chairman: Ajay Jakhar

December 24, 2009

Shri Jairam Ramesh,
Minister of State (Independent Charge) of the
Ministry of Environment & Forests,
Government of India,
New Delhi

Dear Shri Jairam Rameshji,

The Bharat Krishak Samaj (BKS), which was founded in 1955 & is the premier association of farmers with a membership of above 1,00,000 Kisans'. It has branches in across the country. It is a non-political, non-sectarian organization which provides a open forum for Farmers, Governmental officials, Agricultural research workers, businessman, extension and marketing experts, members of legislature - in fact all men and women who are interested in strengthening the agricultural economy of the country. The first National Convention of the BKS was inaugurated by the Pt. Jawaharlal Nehru the then Prime Minister of India. The monthly journal of the Samaj "KRISHAK SAMACHAR" publisned in Hindi and English is mailed every month to about 30,000 Life Members.

GEAC, appointed by the Ministry of Environment and Forests has recommended introduction of Bt Brinjal for commercial cultivation after many years of testing. UN organizations FAO & WHO also EU funded EFSA, private trusts like Rockefeller Foundation (which funded Norman Borlaug who helped kick start Green Revolution) and Bill & Melinda Gates Foundation all support GM crops.

BKS was skeptical about the technology many years ago when BT Cotton was first introduced in India & we said so. But the spectacular success story of BT Cotton in India over last 7 years has overwhelmed us to ask you not to delay your decision anymore.

All new ideas face opposition. That is how it has been & will be in future. You must not buckle under pressure from groups of people who have easy access to & use fax and email, unlike the farmers in India today.

Application of Transgenic technology has led to reduced use of chemical & pesticides. This will help in mitigating soil deterioration & environmental pollution. Will also help ensure food security & sustainability. As farmers, we support agri-biotechnology.

Bharat Krishak Samaj requests you to take a positive decision on the recommendations of the GEAC at the earliest.

Thanking you and awaiting your response,

Yours sincerely,

Chairman
Bharat Krishak Samaj

Office of the Minister of State For Environment & Forests

29/12/09

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Brief Note on

Bt Brinjal: Careful Scrutiny is Needed

SUBMITTED BY
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TO

SHRI. JAIRAM RAMESH
HON. UNION MINISTER FOR ENVIRONMENT & FORESTRY
GOVERNMENT OF INDIA. NEW DELHI

(22 JAN 2010; HYDERABAD)

Background

1 Our farmers obviously need new technologies coupled with a favorable public policy support in order to make agriculture as productive and profitable as in any advanced country. China is a classic example to demonstrate how public sector research system could able to develop advanced biotechnology-based technologies such as hybrid rice, Bt cotton, recently released GM rice and GM maize.

2 In our country, it is unfortunate that public sector research, which has

got high reputation until mid 1990s, but has yet to develop such advanced biotech-based crop varieties for our farmers. Instead, we are increasingly depends upon private sector-especially MNCs for these hi-tech crop varieties. In this process, MNCs are trying to make quick money by releasing GM crop varieties in a hasty manner without full-proof scientific evaluation of GM crops.

3 It is important to note that advance science is essential for future growth in agriculture. One should not oppose any such advance well-proven technologies as long as it is evaluated/tested/developed in scientific manner with scientific spirit and useful for the society.

4 It is highly danger to solely depend upon private sector-especially MNcs for such advanced technologies in the absence of strong public sector technologies. In China, private sector GM crop hybrids/varieties are allowed only after China's public sector also developed and resealed GM crop varieties in order to have a fair competition and also avoid monopoly and exploitation by private sector.

5 Bt Brinjal hybrid of Monsanto-Mahyco is one such GM food crop that is being approved by Govt of India's GEAC a couple of months ago amidst widespread apprehensions on health and environmental consequences of Bt Brinjal.

6 In this context, the following three key issues may kindly consider while taking final decision on approval of Bt Brinjal viz., *is there a real need for immediate release of Bt Brinjal hybrids?; what are the apprehensions on Bt Brinjal hybrids? And how to go ahead with Bt food crops?*

1. Is there a real need for immediate release of Bt Brinjal hybrid?

1 Brinjal is originated in India five thousands of years ago. It is grown in about 5 lakh hectares (about 9% of total Vegetables area) producing about 90 lakh tones in India. In Andhra Pradesh, it is grown in only 30, 000 hectares producing 6 lakh tones every year.

2 There are hundreds of high yielding varieties and hybrids developed by ICAR and state agricultural universities and some domestic seed companies, which are widely grown by farmers.

3 However, most of the Brinjal farmers are small and grow in less than quarter acre in many parts of the state.

4 Further most of the consumers prefer local small-sized brinjal because of taste. Except a few commercial vegetable growers in urban areas, most of the Brinjal farmers do not use much pesticide/other chemicals.

5 Brinjal is one among many many vegetables grown in our country under diversified conditions. \

6 Thus in view of widespread concerns from various stakeholders, pt is ideal to concentrate on rigorous scientific evaluation of Bt Brinjal especially on health and environmental risks, and establish its scientific acceptability and economic superiority before considering for the commercial release.

2. What are the serious apprehensions?

1 The present composition of GEAC has created a lot of concerns about its mechanism, methodology and approaches on evaluation, testing and approval procedures being adopted for GM crops. Because of lack of full-proof transparent mechanism of GEAC, many apprehensions are arising on scientific rationale of GEAC functioning on GM crops.

2 First and foremost apprehension is that the long-run health impacts of Bt Brinjal. So far all other GM food crops such as Corn, Sunflower, Soya, Canola, etc. grown in various countries are consumed in indirect manner either through animal feed or processed food. But in case of Brinjal, it is directly consumed vegetable.

3 No global agencies such as WHO, FAO, and WFP have endorsed Bt Brinjal for direct consumption. That's why no country in the World including China-that produces 30% of global brinjal output gave approval for cultivation.

4 As farmers have to replace seed every year in case of Bt Brinjal hybrid, small farmers are likely to be exploited by MNCs and destroy the conventional seed system in the absence of new seed policy framework.

5 As per some scientific studies, cultivation of Bt Brinjal may effect soil microbial organisms thereby lowering soil fertility status over the period. This aspect has to be further scientifically studied.

3. How to go ahead with GM crops?

1 As we need hi-tech technology for our farmers, Union Government should focus on strengthening public sector research system (in ICAR, and State Agricultural Universities) like in China to develop and release scientifically proven GM crop varieties in order to have a fair competition with MNCs/private sector and avoid exploitation of farmers.

2 The GEAC should be completely revamped in order to have a full-proof transparent and scientific mechanism for evaluation, regulation, and monitoring of GM crops. Unless this is done, stakeholders will not have a confidence on the present GEAC's approaches being adopted for granting approval to GM crops.

3 It is requested the dynamic Union Minister Shri. Jairam Ramesh to revamp GEAC on priority basis in view of widespread concern of GEAC's functional mechanism.

4 Although there has been tremendous change in the domain of seed system especially after entry of MNcs during post WTO era, government of India has not yet come up with any seed policy after 1967 policy despite several seed review committees were set up. As release of Bt Brinjal hybrid open gates for many GM food crops of private sector-origin especially of MNCs in India, Union Government should immediately formulate New Seed Policy incorporating legal, scientific and governance frameworks of such hi-tech and risky GM seeds. It is not ideal for government to allow GM crop seeds without having any seed policy governing all issues of GM crops. Until new such seed policy announced, no immediate decisions should be taken on GM crop seeds and also without clearing all concerns of the stakeholders.

5 Rigorous long term experiments on effect of Bt Brinjal on health and environment should be conducted (6 to 8 years) by independent advance research institutions and establish scientific evidence before releasing to the farmers.

6 Let of us think serious why China and other countries did not approve Bt Brinjal, and Why any developed country like EU nations, USA, etc are not consuming GM foods, but they allowed to produce GM foods only for export/food aid to other poor nations-especially in Africa.

COMMENTS

Should the Bt Brinjal controversy concern healthcare professionals and bioethicists?

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Abstract

The Genetic Engineering Approval Committee's approval of Bt brinjal, the first genetically modified crop for human consumption in India, has sparked off protests across the country. This article questions the so-called benefits of GM crops and highlights some major concerns. These include: inadequately addressed health and environmental risks, inadequate safety guidelines, a lack of transparency in sharing test data, the implications to seed sovereignty of farmers and the lack of informed choice for consumers. Some concerns about field testing by Mahyco, the developer of Bt-brinjal, and the process of evaluation by GEAC remain unresolved. With inadequate information about the crop's long-term safety, a precautionary approach is advocated before national policy allows commercial release of the seeds. A fair process is also needed in the public consultations being proposed by the minister of state for environment and forests. In addition to issues of procedural justice, a basic ethical question remains: do humans have a right to dominate the land and make expendable those creatures that they deem "undesirable"?

On October 15, 2009, the Genetic Engineering Approval Committee (GEAC) of the ministry of environment, the regulatory body for approving genetically modified crops (GM crops) in India, approved Bt brinjal, the first GM crop for human consumption in India, for commercial use (1,2). The approval came following the review of reports submitted by the Maharashstra Hybrid Seeds Company Limited (Mahyco), the Indian subsidiary of the US-based company Monsanto, that uses biotechnology to produce high yielding, pest resistant crops. The Tamil Nadu Agriculture University and the University of Agricultural Sciences, Dharwad, were partners of Mahyco in the development of Bt brinjal.

Bt Brinjal is a genetically modified plant in which a gene from the soil bacterium bacillus thuringensis is inserted into the genome of the brinjal, which can then produce a protein, Cry1Ac. This protein behaves as a toxin against the shoot and fruit borer (SFB), a pest that commonly affects brinjal. The gene modification also includes the addition of two antibiotic resistance marker genes.

Some media reports have been upbeat about the GEAC's approval (3), but the decision also sparked off protests. Environmental and health concerns were cited that extend to other GM crops in the pipeline like GM tomatoes, GM potatoes, GM cabbage, etc. Doubts have been raised about the science used in the technology as well as the interpretation of biosafety tests. The GEAC's decision needs to be ratified by the minister of state for environment and forests, Jairam Ramesh, before it becomes policy. Mr Ramesh announced that a series of consultations with scientists, agricultural experts, farmers' organisations, consumer groups and non-governmental organisations would be held in January and February 2010 before a final decision is taken in March 2010 (4). It is unclear whether healthcare professionals will also have a voice in these consultations.

The ethics of gene manipulations in the animal and human reproductive sciences, their clinical applications, and the impact on people's aspirations and life choices have been debated extensively by the healthcare professions. Genetic interventions in the food that we eat also affect our health, aspirations and life choices. As a healthcare professional concerned with bioethics, I decided to explore this controversy. Numerous and diverse issues emerged as I explored.

Why GM foods?

GM foods have been projected as a solution to world hunger, crop failures and farmer suicides. GM foods are promoted with the claim that they increase yields and reduce pesticide use, which benefits farmers, consumers and the environment (5).

Indeed, many studies demonstrate that GM crops like Bt maize and Bt cotton produce higher yields (6,7). However, it has been argued that such claims are blown out of proportion as the Bt toxin is basically an insecticide, and insecticides cannot increase yields, only reduce losses. It has also been argued that farmers have shown equal or greater yields with high-yielding native (non-GM) seeds and a careful planning of the season and location for planting (8). GM crops cannot even claim to address world hunger, which is due not to a lack of food, but to the fact that the poor do not have buying power. Finally, US studies indicate that pesticide consumption is low only in the first three years, after which its use has actually increased by about 4.1% in farms with GE varieties (9,10).

What are the concerns about GM food?

A number of concerns regarding GM foods have been inadequately addressed: the risk that they pose to people's health and the environment, the inadequate guidelines for assessing safety, the lack of transparency in sharing data related to safety testing, the implications for farmers' seed sovereignty, and the lack of informed choice for consumers.

Any gene manipulation involving the insertion of foreign DNA sequences into a plant genome can cause disruption, silencing or modification of the expression of existing genes. Some effects may be anticipated. Others may come as a complete surprise (11). It is worrisome that Mahyco has overlooked public communication about the potential risks in this technology.

Risks to health and the environment

Mahyco plans to extend Bt brinjal to nearly 50% of the acreage under brinjal cultivation in India (5). Environmental activists and farmers are concerned that gene migration can result in contamination of other crops; resistance can develop to the Bt toxin, which would result in an increased use of pesticides; soil may get contaminated with this increased pesticide use, and weeds resistant to the Bt toxin may emerge (12). Since 2002, three public interest litigations have been filed seeking a moratorium on GM crops (13). Mahyco's strategies for resistance management, submitted to the GEAC, are vague and not reassuring (14).

The gene transfer in Bt brinjal involves two antibiotic resistance marker genes for resistance to Kanamycin and Streptomycin. These are important drugs among the very few that we have in our armamentarium against tuberculosis. Mahyco states that these genes need a bacterial promoter for their expression, which would not be present in Bt brinjal (13). However there is a possibility that these genes can spread to other pathogenic bacteria by horizontal gene transfer and become active (15,16).

Some media reports record allergic symptoms and toxic reactions in both humans and animals after exposure to Bt cotton (17,18). Laboratory studies also show that the Bt protein has immunogenic and adjuvant capacities (19).

The testing requirements for GM crops are more lax than those for drugs. Drug trials are conducted in five stages, with the first stage, known as pre-clinical studies, involving only animals. Safety and efficacy issues in humans are addressed in the remaining phases (20). Government guidelines (21) for research in transgenic seeds or plants only require toxicity (with testing periods of 14 to 90 days) and allergenicity tests (with testing periods of 14-37 days).

It is surprising that regulations for a product meant predominantly for human consumption do not insist on human trials. Though the guidelines state that information related to toxicity and allergenicity to both humans and animals must be generated by the developer (18), Mahyco's toxicology studies have been performed only on animals and are therefore equivalent only to the pre-clinical studies that are prescribed for drug trials. Save a test that demonstrates that the toxin is undetectable within one minute of cooking, there are no other tests that demonstrate the safety of Bt brinjal for human consumption. It must be noted that Bt tomatoes and Bt cabbage (currently under development) would often be eaten raw. It is estimated that a kilogramme of Bt brinjal would contain 5-47 mg of the toxin, 100 times the minimum inhibitory concentration (MIC95) for the pest larvae (13).

The safety assessments done so far cannot exclude the possibility that humans may develop resistance to antibiotics, allergies or biochemical abnormalities due to the toxin. A number of reputed scientists have expressed concerns about GM foods (22). Jeffrey M Smith's *Genetic Roulette* (23) has a long, fully referenced list of the health risks of genetically engineered foods.

Was there research misconduct?

Some science organisations have alleged that appraisals of the Mahyco-Mosanto safety dossiers by independent scientists indicate that there has been incomplete disclosure regarding the bio-safety test results (24, 25). A French scientist, Gilles-Eric Seralini of the Committee for Independent Research and Information on Genetic Engineering, reviewed the safety dossiers. He discovered that safety tests found significant differences between GM and non-GM brinjal. But these differences were deemed biologically irrelevant and not investigated further. Seralini has also stated that some of the testing protocols are inadequate or invalid (22).

Was there conflict of interest?

Several NGOs had opposed the GEAC decision, in 2006, to appoint Deepak Pental, vice-chancellor of Delhi University, as chairperson of the 13-member expert committee on Bt brinjal (26). He was a known promoter of GM crops, he was working on GM mustard and his university was undertaking the same system of biosafety testing followed for Bt brinjal; the committee's recommendations would have a bearing on his own project. Also, at least three other members of the committee were actively involved in testing and developing other GM crops or were associated with biotech companies (27, 28). These commercial interests may have compromised the approval process.

A second expert committee (EC II) was constituted by the GEAC in January 2009 and submitted its report to GEAC on October 8, 2009 (29). The GEAC's approval took only six days and was not unanimous. Three members are reported to have expressed concerns and did not want the approval to be passed (1). Pushpa Bhargava, the only independent expert on the GEAC, a special invitee due to a Supreme Court ruling, is reported to have said that the safety assessment was not complete and noted that the regulators had not asked for an independent validation of any of the test reports submitted by Mahyco. However, his views were not supported by the GEAC.

Implications for farmers' seed sovereignty

Bt brinjal was developed by transforming the brinjal proprietary line of Mahyco, which will therefore own all Bt brinjal seeds. The company is awaiting a patent for its technology (5). Seeds for GM crops have to be bought from Mahyco and their franchisees, at the price set by them, which is a threat to the seed sovereignty of Indian farmers. The high seed cost will surely outweigh any advantage of reduced pesticide use. Farmers in Andhra Pradesh have already protested against the exorbitantly high price levied for Bt cotton seeds (30) -- Rs 1,800-2,000 for 450 gm of Bt seeds, compared to Rs 450 for non Bt hybrid seeds. This amount includes Rs 1,200 as royalty to Monsanto. This is a major concern, given the credit constraints of Indian farmers.

Bt cotton hybrids require more water than the traditional varieties (31). In a predominantly rain-fed agrarian economy, high water requirements may destroy many GM crops as well as deplete already scarce ground water sources.

Implications for people's informed choices

Currently, there are no procedures to ensure that GM foods are labeled as such. When these foods are put on the market, people who would like to avoid GM food cannot exercise their informed choice.

Is there a need for precaution?

Genetic technology in the food industry has uncovered many exciting possibilities, but we must ensure that they are indeed safe and will not spring any surprises in future. We must pay heed to past lessons. DDT pesticide, promising in its early days, is now viewed as a major environmental pollutant and the UN is now considering banning it (32). The much hailed Green Revolution has caused irreparable damage in some regions (12). Since GM seeds will be released widely for agriculture, it is important to consider their effects on the integrity of complicated ecosystems and delicate biospheres. It may actually be impossible to reverse the changes that will occur in the environment.

India is a party to the Convention of Biological diversity (33) and the Cartagena Protocol on Biosafety (34). The Protocol is based on the Precautionary Principle which states that "When an activity raises threats of harm to human health or environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically." The Protocol also states: "Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk;". The brinjal is an indigenous Indian crop with maximum genetic diversity. The Cartagena Protocol calls for extreme caution in introducing GM crops to countries which are the centres of origin for the non-GM varieties of those crops. In view of the seemingly irreconcilable concerns about the biosafety of Bt brinjal, would there not be justification to plead for a more precautionary approach?

In addition to concerns about safety, there is a basic ethical issue here. Do humans have a right to dominate the land and make creatures that they deem "undesirable" expendable? Is an industrial, commercial and profit-driven civilisation our goal?

The Bt brinjal controversy has elicited a very polarised and emotional debate between those for and those against the technology. Jairam Ramesh has an important responsibility to ensure a fair process in the consultations, including issuing advertisements, making documents available to the public for commenting and holding hearings in an empowering spirit. Civil society organisations too have an important responsibility to participate actively in the consultations and ensure that India's policy on Bt brinjal encompasses economic concerns, environmental health, people's health and choices.

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Was the Gadchiroli trial ethical? Response from the principal investigator

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In 2007, Oxford University Press published a book titled *Ethical issues in international biomedical research: a casebook* edited by James Lavery and others (1). One of the case studies presented by the editors and discussed by two discussants, Zulfiqar Bhutta and Marcia Angell, is titled 'Evaluating home-based treatment strategies for neonatal sepsis in India'. This case study is about the field trial of home-based neonatal care (HBNC) conducted in Gadchiroli, India by us (2). Earlier, Prof Anthony Costello from the Institute of Child Health, London (3) and now Sadath Sayeed from Boston (4) have put forward some facts and arguments about the ethics of the Gadchiroli trial. As the principal investigator of that field trial, I wish to add a few things.

1. In 1993, when we started this trial of HBNC, newborn mortality in developing countries was perceived by global policymakers and international organisations as a hopeless case for which not much could be done. For ethical consolation, most standard guidelines on the care of neonates in the community added the sentence: "If a neonate is sick, immediately hospitalise." Usually nothing more was offered to sick neonates. Because hospitals were neither accessible nor affordable, this advice practically meant: "Let them die." Four million neonates thus died every year, mostly in developing countries, the majority of them without receiving any medical care.

When we realised this cruel reality we were baffled but also compelled to do something for these millions of unreached, uncared for vulnerable neonates. There was little precedent to guide us. The challenge was daunting because standard medical advice was a joke in this situation but anything different would require taking an unchartered, risky path. The choice before us was either let four million neonates continue to die silently, every year, or take a risky path.

2. In 1993, our organisation SEARCH in Gadchiroli district had an ongoing child health programme area and also a non-programme area where only demographic surveillance was

RESPONSE TO THE EXPERT COMMITTEE (EC2) ON BT BRINJAL

The following is a response from Kavitha Kuruganti, Kheti Virasat Mission on the EC2 report on Bt Brinjal, as per the call put out by the Hon'ble Minister for Environment & Forests, Govt of India, on October 15th 2009, seeking public feedback.

The responses have been divided into 4 distinct sections as below:

I. **ISSUES WITH THE EXPERT COMMITTEE: IS THIS WHAT THE NATION SHOULD BE ASKED TO RESPOND TO?**

II. **GENERAL RESPONSE TO EC2 REPORT & IMPACT ASSESSMENT OF BT BRINJAL**

III. **SPECIFIC RESPONSES TO EC2 REPORT**

IV. **OTHER VERY IMPORTANT AND FUNDAMENTAL ISSUES:** These include issues like availability of alternatives, pest management and pesticide-related issues with Brinjal, experiences from Bt Cotton, issues around IPRs and farmers' rights, around Indian Systems of Medicine, around consumer choices and labeling, around Event-based approval system and around Liability/Redressal/Remediation regimes.

I. ISSUES WITH THE EXPERT COMMITTEE: IS THIS WHAT THE NATION SHOULD BE ASKED TO RESPOND TO?

The Expert Committee Chairperson, in at least two media interviews (Tehelka and CNN-IBN), expressed the need for more safety tests and long term studies even though the report does not indicate any such views that he holds. There has been at least one more media report based on interviews with expert committee members (Down to Earth, "How Bt Brinjal was Cleared" http://www.downtoearth.org.in/full6.asp?foldername=20091231&filename=news&sec_id=4&sid=3), which further confirms our understanding of the "rigging" of the EC2 report.

This is apart from whether he came under "tremendous pressure" to approve Bt Brinjal or not!

Further, there is the issue of conflicting interest and objectionable presence of several EC2 members in this process. All of this makes it very apparent that the EC2 was designed to approve Bt Brinjal. Attached are two different notes on this matter (**Annexure 1** is a note on how the Terms of Reference were changed for the EC2 without any apparent processes and about the objectionable presence of several members in the EC2; **Annexure 2** is a letter written by scores of organizations and individuals across India to the Prime Minister of India, seeking the withdrawal of the rigged Expert Committee report).

The original Terms of Reference for the Sub-Committee on Bt Brinjal as per the January 2009 GEAC meeting minutes have been changed quite substantially for the constitution of the EC2. No processes have been run to allow for such changes in the mandate and this in itself makes the EC2 process void.

II. SOME GENERAL RESPONSES TO THE EC2 REPORT

The EC2 report is unscientific in its facts and approach and resolutely determined to clear Bt Brinjal and this is apparent almost throughout the report. Just the fact that 16 scientists have apparently gone through thousands of pages of biosafety data without a single adverse comment is really amazing!

1.0 To point out to a few major problems to highlight this aspect (lack of scientific rigour in EC2), one can point out to the references that the EC2 cites – some of these are from 1976 (point 1.2.2 on Page 7), 1982 (point 1.2.7. on Page 10) etc.

2.0 The EC2 outright falsified findings saying that "no statistically significant changes have been observed in the parameters tested" in the Food/Feed Safety tests (Page 59, Point 5.3. and Issue 9 of EC2 report). This is simply not true and the crop developer's own reports do show that there have been statistically significant changes.

3.0 The EC2 ignores much evidence on Horizontal Gene Transfer when it says on Page 55 under Issue 2 that "It has been well established that the probability of transfer of transgenic from GM plant material to bacteria (including that normally inhabit stomach and intestine) is unlikely because of series of well established barriers". There are numerous scientific studies that show that HGT is a phenomenon found to occur in several instances and a list of references for such studies is attached (Annexure 3: Horizontal Gene Transfer studies).

4.0 At least four members (that is 25% of the members) of the EC2 were also members of Expert Committee I which put out several recommendations in 2007. For no sound scientific reason proffered, the EC2 concluded that the tests recommended by EC1 are not needed as per the "newly adopted guidelines" in India. It should be remembered that these tests recommended by EC1 were not part of the guidelines present at that time either and the EC1 however saw a merit in recommending certain things. The EC2's unscientific attitude is reflected in this illustration.

5.0 The statement in the EC report (A1 in table in Annexure 1) on page 66 says: *"The cry1Ac gene inserted in Bt brinjal event EE-1 has been constructed by combining the first 1398 nucleotides of the cry1Ab gene (corresponding to amino acids 1 to 466) (Fischhoff et. al., 1987) with nucleotides number 1399 to 3534 of the cry1Ac gene (corresponding to amino acids 467 to 1178). The resultant protein encoded by this gene is 99.4% identical to native Cry1Ac from Bacillus thuringiensis sub sp. kurstaki. This difference of 0.6% is attributed to the difference in presence of* ***one*** *amino acid at position 766 i.e. serine in place of leucine".*

Simple calculations done by molecular biologists show that if indeed the difference between native Cry1Ac and the chimeric gene in Bt Brinjal is 0.6%, then the number of amino acid differences is **seven and not one**! If the EC2, with its collective scientific capabilities can go wrong on a simple fact like this, it is unclear how it can be trusted to take up a scientific evaluation of the safety of Bt Brinjal!

6.0 **The EC2 ignored several other points that were brought up** (Annexure 4: Compilation of health-biosafety related issues submitted to the EC2) – many points with regard to studies that are needed, problems with protocols of studies that were taken up as well as problems with analysis and interpretations of data generated have been ignored by EC2. It is not clear whether it is because of hasty processes run or whether it is a determined approach to ignore feedback that has been sent to the regulators.

7.0 The EC2 report in many places talks about "history of safe use" (of cry1Ac or antibiotic resistance genes or GM crops like Bt Cotton etc.) without citing any scientific study that concludes that there is indeed a "history of safe use". **On what scientific basis is the EC2 claiming such "history of safe use"?**

8.0 It is very apparent from the EC2 report, wherein **compliance to guidelines is mentioned and commended at least twenty times in the report**, that the EC2 made its main mandate the verification of compliance to guidelines rather than actually scientifically evaluate whether Bt Brinjal is safe. This is unacceptable and is certainly not the mandate given to the EC2 when it was set up. Even as this country is going through a debate on the current regulatory regime and its (in)adequacy, there is no point in an Expert Committee checking on compliance. Several of these members were in fact instrumental in designing the protocols and permitting the crop developer to take up unscientific studies and the very constitution of the EC2 once again came in the way of scientific, independent evaluation of protocols, data generated etc.!

9.0 The EC2 at several places in its **report refers to regulatory authorities elsewhere** accepting something or the other (page 32, 55, 69, 78 etc.) and invokes the example of USA, Canada, Australia etc. What is apparent is that the EC2 wants to make a note of these regulatory decisions from these countries which have allowed GM crops but ignore the regulatory decisions of many other countries or even the regulatory guidelines from countries like Norway, for example. This is very selective and opportunistic on the part of the EC2.

10.0 While the **85th meeting of the GEAC** clearly asks the ICMR representative who concurred with Dr Bhargava on the need for long term tests to look into incorporation of at least three more aspects of assessment (need for extensive DNA fingerprinting and proteomic study; Study of possible interaction with the commonly used drugs (especially pro biotic interferences and Reproductive interference) into guidelines, these are outright rejected in the current analysis by EC2, even though Dr Vasantha Muthuswamy is supposed to have concurred with Dr Bhargava in 2008! She was part of the EC2 too. What has changed in between is unclear.

11.0 The EC2's assessment of Bt Brinjal relies in many places on some **studies on Cry1Ac protein whereas Bt Brinjal has a chimeric protein**. The EC2 brings down safety issues to just one or two genes (that too a wrong one) whereas the latest research in this area is pointing to the process of Genetic Engineering itself.

12.0 The EC2 was privy to information from Large Scale Trials and some other studies and this **information was not put out in the public domain until November 17th 2009**. Procedurally, this does not augur well for transparent evaluation and only raises a finger of suspicion over such hasty and secret functioning.

13.0 Any complacency centred around **"Protocols approved by RCGM"** is indeed an issue and that is the reason why the constitution of the Expert Committee was being objected to by many civil society groups. If the EC2 members are RCGM members who have earlier cleared various protocols for Mahyco, they would obviously defend these rather than take the scientific points on board. The issue raised by Dr Judy Carman about the size of study and control groups of animals in terms of number of animals being too low, not permitting any statistical significance calculations scientifically possible is a good illustration for this. The EC2 did not respond to this point even though this would make all the difference in what a study might actually throw up.

14.0 **Not all studies were done by accredited laboratories** and that is what the ECI report also pointed out (Page 17) – Advinus Therapeutics, Bangalore is a NABL accredited laboratory. INTOX, Pune is an ISO accredited lab and NIN was asked to do an audit of this lab since it is not a NABL accredited lab. Central Institute of Fisheries Education is not an NABL accredited lab. Rallis India Bangalore is not listed in the NABL directory. Vimta Labs, Central Avian Research Institute, IICT, GB Pant University of Agriculture & Technology etc., also need to be seen if they are NABL-accredited. This is an issue that has been taken cognizance of by the Expert Committee 1. It is not rational that the EC2 members, given the kind of overlap that exists in members between the two committees, ignore this valid point made by EC1, which was in the first instance a concern raised by civil society taken on board.

15.0 The **new guidelines in India** have been adopted by the regulators, after receiving support from USAID for this recasting of guidelines. It is obvious that American business interests have a stake in the new guidelines adopted in India and the adoption of the principle of substantial equivalence formally for the first time in India through these guidelines is being questioned by many scientists. Checking for compliance with these guidelines reeks of vested and conflicting interests given that USAID played a part in Bt Brinjal development as well as in evolving the new guidelines.

16.0 **Event based approval system**: It has been pointed out time and again that an event-based approval system that India had embraced, is unscientific and unsound both from a biosafety point of view as well as from an agronomic point of view with new norms that have been adopted recently. The inter-cultivar variability in the protein expressions and other parameters is reason enough to treat each cultivar as a separate GMO. Further, some of the Bt Brinjal hybrids and the Bt Brinjal varieties from the public sector bodies did not even undergo proper agronomic evaluation even as they are being recommended for release by the EC2 and GEAC. This effectively implies that experimentation will take place at the expense of poor farmers, during the period of commercial cultivation! Bt Cotton has valuable lessons to teach on this front where the trials did not comprehensively address various issues and approvals were given hastily in 2002.

17.0 **Backcrossing time and process**: Effective and good backcrossing in breeding requires at least 4-5 years even with the use of modern-day techniques like Marker Assisted Backcrossing, coupled with 'shuttle breeding' etc. which can speed up the processes a bit. With Bt Brinjal, in the case of Mahyco's hybrids as well as public sector Bt Brinjal varieties in the ABSPII project, it is apparent that such time required has not been spent on backcrossing. In fact, pollen flow studies were taken up in 2002, when backcrossing programme was initiated, with Mahyco's Bt Brinjal hybrids! Similarly, while the Material Transfer Agreement with Tamil Nadu Agriculture University was signed in 2005 (between Mahyco and TNAU), the field testing in MLRTs commenced in 2007 itself! This is extremely unscientific and unacceptable – this story was earlier apparent with Bt Cotton too and it is only now that scientists are acknowledging that many of the new diseases being seen with Bt Cotton in Vidarbha and other places (*lalya* disease or bronze wilt etc.) is connected to the original American blood still remaining from the Coker 312 parental line and its particular susceptibilities now affecting Indian farmers. It is found that no regulatory body or Expert Committee has so far looked into this issue in depth and verified this to ensure that farmers don't end up paying the price for such scientific frauds.

III. SPECIFIC RESPONSES TO EC2 REPORT CONTENT

The following points are responses related to biosafety or lack of it, its assessment as well as a few other issues that arise from certain statements made in the EC2 report which have a relevance to the overall assessment of Bt Brinjal, its need, its implications etc. (beyond biosafety too). Several points being raised in these specific responses are a reflection on the state of the regulatory regime in India.

1. The EC2 says (Page 17) that RCGM's 40th meeting discussed in detail on April 25th, 2006 the data generated by Mahyco; however, it is apparent from the EC1 recommendations, finalized in 2007 that no detailed analysis of the raw data ever took place. The EC1 in

fact had asked the Director of National Institute of Nutrition to go through the raw data and as per information obtained under Right To Information, it is apparent that he had looked at the reports of only three studies rather than all the toxicity and allergenicity studies. It is not apparent that this EC2 has studied the raw data either, as they seem to have ignored differences between Bt and non-Bt Brinjal as reflected in different studies.

2. ECI's recommendations in July 2007 were put out with at least 25% of the members of EC2 being part of EC1 also. These recommendations include comments on studies done in non-NABL accredited laboratories, about Bt Brinjal having to be compared with other pest management options available etc. etc. It therefore requires strong scientific rationale to be provided if the EC2 is discounting the suggestions made by EC1. This is not apparent in the EC2 report however.

3. **Table 1.1: Insecticides recommended for FSB**: As per CIBRC website, lindane, cypermethrin, endosulfan, cypermethrin 10%, chlorpyrifos 20% EC, carbaryl and cypermethrin+quinalphos are recommended as per legal registration. Neem seed kernel extract also. The 15 listed in EC2 report are wrong/illegal to be cited and used and if others are recommending these other pesticides, it is not acceptable and requires regulatory action. (http://www.cibrc.nic.in/searchbycropname1.asp).

4. **1.2.6.: Non-target organisms like Parasitoids and predator species getting affected by pesticides used to control FSB** – While it is good to see studies (even if from 1987) cited on unintended impacts on non-target organisms, it is obvious that pesticides and their registration did not capture such impacts. In such a case, it becomes all the more pertinent to ask what studies have been done to look at Bt Brinjal and these parasitoids and impacts on such parasitoids and predator species?

5. **1.2.7.: Genetic Improvement by conventional techniques**: This section too is unscientific and opportunistic, citing a paper from 1982. (a) This ignores that pest management need not be brought down to FSB-tolerant cultivars alone, therefore justifying the entry of Bt Brinjal! (b) In any case, FSB-tolerant cultivars have been evolved/released in the recent past even from Tamil Nadu Agriculture University. (c) Further, this point of the EC2 report ignores that genetic improvement is possible through other techniques too like Marker Assisted Selection. (d) Finally, a paper present on the GEAC website called "Centre of Origin, Inter-relationship, and crossability in Solanum melongena" by Dr Major Singh, IIVR cites De Candolle (1886) and Prain (1903) thus: "*While some taxonomists think that S. melongena has not been found wild, others feel that S. insanum Roxb. and S. incanum Linn., which are wild taxa and considered to be distinct species, are really varieties of S. melongena (De Candolle, 1886: Prain, 1903). De Candolle (1886) and Prain (1903) reported that S. incanum and S. insanum are varieties of S. melongena and not distinct species. This view also gets strongly supported from inter-crossability to produce fertile hybrids and coexistence of S. melongena, S.incanum and S.insanum in different habitats*". If that was the case, then the EC2 point 1.2.7. is not strictly true. The regulators need to first collect data on FSB resistant cultivars evolved in various research centres in the past decade or so and it is apparent that the EC2 did not put in this effort.

6. **1.2.8.: Alternate strategies**: This section fails to mention that alternatives are available. It conveniently talks about non-sustainability of FSB control in future, ignoring the fact that the same would apply to Bt Brinjal too, sooner or later!

7. **1.2.8.: Alternate strategies**: The EC2 report says that adoption of transgenic crops with Cry proteins has given excellent results in maize and cotton and that a 'similar

approach in brinjal is expected to provide substantial benefits to farmers'. The EC2 fails to provide references for making this statement since findings from independent studies show a very mixed picture. It also makes the mistake of equating maize and cotton (a crop where the produce mostly goes into industrial uses and a fibre crop resp.) with Brinjal, an edible crop. Importantly, it fails to recognize latest reports on resistance in these very crops that it claims have given excellent results. (Annexure 5: Tabashnik, 2009 coverage).

8. **1.3. Development of Bt Brinjal by M/S Mahyco**: The EC2 conveniently ignores an important point being made by independent analysts and others that the gene used in bt Brinjal is **NOT** cry1Ac. The fact that it is the same that was used in Bollgard Bt Cotton is also not justification to call it Cry1Ac or to make it more acceptable. There are many unresolved and uninvestigated issues with Bt Cotton too and this is all the more reason not to accept Bt Brinjal with the same gene. The Cry1Ac in Bt Brinjal is claimed to be "similar" in structure and activity to the one found in nature and in commercial microbial formulations and this is not true or scientific.

9. **Page 11: 1.3.:** Bt k formulations not having deleterious effects on non-target organisms including humans is not true. There have been records of negative effects with external sprays too. Further, even the external sprays are not recommended as safe, going by the instructions on such formulations in the market.

10. **Page 12 (point on Bt Brinjal and IPM)**: "Contributes to and provides the foundation for an IPM strategy", says the EC2 report. This is once again a faulty and unscientific understanding of Integrated Pest Management. See Annexure 6 for a note on how Bt crops are a violation of the principles of IPM and sustainable pest management approaches.

11. **Page 12: Chronology of Bt Brinjal development**: In 2002, the backcrossing began, after importing the plasmid from Monsanto in 2000. However, the pollen flow studies were also taken up in 2002 in two locations. How is this possible? Even with some techniques like Marker Assisted Backcrossing, at least three to five years and ideally five years, are required for true back-crossing. How can toxicity studies and allergenicity tests be undertaken without the backcrossing being completed properly in 2003 and 2004? It is only now that the scientists in Indian NARS are acknowledging how the backcrossing programme was not as good as it should have been in the case of Bt Cotton. What is the lesson learnt is not clear and obviously "experts" in the regulatory system are not paying attention to these issues.

12. Page 13 refers to **Studies by the "technology provider"** – so, is the technology provider Monsanto in this case? If that is the case, the IPR implications have to be studied further. It should also be remembered that the studies being cited are on Cry1Ac (not the chimeric gene) and also do not constitute independent research. Nor are these peer-reviewed studies. The EC2 did not also mention which countries did not accept and allow certain products despite the regulatory authorities getting the studies cited here. ***The whole point is not to just accept the reports of the crop developer or technology provider but to take up independent research and analysis, which is sorely missing at this point of time.***

13. **Page 14**: The public sector varieties have not been tried out in Large Scale Trials; they have finished the confined field trials in 2007 and 2008. **This puts into question the event-based approval system adopted in India**. It is obvious that no data exists on these Bt Brinjal varieties and their agronomic performance in a simple protocol that

compares the Bt Brinjal variety with its isogenic counterpart and with the other best pest management options available, even though the Bt Brinjal varieties developed in the USAID-funded consortium project ABSPII are being recommended for release in India.

14. **Section II: Review of regulatory compliance (pp 15-29)** – Around 15-16 pages of the Expert Committee report has focused on this whereas **this does not make Bt Brinjal safe just by virtue of compliance to guidelines – this cannot constitute safety evaluation and this is only a convenient deviation from the original terms of reference for a Bt Brinjal Sub Committee announced in January 2009**. Further, even within this exercise, compliance with regulatory conditions stipulated by GEAC in the permit letter for LST is a wrong thing to do; the checking of compliance should have been against EC1's recommendations.

15. **Page 15, Table 2.1**: The plasmid pMON10518 was imported by Mahyco in March 2000 – It is not clear what the terms and conditions for this are, since this will determine the future of the public sector varieties being touted as the humanitarian side to this PPP effort. It will also determine the IPR issues around Mahyco's Bt Brinjal hybrids, pricing issues etc.

16. **PAGE 15: Table 2.1 – list of regulatory approvals for tests**: There are some questions with regard to permissions given and tests conducted here. For instance, the permission for sub-chronic feeding studies for 90 days in rabbits and goats was given on August 8th 2005 and preparation of feed concentrate for the feeding study happened on 22/12/2005 and 13/2/2006. It is not clear when sowing and harvesting would have taken place and whether fresh test material was supplied to the animals or not. The impact in the study could vary depending on the test material as well as time of harvest to time of diet preparation.

17. **Page 16, Table 2.1**: 2007 and 2008: Experimental seed production permissions were provided to the company thrice (Aug 2007, January 2008 and June 2008) – Why was this done, even without the completion of large scale trials? How is this seed accounted for by the company? Has the GEAC verified the physical availability of these seeds and the biosafety compliance with respect to these stocks?

18. **Page 16, Table 2.1**: "19. Recommendation of RCGM with respect to 90 days goat feeding study with Bt brinjal leaf expressing *cry1Ac* gene. 12/ 81/ 2006-CS-II Feb 06, 2008" – what is this referring to? If this was a permission from RCGM asking the company to take up the foliage feeding study also, then, the decision not to take up such studies came too soon after and the exact reason why this study was dropped is unclear. If this is a letter to Mahyco from RCGM that they need not take up the study as decided in earlier GEAC meetings and by the EC1, where the RCGM promptly communicated a decision from the January 2008 GEAC meeting, then the issue remains that the "conclusions" on Bt Cotton and animal morbidity/mortality by the GEAC are not scientific, based on any investigation nor is it a closed story (Annexure 9).

19. **Page 17: Compliance with 1998 guidelines:** Like Dr Bhargava had already pointed out elsewhere, the issue is not about compliance to existing guidelines – this is a scientific evaluation which can and should question the earlier and existing guidelines too.

20. **Page 17: Point 2.2** – the fact that the RCGM did not do its job in its 40th meeting is already proven by the ECI comments and therefore, to repeat something that is known to be untrue will not make it true, in terms of compliance to 1998 guidelines.

21. **Page 18 has an excerpt from the EC1 recommendation:** "The EC-I further opined that the short term data generated on the environmental safety and socio economic aspects needs to be further substantiated with additional trials/tests to explicitly conclude the benefits from Bt brinjal and *superiority of the technology with respect to existing technologies especially the available methods for pest management and pesticide reduction".* The EC1 came up with this in clear response to a point being raised by civil society groups and some scientists right from the beginning about the variety of alternative pest management practices available for farmers that are ecological, sustainable, affordable and farmer-controlled. This clearly requires Bt Brinjal to have been compared to other pest management methods and not necessarily chemical pesticide treated plots. This did not happen with Bt Brinjal assessment to this day. Table 2.2, points a. and b. conveniently ignore this fact and claim compliance!

22. **Page 19: Table 2.2 a**: Objective is to have an "independent assessment" by IIVR, an ICAR institution? How can this be possible, if IIVR is involved and why choose an ABSPII consortium partner if that is the objective?

23. At least three hybrids, MHB 11 Bt, MHB 39 Bt and MHB 99 Bt have not undergone second year MLRT trials (as apparent from Table 2.1 on Page 15; no trials took place in 2006-07, as is known to some activists who are following the various developments on the GM crops front in India and no permissions are visible in this table either or in the chronology explained on Pages 13-14 of EC2 report); However, Table 4.1. on Page 52 claims that these trials took place in 2006-07. It appears to be a case of the EC2 being more loyal than the King!

24. **Page 20. Point c of table 2.2 on Pollen Flow**: "Sufficient information is available on the biology of brinjal", says the last column as EC2's view. This information shows that brinjal is "an often cross-pollinated crop", with outcrossing ranging between 2 to 48% in brinjal varieties in India. The EC2 then goes on to say in the last column against point c. of Table 2.2. that the "results are in conformity with earlier information supplied by the applicant and available literature". These two don't match and it is not clear how the EC2 reconciled this difference in favour of Mahyco (which claimed 1.46% to 2.7% in its pollen flow study, with IIVR reporting a 0.14% to 0.85% outcrossing in its pollen flow studies in the past two years)! This obviously shows a lot of variance to available literature.

25. **Page 20: Point d of table 2.2: Crossability studies from *melongena* to *incanum*** – EC2 says that these "are in conformity with available literature". However, this is in variance with some literature quoted by Dr Major Singh of IIVR in another paper put up on the GEAC website. Once again, the EC2 reconciled the difference in findings in favour of Mahyco in the current instance. Further, there are studies from TNAU which show crossability with other local species and this has not even been studied in the IIVR crossability studies nor does the EC2 make any reference to such knowledge existing within the NARS.

26. **Data on Aggressive and weediness, on baseline susceptibility** etc., was put up only recently and needs to be studied along with data from large scale trials etc.

27. **Page 22, Point g on Soil Impact Assessment**: The EC1 had clearly said that "Impact on the next crop may be recorded" – this was obviously not done and the EC2 is still ready to conclude that the study is in compliance with stipulated conditions!!

28. **Page 22**: "No cry1Ac was detected in the soil samples" – this contradicts what is known and what the available literature says about this protein and it is interesting to note that the EC2 is ready to accept this finding as is without wondering if something was wrong with the methodology adopted or with the finding itself.

29. **Page 22: Point f: Flavour analysis NOT done by CFTRI** – the response that the recently adopted guidelines do not require such a study is a faulty argument and nullifies the very process taken up earlier.

30. **Page 23, Point i: Foliage studies with goats**: GEAC deciding to dispense with this study is not based on any new investigations and is in fact based on falsified information (Refer to Annexure 9 for more information on this). Therefore, this justification is not tenable and the EC2's readiness to rationalize this on these grounds arouses suspicions.

31. **Page 23: Point j:** Dispensing with the skin sensitization test is not on scientific grounds but only on an argument that recent guidelines do not need it! This kind of selective arguments with regard to suggestions of the earlier Committee are not acceptable – picking up some points and negating some has no scientific basis.

32. **Page 23: Point k:** The NIN director looked at only 3 studies, as per data obtained under Right To Information. Even here, he raised questions that remain unanswered. This is certainly non-compliance on the part of regulators themselves, leave alone the crop developer!

33. **Page 24**: Socio-economic impact assessment of Bt Brinjal - the NCAP study is yet to come in. In fact, the GEAC deciding to clear Bt Brinjal before this study has been finalized is indeed very hasty and unjustifiable.

34. **Page 25, Point 2.4.:** Compliance with the 2008 guidelines. The recasting of these guidelines has been supported by USAID in India and the only apparent reason why this would have been done is to benefit American business interests and not to protect Indians, their health and environment from risks associated with GMOs.

35. **Checklist Point 8 of the new 2008 guidelines**: Assessment of possible allergenicity – the EC2 says "Not applicable as the Bt protein is neither known to be allergenic nor has sequence homology with any known allergen" – this is a very faulty premise for not testing since there could be novel proteins (not necessarily the Bt protein) through the GE process and that is what Prescott et al (2005) show with GM peas shows; there is also scientific literature that shows that the Bt protein could be as potent as the Cholera toxin.

36. **Page 29** – Conclusions at the end of the section on Compliance to Guidelines says, "Since everything is as per guidelines, no additional studies need to be prescribed for safety assessment"...This is absolutely unscientific and does not form part of a scientific evaluation process.

37. **SECTION III – review of bt brinjal biosafety assessment dossier**: Given that the EC2 ignored the points raised by the Director NIN from his earlier analysis of three studies on Bt Brinjal and given that there is no evidence of even a single point raised

now on the biosafety data of Mahyco, there can only be one conclusion – that this Expert Committee did not look at the raw data from the biosafety dossiers of Bt Brinjal. Otherwise, how can there be a scientific evaluation of 1000 PLUS pages by 16 scientists, without a single point being raised, unless there has been no review of such data or unless there is something very fishy!

38. **Page 30: Point 3.1.2.:** not clear what the last line means: "transformation method was a modified method developed at Mahyco". If that's the case, are there any implications for any of the studies being cited being irrelevant for this new transformation method?

39. **Page 30-31: 3.1.3. – description of Cry1Ac gene and protein**: (a) This section ignores the fact that Bt Brinjal does not have the Cry1Ac gene but a chimeric gene. (b) It further ignores scientific evidence that the Bt protoxin is known to bind to (mucosal surface) surface protein in mammalian intestine too (Vazquez-Padron et al, 2000). (c) Finally, this section ignores the fact that it is not just individual genes in a transgene that are a cause for concern in r-DNA technology but the process of genetic engineering itself and transgenic expression of non-native proteins that are a potential cause for concern ("Diversity in translational and post-translational modification pathways between species could potentially lead to discrete changes in the molecular architecture of the expressed protein and subsequent cellular function and antigenicity...These investigations, however, demonstrate that transgenic expression of non-native proteins in plants may lead to the synthesis of structural variants with altered immunogenicity." – Prescott et al, 2005).

40. **Page 31:** "For Cry proteins to be active, it requires alkaline conditions", says the EC2 report: Vazquez-Padron et al (2000) have shown that binding of protoxin to mucosal surface in mammalian gut happened too.

41. **Page 31**: on CaMV 35S promoter and alpha subunit of the *beta-conglycinin* gene of soybean: The EC2 says that "both the regulatory sequences introduced into EE1 event are not capable of causing any disease" – There is at least one published paper in the Lancet that questions this in addition to a published paper where recombination between viral genes in GM plants and infecting viruses has been demonstrated (Wintermantel and Schloez, 1996).

42. **Page 32: nptII gene and aad gene**: the concern is not just with the expression of these genes in the plant but with the possibility of Horizontal Gene Transfer and therefore, the response of the EC2 is inadequate.

43. **Page 33: Point 3.1.5 – Expression of Cry1Ac protein and its quantification**: "The levels of Cry1Ac protein were found to vary between 5 to 47 ppm in shoots and fruits", notes the EC2 report. "Mean molt inhibitory concentration (MIC95 for *Leucinodes orbonalis* has been calculated to be 0.059 ppm for Cry1Ac". In May 2007, the Director, Department of Animal Husbandry (AHD), Andhra Pradesh, sent a letter to the GEAC (ref: No 3531/Epid/2006.dated 9/5/2007), where he reported : "*the Bt protein levels detected in the samples of Bt cotton bolls and leaves sent for analysis to different laboratories was recorded as 5 microgram/gm. This level is within the tolerable range which is said to be "5-10 microgram/gm"*. On this basis, it justified that this level of protein expression in Bt Cotton is tolerable for sheep/goats. In such a case, this clearly shows that the Bt protein far exceeds the "tolerable range" in Bt Brinjal. (Annexure 7 is a letter based on the letter of the Director-AHD, GoAP)

44. **Page 33: Conclusions**: "The EC-II opined that the insect resistance trait is stably integrated in the brinjal genome and there is no evidence or likelihood of genetic

instability". This is a faulty argument since the genetic instability in Bt Brinjal is not about integration of the Bt gene. The crop developer might be interested in that aspect alone but regulators should obviously go beyond this as several studies point to this aspect.

45. **Page 34: Point 3.2.1: Crossability studies:** There are many studies from India which are centred around inter-specific hybrids which also provide an indication of crossability. Nishio *et al.* (1984) observed that crossing *S. melongena* with *S. incanum, S. macrocarpon, S. integrifolium, S. gilo* and *S. nodiflorum* was compatible. The *S. viarum* has been utilized in breeding experiments involving brinjal (*S. melongena*) and viable interspecific hybrids have been realized (Nandakumar, 1983). Nasrallah *et al.* (1963) found that *S. melongena* was crossed with *S. gilo* and *S.indicum*, the F_1's of these crosses were highly sterile and *S. melongena* was not able to be crossed with *S. mammosum* and *S. ciliatum*. *S. melongena* cultivar could cross easily with *S. incanum* and *S. integrifolium*. It gave hybrids with *S. gilo* and *S. indicum* when used as a female parent (Rao, 1968). Anis (1994) reported that the cross *S. melongena* x *S. incanum* yielded seedless fruits. The per cent survival of the hybrid *S. incanum* x *S. melongena* was better than the parents. Preneetha (2002) evaluated the interspecific F_1 hybrids (EP 45 x *S. viarum*, EP 65 x *S. viarum*, CO 2 x *S. viarum* and MDU 1 x *S. viarum*) and found that the F_1 hybrid plants resembled their corresponding female parents morphologically. The IIVR crossability studies however report findings that are in variance with this existing knowledge. **The IIVR crossability study did not use *S. viarum* species or *insanum* at all and there are issues of serious concern with the design of the crossability study itself, as prescribed by the EC1 with a focus on *S indicum*.**

    The Crossability Study b/w *S melongena and S indicum* that was taken up by IIVR further cites the following in its report: *"Rao (1979) carried out a comprehensive survey of inter -specific hybrids of Solanum. Ten species were chosen: S. melongena, S. melongena var. insanum, S. incanum, S integrifolium, S. gilo, S. zuccagnium, S. xanthocarpum, S. indicum, S. sisymbrifolium and S khasianum. Crosses were attempted in all possible combinations. The results are summarized in Table 1 (No Table 1 is in the report however!). Out of 90 pos sible combinations, there was no fruit set in 47, and only parthenocarpic fruits in four. In the remaining 39 crosses which resulted in fruit set, only 24 gave rise to plants which reached the flowering stage".*

46. **Page 35: Outcrossing**: Wide range of outcrossing is acknowledged based on available literature (2 to 48% outcrossing) by the EC2. However, the results of the pollen flow studies are at great variance with this knowledge and the EC2 did not deem it fit for further investigation. The crop developer's pollen flow studies were taken up even as back-crossing programme was underway! In Brinjal, literature shows that 60-70% fruit setting happens through pollination by insects while 30-40% is by selfing. Insect activity is therefore a predominant variable and it is not clear whether this has been factored in into the pollen flow studies taken up on Bt Brinjal.

47. Further, it is pointed out that Bt brinjal pollen traveled to a maximum distance of 30 meters and that **there has been 0.14% to 2.7% outcrossing as per Mahyco's pollen flow studies. EC2 classifies this as "limited outcrossing"! What is limited outcrossing in a country of smallholdings?** Isolation distance and changed planting time is being suggested to minimize outcrossing – who is liable for this? How can small farmers maintain isolation, that too in vegetable plots which themselves are very small, usually leased?

48. **Page 36**: "Further, the EC-II opined that even if there is a very small influx of pollen originating from Bt brinjal varieties, it is not of any consequence, as the Bt protein has been extensively tested for its safety to the environment and food/feed and thus pollen transfer to other cultivated brinjal would not pose any safety risk". This is not an acceptable stand – the EC2 cannot decide on the rights of people who want to remain GM-Free like this! The Bt protein testing that they are referring to is of Cry1Ac and not the chimeric gene used in Bt Brinjal.

49. **Page 36: Horizontal Gene Transfer:** "Horizontal gene transfer from plants to animals (including humans) or microorganisms is extremely unlikely; Similarly, gene transfer from brinjal, or any other plant, to microorganisms is extremely unlikely", says the EC2 report. This is simply not true (Annexure 3) and this kind of a superficial response without any scientific basis and testing especially in the current instance of Bt Brinjal is not acceptable.

50. **Page 37: Aggressiveness studies**: Did they happen during MLRTs or Large Scale Trials? There might be a difference depending on this given how many plants were actually planted per plot in the first instance.

51. **3.2.3.: Impact on non-target organisms and Specificity of Cry proteins**: No in-vitro studies have been taken up with Bt Brinjal, especially at the highest levels of Bt protein expression from this GMO. Further, this analysis once again is a reductionist analysis centred around only Cry1Ac and refuses to acknowledge that other changes in the plant could also result in unpredictable impacts.

52. **Page 38-Table 3.1: Laboratory based eco-toxicology experiments**: It appears that a surrogate protein has been used in all the studies cited in the table and that itself can make these studies invalid. Further, the EC2 says that "No adverse effects were found at the above levels, which are significantly higher than that would be present in the fields" – this is not true since the protein levels in Bt Brinjal are supposed to reach upto 47 ppm!

53. **Page 40: Soil impact studies** – Despite the EC1's recommendation, **no study has been taken up on subsequent crop impact to this day**. (Page 3 of EC1 report: The changes in fertility and impact on next crop may also be recorded. In other words carry over effects of residues of Bt brinjal should be investigated). Further, the soil impacts studies in 2007 and 2008 were taken up by Mahyco and not IIVR!

54. **On absence of detection of Bt protein and such findings from these Bt Brinjal-**related studies, the EC2 observes that findings are in agreement with numerous studies that have shown only target pest impacts and no other impacts. These findings are in fact at great variance with findings from numerous other studies including a recent IARI study with Bt Cotton in India. It is not possible to agree with a finding that says "No Cry1Ac protein was detected in any soil samples". There must be something seriously wrong with the methodology if that were the case! This contradicts numerous other findings!

55. **Page 40 – last para** – The EC2 says: *"It was further noted that cry1Ac gene has been derived from a common soil bacterium and therefore it is expected that soil microorganisms are already exposed to these proteins within the environment".* This is a very unscientific statement since Bt as an organism is certainly present in the soil, but the protein is not in constant expression; and our farm soils certainly do not have Bt as a

protein that is being expressed by GM plants on a large scale. To even equate all these in a superficial, unscientific way is unacceptable on the part of the EC2.

56. **Page 41: "Large scale cultivation of Bt Cotton since 2002 without any toxic effects reconfirms that Cry1Ac protein has no deleterious effect on soil microflora", argues the EC2 report!** On what basis is this being concluded? What studies have been done to show that there are no toxic effects from such large scale cultivation? What about the IARI and UAS-Dharwad experimental studies which do show impacts of Bt Cotton on soil?

57. **Box 3.3 on Possible accumulation and persistence of Bt protein in soil**: Half life in different studies cited here is reported to run into several days - 9.3 days to 40 days depending on the soils and incorporation of plant material etc. If this is the case from available literature, how come there has been no detection of Bt protein in the Bt Brinjal studies conducted by the company and IIVR?

58. **Point 3.3. on Page 43: Food and Feed Safety Assessment**: An Independent Expert Committee (October 2006) noted the following on the genes and vector used in Bt Brinjal. "Though *Cry1Ac* gene was earlier considered generally innocuous, recent published evidence indicates that Cry1Ac protein from *Bacillus thurengiensis* is a potent systemic and mucosal adjuvant as potent as the cholera toxin which enhances mostly serum and intestinal IgG antibody responses specifically at the large intestine (Vazquez et al, 1999). Also another study (Vazquez-Padron et al, 2000) demonstrates the possible interaction *invivo* of Cry proteins with animal bowel. According to Moreno-Fierros et al (2000), caution needs to be exercised while using Cry-containing plants and plant products for human use. Recent reports on *CaMV 35S* (Myhre et al, 2006) note that promoter gene expression in human enterocyte-like cells might have GE food implications. Regarding the *aad* gene used in developing Bt Brinjal [streptomycin resistant gene], this Committee notes that according to the EFSA, this is a potentially dangerous marker to animals and human beings and should not be used in the case of GM plants used as food. The *Agrobacterium tumefaciens* medium was used for the transformation process of development of Bt Brinjal. Strains of agrobacterium were earlier implicated in incidence of bronze wilt in cotton in the US (McGraw, 2000). It is not clear whether its potential impacts have been studied carefully in this case".

59. **Page 43, Point 3.3.1. Toxicity and allergenicity of purified Cry1Ac protein**: All such evidence is irrelevant in the current instance as Bt Brinjal has a chimeric protein. The references are from 1993, 1996 and 1999 while the allergen database could have increased subsequently. Further, while a positive finding of homology may indicate allergenicity, a negative finding may not be a useful indicator of safety! This approach of individual genes and citing safety studies around them is completely inadequate since several studies with GM foods with these genes incorporated into them have shown numerous adverse impacts.

60. **nptII protein**: The half life in simulated intestinal fluids from a 1993 study cited by EC2 is two to five minutes. Can we conclude that there is no safety implication from this, with this information? Further, the implications from HGT of the gene cannot be ruled out.

61. **Page 45: Point 3.3.2.:** Toxicity and allergenicity of Bt Brinjal: Acute oral toxicity test: "proteins that are non-toxic by the oral route are not expected to be toxic by the dermal or pulmonary route". This is something that is routinely used in biosafety dossiers by crop developers, their sponsors (ABSPII, for example) and even "Expert Committees". However, the example of Ricin, a phytotoxin in castor, is worth mentioning here as an

illustration to the contrary. Toxicity of Ricin differed with the route of challenge in experimental studies and the most lethal was the inhalation route, compared to other methods of exposure routes. The toxicity of ricin by the oral route is reported to be several orders lower than by pulmonary or injected routes[1].

62. **Point 3.3.2.:** the sub-chronic oral toxicity study in Sprague Dawley rats is described as "This study provided information on the possible health hazards likely to arise from repeated exposure ***over a relatively limited period of time***". This is an interesting description and admission about this study since the EC2 is also arguing that sub-chronic studies are long enough! Prof Seralini however pointed out to: "Circling disorder and diarrhea were noticed only in the Bt brinjal group, males and females. Moreover liver weight as well as relative liver to body weight ratio decreased in the dose range study in females, by 13% apparently significantly. For the rats fed Bt brinjal water consumption was 8-21% more than the non Bt brinjal group for some periods".

63. **Page 46: Point 3.3.3.: Alkaloid content:** "Alkaloid profile of Bt and non-Bt is the same with not much appreciable variation in their relative abundances", states the EC2 report. Prof Seralini has calculated that the difference is upto 237% and no statistical significance tests have been conducted. The EC2 is however not hesistant to classify this as "not much appreciable variation" and this is unscientific.

64. **Page 47: Detailed compositional analysis**: The EC2 report says that the control substance was collected from 'near-isogenic line': what does that mean, near-isogenic line?

65. **Page 47: Feeding studies on Rabbits**: "It was concluded based on the health, growth and physio-pathological parameters analysed during the experiment that *there were no significant differences* between the groups fed with Bt brinjal containing *cry1Ac* gene and control non-Bt brinjal fruit". However, this is not the conclusion in the study. As per Report of Study No. 4418/05, dated 14/7/2006, as contained in Volume 3 of Bt Brinjal biosafety dossiers on the GEAC website:

    *"6. Haemotology: There were no changes observed in between Control Non Bt Brinjal (G2) and transgenic Bt Brinjal containing Cry1Ac gene (G3) groups except for an incidental but not biologically significant reduction in platelet count in G3 males at interim blood sampling and **significant increase** in Hct, reduced MCHC in G3 males and increased prothrombin time in G3 females at terminal blood sampling".*

    *"7. Clinical Chemistry: There were no changes observed in between Control Non Bt Brinjal (G2) and transgenic Bt Brinjal containing Cry1Ac gene (G3) groups except for an incidental but not biologically significant increase in albumin, and total bilirubin in G3 males and increased total bilirubin, lactose dehydrogenase in G3 females at interim blood sampling and **significant increase** in the AST, ALT, Total Billirubin and Sodium levels in G3 males and increased total bilirubin and decreased glucose levels in G3 females at terminal blood sampling".*

    G3 group in this study is Bt Brinjal-fed animals' group and the results by the admission of the crop developer itself are the above whereas the EC2 chooses to falsify the findings by saying that "there were no significant differences between the groups".

[1] Gill, D.M. (1982) Bacterial toxins: a table of lethal amounts. Microbiol. Rev. 46, 86

These differences are discounted by the study scientists as thus: *"these changes are considered incidental and not related to transgenic Bt Brinjal feeding since the changes were* ***marginal*** *and of no biological significance".* **Beyond this, no rationale is available or provided and the explanation provided by EC2 on Page 59 under Issue 9 is simply not applicable here.** Bt Brinjal cannot be considered safe just because the EC2 concludes so without any scientific basis, falsifying even the findings of the crop developer!

66. **Page 48: Goats study – sub-chronic 90 days study** – "It was concluded based on the health, growth and physio-pathological parameters analysed during the experiment that there were no significant differences between the groups fed with Bt brinjal containing *cry1Ac* gene and control non-Bt brinjal fruit", says the EC2 yet again. However, the conclusions from the study are different and interpretations highly questionable (like above).

    Report of Study No. 4417/05 (page 17 of 131), contained in Vol. 4 of the Biosafety Dossier of Bt Brinjal on the GEAC website has the following: *"There was significant difference in the hay consumption of the transgenic Bt Brinjal and control non-Bt Brinjal fed groups and the control normal diet group except for incidence of lower hay consumption in G3 group males as compared to G2 group during week 11. The change is considered to be marginal and considered to be of no physiological significance"*!

    Haemotology: *"There was no significant difference in the haemotological parameters between the transgenic Bt Brinjal and control non-Bt Brinjal fed groups* ***except*** *for incidental change in the value of prothrombin in G3 group males at termination".*

    The prothrombin time for G3 group was 21.47 seconds with the difference with control groups being statistically significant but justified as being within the range of historical control values (prothrombin time – 11.8 and 21.6 seconds). **The results could easily have been OUTSIDE this range and one can only guess how the crop developer would have justified the statistically significant changes even in this case.**

    Clinical chemistry parameters: *"There were no significant differences in the clinical chemistry parameters between transgenic Bt Brinjal and control non-Bt Brinjal fed groups* ***except*** *for incidental changes in the values of total bilirubin and alkaline phosphatase in G3 group males at termination".*

67. In fact, the EC1 on page 12 of its report refers to mentions that "Two kg of fresh Bt brinjal was considered by the independent testing institution, GB Pant University of Agriculture and Technology, to be appropriate". This is however not reflected in the protocols.

68. **Page 49 Conclusions**: The EC2 conclusion on "lack of toxicity in animal feeding studies" is questionable since the data is actually showing findings that require further investigation if not an outright rejection of Bt Brinjal!

69. **Page 49 conclusion:** "The detailed compositional analysis confirms that Bt brinjal is substantially equivalent to its non-Bt counterpart, as no significant differences were observed in any of the components". This is questionable since no qualitative compositional analysis has been taken up in the first instance.

70. **Page 51: Table 4.1: field trials conducted with Bt Brinjal in India** – This table has incorrect information on three Mahyco Bt Brinjal hybrids having undergone MLRTs with

ICAR in 2006-07. The date of transplanting is not normal and might not have captured peak pest load on the crop.

71. **Page 52: Point 4.2.1.: Efficacy of the intended Trait:** The results are presented through simple averages and standard deviation. No statistical analysis beyond this was done. Further, the fruit yield in Bt Brinjal is reported to be 335.69 q/ha (+/- 39.36 q/ha) and for non-Bt Brinjal, it is reported to be 287.28 a/ha (+/-28.93 q/ha). However, there are several practicing farmers and scientists who are reporting that their normal yields are in the range of what is being reported for Bt Brinjal! This brings to the fore a question being asked repeatedly – where is the need for Bt Brinjal?

72. **Page 52: Efficacy of intended trait: Fruit damage in bt hybrids** – "The cumulative fruit damage during these trials in Bt brinjal hybrids, their non-Bt counterparts and checks was 8.15%, 26.10% and 25.02% respectively. "The mean cumulative fruit damage in Bt hybrids ranged from 6.28% to 10.04%, whereas the range for non-Bt hybrids and checks was 23.52% to 30.36%", reports the EC2. If that is the case, the yield difference if at all should be only around 16.5% to 20%?? However, the next point on Agronomic Performance records this: "The mean increase in marketable yield of Bt hybrids over their non-Bt counterparts and checks was 71% and 97%, respectively".

73. **Page 52: Economics of Bt Brinjal** – The pesticides cost projections are based on ETLs and chemical spray recommendations. The numbers projected here are very unscientific since if the same trial was done with different pest management options, including non-chemical IPM and NPM, the economics would be vastly different!

74. **Page 53: Estimated economic benefit due to increased marketable yield**: on what basis was this calculated? Which year's price and why? Does this take into account a glut in the market?

75. **Page 55: Antibiotic resistance**: Reviews by regulatory authorities worldwide will not be readily applicable here – one, because of antibiotic resistance as a prevalent problem that health workers are already contending with in India, as compared to situation in other countries; two, consumption patterns of food being different in India where highly processed foods are not consumed and in the case of Bt Brinjal, it could be consumed in numerous ways that are more or less involve direct consumption.

76. **Antibiotic resistance**: the issue is not that of these nptII and aad genes making anti-biotics ineffective because of the enzyme that they produce being in low quantities from Bt Brinjal but that of horizontal gene transfer. Without even studying such a transfer in the case of Bt Brinjal, how can any conclusions be drawn, based on what studies?

77. **Page 56: Claim that crops containing antibiotic resistant genes have a history of safe use for more than two decades** – The EC2 has to show scientific proof of "history of safe use" before claiming so. Which studies have shown this? How do we know that the various problems that let us say the Americans are experiencing, are not in some way linked to GM foods?

78. **Page 56: "Point 5.2. Environmental Safety"** – Centre of Origin issue is yet to be resolved, says EC2. However, authorities concerned about plant biodiversity in the country are not questioning the existing knowledge around Centre of Origin and seem to have firm evidence on India being the Centre of Origin for Brinjal. This issue needs to be resolved scientifically and not just cursorily by an EC2 with two agriculture scientists in it who are both Bt Brinjal developers. The concern in any case is that of our existing

diversity being impacted by Bt Brinjal and there are no contentions on the fact that India is a Centre of Diversity for brinjal.

79. **Gene flow to wild relatives**: this cannot be ruled out – not from existing evidence and not from IIVR's study either. Also, the studies done with such crossability studies left out some species which have shown themselves compatible in other studies (for example, in TNAU).

80. The impacts of contamination cannot be measured only in terms of Cry1Ac trait conferring advantage to the wild relatives....Will there be no other changes with the gene transfer occurring? Is there scientific evidence for this that no other changes are to be expected? Also, is it true that no lepidopteran pests occur on the wild species? Amongst the related species, *S incanum* is known to have higher FSB infestation than others and is not devoid of pest infestation as stated by the EC2.

81. **Issue 4: Effect on Non-target Organisms:** Only the EC2 was privy to additional data. Data has been put out in public domain only later and this is being studied.

82. **Page 58: Cooking studies** (Point 5.3. Food/Feed Safety): This does not address the fact that further metabolites have not been tested for and that there could be other forms of consumption of Bt Brinjal, which do not require cooking. The response also looks at Cry1Ac. This also does not explore whether the harm from a GM food like Bt Brinjal limited to Cry1Ac or newer unpredictable proteins too?

83. **Page 58: No long term assessment of chronic effects** – The need for long term studies has been discounted on faulty grounds. The EC2, as in many other places in the report, talks of Cry1Ac being safe; however, the protein and gene in Bt Brinjal is not Cry1Ac, to begin with. There is NO history of safe use of Bt proteins either. Further, 90 days of a rat's age is just 3 months out of 36 months, which is $1/12^{th}$ of its lifetime. This certainly cannot be equal to 21-25 years of human life. Finally, many chronic health effects that we know today from various contaminants, have not been captured in acute effects' assessments and there is a lesson to be learnt there.

84. **Issue 9, Page 59: Differences found in toxicity studies** that have been ignored – The argument that if the values and data are within normal physiological range, that the product is still safe is questionable. "In the animal feeding studies conducted with Bt brinjal, no statistically significant changes have been observed in the parameters tested" is an outright false statement. A latest scientific study (Spiroux et al, 2009) elaborates on what is wrong with the current analysis and interpretation with results from toxicity tests and that should be read as a response to the EC2's comments on this aspect (Annexure 8 – "A comparison of the effects of three GM Corn varieties on mammalian health", 2009). Points 64 and 65 in this note have already addressed the issue of how EC2 is discounting statistically significant differences, even though the crop developer's data and reports contain the same.

85. **Point 5.4. OTHER ISSUES - "Issue No. 10 – Impact on Organic Farming"** – the EC2's lack of knowledge on the subject is showing starkly. Pest management does not rely totally on botanical extracts in Organic Farming as the EC2 seems to think. Even within that limited understanding, we can show an equal number of studies which show efficacy of organic methods too – whose word should prevail? Therefore, this whole section does not merit any response. Further, the callous response towards organic farmers who wish to remain organic is unacceptable. Why should the onus be on them when the problem is arising from somewhere else?

86. **Issue 11: Acceptance of data submitted by Mahyco** – ECI has already made a point on how some of the labs are not NABL accredited labs. There is no reason why the EC2 should go back on that point, given that at least four members, Dr Sesikeran, Dr Anand Kumar, Dr Mathura Rai and Dr Ranjini Warrier were common to both Expert Committees (25% of the members). In fact, Dr Sesikeran had written to the GEAC questioning the lack of authentification of test material, before the actual experiments were taken up. Samples being archived or not archived cannot be verified now.

87. **Issue 12: Adequacy of information/data generated by Mahyco: Page 61** – The response of the EC2 is completely unscientific and inadequate in this context. While on the one hand, India is supposed to have a case-by-case approval system, this response indicates that Bt Brinjal is not being decided on its own merit but on a pre-decided unscientific notion about Biotechnology, for public sector institutions in particular. The EC2 seems to have forgotten that biotechnology is not just transgenics and not symbolized by Bt Brinjal either. The EC2 should appreciate that this evaluation is not about biotechnology and its need in India but about Bt Brinjal and its safety.

    Information obtained under Right To Information shows that the NIN Director sent some comments to GEAC on October 4th 2007. He looked at only three studies: 90 days oral toxicity study (18 different comments but no specific recommendations), Acute Oral Toxicity Test (13 comments) and Allergenicity study (3 comments, on the Rallis study). For all the three studies, one of the things he pointed out was that **characterization/ authentification of the test article provided by the sponsor did not happen.** This is obviously something that cannot be retro-fitted into the tests that have already taken place and it is surprising that the EC2, which has the same NIN Director as a Member did not make any mention of his earlier findings and observations while addressing this Issue 12 or anywhere else!

88. **Section VI: Page 62 – Conclusions and Recommendations** – "Chronic toxicity studies are warranted only if any toxic effects are observed in acute or sub-chronic studies. Since no toxic effects were seen in acute and sub-chronic studies, there is no need and justification for any chronic or long term studies for evaluating the safety of Bt brinjal event EE-1" – this is a faulty and unscientific argument. Chronic effects need not show up in acute studies.

V. OTHER VERY IMPORTANT AND FUNDAMENTAL ISSUES

There are many issues that had not been mandated to be debated by the EC2 which need to be resolved and should have been, at least by the apex regulatory body before it cleared Bt Brinjal for India. After all, our regulatory regime is supposed to have enshrined the Precautionary Principle as a cornerstone by virtue of India being a signatory to the Cartagena Biosafety Protocol. This approach is technically and legally valid in the case of technologies such as GMOs in our food and farming. Some of these issues are discussed below, left untouched or even ignored despite evidence, by the EC2 and the GEAC.

i. **Pest management and pesticide-related issues** with Brinjal – Most brinjal cultivators in India are not cultivators with intensive farming practices and the pesticide use claims on Brinjal being to an extent of 84 sprays (that too, data from Bangladesh!) is very exaggerated. True, in those pockets where vegetable cultivation is in an intensive fashion, there may be numerous sprays of pesticides to control the

FSB and this kind of high pesticide usage obviously has implications for the ecology, farm economics and on other fronts like health. However, exaggerated projections of pesticide use should not form the basis for decision-making. It should be recalled that before the advent of Bt Cotton, the rationale applied was that around 55% of India's pesticide consumption was on Cotton crop alone and that pest management strategies like Bt Cotton were essential to bring down insecticide usage being targeted at the bollworm complex. Claims were made at that time that 60% of the pesticide usage on cotton was to control the bollworm complex. Bt Cotton was proffered as a solution and if projections were right, India's pesticide consumption should have come down by at least 35%. However, the figures of pesticide consumption do not reflect this either in volume and value. The same arguments are being offered for justifying Bt Brinjal and claims of high pesticide usage which are being projected as the average for all Brinjal farmers across the country are highly questionable.

ii. **Alternatives available for pest management in Brinjal**: there are highly successful, sustainable, affordable and farmer-controlled pest management alternatives available for pest control in Brinjal and these alternative practices are in fact holistic and do not necessarily tackle pests in a linear, reductionist fashion, pest by pest. When such alternatives exist both within the NARS system and with practicing farmers, there is really no need for Bt Brinjal as a solution. As the Supreme Court nominee to GEAC had recommended, the GM option should be picked up only in the absence of alternatives to a given problem. It is also apparent that Bt Brinjal is being compared in various studies against chemical pesticides and being projected as highly beneficial to farmers – the framework of analysis itself is obviously very faulty here, comparing one evil with the other so to speak. The Government of India should show the political will of extending and supporting alternative (alternative to GM seeds and synthetic pesticides) ecological technologies to farmers for sustainable livelihoods, as is being done in a government-supported programme called Community Managed Sustainable Agriculture in the state of Andhra Pradesh on lakhs of acres. **Annexure 10** has details on such alternatives.

iii. **Experiences with Bt Cotton have many lessons to be learnt**: The Bt Cotton cultivation experience in India over the past eight years has many valuable lessons to teach policy makers, regulators, farmers and consumers of the country, if we choose to pick them up in pursuit of sustainable development objectives. (a) It has been shown time and again that the Bt technology is unpredictable and the very mixed results over years, locations and hybrids are there for everyone to see. In those places where results have been good, deeper analysis points to good seed source (germplasm into which the Bt gene has been backcrossed), good monsoon years, higher inputs in the form of water and nutrients etc. The technology has failed in many areas which are resource-poor in terms of soils, irrigation as well as farmers' ability to provide inputs. (b) Pest and disease ecology has changed in cotton in unpredictable ways. Secondary pests are emerging into major pests in several places. (c) Impacts on soil are being observed and reported by farmers and there is increased use of chemical fertilizers; a senior agriculture scientist of India had predicted that with even a 6% expansion of GM crop land in the country, there would be a doubling of chemical fertilizer demand and this brings its own problems including that of public financing of an unsustainable input. (d) Stress intolerance is found to be higher on Bt Cotton than on other non-GM cultivars. This has implications for risks and vulnerabilities of our resource-poor farmers. (e) Bt Cotton has left its impacts on animals which have grazed on the crop residues in different parts of the country including from consumption of Bt Cotton seed cake etc. Animals have either died or fallen sick after consuming Bt Cotton and this phenomenon though acknowledged by some officials, has not been investigated scientifically and systematically by concerned agencies to this day (Annexure 9 is a paper on Bt Cotton and animal morbidity/mortality phenomenon). (f) Agricultural workers have also reported allergies after working in Bt Cotton fields and media and NGO reports exist from different states about this phenomenon which is also uninvestigated to this day. (g) On the regulatory front, Bt Cotton has repeatedly showcased the regulatory incapabilities of India, right from the time that illegal proliferation of unapproved Bt Cotton was first noticed in 2001. Regulatory failures were not just on the biosafety front but in terms of monitoring, reviewing, transparent and scientific decision making and so on. (h) State governments also found out through the tough way that there are no legal mechanisms available to them to regulate seed marketing, seed advertising, seed pricing and for liability and redressal for failures. All the above points are still pending, so to speak and would raise their ugly head in the case of Bt Brinjal too. It is very unwise to move into an edible crop, that too a first-of-its-kind in the world and an unneeded product to boot, without learning lessons from the Bt Cotton experience.

iv. **IPRs on Bt Brinjal and farmers' rights**: Even without any legally protected rights in the case of Bt Cotton, state governments and farmers and even Indian seed companies had to contend with the monopolistic behaviour of MNCs like Monsanto and their Indian partner as most other seed varieties got edged out of the market, as farmers lost their own seed stocks rapidly and as prices were fixed at exorbitant levels leading to many farmers getting into deeper distress and even committing suicides. The issues are going to get murkier with Bt Brinjal including an outright violation of farmers' rights over their germplasm and so on. The technology of Bt Brinjal supposedly belongs to Monsanto, as references here and there reveal. Mahyco is also supposed to have obtained a patent on the "Event" EE1 in Bt Brinjal. Further, public sector universities have parted with their germplasm, with the initial varieties obviously belonging to some farming community or the other, to develop Bt Brinjal varieties in a consortium project called ABSPII. In all of this, it is not clear who has the authority to regulate seed sales, pricing and royalty issues, who is claiming ownership and how on the germplasm that belongs to farmers that the public sector then developed into Bt Brinjal varieties and it is not clear who owns the Bt Brinjal varieties!! Annexure 11 is an article on these complicated issues and serious concerns around seed monopolies, violation of farmers' rights and rapid erosion of seed stocks with farmers etc., are yet to be addressed in any meaningful way by policy makers or regulators.

v. **Bt Brinjal and Indian Systems of Medicine**: Brinjal and related species are used extensively in Ayurveda and other Indian Systems of Medicine. Despite several efforts to get the regulators to look at a more comprehensive impact assessment regime, various stakeholders have failed to get the regulators to take this matter seriously. No impact assessment has been taken up to understand the implications and impacts of Bt Brinjal on Indian Systems of Medicine and this is a matter of grave concern. This could have implications not just in terms of a medicine becoming ineffective but potentially even toxic!

vi. **Bt Brinjal and rights of farmers who wish to remain GM-Free and/or organic**: The onus of remaining GM-Free and/or organic is obviously not with the ones who wish to be so since the origin of the problem lies with decision-making elsewhere. Any approval given to Bt Brinjal cultivation in the country will potentially violate the rights of those farmers who want to be GM-Free and/or organic and no attention has been paid in the regulatory decision-making processes to issues such as this so far. The EC2 has callously asked such farmers to follow isolation distances etc., but it is not clear why the burden should fall on these farmers who have chosen sustainable pathways of development.

vii. **Rights of states which wish to remain GM-Free:** There are several state governments, which as per the policies adopted at the state level, wish to ban and disallow Bt Brinjal in their respective states. However, there are many practical issues to be addressed as borders with other states are porous and seeds can travel from one place to the other. As per the Constitution of India, Agriculture and Health are state subjects and any decision at the Centre that allows Bt Brinjal anywhere in India violates the authority and rights of those states which choose to remain Bt Brinjal-free.

viii. **Consumer rights and choices violated:** If Bt Brinjal is approved in India, the rights of consumers to choose what they would like to consume would be violated irreversibly. This is simply not acceptable. On the other hand, a labeling regime is practically impossible to implement for a vegetable crop in a country like India and is no solution for this problem.

ix. **No Liability, Redressal and Remediation regime in place**: Even as GEAC cleared Bt Brinjal for commercial cultivation in the country, it should be noted that no liability, redressal and remediation regime exists in India. Who is to be accountable, by what mechanism, for how much and in what conditions, for things going wrong? It is unconceivable that the regulators have cleared an edible GM crop with the Bt gene in it without resolving this basic issue and putting a sound liability, redressal and remediation regime in place.

GIVEN ALL THE ABOVE, IT IS IMPERATIVE THAT THE GOVERNMENT WITHDRAW THE BT BRINJAL EC2 REPORT AND REJECT ANY APPLICATION FOR COMMERCIALISATION OF BT BRINJAL IN INDIA. IN FACT, THE ABOVE FACTS POINT TOWARDS AN URGENT NEED TO STOP ALL OPEN AIR TRIALS OF GM CROPS IN THIS COUNTRY AND TO A NEED TO CREATE A DEMOCRATIC, TRANSPARENT AND SCIENTIFIC PROCESSES DRIVEN WITH A VISION FOR SUSTAINABLE DEVELOPMENT THROUGH WHICH REAL, LASTING SOLUTIONS CAN BE ESTABLISHED IN INDIAN FARMING AND FOOD SYSTEMS. SUCH PROCESSES SHOULD LEAD TO COMMUNITY-CENTRED AND COMMUNITY-LED SUSTAINABLE AGRICULTURE SYSTEMS, WITH APPROPRIATE SUPPORT STRUCTURES AND SYSTEMS CREATED BY THE GOVERNMENT.

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AS SEPARATE ANNEXURES, OTHER REFERENCES AND MATERIALS RELATED TO SUSTAINABLE ALTERNATIVES, ON HORIZONTAL GENE TRANSFER, ON CROSSABILITY, ON GENETIC INSTABILITY IN TRANSGENICS ETC., ARE BEING PROVIDED.

NEWS STORIES ON THE EXPERT COMMITTEE, ITS PROCESSES AND STORIES AROUND INTERVIEWS WITH EC2 CHAIR/MEMBERS:

1. **"Bt brinjal clearance ignored dissenters?"**
   http://www.gmwatch.org/index.php?option=com_content&view=article&id=11670:bt-brinjal-clearance-ignored-dissenters

2. **"Green Signal for Bt Brinjal"**
   http://www.downtoearth.org.in/full6.asp?foldername=20090215&filename=news&sec_id=4&sid=20

3. **"Bt Brinjals in markets near you"** (Audio recording of Dr. Bhargava's interview with Down To Earth) : http://www.downtoearth.org.in/bt_brinjals.asp

4. **"How Bt Brinjal was cleared" – Down to Earth article on the EC2**

http://www.downtoearth.org.in/full6.asp?foldername=20091231&filename=news&sec_id=4&sid=3

5. **"Bt Brinjal tests inadequate – How safe is it"**

http://ibnlive.in.com/news/bt-brinjal-tests-inadequate-how-safe-is-it/106477-3.html

6. **"Controversy continues over Bt Brinjal approval"**

http://ibnlive.in.com/news/controversy-continues-over-bt-brinjal-approval/106190-3.html

7. **"New twist of controversy over commercial release of Bt Brinjal"**

http://beta.thehindu.com/news/national/article60225.ece from Kheti Virasat Mission

TO:

Members of the Expert Committee constituted on 29/5/2009, to review the biosafety studies and large scale trials of Bt Brinjal

The following are some of the main issues with regard to Mahyco's Bt Brinjal and biosafety assessment, mainly from the health safety angle.

We would like to point out that this Bt Brinjal application should be rejected on the grounds that we have alternatives for pest management in Brinjal (including several research projects within the NARS, the IPM modules that the ICAR has brought out and real life experiences with scores of farmers), that we are the Centre of Origin/Diversity for Brinjal and that this Bt Brinjal has anti-biotic resistance genes in it which pose a public health problem given the potential of horizontal gene transfer.

In addition, we have listed down Here several technical points with regard to the biosafety assessment of Bt Brinjal. For convenience's sake, we have grouped them under the following heads:

- Studies pending that have been already asked for earlier but not yet conducted or reported (this includes GEAC's Expert Committee on Bt Brinjal and Dr Pushpa Bhargava's note for an ideal regulatory regime, to the GEAC)
- Studies being demanded by civil society groups for a long time now
- Problems with the protocols adopted for the studies already undertaken
- Problems with the analysis of data for the studies already undertaken
- Problems with the interpretation of results for the studies already undertaken (this in fact is a section which already has clinching evidence against Bt Brinjal, with results that have already emerged in Mahyco's own studies)
- Problems with the reporting of data in Mahyco's dossiers
- Problems with some general procedures

STUDIES PENDING THAT HAVE BEEN ALREADY ASKED FOR EARLIER BUT NOT YET CONDUCTED OR REPORTED:

I. An expert committee set up in 2006 (headed by Dr Deepak Pental initially and later by Dr C R Babu and report finalized in July 2007) had asked for the following: (full list of tests given as Annexure 2, incl. environmental studies)

a. "While the data generated by the Applicant concludes that the Bt brinjal is safe and equivalent to its non Bt counterpart, the Committee was of the opinion that more independent studies especially with respect to toxicity assay in NABL accredited laboratories may be required to reaffirm the findings made in the earlier studies".

OUR COMMENT: No independent studies have been done so far. Similarly, studies in labs that are not NABL accredited should not be taken into account (some studies with regard to Mahyco's Bt Brinjal biosafety have been done in such labs).

b. "The Committee further opined that the short term data generated on the environmental safety and socio economic aspects needs to be further substantiated with additional trials/tests to explicitly conclude the benefits from Bt brinjal and superiority of the technology with respect to existing technologies especially the available methods for pest management and pesticide reduction".

OUR COMMENT: It is obvious from both GEAC's and IIVR's responses to RTI applications that protocols have not been re-designed to look the superiority of the technology with respect to existing technologies for pest management and pesticide reduction. We had earlier submitted to GEAC and others several NARS studies which showed that non-chemical IPM methods do give excellent results in Brinjal. Such methods were not part of the protocols adopted, even though the 2007 committee recommended this.

c. "Bt brinjal being a food crop, a flavour analysis of Bt and non-Bt fruits may be included as an additional parameter and this study may be undertaken at CFTRI".

d. "The Company to review if the highest MIC95 value should be kept for monitoring rather than the average for the target pest vis-à-vis Cry1Ac protein expression levels".

e. "The Food / Feed Safety assessment should include foliage toxicity study in Goats".

f. "The skin sensitization test of transgenic material in guinea pigs as laid down in the DBT guidelines has not been taken up. The Committee recommended the study may be conducted".

g. "Additional toxicity / allergenicity / compositional / nutritional studies as recommended by Director, NIN after examining the raw data on food and feed safety generated by the Applicant".

OUR COMMENT: information obtained under Right To Information shows that the NIN Director sent some comments to GEAC on October 4th 2007. He looked at only three studies: 90 days oral toxicity study (18 different comments but no specific recommendations), Acute Oral Toxicity Test (13 comments) and Allergenicity study (3 comments, on the Rallis study). For all the three studies, one of the things he pointed out was that characterization/authentification of the test article provided by the sponsor did not happen. This is obviously something that cannot be retro-fitted into the tests that have already taken place.

In addition to the above, several new studies and parameters were laid down for the field trials for agronomic evaluation, pollen flow, soil impact tests, fruit dry matter assessment, Cry1Ac expression levels, socio-economic impact study etc. etc. (Annexure 2)

You will therefore have to ask the following questions:

- have each of the above tests been done? Who did it? What was the protocol adopted? What are the results?
- In one GEAC meeting, they decided to drop the foliage toxicity study in goats. You should find out how they allowed that, given that there are so many reports of animal illness/deaths after grazing on Bt Cotton plants.
- Has the NIN Director examined all the raw data of the crop developer? If yes, what recommendations does he have or did he find everything adequate? How were his points on three of the tests get addressed?

II. Dr Pushpa Bhargava, as the Supreme Court's appointee into the GEAC had asked for the following set of tests for each GMO and the ones not taken up on Bt Brinjal have been highlighted in bold and italics below:

a. ascertain after careful analysis of existing information (and, if need be, relevant new information that could be generated within a short period) that there are no alternatives to the GMO and that the GMO will, if it meets the stipulated requirements, bring substantial benefit to the country and to one or more classes of its citizens (such as farmers). *(OUR COMMENT: THIS HAS NOT BEEN DONE TO THIS DAY OF COURSE)*

There should be a protocol/set of guidelines for the analytical process to ascertain that no alternatives exist.

b. If the GMO is truly required, the following risks must be recognized and assessed:

(1) Introduction or creation of a new or known toxin or allergen, or generation of toxicity to humans or animals. (An example would be the Brazil nut-soyabean case.) For this it will be necessary to have an extensive DNA fingerprinting and proteomics analysis done of the GMO and for comparison, of the parent organism. Any difference found must be fully characterized, both structurally and functionally. The total sequence of the transgene and the flanking regions must be done. Any change in the glycosylation pattern must be characterized. All toxicity studies must be done on the protein in the GMO (for example, appropriate extracts or whole parts of the plant). Toxicity studies done with the surrogate protein made, for example, in E.coli, will not be relevant.

OUR COMMENT: While in-planta toxin has been used for most of the studies, proteomics analysis and characterization, characterization of glycosylation pattern has not been taken up so far.

(2) Gene flow (lateral gene transfer) that could have adverse effects. For example, marker genes conferring antibiotic resistance that are often used in genetic engineering could be transferred to pathogenic microorganisms, thus making them resistant to antibiotics. It appears that 10-20 percent genes have been laterally transferred in the last one hundred million years on our planet. Lateral gene transfer, specially to human and animal GI microflora, must be looked at in depth.

OUR COMMENT: No studies for horizontal gene transfer to human and animal GI micro-flora have been taken up for Bt Brinjal so far.

(3) Experimental errors.

(4) Competing of the genetically engineered organism with wild or other desirable strains or varieties on account of growth advantage or other advantages. The existing protocol has been found to be inadequate and this should be re-assessed.

(5) Stability of the transgene product in the whole organism and, in case of plants, the amount expressed in various parts of the plant (not only parts that are used but all other parts as well).

(6) In the case of GM food material, possible interaction with commonly used drugs, especially probiotics.

(7) Interference with a desirable symbiotic relationship. For example, Bt crops could destroy useful insects as well as change the microflora of the soil. The study should, therefore, include the effect on human and animal (cattle) GI microflora; studies done on rats cannot be extrapolated in this respect to higher organisms (in fact, no studies exist even for rats on this aspect).

(8) Dispersal into areas where positive harm could be done.

Our comment: This should include an assessment of biological as well as physical dispersal.

(9) Changes in surface properties that may affect normal interaction between species in a viable and useful ecosystem.

(10) Effect on soil flora and micronutrients in every region (rain-fed, irrigated, semi-arid etc.) where the GMO is likely to be released or find its way.

(11) Reproductive interference. Studies should be done in at least three mammalian species.

OUR COMMENT: this obviously requires a long-term protocol like the Austrian government study.

(12) A second-site change. Thus, an insertion of the desired gene in the genetically engineered organism could take place not only at the desirable but also at an undesirable site in the host genome, which could have deleterious effects. This could be checked by studies mentioned under (1).

(13) Increased selective transcription and translation. Transcription and translation are processes in cells which lead to the transmission of information contained in the genetic material, DNA, to proteins. Vast changes in concentrations of precursors following genetic engineering could, in some cases, lead to increased transcription or translation of certain genes, leading to an undesirable imbalance in the cell. This can be checked experimentally by comparing the pool of free precursors and metabolites in the parent and the GMO under otherwise identical conditions.

(14) Changes in <u>relative</u> concentration of intracellular metabolites. This again could lead to metabolic imbalances, and must be checked.

(15) Development of resistance to the trait that is introduced.

(16) Increasing requirement for refuge crops in case of, for example, Bt crops. Development of resistance in insects to the Bt toxin produced in genetically engineered Bt plants, such as Bt cotton, is now widely known, requiring plantation of refuge non-Bt crops to attract the insects that are resistant to Bt. The exact nature and extent of this requirement would need to be determined under actual field conditions.

(17) Increase in susceptibility to pests, and infectious agents other than those that may be expected to be killed by the transgene.

(18) Emergence of new dangers, e.g. of superweeds on prolonged use of GM herbicide-resistant GM crops.

(19) Toxicity of GM crops to humans or farm animals as appropriate. (Dr Bhargava has pointed out to lack of chronic toxicity studies – in many cases, the effects may be only long term effects, he points out)

(20) Pleitropic effects leading to unexpected undesirable changes, for example in ecology. In fact six areas of such effects have been identified: metabolism, tolerance of physical factors, behaviour, factors regulating populations, demography and life history, and morphology. In GMOs, any one or more of the above could be drastically changed. The above-mentioned six classes of changes could lead to more than 70 identifiable phenotypic changes and more than 30 potential ecological effects.

(21) Effect on ecology and environment.

(22) Effect on the population density of non-susceptible pests following at least five successive plantations in the case of GM plants.

(23) Event-based approval non-scientific – each hybrid to be assessed for its own bio-safety

AN ANNEXURE PROVIDES A LIST OF TESTS CALLED FOR BEFORE THE RELEASE OF A GMO.

STUDIES BEING DEMANDED BY CIVIL SOCIETY GROUPS:

- Animal morbidity and mortality after grazing on Bt Cotton fields needs to be investigated before decisions on Bt Brinjal can be taken. This is a long-pending issue and this phenomenon has been acknowledged even by the animal husbandry department of Andhra Pradesh.

- Scientific investigations into skin allergies of farmers and agricultural workers working in Bt Cotton fields especially during harvest time. Skin prick tests have confirmed this. Immunological tests for specific anti-bodies could confirm more definitively.

- Chronic toxicity studies for endocrine disruption, teratogenicity, carcinogenicity, reproductive health impacts etc.

- Reproductive studies (as indicated by Dr Bhargava) need to be taken up as other studies indicated serious problems with GM foods on this front.

- Impacts of Bt Brinjal on Indian Systems of Medicine to be taken up. This includes Bt Brinjal's utilization as an ingredient in some medicines which use normal Brinjal right now as well as the possibility of contamination with related species used in various sytems of medicine.

- In vitro studies should be performed with the Cry1Ab-Cry1Ac chimeric modified insecticide extracted from brinjal, and with various mammalian cells including human digestive epithelia and hepatocytes. (Prof Seralini)

- A compositional analysis of Bt Brinjal vs. non-Bt Brinjal is not enough (for moisture, protein, ash, oil, carbohydrates etc.); a full protein analysis is required to check for novel substances. Amino acid and fatty acid profiling to be taken up. (Prof Judy Carman)

- Compositional analysis should consist of comparing Bt Brinjal with non-Bt Brinjal grown in identical conditions AND comparison of such sets of fruits from different parts of India [multi-locational].

- Impact assessment on special (particularly vulnerable) categories of the population like infants, elderly people and invalids through long-term studies.

THINGS THAT ARE PROBLEMATIC WITH THE PROTOCOLS OF THE STUDIES ALREADY CONDUCTED:

- Compositional analysis of Bt Brinjal vs. non Bt Brinjal is valid only if the two test materials were grown in identical conditions – the Mahyco analysis does not appear to have addressed this; further, 3 brinjal fruits per sample is inadequate
- All tests where cry1Ac toxin has been used are invalid since Bt Brinjal consists of a chimeric toxin consisting of Cry1Ac and Cry1Ab.
- Reference groups larger than the nearest control groups – camouflaging the results
- In the cooking tests, toxicity of the degraded products (insecticide metabolites) have not been studied – only the presence or absence of cry1Ac toxin was presented
- A maximum period of 3 months (90 days) for sub-chronic toxicity in adult mammals (rats, rabbits and goats) is inadequate upon which to estimate the effects on farm animals and humans.
- In the goat-feeding study/sub-chronic toxicity test with goats, 500 gms of bt brinjal was used as the test material whereas the Expert Committee on Bt Brinjal notes that 2 kilos of fresh Bt Brinjal is considered appropriate as per the GB Pant University of Agriculture & Technology.
- Feeding study with lactating cows: The Bt toxin was claimed not detected in blood, but there was only a short description of the method of detection and its limits and efficiency as well as repeatability were not indicated.
- Sub-chronic study with Sprague Dawley rats - only 90 days, maximum one dose and number of animals per treatment and sex too low
- Fixing of safe dose levels (at 1 gm per kg of body weight in the case of rats for instance, corresponding to about 50 – 100 gm per day for humans) could be unscientific.
- Primary skin irritation test with rabbits – three animals in the study group out of a total of 12 animals is too small.
- Broiler chicken study: 40 chicken received 5% GM diet, 40 others received 10% GM brinjal diet and 200 other birds received different non-GM diets – 10% is too low to capture unintended consequences.
- Feeding study with fishes [common carp]: There were finally only 6 pools of 60 fishes (360) receiving Bt brinjal in the feed on a total of 24 pools, i.e. 1440 fishes, instead of having two main groups. There were numerous unnecessary non transgenic control groups masking the significant effects between the two closest groups, Bt and non Bt.
- Reference groups: either the numbers were too high compared to the study group or some unnecessary reference groups were added; test material was also not isogenic in some studies.
- In allergenicity assessment, the novel GM protein is compared with some known allerges; however, not all allergens are known and two, there is no inclusion of unexpected proteins in this assessment.
- Skin irritation test and mucous membrane test under allergenicity testing: test material was applied only once and only 3 rabbits used for each treatment; allergies generally develop over repeated exposure, however.
- The methodology of the allergy study undertaken in Brown Norway rats does not meet the standards of allergy testing employed by other researchers that **have** found allergic reactions due to consumption of GM crops1 and the full results were not given in the text. (Prof Judy Carman)
- Digestive studies used an *in vitro* (in glass) method of determining how quickly the protein that is expected to be produced will break down in the intestine. No data appear to have been given for the digestibility of GM DNA. Such studies are notorious for providing false assurances about the digestibility of GM DNA and proteins. For example, such studies often use unrealistically high levels of stomach acid and digestive enzymes. The level of acid in a human stomach moves towards neutral once food enters it. The only real way to determine how quickly GM DNA and protein are digested is to do experiments in animals or humans. Several of these *in vivo* studies have shown that GM DNA can and does survive digestion and can be found in tissues of the body. A recent

study in Italy found that GM DNA present in the feed of cows could even be found in milk on supermarket shelves4.

- Acute toxicity study on mice where surrogate Bt protein was used and nptII protein results were shared: Refer to Judy Carman's paper for scientific flaws in the study
- **Oral toxicity study on rats**: This study used only 5 male and female rats per group, which is an completely inadequate number to determine the true toxicological effects of GM brinjal on these rats. To give just one example of how inadequate this is, the concentration of a key liver function enzyme in the blood, AST, gives a measure of the health of the liver. Male rats fed GM brinjal had a concentration of AST that was 48% and 63% higher than feeding rats non-GM brinjal. Yet, this clinically significant finding was not found to be statistically significant. Calculations indicate that adding just a single extra rat to each group to bring the number of rats to a still tiny 6 per group, would have made this difference statistically significant, which would in turn have indicated that feeding GM brinjal to male rats could cause liver damage. It appears that only one dose per rat was given and then the rats were followed for only 14 days. Food consumption, and only some haematology and biochemistry measurements were taken. It is normal to take 18-20 clinical biochemical measurements on blood from animals and humans to determine health. Yet only eight standard biochemical results are shown in the tables associated with this study. Only overwhelmingly adverse effects could be picked up this way using this number of animals for this time period and the study is simply inadequate to predict the effect of feeding this GM crop to 1.15 billion Indians for generations. Moreover, the company rarely reports the nature of the tests undertaken, the means, standard deviations, statistical tests undertaken or the p-values of the statistical analyses.
- Several animal feeding studies are presented in an effort to show that Bt brinjal is safe to eat. They include studies on fish, chickens, goats, rabbits, cows and rats. Most of these species are most unusual to use for human health studies, and many of the measurements taken on these animals are also unusual measures of human health. For example, chickens and fish are not even mammals.
- Sample size in several experiments too low for any statistically significant differences to emerge. No. of animals in several of the studies like the sub-chronic study with rabbits is too less to calculate statistically significant differences.
- Sub-chronic toxicity study in rats: raw data indicates that the rats were highly variable within a group at the beginning of the study – body weights varied by as much as 31% within a group! It is standard to take 18-20 biochemical measurements in blood to determine the health of an animal – this study takes only seven.
- No studies were done with blinded researchers.

THINGS THAT ARE PROBLEMATIC WITH THE ANALYSIS OF DATA SUBMITTED:

- Bt brinjal appears to contain 15% less kcal/100 g and 16-17 mg/kg Bt insecticide toxin poorly characterized for side effects. This has not even been analysed for why and what potential implications.
- Alkaloïdal content was measured: Bt fruit powder and roots contain less solamargine, solasonine is more elevated in Bt fruits and roots than in non Bt. Data did not calculate the statistical significance of these differences (up to 237% for instance). Information about the chemical composition and alkaloid content measurements did not provide the following standard and required statistical information: the mean and standard deviation of each group, the nature of the statistical test done and the p-value resulting from the statistical test. Furthermore, the analysis of alkaloid content in GM brinjal does not even provide information as to how many brinjal were tested in each group.

- Acute toxicity tests with rats showed female GM-fed rats consuming 32% more than the corresponding controls – this has not been reflected in the summary.
- Broiler chicken study: feed intake differences – statistical significance was not calculated
- Generally, are there differences present in the raw data, not reported in the summary and main report? This has to be checked for all studies and appropriate statistical analysis re-conducted.
- In the animal feeding studies, no data is provided on the nutritional adequacy of the diets provided to different treatment animals in the study.

Differential effects should be brought out primarily with the closest control. In experiments meant for biosafety assessment, comparison should not be with historical data or with a wide range of US data, just to shroud the statistically significant differences between the study and closest control groups.

THINGS THAT ARE PROBLEMATIC WITH THE INTERPRETATION OF THE RESULTS:

- Statistically significant differences cannot be disregarded just because no linear dose-related response or time-related response is seen. Many chronic diseases show similar build-ups.
- Goat feeding study showed differences in hay consumption, prothrombin time, bilirubin, alkaline phosphatase, weight gain etc. –seems like a sex-dependent effect like in the case of endocrine diseases. Cannot be disregarded.
- Several differences found in the rabbit toxicity study disregarded as incidental and not treatment-related.
- In the cow feeding study, significant differences along different parameters (milk production, dry matter intake, ash content of the milk etc.) were disregarded.
- In the Sprague Dawley rats' sub-chronic toxicity study, significant differences for various parameters (circling disorder, diarrhea, liver weight and liver to body weight ratio, water consumption etc.) were disregarded to call Bt Brinjal safe.
- Broiler chickens study: blood glucose level differences disregarded
- Common carps feeding study: average feed conversion and efficiency ratios showed differences – however, safety was concluded

Significant differences found during some periods of the experiments were disregarded; or differential effects between male and female animals were disregarded. Absence of linear correlation with doses was also used to discount some significant differences. However, chronic effects like endocrine effects or carcinogenicity is still possible with such differences.

THINGS THAT ARE PROBLEMATIC WITH THE REPORTING BY MAHYCO:

The methodology and results are often insufficiently reported to be able to determine what the studies were actually measuring or how various variables were measured. Included in this, the statistical results have not been reported to a suitable standard. For example, means, standard deviations, and p-values, which would be required for any peer-reviewed scientific journal, are usually omitted. (Prof Judy Carman)

THINGS THAT ARE PROBLEMATIC WITH THE PROCEDURES ADOPTED:

- All studies have been paid for by the company – DBT, which provides so much tax-payers' funds for GM crop development should also spend on safety testing on an independent basis; with Bt Brinjal, there has been no independent research so far

- There has not even been any independent analysis/review commissioned by the regulators on Mahyco's data.

- Not all laboratories used for the biosafety data generation so far are accredited

- The samples given by Mahyco have been used as are, without any verification of whether they are Bt or non-Bt as claimed. No blinded research.

Annexure 1

DR. BHARGAVA's BIOSAFETY ASSESSMENT RECOMMENDATIONS: TESTS THAT MUST BE CARRIED OUT BEFORE A GMO IS RELEASED INTO THE ENVIRONMENT

TESTS PRESENTLY NOT DONE FOR ANY GMO	**TESTS PRESENTLY NOT DONE FOR ANY GMO**
• DNA fingerprinting and proteomics analysis and full characterization, both structurally and functionally, of the differences between the GMO and the parent organism • The total sequence of the transgene-flanking regions and the transgene, and identification of the site(s) of integration of the transgene in the GMO • Changes in the glycosylation pattern • Determination of any selective increase in transcription and translation, thus including a study of the transcriptome • Changes in the relative concentration of major and important intracellular metabolites • Changes in surface properties that may affect normal interaction between species, and with the environment, studied through scanning electron microscope and atomic force microscope • Reproduction interference • Gene flow • Dispersal into areas where positive harm could be done (as happened with water hyacinth and parthenium) • Development (if not already available) of a technique to determine with accuracy 0.01 percent contamination with GMO or its product • In the case of GM food material, possible interaction with commonly used drugs, especially probiotics • Acute toxicity studies with native **(not "surrogate"**) protein, GM seeds and other GM plant material that is normally ingested by animals, including cattle. These studies sh	• Chronic toxicity studies (including carcinogenicity) as above • Effect on cattle GI microflora • Effect on soil micronutrients in every region concerned (rain-fed, irrigated, semi-arid, etc.) where GMO is likely to be released or find its way • Development of resistance to the trait that is introduced • Increasing requirements for refuge crops, if any. • Increase in susceptibility to pests and infectious agents other than those that may be expected to be killed by the transgene. • Comparison of the growth characteristics of the GMO and the parent organism. • Emergence of new dangers, for example of super weeds, following prolonged use of herbicide-resistant GM crops. • Effect on the population density of non-susceptible pests, following at least five successive plantations – for example in the case of GM Bt plants. • Automated karyotyping and gross chromosomal analysis. • If the GMO is a plant, its biomass productivity in comparison to the parent. • Comparison of inputs required for optimal growth of the GMO in comparison to the parent organism. • Impact on ecology in controlled field trials (for example, on population of bees, and other useful insects). This would require total mapping of insects and other living species in every region where the GMO is intended to be released, over a substantial period of time.

TESTS CLAIMED TO BE DONE BUT AS GOOD AS NOT HAVING BEEN DONE
• Stability of the transgene product in the whole organism and/or parts thereof, under various conditions of storage or handling (e.g. cooking in case of an edible GMO) • Efficacy on useful insects. • Effect on microflora of the soil • Allergenicity

According to Dr Pushpa Bhargava's note to the GEAC, it should be obligatory to obtain the following information (as applicable) for risk assessment in respect of the GMO that is intended to be released in the environment for commercial purposes without containment:

(a) Molecular characteristics of the GMO (e.g. through DNA fingerprinting and proteomics as mentioned above), with complete information on the site and sequence of every genetic change that has occurred in the GMO. Thus, the total sequence of the transgene should be available with details, for example, of glycosylation.

(b) Details of the technology, with all steps clearly stated, that was used to effect the above-mentioned genetic changes (intentional or unintentional).

(c) Automated karyotyping and gross chromosomal analysis.

(d) Details of plasmids, transposons or insertion elements introduced.

(e) Properties of the product of the gene(s) considered to be introduced (allergenicity; toxicity; will it lead to resistance to a microorganism or pest?).

(f) Growth characteristics of the GMO (comparison with the starting host organism).

(g) Nutrient, soil, climatic and other requirements of the GMO (comparison with the host or wild type).

(h) The nature of interaction (including symbiotic) with other organisms (comparison as above).

(i) Exhaustive nutritional and toxicity studies with the organism or its product (the real and not a surrogate one) that may be intended to be used as food, using a spectrum of targets.

(j) Dispersal patterns of the GMO where applicable, and comparison with those of the starting organisms.

(k) Gene flows from the GMO under normal ecological conditions.

(l) If the GMO is a plant, the viability of hybrids (comparison as above).

(m) If the GMO is a plant, its biomass productivity.

(n) Detailed chemical composition of the GMO with respect to all nutrients, including amino acid composition and glycosylation pattern of total protein, and comparison with the parent.

(o) Stability of the transgene product in vivo and in vitro.

(p) Interaction with probiotics, in vitro and in the GI tract.

(q) Lateral gene transfer in the gut (GI tract).

(r) Toxicity against a range of animal species, using native and not surrogate protein.

(s) Details of any structural or surface changes in the GMO through scanning electron microscopy and atomic force microscopy.

(t) Impact on ecology in controlled field trials (e.g. on population of bees and other useful insects). (This would require total mapping of insects and other living species in every region where the GMO is intended to be released , over a substantial period of time.)

(u) The proposed manner and mode of the use of the GMO (when and where will it be grown, harvested and processed? If it is to be grown in a containment facility, what are the chances of its escape?)

ANNEXURE 2: Extracts from meeting of Expert Committee on Bt brinjal held on 3.07.2007

"The Committee further recommends conduct of the following studies during large scale trials:
i. Field trials for assessing the environmental safety and agronomic advantage of Bt brinjal needs to be repeated at a minimum of 10-11 locations to represent different agro climatic zones for two seasons. The protocols for the trials would be finalized by RCGM in consultation with Director, IIVR.
ii. The pollen flow would be recorded during the field trials every 10 m up to 200 m in one trial plot at a minimum of 6 locations representing different agro climatic zones for a period of two years. The pollen flow study should be conducted with a minimum of around 100 standing plants, planted at an interval of 75x50 cm spacing.
iii. The field trials should include at a minimum of one location (at IIVR, Varanasi) to assess the extent of cross ability of Bt brinjal (Solanum melongena) with S. incanum. The trial should also record the findings with respect to weediness and invasiveness of S.incanum containing transgene.
iv. As per the directions issued by RCGM baseline susceptibility data needs to be generated for at least three pests - Fruit and Shoot borer (Leucinodes orbonalis), Gram caterpillar/fruit borer (Helicoverpa armigera) and Stem borer (Euzophera perticella), over a minimum of two years (two seasons). The Committee noted that baseline susceptibility data for stem borer have not been generated. The Committee advised that the same may be conducted during the two year field trials.
v. The Cry1Ac protein expression levels were assessed every 30 days and not every 15 days as prescribed by RCGM through the crop cycle. The Committee recommends the study be repeated in accordance with the procedure prescribed by RCGM.
vi. Soil impact assessment study should include tests on the counts related to Rhizobium in the soil of Bt and normal plots and for the presence/absence of Cry1Ac protein at different depths (up to one metre) in the soil at one location. The changes in fertility and impact on next crop may also be recorded. In other words carry over effects of residues of Bt brinjal should be investigated.
vii. Bt brinjal being a food crop, a flavour analysis of Bt and non-Bt fruits may be included as an additional parameter and this study may be undertaken at CFTRI.
viii. The Company to review if the highest MIC95 value should be kept for monitoring rather than the average for the target pest vis-à-vis Cry1Ac protein expression levels.
ix. The Food / Feed Safety assessment should include foliage toxicity study in Goats.
x. The skin sensitization test of transgenic material in guinea pigs as laid down in the DBT guidelines has not been taken up. The Committee recommended the study may be conducted.
xi. Additional toxicity / allergenicity / compositional / nutritional studies as recommended by Director, NIN after examining the raw data on food and feed safety generated by the Applicant.
xii. Detailed socio economic study as prescribed by a three member Sub Committee comprising of Dr. S. Parasuraman, Director, TISS, Mumbai, Dr. M.N. Murthy, Director, IEG and Dr. Mathura Rai, Director, IIVR, Varanasi.
xiii. Analysis of fruit dry matter to determine differences in yield from the agronomic trials in respect of Bt and check entries.

Results from all studies must be reviewed along with the socio economic study to decide on the introduction of Bt brinjal in India".

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To

Dr. Manmohan Singh,
Prime Minister
New Delhi

Dear Mr. Prime Minister,

This is to bring to your attention the resolution adopted at the Colloquium on Bt Brinjal organised by the Centre of Social Medicine and Community Health (CSMCH), School of Social Sciences, Jawaharlal Nehru University (JNU), New Delhi, in collaboration with Hazards Centre, New Delhi on the 27th of January. The resolution is enclosed.

As public health workers, we are seriously troubled with this move to permit commercial cultivation of Bt brinjal. While we feel hunger is a public health issue that needs profound policy commitment that it does not obtain, this does not imply that the introduction of a genetically modified vegetable is a priority.

Our concerns stem from several factors:

1. First of all, this is entirely unnecessary from a public health perspective, indeed undesirable. The argument that Bt brinjal would not require pesticides is dissembling. There are other, better, pest management methods like non-pesticidal management that we need to utilize.

2. We believe that there are serious issues of safety that are not yet addressed through long term studies. There is some data that these crops could be allergy-inducing, and indeed that they might be mutagenic. Countries in EU have a precautionary approach towards GM crops and major countries like Germany, France, Hungary, Greece etc have imposed a ban on their cultivation".

3. There are serious methodological flaws in the studies that have been carried out, not to mention ethical ones.

4. There are profound conflict of interest issues involved in the studies carried out in India. The companies that stand to gain by the introduction of these crops into the market were the sponsors of the studies. This is entirely unacceptable.

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Submission by Dr. Vandana Shiva
at
Public Hearing on Bt. Brinjal
Organised by Ministry of Environment
held at
IMA's J.R Shaw Auditorium, Nagpur on 27th January, 2010

Bt. Brinjal is a test for India's Seed Sovereignty, Food Sovereignty and Knowledge Sovereignty

The approval of Bt. Brinjal by the GEAC has exposed the unscientific basis on which genetically engineered crops are being commercialized and the regulatory chaos and corruption introduced by the biotech industry with its undue influence on the decision making on Biosafety.

The admission by the Chair of the panel EC II on the Bt. Brinjal Dr. Arjula Reddy, that the Agriculture Minister pressurized the panel to approve the Bt. Brinjal is a symptom of the corruption that needs investigation. The continued declarations by the Minister that the decision of the panel which he has unduly influenced should be final and the public hearings and national consultations undertaken by the Minister of Environment should not be taken into account is additional evidence of the corrupting influence of the biotechnology industry. Monsanto was caught bribing officers in the Indonesian regulatory system for approval of Bt. Cotton. The Government and the Central Bureau of Investigations (CBI) should investigate the corruption involved in the approval of Bt. Cotton and Bt. Brinjal.

Monsanto's Bt. Crops are corrupting and polluting our biodiversity and seeds, our food and agriculture, our science and knowledge systems, and our regulatory processes and democratic fabric.

The Bt. Brinjal debate is not just about a vegetable. It is a test for our seed sovereignty, our food sovereignty, our knowledge sovereignty, our democracy. This is why it was so important to take it to the public through the series of public hearings that have been organized by the Ministry of Environment. The public hearings should be treated like a referendum on GMOs, like the referendum in Switzerland which has led to a five year GMO moratorium. This is vital for democracy in the most vital aspect of life – the food we eat.

Ecological and Health risks are inherent to Genetic Engineering

Genetic engineering needs careful assessment because it allows the transfer of genes from one organism to a totally unrelated organism, crossing species barriers. This has consequences for the organism, for the environment into which it is released, and for the species which consume it as food.

It was these unpredictable consequences that led the founding fathers of genetic engineering or recombinant DNA research to call for a moratorium on genetic engineering at Asilomer, California in 1972.

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However genetic engineering was hijacked by Wall Street and the biotechnology industry and they started to rush GM crops with false promises to the market.

Not only are the consequences of genetic engineering unpredictable, the technology itself is unpredictable. It has been falsely projected by the biotechnology industry that because the manipulation of plants is at the genetic level, genetic engineering is more accurate and precise than conventional breeding. This is not true. There are only two tools used for current genetic engineering – one is the gene gun, the other is a plant cancer – Agrobacterium tumefacieus.

And in both tools, it is uncertain if the gene transfer is successful or where in the genome the introduced gene is inserted. Unlike machines, living organisms have the capacity to organize themselves. Introduced genes can function differently than predicted and they can move unpredictably into other organisms. Engineering is in fact an inappropriate word for genetic manipulation. Basically, a plant's genome (all of its genes taken together) is a block box. Genetic engineering takes a gene from one black box and forces it into a second black box, hoping that the new gene will be taken up. Most of the time the experiment fails. Once in a thousand times the foreign gene embeds itself in the recipient plant's genome, and the newly modified plant gains the desired trait. But that is all the technicians know. They have no idea where in the receiving plant's genome the new gene has found a home. This fundamental ignorance, combined with the speed and scale at which modified organisms are being released into the global ecosystem, raises a host of questions for the future on the safety of agriculture, of the environment and of human health (Against the Grain, Rachel's Weekly, 18 February 1999)

The uncertainty of the technology is the reason that antibiotic resistance marker genes are used to separate the cells whose genome absorbed the foreign gene from those that do not. The Bt. Brinjal uses a gene Cry 1 Ac to produce a toxin from a soil organism – Bacillus Thurengensis (BT) as well as two antibiotic resistance marker genes. The npt 11 gene confers resistance to the antibiotics kanamycin and neomycin. The aad gene confers resistance to antibiotic resistance marker genes is to separate the cells that absorbed the Bt. Gene from those that did not.

The use of antibiotic resistance markers is in fact a proof of the inaccuracy and unreliability of genetic engineering as a technology. Medical associations in U.K and the U.S have called for a stop to the use of antibiotic resistance markers to avoid a public health disaster.

While having no advantage for plant breeding, anti-biotech resistance genes create a major public health risk through horizontal gene transfer.

Horizontal, or lateral, gene transfer is defined as the non sexual transfer of genetic information between organisms. Ordinarily gene transfer takes place vertically from parent to offspring. Horizontal gene transfer has been identified as the reason for the emergence of antibiotic resistance. The first definitive evidence for this came from DNA sequence analysis of the genes for neomycin-kanamycin resistance to Staphylococus aureus, Streptococci and Campylobacter. Antibiotic resistance gene, especially those carried on plasmids and transposcons, can in principle, cross species as well as genera and even kingdoms. Horizontal gene transfer is also identified as the process behind the emergence of new and virulent streams of pathogens since the 1980s. A sever infection by streptococcus pyogenes was traced to toxin encoded by a gene belonging to a bacterial genome.

Genetic engineering can increase the risks of horizontal gene transfer. Firstly,the vectors used for transferring genes from one organism to another can themselves become mechanisms. These vectors are

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aggressive hybrids made by joining together bits of natural gene-transfer vectors – viruses, plasmids and transposons. They are designed to be promiscuous, so that they can effectively smuggle genes into cells that would other exclude them. The most common vector used is Agrobacterium tumefacieus, which causes cancerous tumors, known as crown galls, in plants. This is the vector that has been used Bt. Brinjal. In addition, Ca MV 35S, a virulent virus has been used a viral promoter.

Testing the naturally occurring Bt. is not the same as testing the Transgenic Bt

To assess biosafety, safety tests need to assess the transgene – i.e the Bt. Gene Cry 1Ac plus antibiotic resistance marker genes (npt 11+aad) plus the viral promoter (Ca MV3 35S) plus the vector (Agrobacterium).

However, the tests on biosafety of Bt. Brinjal done by Monsanto / Mahyco and approved by GEAC have not tested Bt. Brinjal at all. They have used the naturally occurring and safe microbial Bt.

The surrogate Bt. protein is not the same as the transgenic protein. Plants and bacteria are very likely to produce different proteins even when transformed with the same gene (Ref. D. Schubert, A different perspective on GM food, Nature Biotechnology, 20, 215-249, 2002). One difference is that bacteria do not add sugar molecules to proteins, but plants do glcosylation which can contribute to allergenic proteins.

The National Academy of Science has recommended that "tests should preferably be conducted with the protein as produced by the plant".

The safety of microbial Bt. sprays cannot be used as proof of safety of transgenic Bt. Bt sprays are composed primarily of endotoxins in an inactive crystalline form. They are only toxic to insects with alkaline gut conditions that permit solubilisation of the crystal to protoxin, followed by proteolytic cleavage to the active toxin. Bt. crops on the other hand are genetically engineered to produce the Bt. toxin, which is active without processing. There is also evidence indicating that Cry toxins are more immune reactive than Cry protoxins (Ref. William Freese and David Schubert, Safety Testing and Regulation of Genetically Engineered Foods" in Stephen Harding (Ed) Biotechnology and Genetic Engineering Reviews – Vol 21, no. 2004, p. 299 – 324, Int.)

The scientific corruption by the biotech industry and the sacrifice of knowledge sovereignty began in 1992 with the concoction of the false principle of substantial equivalence. The false assumption of 'susbtantital equivalence' was introduced by President Bush in US policy immediately after Rio to blunt the call for biosafety regulation. It was later formalized and introduced in 1993 by OECD (UN Organisation for Economic Cooperation and Development), and subsequently endorsed by

FAO (UN Food and Agriculture Organisation) and WHO (World Health Organisation). The OECD document states –

> *"For foods and food components from organisms developed bythe application of modern biotechnology, the most practical approach to the determination is to consider whether they are substantially equivalent to analogous food products if such exist. The concept of substantial equivalence embodies the idea that existing organisms used as foods, or a s a source of food, an be used as the basis for comparison when assessing the safety of human consumption of food or food component that has been modified or is new."*

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Apart from being vague, this definition is unsound. Foods with Bt. Toxin genes are not the same as foods without. Herbicide resistant crops are different from existing varieties because they have new genes for resistance to herbicide. An article by Marc Lappe and others in the Journal of Medicinal Food (1999) has established that Monanto Roundup Ready soya beans change the levels of phytoestrogens by 12 to 14 percent. To treat these differences as insignificant when it is a question of safety, and as significant when it is a question of patentability, is totally unscientific. As Millstone, Brunner and Mayer have stated in "Beyond Susbtantial Equivalence' (Nature, 7 October, 1999) :

> *"Substantial equivalence is a pseudo-scientific concept because it is a commercial and political judgment masquerading as if it were scientific. It is, moreover, inherently anti-scientific because it was created primarily to provide an excuse for not requiring biochemical or toxicological tests. It, therefore, serves to discourage and inhibit potentially information scientific research."*

The bias of the panel is evident in the fact that it cites the non-regulation and non-assessment in U.S as evidence of "safety" but ignores the safety test results in France and Austria which have led to the GM bans in these countries.

The scientifically false principle of substantial equivalence was put in place in U.S immediately after the Earth Summit to undo the articles on Biosafety in the Convention on Biological Diversity.

The false assumption of "substantial equivalence" of GMOs and non-engineered organisms establishes a strategy of deliberate ignorance. Since the transgenic is never assessed, ignorance of risks is then treated as proof of safety. "Don't look, don't see, don't find" leads to total lack of information about the ecological impacts of genetic engineering.

"Substantial equivalence" also contradicts the claim to novelty and invention through patents. Mahyco has a patent on Bt. Brinjal. When industry wants to avoid risk assessment and issues of liability, the argument used is that the genetically engineered organism is "substantially equivalent to the non-engineered parent organism. However, when industry wants intellectual property rights and patents, the same GMO become "novel" or substantially in-equivalent to the parent organism". This is ontological schizophrenia.

Bt. crops create pests and increase pesticide use

The more the biotechnology industry talks of science, the more it undermines it. Bt. Brinjal illustrates this so well.

The rationale for Bt. Brinjal is unscientific because it does not compare all available options for pest control, and it does not fully assess the performance of Bt. Crops as a pest control strategy.

The "Rationale for the development of Bt. Brinjal" presented by EC-II, is based on the false assumption that genetically engineered Bt. crops like Bt. Brinjal are an alternative to the use of chemical pesticides for pest control.

The panel does not address the real alternative to chemical agriculture which is organic farming based on the principles of agro-ecology. Biodiverse organic farming controls pests at the systems level by enhancing pest-predator balance and by growing crops with pest and disease resilience. Increasing ecological balance and resilience are the only effective and sustainable strategies for controlling pests. The 500,000 members

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of Navdanya know this through practice. Research on agro-ecology confirms that ecological / organic farming systems reduce pests and have no need for the use of pesticides.

In Indonesia, restrictions were introduced on the use of 57 pesticides in rice-growing, and subsidies for pesticides were eliminated. From 1987 to 1990, the volume of pesticides used on rice fell by over 50 per cent, while yields increased by about 15 per cent. Farmers' net incomes increased by $18 per farmer per season. The Government saved $120 million per year by ending pesticide subsidies. (Thrupp, 'New Partnerships for Sustainable Agriculture', 1997)

In Bangladesh the 'No Pest' programme led to pesticide reduction of 76 per cent and yield increases of 11 per cent. Returns increased by an average of 106 per cent in the dry season and 26 per cent in the wet season (Thrupp.)

The panel has totally ignored the real alternative to chemical pesticides – organic farming - in its rationale. It has distorted the organic alternative in its "responses". Instead of seeing organic as a farming system, it has reduced it to external inputs. The report states "In organic farming, the pest management totally relies on the use of botanical insecticides like neem oil, pongam oil, illupai oil or seed kernel extracts or leaf extracts which act as repellent, antiferdant or in some cases as toxins. None of the botanical pesticides are expected to perform well against the fruit and shoot borer (FSB) since the pest hides itself from the sprays while staying inside the fruits / shoot borer" (p.60)

This is an unscientific and false representation of the agro-ecological principles on which we have built the organic movement. Organic / ecological farming is not an input substitution system. It recognizes and respects the ecological processes through which pests are controlled and it also recognizes the processes through which pests are created.

Pests are created through –

1. Promotion of monocultures
2. Chemical fertilization of crops which makes plants more vulnerable to pests
3. Emergence of resistance in pests
4. Killing of friendly species which control pests and disruption of pest-predator balance

Bt. crops are not an alternative to these pest creating systems. They are a continuation of a non-sustainable strategy for pest control which instead of controlling pests creates new pests and super pests. Bt. Brinjal, like Bt. Cotton, is grown as a monoculture, and is part of the package of chemical farming. Bt. Cotton, like Bt. Brinjal, was supposed to control the lepidopteron insects. In the case of cotton, the pest was the bollworm. In the case of Bt. Brinjal it is the fruit and shoot borer.

In Bt. Cotton we have witnessed the emergence of new non target pests and diseases such as aphids, jassids, army bug, mealy bug and "laliya". This has led to an increase, not a decrease in pesticide use. Navdanya studies show a thirteen fold increase in pesticide use in Vidharbha after the introduction of Bt. Cotton.

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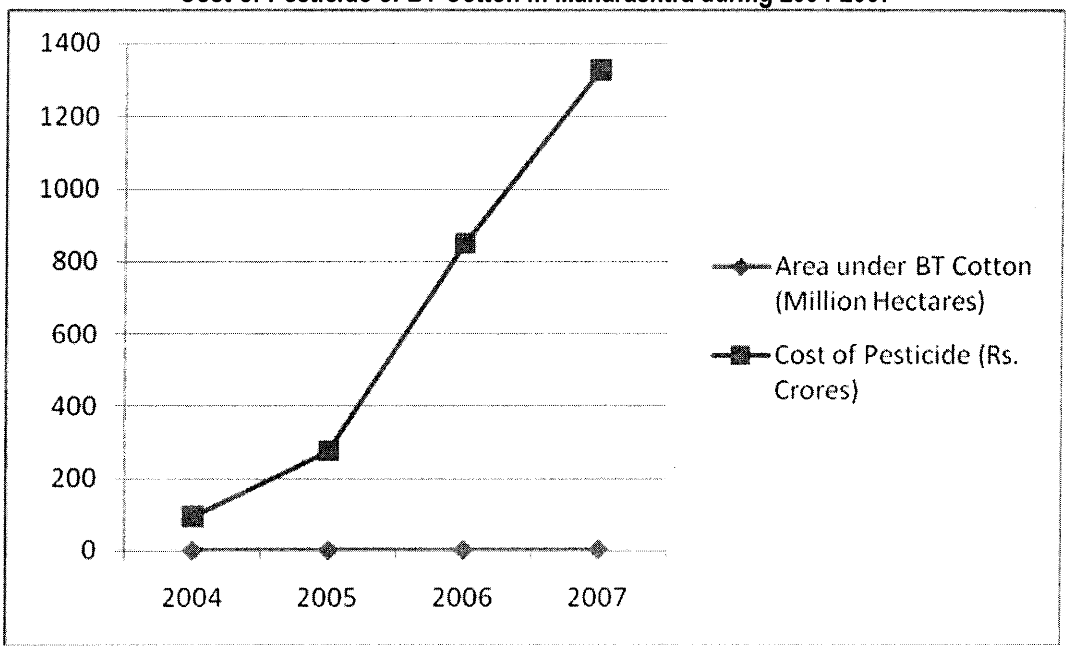
Area under BT Cotton and cost of Pesticide in Maharashtra

Year	Maharashtra	
	Area under BT Cotton (Million Hectares)	Cost of Pesticide (Rs. Crores)
2004	0.200	92.10
2005	0.607	273.45
2006	1.840	847.32
2007	2.880	1326.24

Cost of Pesticide of BT Cotton in Maharashtra during 2004-2007



Genetically engineered Bt. crops also contribute to emergence of resistance in the target pests. The bollworm becomes resistant to the Bt. toxin when every cell of the plant releases it in high doses all time. The need for refugia and the introduction of Bollgard II are evidences of the emergence of resistance in pests as a result of using GM Bt. technologies.

The economic benefits of Bt. Brinjal are distorted because they are based on the false assumption of savings of pesticide sprays and yield benefit due to protection of fruit and shoot borer. Bt. Cotton led to increased sprays and emergence of new pests. This risk in Bt. Brinjal has not been addressed. Nor has the cost of royalties, since Bt. Brinjal is patented. Seed cost in cotton jumped from Rs. 7 to Rs. 1700/- when Bt. Cotton was introduced.

The real cost benefit calculation and comparison should be between organic brinjal cultivation based on open pollinated seeds that farmers can save and Bt. Brinjal whose seeds farmers must buy every year, and which will be suceptable to new pests for which more pestices will need to be used.

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In an honest and scientific assessment, benefits of biodiverse organic farming outweigh the "benefits" of Bt. Cotton. Navdanya's organic farmers have increased their incomes tenfold when they shifted from Bt. Cotton to organic cultivation.

The risks of biopollution of our rich biodiversity heritage

India is recognized as the centre of diversity of Brinjal. Yet the panel wants to disown our rich biodiversity heritage in the year of biodiversity just to help Monsanto to spread its bioimperalism.

The panel is also totally irresponsible about biopollution. Genetically engineered Bt. Brinjal can lead to genetic pollution and contamination, by destroying the unique characteristics of biodiversity, by contaminating organic farms and by effecting beneficial species. Here too, totally unscientific arguments have been used by the panel to deny the ecological risks of genetic pollution. The panel cannot make up its mind whether Brinjal is self-pollinated or cross pollinated.

"Brinjal is a normally highly self-pollinated crop, however the scientific data with regard to cross pollination generated independently by various agencies shows a wide range of out crossing, suggesting its classification as "an often cross pollinated" crop. Therefore Indian researchers have reported 2 to 48% out crossing in brinjal varieties in India" (p.38).

There is similar variation in the pollen flow studies carried out by Mahyco and reported in the panel. When Mahyco did the pollen flow study in 2002, the percent out crossing of the Bt trait ranged between 1.46 to 2.7% and the maximum distance transversed by pollen from Bt. Brinjal plants was 20 m.

In 2007, the out crossing had dropped to the range of 0.14% and 0.85%, and the distance the Bt. Pollen traveled had increased to 30 metres.

These unscientific claims go counter to the established science of plant breeding which has established 200 metres as the isolation distance for breeding foundation seed and 100 metres for breeding certified seed for Brinjal. The pollution from transgenic crops is spreading through cross-pollination and hybridization, as well as through vertical gene-flow through the food chain. There are no biosafety regulations to stop this genetic pollution. In India, the buffer zone in GE trials is a mere 5 metres (about 16.5 feet). In the UK it is 200 metre (about 660 feet). But the canola seed from Canada introduced into Europe had been contaminated in spite of a 800 metre (2600 feet) buffer zone. The former UK Minister for the Environment, Michael Meacher had to admit that bees, which may fly upto 9 kilometres (6 miles) in search of nectar, cannot be expected to observe a "no-fly-zone' (Greenpeace and the Soil Association, the True Cost of Food, 1999). A study by the National Pollen Research Unit in 1999 shows that wind can carry viable maize pollen hundreds of kilometers in 24 hours. Transgenic pollen was found 4.5 km (nearly 3 miles) from a field of GM oilseed rape in the Oxfordshire. This was at least 20 times over the limit set by the regulatory agencies (Reuters, 30 September, 1999)

Our vegetable growers often have less than a bigha of land. This level of genetic pollution will destroy our farmers who with love and care produce pesticide free, GMO free vegetables for citizens. Instead of recognizing that approval for commercial cultivation of Bt. Brinjal is a threat to organic growers, the panel carelessly and callously states –

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"The section of farmers who have a preference for organic farming can do so by following established agronomic practices such as maintaining isolation distance, differences in flowers time etc. for preventing cross contamination and ensuring identity preservation for organic produce" (p.60)

Why should our small organic growers have to bear the burden of genetic pollution and the burden of avoiding contamination of their crops? Liability systems need to be evolved which make the company liable for economic damages to organic farmers. And till then there should be a moratorium on Bt. Brinjal.

During the moratorium, the Government needs to set up interdisciplinary biosafety assessment labs and teams, and inter-ministerial biosafety regulatory processes which should be independent of the biotechnology industry.

This is imperative to protect our seed sovereignty, food sovereignty and knowledge sovereignty – the foundations of our Food Democracy and Food Freedom.

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5. There has not been adequate assessment of the ecological consequences of the introduction of this food crop. These concerns regarding the health and environmental risks associated with GM crops are too serious to be disregarded.

6. Given our retailing structure, labeling is impossible in India and contamination is inevitable.

7. Finally, we believe that increasing the role (and control) of multinationals in our agrarian economy is undesirable.

In short, this policy move is entirely unnecessary, has not been transparent and is potentially injurious to public health. We believe there should be a moratorium on such technologies till their safety both to human beings and the environment is proven.

Best wishes,
Mohan Rao
Dr.Mohan Rao
Professor,
Centre of Social Medicine and Community Health
Jawaharlal Nehru University
New Delhi 110067

Copy to:

Shri Ghulam Nabi Azad, Union Minister of Health & Family Welfare
Shri Sharad Pawar, Union Minister of Agriculture
Shri Jairam Ramesh, Union Minister of Environment & Forests
Shri Basudev Acharya, Chairman, Parliamentary Standing Committee on Agriculture

Encl. Resolution of the JNU Colloquium on Bt Brinjal

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RESOLUTION

The Centre of Social Medicine and Community Health, School of Social Sciences, Jawaharlal Nehru University, New Delhi, in collaboration with Hazards Centre, New Delhi, organised a Colloquium on Bt Brinjals on the 27th of January 2010. Attended by students and faculty, the house resolved as follows.

Various issues are unresolved about the problematic nature of transgenic technologies in general and Bt in particular. One core issue was the competence, the transparency and the conflict of interest in the regulatory process prior to the grant of licence to market Bt brinjal.

Safety issues have not been adequately dealt with both in terms of food safety and environmental safety. Long-term studies on allergicity and toxicity have not been carried out prior to approval.

We are also concerned about the implications for food security for the country. It is not desirable to hand over the control of seeds to transnational monopolies. To ensure that access to seed is ensured, the Intellectual Property Rights (IPR) regime must retain farmer's rights and must not reduce flexibilities in Indian law.

As per the Cartagena protocol, to which India is a signatory, transgenic versions of crops for which we are the country of origin should not be permitted. Mexico, China and Peru follow this protocol. Thus transgenic varieties of Bt brinjal cannot be permitted in India.

A system of post-release monitoring must be put in place before commercial release is allowed into the environment to assess the performance and impact. Exhaustive socio-economic studies are necessary to assess the impact of transgenic crops on traditional agricultural systems and indigenous crops.

A proper system of labelling of GM crops must be put in place with public awareness to enable informed choices.

A system of public participation in decision- making and in regulatory bodies must be put in place. All regulatory data and bio-safety data should be available to the public.

A law of liability must also be in place before commercial release is permitted so that companies are liable to health and environmental damage that might ensue.

Till such systems are in place, this house calls for a moratorium on all transgenic crops.

The herbicide tolerant trait should not be permitted in India as this will displace agricultural labour and destroy valuable plants used as food, fodder and medicines.

There is indeed an acute agrarian crisis in the country. The solution to this does not lie in GM technologies. There are cheaper, safer, healthier options that must be explored and supported.

GM CROPS: CITIZENS WRITE TO THE PRIME MINISTER AND MRS SONIA GANDHI

Smt. Sonia Gandhi,
Chairperson,
United Progressive Alliance (UPA),
10, Janpath,
New Delhi 110011

Dear Shrimati Sonia Gandhi

In July 2009, Dr Anbumani Ramadoss received a formal reply to his letter dated 2nd February 2009, from Mr Prithviraj Chauhan in his capacity as Minister of State in the PMO. (This letter is enclosed). Dr Ramadoss addressed his letter to you when he was Minister of Health and Family Welfare.

We are understandably concerned at the contents of this letter. Its admitted source for much of the content is the organisation called International Service for the Acquisition of Agri-biotech Applications (ISAAA). This organisation is part of the marketing arm of the major international biotechnology companies and not a source of unbiased or peer-reviewed information. The information coming from the ISAAA is contested and rejected by many. Its stated objective is to promote GM crops, with India and other developing countries as the focus. Given this fact, it is not surprising that the letter is factually incorrect in virtually the whole of its content and is not science-based. We enclose a response to this letter addressed to you as our Prime Minister, endorsed by leading *independent* academic scientists of international standing. We urge you to please read it.

This communication proves that significantly erroneous views are formally held by the PMO and several of your Cabinet colleagues about the supposed benefits of GM crops. These views have driven successive government policy, including the Congress Party policy on agriculture and the role of genetically engineered food crops. We therefore, must conclude that there has been a purposeful and systematic intent by the Regulators (GEAC, RCGM and DBT), to mislead you and former prime ministers about the truth of GM crops. We are furthermore, convinced by the evidence on record, of a blatant conflict of interest within the regulators and the committee charged with the appraisal of Bt brinjal called the Bt brinjal Expert Committee II (EC II). The evidence also shows that the appraisal process, minimal guidelines used and subsequent approval are fraudulent. Information just received under the RTI for example, squarely refutes the Regulators claim that the extensive reports from several States in India of allergenicity and specifically, animal deaths from toxic reactions attributed to grazing in Bt cotton fields, have no substance. This is a serious falsification of the true facts. No investigation of any depth, leave alone of scientific rigour, has been conducted to ascertain the safety of the Bt gene in Bt cotton and the reason for the animal deaths. We quite simply have not done the studies. Moreover, we do not have the means to test for allergenic reactions to Bt toxins. Unfortunately, the Minister of Agriculture, Mr Sharad Pawar even allegedly saw fit to bring inappropriate pressure on the Chairperson of the Committee and interfere with the regulatory process. It is deeply worrying that Monsanto is also in a position to influence the regulatory process in India. Monsanto has been indicted for and convicted of serious crimes for repeated fraudulent processes & procedures in safety-testing of GM crops, and is presently under investigation by the US Justice Department for antitrust law violations. These are a matter of record and will be furnished if you so wish, along with other evidence of impropriety by the Regulators.

These are serious charges, Madam. We are fully conscious of the implications of our charge and are driven by the undeniable fact that India has a just one chance to get things right. The impacts of GM Crops are irreversible. The greatest single danger India faces today is the massive disinformation on GM crops. Wrong briefs and erroneous facts cannot produce sound public policy. Nor may we accept hurried approvals unsupported by the most comprehensive, stringent and rigorous adherence to safety protocols, in their processes & procedures. Independent testing in labs working to accredited international standards is the sine qua non of bio-safety regulation to address the unique risks that GM crops pose. Unfortunately, none of this is in place. We have upwards of 20 independent appraisals by world eminent scientists of Monsanto's safety dossier/and or the Bt brinjal EC II Report. These reveal significant gaps in safety testing, cover-ups, & shoddy protocols. The greater charge must be levelled against the GM Regulators, who are responsible for the Nation's bio-safety. They have not only defended these serious shortcomings, but have given overtly hasty approval to the commercialisation of Bt brinjal.

GM crops thus far are NOT engineered for yield gain and to date, not a single GE plant offers this trait or any other trait. There is no one alive today who would otherwise have starved if there were no GM crops ever grown. In fact, there may be less food in a GM world than a conventional world because GM crops are suited to the inefficient production of ethanol which is subsidised by the US government. If those subsidies did not exist, there would be more food for people. You may rightly be anxious about where we will find the answer to yield increase in Indian agriculture and other developing countries and how may we meet the challenge of global food production and genuine food security through productive agriculture in the next 50 years? There is no need to worry: India has already endorsed the solution.

The IAASTD Report: We point you to the IAASTD Report (the International Assessment of Agricultural Knowledge, Science and Technology for Development), a UN and World Bank report that India ratified in 2008. These questions were considered methodically and holistically by the single largest research exercise in history. This report, published in January as *Agriculture at a Crossroads*, was produced under the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD). It involved around 400 researchers and twice the number of peer-reviewers. The agricultural equivalent of the IPCC and modelled on it, it underwent two rounds of open international peer-review and was ratified overwhelmingly at the intergovernmental plenary in April 2008.

The "IAASTD" sees no role for GM crops in developing countries. It makes it clear that the road map for agriculture for the next 50 years must be through localised solutions, combining scientific research with traditional knowledge in partnership with farmers and consumers. *The Report calls for a systematic redirection of investment, funding, research and policy focus toward these alternative technologies, such as agro-ecological agriculture, and the needs of small-farmers.* 'Business as usual' will inevitably result in food and fuel needs exceeding global ability to meet them. However, this isn't a food shortage problem. The problem historically and presently is caused by social barriers and because of the model of industrial agriculture (external input intensive) for which most GE products are designed. In fact, more GE is more 'business as usual'.

The urgent question is why this timely report which we have ratified has been comprehensively ignored in formulating India's official policy for a road map for agriculture and food security? The Union of Concerned Scientists too makes unequivocal analyses of the solutions. "*It makes little sense to support genetic engineering at the expense of technologies that have proven to substantially increase yields, especially in developing countries... these include modern, conventional plant breeding methods, sustainable and organic farming and other sophisticated farming practices that do not require farmers to pay significant upfront costs...*"

The critical requirement is to protect our farmers, crops and livestock from biotechnology corporations through their patenting of the germplasm of both plants and animals. This will result in the undoubted colonisation and industrialisation of Indian farming. National food security also critically means safe food. GM crops will lead to a collapse of our food security, subjecting us to an impossible future because it will be both unsustainable and unsafe.

It would be a profound disservice to our Country if Bt brinjal were allowed to be released. We therefore, respectfully request you to call a moratorium on all field testing of GM Crops and Bt brinjal and an independent nationwide review of Bt cotton. We also require a fundamental reassessment of agriculture policy, redirecting investment in alternative biotechnologies in line with the IAASTD.

We remain,
Respectfully yours,

- Dr Lalith Nath: Epidemiologist: Retd. Dean, Centre of Community Medicine, AIMS Delhi
- Admiral R.H. Tahiliani (Former Navy Chief, and Chairman of Transparency International)
- Dr. CS Pandav : Prof and Head, (c/o) Dept of Community Medicine, AIMS, New Delhi
- Aruna Roy: Social Activist, MKSS
- Mahesh Bhatt: Writer and Filmmaker
- Prof U R Ananthamurthy: formerly Vice Chancellor, M G University, Kottayam, Kerala. Jnanapeeth Award for Literature; Padma Bhushan
- Lalita Ramdas: President YAKSI, Hyderabad, (YAKSI works with Adivasi communities on Rights'-based issues); CNDP; (Coalition for Nuclear Disarmament and Peace).
- Dr Rajesh Kumar: Prof & Head, School of Public Health, Post Graduate Institute of Medical Education and Research
- Dr. Anant Phadke: Co-convenor, Jan Aarogya Abhiyan, Maharashtra
- Dr. Thelma Narayan: Centre for Public Health and Equity (SOCHARA) Bangalore Governing Body Member of National Health Systems Resource Centre, New Delhi
- Dr. Ravi Narayan: Centre for Public Health and Equity, (SOCHARA) Bangalore, Governing Body Member of Public Health Foundation of India
- Dr Vandana Shiva: Founder, Navdanya, Chair International commission on the Future of Food: Director Research Foundation for Science, Technology and Ecology
- Admiral Laxminarayanan Ramdas: (Retd) Chief of Naval Staff: Magsaysay Award for Peace; Member, National Co-ordination Committee of the CNDP (Coalition for Nuclear Disarmament and Peace)
- Mira Shiva: Initiative for Health Equity & Society; Third World Network

- Alex Hankey PhD: Dean, Academic Studies Institute of Ayurveda Integrative Medicine Executive Editor, Journal of Ayurveda and Integrative Medicine, Bangalore
- Madhu Bhaduri: Former Indian Ambassador to Mexico
- Teesta Setalvad: Lawyer: Founder, Citizens for Justice and Peace; Editor, Communalism Combat)
- Jagdeep S. Chhokar: Professor, IIM Ahmedabad
- Dr Sagari R Ramdas, MS Animal Breeding and Genetics (BVsc &AH): Director , Anthra, India
- Kamini Jaiswal: Advocate, Supreme Court
- Kavitha Kuruganti: Kheti Virasat Mission, Punjab
- Dr Ramanjaneyulu: Agriculture Extension Scientist : Ex. Director, Centre for Sustainable Agriculture (CSA).
- Aruna Rodrigues: Sunray Harvesters: Lead Petitioner, PIL (in Supreme Court)
- Prashant Bhushan: Advocate, Supreme Court

Enclosed: Letter from eminent Academic Scientists to the Honourable Prime Minister of India
Letter from Shri Prithviraj Chauhan to Shri A Ramadoss

BHARATIYA KRISHAK SAMAJ

(Farmers' Organisation)

President :
Dr. Krishan Bir Chaudhary
Former Chairman, State Farms Corporation of India

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Ref. No. ..07/07/10.......... Date ...5-2-2010..........

Dear Sh. Jairam Ramesh jee,

Bharatiya Krishak Samaj held its National Convention at Lasalgaon Distt. Nashik (Maharashtra) on 27th Dec., 2009. More than five thousand farmer delegates and leaders participate in the convention from all over the country and share their views on different farmers problems.

I am sending the copy of the resolutions passed in the convention for your kind perusal and necessary action.

With kind regards,

Yours sincerely

(KRISHAN BIR CHAUDHARY)

To

Sh. Jairam Ramesh
Hon'ble Union Minister of Environment and Forest,
Paryavaran Bhawan, C.G.O. Complex,
Lodhi Road,
New Delhi.

Resolutions Passed In National Convention of Bharatiya Krishak Samaj held at Lasalgaon, (Maharashtra) on 27th Dec., 2009

The Govt. should put moratorium on GM Crops :

The Govt. should put moratorium on GM Crops in the Country because GM Crops will not increase the productivity and these crops will polluted the seeds of farmers owned traditional varieties by cross-pollination. Under IPR regime there is a game of MNCs to capture the seed security for royalty. Because seed is the basic need of food security, if seed will be controlled by MNCs then automatically food security will be govern & controlled by them.

Seed Bill - 2004 :

If the Govt. wants to re-introduce the "Seed Bill - 2004", it should incorporate the all recommendations of the Parliamentary Standing Committee on Agriculture, because seed is the basic need for food security which should not be surrendered to corporates & MNCs at any cost. Further there is no need for any new act for regulating the seed sector. The PVP & FR Act is already TRIPS consistent and there is no need for a patent regime on micro-organisms, genes and other life forms.

Minimum Support Price :

The minimum support price (MSPs) of different crops estimated by the Commission for Agricultural Costs & Prices (CACP) are low and not remunerative. There is need for up-gradation of the methods for estimation of real cost of production and arriving at the real remunerative prices. The process should be transparent and open to farmers.

Subsidy :

The total amount of subsidy on agriculture should be given directly to Farmers in there accounts as per the holdings. Because the farmers is not getting the benefit of the subsidy. The all developed countries is giving Subsidies directly to the Farmers.

SEZs :

The Govt. should scrap all Special Economic Zones setup on farm lands acquired from farmers against a mere compensation, SEZs should not be promoted as such policy tends to usurp fertile farmlands leading to food security problems. Rather the Govt. promote and encourage Agri Export Zones (AEZs) which is aimed at integrated rural development.

Agro based Small Scale Industrial Units in Rural Area :

Sustenance is just not possible from ever increasing fragmentation of family farms. To give employment for unemployed youths in Rural Area. The Govt. should come-up on agro based small industrial units in the villages and should provide adequate incentive, technical and financial assistance.

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Impact of WTO :

Unfortunately Indian agriculture has been dragged into the ambit of the WTO and the Govt. have given market access for agro produces at a time when the developed countries have distorted global prices by their huge support to their farm sector. In this situation Indian farmers cannot compete with the farmers in the developed world. Both EU and US have protected their markets through high tariffs barriers and non-tariff barriers. The US through its Farm Bill has increased direct payments to farmers by 10% over the previous years. It has increased direct payments by $ 5.5 billion.

Irrigation Facilities :

The Govt. should plan the policies to recharge the level of ground water. The irrigation projects and schemes to be made on priorities and the funds allotted to state Govt.'s should not be diverted to other heads. Because the water is the lifeline of agriculture, therefore, it should be saved. The farmers should use the sprinkler and drip irrigation system for irrigation to save the water. The Govt. should give subsidy on it directly to farmers.

Export of Organic Foods :

There is an increasing demand and unlimited scope for the export of organic food across the world and Indian farmers are missing this opportunity. The Government should bear the cost of certification of organic produces which is presently high and beyond the reach of farmers. The National Horticultural Board & APEDA should bear this responsibility immediately. The Government should also give adequate level of subsidies for cultivation of organic produce and for encouraging their exports.

Imports of Agro-produce :

With a view to contain rising prices, the government is encoucraging import of agro produces. This measure will be detrimental to farmers' interest in the long run and destroy country's food security. Imports of agro commodities should not be encouraged.

Exempt Agro Machines, Tools, Equipments etc., from Excise & Vat :

Utility items like tractor, agricultural equipments & machinaries, drip and sprinkler irrigation installations, fertilizers, seeds and agro-chemicals should be kept out from the ambit of excise and vat. Also, the subsidy on them should be enhanced and given directly to the farmers.

Testing Laboratories :

Well equipped soil, fertilizer, agro-chemicals and seeds Testing Laboratories should be established in every District Headquarter for the benefit of the farmers.

Farmers' representation :

The Govt. should co-opt farmer leaders in all decision making bodies related to agriculture so as to make the policies more realistic, effective and action-oriented.

Krishan Bir Chaudhary