MATERIAL USED IN PREPARATION OF THE FINAL REPORT

1. Annexure 1: Order of the Honourable Supreme Court D.No.l944/2005/SC/PIL W dated 12 May 2012

2. Annexure 2: The Ministry of Agriculture Affidavit in the Honourable Supreme Court and its submission to the Technical Expert Committee (TEC)

3. Annexure 3: TEC's brief response to the affidavit filed by the Ministry of Agriculture

4. Annexure 4: General and Specific Considerations of Genetically Engineered Foods

5. Annexure 5: The 3 - Tier recommendations of the Interim report by theTEC

6. Ann§xure6: Biosafety evaluation of GM crops

7. Annexure 7: Scientific literature on Bt-transgenic crops

8. Annexure 8: Herbicide-tolerant Ht-transgenics

• 9. Annexure 9: Ht-transgenics: crop yields and emergence of super weeds

10. Annexure 10: Ht- and sustainable farming practices

11. Annexure 11: Harmful biological effects of 'Roundup' herbicide

12. Annexure 12: The Performance of Bt cotton. What are the indicators and the indications of its impacts?

13. Annexure 13: Some Main Issues and Impacts of Bt-hybrid cotton

14. Annexure 14: Bt hybrid cotton performance analyses (yield and area) and (charts #1,#2 and #3)

rmai Report submitted by the TEC to the Honourable Supreme Court

Annexure 1

Order of the Hon'ble Supreme Court D.No.l944/2005/SC/PIL W dated 12 May, 2012

The Interim Report submitted in October 2012 to the Honouable Supreme Court adhered to the following relevant portions of the Order;

"™ Later, it was stated before us that the Government prayed only for constitution of the Committee as well as the terms of reference, exactly as proposed in its Minutes dated 15th March, 2011, without any amendments.

6. We heard the learned counsel appearing for the different parties at some length. They all were ad idem on the constitution of the Expert Committee and the terms of reference as suggested in the Minutes of the Ministry's meeting dated 15th March, 2011 and jointly prayed for its implementation. —

5.—In the event and for any reason whatsoever, the Committee is unable to submit its final report to the Court within the time stipulated in this order, we direct that the Committee should instead submit its interim report within the same period to the Court on the following issue:

"Whether there should or should not be any ban, partial or otherwise, upon conducting of open field tests of the GMOs? In the event open field trials are permitted, what protocol should be followed and conditions, if any, that may be imposed by the Court for implementation of open field trials."

(Emphasis by theTEC)

. The Technical Expert Committee (TEC) has as its mandate seven TOR a to g, which are specified by the Hon'ble .SC in its above Order. These are as follows:

(a) To review and recommend the nature of sequencing of risk assessment (environment and health safety) studies that need to be done for all GM crops before they are released into the environment.

(b) To recommend the sequencing of these tests in order to specify the point at which environmental release though Open Field Trials can be permitted.

(c) To advise on whether a proper evaluation of the genetically engineered crop/plants is scientifically tenable in the green house conditions and whether it is possible to replicate the conditions for testing under different agro ecological regions and seasons in greenhouse?

(d) To advise on whether specific conditions imposed by the regulatory agencies for Open Field Trials are adequate. If not, recommend what additional measures/safeguards are required to prevent potential risks to the environment.

(e) Examine the feasibility of prescribing validated protocols and active testing for contamination at a level that would preclude any escaped material from causing an adverse effect on the environment.

(f) To advise on whether institutions/laboratories in India have the state-of-art testing facilities and professional expertise to conduct various biosafety tests and recommend mechanism to strengthen the same. If no such institutions are available in India, recommend setting up an independent testing laboratory/institution.

(g) The Expert Committee would be free to review reports or studies authored by national and international scientists if it was felt necessary. The petitioners opined that they would like to formally propose three Expert Reports from Prof. David Andow, Prof. Jack Heinemann and Dr. Doug Gurian Sherman to be a formal part of the Committee's

The Interim report of the TEC dealt with TORs a- g, and to meet the specific purpose of the Court as given above (ref. point 5 pgs 7-8 of the Order dated 12 May, 2012

This section of the final report provides the scientific background for the recommendations made in the interim report of the TEC. It also responds to the Affidavit of the Ministry of Agriculture and to other queries as relevant made by various parties that were interviewed by the TEC during the period July 2012 to March 2013. And it strengthens the scientific basis of the report of the Parliamentary Standing Committee which submitted its report on 'Prospects and Effects of GM Food Crops' to Parliament in August 2012.

The other sections of the final report deal with the remaining TOR as instructed by the Hon'ble court with recommendations.

The Ministry of Agriculture Affidavit in the Honourable Supreme Court and its Submission to the Technical Expert Committee (TEC)

There are two submissions by the DAC of the Ministry of Agriculture: the first one to the Honourable Supreme Court in their Affidavit filed by the DAC_5 on 08/11/2012 which is a Reply to the Interim Report of the TEC and the second, a formal submission to the TEC (DO.No.4-15/2011/SD-V, dated 13/12/2012).

The first report is a stinging criticism of the TEC report, calling it "unscientific" and raises several issues. Some of these issues, as appropriate, are dealt with by the TEC in this report.

On the other hand, the Department of Agriculture & Cooperation (DAC) of the MO A in its submission to the TEC states the following on pages 3 and 4: "The DAC has no direct role in policy matter related to research and development of GM crops, labeling for consumer awareness, assessing impact on biosafety and human health, livestock health etc.

- ..... DAC keeps a watch on the research and development and supports biotechnological intervention for enhancing the production and productivity in agriculture"....."

and

"..... as per the order of the Honourable Supreme Court dated 14 April 2011 para 6.2 (a) to (g) deals with the Terms of reference (TOR) for the Committee. The TOR in totality, raises technical issues related to aspect of GM trials and DAC has no mandate in this regard. These technical issues fall within the Mandate of Ministry of Environment & Forest, Department of Biotechnology".

Yet, the Affidavit of the DAC (MOA) in the Supreme Court raises just these issues of policy and most critically, safety-testing and regulation. But now the TEC hears that the "DAC has no mandate in this regard".

Is the TEC to understand therefore, that the MOA agrees with the TEC that it may not be the judge in these matters of risk assessment and regulation, that it really does not know much about these matters? The submission of the DA'C to the TEC stands in opposition to its Affidavit in the Supreme Court This matter is brought to the attention of the Honourable Supreme Court.

Furthermore, given the fact that the MOA is also a promoter of GM crops, it is manifestly operating under a clear conflict of interest. Indeed, this is what the DAC says in its submission at point 6 quoted below, judging that GM technology is advantageous for Indian farmers. India has just one crop that is commercialized, Bt cotton, where its performance is surrounded by controversy in the absence of any post-market monitoring (PMM) of it, which the regulators and the ICAR (MOA) failed conspicuously to carry out. Indeed, even official data-based analyses by us do not find a correspondence with the conclusions of the MOA which supports the Industry viewpoint. Yet, v/e have the significant statement of socio-economic benefit of GM crops generally and that it should be made available to our farmers in India. The TEC asks quite simply, on what independent evidence that is not surrounded by a conflict of interest?

The TEC's scrutiny of India's only commercialised crop Bt hybrid cotton, GM crops commercialised worldwide, their performance data and the biosafety issues still current, do not allow us to support the ICAR's conclusion of benefit ascribed to GM crops and especially to Indian farmers. That conclusion must be termed as premature, ill-founded and irresponsible. It is repeated for emphasis that the benefit of GM crops to farmers may also not be reached from the commercialisation of Bt cotton in India. It is clear that the experience with Bt cotton and what can be analysesd based on limited data, may not be used as a launching pad for other crops The feedback received by the TEC from various stakeholders that we have interviewed at length and including the premier institute for cotton in India, the CICR, and furthermore, and especially, in the absence of a PMM, suggests that there are many issues that are at odds with the success story being propounded by the MOA and the crop

biotech crop developers are on the same side, supporting the same conclusions of its runaway success without the science to back these claims. More time and much work on its impacts are needed. And time will tell and provide a trend and data for sound conclusions. Given below is the relevant quotation from the submission of the DAC (MoA)/ICAR to the TEC:

"Department of Agricultural Research and Education (DARE)/Indian Council of Agricultural Research (ICAR), Ministry of Agriculture, Government of India have been supporting the development of GM crops and research is being carried out in its various institutes over the past several years on development of transgenic crops. ICAR has always been keen to use science based technology for crop improvement. Since the GM technology has given advantage .to the farmers and growers across the world, ICAR always feels that GM technology and products thereof should be made available to the farmers in India." (See 6, .6.1 of 'Response to the Technical Expert Committee, Department of Agriculture and Cooperation, submitted by Ms. Smriti Sharan, Director (Seeds) vide D.O. No.4-15/2011/SD-V dated 13th December 2012.

It is very clear therefore, that the MOA is driven by a serious conflict of interest and their evidence therefore raises the most important issue of credibility. As the full report of the TEC and the first (Interim) reports demonstrate in several sections, there is an absence of science and data to support the criticisms of the DAC (MOA) in their Affidavit.

TEC's brief response to the affidavit filed by Ministry of Agriculture

The affidavit filed by the Ministry of Agriculture Union of India refers to the interim report of the **TEC as unscientific and that** it went beyond **the** TORs. Neither is true. **There is no question of the** TEC going beyond its terms of reference. Every aspect **that** has a bearing **on** open field trials is relevant for enquiry and this is how the TEC has correctly interpreted its mandate.

The TEC's recommendations are backed by data, a wide range of scientific enquiry and peer reviewed studies. The MoA does not demonstrate how factors that have a direct bearing on the TORs specifically regarding open field trials and risk assessment are outside its mandate. How can they be? No such restriction was placed on the TEC by the Supreme Court. The TORs stipulated by the Honourable Supreme Court required a comprehensive analyses of attendant issues that effect and impact the outcome. This is exactly what the TEC have done to fulfill its mandate specified by TOR 'a' through to T. It also appears to be the case from the Affidavit and submission filed by the DAC that they are ill equipped to deal with matters of regulation and risk assessment by their own admission (refer submission to the TEC and point 2 of this report). These aspects will be dealt with later in specific detail. It is emphasized that the Interim report of the TEC recommended a time- bound ten-year moratorium only in the case of Bt-transgenic food crops. In the case of HT crops, it required a thorough review by a specially-constituted multidisciplinary committee to **make an** assessment **of HT** crops in view of the well-documented health and **environmental hazards of the** herbicides Roundup, and other similar formulations. However, since the submission of the interim report in October 2012 to the Honorable Supreme Court, the TEC have now had the opportunity to address this issue at considerable depth. The evidence of harm is significant. 'Roundup' is also a potent carcinogen; it causes mammary cancers in rats which are equivalent to breast cancers in humans. It is also important to note that the Task Force set up with Professor M.S. Swaminathan as Chairman to develop the National Agricultural Biotechnology Policy in

its report (2004) (http://agricoop.nic.in/TaskForce/tf.html) has recommended precautionary principles in introducing GM.crops. It is reproduced below: *"The bottom line for any biotechnology regulatory policy should be the safety of the environment, the well-being of farming families, the ecological and economic sustainability of farming systems? the health and nutrition security of consumers, safeguarding home and external trade and biosecurity of the nation"*. It further states:

1.6. *"Since there is public, political and professional concern about transgenics with reference to their short and long term impacts on human health and the environment, their testing, evaluation and approval have to be stringent, elaborate and. science-based. The general approach in this respect, therefore, should be that: Biotech applications, which do not involve transgenics as biopesticides, biofertilizers and bio-remediation agents, should be accorded high priority"*.

In the light of the above, and the up-to-date science-based data on the bio-hazards of Ht-transgenics, the TEC no longer requires a specially-constituted multidisciplinary committee to look into the matter. Instead, having examined the issue of HI crops in the detail required to arrive at a decision, the TEC recommends a complete ban on HT crops. It is satisfied, that this recommendation is based on sound science. It is a responsible and well judged conclusion for India.

vienerai ana, Specific Considerations of Genetic Engineering Technology:

Recombinant DNA (rDNA) technology, generally referred to as 'modern biotechnology' used in plant breeding is radically different from traditional plant breeding which is based on the principles, tools and techniques of Mendelian genetics. It is relevant to state the definition of modem biotechnology from the Cartagena Protocol, whose definition has been ratified by India.: Article 3: "Modern biotechnology" means the application of: ;

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid. (DNA) and. direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

rDNA technology is accompanied by several undesirable effects some of which are as follows:

- Insertion of a trans- or cis gene is done by using stressful mechanical means, or by pathogenic viral vehicles into the genome of a recipient plant. Consequently, there are DNA fragments entering along with the intended transgene. The random, uncontrolled insertion of a transgene into the native genome leads to 'insertion mutagenesis' and 'unintended effects'. It is quite naive to say that the inserted transgene simply does what is intended of it, and that genes of a genome act independently of each other. Scientific papers, published in refereed international journals (presented in this report), on the other hand, reveal that the entire genome responds to a transgene in unpredictable ways. o Often an antibiotic marker gene is used to detect the transformed plants (i.e. the plants carrying the transgene inserted into them). This poses a problem of transfer of antibiotic resistance to the pathogenic bacteria and resulting in serious therapeutic concerns.

o The transgene construct often carries with it a cauliflower mosaic virus 35 S . promoter (CaMV35). Recently, in the course of analysis to identify potential allergens in GMO crops, the European Food Safety Authority (EFSA) has found that the most common genetic regulatory sequence in commercial GMOs also encodes a significant fragment of viral gene (called Gene VI). The authors, Podevin N and du Jardin P (2012, *GM Crops and Food* 3; 1-5) have found that of the 86 different transgenic events (unique insertions of foreign DNA) commercialized to date in the United States, 54 contain portions of Gene VI within them. Gene VI is an integral part of the regulatory sequence called the CaMV35S promoter, from cauliflower mosaic virus. The BTMON810 maize and the HtNK603 maize (reported as causing tumors in rats by.Seralini et al (2012, *Food Chem. Toxicol, 56,* 4221-423*1)* have the CaMV 35 promoters. There are . already several scientific papers that viral genes expressed in plants raise both agronomic and human health concerns (Dasgupta R et al. 2001, *PNAS,* USA 98, 4910-4915; Latham J R, and A. J.Wilson 2008, *Mol. Plant. Pathol* 9, 85403). Gene VI through RNA silencing impairs an important antiviral defense / mechanism in both plants and animals. Viruses need Gene VI in order to infect plants and animals including humans. So, this amounts to favouring pathogenic viruses in their infecting plants, animals and humans. o The world's first commercialized GM crop was a flop. Calgene's Flavr Savr tomato was genetically modified so that they could be picked when ripe and transported without bruising, promising a longer shelf life and better taste. USDA and FDA approved the product without scientific evidence that it was safe for human consumption, and it was released for human consumption in 1994. However, this tomato was withdrawn from the market by 1997 because of safety concerns (studies showed the GM tomato potentially caused stomach lesions), flavour (not better than conventional tomatoes), and their tendency to bruise. Since then, there has been considerable progress in our scientific understanding of the molecular events triggered by transgene insertion. Gene silencing using RNA regulatory molecules such as RNAi used in Flavr Savr

* RNA and ds RNA: A significant gap in Risk Assessment The recent paper "A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assessment" by J.A. Heinemann, S.Z. Agapito-Tenfen and J. Carman, published by Environment: International 2013, chronicles the *systematic neglect by leading food and environmental safety regulators* of important safety issues with GM crops, and -emerging products containing molecules called double-stranded RNA (dsRNA). The record of neglect and the analysis of the failings have been verified through the judgment of rigourous blind peer-review,

It establishes that *all GM crops should be evaluated for the presence of unintended dsRNA molecules.* That is, even crops not purposefully constructed to express these molecules need to be evaluated for them, because they are a common by-product of the engineering process. To date, GM crops have not been evaluated in this way.

It shows that the *prevailing systems for evaluating the potential for adverse effects from dsRNA would fail.*

For the first time, the study describes *a robust process for testing GMOs or other products that may contain dsRNAs.*

The Paper shows that the regulators have *a priori* denied the need to assess either the direct or important potential secondary effects of the dsRNA molecules, instead resorting to flawed and out-dated assumption-based reasoning on the biochemistry of dsRNA. Thus, there is no public record of regulators ever having required or reviewed studies that provide evidence for no: (a) off-target effects of intended novel dsRNA molecules in the GMO; (b) effects of unintended novel dsRNA molecules in the GMO; and (c) production of unintended secondary dsRNA molecules in the GMO or in those exposed to the GMO (e.g., through ingestion, inhalation or absorption) - including non-target insects, wildlife and people.

Consequently, there has never been an acute or chronic toxicity study done, for any commercial GMO that has had the ability to detect any effect that could arise specifically from the primary or secondary dsRNA molecules that could be generated by the GMO.

Example: Corn rootworm has always eaten maize roots and maize roots contain RNA (including forms of dsRNA). However, when Monsanto introduces a novel dsRNA of a specific sequence into the cells of the plant, the corn rootworm eating that RNA dies. Baum J. A et al 2007 *Nat. BiotechnoL* 25, 1322 - 1326; Gordon KHJ and Waterhouse P.M. 2007 *Nat. Biotech* 25, 1231-1232.

It is significant that it has taken this long, over 20 years for this subject to surface and it has done so outside the regulatory bodies worldwide. Other unintended effects are ■also being discovered all of which reinforces the issue that we must take our time with this technology and not rush in but rather uphold the PP in its RA and regulation. Without any iota of doubt, all these reveal that the present regulatory system in India, for reasons of conflict of interest coupled with ineptitude (both lack of knowledge and lack of-a proven track-record of experience in state-of-the-art knowledge) in food safety evaluation of genetically engineered foods, could endanger the health of animals, humans and the. environment. We just do not know because the tests have not been done.

Indeed, Monsanto actively blocks research of its raw data in its dossiers as is clear from their threat to sue EFSA for publishing data on GM NK603 maize. NK603 was used in the much debated study published in Food and chemical Tooxicology by Seralini et a! in September last year. This on-going current debacle clearly demonstrates the aims and objectives of Monsanto in blocking transparency and independent research and of study findings in their safety dossiers. (httpi//www.efsa.europa.eu/en/press/news/l30114.htm and http://www.foodnavigator.com/Legislation/Monsanto-threatens-to-sue-EFSA-over-publication-of-maize-GM-data report dated 8 March 2013

With all genetically engineering crops, the causes of concerns are (i) insertional mutagenesis (ii) unintended effects (iii) antibiotic marker genes and (iv) Gene VI

should be summarily rejected.

Our Regulatory bodies have so far largely employed 'substantial equivalence[5] (SE) as the regulatory basis for assessing a GMO, The underlying presumption is that comprehensive protocols of Regulatory Act for example, allergenic, and toxicological studies of GMOs are unnecessary because the GM crops are quite substantially similar to their non-GM counterpart. The GM lobby has actively driven this 'notion[5] (which. has its roots in US regulation of GMOs) to push the rapid commercialisation of GM crops. It also provides the route to substantial savings in costs involved in food safety evaluation. It also appears from the growing evidence, that the purpose includes the avoidance of detection of undesirable and even harmful components in genetically engineered foods that might become evident through appropriately designed protocols and thorough food safety evaluation.

The incident involving genetically-engineered L-tryptophan (a food supplement) in the USA is yet to be settled as litigation of over 2 billion US dollars is still going on. More than the monetary compensation, the tragedy resulting from the consumption of r-DNA L-tryptophan was that 37 people died and over 1500 others are paralysed. L-tryptophan generally produced by fermentation process has never caused any adverse . health effects. Detailed enquiries revealed that genetically engineered L-tryptophan contained a toxin called 'EBT' (a dimerized product of tryptophan) which caused deaths and paralysis. The human disorder caused by 'EBT' is called 'Esoinophiiia Myalgia . Syndrome'. Since EBT caused striking and hence readily noticeable health effects (e.g. deaths, paralysis), it was possible to stop the production of L-tryptophan by rDNA technology. Had the .deleterious effects been chronic and not-readily-perceptible, several millions of people would have been adversely affected over the last few decades. In the case of foods, any harm arising from "unintended effects" would result in adverse health effects on the general population and particularly on the young and the old who consume these foods. While drugs causing adverse side effects can be withdrawn, GMOs (seeds and crops) will impact our foods irreversibly with no scope for withdrawal because of contamination.

It is therefore, necessary to dismiss the assumption of 'substantial equivalence' unconditionally when it comes to food safety evaluation of genetically engineered foods. This applies to all genetically engineered crops irrespective of the transgenic trait: However, in the case of agri- crops which are genetically-engineered to produce toxins such as in Bt/HT crops (these are clearly pesticidal crops), great concern is called for. Hence,, the current list of GM crops can be broadly categorized under the two following categories for the purpose of food safety protocols and environmental impact assessment.

Genetically - engineered crops

Those which are not genetically engineered to produce, a pesticidal toxin Examples - Crops with transgenes fortifying against nutritional inadequacies such as vitamin A (golden rice), iron, proteins etc. - Crops with transgenes for making crops climate-resilient- such as salinity, drought, temperature rise tolerant strains - 'Delaying fruit - ripening' (e.g.) 'Flavr Savr' tomato which was released for marketing in 1994 but withdrawn in 1997 following findings of stomach lesions and haemorrhage in rat studies.	- Those which are genetically-engineered to produce pesticides (e.g. Bt-toxin, Cry proteins) or to tolerate weedicides such as 'Round up' (with glyphosate as the main ingredient). - Bt-transgenic plants produce toxic insecticide and these are insecticidal crops. Therefore, these need to be evaluated in the same way as insecticides. These crops may not be assumed to be safe based on currently available data from carefully carried-out scientific studies published in referred international journals. The regulatory committees may not ignore these data. Their potential hazardous impacts are on animal and human health and the environment (e.g. beneficial soil microorganisms, contamination of non-transgenic food crops etc.)

me 3-tier Recommendations of the Interim Report by the TEC:

The above considerations were the basis for the TEC's Interim report. The interim report recommends a three-tier system with regard to imposing a moratorium on open field trials of GE crops. These were misreported as stopping all GM research. It is emphasized that basic research in GMOs and their technology are not impeded by a moratorium on open field trials. The research continues up to the point when they have to be tested in the environment There is absolutely no justification to release untested GMOs in open field trials, leave alone commercialize any GM crop, on the false premise that untested GMOs will impede GM research. Untested GMOs are by definition unsafe because they could adversely impact human health and the environment This is because transgenic crops once released have the potential to irreversibly contaminate non-GMO crops and seeds.

The essence of the recommendations made in the interim report could be divided into the following parts:

1. Stop all field trials until the following conditions have been met:

(i) Specific sites for conducting field trials have been designated and certified and sufficient mechanisms for monitoring the trials are put in place (ii) A panel of independent scientists, qualified in evaluation of the biosafety data . of Genetically Modified Crops has been engaged for scrutiny and analyses of the safety data (iii) Conflict of interest in the regulatory body has been removed as discussed above (iv) The requirement for preliminary biosafety tests prior to field trials including sub-chronic long term testing toxicity in small animals has been included

Outsourcing/subcontracting of field trials should be banned

2. Justification for 10-year Moratorium on field trials (not research) of Bt trangenic food crops (e.g. brinjal, bhendi (okra), papaya, cauliflower, wheat, rice etc.)

Based on the current overall status of food safety evaluation of Bt-transgenics including data on Bt cotton and Bt brinjal examined by the TEC and in accordance with the precautionary principle, the TEC recommends a ten year moratorium on

field trials of Bt transgenics in all food crops (those used directly for human consumption). Detailed review of papers published in peer-reviewed scientific journal on the harmful health effects of Bt is presented in the sub-section 4-3.

The TEC is of the view that a period often years is a reasonable length of time for addressing matters relating to independence and conflict of interest, the restructuring and operationalization of a strengthened regulatory regime, developing a cadre of experts in areas of relevance to food safety evaluation, environmental impact assessment etc. It is also expected that during this time additional data should emerge relating to post-release monitoring, (note that Bt cotton (hybrids) was released in 2002, and there has been no post-market monitoring of socio-economic and ecological impacts, including (of particular mention), soil health, effects on beneficial organisms, gene-flow, performance yield, IRM (Insect Resistance Management through refuges etc. and other biosafety impacts (i.e. health of animals grazing on Bt-cotton leaves and stubble) etc., and long term, lifetime toxicity tests as proposed above. Furthermore, it is expected that long-term health and environmental impacts of Bt-transgenics will be more adequately understood as additional data including from other countries becomes available. There are two significant additions to this list as recently as March 2013 which reinforce the timeline for a 10 year moratorium on Bt food crops: the first, after 20 years of commercialised Bt cotton and other Bt crops we have a new report by Steffen-Hagenbucher et al, (2013 . *Proceedings of the Royal Society)* (http.7/dx.doi.orq/10.1098/rspb.2013.0042). The Study signifies that Bt will lead to the possibility that non-target herbivores develop into pests (like aphids). The authors point out that the reduced damage by the major pest *(Heliothis virescens)* to Bt cotton reduces the induction of terpenoids. Terpenoids afford protection against other pests such as aphids. The emergence of aphids and other sucking insects as major pests in Bt cotton is discussed in another section in this report; the second, the regulator)' gap demonstrated by Prof Jack Heinemann et al in their peer reviewed publication on the role of ds RNA (see the portion on RNA and ds RNA).

recommended a moratorium on field trials of herbicide tolerant Ht transgenic crops until an independent committee, comprising of experts and stakeholders has examined and assessed the potential impact of Ht-technology and its suitability in the Indian context. In the final report, however, having had the advantage of a considerably longer period of time, the TEC recommends a total ban on Ht-crops. The data is up-to-date and includes the data from long-term safety evaluations, including actual field data in the US.

4. The TEC recommends a ban also on open field trials of transgenics in those crops for which India Is a centre of origin or a center of diversity, as GMOs can contaminate and adversely affect the gene pool/biodiversity in sexually compatible species. This is also an issue that is rightly addressed by the Cartagena Protocol of the CBD.

The TEC has felt it necessary to comment on the regulatory process as a whole since that is an overarching issue that has a direct bearing on the issue of open field trials and their evaluation in RA protocols.

mosaieiy evaluation ol iiJVI Crops (Bt/Ht)

* At least two major in-depth science-based critical reviews are required to assess and comment on (a) the sate-of-art food safety evaluation and testing of the genetically engineered foods[5] and expertise thereof, available in India, and (b) transgene trait-specific biosafety and environmental impact assessment studies published in **refereed** national and international journals. There is also a need to . evaluate these studies based on their scientific merit and also whether these are free or **not** free from conflict of interest. ® . It is quite well documented that independent scientists who have been publishing papers containing 'inconvenient truth[5] (i.e. results showing adverse biosafety and environmental effects and which, therefore, jeopardize the commercialization of such GM crops) have been frequently subjected to significant harassment, mental, physical and financial by multinational crops developers, which have also influenced the national regulators in many countries including the US and Europe. The Interim Report submitted by the Technical Expert Committee (TEC) addresses these concerns. • **In the climate** that prevails **today** 'professional expertise' must first be qualified **and** judged by a lack of 'conflict of interest[5] of ajny kind in those engaged **in** the science of genetically engineered crops. This must be -especially judged to be true of its regulators under the scrutiny of a microscope. Clearly, it is independent science and hard scientific knowledge and ability in combination that will deliver sound protocols of risk assessment and "hazard **identification"** (HI) for GM crops in human health, (including allergenic testing) and ERA (environment risk assessment). Instead, the RCGM and GEAC have consistently adopted "the **unscientific and** unsafe, **but** convenient notion" of **'substantial equivalence' overriding science and the 'precautionary principle' (PP).** This has resulted in ignoring several independent and critical scientific publications which indicate harmful effects of Bt- and Ht transgenic traits to biosafety and environment.

When serious issues of health and environmental safety are raised, the Ministry of Agriculture (MoA), Government of India, Indian Council of Agricultural Research (ICAR) and the National Academy of Agricultural Sciences (NAAS) divert attention to food security at the national level (relying singularly on food production) and not the access to food by low income households. In his deposition in January 2013, the President ; NAAS went further to declare that precautionary principles should not come in the way when food security is concerned (his letter is reproduced jn this document). These agencies also claim that the people in the USA have been eating GM foods for over two decades and so far there has been no case of adverse health effects. These statements are deeply flawed, because they are unverifiable, are not based on facts and must be rejected for the following reasons:

- In the USA, GM corn, soy and cotton are essentially animal feed. . These animals have short lives being slaughtered young for human food. The animals do not live long enough to reveal health hazards, if any, caused by GM feed. Despite this and the fact that animals fed on GM feed serve to filter and dilute the Bt toxin, a Canadian study (A. Aris and S. Leblanc 2011, *Reproductive Toxicology* 31, 528-533) clearly shows that Bt-toxin in such animal products (beef etc.) pass on to and is present in the blood of pregnant mothers and their fetuses.
- In the US, a smaller proportion of GM food (than animal feed) is used in processed foods. Processing denatures the Bt-protein. It is almost impossible to pinpoint any adverse health effects ascribable to Bt toxins and their residues as there is no labeling of GM foods. In such a situation, epidemiological studies are impossible because they would not be able to link a health disorder with the consumption of GM food ingredients. This point has been elegantly presented by Professor David Schubert of the renowned Salk Institute for Biological Studies, La Jolla, California, in his letter dated November 18, 2009 to. Mr. Jairam Ramesh the then Hon'ble Minister of Environment and Forests,(MoEF). In the context of the claims

eat, Prof. Schubert writes, *"First, only a small fraction of the Bt maize produced in the US is eaten directly. The vast majority is 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, ifBt 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".

- Serious regulatory lapses on the part of the Review Committee on **Genetic Manipulation (RCGM),** and Genetic Engineering Approval **Committee** (GEAC) at virtually every level of regulatory oversight, the significant gaps in risk assessment protocols, the lack of competence and a serious conflict of interest makes the regulation of GM crops ineffective and impossible.

  These have been the findings of the interim report of the TEC. Now, the Sopor}' Committee report, on the BNBt (Bikaneri Nerma Bt) or 'Desi' gene is informative for the TEC. The correspondence of this official report of the government (ICAR) with the findings of the TEC report can only reinforce and highlight the shocking state of regulatory collapse in the matter of GM crops along with the eroding of institutional integrity in concerned public sector institutions, including the ICAR.

Scientific literature on Bt-transgenic crops •

Toxicity and Specificity of Bt-toxin

Bt-toxin derived from a soil bacterium *Baccillus thuringiensis* in its natural form is used as an insecticide! spray in the IPM (Integrated Pest Management) schedule of . intensive as well as organic farming. This practice is wrongly used by the Regulators to argue that Bt toxin has a history of safe use and therefore, the Bt toxin in the Bt transgenic plants should be harmless. The facts to be noted are that Bt- as an external insecticidal spray is open to rain and sun, and ultraviolet light in solar radiation rapidly decomposes the Bt-toxin. Since it does not persist in the environment, it is unlikely to find its way into animals and people who eat the crop. Besides, a 40 percent difference in chemical composition between the natural Bt toxin, and that derived from Btl76 maize (formerly commercialized in the EU_5 now withdrawn) has been demonstrated (Seralini G.E, *Environmental Sciences Europe,* 23, 10). It is now becoming increasingly evident that the Cry toxin varieties expressed in Bt plants are not necessarily the same as those in the corresponding Bt bioinsecticides for spraying. For instance, MON 810 maize produces a single preactivated CrylAb toxin of about 91 kDa molecular mass, a truncated form of the bacterial CrylAb protoxin that undergoes enzymatic cleavage in the insect midgut resulting in the same hydrolyzed, 63-65 kDa active toxin as Dipel (Hilbeck A, 2001, *Perspect Plant Ecol Evol Syst* 4, 43-61; ' and Sze'kas A, Lauber E, Juracsec J and Darvas B, 2010, *Environ, Toxicol, Chem.29,* 182-190). These will result in differences in biochemical, consequences. The CrylAb active ingredient in Bt bioinsecticides is not identical with Bt transgenic plants; this fact has implications of utmost importance in pesticide/crop registration and in analysis of the active ingredient content What is to be noted from the point of actual practice is that the CrylAb active ingredient in MON81'0 maize varieties is preactivated CrylAb toxin (91kDa), whereas the toxicological studies in the registration documentation have been carried out with either bacterial protoxin (one of the active ingredients of Dipel, 131kDa) or with the active toxin (63-65kDa). It is well established in the registration of pesticides or pharmaceuticals, that toxicological evaluation is

required for authorization of an active ingredient even if it differs structurally only slightly (e.g. in a single substituent) from a registered active ingredient. This should also strictly apply to insecticidally active proteins, such as Cry proteins. The point that is completely neglected by the Regulatory agencies is that Bt as a biopesticide is quite different from the one produced in a transgenic Bt crop plant. More such serious omissions with regard to the toxicological evaluation of the Bt-brinjal (Mahyco Bt-brinjal) dossier are dealt with at length in the other sections of this report.

It is a dangerous assumption that Bt Cry proteins are specific only to the insects of certain orders* The evidence from scientific studies is that Bt toxins are not so very specific as not to cause any harm to the organisms belonging to widely different taxa. It is not true that Cry 1 Ac proteins are specific to Lepidopteran pests (i.e. moths and butterflies). It has been well demonstrated that these cause developmental abnormalities in the cells and tissues of the recipient plant. This has been reported in a paper published in *Journal of Bioscience* (2011, 36, 363-376) by Rawat P et al. of which Professor Deepak Pental (a former GEAC Member and who has also filed an affidavit against the TEC's Interim R of October 2012) is the senior co-author. Dr. Pental was also the Chairman of the. Expert Committee.I to assess the Bt-brinjal Event EE-1 developed by M/S. Mahyco.

The available scientific data do not support the claim that Bt toxin Cry proteins are. specific in their toxic action to the target pests and therefore, they do not induce harmful effects in animals and humans. The notion that Bt toxins are only specific to the alkaline gut system of target insects is the basis for health safety claims and the rejection of studies demonstrating toxic effects in non-target organisms. During the 1980s and 1990s, a few scientific papers suggested that Bt-endotoxin is specific to alkaline gut system found in a few categories (orders) of insects, but this has been discredited by more recent studies. The finding that Cry lAc protoxin binds to surface proteins in the mouse small intestine and permealizes the gut epithelium which then becomes susceptible to commensal bacterial to cause septicaemia dismisses the notion of specificity (Vazquez-Padron RI et al 2000, *Biochem. Biophys.Res.Commun.211,* 54-58). The point therefore, is that the long-held view that Cry proteins are only toxic to an alkaline gut system of certain categories of insects, is not the mechanism of killing. The implication of the new

paper by Broderick N.A et al (2G06$_5$ *Proc. Natl, Acad. Sci.* USA 103, 15196-15199) raises issues of uncertainty surrounding effects of non-target animals. In the context of ' Cry-expressing Bt-transgenic plants, there is the possibility of exposing a vast 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 organisms.** The Mahyco brinjal dossier does not cite the literature on the new model, and therefore, it is most unlikely that their experimental design was influenced by the latest scientific knowledge of Cry toxin activities.

Yet another finding that proves the lack of science in the concept of 'substantial **equivalence**[5] and calls for rigorous testing and adherence to the 'precautionary **principle'** is reviewed by Schubert D (2005, *Nature Biotechnology* 23, 785-787). Ke refers to the well-documented unintended effects in Bt-corn hybrids derived from Monsanto's MON810 and Sygenta's Btll plants as well as glyphosate-tolerant (Ht) transgenic soybeans. The unintended effect results from the alteration in the shikimic acid pathway of the Bt toxin in plants. These plants are also found to contain elevated levels of lignin, an abundant nondigestible woody component that makes plants less digestible as animal feed. Further components of this same biochemical pathway also produce both flavanoids and isoflavanoids (that have high nutritional value) and **rotenone,** a plant-produced insecticide that has been associated with Parkinson's disease (Betarbet R. et ah *Nature, Neurosci,* 3, 1301-1306). Isoflavanoids are abundant in legumes like soybeans and rotenone is synthesized directly from isofiavones in many legume species. While there is no evidence of any testing of GE soybeans for rotenone, an earlier paper by Lappe, M.A et al 1999, *Med. Foods* 1, 241-245 has shown that **glyphosate -tolerant** soybeans sprayed with glyphosate have reduced flavanoid content. So, there is need to test for rotenone in Ht-transgenic crops. The regulators have not done the necessary tests for these despite the growing scientific knowledge on these issues.

Furthermore, by closing the investigation on reported cases of animal deaths following their grazing on Bt-hybrid cotton stubbles/ leaves etc. also shows sub-standard regulatory oversight and even negligence. The details are as follows:

Dr. Sagari Ramdas, a veterinary doctor currently associated with the non-governmental organization (NGO) Andhra, made a powerpoint presentation to the TEC on the 14(July 2012. She showed post-mortem photographs of the damage to goats that allegedly died after grazing on Bt-hybrid cotton leaves and stubbles in the cotton-growing tract of Andhra Pradesh. She produced copies of her correspondence with several departments of the government and the GEAC. She also made a submission of the report entitled, *"Interrogating the science of safety: Unknown Aspects ofBt toxin that continue to pose a threat to the Health of Domestic Animals in India and its implications for risk assessment and biosafety protocols"*. None of these has elicited a responsible and science-based response from the RCGM and the GEAC.

The evidence of Dr Sagari Ramdas

Since 2005, shepherds and farmers from different parts of India- particularly from the states of Andhra Pradesh, Haryana, Karnataka and Maharashtra have reported that their animals (cattle, buffaloes, sheep and goat) that have grazed on genetically modified cotton or have been fed genetically modified cotton seeds or cotton seed cake have fallen sick and in some instances have died. Despite several reports and representations to concerned regulatory (GEAC) and research institutions (IVRI, Veterinary University, Animal Husbandry Department) both at national arid state levels, alerting them to the seriousness of the issue, there has been a persistent reluctance amongst the scientific establishment to respond, investigate and research into the problem. On the contrary the reaction of the establishment has been bureaucratic, dismissive of the field and clinical observation of shepherds whose animals suffered, and of non-government veterinary scientists who have been tracking the problem, describing these as being "unscientific", "exaggerated and blown out of proportion", and not based on insufficient research and hard facts. The Indian regulatory authorities such as the Genetic Engineering Approval Committee (GEAC) and top Indian research universities have exhibited incapacity to rigorously investigate the problems experienced and observed by farmers and shepherds,

could not be the cause of morbidity and mortality. To-date not one public research institution has undertaken to systematically investigate the problem at the farmers field.

The submission by Dr Sagari R Ramdas highlights the absence of scientific rigour by regulatory authorities, such as the GEAC (evident in decisions taken by them in their 78[l], 81[st] meetings) with respect to their circular arguments of safety, being cited as "evidence" that animal deaths after being grazed on Bt cotton, were not caused by Bt toxin. The evidence of safety was obtained by Dr Ramdas through filing an RTI with GEAC, and consisted of 4 letters:

Proof: A letter from the Department of Animal Husbandry, Andhra Pradesh sent by the then Director Dr L.Mohan to the GEAC, wherein he states that Bt cotton samples were sent to 4 different laboratories. These results have been cited as evidence that animals uied Oj otuer causes anu not B± toxin.

- « *However there is no information provided on the entire protocol of tests and investigations conducted by each laboratory.*
- *There is no information as to whether the laboratories tested for presence I absence ofBt toxin in the cotton samples.*
- « *The results from each laboratory contradict the other.*

  Bt cotton sample is negative for HCN in results from Western Regional Disease Diagnostic Lab, and positive for HCN in VBRI, Hyderabad. Bt cotton sample is positive for Nitrite in VBRI results, and positive for Organophosphate in the AP Forensic Science Lab, Hyderabad, results.
- *The presence ■ or absence of a mineral deposit in a plant sample does not automatically translate into that being the cause of death in the animal.*
- *These are reports of only results of testing of Bt cotton PLANT samples. What about the testing of the animal tissue samples? None of the labs appear to have tested the animal tissue samples.*

Proof 2: a letter from the Venkateshwara University requesting further Biosafety studies,

Proof 3: a letter from the Joint Director of a district called Ranga Reddy (which never had deaths of sheep), in Andhra Pradesh, stating that no deaths due to Bt cotton were reported from his district,

Proof 4 : A letter from the 1VRI stating that they had conducted tests on goats and rats, and that Bt cotton samples tested in their laboratory tested negative for HCN, Nitrate, Nitrite, Gycosoides and Alkaloides.

Such "evidence" would not stand any kind of international scientific scrutiny based as they are on incomplete testing / investigation protocols, compounded by admissions by top Indian research institutions of the absence of facilities to test for the effects of the toxin on animals, and citing company data on toxin-safety levels. There continue to be numerous unanswered questions with respect to the effects of the Bt toxin on animals, which require urgent attention.

i The persistence of Cry 1 Ab toxin in the gastro-intestinal contents of livestock fed on Bt-corn has been demonstrated in animals (Savitz, D.A., Arbuckle, T., Kaczor, D., « Curtis, K.M. (1997): 'Male pesticide exposure and pregnancy outcome'. AM. J. *Epidemoil.* 146, 1025-1036). There are several other reports on the disruption of endocrine systems, and Cry 1 Ac inducing immune responses in mice similar to Cholera toxin (Vazquez R.I et al 1999 *Scandinavian J.. Immunology* 49, 578-584).

Externally applied biopesticides can be washed off easily, as opposed to those produced internally in Bt crops where the toxin is an integral constituent of the cells and tissues of the plants.

The Biotech giant Sygenta denied knowledge of its genetically engineered Bt-cotton killing livestock during a civil court action that ended in 2007 (Sygenta charged with lying over cattle death, GM Watch, 25 May 2012) http://www/gurwatch.org/latest-listing/1-news-items/13_926-sygenta-charged-with_lying-over-cattledeaths. In an earlier paper, Ho MW and Burcher S published an article "Cows ate GM maize and died" in *Science in Society* 2004, 21, 4-6. There are a few scientific studies in sheep (Trabalza-Marincci M et al (2008, *Livestock Science* 113 (2), 178-190) and aquatic organisms (Rosi-Marshall E.J et al 2007, *Proc. Natl Acad. Sci. USA* 104, 16204-16208) demonstrating adverse biological health effects.

transgenic feed. Several scientific investigations have unequivocally demonstrated the presence of trace amounts of the Cry 1 Ab toxin in the gastrointestinal contents of livestock fed on GM corn (Chowdhury EH et al. 2003. *1 Animal Sci.* 81, 2546-2551; Lutz B et al 2005. *J. Agri. Food Chem* 53, 1453-56). A recent study by Aris A and Leblanc S (2011, *Reproductive Toxicology* 31, 528-533) entitled, *"Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada"* showed that CrylAb toxin was detected in 93% and 80% of maternal and fetal blood samples respectively and in 69% of tested blood samples from ■ nonpregnant women. This study shows that the Bt-toxin does not degrade in the stomach of animals fed on Bt-transgenic feed, and persists long enough to get passed on to human consumers of the flesh of animals which have ingested GM feed. It bears repeating that there is no scientific evidence for the claim that Bt toxins are rapidly degraded in the stomach.

The Aris and Leblanc paper was criticized by scientists of (i) Bayer Crop Science Ltd., (ii) Monsanto and (iii) Food Standards Australia New Zealand in 'Letter to the Editor' in the same journal, *'Reproductive Toxicology'*. These criticisms have been convincingly replied by Prof. Aziz Aris of the Department of Obstetrics and Gynecology, FMSS, University of Sherbrooke, Quebec, J1H5N4 Canada in the same journal. The criticisms and responses are briefly presented below:

Of these three, Monsanto, and Food Standards of Australia New Zealand focus more on Bt toxin, whereas Bayer Crop Science's concerns are mainly on the findings of glufosinate and its metabolite. These are as follows:

(i) In their Letter to the Editor, *Reproductive Toxicology* 33 (2012) 120-121, the Monsanto scientists D.A. Goldstein et al, equate the CrylAb from the Bt-transgenic crops to Bt-biopesticide used as msecticida! spray in organic farming. It has already been discussed that the Bt toxin in the biopesticide is very different from that in the Bt-transgenic plants in terms of molecular weight, and that the Bt biopesticide spray gets degraded in sunlight, and washed off in rain etc. Further the Bt toxin in the transgenic plant is continuously present in plant tissues, whereas Bt-spray resides on the surface

of the plants only and for limited periods. These substantially different reasons allow Bt to be used as a biopesticide spray and used judiciously in organic farming: A Bt-transgenic plant on the other hand may not be so used for valid reasons. The authors (Goldstein et al.) have ignored the fact that the two are not similar and therefore comparable. The statements of Goldstein et al (2012) are of special relevance to the Indian situation. These are as follows:

"CrylAb is present in GM maize intended primarily for animal feed and processing to food ingredients (corn syrup, starch etc.), and human consumption is expected to be quite low. Further, very little corn is.consumed by humans in a raw slate, and cooking denatures CrylAb eliminating its biological (insecticidal) activity".

The TEC notes that the statement of Goldstein is indeed "true and it supports the scientific data available in the literature. Goldstein seems to be aware of the fact that in India humans and animals directly consume corn whether GM or non-GM unlike in the USA.

Monsanto scientists also question the sensitivity of detection methods, and state that detection of CrylAb appear to be over-reported. However, as stated in the response by Aziz A (2012, *Reproductive Toxicology* (2012), 122-123), Monsanto scientists admit that CrylAb protein can be present in blood. The Monsanto scientists, however, rule out any mammalian toxicity by CrylAb or related Cry proteins. What are confirmed is that (a) Cry proteins are not readily broken down in mammalian (including human) gut and (b) these are transmitted to humans from Bt-transgenic crops, and from the meat of animals fed Bt-transgenic feed. It has to be proven that Bt protein which is a toxin in the blood stream is harmless!

Utz Mueller and J. Gorst of the Food Standards Australia New Zealand in their Letter to the Editor, *Reproductive Toxicology* 33 (2012), 401-402 have raised questions on the potential sources of detected pesticides, and the sensitivity of detection method for CrylAb protein. In his reply Aziz A (Reply to Letter to the Editor, *Reproductive Toxicology* 33, (2012) 403-404) points out that as the labeling of GM foods is not mandatory and systematic, it is not really possible to identify the various products derived from GM foods we eat Aris, having clarified the question regarding the

mc mmr riuna, ine quesnon tnat Has arisen is can we consider a concentration oj 0.14 ng/ml (140 pg/ml) Bt-toxin as safe for human fetuses, when the sensitivity of our method detection reaches 0.02 ng/ml (20pg/ml)? Can we consider a concentration of 0.14 ng/ml (140 pg/ml) as null (zero), when we know that major hormones in human reproduction act at similar levels or lower (i.e. GnRH:0.02 ng/ml; estrogemO.1-0.3 ng/ml and progesterone: 1-15ng/ ml)? In other words, when the.same concentration could explode the gut of a lepidoptera larva measuring between 0.5 and 3 mm, can we be worried about a human embryo which has the same size (0.4 mm) on the tenth day of pregnancy? "

The Bayer Crop Science's position was largely confined to the findings of glufosinate and its metabolite. These authors A, Blacker et al (Letter to the Editor, *Reproductive Toxicology* 32, (2011) 494-495) question the accuracy and credibility of the , author's findings and conclusions related to glufosinate and the metabolite 3-MPPA. In his response, A.Aris ('Response to Bayer Crop Science's position on the findings.of glufosinate' and its metabolite', *Reproductive Toxicology* 32 (2011) 496-491) have drawn the attention of the Bayer Crop Science scientists to several earlier scientific publications in support of their findings. They also point out that all the previous studies involved animals, whereas their data are directly from humans. It is also mentioned that the *"WHO/FAO recommended acceptable daily intake (ADI) for glufosinate is 0.02 mg/kg. However, Blacker et al report values much higher than what is recommended. Thus, they mentioned 6 mg/kg in lentils (300 - times higher), 0.1 mg/kg in apples (5-times higher) and 0.2 mg/kg in corn (10-times higher). These are quite disturbing".*

The abovementioned review establishes that independent scientists with no ties directly or indirectly to the biotech Industry arrive at different conclusions of safety than the biotech industry and its scientists or those funded by them.

The Regulatory agencies in India such as RCGM and GEAC have failed in discharging their responsibilities to the people of India for following reasons amongst others:

- Bt toxin is not specific to alkaline gut of certain orders of insects. It binds to surface proteins in the small intestine of mice. The regulators should not be relying on obsolete or inaccurate statements with regard to GM crop.

« Bt-does not fully degrade (i.e. broken down and excreted) in the gastrointestinal tract. In fact, it not only persists, but is also transmitted from transgenic plants to animals and to humans through the food chain.

. • An 'unintended effect' of Bt in plants is the increase in lignin content, and there is indirect evidence to suggest that 'rotenone', a plant-derived insecticide known to be associated with Parkinson's[1] disease could be formed. This needs to be verified by additional experiments.

- Cry 1 Ac-also inhibits certain types of cytokines involved in immune response (Guerrepp, WM. et al 2007. *Molecular Immunology* 44, 1209-1217)..
- Reported cases of morbidity and mortality of sheep/goats grazing on Bt-hybrid cotton leaves/stubbles etc., in certain parts of Andhra Pradesh were not adequately investigated. This remains an enigma.
- No testing of Ds RNA (double-stranded DNA)
- Thus, lack of comprehensive testing and lack of rigour in RA protocols including long term testing for chronic toxicity.

Besides these,, the ' adverse effects of Bt toxin on non-target beneficial soil microorganisms have also been reported. These are discussed in the context of adverse effects on biodiversity and sustainable agriculture in the following section.

- (iii). Masking and unmasking of the results of biosafety evaluation of genetically engineered crops.

The pro-GM lobby, and strangely even the affidavit filed by the MOA against the TEC interim report often claim that the European Union research shows GM foods are safe. It may be noted that the EU has also been challenged over revolving doors and a serious conflict of interest. The evaluation of available scientific literature and data, however, challenges such claims and notes serious flaws and non-disclosure of •harmful effects. Often the regulator's actual statements are equivocal, or are even based on the results provided in a self-assessed safety dossier by the crop developer is accepted by the regulators (as in the case of the Bt-brinjal dossier provided by Mahyco to the GEAC), This is the common experience. Often, these raw data are not made public until a

of the data by independent scientists as happened in the case of Bt brinjai and Monsanto's Bt maize in Germany among other examples, it became evident that the results in the dossiers were under-reported or masked undesirable biological changes. More studies were called for specifically feeding studies for chronic toxicity extending over lifetime and multigenerations. These should be made mandatory in our protocols. The case of a paper entitled *"New Analysis of a Rat Feeding Study with a Genetically Modified Maize Reveals signs of Hepatorenal Toxicity"* by Seralini G.E. et al *(Archives in Environmental Contamination and Toxicology,* 52, 596-602,2007) is just an illustration of mis-reporting . and under-reporting of results in the area of biosafety evaluation of genetically engineered foods. The case in question pertains to the biosafety evaluation of genetically engineered corn MON 863. The biosafety study was conducted by Monsanto and the results were published after the authorities' assessment by Hammond B et ai (2006, *Food Chem. Toxicol* 44, 147-160). The raw data at first kept confidential, were subjected to questions from regulatory reviewers in Europe, where it was finally approved in 2005. After obtaining these data after a court action, Professor Seralini and his team re-analyzed the data and published the results *(Arch.Environ.Contam.Toxicol.52,596-602,* 2007). The re-analysis of the 90-day rat-feeding study showed that after consumption of MON 863, rats showed dose-related significant variations in growth for both sexes, hepatorenal toxicity and changes in chemical compositions of urine excreted. However, all the statistically significant effects found in reanalyses were dismissed by the European Food Safety Authority (EFSA) in its favourable safety assessment of the maize. EFSA **claimed that the statistically** significant effects were not "biological meaningful". **But** EFSA's **opinion** failed to give a rigorous scientific or legal definition of what **makes** a **statistically** significant finding not "biologically significant".

Since there is no sound definition of what data are 'biological meaningful', it is difficult to regulate genetically engineered crops. It is, however, important to place on record tha,t EFSA's opinion is not surprising, given the fact that it is authored by several affiliates of the industry-funded group, the International Life Sciences Institute (ILSI) , including Harry Kuiper (also the Chair of EFSA's GMO panel), Joseph Schlatter, and

Susan Barlow. Because ILSI is funded by GM crops developers, allowing ILSI affiliates to write EFSA's scientific advice on how to assess the safety of GM foods and crops is exactly similar to allowing a student to write his or her own examination paper- or allowing scientists to review their own papers submitted for publication!

It is on record that Professor Gilles-Eric Seralini who concluded that MON 863 is not safe and has asked for such studies to be extended to beyond 90 days so that the consequences of the initial signs of toxicity could be adequately known, was subjected to a vicious smear campaign. This campaign appeared to come from the French Association of Plant Biotechnologies (Association Francaise des Biotechnologies Vegetable (AFBV) Chaired by Marc Fellous. Prof Seralini sued Marc Feilous for libel, arguing that the smear campaign had.damaged his reputation, reducing his opportunities for work and his chances of getting funding for his research. It turned out that Marc Fellous owned patents through a company based in Israel and that this company sells patents to GM corporations such as Aventis. Seralini's lawyer showed that other AFBV members also have links with agribusiness companies. The court's judgment was in favour of Seralini. The judge sentenced the AFBV to a fine on probation of 1000 Euros, 1 Euro for compensation (as requested by Seralini) and 4,000 Euros in court fees (GM free Cymru. Independent GM researcher wins court victory for defamation (Press release) 19 January 2011. http://www.gmwatch.org/latest-listing/l-news-items/1281). This case is an example of vested interests in the regulatory bodies covering up scientific truth and jeopardizing public health for personal gain.

As already discussed, consumption of GM foods could result in adverse biological and health consequences. Professor David Schubert of Saik Institute for Biological Studies, La Jolla, California in his letter dated November 18, 2009 to Mr. Jairam Ramesh, the then Honourable Minister of Environment and Forests, Government of India has summarized at east **four** mechanisms by which introduction of a Bt toxin gene into a **plant** can cause harm. These include (i) the random insertion of the Bt gene into the plant DNA and the resulting unintended consequences, (ii) alterations in crop metabolism by the Bt protein that results in new, equally unintended and potentially toxic products, (iii) the direct toxicity of the Bt protein, and (iv) an immune response elicited . by the Bt-protein. There are scientifically documented examples of all four toxic

"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. 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) . Importantly, the synthetic route to lignin in plants is shared with that ofrotenone, 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.

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"' Most importantly, it should

be emphasized that the concentration and amount ofBt 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 " . Based upon these data, the US Environmental Protection Agency (EPA) recommended extensive safety testing of Bt crops for this trait , but due to the lack of required safety testing for GE food crops in the US, this was never done . 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 GEfood 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 [4], 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 ofBt 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 . 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.

population, if the introduction of Bt brinjal is allowed, an enormous number of individuals are going to consume amounts ofBt 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 ofBt 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 ifBt brinjal were allowed to enter her food supply.

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9".

(iv) Certain Observations on the safety reports often cited by the **Regulatory** Agencies:

Not providing raw data and details of the publications such as where these are published etc.. For example, a 90-day feeding study on hamsters is said to show that **"the GM potato** was as safe as the non-GM potato", but no reference is given to any published study or other source of data (European Commission. ('A decade of EU-fimded GMO research (2001-2010)').

The European Commission does not always cite references (for studies which have been published in peer-reviewed journals). Eg the harmful biological effects of GM potato (Ewen SW and Pusztai A 1999 *Lancet* 354, 1353-1354; Domingo J.L 2000 *Science* 288,1748-1749). In a study on humans, one of the experimental subjects showed an immune response to GM soy but not to non-GM soy. The GM soy was found to contain a protein that was different from the protein in non-GM soy. This shows that GM foods could cause new allergies (Yum Hy et al.2005, *Allergy Asthma Proc.* 26, 210-216). A GM soy variety modified with a

gene from Brazil nut was found to react with antibodies present in blood serum taken from people known to be allergic to Brazil nuts. (Nordlee J.A et al 1996 *Engl. J. Med.* 334,688-692). * Several other papers published in peer-reviewed journals likewise raise serious doubts on the health safety of genetically engineered foods. Some of them, in fact, unequivocally demonstrate long-term serious adverse biological effects. However, the biotech companies and the GM lobby use various means to suppress science and the truth about the transgenic crops. The Editorial of *Scientific American* (13 August 2009, 'Do seed companies control GM crop research? -http://www.scientificamerican.com/article.cfm?id=do-seed-companies-control-. gm-crop research) states the following, *"Unfortunately, it is impossible to verify that genetically modified crops perform as advertised. That is because agritech companies have given themselves veto power over the work of independent researchers .... Research on genetically modified crops is still published, of course. But only studies that the seed companies have, approved ever see the light of a peer-reviewed journal. In a number of cases, experiments that had the implicit go-ahead from the seed company were later blocked from publication because the results were not flattering .... It would be chilling enough if any other type of company were able to prevent independent researchers from testing*

> *its wares and reporting what they find.... But when scientists are prevented from examining the raw ingredients in our nation's food supply or from testing the plant material that covers a. large portion of the country's agricultural land, the restrictions on free inquiry become dangerous ".*

- *In 2009, 26 scientists took the unusual step of making a formal complaint to the US Environmental Protection Agency, which said, "No truly independent research can be legally conducted on many critical questions involving these (GM) crops".*
- *The aims and objectives of Monsanto in blocking transparency and independent research and of study findings in their safety dossiers has been most emphatically made visible by their threat to take legal action against EFSA for publishing data on ot GM NK603 maize, NK603 was used in the*

and http://www:foodnavigatorxom/Legislation/Monsanto-threatens-to-sue-EFSA-over-publication-of-maize-GM-data report dated 8 March 2013

The TEC interim report in its decisions and recommendations on a conditional moratorium on different categories of open field trials, does not bar basic GM research, but it would seem that this is exactly what crop developers like Monsanto are doing with dogged determination, by muzzling and threatening research, denying reference materials needed for such research. This has been the consistent pattern, Dr. Arpad Pusztai being a leading example for his research published in the Lancet that rats fed GM potatoes showed excessive growth lining of the gut similar to a pre-cancerous condition, and. toxic reactions in multiple organ systems. (Pusztai A Home page 2003 .http://www.freenetpages.co.Uk/hp/a.pusztai/Accessedl 7April2012).

The TEC Interim Report has also come under severe criticisms of being flawed and unscientific, by the Industry (expected), but also by different departments of government, principally in the MOA. Its Affidavit through the DAC is by their own admission, in matters of regulation and risk assessment, an area where it has no "mandate" and "no direct role in policy matter related to research and development of GM crops". The MOA also has a serious conflict of interest (declared). These 'interested[5] parties were not able to substantiate their criticisms in their personal depositions.

In the aftermath of the TEC Interim Report submitted to the Honourable Supreme Court in October 2012, Seralini published his new research on rats that had been fed a Monsanto HT maize resistant to Monsanto's Roundup. Rats were also fed low doses of Roundup itself.' This first lifetime study found in both cases that the rats were many times more likely to develop lethal tumours and suffer liver and kidney damage than the controls. This study is entitled "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize" by Gilles-Eric Seralini et al (2012, *Food and Chemical Toxicology* 50,4221 -4231).

We are familiar with the vast criticism of this report, which appeared very quickly after the study findings were published, more akin to a knee-jerk reaction rather than an objective, thought-out response. Seralini himself asks for further research after pointing out that his protocols (apart from the duration), are the same as what Monsanto has used, as well as in other feeding dossiers. What is very clear is that no other studies match the duration of his study. Nor can any 90 day study refute the findings of his long term study, when the effects become manifest after 90 days.

Prudence and the Precautionary Principle necessitate that our protocols include similar studies of 240 days. It is also noted that GEAC has approved Ht-tolerant (Roundup - tolerant) crops for field trials in India without even conducting necessary preliminary laboratory-based studies. The paper by Seralini et al (2012) will be discussed in detail in the section on Ht-transgenic crops. Roundup induces cancers.

The Mahyco dossier on the safety evaluation of Bt-brinjal has attracted considerable attention. Its appraisal by leading international scientists demonstrated incompetence, lack of expertise/ professionalism and proper regulatory oversight by our Regulators including the EC II. The conflict of interest furthermore, made it impossible to appraise the safety of Bt-brinjal Event EE -1, for the Regulators to acknowledge the significant cover-up with regard to studies not done. For example, on gene flow, Prof David Andow in his ERA of Event EE -1, *('Bt* brinjal: the scope and adequacy of the GEAC environmental risk assessment, 2010) (and others) pointed to studies quite simply not done, including gene flow. This was denied. The official- stance has always been that contamination would not take place. The biosafety of Bt brinjal has been proclaimed by the 6 Indian Academies of Science. It is significant that the above criticisms of the regulators have also been separately expressed by the Sopory Committee Report on the indigenous Bt-transgenic cotton, BNBt

The recent article 'Bt brinjal: a risk worth taking?' (J Samuels 2013, Current Science, 104 (5) 571-572) throws light on the significant levels of pollen transfer among the related species of brinjal.

It has been suggested that the appropriate regulatory tests can be dispensed with because certain environmental impacts including tpollen transfer, have no scientific basis. In the course of the on-going international crop improvement programme for brinjal, over 50

reported an extremely high crossing success rate. At this point it is important to note that six wild relative species and four cultivated *Solarium* species found in India are known to be able to cross with brinjal to produce reproductively fit hybrids. It has been suggested that the chances of natural hybridization (as opposed to artificial hybridization via hand-pollination, described above) taking place are low. However, pollination in brinjal may consist of up to 47% natural cross-pollination, with up to 70% of fruit set arising as a consequence of pollination by insects - many trials indicate that insects play a major role. Brinjal has thus been described as 'an often cross-pollinated crop'. The neglect of pollen transfer tests would thereby disregard'this potential hazard. Furthermore, any investigations into this factor should involve a wide range of potential recipient species, including cultivated *Solarium* relatives, other than brinjal For a thorough assessment to be possible, data which are extensive, interpretable and unambiguous must be made available.

- (v) Bt-transgenic crops - a threat to sustainable productivity

The green revolution of the 1960s provided immense good in a very short time (i.e. it changed India's image as 'begging bowl' to 'bread basket'), and built food security at the national level, though not at the individual household level of about three hundred million women, men and children predominantly in the rural areas. The paradox was "mountains of grains on one hand, and millions of hungry people' on the other. The lesson learnt, among other things was that surplus food in national warehouses does not just percolate down to the households of the hungry and the needy. Furthermore, intensive inputs of chemical fertilizers and pesticides requiring copious irrigation notwithstanding scarce groundwater without drainage etc., resulted in the degradation of soil properties including soil health governed by earthworms, and beneficial microorganisms. , As all of us now realize, the ecological problems caused by the green revolution became manifest in the long term (or the 'exploitative agriculture' as it was referred to it by Professor M.S. Swaminathan in his Presidential Address to the Agricultural Section of the 55th Session of the Indian Science held in January 1968 in

Varanasi). There was also significant depletion of biodiversity of the locally-adapted traditional varieties of wheat and rice. Any loss of a variety is indeed an increase in vulnerability to challenges of food security in the future, especially in an era of climate change.

The evidence shows that Bt and Ht-transgenic crops also demonstrate negative impacts on ecological and social risks of the green revolution (or the exploitative agriculture), without, of course, the positive element of quantum yield increases! We discuss some of these, issues below:

e Bt transgenic adversely affect beneficial. soil microorganisms

Several papers reveal that soil microorganisms coming into direct contact with the root exudates from the transgenic Cry endotoxin (note that this is not the same as Bt-endotoxin from biopesticide formulations) suffer adverse biochemical effects. A study of comparison between the dynamics of nitrogen and phosphorus availability in the rhizosphere of Bt and non-Bt isoline, revealed a significant reduction in dehydrogenase activity (-17%) and soil respiration (-3.5%) in the rhizosphere of Bt-cotton over non-Bt alone. The authors (B. Sarkar et al, 2008, *J. Agronomy and Crop Science* 194, 289-296) suggest that Bt-cotton may constrain the availability of nitrogen in the soil. It is also suggested that Bt-cotton root exudates could enhance phosphorus availability in the soil. In China, Chen et al (2011, *Plant Soil Environ.* 57, 67-74) have shown that the Bt-toxin (Cry 1 Ac) from Bt-cotton was persistent in soil under a 4-year consecutive cultivation of transgenic cotton. In comparison with non-Bt isoline, the soil microbial biomass carbon, microbial activities, and soil enzyme activities (except urease and phosphodiesterase) significantly decreased in soil under transgenic conditions. More recently, Tarafdar J.C et al (2012, *Applied Biological Research* 14 (1), 15-23) investigated the effect of Bt-cotton (with Cry 1 Ac gene) on several microbial and biochemical indicators in 25 fields selected in the Vidarbha region, India. Bt-cotton was cultivated for at least three consecutive years. The results revealed a significant decline in actinobacteria (17%), bacterial count (14%), acid phosphatase (27%), phytase (18%), nitrogenase (23%) and dehydrogenase (12%) activities. There was also a significant decline in biomass nitrogen (MBN) and biomass carbon (MBC).

- ui-uaii5geiiics: uKivi require 'refuge' (i.e. non-ist) crops to delay the onset of resistance in the pest

The genetic engineering of the *Bacillus thuringiensis* (Bt) cystai (Cry) toxin genes into hybrid cotton was primarily to target the cotton bollworm *(Helicoverpa armigera).* This lepidopteran moth is a polyphagous pest with a wide range of 181 plant species including cotton, pigeonpea, tomato, chickpea, maize, sunflower and .several vegetable crops. Given the capability of *H.armigera* for developing resistance against several insecticides used as external spray, it was considered that the introduction of insect-resistant Bt-transgenic crops would provide a more effective,and long-lasting solution. However, it was also known as early as 2000 (Kranthi K.R., Kranthi S., Ali S and Banerjee, SK., *Current Science* 78, 1001-1004) that long-term exposure to Bt-transgenic crops is likely to render lepidopteran pests resistant to the Cry toxins due to continuous selection pressure. Since the development of resistance to Bt toxins can be quite distinct depending upon the genetic constitution of the species, selection regime or geographical origin of the 'founder colony' (Heckel. D., 1994, *Biol. Technol* 4, 405-408), an initial survey to assess the susceptibility of test insect to Cry toxins was undertaken by Fakrudin B et al (2003, *Current Science* 84, (10), 1304-1307). These authors have reported ' resistance of *H.armigera* to Cry 1 Ac toxin in 11 geographic populations representing the entire south Indian cotton ecosystem. It was found that the insecticide-susceptible strain of *H. armigera* from ICRISAT, Hyderabad (called herein as ICRISAT strain) was most susceptible with LC50 value (ug/ml) of 0.130. The LC50 value for Nagpur, Nanded and Guntur strains were 0.927ug/ml, 1.095ug/ml and i.044ug/ml respectively. The strains from Nalgonda and Madhira had LC50 values of 1.00lug/ml and 0.927ug/ml respectively. What is important to note is that the data show that even before the use of Cry 1 Ac transgenics, the level of resistance was 8.4-fold in Nanded strains followed by 8.03,7.70, 7.13,6.80 respectively for Guntur, Nalgonda, Madhira and Raichur strains. So, variability for response to Cry 1 Ac toxin exists in the population, whether or not previously exposed to the toxin. A few individuals of *H.armigera* in almost all the populations tested were found to survive even the highest concentrations of Cry 1 Ac. Studies carried out as early as 1998 showed that in Bt-transgenic plants, the Cry 1 Ac

protein production decreased over the growing season and that the bio-efficacy of the protein was reduced by interaction with increasing levels of secondary plant metabolites (Federici B.A., 1998, *Calif. Agric* 52, 14-20). The point that ought to have been taken into account is that sublethal concentration of the Bt toxin may contribute to the development of Cry resistance due to low gene expression levels and thus insufficient exposure of the pest.

Darvas B (2011, GM plants and resistance-resistance management. *In:* Darvas B, Szekacs A (eds) Hungarian background on views of 1st generation genetically modified plants. Agricultural Committee on the Hungarian Parliament, Budapest, Hungary, pp 140-141 (http://vAvw.kormanv.hU/download/2/gd/20000/GenetEM.pdf) found that the Indian meal moth *(Plodia interpunctella)* developed resistance already in the 10th generation, indicating rapid obsoletion of Bt-varieties. An even more serious problem is that the *Plodia interpunctella* larvae resistant to MON810 show tolerance also to Dipel- which is a balanced blend of five bacterial *(B.thuringiensis)* proteins viz., CrylAa, Cry2Aa,CrylAb,Cry2Ab and Cry 1 Ac. Such cross-resistance means that development of resistance to Cry toxins, may lead to loss of applicability to both Bt crops and conventional Bt preparations.

Field-evolved Cryl toxin resistance has been documented in *Spodoptera frugiperda* to CrylF toxin in Puerto Rico, *Busseolafusea* to CrylAb toxin in Bt maize in South Africa and *Helicoverpa zea* to Cryl Ac and Cry2Ab toxins in Bt cotton in the Southern United States (Tabashnik BE et al. 2009, Field-evolved insect resistance to Bt-crops: definition, theory and data. *J.Econ. Entomol* 102, 2011-2025). in 2001, CrylAb resistant individuals of European corn borer, *Ostrinia nubilalis,* were identified from a field collection from Kandiyohi, Minnesota, based on increased survival at a diagnostic CrylAb concentration. The resistant strain exhibited later over 800-fold resistance to CrylAb. The investigators, (Crespo, ALB et al. 2009, *Pest Manag. Science* 65, 1071-1081) also reported that the resistance was controlled by more than one locus or multiple genes at one locus.

It is clear from the evidence that the developers of the Bt-transgenic crops are fully aware of the impending development of pest resistance against the Bt toxin in transgenic plants. In order to delay or mask this negative aspect of Bt- transgenics, they

small and medium farms in India and in other developing countries. These are:

(a). **Refuge strategy**

The 'refuge[5] concept lends itself to a humorous interpretation. The word 'refuge[5] means shelter from pursuit, danger or trouble, and a person or place etc. offering this (see Oxford Dictionary). The idea of 'refuge[5] according to the Bt-transgenic crop developers is that a non Bt-plant (therefore susceptible to the pest) will act as 'refuge' to the pest running away from the Bt-plant (resistant to the pest because of its production of Bt toxin). The expectation goes further that is that 'refuge[5] crop also allows the Bt toxin-susceptible pests to proliferate in numbers since there is no adverse selection pressure from Bt-toxin and significant numbers would mate with those emerging from the Bt-**fields.** The refuge strategy has helped to delay evolution of pest resistance to Bt-crops. (Carriere Y., et al., 2010, *Evol Appl* 3, 561-573 (cited in Ronald P, 2011, *Genetics* 188, 11-20). Resistance to Bt-toxin develops when the concentration of Cry 1 Ac in Bt crop is not high enough to kill the hybrid offspring produced by matings between susceptible and resistant *H. zea* (Tabashnik et al. 2008 *Nature Biotech,* 26, 199-202). When resource-poor farmers in India are not in a position to provide adequate refuge of non Bt-cotton, resistance by pink bollworm developed much earlier than expected (Bagla P.2010, *Science* 327,1439).

Y.B. Srivastava and Prabhuraj A (2012 *Current Science* 102, 1504-1506) observe that (i) there is no evidence that resistant pests surviving on Bt-cotton mate with the susceptible ones on the refuge crops. "There is no field reality or theoretical **confirmation** of **the** refuge hypothesis even after a decade of adoption in India". (ii) the poor firmer is left with no choice today; as non Bt cotton seeds have been **withdrawn from retailers[5]** shelves. This raises the question of proportion of Bt-cotton vis-a- vis non-Bt cotton (refuge) to be planted in order to achieve the goal. While ideally the refuge would have to be about 50 percent, in actual practice, it is impossible to exceed 5% or so, and even this is proving difficult because the average farm size in India is about 1.8 ha. It is also noted that even where a much higher proportion of refuge is used as in US, the resistance still develops.

A recent review on 'Advanced Technologies for Managing Insect Pests" by Sze'kac's A and Darvas B, 2012 In: *Advanced Technologies for Managing Insect Pests* (Editors LIshaaya, S.R. Palli and A.R. Horowitz) Springer Dordrecht Heidelberg New York London ISBN 978-94-007-4497-4 (e-Book)$_5$ brings out several flaws of the refuge theory in practical terms:

(i) the pest is being "bred" in substantial areas, bringing pest damage to a constant level, which is practically nonsense; (ii) in refuge zones where non-GM hybrid variety equivalent to the GM MON 810 corn are frequent, different seeds in a cob result in greater survivor of pest and help the selection of a Cry 1 resistant sub population; (iii) the developmental time is substantially different for survivor pests in the MON810 field and in the refuge zone (pests may develop twice as slow on Bt maize than on non Bt maize of similar genotype).

(b) US EPA review of Bt maize resistance in the US

Ref: Nov 2011 report of the US EPA: Updated BPPD (Biopesticides and Pollution Prevention Division) IRM (Insect resistance monitoring) Review of Reports of Unexpected Cry3Bbl damage in Monsanto's 2009 corn Rootworm dated 22nd Nov 2011.

Bt corn in the US demonstrates a serious and outstanding example of *"unexpected"* insect corn rootworm resistance to a Bt toxin, which has caused severe rootworm injury to Bt maize and which was recorded for the first time in Iowa in 2011. The problem appears to be also emerging in other key maize producing States of the US and becoming chronic. This is the first time in over 20 years of planting Bt that resistance has been confirmed in the US, which has the longest history of any country under GM crop cultivation and because, a 20% *'refuge'* policy to manage resistance is mandated by law.

Admission of how serious the problem is comes from 22 leading US academic corn experts in their strong message of caution (http://in.reuters.com/articie/2012/03/09/us-monsanto-corn-idrNBRE82815Z20120309) in a letter dated March 5 2012 to the Environmental Protection Agency telling regulators

The reduction of the recommended refuge from 50% to 20% is "likely the reason for the development of resistance").

The US EPA review describes Monsanto's insect resistance monitoring strategy for Bt maize in the US Midwest as "inadequate and likely to miss early resistance events". It also highlights how the crop itself may be causing the problem and how a failure to enforce mitigation measures, like refuges and rotations, is making it worse.

It severely criticizes Monsanto [5]s approach to monitoring resistance in the maize •■: pest.in four US States and less than transparent reporting. Starting in 2009, possible increases in resistance to the Bt toxin CrySBl (events Mon 863 and Mon 88017) were noted with the EPA giving several reasons for this including, failure to sample for resistant adults from problem fields and failure to do follow-up studies to determine resistance to its gene. An important implication of this is that more chemical insecticides may be used to control the resistant rootworms.

The EPA findings are not a surprise. Laboratory breeding experiments with western corn root worm have demonstrated that, *"Resistance evolved after just three generations of selection on Cry3B maize."*

. The US EPA review suggests the breakdown in effectiveness of GM maize is caused by a number of factors including:

■a) Bt plants producing too low a dose of toxin to kill pests, and hence fostering resistance developing in those that survive.

b) Farmers failing to plant non-GM crops refuges to ensure sufficient non-resistant adults are present to mate with resistant individuals, preventing the recessive resistance from becoming dominant in the population.

c) Continuous cultivation of the same Bt maize on the same land for several years without rotation

d) The US EPA also presents data showing the amount of toxin needed to kill the western corn root worm in *problem areas* has increased by as much as one hundred times.

The Agency warns that merely resorting to other GM maize varieties using several Bt toxins may not provide a lasting solution. Pyramiding Bt genes in one plant will not solve the problem. That this is scientifically a fact of occurrence has been recently verified by a team of University of Arizona entomologists (see the article by Brevault T, S. Heuberger, M. Zhang, C. Ellers - Kirk, X-Ni_5 L-Masson, X-Li_s B.E. Tabashnik, Y.Carriere 2013 'Potential shortfall of. pyramided transgenic cotton for insect resistance management' *Proc. Natl Acad. Sci.* USA: DOI:10.1073.pnas.l2'l6719110). It is widely believed that two or more Bt-toxins will be more durable - that is delaying the onset of pest resistance to the Bt in transgenic crops. The assumption here is redundant killing achieved by Bt plants producing two or more toxins that act in different ways to kill the same pest. That this assumption is not valid came from a study in which the pest *(Helicoverpa sp)* already having developed resistance to one Bt toxin (Cry 1 Ac) was exposed to pyramided Bt cotton containing Cry 2Ab and Cry lAc. Contrary to the assumption, on the two-toxin plants the caterpillars selected for resistance to one toxin survived significantly better than caterpillars from a susceptible strain. The team's analysis of published data from eight species of pests reveals that some degree of cross-resistance between Cryl and Cry2 toxins occurred in 19 out of 21 experiments. Contradicting the assumption of redundant killings cross-resistance means that selection with one toxin increases resistance to the other toxin. This study further illustrates the possible view that is industry-driven and Bt-technology not science-based.

(c) Integrating Bt-transgenic crops with IPM

Bt-transgenic crop developers would like to include Bt-transgenic Crops in IPM (Integrated Pest Management) farming. The untenable premise is that Bt-biopesticide spray is allowed in IPM. It has already been discussed how Bt toxins in transgenics is not of the same composition (in terms of active principle and their molecular weights) as traditional formulated Bt-biopesticide used in the organic farming. These are the facts:

from the surface of the plants by water application, or rain. In contrast, Bt plants provide relatively continuous protection against target pests and related species. This, means that the truncated Cry toxin is synthesized by the Bt plant continuously, regulated by the gene construct introduced into the plant and by the own genetic programme of the Bt plant, independently of the actual occurrence and population dynamics of the pests, causing an extensive presence of the Cry toxins in plants. In this context, Bt plants do not comply with the principles of integrated pest management (IPM), as the occurrence of the toxin Is **not limited to the duration** of the possible damage by the pest, and it does not follow a threshold value to. the acceptable damage level The U.S. National Research Council (2010 The impact of genetically engineered crops on farm sustainability in the United States, National Academies Press, Washington, D.C) notes that Bt crops help in reducing • the need to use broad spectrum insecticides and this is indeed one of the nrimarv ^oals of IPM. The fact, however, is that regardless of how mild the transgenic protein may be, the use of the Bt-crops cannot fulfill the **main** ecological principle of IPM that any **protection step against any given pest is justified** only if the pest damage exceeds a **critical threshold level,** the "economic injury level" or what is now referred to as **'economic threshold level' (ETL).**

Yet another worrisome fact is that Cry toxin varieties expressed in Bt plants are **not** necessarily the same as those in the corresponding Bt bioinsecticides. For example, maize varieties in the MON810 group produce a single preactivated CrylAb toxin of approximately 91kDa molecular mass, a truncated form of the bacterial CrylAb protoxin that undergoes enzymatic cleavage in the insect midgut, resulting in the same hydrolyzed, 63-65kDa active toxin as Dipel (Sz'ek'acs A et al; 2010; *Environ. Toxicol Chem.29,* 182-190). Apart from biochemical consequences, this fact of not identical CrylAb active ingredient in Bt bioinsecticides and Bt plants has connotations of utmost importance in pesticide/crop registration and in analysis of the active ingredient content.

For registration issues, on the basis of the above, MON810 maize produces an active substance that is not a registered biopesticide ingredient. The CrylAb active ingredient of MON810 maize varieties is preactivated CrylAb toxin (91kDa), yet

toxicology studies in the registration document have been carried out with either bacterial . protoxin (one of the active ingredients of Dipel, 131kDa) or with the active toxin (63-65kDa). It is noted that no pesticide active ingredient, regardless of how similar it is to a registered one, can be exempt from individual registration and toxicological and environmental impact assessment.

The woes of farmers, especially the millions of resource-poor small and marginal farmers in India and other developing countries are hardly addressed by Bt-transgenic , . hybrid cottons now numbering over 1200 varieties. What we are now seeing is the emergence of new or minor pest of cotton as major pests. In China, a ten-year study (1997-2008) revealed that Bt cotton cultivation has resulted in a 12-fold increase in mealy bugs, formerly a minor pest in cotton, making it a major pest of cotton and inducing the farmers to spray pesticides extensively. In India too, Dr. Kranthi of the Central Institute for Cotton Research has observed that due to the widespread adoption of Bt cotton, secondary pests like mealy bugs, and whiteflies have emerged as major pests. The farmers are forced to spray chemical pesticides and hence their usage in Bt cotton is on the rise after an initial decline (Bt-cotton: A critical appraisal, K.R. Kranthi, Annexure to Bt-brinjal decision note, Ministry of Environment and Forests, page 180-190 <http://moef.nic.in/downloads/public-information/Annex Bt.pdf>). Dr. Kranthi points **out** that since Bt-hybrid cotton is highly susceptible to mealy bugs and whiteflies, the insecticide use in cotton has increased from Rs.640 crores in 2006 to 800 crores in 2008

« Unintended effect in Bt cotton: New study

A recent report adds to the troubling question of the sustainability of Bt crops. The peer reviewed study 'Pest tradeoffs in technology: reduced damage by caterpillars in Bt cotton benefits aphids[5] by Steffen Hagenbucher et al (http://dx.doi.org/10.1098/rspb.2013.0042). The rapid adoption of genetically engineered (GE) plants that express insecticidal Cry proteins derived from Bacillus thuringiensis (Bt) has raised concerns about their potential impact on non-target organisms. This includes the possibility that non-target herbivores develop into pests. Although studies have now reported increased populations of non-target herbivores in Bt cotton, the underlying

contains reduced levels of induced terpenoids. Changes-in the overall level of these defensive secondary metabolites are associated with improved performance of a Bt-insensitive herbivore, the cotton aphid, under glasshouse conditions. These effects, however, were not as clearly evident under field conditions as aphid populations were not correlated with the amount of terpenoids measured in the plants.

The obvious question is: which other non-target herbivores other than aphids, develop into pests? As stated earlier, Bt cotton has seen major insect shifts in India and China devastating the Bt cotton crop.

This report, and the serious cracks in IRM strategies, for Bt crops raise real questions about the sustainability of this technology. In the US (as stated earlier) an official panel of scientists recommended a 50% refuge. The EPA went with the minority v'ew 0^ 90% and the nrnhlpm *nf* rpsistflnt rnnfwnrm ic nflrtlv ac a rpeult r\f tViic Anv technology that requires a 50 % refuge is likely doomed. In India, even given that there are other crop hosts that may provide a natural refuge to Bt cotton like pigeon pea, small farm sizes make IRM strategies in India a significant problem, if not impossible. There are questions about the effectiveness of [6]refuge-in-the-bag. If Bt cotton also causes non-target herbivores to develop into pests, then this technology looks unsustainable. Further research is required and must be done.

On its own, even without the serious implications of the above study, difficult and failing IRM for Bt cotton must raise the question of its sustainability. Pest management in alternative farming methods as opposed to resistance management in Bt is increasingly more logical.

Therefore, we conclude that Bt-transgenic crops are not candidates for sustainable agriculture and crop productivity, particularly in the Indian context which requires appropriate crop rotation. Since soil health is adversely affected by root exudates from the Bt-transgenic crops, it should not be included in the IPM schedule. Morover, after a few years of consecutive cultivation of Bt-transgenic crops, the soil would not be able to support the growth and yield of crops (ref the following published papers). One may accept them as such, or ask for more studies for long periods.

The relevant scientific papers in support of the aforementioned are as follows: 1. A study done in Karnataka by scientists from the University of Agricultural Sciences in Raichur (Ranjith M T et al, 2010, *Current Science* 99 (11), 1602-1606) reveals that the bollworm in India has developed resistance against both the single gene (Cryl Ac) Bt-cotton and the double genes (CrylAc and Cry2Ab) Bt cotton. This does not augur well for cotton pest management for sustainable productivity. The developers and promoters of the Bt-transgenic crops deposing before the TEC complained that the farmers are not sowing refuge and therefore, the pest would develop resistance sooner than later. Are.^these persons then blaming the farmer for resistance developing to Bt cotton? It is obvious that these persons have little knowledge of either laboratory-based studies or the field realities.

2. Western Com rootworm on transgenic corn developed increased survival (i.e. resistance) within three generations of on-plant greenhouse selection. This also establishes the fact that preliminary and important data can be generated in the greenhouses without rushing to fields (Meihis L N et al 2008, *Proc. Natl. Acad. Sci, USA* 105 (49), 1917782).
3. Field-evolved resistance to Bt maize by Western Corn Rootworm (Gassmann AJ. et a; 2011, *PLoS One* 6 (7) 222629.
4. Field-evolved resistance to Bt-toxin Cryl Ac in the pink bollworm, *Pectinophora gossy-piella* (Saunders) (Lepidoptera:Gelichiidae) from India (Dhurua S and Gujar G T,2011, *Pest Management Science* 67 (8), 898-903.
5. Outbreak of secondary pest infestations in Bt-cotton (Wang S et al 2008, *Int. J. Biotechnology* 10 (2-3) 113-121.
6. Contamination of refuge by B.thuringiensis toxin genes from transgenic maize, (Chilcutt C.H. and Tabashnik B E, 2004, *Proc.Natl Acad. Sci* USA 101, 7526-7529. This establishes the gene-flow from the Bt-transgenics to the non-Bt refuge.
7. Bt-transgenic crops adversely affect soil ecosystems: a review of 10-year research in China (Liu W 2009 *Front. Agric. China* 3 (2), 190-198.

management, jxesuvan r.u. ana Maiarvannan S (2010, *Current Science yy* (7), 908 -914) concluded that Bt-transgenics do not suit the goal of sustainable eco-friendly agriculture. On the other hand, the IPM strategy consisting of 'native' genes from naturally resistant cultivars, sex pheromone, crop rotation, and cultural, mechanical and biological control methods are now being quite successfully adopted in a few places in India is most effective for sustainable agriculture.

Herbicide- tolerant Ht-transgenics:

Herbicides are used for weed-control by chemicals which interfere with essential metabolic pathways of plants. Any agent/substance which interferes with natural biosynthetic pathways needs to be thoroughly investigated for possible harm to nontarget organisms. .Herbicides like the insecticides (e.g. DDT) can cause adverse biological effects in a wide spectrum of non-target organisms. It may be recalled that Paul Muller was awarded Nobel Prize 1948 for demonstrating the insecticidal property of DDT. In 1962, Rachel Carson published her epoch-making book *"Silent Spring"* which vividly brought out the harmful effects on a wide range of non-target organisms. In all likelihood, the herbicide 'Roundup' would also result in a second *'Silent Spring'*.

It is now well known that all herbicides have their environmental and human. health costs. The herbicide-tolerant (Ht) transgenics are engineered to tolerate the toxicity and lethal activity of a herbicide called 'Roundup'. The active ingredient of the Roundup is glyphosate. Glyphosate inhibits an essential plant enzyme called EPSPS (5 - enolpyruvyl - shikimate -3-phosphate synthase) which is required to synthesize certain essential components of proteins. Hence, its inhibition triggers a number of adverse metabolic consequences. What is more important than all the reported adverse metabolic effects of 'Roundup' is that the target weeds (plants) under 'selection pressure' develop genetic (mutations) and biochemical mechanisms to acquire resistance to the lethal action of the herbicide. The consequence is the emergence of Roundup-resistant 'super weeds'. Today, the super weeds, quite aggressive and some even possibly invasive, are spreading rapidly in the farmlands across several states in the USA. Even the advanced science and technology in the US do not seem effective enough to combat the ecological disaster and the economic misery being caused by Roundup of the farmers. Reddy, K.N (2001, *'Glyphosate - resistant soybean as a weed management tool: opportunities and challenges' Weed Biol. Manag.* 1,193-202), observes that the use of Roundup to control gives a short-term relief, but in the long-term, it results in the development of highly resistant 'super weeds'. With ever-increasing acreage in Ht-transgenics, even a rare mutant (with resistance to Roundup) could establish a population of progeny that would

persist under the umbrella of repetitive glyphosate applications. The amplification would gain accelerating momentum because each season more glyphosate-tolerant weed seeds would be added to the soil bank. Resistance can spread globally because of widening trade in agriculture. It is difficult to imagine a.world scenario in which crops are sown, but weeds only are harvested!

This is not the only consideration. The adverse health effects mainly in the nature of endocrine disruption, induction of cancer and teratogenic abnormalities in animals and humans which are all published in leading, peer-reviewed International journals, cannot be dismissed by untenable and unsubstantiated arguments by the crop developers and those who support them. The TEC cannot support irresponsible and unscientific views just because the Roundup is an enormously money-making business!

Since the submission of the Interim Report by the TEC in October 2012, substantially new facts and knowledge on the action of the ingredients other than glyphosate of Roundup have emerged. Two of these which necessitate a revision of the earlier recommendation of the TEC in. favour of (a) canceling the suggestion of setting up an independent committee of experts and stakeholder to look into all related aspects and make appropriate recommendations on the field trials of Ht-transgenics and (b) now recommending a total ban immediately on field trials of all Ht-transgenics are the following:

(i) Normally, the toxicity studies in rats are not extended beyond 90-days. However, one study (Seralini G.E et al 2012, *Food and Chemical Toxicology* 50, 4221-4231) extended for 2 years revealed severe kidney chronic deficiencies, nephropathy, liver congestions and necrosis and most significantly large mammary tumours in females. This conforms to contemporary reports that these herbicides are toxic and endocrine disrupters (Romano M.A. et al 2012, *'Glyphosate impairs male offspring reproductive development by disrupting gonadotropin expression'. Arch. Toxicol* 86. 663-673; Vandenberg L.N. et al. 2012 *'Hormones and endocrine - disrupting chemicals: low dose effects and nonmonotonic dose responses'. Endocr. Reviews* 33, 378-455). (ii) A very recent report (Mesnage R et al 2013; *"Etoxylated adjuvants of glyphosate - based herbicides are active principles of human cell toxicity"*. (Toxicology http://dx.doi.Org/l0.1016/i.tox.2012.09.006) is that the adjuvants are far more

not in long-term chronic studies) on mammals for the purposes of regulatory risk assessment, the adjuvants in the commercial formulations of Roundup are not safety tested. .These are often classified confidential and described as *"inerts"*. These so-called. inerts help to stabilize the active ingredient glyphosate and help it to penetrate plants, in the manner of corrosive detergents.

The most fundamental problem is that glyphosate (whose safety is not unequivocally established) and Roundup (which is known beyond any doubt to be toxic, teratogenic and carcinogenic) are treated as exactly the same by industry and regulators on safety evaluation studies. The *'supposed'* non-toxicity of glyphosate serves as a basis for' commercial release of Roundup. It is stated that the details of this regulatory . assessment, are jealously kept confidential by the developers of the Ht-transgenic crops (e.g. Monsanto in the present case).

The new finding on the significant toxic effects of the adjuvants of the POE-15 family (polyethoxylated tallowamine) on human cells requires further long-term studies. The present trend is that papers reporting on the toxic, carcinogenic and allergenic activity -of Roundup are severely attacked often on untenable grounds. Covering up intrinsic health and environmental risk under confidentially is unethical and scientifically unacceptable. Hence, the premise to recommend a total ban forthwith is elaborated in the following sections.

* Revisiting the relevant sections of the Report on Application of Agricultural Biotechnology by M.S. Swaminathan, Chairman, Task Force on Agricultural Biotechnology accepted in May 2004 by the Ministry of Agriculture, Government of India.

(i) The basic guiding principle adopted by the Task Force (see Agricultural 'Biotechnology: Safe and responsible use' - Commentary in *Current Science,* Volume 87, No.4,25 August 2004, pages 425-426) is the following:

"The bottom line of our national agricultural biotechnology policy should be the economic well being of farm families, food security of the nation, health security of the

consumer, protection of the environment and the security of our national and international trade inform commodities".

(ii) The Task Force on Agricultural Biotechnology Chapter II. 'Application of Biotechnology in Agriculture states in section 1.4 "A long-term policy on Biotechnology Application in Agriculture" calls for Providing direction to research and development in relation to priorities, based on social, economic, ecological, ethical and equity issues" and in section 1.5 "The long-term policy should also take into account the need and relevance of the technology to agriculture and should be in tune with and derived from the National Policy on Agriculture, the overall goals of which are:

» Increasing productivity, profitability, quality and total agricultural output

- Promoting environmental sustainability through natural resource conservation and enhancement
- Improving factor productivity in order to reduce the cost of production and enhance net earning from marginal and small holdings
- Ensuring food and nutrition security

» Generating employment, reducing gender and social inequality and regional imbalances in agricultural growth

- Enhancing agricultural competitiveness in relation to global standards
- Strengthening national capability in facing the potential adverse impact of climate change and sea level rise

It goes on: "1.6 Since there is public, political and professional concern about transgenics with reference to their short and long-term impacts on human health and the environment, their testing, evaluation and approval have to be stringent, elaborate and science-based.

- Biotech applications, which do not involve transgenics such as biopesticides, biofertilizers and bio-remediation agents, should be accorded high priority. They will help to enforce productivity in organic farming areas
- Transgenic approach should be considered as complimentary and resorted to when other options to achieve the desired objectives are either not available or not feasible"

horticultural and medicinal plants".

The Task Force surely accords low priority, if at all, for genetic engineering with biopesticides. Despite the fact that pests and weeds can be effectively managed below economic threshold level (ETL), the Ministries and Departments concerned of the Government of India have introduced only the biopesticides (Bt and Ht) transgenic crops in a big way. Monsanto has been the substantial beneficiary, and the millions of resource-poor farmers, consumers, organic farming systems and environment of India are the greatest losers.

The spirit and substance of the excerpts from the abovesaid report are totally negated by the introduction of GM transgenics which produce toxins of one kind or another. In addition, the Ht-transgenics replace atleast in short term the manual weeding by landless women. That amounts to loss of livelihood for millions of landless rural women. The emergence of superweeds as a consequence of selection pressure is a major . disaster to both ecology and agriculture.

It is the considered view of the TEC that in accordance with the principles enshrined in Report of the Task Force on Application of Agricultural Biotechnology, Ht-transgenic crops are not conducive for Indian agriculture from socio-economic and ecological points of view.

Ht-transgenicss Crop yields and emergence of super weeds

Several papers published in peer-reviewed International journals show that glyphosate (the active ingredient in Roundup) exerts negative effects on soil and crops, some of which impact plant health and yield. For instance, the paper entitled *'Glyphosate effects on the diseases of plants'* by G.S. Johal and D.M. Huber in 2009 *(European J, • **Agronomy*** **31,** 144-152) reports that glyphosate enhances the deterioration of general physiology and health of plants caused by the transgenic stress; this possibly explains several earlier reports linking glyphosate application with enhanced infection with a fungal disease (Fusarium) (Kremer RJ et al 2005, *'Glyphosate affects soybean root exudation and rhizo sphere microorganisms, Int. J. of Analytical Chemistry* 85 (15): 1165-1174). Further, the Fusarium-contaminated feed impaired development of oocytes (female reproductive (germ) cells) and increases still births (Aim, H. et al 2006, 'Influence of Fusarium toxin contaminated feed on initial quality and meiotic competence of gilt oocytes', *Reproductive Toxicol* 22,44-50).

It is stated that spraying glyphosate on plants is as US agronomist Michael McNeill said, "like giving it AIDS" (Dodge J. Expert: GMOs to blame for problems in plants, animals. Boulder weekly. 11 August 2011 (http://www/boulderweekly.com/article-6211 -expert-gmos-to-blame-for-problems-in-plants-animals.html). The demonstration of glyphosate associations with cereal diseases caused by Fusarium spp. In Canadian Prairies needs to be viewed with deep concern in the context of the food security of India. The Ministry of Agriculture might like to refer to the paper by Fernandez, M.R. et al (2009, *European J. Agron.* 31, 133-143).

Glyphosate is also known to inhibit nutrient uptake by plants. Cakmak, I et al (2009, *European J. Agron.* 31,114-119) have noted that glyphosate reduced seed and leaf concentrations of calcium, manganese, magnesium and iron in non-glyphosate resistant soybean. A few years earlier, Eker S et al (2006, *J, Agric, Food Chemistry* 54, 10019-10025) had reported that foliar applied glyphosate substantially reduced uptake and transport of iron and manganese in sunflower plants. It is also reported that glyphosate

impairs nitrogen fixation, a process that is vital to plant growth and depends on the beneficial relationship between the soybean plants and nitrogen-fixing bacteria. In young Roundup soy plants, glyphosate is found to delay nitrogen fixation and reduce the growth of roots and sprouts, resulting in yield decline. In drought conditions, yield can be reduced by up to 25 percent (King C.A et al 2001 *'Plant growth and nitrogenase activity . of glyphosate-tolerant soybean in response to foliar glyphosate application, 'Agronomy Journal'* 93, 179-186. Recently, Marjo Helander et al (2012, *Trends in Plant Sciences* (October 2012), volume 17 (3), 569-574) have discussed the adverse impact of : glyphosate in northern ecosystems. They also point out that an assumption of biosafety of glyphosate to non-target animal systems is wrong. The pro-Roundup lobby's argument is that glyphosate blocks the shikimate pathway which occurs only in plants and not animals and humans. More recent scientific studies reveal that glyphosate, in fact the Roundup with several adjuvants (the details of which are often declared 'confidential[5] for commercial purposes) are indeed severely cytotoxic and possibly carcinogenic on account of their property of endocrine disruption in animals. These are discussed in detail in the following section. Therefore, the proclamation by Duke, S.O and Powles, S.B. (2008, 'Glyphosate: once-in-a-century herbicide. *Pest. Manag. Set* 64, 319-325) that glyphosate is absolutely safe to nontarget organisms is in serious error. Helander M et al (2012, *Trends in Plant Sciences* 17,569-574) point out that studies on herbicide residues in boreal environments have demonstrated that glyphosate and the main metabolite of glyphosate degradation 2-amino - 3- (5-methyl-3-oxo-l-2-oxazol-4 yl) propionic acid (AMPA) can be traced from soils even years after last spraying. They cite the studies of JLaitinen P et al (2009, *Plant Soil* 323,267-283).

With regard to agriculture and ecosystems management, the most disquieting fact is the emergence of 'super weeds' which are aggressive and resistant not only to Roundup but also to most other herbicides. Today, in the United States, glyphosate-resistant weeds have been identified in 22 states (Herbicide Resistance Action Committee. Glycines (G/9) resistant weeds by species and country: 2012 http://www.weedscience.org/Summary/Uspecies MOA. asp? 1st MOAID=12). Resistant weeds include pigweed, ryegrass, marestail etc., The recent survey suggests that Roundup-resistant superweeds has invaded about 70 million hectares in the US alone. It

., __. „„*„ umi wccus are Decerning increasingly resistant to glyphosate, a report from the US National Academy of Sciences (UAS). The report also observes that the driving force is increasing dependence of farmers on the weed killer.

It is worth referring to the article *'Roundup's potency slips, foils farmers'* by G, Gustin (St. Louis Post Despatch July 25, 2010. http:/Avww.soyatech.com/newsstory.php?id=19495. This article states that awareness is growing that many modern agricultural practices are unsustainable and that alternate ways of ensuring food security must be found. In recent years, various agencies have joined the sustainability debate by attempting to define the production of genetically modified Roundup Ready soy as sustainable and responsible. These include:

* ISAAA, a GM-industry-supported group
» . Plant Research International at Wageningen University
* The Round Table on Responsible Soy (RTRS), a multi-staker forum with membership including NGO such as WWF and multinational companies such as Monsanto, Cargill, Shell ADM etc.

With regard to Roundup transgenics, the final question to be asked is whether these have really and effectively reduced the dependence and use of chemical pesticides over • the years. The answer is unfortunately an emphatic 'No'. Bill Christensen President of the US National Family Farm Coalition stated, *"The promise was that you could use less chemicals and produce a greater yield. But let me tell you none of this is true ".*
(In Motion Magazine 29 July 1998 http://www.inmotionmagazine.com/,genetl.html)
Dr. Charles Benbrook, an agronomist in his article, "Impacts of genetically engineered crops on pesticide use in the United States. The first thirteen years". The Organic Center. November 2009. http://www.organic-center.org/reportfiles/13years20091126_FullReport.pdf, states the following; "GE crops have been responsible for an increase of 383 million pounds of herbicide use in the US over the first 13 years of commercial use of GE (genetically engineered) crops (1996-2008). The dramatic increase in the volume of herbicides applied swamps the decrease in insecticide use attributable to GE corn and cotton, making the overall chemical footprint of today's GE crops decidedly negative . .....The primary cause of increase

is the emergence of herbicide-resistant weeds. During the period of reporting (13 years, the Bt maize and Bt-cotton delivered reductions in chemical insecticide use totaling 29.2 million kg (although the use of insecticide has also been increasing since 2008-2009 due to development of insect resistance), whereas the Ht-maize, soy and cotton caused farmers to spray additional 174 million kg of herbicides. In 2008, GM crop fields required 26% more pounds of pesticides per acre (i.e. 0.4 hectare) than fields which had planted non-GM varieties. The 'return' to increased use of 'Roundup' by the US farmers is not in itself the major cause of deep concern, it is that as time passes no amount of Roundup is effective and therefore, farmers are forced to resort to potentially even more toxic herbicides such as 2,4,-D and mixture of herbicides. The US farmers are even going back to more labour-intensive methods like ploughing-and even pulling weeds by hand. These aspects are dealt in detail by W. Neuman and A. Pollack (May 03, '2010, New York Times. http://www.nytimes.com/2010/05/04business/energy-environment/04weed.html?pagewanted=18hp).

Dr. Charles Benbrook is a Professor at Washington State University and former Executive Director of U.S. National Academy of Sciences Committee on Agriculture. His authorative analyses reveal that (a) 'super weeds' in the recent years have become resistant to Roundup, the Ht-transgenics have led to dramatic increase (not decrease as was expected) in the use of toxic herbicides and that GM technology in food production is unnecessary . (Summary of 2012 Benbrook findings are attached herewith).

Dr Charles M *Benbrook*
Genetically Engineered Crops
And Pesticide Use In The United States
www.nlpwessex. org/docs/benbrook. htm
USDA Survey Data

'Farmers Weekly' USDA Data Shows GM Crops
Use More Pesticides

; "Farmers in the USA have increased their use of pesticides since the introduction of genetically modified crops. | ! according to a new study. Washington State University professor Charles Benbrook has studied the use of crops I that have been genetically modified for resistance to the glyphosate weedkiller, Roundup, produced by US biotech j company Monsanto. Producers of GM crops, suchas Monsanto, claim they require less chemicals as plants are j engineered to repel crop pests, such as aphids. But the study, published in the peer-reviewed journal j

s ui ui&u coiiy ycai»i uig a.muy WJUIIU. DUI in receni years, so^canea 'superweeas' have oecome resistant to glyphosate! - Roundup's main active ingredient. Superweeds such as horscweed, giant ragweed and pigweed are developing resistance to Roundup (glyphosate) and taking over millions of hectares in the USA. Since about the year.2000, •farmers have used increasing amounts of Roundup and 'two or three additional herbicides' to fend off these resistant ' weeds, said Prof Benbrook. 'Resistant weeds have become a major problem for many farmers reliant on GM crops, and are now driving up the volume of herbicide needed each year by about 25%,' he added. Prof Benbrook estimated the use of GM crops had increased herbicide use by 239 million kg between 1996 and 2011. Overall,! in this period pesticide use in the USA had increased by an estimated 183 million kg, equivalent to 7%, the study j found. The research would appear to undermine claims from biotech companies, such as Monsanto, that GM j crops need less chemicals - one of their major selling points. Farmers in the UK are banned from growing GM j crops for commercial use, but two experimental field trials, of GM potatoes and a trial of GM wheat, began in 2012.1 GM crops do, however, enter Britain mainly as animal feed. Monsanto has so far not made an official comment on j the findings of the study."

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US farmers using more pesticides with GM crops

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Farmers Weekly. 23 October 2012 J

Click Here For Summary Of 2012 Benbrook Findings

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"Charles Benbrook is a pesticide policy expert who became involved in the Food Quality Protection Act (FQPA) debate in the early 1980s when it was still called 'Delaney reform.' Former executive director of the National Academy of Sciences (NAS) Board on Agriculture, he oversaw the 1987 NAS 'Delaney Paradox'report that set the framework for many FQPA provisions. Benbrook is now a consultant based in Sandpoint, ID, and is working as an analyst for the Consumers Union FQPA project. A report on alternatives to organophosphates (OPs) and carbamates is due out in September."

An 'alternative' view: Charles Benbrook on FQPA

Farm Chemicals. September 1998

"Charles Benbrook worked in Washington. D.C., on agricultural policy, science, and regulatory issues from 1979 through 1997, with roles as the agricultural staff expert on the Council for Environmental Quality, executive director of the subcommittee of the House Committee on Agriculture, and executive director of the Board on Agriculture of the National Academy of Sciences. In 1998 he developed Ag BioTech InfoNet (www.biotech-info.net), one of the Internet's most extensive independent sources of technical, policy, and economic information on biotechnology. Currently Benbrook runs Benbrook Consultant Services, a small firm basedin Sandpoint, Idaho. His activities include consulting for the Consumers Union to ensure implementation of the Food Quality Protection Act (www.ecologic-ipm.com/proiect.htmn. a key piece of legislation signed in 1996 that is prompting important changes in pesticide use patterns and. pest management systems."

Charles Benbrook, Ph.D. - Biotechnology And The Nature Of Food

Northwestern University. 3 April 2004

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Impacts of Genetically Engineered Crops on Pesticide Use: The First ,

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Impacts of Genetically Engineered Crops on Pesticide Use: The First ,

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"U.S. farmers are using more hazardous pesticides to fight weeds and insects due largely to heavy adoption of genetically modified crop technologies that are sparking a rise of'supervveeds' and hard-to-kili insects, according to a newly released study.Geneticaliy engineered crops have led to an increase in overall pesticide use, by 404 million pounds from the time they were introduced in 1996 through 2011, according to the report by Charles Benbrook, a research professor at the Center for Sustaining Agriculture and Natural Resources at Washington State University.... Of that total herbicide use increased over the 16-year period by 527 million pounds while insecticide use decreased by 123 million pounds. Benbrook's paper-- published in the peer-reviewed journal Environmental Sciences Europe over the weekend and announced on Monday - undermines the value of both herbicide-tolerant crops and insect-protected crops, which were aimed at making it easier for farmers to kill weeds in their fields and protect crops from harmful pests, said Benbrook.... The crops were a hit with farmers who found they could easily kill weed populations without damaging their crops. But in recent years, more than two cozen weed species have become resistant to Roundup's chief ingredient glyphosate, causing fannersto use increasing amounts both of glyphosate and other weedkilling chemicals to try to control the so-called 'superweeds.[1] 'Resistant weeds have become a major problem for many farmers reliant on GE crops, and are now driving up the volume of herbicide needed each year by about 25 percent,' Benbrook said. Monsanto officials had no immediate comment."
Pesticide use ramping up as GMO crop technology backfires: study
Reuters, 2 October 2012

"A study published this week by Washington State University research professor Charles Benbrook finds that the use of herbicides in the production of three genetically modified herbicide-tolerant crops -- cotton, soybeans and corn - has actually increased. This counterintuitive finding is based on an exhaustive analysis of publicly available data from the U.S. Department of Agriculture's National Agriculture Statistics Service. Benbrook's analysis is the first peer-reviewed, published estimate of the impacts of genetically engineered (GE) herbicide-resistant (HT) crops on pesticide use. In the study, which appeared in the open-access, peer-reviewed journal Environmental Sciences Europe, Benbrook writes that the emergence and spread of glyphosate-resistant weeds is strongly correlated with the upward trajectory in herbicide use. Marketed as Roundup and other trade names, glyphosate is a broad-spectrum systemic herbicide used to kill weeds. Approximately 95 percent of soybean and cotton acres, and more than 85 percent of corn, are planted to varieties genetically modified to be herbicide resistant. 'Resistant weeds have become a major problem for many farmers reliant on GE crops, and they are now driving up the volume of herbicide needed each year by about 25 percent,' Benbrook said. The annual increase in the herbicides required to deal with tougher-to-control weeds on cropland planted to GE cultivars has grown from 1.5 million pounds in 1999 to about 90 million pounds in 2011."
'Superweeds' Linked to Rising Herbicide Use in GM Crops, Study Finds
ScienceDailv. 2 October 2012

: "Genetically engineered, herbicide-resistant and insect-resistant crops have been remarkable commercial successes \
\ in the United States. Few independent studies, have calculated their impacts on pesticide use per hectare or i
overall pesticide use, or taken into account the impact of rapidly spreading glyphosate-resistant weeds. j

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"Planting GM crops has led to an increase rather than a decrease in the *mc* of pesticides in the iast 16 years, according to US scientists. The researchers said that the plants have caused superweeds and toxin-resistant insects to emerge, meaning farmers have not only had to use more pesticides on their crops overall, but are also using older and more dangerous chemicals. The findings dramatically undermine the case for adopting the crops, which were sold to farmers and shoppers on the basis that they would reduce the need to be treated with powerful chemicals. The team at Washington State University found the weight of chemicals used on US farms has increased by 183million kilos since GM crops were introduced in 1996. Of that total, herbicide use increased over the 16-year period by 239 million kilos while insecticide use decreased by 56 million kilos. Most GM crops produced to date - such as corn, soya and cotton - have been modified in the laboratory' to make them immune to certain weedkillers, such as Monsanto's RoundUp. It means the GM plants can thrive while the surrounding weeds are wiped out. However, the reality is that a number of weeds have developed an immunity to the chemical and are now able to swamp fanners' fields. The biggest threats are giant ragweed and pigweed, which grows at a rate of more than one inch a day and reaches a height of three metres. The so-called perfect superweed is extremely hardy, produces 10,000 seeds at a time and will smother food crops in the same field. The overall effect is that desperate farmers are now using a cocktail of many-different chemicals to try and tame the weeds. A number of GM plants, including some types of com, have been modified to include a toxin called Bt that kills predator insects that feed on them. But again, these insects are developing an immunity to the toxin included in the plants, which means farmers have to resort to chemical sprays. Study leader Professor Charles Benbrook. of the university's Center for Sustaining Agriculture and Natural Resources, said: 'Resistant weeds have become a major problem for many farmers reliant on GM crops and are now driving up the volume of herbicide needed each year by about 25 per cent. .... Professor Benbrook's paper is published in the peer-reviewed journal Environmental Sciences Europe and conies two weeks after a feeding trial in rats raised concerns that consuming GM corn might trigger a rise in breast caucer and organ damage." How GM crops have increased the use of danger pesticides and created superweeds and toxin-resistant insects Mail 3 October 2012

2009

"The rapid adoption by U.S. farmers of genetically engineered corn, soybeans and cotton has promoted increased use of pesticides, an epidemic of herbicide-resistant weeds and more chemical residues in foods, according to a report issued Tuesday by health and environmental protection groups. The groups said research showed that herbicide use grew by 383 million pounds from 1996 to 2008, with 46 percent of the total increase occurring in 2007 and 2008. The report was released by nonprofits The Organic Center (TOC), the Union for Concerned Scientists (UCS) and the Center for Food Safety (CFS). The groups said that while herbicide use has climbed, insecticide use has dropped because of biotech crops. They said adoption of genetically engineered corn and cotton that carry traits resistant to insects has led to a reduction in insecticide use by 64 million pounds since 1996. Still, that leaves a net overall increase on U.S. farm fields of 318 million pounds of pesticides, which includes insecticides and herbicides, over the first 13 years of commercial use. The rise in herbicide use comes as U.S. farmers increasingly adopt corn, soy and cotton that have been engineered with traits that. allow them to tolerate dousings of weed killer. The most popular of these are known as 'Roundup Ready' for their ability to sustain treatments with Roundup herbicide and are developed and

marketed by world seed industry leader Monsanto Co. Monsanto rolled out the first biotech crop, Roundup Ready soybeans, in 1996.... The report by the environmental groups states that a key problem resulting from the increase in herbicide use is the emergence of super weeds,' which are difficult to kill because they have become resistant to the herbicides. 'With glyphosate-resistant weeds now infesting millions of acres, farmers face rising costs coupled with sometimes major yield losses, and the environmental impact of weed management systems will surely rise,' said Charles Benbrook, chief scientist of The Organic Center. The groups additionally criticized the agricultural biotechnology industry for claiming that higher costs for genetically engineered seeds are justified by multiple benefits to farmers, including decreased spending on pesticides. The group said biotech com seed prices in 2010 could be almost three times the cost of conventional seed, while new enhanced biotech soybean seed for 2010 could be 42 percent more than the original biotech version. 'This report confirms what we've been saying for years,' said Bill Freese, science policy analyst for the Center for Food Safety. 'The most common type of genetically engineered crops promotes increased use of pesticides, an epidemic of resistant weeds, and more chemical residues in our foods. This may be profitable for the biotech/pesticide companies, but it's bad news for farmers,'humah health and the environment.'"

Biotech crops cause big jump in pesticide use: report
Reuters. 17 November 2009

"One of the claims supporting biotech seed may not be true - that genetically enhanced seed means using leSS herbicide rCharlM Rppbrnnkl «aiH 'Rrmnrtnn Rpprk/ tptidc *tn* rpflurp *hcrhiriAp* IKP fnr twn tn tVii-f»p year's, but then there starts to be a shift in the weed community,' he said. That shift involves weed resistance - resistance that grows every year, said Benbrook. 'Illinois farmers are dealing with two to three different (glyphosate) resistant weeds,' he said. 'Our research shows that for every acre of Roundup Ready seed applied, two-thirds to three-quarters of a pound more herbicide per acre is used than conventional seed. 'Farmers are just beginning to deal with a serious resistance problem,' he said. Outbreaks of so-called 'superweeds' that defy herbicide treatments will become more common, said Benbrook. 'That's the future for central Illinois.'.... While resistance is one issue farmers will face, another is the rising cost of putting a crop - whether corn or soybeans - in the ground. Seed and fertilizer costs went up 40 percent between 2003 to 2007, said Dale Laatz, U of I Extension farm financial management specialist. Farm income also rose in that period, especially in central Illinois, he said. In 2008, the average net farm income for the state's central region, an area that includes Peoria. Tazewell and Woodford counties, was $255,900, the highest in the state, said Laatz. Genetically modified seed is also reaching new heights, said Benbrook. 'You're probably looking at the first S300 bag (for about 50 pounds) of (com) seed this year. Farmers that used to spend between $15 and $20 a pound on seed per acre are now spending $100,' he said."

Attack of the Superweeds Peoria Journal
Star. Illinois. 6 April 2009

"Official U. S. Department of Agriculture (USDA)-suryeys are the'source of most of the data used in this report on i the acres;planted to each GE trait inlcorn, soybeans, and cotton.:..'Pesticide use .data come from annual surveys done! , by theUSDA's National;Agricultural Statistics Service (NASS)....HT [herbicide tolerant} crops have increased j ■ herbicide' use by a;total of 382-6 million pounds over-13 years. HT soybeans increased herbicide use by 351 j pounds (about,0.55 pdund per acre),.accounting for *92%* of tlie total increase in.herbicidc use across the three! HT crops....Recently herbicide useon'GE acres has veered sharply upward. Crop years 2007-and 2008 accounted j for 46%-of the increase'in herbicide,use.over"13"years across the three HT crops. Herbicide use on HT crops rose a j remarkable 3,1.4%,frorn 20.07.to 2008; GE crops reduced overall pesticide use in' the "first three years of commercial j introduction (1996-1998) by 1.2%; 2.3%, and 23% per year, but increased pesticide use by 20%-in 2007 andby ; 27%-in/2008. Two major factors' are driving the trend toward larger margins of difference in the pounds of i herbicides usedto control-weeds on an acre planted to HT seeds, in comparison to conventional seeds: • The i emergence and rapid spread of weeds resistant to glyphosate, and .♦ Incremental reductions in the average ' application rate of herbicides applied on nbn-GE crop acres.... The USDA's Economic Research Service (ERS) has j collated NASS figures on the percentage of crop acres for each GE category from 1996 to present...A report by the i ERS was issued in May 2002 entitled Adoption of Bioengineered Crops..... This 2002 ERS report concluded that) herbicide use on HT soybeans went up in 1998 because 13.4 million pounds of glyphosate were substituted for! 11.1 million pounds of other herbicides. The ERS projection of a 2.3 million pound increase in herbicide pounds ■ applied on HT acres is also very close to the *2'2* million pound increase based on the methodology used in this >

2004

"Eight years of planting genetically modified maize, cotton and soya beans in the US has significantly increased the amount of herbicides and pesticides used, according to a US report which could influence the British government over whether to let GM crops be grown. The most comprehensive study yet made of chemical use on genetically modified crops draws on US government data collected since commercialisation of the crops began ..... Charles Benbrook, the author of the report, who is also head of the Northwest Science and Environment Policy Centre, at Sandpoint, Idaho, found that when first introduced most of the crops needed up to 25% fewer chemicals for the first three years, but afterwards significantly more. In 2001, the report states, 5% more herbicides and insecticides were sprayed compared with crops only of non-GM varieties; in 2002 7.9% more was sprayed; and in 2003 the estimated rise was 11.5%. In total, £73m lb [pounds weight] more agrochemicals were sprayed in the US during 2001-2003 because of GM crops, says the report, which was commissioned by Iowa State University, the Consumers' Union and others. During 2002-2003, an average of 29% more herbicide was applied per acre on GM maize. But this trend was not sustained over the eight years. Overall, modest reductions in insecticide usage with maize and cotton were recorded.....[Former executive director of the National Academy of Sciences (NAS) Board on Agriculture] Dr Benbrook said: The proponents of biotechnology claim GM varieties substantially reduce pesticide use. While true in the first few years of widespread planting... it is not the case now. There's now clear evidence that the average pounds of herbicides applied per acre planted to herbicide-tolerant varieties have increased compared to the first few years." .

GM crops linked to rise in pesticide use

Guardian. 8 January 2004

2001

"Monsanto's recommended RR ['Roundup Ready] com systems include several optional herbicide programs ranging from a total glyphosate system, to systems combining a pre- or at-plant residual herbicide followed by Roundup post-emergence, or total post-emergence program involving applications of a residual post-product plus Roundup (Monsanto, 2000a and 2000b). In the total Roundup program, glyphosate is applied on average about 2.0 times. In 1999 the average application was about 0.7 pounds, resulting in 1.4 pounds Roundup applied on the average acre of RR corn. An estimated 70% of RR corn acres were managed under the 'Residual Herbicide Applied' program. Either before or at-planting in such programs, fanners apply a tank-mix containing a residual broadleaf product like atrazine at about 0.8 ■ pounds per acre, plus an acetanilide herbicide at a rate of about 1.2 pounds per acre on average, mostly forgrass weed control (see recommended rates on either Roundup labels or the labels of several herbicide products containing mixtures of atrazine and an acetanilide). Total corn herbicide use under the 'Residual Herbicide Applied' program averages about 2.75 pounds per acre, with Roundup accounting for 0,75 pounds of this total.USDA data suggest that average per acre use on RR corn acres has risen from about 2.5 pounds in 1999 to 2.75 pounds in 2000 (Benbrook, 2001b). On conventional acres, about 2.25 pounds were applied in 1999 and 2.08 pounds in 2000. Accordingly, in 2000 the average RR corn acre was treated with about 30% more herbicide than the average non-GM corn acre."

DR CHARLES BENBROOK - DO GM CROPS MEAN LESS PESTICIDE USE?

Royal Society of Chemistry, Pesticide Outlook. October 2001

"Lessons learned from five-decades of insecticide-based cotton pest management are relevant in assessing the likely longer-run Impacts of GM crops on pesticide use. The OP, carbamate and synthetic pyrethroid doomrtobust cycles each lasted about a decade. Despite today's 5/crop... The greatest long-term pest management benefits from agricultural biotechnology may well be process- and management based, as opposed to product-based, [i.e. non GM biotech] Sophisticated pest management systems in the future will rely on biotech to help evoke, and sometimes strengthen, natural plant defense mechanisms, Biotech

will make it possible for farmers to subtly tip the competitive balance within agricultural systems toward beneficial organisms at the expense of pests (for a review of promising technologies, see Benbrpok,2000),It will expand the range and deepen the effect of a new era of 'countermeasures' that together might finally pull the plug on the pesticide treadmill."

DR CHARLES BENBROOK - DO GM CROPS MEAN LESS PESTICIDE USE?
Royal Society of Chemistry, Pesticide Outlook. October 2001

Dr Benbrook's Work Appears To Have Made Some People Unhappy
USDA Pesticide Data Collection Was Cancelled By Bush Administration

"The Bush administration's crackdown on the public's right to know continues: Officials at the US Department of Agriculture (USDA) have quietly closed down the only federal program that tracks the types and quantities of chemical pesticides and fertilizers being used by America's farmers. Since 1990, the USDA's statistical wing has published annual surveys detailing the chemicals that farmers spray on our food. The reports are a vital source of information for government regulators, environmental activists and industry analysts - but in recent years,,agency chiefs have begun to dismantle the program. Last year, officials ordered staff to gather chemical-usage data only for cotton and apple crops; this year, they've gone further still, saying they can no longer afford the program's $8 million price-tag and won't be collecting any data whatsoever for the 2008 growing season. The decision to scrap the program has caused panic among researchers who rely on the data. They say there's simply no alternative to the federal reports: Private companies that collect similar information charge up to S500,000 a year for their services, putting them out of reach of most government agencies and all academic or non-profit researchers..... The absence of proper data will also impact on the ability of journalists, environmental activists, and the general public to push for tighter controls on pesticide use; after all, it's hard to demand limits on pollutants if you don't know they're there. 'Without [the USDA] data, all the policy issues and debates that have been going on for the last 15 or 20 years over pesticide use would be based largely on speculation,' says Charles Benbrook, chief scientist for the non-profit Organic Group. Lawmakers on the Senate's Appropriations Committee are working to reinstate the chemical monitoring program; earlier this year they ordered agency officials to reverse their decision and warned them not to cancel any other data-gathering activities without first informing Congress. Still, that ticking-off won't carry much weight unless both the Senate and the House pass it into law - and that could be a long process."

USDA stops tracking chemicals
Plenty Magazine. August 2008

Obama Administration Restores Pesticide Survey

"Pesticide use data come from annual surveys done by the USDA's National Agricultural Statistics Service (NASS).... NASS has dramatically scaled back its program in recent years. First, NASS replaced its annual surveys of major fi eld crops with less frequent ones beginning in 2002. Then, in the 2007 growing season, data collection was limited to just two crops—cotton and apples. NASS did not collect pesticide use data on any crops during the 2008 growing season, citing a shortage of funds and the availability of private sector survey data as reasons for cutting the program. Of the three major crops covered in this report, NASS data are available in most years for cotton through 2007, through 2006 for soybeans, and through 2005 for corn. The absence of a continuous series of NASS data since 2005 for the three major GE crops hampers the ability of independent analysts and government scientists to track the performance and impacts of GE crops. The lack of NASS pesticide-use data covering recent crop years is a special concern, given the dramatic impact of resistant weeds on the number and volume of herbicides applied to HT crops. USDA's decision to drop the pesticide-use surveys led to strong protests from a wide range of groups, including The Organic Center, Center for Food Safety, Union of Concerned Scientists, Natural Resources Defense Council, and many other organizations, including several with close ties to the pesticide industry. In 2008, the administrator of the EPA voiced concern to the Secretary of Agriculture about the loss of NASS data, joining several government offi cials at the state and federal levels. In May, 2009, the new USDA leadership announced the reinstatement of the program,

The Organic Center, November 2009

Other Updates

"The area of U.S. cropland infested with glyphosate-resistant weeds has expanded to 61.2 million acres in 2012, according to a survey conducted by Stratus Agri-Marketing. Nearly half (49%) of all U.S. farmers interviewed reported that glyphosate-resistant weeds were present on their farm in 2012, up from 34% of farmers in 2011. The survey also indicates that the rate at which glyphosate-resistant weeds are spreading is gaining momentum, increasing 25% in 2011 and 51% in 2012. The Stratus Glyphosate Resistance Tracking study is conducted annually. It's now in its third year. In 2012, Stratus completed interviews with nearly 3,000 farmers during the summer and fall. 'We asked fanners to share their experiences with glyphosate resistance on their farms and we're clearly seeing the problem intensify,' explains Stratus Agri-Marketing vice president Kent Fraser. Increases were reported in most states but especially in the Midwest. Not only are glyphosate-resistant weeds spreading geographically, the problem is also intensifying with multiple species now resistant on an increasing number of farms. 'There is a very high rate of resistance in the southern states like Georgia where 92% of growers reported having glyphosate-resistant weeds,' reports Fraser. 'And we're also seeing the problem intensify[7] in the midwest. In Illinois, 43% of farmers reported having glyphosate-resistant weeds in 2012.' Marestail (horseweed) was the weed species most commonly reported as resistant to glyphosate herbicides, followed by Palmer amaranth (pigweed). Other glyphosate-resistant weed species were also tracked in the study. In 2012,27% of U.S. farmers reported multiple glyphosate-resistant weeds on their farm, up from 15% in 2011 and 12% in 2010. For more insights from the Stratus Glyphosate Resistance Tracking study visit http://www.stratusresearch.com/blog07.htm"

Glyphosate-resistant weed problem extends to more species, more farms

Farm Industry News. 29 January 2013

"Using genetic engineering to endow corn with protection against pesky weeds and insects was supposed to cut back on use of agricultural chemicals and the risk they pose to the environment. But the recently released report on 2010 Agricultural Chemical Use from the National Agricultural Statistics Service carries at least one major twist on the pesticide pattern in Nebraska. Even as use of the popular weed killer atrazine held close to the level it was at for corn in 2003, the glyphosate option more commonly known as Roundup has gone from about 1.25 million pounds in 2003 to almost 3 million pounds in 2005 and to 7.1 million pounds last year. The major spike means more fanners have been choosing corn varieties that carry resistance to Roundup and other products with glyphosate as their active ingredient in the seed sack. That makes them a biotechnology tool in a weed-killing approach in which the chemical can then attack both grass and broad-leaf invaders without hurting the com. But as McCool Junction crop consultant Bill Dunavan and other weed-wise observers in Nebraska know, Roundup has not held on to its reputation for being the only herbicide treatment farmers would need for the whole growing season. *In* fact, resistance to glyphosate has been showing up in such common invaders as mare's tail, and atrazine remains a prominent second treatment in the weed arsenal to combat resistance - and to keep more weeds from becoming resistant.... The 2010 report put total Nebraska pounds at about 5.5 million, down from 7 million in 1997. But atrazine use on corn was as high as 7.4 million pounds as recently as 2005.... Lowell Sandell, a weed science specialist at the University of Nebraska-Lincoln, said earlier claims that biotechnology would dramatically cut chemical use have not proven especially true on the weed side. 'I would suspect that the whole level, the total level of use, would be roughly similar,' Sandell said. 'The biggest shift has been from non-Roundup ready crops to Roundup ready crops'. The university strongly backs the idea of using more than one strategy to control weeds, he said. Roundup is 'a very good product, but with the development of glyphosate-resistant weed species, one of the things the university always tries to promote is an integrated management approach - which is multiple effective means of action.' Randy Pryor, based in Wilber as an NU Extension educator, said Nebraska is certainly not the only place where resistant weeds are

turning up. 'Other states are documenting other weeds that are now truly resistant to Roundup,' Pryorsaid." Insecticide usage down, herbicides not so much Lincoln Star Journal (Nebraska), 29 May 2011

"According to the 2010 Agricultural Chemical Use Report released last week by the U.S. Departed of Agriculture's (USDA) National Agricultural Statistics Service (NASS), use of the herbicide glyphosate, associated with genetically engineered (GE) crops, has dramatically increased over tlu last several yearsi while the use of other even more toxic chemicals such as atrazine has not decline* Contrary to common claims from chemical manufacturers and proponents of GE technology that t) proliferation of herbicide tolerant *GE* crops would result in lower pesticide use. rates, the data shoi that overall use of pesticides has remained relatively steady, while glyphosate use has skyrocketed 1 more than double the amount used just five years ago. The 2010 Agricultural Chemical Use Repor shows that, in the states surveyed, 57 million pounds of glyphosate were applied last year on corn fields. Ten years prior, in 2000, this number was only 4.4 million pounds, and in 2005, it was still ie than half of current numbers at 23 million pounds. Intense corn growing regions have experience! an even greater increase in glyphosate applications. Glyphosate use in the state of Nebraska increased by more than five times in just seven years, going from 1.25 million pounds applied in 20 to more than seven million pounds last year. GE proponents have often said that, even if farmers a increasingly reaching for glyphosate, this simply means that they are using less of more toxic wee< killers like atrazine. However, the data tell a different story. In 2000, 54 million pounds of atrazin were applied across surveyed states. With glyphosate use increasing by more than five times betwe 2000 and 2005, atrazine use should have significantly declined over this period. However, the tota pounds applied actually increased by more than three million, to 57.4 million total pounds appliei across surveyed states in 2005. By 2010, atrazine use had just barely declined, with 51 million poun still being applied, only slightly less than the 57 million pounds of glyphosate applied. Such widespread use of atrazine is a concern due to the chemical's links with serious human health effects, including birth defects and disruption of the endocrine and reproductive systems. Additionally, it is a ma threat to wildlife as it can harm the immune, hormone, and reproductive systems of aquatic species. Th rise in glyphosate applications has almost certainly come as a result of farmers increasingly planting G crops such as corn and soybeans, which are engineered to be resistant to the chemical...Coupled with tl dramatic rise in glyphosate applications has been the spread of wild plant species that are resistant to tr herbicide. Over-application and over-reliance by farmers on glyphosate to solve ail of their weed proble has led to the proliferation of so-called "superweeds" which have evolved to survive the treatments throi repeated exposure. The most common species which have evolved these traits include pigweed (palme amaranth), mare's tail, and ryegrass. The spread of resistance is what has led fanners to increasingly re on more toxic alternative mixtures including weed killers like atrazine. There has also been an increase push by chemical companies to engineer seed varieties that are resistant to multiple herbicide treat-men such as glyphosate and 2.4-D, or glyphosate and acetochlor."

Despite Industry Claims, Herbicide Use Fails to Decline with GE Crops
Beyond Pesticides, 3 June 2011

GM Crop'Reality Check'Archives

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j www.nIpwessex.org/docs/gmagric.htm j
j USDA Report Exposes GM Crop Economics Myth !
j www.nlpwessex.org/docs/usdagmeconomics.htm '
| More USDA Data On Rising Pesticide Applications On GM Crops
I www.nlpwessex.org/docs/beiibrook.htm !
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"GE crops available for commercial use do not increase the yield potential of a variety... the adoption of herbicide-tolerant soybeans does not have a statistically significant effect on net returns.... the soybean results appear to be inconsistent with the rapid adoption of this [GE] technology....An analysis using broader financial performance measures (including net farm income and return on assets) did not show GE crops to have a significant impact.... 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.... Even more puzzling, the adoption of herbicide-tolerant soybeans and Bt corn has been rapid, even though we could not find positive financial impacts in either the field-level nor the whole-farm analysis.... the adoption of Bt com had a negative impact on the farm financial performance,...the total herbicide pounds used on [GE] soybeans actually increased as glyphosate was substituted for conventional herbicides... the data indicate that an estimated 13.4 million pounds of glyphosate substituted for 11.1 million pounds of other synthetic herbicides.....Change, in pesticide use from the adoption of herbicide-tolerant cotton was not significant .... Availability, since the 1980s, ofpostemergent herbicides that could be applied over a crop during the growing season has facilitated the use of no-till... using herbicide tolerant seed did not significantly affect no-till adoption."

'The Adoption of Bioengineered Crops'
US Department of Agriculture Report, May 2002

GM Technology In Food Production Is Unnecessary There Are Better Biotechnology Alternatives Which Are Publicly Acceptable Such As Marker Assisted Selection

"There's a lot of technology we could look at, even if Europe didn't look at GM for life. GM only accounts for about 1 % of what we spend money on right now. It's not an awful lot. It's all experimental, not commerical. I think the big revolution is in systems biology; about the use of genomics, understanding the use of metabolites and proteins use in a plant, as well as 'transcriptomi.cs' - the expression of genes and how these genes function. For example, marker- assisted selection is making plant breeding an awful lot easier by being able to pinpoint specific genes we need."

Professor Maurice Maloney, Director of the Rothamstead Research Institute, the body in charge of controversial GM wheat trials in Britain, responding to the question 'Where do you believe the technologies for pushing production might come from in the future given that GM is not palatable in the EU and that agrochemical actives are under increased pressure of de-listing'

Research Revolution
Farmers Weekly. 18 May 2012. Print Edition, P22

"There are a lot of new breeding technologies today that don't use GM food. You can do a lot of things | without GM .... We [Nestle] have a very simple way of looking at GM listen to what the consumer wants. If they j don't want it m products, you don't put it in them."

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Hans Johr, corporate head of sustainable agriculture at Nestle
Food Navigator, 30 August 2012

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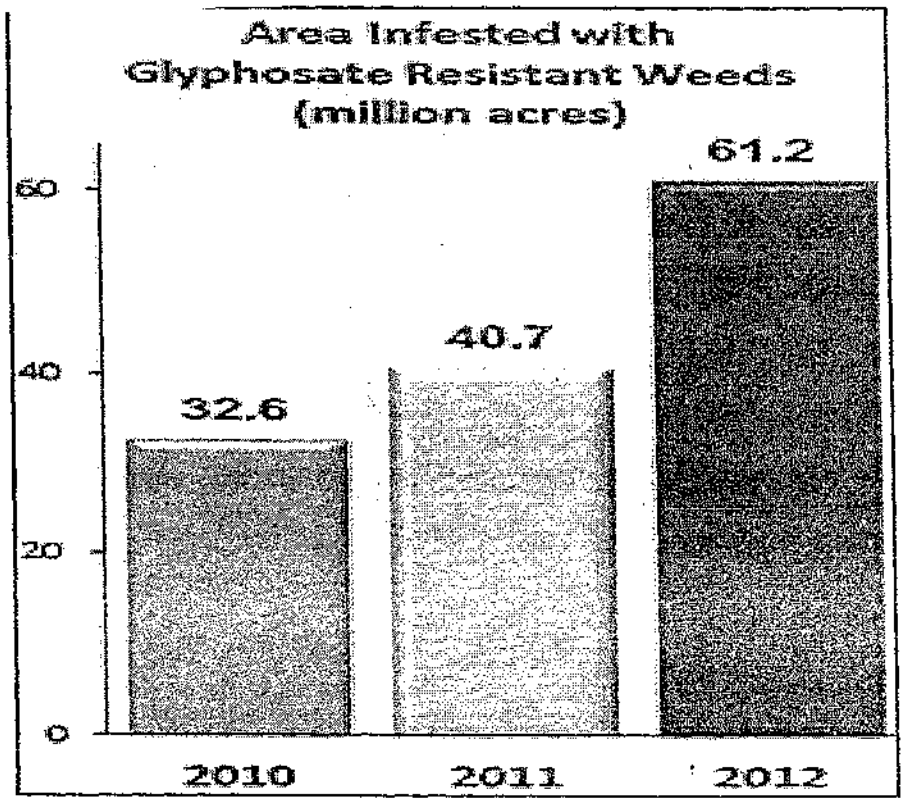
The Ministry of Agriculture, Government of India and the GEAC, Ministry of Environment and Forest, Government of India have systematically ignored the prudence and precaution contained in the Report of the Task Force (Dr. M.S. Swaminathan) on National Agricultural Biotechnology Policy. As stated earlier, that report looked at the socio-economic (i.e. rural livelihoods of landless women who manually pull our the weeds), and ecological (i.e. no indiscriminate killing of all plant species not engineered for Roundup tolerance) aspects for cautioning against herbicide-tolerant transgenics.

The final report of the TEC takes into all these but its recommendation of toal ban on introduction, development and field trials of any kind of Roundup-tolerant transgenic is science-based. More than the adverse effects on plants, the highly unacceptable detrimental biological/health effects are the driving force to recommend a total ban. These are elaborated below.

- A **treadmill of herbicide** use progressing to the use of more dangerous **herbicides, combinations of herbicides and adverse consequences** for the **environment and health**

Benbrook estimates that by 2012 (the first 16 years) herbicide-resistant weeds have spread to 20 to 25 million hectares. However, even these large numbers are dwarfed by estimates of Stratus research http://www.stratusresearch.com/blog07.htm). *"In 2012 US farmers told us that 61.2 million acres of cropland are infested with glyphosate resistant weeds, almost doubling since 2010 ".*



The problems resulting from this rising tide of resistance of weeds to herbicides and insects to Bt are serious, from loss of conservation tillage that preserves soil fertility, to increased use of older, more toxic herbicides, and greater use of insecticides. The biotechnology-seed-pesticide industry's primary response to the spread of glyphosate-resistant weeds is development of new HT varieties resistant to multiple herbicides, including 2,4-D and dicamba. These older herbicides (3 of these with triazines are among the riskiest herbicides still in widespread use, 2,4-d, dicamba and paraquat), *"pose markedly greater human health and environmental risks per acre treated than glyphosate. ").* Approval of com tolerant of 2,4-D could lead to an additional 50% increase in herbicide use per acre on 2.4-D HT com, (WSU http://cahnrsnews.wsu.edu/2012/10/0 l/pesticide-use-rises-as-herbicide-.resistant-weeds-undermine-performance-of-major-ge-crops-new-wsu-study-shows/and Gurian-Sherman: http://blog.ucsiisa.org/resistant-weeds-according-to-monsantoless-than-half-the-storv-2/). Scientists from Dow and Monsanto have been advocating herbicide programmes that combine current rates of glyphosate with 225-2240 grams (g) per ha of dicamba (Arnevik 2010) or 560-2240 g per ha of 2,4-D (Olson and Peterson 2011).

Therefore, the technology will not involve a substitution of herbicide active ingredients but will instead lead to additional herbicide use. If the rate of adoption of this technology follows the general trajectory of glyphosate-resistant crops, the result could be a profound increase in the total amount of herbicide applied to farmland. Historically, the use of the synthetic auxin herbicides has been limited to cereals or as preplant applications in broad- leaf crops. The new transgenes will allow 2,4-D and dicamba to be applied at *"higher rates, in new crops, in the same fields in successive years, and across dramatically expanded areas, creating intense and consistent selection pressure for the evolution of resistance".* And the likelihood of these herbicides moving off site and harming sensitive crops and the environment is well above set levels of concern (USEPA 2005-06); Peterson and Hulting (2004) reported the risk to terrestrial plants by dicamba and 2,4-D as being 75 and 400 times greater than glyphosate, respectively. This trend would move us in the opposite direction of the reduced chemical inputs that scientists in sustainable agriculture have long advocated. (DA Mortensen).

Based in part on the pesticide/seed industry's own analysis that both glyphosate and these other herbicides will be used together on engineered soybeans and corn, total herbicide use is projected to increase more than twofold over the next decade, Dicamba and 2.'4 - D are projected to increase almost tenfold, (http://blog.ucsusa.org/are-genetically-engineered-herbicide-resistant-crops-leading-to-the-demise-of-sustainable-weed-control/ and http://biog.ucsusa.org/midwest-farms-too-big-to-be-sustainable/ and http://blog.ucsusa.org/resistant-weeds-according-to-monsantoless-than-half-the-story-2/). "It is clear to most weed scientists who are involved in herbicide research and even those who are not, that the best way to reduce selection pressure for herbicide resistance is to minimise herbicide use. *"However, the 'solutions' that have emerged in —- meetings on herbicide resistance have usually involved more herbicide use"* (Weed Science 2012 Harker et al). Six academic weed scientists had this to say: " *are we as a discipline so committed to maintaining profits for the agrochemical industry that we cannot offer-up realistic long-term solutions to this glyphosate resistant weed problem?"* (Weed Science April-June 2012 issue: Harker et al 2012).

Ht and Sustainable farming practices

On the other hand, the best resistance management involves using long crop rotations, cover crops, mulches, and similar practices, along with minimal use of pesticides where needed. This greatly reduces pest numbers, is highly productive, and can be economically successful These practices are being advocated more and more by mainstream scientists (Charles Benbrook, David A. Mortensen and several others). Agroecological farming might also threaten the economic viability of genetic engineering. Development of an engineered crop trait is very expensive, about $136 million on average according to a recent industry report compared to $1 million for conventional breeding. That is one reason why most GE crops so far are big-acreage row crops like corn, soybeans, and cotton. But the value of many of these traits would be greatly reduced when used in truly sustainable agroecological systems, because pest infestations would be much lower and cause much less damage. It would be hard for companies to charge farmers the very high prices for seed as they do now, because they would have less value where pests are less of a problem. And without those high prices, it is unclear whether the companies could afford to develop these seeds. (Gurian -Sherman: http://blog.ucsusa.org/resistant-weeds-according-to-monsantoless-than-half-the-storv-2/)

Classical Breeding and Monsanto admissions: The myth of how rapidly genetic engineering can produce a commercial GMO compared to breeding is not even believed by the largest genetic engineering company in the world. Dr Robert Reiter, a molecular biologist and VP Biotechnology at Monsanto said in New Zealand (Heinemann: Hope not Hype) that: *"Conventional crop breeding requires a 7 - 8 year cycle, compared to 10 - J 5 years from inception to development for genetically modified crops..r.* "It's significantly cheaper and with a different regulatory requirement, and let's face it, a different public perception," (Stark - Monsanto); *"Genetic transformation can only be used to introduce one segment of novel genetic material to a variety at a time? but biotech tools can be used to enhance a host of existing traits. It's a numbers game and ultimately non-transformation [ie non-GM] biotech offers the greatest*

potential" (Farmers Weekly, quoting Monsanto's global head of plant breeding). To clarify, what this means is that all of the (few) successful engineered traits are coded for by single genes, and typically have a direct effect in producing the. desired trait. For example, Bt genes code for a protein toxin that directly kills the insect pests that ingest it. But many useful crop traits are very complex; many genes control the successful expression of these traits (like drought resistance), which genetic engineering so far is not capable of doing. On the other hand, breeding, for example using newer genomic methods, can manipulate several genes found in the plant at the same time.

Tillage: Despite a common misconception that tillage is always destructive to soil, a growing body of cropping systems research has demonstrated that where limited tillage is balanced in an IWM (Integrated Weed Management) context with soil-building practices such as cover-cropping or manure applications, high levels of soil quality can be maintained. For example, rotational-tillage systems have recently been reported to accumulate and store more soil organic matter than no-till systems. Greater soil carbon and nitrogen were observed in integrated systems that used tillage, cover crops, and manure than in a conventionally managed no-till system, regardless of whether cover crops were used in the no-till system. These results illustrate that soil-quality benefits associated with no-till systems can also be achieved using IWM that includes limited tillage. (No-till acreage grew rapidly in America from the late 1980s through the mid-1990s, before GE crops had gained much market share. The percentage of corn acres planted using no-till rose from 8.5% in 1990 to 17% in 1996, but then only another 2% (to 19%) and 4% (to 21%) in 2002 and 2008 respectively (Benbrook; Mortensen; Gurian Sherman; NRC 2010 http://www.nap.edu/cataioq.php7record id=12804).

Benbrook is of the view that should the EU approve RR technology as has been done in the USA, it will almost certainly trigger

- " increases in the volume of herbicides applied
- the emergence and spread of resistant, weeds
- « higher costs

Benbrook's model under his scenario 2 *of unlimited adoption pattern after the trajectory ofRR crop adoption and herbicide use in maize and soy production from J 996-2010 in the US,* if applied to the EU provides an insight into what would happen in the EU. He applied the model to projection in 2012 through 2025 for 27 EU member States (this corresponds to roughly the same period of time, 13 years of HT crops in the US).

- Maize: Glyphosate would rise 1,040% above the 2011 baseline to 22.5 kilo tonnes in 2025. Overall herbicide use (all herbicides) would double in 2025 (33.2 kt).'

« The volume of glyphosate-based herbicides in 2025 across the EU: for each kg applied in 2011 on soya, 15.6 kg would be applied in 2025.

- Because substantial quantities of glyphosate have been used in the EU for many years resistant weeds in RR crops are likely to emerge more quickly than they did intheUS.
- Continuous planting for 5-7 years would hasten the emergence and spread of multiple GR (Glyphosate Resistant) weeds and farmers will then have to spray additional herbicides by 2020 to 2025.

Note: In the US it took just 4 years to trigger the 1st new glyphosate resistant weed (horse weed in Delaware). After 10 years in 2005 the (GR) weed tipping point occurred as a result of the emergence of GR (glyphosate resistant) palmer amaranth and common water hemp. A mature GR horse weed produces on average around 130,000 seeds; common water hemp, 400,000 seeds per plant. Resistant weeds can travel up to 122 km with wind speeds of just 17.5 km/hr and can move much farther in extreme weather events. A serious flood may disperse resistant weeds for hundreds of km, making low lying farmlands, reservoirs for further dispersal. (Benbrook: HT Crops in the EU: A Forecast of Impacts on Herbicide Use; Oct 2012).

The TEC have seen no data of serious weeds prevalent in India, yet the regulators and MoA are promoting HT crops and field testing them and even allowing illegal HT cotton

to proliferate. In several States beginning in Gujarat, over the last 5-6 years, illegal RR cotton has been planted by farmers in large tracts of farmlands (ref. GEAC Minutes of the 95th Meeting, Agenda Item 6.2 of 8.7.2009). It is worrying indeed that the Regulators and the Government at the Centre and in the States concerned have virtually ignored this developing problem. What would be the situation if this happened with some of our food crops; is there illegal planting of GM and/or contamination as an outcome of open field trials? Despite a SC Order on contamination protocols *"to an LOD of at least 0.01%"* (and this aspect is part of the TOR of the TEC), no testing for contamination has been done, The way GM crops are regulated in India poses a present and significant bio-security risk to our farming and our food*

- **The case of Argentina;** Heavy socio-economic and environmental costs **and** super weeds.

Argentina is the leading exporter of RR Soybean/oil/cake. More than 18 million hectares are planted to RR soya requiring an application of more than 300 million litres of pesticide. Numerous medical experts are attesting to the serious detrimental health and environmental impacts of RR pesticides. The doctors and scientists claim that babies are being born with crippling birth malformations; that in recent years the incidence of childhood cancer has soared. It is a phenomenon, they say, that has coincided with the introduction of Monsanto's seed. Montenegro, a world-renowned biologist, says, *"I have pesticide in me"; "Here we all have pesticide in our bodies because the land is saturated with it. And it is a huge problem. In Argentina biodiversity is diminishing. Even in national parks, because pesticides don't recognise the limit of the park.*"

Doctor Seveso asserts, *"I have practiced medicine here for 30 years. 20 years ago we never saw malformations;"* She maintains that RR is responsible for what she referred to as *'an epidemic of birth malformations'* In this she is supported by Argentina's leading embryologist, Professor Andres Carrasco, who runs the Molecular Embryology Laboratory at the University of Buenos Aires. Carrasco observed a link between glyphosate and malformations under laboratory conditions some two years ago.

Argentina's Chaco region is dominated by small-holder farmers, presenting a **model for India.** As **a** result of the 'soyaisation' of Argentina's agriculture, thousands of **small-** and medium-scale farmers have been forced out of the production system. In the **10 years,** (to around) 2005 the country lost its food sovereignty by concentrating on a few commodities for agro-export without value-addition. Poor people cannot afford a diverse diet any more. The protein basis of their meals has changed from high-quality meat proteins to soy protein. 20% of the children show signs of undernourishment.

Landscape transformation in the rural sector is evident, and the appearance of glyphosate-tolerant weeds is becoming a common occurrence. Nutrient depletion, soil-structure degradation, potential desertification, and loss of species are some of the results of the overexploitation associated with the monoculture production of RR soybean. Migration from rural areas, concentration of agribusiness, loss of food diversity and food sovereignty are some of the socio-economic consequences. Estimations based on 2003 to 2004 showed that about 30% of the whole soybean area (at that time of 4.5 million hectares) was fertilized with mineral fertilizers. This shows a trend toward substantial depletion of nutrients in Argentinean soils, and if the trend continues, nutrients will be totally extracted in 50 years ((Ventimiglia, 2003).
(Walter A. Pengue Bulletin of Science, Technology & Society, Vol. 25, No. *A,* August 2005 Transgenic Crops in Argentina: The Ecological and Social Debt)/

- The **Indian** Context

On-the-ground experience, the evidence of empirical data from the US provides the TEC with the strongest possible evidence and therefore, a sound basis to conclude that Ht crops are even more problematical than Bt crops and that this technology will not be suited, even more so, to India's essentially small-holder farming. In this, the Report of the *'Task Force on Application of Agricultural Biotechnology, 2004* chaired by M. S. Swaminathan, a formal document of the Ministry of Agriculture is clear. It says:

"~ Viable alternatives available for meeting the food/feed and nutritional needs should be viewed comprehensively before resorting to recombinant DNA technology". — "such areas of biotechnological applications, which can reduce employment and impinge on the livelihood of rural families, should be avoided. Breeding for herbicide tolerance, for example, may have low priority on this account in several parts of India where there are large numbers of landless labour families" (ref: Chapter 11 http://agricoop.nic.in/TaskForce/chepll.htm).

"Since there is public, political and professional concern about transgenics with reference to their short and long term impacts on human health and the environment: their testing, evaluation and approval have to be stringent, elaborate and science-based. The general approach in this respect, therefore, should be that Biotech applications, which do not involve transgenics such as biopesticides, bio fertilizers and bio-remediation agents, should be accorded high priority. They will help to enforce productivity in organic farming areas. Transgenic approach should be considered as complimentary and resorted to when other options to achieve the desired objectives are either not available or not feasible" (Chapter II of the Task Force: Application of Biotechnology in Agriculture...)

Highlighting the need for stringent, elaborate and science-based evaluation of transgenic crops, Dr MS Swaminathan had called for tests to detect potential chronic effects of eating Bt brinjal, of the type used to establish the causes of cancer due to smoking cigarettes. (Letter from MS Swaminathan to Shri Jairam Ramesh, Minister MoEF dated 4 February 2010).

Weeding in India is done mostly by women from the poorest households of landless and marginal land-holding households. The Government of India has also introduced MGNREGA (Mahatma Gandhi National Rural Employment Guarantee Act), an ambitious scheme costing the exchequer several thousand crores to provide employment and income to rural households. HT transgenics flies in the face of these very important and laudable economic policies of the government, is in fact a

In India, what would be considered weeds in 'industrial' farming systems are not weeds; they have important and economically valuable, nutritional, medicinal and biomass uses in small-holder farms. Herbicide drift over small land-holdings would destroy diverse crops including this vegetation, a significant resource for small farmers and in agri-ecological systems in India. Studies have documented the high nutritional value of *"uncultivated foods/greens",* often classified as weeds. Such uncultivated nutritious greens usually thrive in organically grown fields and offer opportunities of nutrition security for poor households and for grazing live stock). They are also an important source of valuable biomass for mulch or for adding into the soil as nutrients for better productivity (Nourishing Traditions, Andhra Pradesh Farmer Managed Ground Water Systems Project, 2006).

Harmful Biological Effects of'Roundup' herbicide

It has already been mentioned that glyphosate is the active ingredient of Roundup and there are also a few adjuvants whose effects on biological systems remain largely unknown. Often the presence of the adjuvants in Roundup is kept 'confidential' by the multinational companies, and therefore, there is no question of their being subject to toxicological evaluation as is done for glyphosate for regulatory purposes.

In 1993, Dallegrave E et al *(Toxicol. Lett.* 142, 45-52), demonstrated the teratogenic potential of herbicide glyphosate - Roundup in Wistar rats. The authors noted that Roundup induces developmental retardation of the fetal skeleton.

Spraying with glyphosate added to a surfactant solution in the northern part of Ecuador has been shown to result in DNA damage (assessed by 'Comet assay') in the exposed individuals (Paz-y-Mino, C et al. 2007 'Evaluaiton of DNA damage in an Ecuadorian population exposed to glyphosate[5] *Genetics and Molecular Biology'* 30, 456-460.

Benachour N and Seralini G-E (2009, *Chemical Research in Toxicology* that four glyphosate-based formulations, from 105 times dilutions induced apoptosis and necrosis (i.e. cell death of one or another kind) in three different human cell types. There are several reports of adverse biological effects induced by Roundup. Most of them are published in peer-reviewed international journals. Providing a list of all these papers is beyond the scope of this report. However, a few of the very recent and noteworthy papers (from the point of awareness to the policy makers, media and general public) are discussed below.

In 2010, two important papers on the adverse biological effects of glyphosate were published. Romano R.M et al (2010, *'Prepubertal exposure to commercial formulation of the herbicide glyphosate alters testosterone levels and testicular morphology' (Arch. Toxicol* 84, 309-317) found that Roundup is a potent endocrine disruptor and. disturbed the reproductive system development of rats with exposure

during puberty. Delayed puberty, and reduced testosterone production were found at all dose levels, with a clear dose-response relationship.

In the same year (2010, Paganelli A. et al (2010 '*Glyphosate-based herbicides produce teratogenic effects on vertebrates by impairing retinoic acid signalling', Chemical Research Toxicology* 23; 1586-1595) showed that Roundup caused severe malformations in embryos of the South African clawed frog Xenopus laevis and chickens. In frogs, very high dilutions of about 1/5000 of the formulation induced severe malformations of the young ones at tadpole stage. The authors using appropriate scientific methods also showed that. Roundup produced adverse biological effects via disruption of the retinoic acid signaling pathway. It is noted that this study is relevant to human risk assessment because the retinoic acid signalling pathway is a central signalling pathway in embryonic development that operates in virtually all vertebrates including humans. These findings should be linked with several reports from different parts of the world that the children of farm workers using Roundup have had children with several malformations.

In a very detailed review on the. teratogenic effects of glyphosate-based herbicides, Antoniou M et al (2012, J. Environ. Anal Toxicol. S4:006.doi: 10.4172/2161 -0525.S4-006) have brought out the divergence of regulatory decisions from scientific evidence. The Table 1 in their paper shows the range of malformations found in the industry-sponsored teratogenicity studies. This Table 1 from Antoniou M et al is reproduced for the information of the Honourable Supreme Court of India.

Table 1

Study (author Submitter land company idate	Experimental animal/exposure route	Doses 1 used img/kgj lbw/d	Effects found	Dose-related effects/Statistical significance
Suresh, 11993	Feinchemie Rabbits/gavage	lo, 20, lOO, b00	Dilated heart	Linear dose-response (relationship.

					doses, including low dose
			~ -	Unspecified "major visceral malformations"	Linear dose-response relationship. Increased in all treatment groups, significantly increased at highest dose
					Linear dose-response relationship. Statistically significant increase at highest dose
prooker let ai., (1991	Monsanto/Cheminova	Rabbits/gavage	0,50, 150, 450	Heart malformations only type specified is interventricular) septal defect)	highest dose. No information provided by Germany on statistical
				Embryonic deaths	Significant at all doses, though no clear dose/response Relationship
Bhide [and Patii, 1989	Barclay/Luxan	Rabbits/route unstated	0, 125, 250, 500	Heart malformation (ventricular septal defect)	Linear dose-response Relationship. No (statistical analysis provided by

			authors. Increased heart malformations! found in all treatment groups
			(Linear dose--esponse relationship. No statistical analysis provided by authors. Dose-dependent increases! found m an treatment groups
		.ungs: (postcaval iobe [absent	
			Linear dose-response relationship. No (statistical analysis provided by authors. Dose-dependent increases! found in all treatment groups
		Kidneys absent	
			JNo statistical (analysis provided by) lauthors. Dose-jdependent increases!]
		1 Rudimentary 14th rib, unilateral jfound in mid- and	1 (high-dose groups
			Linear dose-(response ^relationship in case of non-viable Implants. No
		(decreased and jnumber of	

				[implants	provided by
				Increased	authors. Effects
				!	found at high dose
				!	Linear dose-response
Tasker let a!., 11980	Monsanto/Cheminova -	Rabbits/gavage	0,75, 175, 350	Increased number of deaths in dams	low, mid- and high-do°se treatment groups respectively (no. of rabbits per group: 16 or 17).. 75 mg/kg stated by Germany to be NOAEL
Anon. 11981	Alkaloida	Rats and . rabbits/oral feeding	0, 10.5, 50.7,	Increased number of foetal deaths	Effect seen at two upper dose levels
				Germany comments that there is "No evidence of	
lZhu et [al., ;1984	Barclay	Mice/gavage	80, 420, 1050	dose-related toxic effects" and "no ... structural malformations"	Data not provided by Germany
				but that description of experiment	

				was "poor"	
iBrooker jet al,, 1991	Monsanto/Cheminova	> Rats/gavage	0, 300, 1000, 3500	jDistortions affecting thoracic ribs	Dose-dependent increases found, in mid- and high-dose groups. Statistically significant at high dose
				—,_ ----- Reduced ossification of jone or more (cranial centres	Dose-dependent increases found in mid- and high-dose groups.
				Reduced ossification of lsacro-cauda! vertebral arches	Dose-dependent ncreases found in mid- and high-dose groups
				isternebrae	[ncreases found in all treated groups, statistically significant at high
dasker				Skeletal jvariations	Dose-dependent ncreases found in ill treated groups, statistically significant in mid- Jose and high- roups.
jMonsanto/Cheminovaji iRodwell,j 11980		]0, 300,1 ^ats/gavage j 3500	jlOOO,	Jnossified |3 sternebrae [Unspecified	ncrease found at lighest dose ievel ncrease at highest [

				No. of viable foetuses per litter and mean foetal weight	Effects found at highest dose level
				decreased	
				Early resorption of embryos	Data not provided by Germany
				Increase in delayed ossification (caudal vertebra! arch, forelimb proximal and hindlimb distal phalanges) found in treatment group, but increase in delayed [ossification of skull found in control group	(Conflicting data led Germany to conclude that the NOAELfor developmental toxicity was 1000 mg/kg
Surest), 1991.	Feinchemie	Rats/gavage	0, 1000		
Bhide, 1986	Barclay/Luxan	Rats/gavage	0, 100, 500	No effects found but commented that "serious reporting deficiencies"	In spite of lack of (reliable data, Germany derived a NOAEL for developmental toxicity of 500 mg/kg

				and lack of statistical analysis led it to consider the study as supplementary information only	
				Germany commented that description of study is so "poor" that it only considered the study as supplementary information.	In spite of lack of {reliable data,
Anon., 1981	[Rats and rabbits/oral (feeding	[22,. (103, J544	There were "no malformations recorded" and "not observed" but it is	Germany derived a JNOAEL for developmental effects on foetuses were,	toxicity of 544 img/kg
			unclear from [Germany's summary [whether this was due to poor reporting by the study's		

The epidemiological studies confirm that the adverse reproductive and developmental abnormalities (i.e. birth defects, malformations, (teratogenic)) found in experimental (test) animals occur also in.humans. The malformations observed included craniofacial defects, anencephaly, microcephaly, cleft plate, polydactyl, syndactyly and congenital heart defects in the offspring of women exposed in pregnancy to pesticides, compared with control as well as those in a similar epidemiological study in Argentina are discussed by Antoniou et al (2012, J. Environ. Anal Toxicol S4:006.doi:i0.4172/2161-0525.S4-006).

Epidemiological studies in Canada have also revealed an association between exposure to glyphosate herbicides and adverse reproductive and . developmental outcomes. (For instance, Savitz, D.A. et al (1997. *Amer. J. Epidemiol. 146,* 1025-1036) have found an association between pesticide exposure of males and higher rate of miscarriages, pre-term deliveries etc.

Among the several kinds of Roundup-induced birth malformations, the occurrence of neural tube defects (NTDs) is stated to be consistent with retinoic acid-linked teratogenicity (Rull et al. 2006 *Amer J. Epidemiol.* 163: 743-753).

It is not that these studies demonstrating harmful effects of glyphosate-based herbicides are not challenged and rejected by other scientists especially those supported by industry. One significant paper published by Williams A.L. et al (2012, "Developmental and reproductive outcomes in humans and animals after glyphosate exposure: A critical analysis". J. *Toxicol Environ Health* B Grit Rev 15, 39-96) cites GLP (Good Laboratory Practice) status of industry study to argue that glyphosate-based herbicides are safe to animals and humans. The data presented in Table 1 include studies based on GLP, but found teratogenic effects of glyphosate.

It is now widely acknowledged that GLP is not a measure of scientific reliability or validity, but a set of laboratory management rules instituted by regulators in the 1970s

and 1980s to combat fraud in industry testing. Today, advances in molecular and cell biology have opened up huge avenues to understand more precisely the alterations in signaling and gene expressions and the ensuring cellular consequences following exposure of cells and organisms to environmental carcinogens, mutagens and teratogens.

Therefore the TEC is of the considered view that the harmful effects of glyphosate-derived herbicides on animals and humans be taken quite seriously.

During the last 8-9 months, the TEC has been receiving several verbal and written depositions from the industry, pro-industry individuals and the Government (MoA, RCGM and GEAC). Most of them are also in the nature of discrediting the findings of harmful, biological effects of Bt- and Ht- by the scientists working independently in Universities and institutions which have not received any support from industry. In other words,; they are not obliged in anyway to industry. Notably these criticisms are rarely [v] based on data from their experiments contradicting those of the independent scientists. As had already been discussed in the case of the paper by A. Aris and S. Leblanc (2011) 'Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada)', the industry leveled flimsical and unsustainable criticisms which the authors were able to answer in decisive manner, and dismiss them.

As this report is being written, there has arisen another similar case. This case offers an opportunity for the TEC to project its analyses to the Honourable Supre Court which can readily perceive as to how the industry' scientists misrepresent facts, deliberately omit the authors' response to the critics, quote relevant.

The paper entitled, 'Long-term toxicity of a Roundup herbicide and a Roundup- tolerant genetically modified maize' in Food and Chemical Toxicology 50 (2012) 4221-4231, by Giles-Eric Seralini and seven other co-scientists from the University of Caen, Institute of Biology, Caen Cedex, France, and University of Verona, Department of Neurological, Neuropschological, Morphological and Motor Sciences, Verona, Italy created panic and shock worldwide among the Ht-transgenic crop developing industry as well as those who have introduced these crops in an authorative 'top-down[5] manner in their own countries. India, despite ao advisory in the Task Force Recommendations in 2004, let the Ht-transgenics take root in the Indian soil.

Kounaup-toierant genetically modified maize, cultivated with or without Roundup, and Roundup alone (from 0.1 ppb in water) in Virgin albino Sprague-Dawley rats. The transgenic maize 'used in the studies was herbicide-tolerant maize (Monsanto 00603-6, commonly referred to as NK603). Usually, the biosafety studies involving genetically engineered foods are terminated by 90 days at the most. However, Seralini and his co-scientists extended the studies on the biological health effects in the rats upto two years. Briefly the essence of the findings that sent shock-waves in the industry circles are: A. Mortality:

In the 'control group, male animals survived on average 624±21 days, whilst females lived for 701 ±20. Before this period, 30% control and 20% females died spontaneously, while upto 50% males and 70% females died in some groups containing the GM maize.

The first two male rats which died after fed on the Ht-transgenic maize had developed kidney Wilm's tumours which were over 25% of body weight. This was approximately a year before the first control animals died. The first female death occurred in the 22%o GM maize feeding group and resulted from a mammary fibroadenoma (cancer) 246 days before the first control.

The maximum difference in males was 5 times more deaths occurring during the 17 month in the Group consuming 11%> GM maize, and in females 6 times greater mortality during the 21st month on the 22%> GM maize diet with and without Roundup. In the female cohorts, there were 2-3 times more deaths in all treated groups compared to controls by the end of the experiment and earlier in general. Females were more sensitive to Roundup in drinking water than males, as evidenced by a shorter lifespan.

Be Anatopathologicai Observations

Tumour growths, often 2-3 times more in both sexes appeared in animals fed GM maize with or without addition of Roundup diet. In females, the largest tumours were in total 5 times more, frequent than in males after 2 years, with 93% being mammary tumors. Adenomas, fibroadnomas and carcinomas were deleterious to health due to very

large size, rather than the grade of the tumour itself. Large tumour size caused impediments to either breathing or nutrition and digestion because of their thoracic or .abdominal location and also resulted in hemorrhaging. In addition,one metastatic ovarian cystadenocarcinoma and two skin tumours were identified.

Up to 14 months, no animals in the control groups showed any signs of tumours whilst 10-30% of treated females per group developed tumours, with the exception of one group (33% GMO + Roundup). BY the beginning of the 24th month, 50-80% of female animals had developed tumours in all treated groups, with upto 3 tumours per for one female, in each group. While mammary tumours were most frequent, occurrence in female animals fed Ht maize (Monsanto's NK 603) with or without Roundup, the second most affected organ in females was the pituitary gland, in general around 2 times more than in controls for most treatments. Adenomas and/or hyperplasias and hypertrophies were notices. For all R treatment groups, 70-80% of animals presented 1.4 to 2.4 times more abnormalities than, controls in this gland.

Big palpable tumours in males (in kidneys and most skin) were by the end of the experimental period on average twice as frequent as in controls, in which one skin fibroma appeared during the 23ld month. At the end of the experiment, internal non-palpable tumours were added, and their sums were lower in males than in females. They were not really different from controls, although slightly above in females.

The most affected organ in male animals were the liver, together with the hepatodigestive tract and kidneys. Hepatic congestions, maeroscopic and microscopic necrotic foci were 2.5-5.5 times more frequent in all treatments than in control groups. Liver disorder as judged by an increase upto 5.4 times of Gamma GT hepatic activity particularly in the GMO+R groups was also evident. Degenerating kidneys with turgid inflammatory areas demonstrated the increased incidence of marked and severe chronic progressive nephropathies, which were upto 2-fold higher in the 33% GM maize or lowest dose of Roundup treatment groups.

C. Biochemical analyses

For control and treated groups, biochemical analyses revealed no particular difference. This could be used to argue in favour of substantial equivalence, except for

muuiucu uj VJIVI maize ana *K.* treatments at *yy/o* contidence level and for male animals, ' the levels of estrogens were more than doubled at the highest R treatment dose.

- Implications: This study is indeed the first life-long rodent (rat) feeding study to investigate possible toxic effects associated with Roundup - tolerant GM maize (NK 603) and a complete commercial formulation of Roundup herbicide (i.e. not just glyphosate alone without the adjuvants). One striking observation is that the adverse biological/health effects were not proportional to the dose of the treatment (GM maize with or without Roundup application: Roundup alone). This suggests occurrence of 'nonmonotonic threshold'effect. The critics have argued that nonmonotic biological effects of Ht-transgenic maize and Roundup represent a serious flaw in the study. The TEC would like to ask the critics to appreciate the fact that monotonic dose response is commonly observed for hormones and endocrine - disrupting chemicals such as pesticides. **(Vandenberg L.N and 11 other** scientists 2012, *Endocr. Rev.* 33_5 378-455).

D. Criticisms of Seralini et **ai** (2012) paper and authors' response

The herbicide tolerant Ht-maize and Roundup enhanced large tumour incidence by 2-3 fold in both sexes in comparison with control (non GM maize). The Sprague Dawley female rats are known to develop mammary tumour spontaneously, but the significant fact is about 3-fold increase in comparison with the largest study with 1329 Sprague Dawley rats conducted in 1992 by Chandra M et al *(Arch. Toxicol 66,* 496-502). Therefore, any criticism that cancer-prone strain of rats has been used in the studies by Seralini et al (2012) is not tenable.

More importantly the basic science should be kept in view while making scientifically untenable attack on this paper. Way back in 2009, Gasnier C. et al (2009, *Toxicology* 262, 184-191) have shown that glyphosate-based herbicides are toxic and endocrine disrupters.

« All criticisms of the Seralini et al (2012) paper have been effectively answered and put at rest.

Criticism - 1: Statement of EFSA (European Food Safety Authority) under the title Review of Seralini et al (2012) publication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK 603 as published online on 19 September 2012 in Food **and** Chemical Toxicology in EFSA Journal 2012 10 (10); 2910 (9pp) doi: 10:10.2903 lj.efsa2012.2910 (Available online:www.efsa.europa.eu/efsajournal) EFSA states that the review was requested for by the European Commission. The conclusions drawn by EFSA are reproduced below:

"EFSA notes that the Seralini et al (2012) study has unclear objectives and is inadequately reported in the publication, with many key details of the design, conduct and analysis being omitted. In particular, *'Seralini et al (2012) draw conclusions on the incidence of tumours based on 10 rats per treatment per sex which is an insufficient number of animals to distinguish between specific treatment effects and chance occurrences of tumours in rats* .... Therefore, EFSA, concludes that the Seralini et al study as reported in the 2012 publication does not impact the on-going re-evaluation of glyphosate, and does not see a need to reopen the existing safety evaluation of maize NK 603 and its related stacks. EFSA will give the authors of the Seralini et al (2012) publication the opportunity to provide further information on their study to EFSA".

The TEC'has considered the comments/criticisms by the EFSA

- EFSA's first criticism is *"that the study objectives are unclear. And it goes on to say that "without clearly stating the study objectives, it is difficult to determine whether the study design and sample size used are fit for purpose or indeed what that purpose is".*
- The EFSA's second criticism is that *"Given that Seralini et al (2012) conducted a two-year study, it is unclear why an OECD guideline suitable for a two-year chronic toxicity or carcinogenicity study (i.e. OECD 451, OECD 452 or OECD 453) was not adhered to "*
- The third criticism was that *"the strain of rats chosen is known to be prone to development of tumours over their life"*

A few other criticisms leveled against the Seralini et al (2012) are even more trivial from the point of those scientists who believe that the said study has indeed revealed the

The Performance **of Bt cotton.** What are the Indicators and the **Indications** of **its** Impacts?

- **Background**

Bt cotton, introduced for commercial planting about 10 years ago, has been officially claimed to be a success, in terms of yield and several other socio-economic indicators benefiting particularly farmers, by the Ministry of Agriculture and its Institutions of the ICAR and affiliates and the Regulators. It has been declared completely safe with no health or environmental impacts. Such is the claimed success of Bt cotton that the official call is to expand this experience into other Bt crops, especially food crops which should be cause for great concern because of the direct action of the toxins and other GMO technologies on human health and non-target organisms. Therefore, it is of outstanding importance and concern to the public interest that these claims are verified. It must also be verified whether' Bt cotton was introduced in hybrids as the route to 'value capture' for Monsanto and the Industry, as the only way to control the seed market. **The claims of substantial equivalence** in the United States USDA have **not been rigorously tested and** there **is** indication of potential harm **(Seralini, G.E., R. Mesnage, E. Clair, S. Gress, J. Spiroux de Vendomois, and D.Cellier., 201L "Genetically modified crops safety assessments: present limits** and possible **improvements"*** Environ. Sci. **Europe 23:10).**

Based on the extensive review of Bt toxins, (see Section I), it is the conclusion of the TEC that there is no scientific basis for the official reassurance on biosafety issues of Bt toxin in food crops because the tests have not been done in the USA, much less India, for the expansion of the technology in food crops. In fact, new research adds to the evidence of older studies that there are serious health, and environmental risks, which the TEC could not ignore. Based on the international appraisal of Mahyco's

biosafety dossier of Bt brinjal (eggplant), Event EE 1 had the same fusion Bt gene as in Bt cotton, Cry 1 Ac and hence the subsequent unconditional moratorium on Bt brinjal, along with TEC's review in Section I and findings and recommendations of the Interim Report, the TEC cannot endorse the safety of Bt brinjal nor of Bt cotton derived food and feed for that matter. Furthermore, in the extended period that was given to the TEC to deliver its final report, it again met with several proponents of GM technology as well as the Ministry of Agriculture, which is also officially promoting GM crops. None of these agencies, firms or their officials were able to substantiate their claims of the safety of the Bt toxin. The significant lack of regulatory oversight that we have found including in the matter of field trials, along with the BNBt (Desi gene) incident (ref the Sopory Commmittee Report of Aug. 2102), which confirms that BNBt was contaminated with a Monsanto gene before its approval for commercialisation, (i.e. It 'passed' all the regulatory processes of regulation with the Monsanto gene contamination, finally culminating in the GEAC, which gave its nod for commercialisation without apparently a molecular analysis or any assessment of health impacts). This failure does not instill confidence in our institutions and regulators. The Sopory Committee Report lends support to the conclusions of the TEC; it indicts the regulators and public institutions in the Ministry of Agriculture with a conflict of interest, a lack of competence and expertise in GM technology, as well as faults them on a benchmark of integrity. The TEC's interim report is certainly not unscientific and flawed.

In addition to the MOA, Dr Keshav Kranthi, Director of Central Institute of Cotton Research (CICR), and Industry representatives, we interviewed several stakeholders including farmer representatives, civil society groups, P Sainath (the well known commentator and Editor), Rural Affairs, The Hindu, the Petitioners amongst others (listed separately). We also rely on information published by the Ministry of Agriculture, and research published within and outside India to inform our analyses on

r ___ .—D — .^w^wn ^^ iuiuuiga un uic unpads aim. periormance 01 m couon, me TEC notes that the regulators and the MoA failed to institute a process of Post Market Monitoring (PMM) of Bt cotton, which would have provided essential data to inform our analyses of impacts on many critical issues: soil health, resistance to the toxin by different pests or its efficacy, irrigated and non-irrigated farming comparisons, yield of Bt vs non Bt, and alternate sources of non-GM seed availability, shrinking of the cotton gene pool, GMO contamination of organic cotton for export, and other impacts through stealth foods (cotton-seed oil), effects of variety scarcity on India's Weaving Industry.etc. Yield, data for different agri-climatic and rainfall zones is essential, and should also have been required studies of Bt cotton with controls of near isogenic lines of non-Bt. cotton to allow us the separation of the yield component attributable to other factors including the use of hybrids as opposed to the performance of Bt transgenes in controlling cotton pests. We note that Bt cotton has no trait for intrinsic yield gain. Bt cotton is engineered to kill the cotton bollworm, and yet there are several other pests that the technology does not address (examples are; *sap-sucking insects, leaf-curl virus and leaf reddening).*

The opinion of Clive James (Founder and Chair of ISAAA, a pro-industry group) quoted in a Times of India Article below is a good example of the prevailing view held alike by the Industry and the MOA.

Malcolm Elliot (http://articles.timesofmdia.indiatimes.com/2013-01-16/edit-pa,ge/36353683) cites Clive James to record: *"Bt cotton has brought spectacular benefits to India's economy. Seven million small farmers planted 10.6 million hectares ofBt-cotton in 2001. Average cotton yield and production increased from 13.6 million bales in 2002 to 35.5 million bales in 2010 alone";* (or an increase of 2.6 times in both production and yield TEC comment). Various claims of 'spectacular' success have been made which even better these yield claims. Answering a question in the Lok Sabha, Mr. Sharad Pawar, the Honorable Minister of Agriculture, chose to demonstrate the success of Bt cotton by showcasing the 'adoption rate' as a measure of success (un-starred Q 1216 answered on 5-3-2013). The adoption rate or market share of Bt cotton rose from zero in

2002 to over 90% in 2012. It is quite true that the rate of adoption of Bt cotton is spectacular but that is without meaning on its own. So we ask, what does the success of 'adoption' of Bt cotton translate into without the accompanying critical analyses of other indicators to support such a conclusion of the success of Bt cotton across parameters, particularly when Bt hybrids are adopted in marginal soils and rain-fed farmlands[5] and once adopted the saved seed system for local varieties is destroyed leaving farmers with no alternate source of non GMO seed? Is there benefit to the farmer just because he adopts Bt cotton? Sainath writing on yield reports: *"Vidarbha produces about 1.2 quintals [cotton lint] per hectare on average,"* Sharad Pawar told the Parliament on December 19, 2011. That is a shockingly low figure seven years after BT cotton introduction. *"Twice that figure would still be low"* —.

We can only agree that there is no doubt that this kind of adoption by our farmers is clearly a measure of the success of marketing tactics employed to promote Bt crops, underpinned, it must be made clear by the assurance and backing of the technology by the Indian government, that it is sound, safe and productive. The marketing tactics employed Bollywood actors to promote the technology, false advertising in Vidharbha (Reaping Gold through Bt Cotton by P Sainath: the Hindu dated 10-50-2012), and claims that Bt cotton was sold as a 'magic bean' that'was both high-yielding and killed pests. The twin claims of high yielding and efficacy against the bollworm are the basis of the demand by the MOA, the regulators and the Industry alike to accept Bt technology, based on the 'proven' success of Bt cotton, and by extension, reason to incorporate it in our food crops for food security reasons. This in our opinion, points to the fact that Bt cotton is promoted on virtually magical claims, the evidence for which is unsubstantiated as our analyses show. It is for example scientifically false that Bt crops are high yielding in themselves, which is a major message of this claim, and yet the Industry was allowed by the government to make this implicit false claim. The science shows that *Bt- transgenes are not pari of the quantitative trait loci (QTL) which influence the yield in crop plants.*

. Some Main Issues and Impacts of Bt-hybrid cotton varieties

- The decision to engineer hybrids of cotton and their consequences:

India is the only country in the world that has engineered Bt endotoxin proteins into hybrid cotton. In the rest of the world, Bt cotton is available only in a few 'varieties' that produce fertile seed as opposed to hybrids, *Monsanto preferred Bt hybrids in India as a means of 'value capture', (Kranthi),* since the technology is designed to keep farmers from using now sterile saved seeds. In all other countries where the number of farmers is relatively small, Monsanto transferred the genes into the local fertile varieties because Monsanto requires farmers to sign an agreement form that they can not reuse the seeds. In China and Pakistan, where the number of farmers is huge, the agreement form system was not acceptable. China's public sector research system succeeded in developing its own Bt in fertile varieties (many of dubious quality) (Pemsl, D., Gutierrez, A.P., Waibel, H. 2007. *The Economics of Biotechnology under Ecosystems Disruption. Ecological Economics*. 66:177-183.), and went ahead with commercialisation. As a result, Monsanto does not have much of a presence in China now, and because Pakistan refused to take the technology in hybrids, Monsanto does not have a presence there either. If Bt cotton is so great, the obvious question is why doesn't *"India ... have ... Bt technology in fertile varieties"?* Is it because it is the only mechanism the Industry, essentially Monsanto has to control the seed market? The alternative way to control the seed market was for Monsanto to require millions of farmers including small-holder farmers to sign a Monsanto agreement not to re-sow seed; a politically explosive proposition.

- Bt cotton hybrids: The Bt cotton became available only as Bt hybrids in over 1,000 brands in the ten years since its release in India, causing confusion amongst farmers of the pros and cons of each hybrid variety. The release of several hundred hybrids has been without discipline and includes unapproved and spurious brands. *"The identification of varieties and hybrids suitable for specific regions was always in the domain of the ministry of agriculture, but*

this is not now the case with Bt hybrids " - Furthermore, *"Most of the Bt hybrids are of 180-to 200-day duration and are not suited for rain-fed conditions", "Hybrid seeds are costly and are generally sown late after ensuring adequate soil moisture to avoid the economic burden of re-sowing. Late sown maturing hybrids suffer from severe moisture stress during the critical period of peak boll formation, which takes place much later after the rains recede. The moisture stress is higher in rain-fed regions in shallow, marginal soils, which do not hold water adequate to support boll formation. This results in low yields". "Hybrids also tend to be input-intensive, so they are not suitable for at least half the, area in the country, which 4s under marginal soils in rain-fed regions* ".(K.Kranthi:http://businessstandard.com/iridia/news/ indiscriminate-useany-tech-nologv-becomes-counter-productive-k-r-kranti/480232/ and 10 years of Bt cotton part III).

The TEC notes that it has been known from the start that hybrid Bt cotton is unsuitable for and has failed repeatedly under rain-fed farming This problem gathers even more gravitas on the basis that 65% of our farming land is rain-fed with the balance being irrigated. This is also reflected in the pattern of cotton sowing in non-irrigated and irrigated farmlands which is in the same proportion respectively which has biological and economic consequences ('Revolution in Indian Cotton': Directorate of Cotton Development, DAC MoA, 2009). The TEC also notes that Bt cotton.is the common factor in many of the farmer suicides across India (P Sainath, editor rural affairs of'the Hindu'), but in Vidharbha, it is official that Bt cotton failure is linked with farmer suicides. The Minister of Agriculture, (Maharashra) Shri Radhakrishna Vikhe-Patil, said in April 2012:

"The cotton crop yield this year is 45 lakh bales (need year). Last year, it was 85 lakh bales — Bt cotton cultivation is not working in Vidarbha region. It is causing more distress to the farmers" (1ittp://www.dnaindia.com/mumbai/report more-trouble-for-. debt-hit-vidarbha-farmers_ 1679818)

Kranthi says, *"Additionally, many hybrids are susceptible to sap-sucking insects, leaf-curl virus and leaf reddening, adding to input costs and loss of yield. Bt cotton in*

By 2011, more than 96 per cent of the cotton area was under hybrid cotton, more specifically Bt hybrid. For rain-fed regions, especially with shallow-marginal soils, characterized by low input use, early maturing straight (fertile) varieties are the best option. The main advantage with straight varieties is that farmers can reuse farm-saved seeds and can take the liberty of early dry sowing, even before the onset of the monsoon, without having to worry about the risks of poor germination and re-sowing. For best yield benefits, it is important that the hybrids or fertile varieties must be ideally suited for specific agro-eco-zones. For example the best options for rain fed regions would be early-maturing short duration straight varieties, resistant to sucking pests, dwarf statured, zero-monopodial, which are amenable for high-density planting at populations of100,000 per acre or more. For deep-black soils and irrigated regions, sap-sucking-pest resistant long duration hybrids can be an ideal option ".

To sum up this evidence: Bt-hybrid seed is much more expensive than locally adapted 'desi' varieties. Hybrid cotton varieties also require more expensive inputs and have less capacity to compensate for pest damage. In much of the rain-fed farming, it would be beneficial to use early maturing, short duration straight varieties in high density planting systems (HDPS). This will also help in reducing the cost of seed, pesticides and weed management, and would avoid the late season build up of pests. For sustainability and establishment of a resilient crop production system, "straight varieties' always score better as compared to hybrids. Hybrids are inherently responsive to high level of inputs and are consistently profitable only in high-input intensive irrigated systems. For achieving high yields in a sustainable manner, cultivating straight varieties as occur in rain fed systems with low input costs is the best option in 2/3 of Indian cotton.

Given the wide ramifications for farmers of the decision favouring Bt cotton in hybrids including: their unsuitability to 2/3 of agriculture in our country (in marginal soil and rainfed conditions), the chronic and growing water scarcity, the dire threat of climate change that is already apparent and which will put further pressure on water resources in

agriculture, resultant increased crop failures in rain fed farmlands and economic ruin of small farmers and the ultimate cost in life to some of these farmers, and the commercial 'value capture[5] strategy of Industry, particularly Monsanto, the TEC recommend a high level enquiry into the decision to engineer Bt into hybrid varieties of cotton. • Sustainability of Bt cotton: Annexure 8 Odeals with this question in some detail. There is substantial literature both laboratory-based, glass-house based as well as in the field to inform our opinion on this issue, on the basis of which the TEC conclude that Bt transgenics is not a sustainable technology and particularly for India with our preponderance of small holder farmers, and especially in a-"value capture system". This is particularly true of hybrid varieties in Bt cotton (ref. (i) above). The field data (on-ground reality) is especially valuable coming as it does from the US which keeps reliable records, and where we have the longest commercial planting of Bt and other GM crops for meaningful analyses. It is worth reproducing from Section 1 two aspects of the evidence, field-based data and a glass-house study as follows.

US EPA review of Bt maize resistance in the US

Ref: Nov 2011 report of the US EPA: Updated BPPD (Biopesticides and Pollution Prevention Division) IRM (Insect resistance monitoring) Review of Reports of Unexpected Cry3Bbl damage in Monsanto's 2009 corn Rootworm dated 22nd Nov 2011.

Bt corn in the US demonstrates a serious and outstanding example of *"expected"* insect corn rootworm resistance to a Bt toxin, which has caused severe rootworm injury to Bt maize and which was recorded for the first time in Iowa in 2011, but likely had been developing for some time (Gassmann, Aaron J., 2012) 'Field-evolved resistance to Bt maize by western corn rootworm: Predictions from the laboratory and effects in **the** field' . *Journal of^ Invertebrate Pathology* 110: 287-293. DOI: 10.1016/j.jip.2012.04.006

The problem appears to be also emerging in other key maize producing States of the US and becoming chronic. This is the first time in over 20 years of planting of Bt corn that resistance has been confirmed in the US, which has the longest history of any country under GM crop cultivation and because, a 20% *'refuge'* policy to manage

Admission of how serious the problem is comes from 22 leading US academic corn experts in their strong message of caution in a letter dated March 5 2012 to the Environmental Protection Agency telling regulators they are worried about long-term corn production prospects *because of the failure of the genetic modifications in corn aimed at protection from rootworm.*

(http://in.reuters.com/article/2012/03/09/us-monsanto-corn-idINBRE82815Z20120309)

The US EPA review describes Monsanto's insect resistance monitoring strategy for Bt. maize in the US Midwest as *"inadequate and likely to miss early resistance events "*. It also highlights how the crop itself may be causing the problem and

• how a failure to enforce mitigation measures, like refuges and rotations, is making it worse.

It severely criticizes Monsanto's approach to monitoring resistance in the maize pest in four US States and their less than transparent reporting. Starting in 2009, possible increases in resistance to the Bt toxin Cry3Bl (events Mon 863 and Mon 88017) were noted with the EPA giving several reasons for this including, failure to sample for resistant adults from problem fields and failure to do follow-up studies to determine resistance to its gene. An important implication of this is that more chemical insecticides may be used to control the resistant rootworms in the face of continued high cost for Bt seed.

The EPA findings are not a surprise. Laboratory breeding experiments with western corn root worm have demonstrated that, *"Resistance evolved after just three generations of selection on Cry3B maize."*

The US EPA review suggests the breakdown in effectiveness of GM maize is caused by a number of factors including:

a. Bt plants producing too low a dose of toxin to kill pests, and hence fostering resistance developing in those that survive.

b. Farmers failing to plant non-GM crops refuges to ensure sufficient non-resistant adults are present to mate with resistant individuals,

preventing the recessive resistance from becoming dominant in the population.

c. Continuous cultivation of the same Bt maize on the same land for several years without rotation that without Bt maize could resolve the rootworm problem (work of Tom Turpin, Purdue University circa 1968)

d. The US EPA also presents data showing the amount of toxin needed to kill the western corn root worm in *problem areas* has increased by as much as one hundred times indicating the severity of the resistance problem. The data on LC (90), (i.e. the concentration of toxin required to kill about 90% of the pest larval) published in the Annual Reports of the Central Institute for Cotton Research, also suggest that the cotton pest *Helicoverpa* is progressively enhancing the level of resilience to Bt-toxin.

The Agency warns that merely resorting to other GM maize varieties using several Bt toxins may not provide a lasting solution because of the likelihood of cross resistance.

* Pest Tradeoffs in Technology:

The rapid adoption of genetically engineered (GE) plants that express insecticidal Cry proteins derived from *Bacillus thuringiensis* (Bt) has raised concerns about their potential impact on non-target organisms (Ponsard, S., A.P. Gutierrez and N.J. Mills 2002. Effects of Bt-toxin in transgenic cotton on the adult longeviety of four **heteropteran predators.** *Environ. Entomol.* 31(6): 1197-1205), The survival of predators was adversely affected. This includes the possibility that non-target herbivores released from natural controls may develop into pests (plant bugs in the USA. China and India). For example, in China, Zhao et al. (2011) found empirical evidence that farmers in China perceive a substantial increase in secondary pests after the introduction of Bt cottonj, Zhao, JH , Ho, P ; Azadi, H 2011 *Benefits ofBt cotton counterbalanced by secondary pests? Perceptions of ecological change in China Environmental Monitoring and Assessment* 173: 985-994 DOI: 10.1007/s 10661-

by Gutierrez et al (2006) show that reduced survival of natural enemies also lead to increase in secondary pests that are not well controlled by Bt cotton, among them armyworms, whiteflies and plant bugs (Gutierrez, A. P., J J. Adamcyzk Jr. and S. Ponsard. 2006, *A Physiologicallybased model of Bt cotton-pest interactions: II bollworm-defoliator-natural enemy interactions. Ecological Modelling* 191: 360-382.).

The second is a study conducted under glass house conditions by Steffen Hagenbucher et al (2013, *Proc. Royal Society B,* 280 http://dx.doi.org/10.1098/rspb.2013.0042) 'Pest tradeoffs in technology: reduced damage by caterpillars in Bt cotton benefits aphids': Steffen Hagenbucher et al 2013 (http://dx.doi.Org/l0.1098/rspb.2013.0042). The authors propose that lack of herbivore-induced secondary metabolites in Bt cotton represents a mechanism that benefits non-target herbivores. In nature, plants produce allelo-chemicals in response to herbivore feeding, and the study shows that (with) the effective suppression of Bt-sensitive lepidopteran herbivores in Bt cotton, that levels of induced terpenoids are reduced. The report also shows that changes in the overall level of these defensive secondary metabolites are associated with improved performance of a Bt-insensitive herbivore, the cotton aphid, under glasshouse conditions. These effects, however, were not as clearly evident under field conditions as aphid populations were not correlated with the amount of terpenoids measured in the plants, but this is to be expected as the accuracy of the two measures are orders of magnitude different. Nevertheless, increased aphid numbers were visible in Bt cotton compared with rion-Bt cotton on some sampling dates, and aphids are known vectors of plant viruses. Identification of these mechanisms increases our understanding of how insect-resistant crops impact herbivore and natural enemy communities, and helps us understand the variable results of GE varieties.

There is also evidence of the development of Bt resistance in bollworm in Pakistan.

(AM, Anwaar et al 2012 'Field Evolved Resistance in *Helicoverpa armigera* (Lepidoptera: Noctuidae) to Bacillus thuringiensis Toxin CrylAc in Pakistan[5] . *PLOS ONE* Volume:? Issue: 10 Article Number: e47309 DOI: 10.1371/journal.pone.0047309 Published: OCT 15 2012). The study authors want to carry out research further into what other Bt insensitive herbivores may develop into cotton pests (e.g., defoliators, plant bug, mealybugs). This is an important question that must be taken seriously, as in India, China and elsewhere, there have been several Bt cotton crop failures due to 'other' pests, some never seen before in India. These have been explained, away as 'secondary pests' as if this problem somehow, is unconnected with Bt crops/cotton, and is not an impact of the technology. In China, fertile varieties are used in Bt cotton not hybrids, but secondary pests are nevertheless infesting the Bt cotton crop. So this is a common problem to both hybrids and straight varieties of Bt cotton that the Bt technology does not solve (e.g., the current outbreak of armyworms in Bt and non Bt Maize in Brazil). The above study presents a new dark side to the picture of secondary pest infestation emerging as an 'unintended[5] effect after more than 2 decades of Bt crops, and provides a reason for pest attacks by aphids and other pests, and requires to be thoroughly investigated,

As already discussed earlier, these reports, and the wide literature available on the shortcomings of Insect Resistance Management strategy (IRM), demonstrate a serious deficiency in Bt crops, and raise real questions about the sustainability of the technology. In the US (as stated earlier) an official panel of scientists recommended a 50% refuge, that if the pests are a serious problem would leave 50% of the crop unprotected. Clearly this is unacceptable for small farmers. Despite this recommendation, the EPA went with the minority view of 20%, with the current problem of resistance in rootworm being partly a result of this decision. Any technology that requires a 50 % refuge is likely doomed (what would be the point). In India, even given that there are other crop hosts such as pigeon pea that may provide a natural refuge for susceptibility in bollworm that is the target pest of Bt cotton, small farm sizes make IRM strategies based on 'killing[5] the pest and managing insect resistance through transgenics unsustainable. There are questions about the effectiveness of 'refuge-in-the-bag[5] and the reduced efficacy of a

research must be done.

Therefore,' it is evident that on its own, even without the serious implications of the above study, difficult and failing IRM for Bt cotton and other Bt crops must raise the question of the sustainability of Bt transgenics. Considering the cumulative evidence, the TEC is of the opinion that pests need to be 'managed[5], and this requires renewed public investments in a restored extension services, in alternative agri systems like NPM/IPM (Non-pesticidal management/integrated pest management) etc which are demonstrating ' resilience and success. Pest management in alternative farming methods as opposed to insect resistance management looks increasingly more logical as a sustainable approach, based on the very robust evidence we have provided. Furthermore, because of intellectual property rights (IPRs) restriction in GMO crops in many areas (e.g., the USA), research of IPM approaches is becoming increasingly difficult to conduct in the USA (e.g., the letter of protest of leading maize Entomologists in the USA), and as the GE technology matures in India may also restrict research here.

* Impact on India's weaving industry and organic cotton production:

According to the Confederation of Indian Textile Industries (CITI) there is a mis-match between what is produced and the current requirement of the Indian Textile Industry which is 37% long and extra-long staple cotton, 53% medium staple and 10% short staple. The supply on the other hand is predominantly long staple (US cotton) with medium at around 11% and a negligible quantity of short staple, the last two characterized by desi varieties. As soon as the Bt hybrids were approved for commercial cultivation in the year 2002, the composition of species drastically changed. Presently all the cotton in India is under *hirsutum* (90%) leaving only 4-5% under *arboreum* & *harbaceum* and negligible area under *barbadance*.. As a result there is a shortage of short & ELS (extra long staple) cotton in recent years as demanded by the textile Industries.

India is a major player in world cotton production. As an Industrial' activity, employment and foreign exchange earner$_s$ it provides raw material for approximately 15 00 mills, 4 million handlooms, 7 million power looms, the livelihood of 60 million people in cultivation, processing, trade and textiles, employment to 30 million, second only to agriculture. Yet, there has been no mention of the impacts of Bt cotton on this sector. These impacts also enter the domain of the vast cultural heritage of India in weaving and spinning, which have evolved over thousands of years in different styles and patterns in different parts of the country.

The TEC is of the view that these matters should have been studied comprehensively before a decision to commercialise Bt cotton was taken. This is part of the protocols of risk assessment to ascertain before hand, before a decision is taken to ■ introduce GM crop, whether it is required or not, and assessing its' likely multiple impacts on several socio-economic aspects. It doesn't stop there; thereafter, matters should have been closely watched, during cautious releases of the technology in consultation with numerous stakeholders and other Ministries. There has been no mention of any of this. Obviously, these are not matters for Regulators who may not decide as scientists on matters encompassing the knowledge of the art and culture of weaving or its 'industrial[5] economic activity including a market competitive advantage in the production and supply of organic cotton for export. Cotton is all of this, an amazing crop of great importance to peoples and India. The TEC finds agreement with Dr Kranthi when he says of the limited point concerning the choice hybrids and varieties:

"— *The presence of Bt-varieties could have changed the Indian cotton scenario. Also, while GEAC and RCGM should have focused only on biosafety approval, instead of evaluating and approving 1128 Bt-hybrids, the identification of appropriate Bt-hybrids or varieties should have been the domain of the ICAR (Indian Council of Agricultural Research) and the NARS (National Agricultural Research System) ".*

inuia is currenuy me largesi organic corcon proaucer m me wona ana us leaamg exporter. In 2010-11, India exported 17,363 Metric Tonnes of organic cotton and textiles or 25%. share of this market (Source: APED A, Ministry of Commerce). Nearly 200,000 farmers are part of the organic cotton movement in India. The TEC has however, received reports of the significant incidence of contamination of organic cotton at different points in the supply chain. In 2008, two certification agencies had their accreditation with APEDA suspended for failing to detect Bt contamination of organic cotton. The Agencies were fined Rs. 15 lakhs and Rs. 7.5 lakhs for this failure. (Source: http://www.business-standard.com/article/economy-policy/reports-of-bt-contamination-stain-premium-organic-cotton-exports-110020600073_1.html). The contamination of < organic cotton is affecting our export markets and export potential. It seems that no proactive action has been taken by the government to address the issues according to industry players (ref: 'Integrity in the Indian Organic Cotton Value Chain: a summary of issues and gaps for potential action, a public interest report by ICCO, Organic Exchange and Solidaridad, February 2010).

There is also the connected matter of the non-availability of non-GM seed and quality seed. We note that a similar pattern with the cotton, corn and soy non-gm seed supply in the US, where farmers are finding it impossible to source Non-GM seed. Over 90%-of India's cotton seed is in 'Industry' hands, essentially Monsanto. This too is the prevailing pattern in other GM producing countries including the US.

These are matters of profound concern to the national interest and our farmers, especially in view of the "value capture strategy" used by Monsanto in India. The issue of sovereign food ownership in the form of our seeds, and the resulting issue of food security are concerns which arise directly out of the answer to the question ~ who owns our seeds? If India, despite the questionable evidence to the contrary, decides nonetheless, to expand GMOs into other crops including food crops and oil seeds, we must expect the patterns we

are seeing for Bt cotton to be repeated with enormous biological, health and economic implications for the country. This is a central issue of food security in all its reality.

- Pesticide use and Bt cotton:

The table on the next page for the years 2002-2010 shows that the use of pesticides in value terms in major cotton growing States is rising despite the introduction of Bt cotton, and this is despite the replacement of high volume pesticides by low volume ones. Dr. K R Kranthi of Central Institute of Cotton Research says: *"The quantity of pesticide, generally shown in litres or Kgs does not actually represent the correct trends. The new generation insecticides are recommended to be used at 100-200 ml per hectare with 10-50 gms active ingredient in them, as compared to the conventional insecticides which were used at 3-5 litres per hectare with 500 gm to 2 kg active ingredient. Insecticides such as BHC were recommended at 15 to 20 kg per hectare. Therefore, the net insecticide quantity per hectare would get reduced significantly, despite the fact that farmers may have spent more. "(http://agrariancrisis.in/20I2/06/28/pesticide- use-in-bt-cotton-dr-kesavraj-kranthi/).*

It is also noted that overall pesticide use has risen in the last 5 years despite the fact that the CICR acknowledges that susceptible bollworm populations are on the ■ decline. Therefore, while the per hectare value of pesticides used to control the bollworm may have decreased, the incidence of 'secondary' pests (sucking insect pests) of Bt cotton are causing a significant rise in the total value of pesticides used in Bt cotton cultivation. *"A mealybug named Phenacoccus solenopsis, not observed earlier in India, has spread across northern, central and western states after it was first recognized as a cotton pest about five years ago. In desperation, farmers have begun to spray "extremely hazardous" pesticides on the cotton to fight the insect, which has a waxy coating over its surface that makes it hard to kill with less toxic pesticides" (Kranthi, in his 10 year review in 3 parts).* Insecticide use on sucking pests has increased from 2374 M tonnes in 2006 to 7270 M tonnes in 2010 and 6372 M tonnes in 2011. The value of insecticides used on cotton for sucking pest control was Rs 272 crores in 2006, which increased to Rs

- Approval of 1128 Bt-hybrids across the country by 2012, many of which are susceptible to sucking pests.
- Increase in the area under sucking pest-susceptible hybrids
- Increase in resistance levels of jassids to Imidacloprid and many other recommended insecticides that increase insecticide use,

Since 2002, every Bt-cotton seed has been treated with the highly effective systemic insecticide imidacloprid. (Bt cotton Q & A, Dr K R Kranthi, 2012; and Down To Earth report - http://www.downtoearth.orR.in/content/cotton-saga-unravels).

Imidacloprid is a systemic insecticide which acts as an insect neurotoxin, that applied to seed insures that not only would early season pests such as mealybug are killed but also their natural enemies that early in the season (at their most vulnerable stage) releases the pest, from control later in the season. It appears to be a classic case of secondary pest outbreak created by adverse insecticide use associated with Bt hybrid cotton and possibly by the Bt cotton toxin itself.(Plant bugs have also increased in importance in Bt cotton in the USA). Moreover, Bt crops are pesticidal crops which internalise the toxin or pesticide. More indicative that insecticidal GM crops actually increase the insecticide load in agriculture is the analyses presented by Dr. Charles Benbrook; He analysed insecticide use in GM and non-GM equivalent crops over the first 16 years of use in the US, from 1996 to 2011. The analysis is based on widely accepted . USDA data. He compares insecticide (endotoxin) production in Bt corn (for the European corn borer), compared with chemical insecticide sprays displaced. The data confirm that GM Bt crops do not reduce or eliminate insecticides, but simply change the way that pesticides are used, from sprayed on, to built in. (ref GM watch 4 July 2012). For example, in Bt corn for rootworm control insecticide (endotoxin) production compared with chemical insecticide sprays displaced:

For 0.19 pounds. chemical insecticide sprays applied per acre for rootworm control on non-GM corn in 2010 (MON 88017), CrySBbI produces 1.7 pounds endotoxin

per acre, Dow/Pioneer (DAS 59122-7), Cry34Abl plus Cry35Abl produces 2.5 pounds per acre.

Other GE' technologies such as herbicide tolerance (HT) has greatly increased herbicide use in areas around the world where it has.been introduced, with attendant pollution of waters that create human and biodiversity problems.

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Source: Directorate of Plant Protection, Quarantine & Storage data, Govt of India).

Bt hybrid Cotton Performance Analyses (yield and area)

At the outset, it must be stated that we are nowhere near a long enough period under commercial planting of Bt cotton for a trend to become visible to give us a clear picture. Bt cotton was first planted in 2002, when the market share (MS) of Bt cotton was negligible and even by 2004-05 it had reached a mere 5.6% (Dr K Kranthi's estimates of adoption are used in these analyses, table. 1 and charts 1-3). These estimates are generally accepted as good indicators of the rate of adoption of Bt cotton. It therefore makes sense to call 2004-05 (or 2004) as a watershed year which divides the pre Bt era from the post Bt era to aid the analyses even in 2005, the market share of Bt was just 11.5%. On this basis, and starting from 2005-06 (or 2005) we have just 7 years of data for Bt cotton (up to 2012), not 10 years (as the Industry and Mo A claim).

Published official data are from two sources: the DES (Department of Economics and Statistics) and. the CAB (Cotton Advisory Board), and show that the area figures are virtually the same. The TEC notes that CICR prefers to use CAB data for yield as they are considered more reliable and external, to in-country bias. The TEC analyses, however, in Charts 1-3, has used both sources of data.

« **Dr Kranthi's analyses of yield:** Given in kg/hectare (CAB data) are provided below in Table 1. Area figures are DES data.

Table 1:

Yieidshave certainly increased after the introduction of Bt cotton in India.

	Total area lakh ha	BG	BG-II	Bt area, lakh ha	Btaiea%	'Lakh bales	Kg/hectoK	
2001	87					158		*m*
2009	78	0.294		0.294	0.38	139		302
2003	77.85	0.931	0.931	1.2		182		399
9(304	■ 89.2	4.985		4.985	5.59	246		470
?005	88.17	10.15-	■	10.148	11.51	244		472
2006N	91.73	36.5	1.5	38	41.42	281		521
2007	94.39	58.74	'■ 4.6'63.34	67.1		307		554
2008	94,06	55.6		20.4		76	80.8289	524
2009	103.12	36.8		48.2,	85	82.43	305	503
9010	111.61-	37,4	63,8	101.2	90.67	339	517	
2011	121.91	26.5		85.4	111.9	91.79	352	492

Compiled by Kranthi, CIGR

From Chapter 4, p.20, Q.No. 27 'Have Yields increased in India after the introduction of Bt-cotton? By Kranthi in Bt-Cotton Q & A, (2012)

Comments:

i. During 1999-2000 and 2000-01 the cotton area in the country again declined to 85-87 lakh hectare. In the year 2001 -02, the cotton area in our country again increased to 91.30 lakh hectares and thereafter the area declined to 76.00 -77.00 lakh hectares in the year 02-03 & 03-04 and again come up to the level of 87.90 lakh hectares in the year 2004.05. (Ref pg 19 of Q & A) (DES).

ii. Since 2006, the productivity (kg/hectare) is stagnating at around 500 kg/ha, whereas the area under cotton cultivation has been steadily increasing from 91.73 lakh hectares in 2006 to 121.91 lakh hectares in 2011 mostly as Bt cotton. Table 1 also show that in 2004 and 2005, the productivity was about 470 kg/ha from about 89 lakh hectares, and the productivity rose to about 500 kg/ha in 2010 - 2011 from, about 120 million hectares of which 90% was

«vw»uac ui uic piauuug ui a vast majority oi inappropriate hybrids, and not the Bt technology which protects against bollworms and a few caterpillars, but is not a component of yield enhancement.

Dr Kranthi also suggests that if yields have to be increased, new strategies appropriate for rainfed regions (nearly 2/3rd of the cotton cultivation area) need to developed. He cites the examples of Brazil and China where yields of 40 to 50 Quintals/ha (4000 to 5000 kg/ha) are obtained under rain-fed conditions using high density planting of straight varieties.

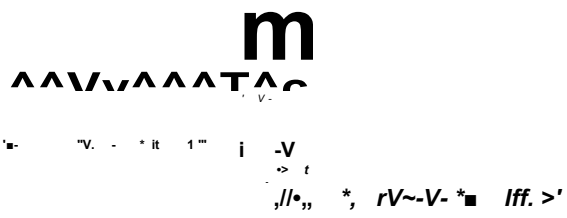
iii. As to the question of reducing the cost of cotton cultivation and enhancing yields, Dr. Kranthi submits that Bt-hybrid seed is much more expensive than locally adapted 'desi[5] varieties (and they are not bred for local conditions). Hybrid cotton varieties also require more expensive inputs. In much of the rainfed areas, it would be beneficial to use early maturing, short duration straight varieties, in high density planting systems (HDPS). This will also help in reducing the cost of seed, pesticides and weed management. Further, he points out that for sustainability and establishment of a resilient crop production system, straight varieties always score better as compared to hybrids. Hybrids are inherently responsive to high level of inputs and are profitable in high-input intensive . irrigated systems that are the exception in India. For achieving high yields in a sustainable manner, cultivating HDP of straight varieties with low input costs is the best option in most of India. iv. Finally, to a specific and important question of whether the increase in yield is because of Bt-cotton alone, Dr. Kranthi emphatically states that it is not correct to assume that cotton yields

in India doubled because of Bt-cotton. His statements are found in . pages 21-22, from "Bt-cotton, Q& A, K"Kranthi 2012.

32. Is the increase in yield because of Bi cotton alone?

Though GM Bt cotton technology has brought down pesticide use by about 50 per cent, it is not correct to assume that cotton yields in India doubled only because of Bt cotton.

Bt cotton was introduced in 2002 primarily for bollworm control. Subsequently, there has been a significant leap in the cotton production. During 2001, India produced about 158 lakh bales, which increased to 243 lakh bales in 2004 and 345 lakh bales by 2011. However, it is interesting to note that the yield, increase by 2004 was mainly due to the IPM/IRM strategies, new insecticides, new hybrids, new area in Gujarat, apart from the 5.4% area under Bt cotton. The area under non-Bt straight varieties was about 55.0% in 2004. and non-Bt hybrids at 38.0%. Cotton ' Advisory Board data show that cotton j vields increased by about 60 per cent in ' three vears between 2002 and 2004when *I* the area under Bt cotton was a meager i 5 6 per cent and the area under non-Bt % cotton was 94.4 per cent. The yields did 1 not increase significantly more than the \ pre-Bt era even until* 2011 when the Bt *i* cotton area touched 96 per cent.



The area under irrigation increased mainly in. Gujarat after the year 2000 especially in the form of check-dams in the Saurashtra belt which had new areas of about 8-9 lakh hectares under cotton. Currently about one-third of India's production is derived from the state which has one-fourth of the cotton area. Clearly, apart from the contribution 6f Bt cotton, the increase in yield may have also been due to other major changes in the past 8 years. Some perceptible changes include, implementation on IPM and IRM on a large scale by the Ministry of Agriculture and ICAR, the introduction of some excellent cotton hybrids, increase in cotton area in Gujarat from 15

lakh ha to 26 lakh ha, increase in check dams and drip irrigation systems, increase in hybrid cotton area from 40% to 90% and introduction of 6-7 new effective insecticide molecules for bollworm control and,sucking pest management

- The TEC Analyses of Bt cotton performance, reference bar charts 1-3

  Some guiding observations to the analyses are as follows (based on the valuable 'insider' knowledge of the CICR and other data sourced in the MoA, which must be kept in mind when assessing Bt cotton vis-vis 'other' factors affecting yield:

oi syninenc pyrethroids which were cheap and effective and killed everything, not just the bollworm (DES data shows a 30+% increase). ii. In 2000, there was a significant dip in yield, a year of high bollworm attack which is reflected in both DEA and CAB data (see charts 2 & 3). As stated earlier, 2002 and 2003 were also years of decline in area planted under cotton. iii. 2004 and 2005 shows significant recovery; these peaks are not primarily due to Bt cotton (given its low market share in those years), but to the introduction of seed-treatment insecticide (Gaucho) and several other insecticides such as Spinosad (Tracer), Indoxacarb (Avaunt), Emamectin, Rynaxypyr (Coragen) etc which were effective in controlling bollworms on the dominant non-Bt cottons at the time. iv. In Gujarat, irrigation from 100,000 check dams had a significant impact on Bt cotton in Saurashtra giving yields of 650 kg /hectare for first-time planting of Bt cotton on rich soils of displaced groundnut. During 2002 to 2006 an area of about 3.0 lakh hectares of fertile irrigated cotton area was added in Saurashtra (Gujarat), which resulted in yield increases. This shows two factors, the effects of good soil and irrigation.

- **AREA: Analyses of area planted under Bt** cotton **(a measure of** adoption):

The 3 bar charts (see Charts 1, 2, 3) provide easy-to-read analyses of the performance of Bt cotton. Based on the foregoing comments, the analyses of the biotech industry on adoption of Bt cotton i.e. area and which the Ministry of Agriculture also supports is based on an untypical, erroneous starting year of 2002, when we might note the DES-CAB data also show a significant dip in the area planted under cotton of 7.7 million ha. As a further point the market share in 2002 of Bt cotton was a mere 0.38%, hence clearly, choosing 2002 as the starting point of the industry analyses is not justified. The figures on this basis bear no relation to the Clive James' (ISAAA, an Industry-funded promoter of GM crop technology) statistics claiming production and yield increased by a factor of more than 2.5 times.

On the other-hand, it makes better sense to use 2005 (2005-06) as the base year for analysing Bt cotton adoption despite the fact that the market share of Bt cotton was around 11.5% which would still be biased toward the industry perspective. Thus, the Bt cotton era of 2005 -2011 is only 7 and not 10 years. On this basis, the (simple) area increase in the expansion of the 'Cotton Economy' is 40% (rounded-up) during a 7 year period. As much as anything, the increase demonstrates the 'hopes' expressed by farmers in the 'promise' of Bt cotton. In this time, the market share of Bt cotton reached over 90% with a monopoly control on seeds, a reduction in Desi varieties, the displacement of Indian short staple varieties giving way to long staple American cotton hybrids, and a commensurate reduction in the gene pool of adapted local varieties. Furthermore, the government has failed to demonstrate that the rate of adoption of Bt cotton has increased farmer income or cotton yield.

- Yield: Analyses of yield of cotton and Bt cotton:
  - The pre Bt Cotton era 1996 - 2004: For both DES and CAB data, these analyses are based on the starting base year of 1996 in the pre-Bt cotton era, using a 4 year average (1996-1999). (There are fluctuations in each of these years, making it difficult to choose a base year, hence an average for the 4 years has been applied).. Both DES and CAB data show a significant increase in the pre-Bt cotton era yields of 38% and 52% respectively. This increase continued from the trend of the 90s and is attributed to the use of hybrid cotton seed vigour, seed treatment, the use of effective pyrethroid insecticides and irrigation in some areas.

  - Bt Cotton era 2005 - 2011: In the Bt era starting 2005 to 2011-12, DES data shows a 3% increase in yield compared over the pre Bt era. The CAB data on the other hand shows a levelling off, of virtually no increase over the pre-Bt years. Both the CAB and DES data show that Bt cotton yields level off to around a figure of 500 kg+/hectare. Yet the official stance of Industry and agencies-such as IFPRI etc. is claims of spectacular doubling of yield gains from Bt cotton attributable to the Bt gene . They base this erroneous

__ ,—__«,vawuovu *uy* a racier or *A . I* times. There is absolutely no justification for this as it is a distortion of the facts.

Therefore, the TEC's observation is that the yield growth (DES data), which started in the closing decade of the 80s and continued right up to 2004 has continued at a reduced pace into the Bt cotton era when yield increase virtually stopped. CAB data shows virtually no change in yield compared to the pre-Bt era. It furthermore, does not take a sophisticated statistical analysis to observe that in the short period of 7 years which characterise the Bt era 2005-2011, there is a levelling off in yield ■- DES and CAB data are both consistent in this observation. Furthermore, even given these modest gains, in the absence of a comparison with the nearest isogenic lines of Non-Bt cotton, no claims about the contribution of the Bt trait to yield is possible. Furthermore, other 'factors' are of key importance to the increased yield and include the use of hybrids, seed treatment, the increase in irrigated farm lands especially in Gujarat (vs yield in un-irrigated areas), the low incidence of the bollworm in the Bt era that likely had as much to do with reductions in pesticide use), etc.

The TEC also draws attention to other data ie the experience of Bt crops in the ■ US which is relevant for analyses because of the long experience of growing Bt crops in the US and the availability of reliable data.

« **Other Data**

i. US: Genetic Engineering and Crop Productivity in the U.S (Gurian **Sherman 2009** - relevant sections quoted below)

To evaluate the contribution of GE to crop yield, Gurian Sherman of Union of concerned Scientists (UCS) evaluated *peer-reviewed science research and data from the US Department of Agriculture.* He states that:

. *"The yield effects of the crop variety are especially difficult to separate from the effects of the transgene, because both are encompassed in the growth of the plant and not readily separated from each other. Farmers, for example, may buy a new engineered crop variety and obtain higher yields than for a previous non-engineered variety. It would be natural to attribute these yield gains to the engineered gene, when typically the crop variety that the gene has been placed into is already improved for yield compared to the older variety".* (This comment is particularly relevant to the Indian context where we know from our study of the available literature and feed -back from farmer groups/civil society groups that the best improved hybrids were.engineered to , include the Bt gene (TEC comment). For Bt corn, this would be true of the US as well.

For example, data from the USDA show that corn productivity increased by about 28 percent between 1996 and 2008. 25% was due to factors other than GE_3 or about 86 percent of the total increase in yield in corn in those years. Factors that typically increase crop productivity fall into two general categories: crop breeding and improved agronomy. Historically, about half of the yield increases in corn have been attributed to breeding. GE contributed about 14 percent of the yield increase between 1996 and 2008.

* Georgia Study (4-year study reported in *Agronomy Journal* by researchers at the University of Georgia and the US Department of Agriculture):

Conclusion: The use of transgenic cotton does not provide increased returns to the farmer.

The researchers grew a number of different cultivars of cotton at two locations in the state of Georgia. The transgenic varieties consisted of two main traits, herbicide tolerance and Bt biopesticides, alone and variously combined (stacked).

Five different non-transgenic cotton cultivars were also grown. Each cultivar, whether transgenic or not, was managed to maximise profit, as consistent with practices recommended by the University of Georgia.

_-0_ ,,,, _ ,v b«^^»w .vi$_U$>iio m«i* a uwu"uiiusgcuiu system in any year or location." The returns were dominated by yields that could be reduced by 30-40 percent, as in 2004 at one of the two locations, when the non-transgenic variety produced a return of $1274.81 per ha compared with $858.73 for BR, $737.41 for B2R$_5$ and $876.14 for LL.

- http://www.i-sis.org.uk/noAdvantageInTransgenicCotton.php

India should have done similar studies to produce such comparisons for **Bt and non-Bt near isogenic** lines before **the** wide spread introduction.

• Conclusions: Bt cotton

The TEC is of the view that on the basis of. current data there is no spectacular yield gain that may be claimed for Bt cotton and if there is, it has yet to be determined. At best, the current data shows a levelling off of yield to a level of around 500kg+/nectare. Within this figure is a factor for yield attributable to reasons (as listed earlier) other than the Bt gene. More detailed analyses over a longer time period will be required to provide answers, to separate the effects of weather limitations, such as water stress and poor agronomic practices that limit yield potential In the US, yield was never the reason for the introduction of Bt crops, as *insignificant* yield gain accrued from. Bt varieties fas opposed to hybrids). Lower insecticide usage was the aim. However, this position is seen to be threatened by the rising and significant resistance to the Bt gene in corn pests (and by the rapid rise in herbicide use and the attendant development of resistant weeds).. The position in India with secondary pests of Bt cotton on the rise, and crop failures in many States directly attributable to these pests, have increased insecticide use that exacerbate secondary pest outbreaks that the Bt technology does not address, also perhaps the reported resistance of the cotton bollworm to Bt and insecticides. The recent new study raises concerns with respect to Bt technology because of its potential impact on non-target organisms (secondary pest outbreaks and natural enemies). In India, this includes the possibility that non-target herbivores develop into major pests (the cotton mealybug and the jassid bugs and others). We note_that IRM and refuge strategies are not practiced in India and are showing serious cracks, and the need for a refuge is a serious flaw in

the technology. Stacked genes are not the answer even according to the US EPA. Further, the TEC's position is in line with the UNEP/IAASTD call for diverse sustainable agri solutions to provide solution for pest problems; that pests must be *'managed' for sustainable solutions in agriculture.*. It is our overall conclusion that the use ofthe Bt gene is not a sustainable technology under Indian conditions.

Based on our findings in Section I, we also do not accept that Bt crops have been shown to be safe, especially when used in food crops. On the contrary, there are serious health concerns with the direct effects of these toxins, and these will only increase as new technologies are pyramided (RNA manipulations technology) - (Heinemann, J.A., S. Z.Agapito-Tenfen. And J. A. Carman. 2013 'A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assessments'. *Environ. Int.* 55: 43-55.)

The wider assessment of the performance of Bt cotton in terms of soil health, and other impacts would also have become apparent had comprehensive PMM models been instituted with the transparent objective to really assess what was happening on the ground, and the failure to do this is cause for serious concern. The TEC notes:

® There is a near total monopoly of seeds and intellectual property rights and the research constraints they impose in the hands of mainly Monsanto.. • This pattern of control in India and in other countries, including the narrowing of the local gene pool of crops, has disastrous implication for sovereign food and India's food security, were industry using the experience of Bt cotton seeks to extend the technology to our food crops. 9 The rapid loss of non Bt cotton seeds impacts on non Bt cotton farmers, and especially organic farmers as contamination of organic cotton may occur at various points in the supply chain, and raises the spectre of future legal challenges as to ownership of contaminated seed as commonly occurs in North America. * In addition, we note that there is a mis-match in the supply vs the demand for. different, kinds of cotton staple length and other factors which have

Textiles and Commerce and APEDA has not undertaken a pro-active role as responsible stewards for matters in their charge, including the real potential for the loss of the production and supply of organic cotton for export in which Indian farmers have a competitive advantage. ® **We furthermore,** ask **why cotton** in the US, **which** is now **predominantly Bt,** requires US government subsidies, **that** de-stabilise **and harshly impact the livelihood of poor cotton farmers** in third **world countries?** If Bt cotton is so great a technology and profitable, why is it being subsidised in the US and then sold in developing countries where unbelievably, poor cotton farmers can't compete with their rich American counterparts? In the 9 years to Nov 2010, subsidies paid in the

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(CRS Feb 2, 2012) despite the fact that the WTO ruled that US cotton subsidies are illegal

http://www.law.illmois.edu/bliournal/post/2012/02/02/United-States-Last-Option-in-Cotton-Dispute.aspx ("http://www.guardian.co.uk/environment/2010/nov/l 5/cotton-subsidies-west-africa#start-of-comments)

http://www.i-sis.org.uk/noAdvantageInTransgenicCotton.php

In India, farmers in Vidharba have committed suicide because of failed crops and high input costs of Bt seed, pesticides for Bt induced pests, fertilizer to nourish hybrid plants, and all in the face of uncertain water which, greatly increases yield variability... Our government does not subsidise cotton farmers and have even shown tardiness about stepping in to assist them, even in a region that has the highest incidence of suicides in

' India now linked officially to Bt cotton.

It is incomprehensible to the TEC that the government is promoting GM crops based on the experience of Bt cotton, and the false claim that it has been an astounding success based on faulty-interpretation of data. The data and the science

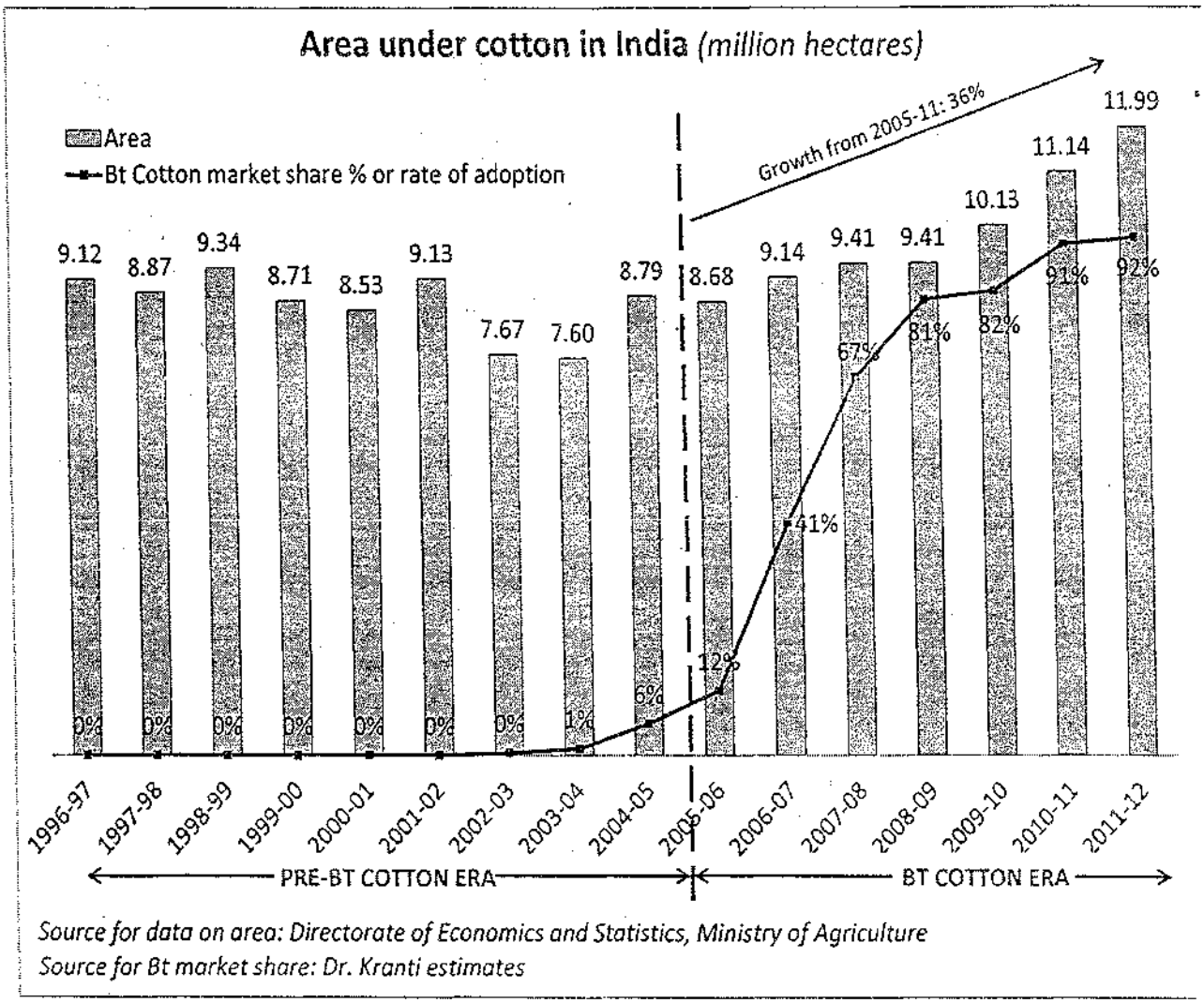
do not support at all the conclusion for declaring Bt cotton a success in India. It is therefore, even startlingly irresponsible for the MoA and the Regulators to willingly risk India's agriculture, which has considerable genetic diversity in small-holder farming and food production, on the basis of what can only be described as dodgy supposition of the success of Bt technology, and especially with the. advent of new more worrisome GM crops being developed that would lack proper oversight in 'their introduction and assessment. At the same time, research on the overuse of pesticides needs to.be conducted to determine the true status of pests that are being targeted by GM crops, to determine if the technology is needed in the first place. There is, consistent with these claims, evidence of a clear conflict of interest in our public institutions and regulatory bodies that *do* not augur well for our country and our citizens.

The TEC mandate for the Interim report was to provide our recommendations on OPEN FIELD TRIALS (TOR (b) of the Order of the SC based on the Minutes of the MoEF dated 15 April 2011). It is very clear to us that a GM crop must be properly assessed to answer the Questions of whether it is required in the first place, and whether it is efficacious. It is not logical for us to recommend open field trials in Bt/GM crops if that crop is not required in the first place. This is because of the clear and present risk of irreversible contamination that open field trials present and the historical lack of oversight in conducting them with rigour.

At the heart of the Bt cotton saga in India and the matter that deserves the most serious investigation is the decision by Monsanto to use hybrids as a means of economic 'value capture' because it would have been politically explosive if our small holder farmers were forced to sign agreements not to re-sow seed. Once farmers begin using GMO seed, there are few avenues for returning from the GMO path - it becomes an obligatory addition. Nor were the necessary studies done with isogenic lines of non-Bt crop nor a PMM (post market monitoring).

The TEC is of the view that there could be no open field trials for Bt-transgenic crops. Instead, basic research to gain better understanding of the impact of.antibiotic markers, CAMV35s promoters with DNA fragments, possible role of DsRNA, the toxicity of Bt-toxin to non-target organisms, the enhanced scope of Bt-toxin contaminating organic cotton in the resource-poor small and medium farms and several other issues raised in this report need to be promoted with sufficient financial support. The TEC recommends a ban only on field-trials pre-requisite for commercialization and not the GJVI research that is essential to assess the relevance and tenability of this technology to achieve sustainable productivity in. perpetuity without accompanying social and ecological harm,

Chart #1: DES DATA: AREA



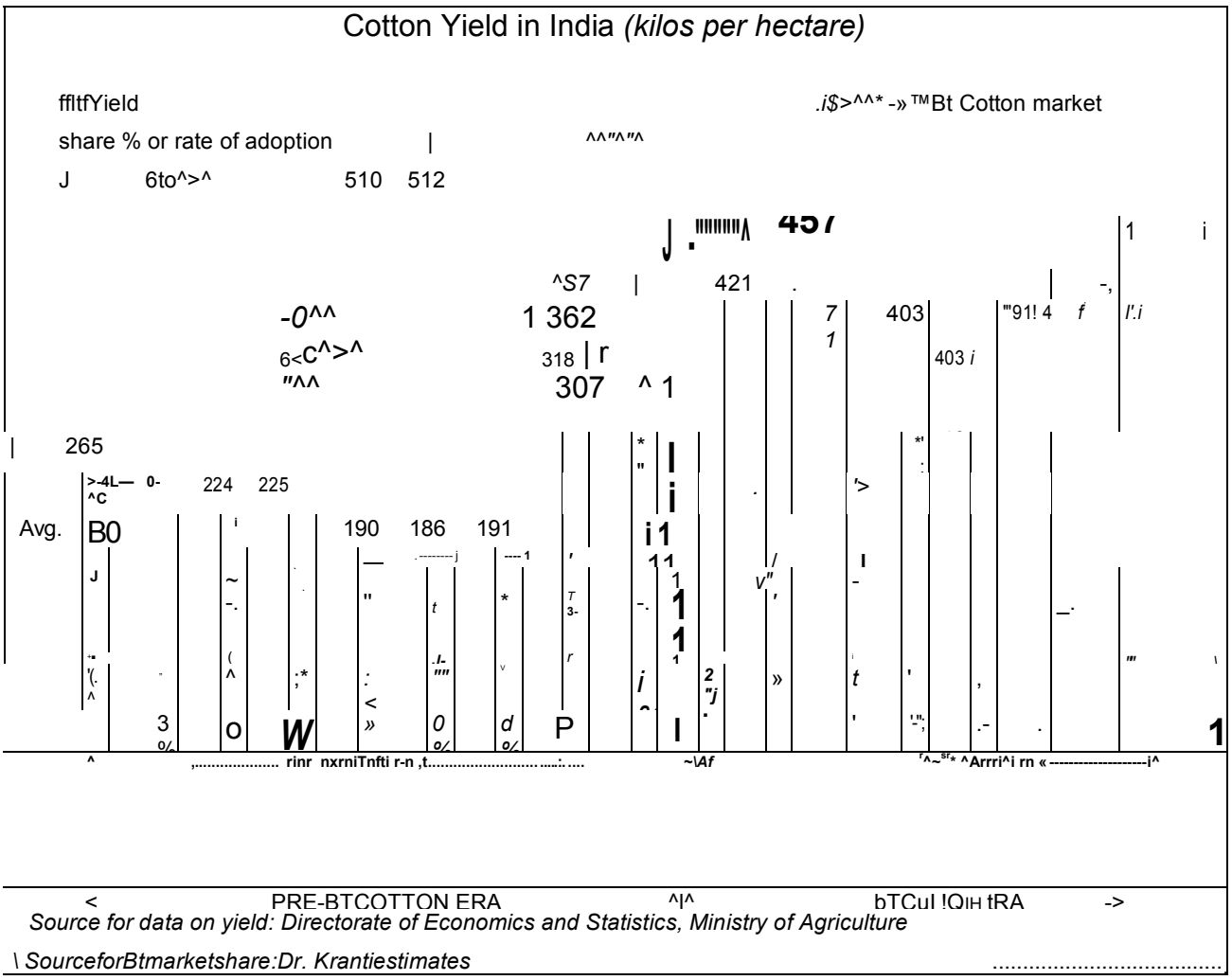
Source for data on area: Directorate of Economics and Statistics, Ministry of Agriculture
Source for Bt market share: Dr. Kranti estimates

Note:

1. The expansion in area under Bt cotton in the Bt cotton era starting 2005 onward according to DES data is 36% over seven years (base year 2005 when Bt cotton penetrati ., of the market was around 12%).

2. , ■ Both DES (Department of Economics and Statistics) and CAB (Cotton Advisor Board) use the same source of data for area statistics, ie Mo A. There are slight difference though.

3. In 2002-03 and 2003-4 cotton areas declined. That dip was restored in the following year. 2003 and 2004 are untypical years to use as a base. They stand, out as exceptions.



Notes:

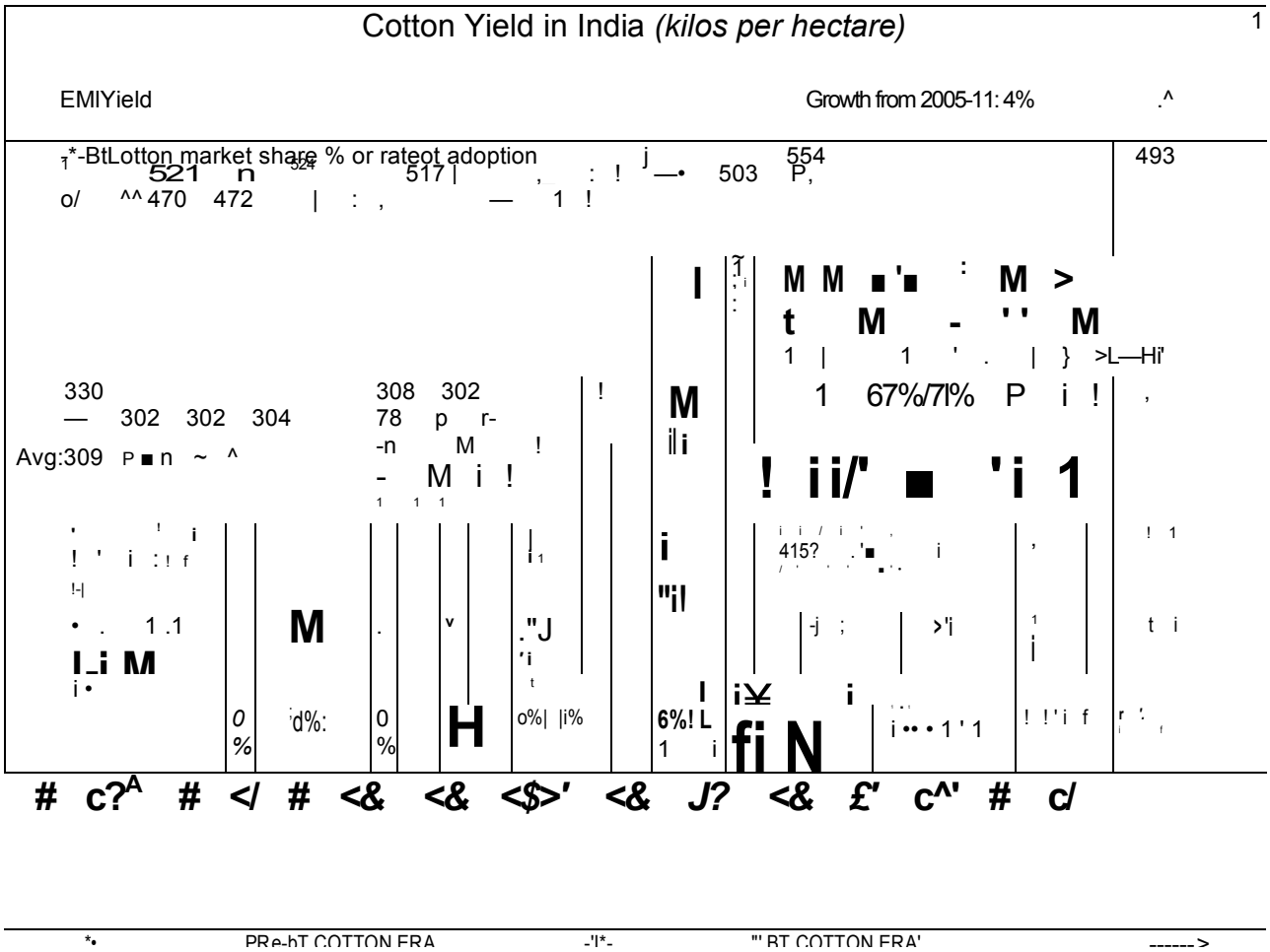
1. The four years 1996-97 to 1999-2000 show significant variation; we take an average yield for these 4 years of 230 kg/hectare, which is used for 1996 as the base year for analyses of growth in the pre-Bt era.

2. Guiding comments in the text of our analyses draw attention to dips in yield in 2000-2003 for various reasons. There is some reflection of this in the DES data. The dip in yield data for 2000 to 2002 is significant compared to both preceding and succeeding years in the pre-Bt era

3. It can be said that the difference in the growth figures for yield between the pre-Bt cotton era and the Bt cotton era is containeaV/marginah Growth in yield which started in the pre Bt area is attributed to the use of highly effective seed treatment, the use of high yielding hybrids etc (see report analyses).

4. It is of singular importance to note that dividing growth rates into two eras as shown, with the watershed year falling between 2004 and 2005 alters the picture of growth of Bt cotton. Additionally, the use of the year 2002 as the starting base year for projections of growth of Bt Cotton is unsupportable for reasons explained in the text. Such a basis translates into an exaggerated increase of 2.68 times (see report analyses).

Chart #3: CAB DATA: YIELD



Source for data on yield: Cotton Advisory Board (CAB); the figures'for 1997-2000 are an average for these 4 years.

Sourcefor Btmarketshare: Dr. Kranti estimates

Notes:

1. CAB data are preferred by the CICR to DES as they are considered to be more accurate. The levelling off in yield over the last 4 years, 2008-2011 to around 500kg+/hectare is very apparent from these data

2. The four years 1996-97 to 1999-2000 show significant variation; we take an average yield for these 4 years of 309 kg/hectare, which is used for 1996 as the base year for analyses of growth in the pre-St era.

3. The years 2000 to 2002-03 reflect the dip in acreage planted to cotton as discussed earlier.

4. No great reliance is being put on a simple calculation of growth between 2005 and 2011. What is important is that the growth trajectory in the pre Bt era is just not maintained in the post Bt era. It remains to be seen how Bt cotton will perform in the future. The problem of separating the performance of the Bt trait from 'other' factors still remains in the absence of studies with near isogenic lines.

CONTRUBUTIONS BY DR. R.S. PARODA

lor an liivi crops oeiore tliey are released Into the environment

In view of requests from petitioners to include requirements of various studies during safety assessment process, the TEC with expertise in different fields has been asked to review and recommend the nature and sequence of risk assessment encompassing both impact on human health and environment before they are released into the environment. This process of safety assessment is generally called PRE- MARKET or PRE-RELEASE SAFETY ASSESSMENT by the regulatory authorities in various countries.

Summary of Current Situation in India

LIBackground

The response to this Term of Reference requires an. understanding of:

1)
the sequence of steps that leads to a genetically engineered (GE) plant (variety or hybrid) being released for cultivation by the farmers;

2)
the purpose of the activities that take place at each step; and

3)
the purpose of specific biosafety regulations and operations at each step.

These are described in Table 1 and Figure 1 below.

The development of a GM or a GE plant starts with the laboratory research and green house studies to undertake plant transformation with the gene of interest followed by screening in contained conditions such as greenhouse or ascreenhouse. After event selection (Table 1, Step 3), product developers undertake the laboratory and field studies needed to address the safety assessment questions that are relevant to that specific event.

Table 1. Steps that lead to a GE plant being released as seed for farmer

	Activity	Purpose of Activity	Purpose of Biosafety Regulation/ Operation
Ste 1	Laboratory research under contained conditions prescribed procedures designed to release of biological materials).	To conduct preliminary research e.g., construct development, plant plant regeneration; tissue culture etc	To ensure R&D activities are carried out safely in terms of human health and the environment, and under conditions that will ensure no release of experimental material outside of the contained facility.
	I		

			environment, and under conditions that will ensure no release of experimental material outside of the contained facility.
Step 3	Confined field trials for event selection.	To evaluate events for desired trait(s) under relevant environmental conditions. This permits developers to subsequently focus on only a few efficacious events. This step of confined field testing is necessary because biosafety testing is very costly and hence, a few events showingpromise are taken forward.	Tisp ant material is carefully managed to: (^ prevent my acc)idental release from ^ ^ site; storage facilities 0r during transportation to or from the trial site- (2) prevent any establishment on the trial site after the harvest
Ste 4a	) Confined field trials for the collection of biosafetj'-relatedlenvironmental data.	To undertake studies required for human and environmental safety assessment with experimental GE plant material and also to establish efficacy of the trait. Confined field]/n rials are typically run'for a number of years it multiple sites, representative of where the < :rop is to be cultivated.	To ensure that experimental GE plant material is carefully managed to: prevent any accidental release from Uie ^ sit^ torage facilities or during ransport to or from the trial (2) prevent any establishment on the trial site after harvest.
St 4b	sp Laboratory studies to information and data requirements related to food/feed safety and environmental risk assessment	These studies are conducted in parallel with Step 4a. These include toxicology and nutritional analyses and *vitro* eco-toxicology tests are applicable on a case by case basis depending on the source of gene, nature of expressed	To ensure that GE plants and derived foods are tested demonstrate that they are as safe as their conventional counterparts.
St 5	ep Application submitted "to regulatory aauthorities to approve the GE event for commercial release.	Environmental risk and food/feed safety assessments are conducted by the regulatory authorities based on: (1) data submitted by the applicant from Steps 2-4; (2) information and data from the scientific literature; (3) information and data from risk assessments of similar events by some	To ensure that GE events are approved only if they determined to be as safe as conventional non GE counterpart.
s 6	tep Variety/hybrid release registration	■Variety registration systems have developed to evaluate the performance o new varieties/hybrids against acceptec standards.	iThe National Seed Policy and f the Seed Act are the applicabl i legal instruments here. At mi stage, biosafety isdues hav already been addressed; issue of relevance are thus limited t agronomic performance
S	tep Seed multiplication	Multiplication of progeny derived fror approved GE events in accordance wit prescribed processes for non-G varieties/hybrids of the same plant species.	nThe National Seed Policy lSeed Act are the applicab E legal instruments here und< which required see multiplication is allowed.
<	5tep General cultivation of *I* varieties/hybrids.	B This includes education about and stewardship practices, including ti required post-release monitoring or ar other condition required durir cultivation of GE varieties/ hybrids.	it Audits or momtoring may e required by regulate y authorities on a case-by-ca lg basis, as required within the mandate. Performance monitoring

*

Figure 1: Positioning confined field trials in the product development pathway*

Safety assessment of a GM crop is the most important step in its development process. It is a scientific process that makes use of best up-to-date scientific knowledge and experience.. It is to be noted that safety assessment of GM or GE crops is a multidisciplinary activity requiring a series of studies to generate sufficient data .This is coupled with peer reviewed scientific information, status of approval and use in other countries etc for consideration by regulatory authorities. Further, the food and feed safety (referred as health safety in the TOR) assessment and the ' environmental risk assessment of GM crops are separate and distinct evaluations., Information obtained through the molecular characterization of the GM plant and characterization of the proteins expressed by the inserted genes provides basic details which are used for studying both food and feed as well as environmental safety. Details of safety assessment vary from case to case with some logical steps that need to be followed. Further, information requirement and analysis by regulatory authorities depends on the stage and application area of a particular product. It is extremely important to understand that the level of regulatory scrutiny is proportional to the level of risk and accordingly, data requirements for each stage are different and may increase as an application progresses through the development process.

1.2 Indian Regulatory System

In India, GMOs and products thereof including GM crops .are regulated as per the "Rules for the Manufacture, Use /Import /Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989 (commonly known as 'Rules 1989)" notified under the Environment (Protection) Act, 1986. These rules cover areas of research as well as large scale application. The rules are implemented by the Ministry of Environment & Forests (MoEF), the Department of Biotechnology (DBT)and the state governments through six competent authorities viz Recombinant DNA Advisory Committee (RDAC), institutional Biosafety Committees (IBSC), Review Committee on Genetic Manipulation (RCGM), Genetic Engineering Appraisal Committee (GEAC),

RCGM, and GEAC are of regulatory function. SBCC and DLC are for monitoring purposes. The composition of each of these committee is defined intheRules,1989.

Out of these, the Genetic Engineering Appraisal Committee (GEAC) and the Review Committee on Genetic Manipulation (RCGM) are responsible for evaluating the health and environmental safety aspects of proposed activities involving GM crops during the product development. Both these committees have members chosen from public sector research institutions and universities having expertise in multiple disciplines required to perform the risk assessment. Further, these committees have inter-ministerial representations to ensure the coordination amongst the concerned ministries.

The Rules, 1989 are supported by biosafety guidelines adopted by RCGM and GEAC from time to time based on the national requirements and taking into account the international developments. The list of guidelines relevant for GM crops released so far by the Indian regulatory agencies is as follows:

>
Recombinant DNA Safety Guidelines, 1990
>
Revised guidelines for research in transgenic plants & guidelines for toxicity and allergenicity evaluation of transgenic seeds, plants and plant parts, 1998
>
Guidelines for generating preclinical and clinical data for rDNA vaccines, diagnostics and other biologicals, 1999
>
Guidelines for the Conduct of Confined Field Trials of Regulated, Genetically Engineered Plants, 2008
>
Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered Plants, 2008
>
Guideline for the Monitoring of Confined Trials of Regulated, Genetically Engineered Plants, 2008
>
Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2008
>
Protocols for Food and Feed Safety Assessment of GE crops, 2008

It is to be noticed that while these guidelines provide for a broad framework for undertaking various activities and safety assessment, each GM crop has

aeveioper while planning to allow risk assessment by the regulatory agency while reviewing the generated data. Further, it is scientifically not tenable to prescribe a common list for safety assessment studies to be provided for ail GM plants. Hence, regulator has to decide on case by case basis the specific data requirements.

It is understood that an indicative list of information/data requirements with the logical sequencing has been prepared by RCGM and GEAC in a document entitled "Guidance for Information/Data Generation and Documentation for Safety Assessment of Regulated, Genetically Engineered (GE) Plants" after due consultation with the stakeholders as well as public review process, but the same is still at a draft stage and not yet adopted.

. Relevant Information from other Biotechnology Regulatory Authorities

Food safety assessment (Impact on health)

The principles and practices necessary to undertake a robust, science-based GM food safety assessment have been agreed internationally under the Codex Alimentarius.- This means that a systematic and structured approach to GM food safety assessment has been established by international experts, adopted by Codex Alimentarius after review by Member Countries including India and Observer Organizations, and subsequently put into practice by governments around the world. The guidelines published by Codex as regards GM food safety assessment form the basis of the Government of India's "Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants" adopted by RCGM and GEAC in 2008.

Environment risk assessment

A framework for environmental risk assessment of living modified organisms such as GM plants is described in Annex III of the Cartagena Protocol to the Convention on Biological Diversity. According to Annex III, the risk assessment takes into account the relevant technical and scientific details regarding differences between the biological characteristics of the living modified organism (i.e., the GM plant) and those of the parental organism (i.e., the non-GM parental line). This requires a combination of laboratory and field studies designed to answer case-specific risk hypotheses *i.e.,* there is not a generic list of studies which is required in all cases.

The Cartagena Protocol on Biosafety differentiate between contained use (exempt from the advanced information agreement procedure) and intentional introduction into the environment (advanced informed agreement procedure applies). The Cartagena Protocol does not clarify the different

rcguiaie coin me activities i.e. conduct of confined field trials and unconfined general releases as separate activities. Accordingly, a detailed risk assessment as per Article 15 and Annex III is applied for the environmental release of GE events outside of confinement and the risk management practices as per Article 16 are used for conduct of confined field trials i.e. "to establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms."

Molecular Characterisation The molecular characterisation of GE plants is used to gain an understanding of the genetic material introduced and expressed in them. It is one component of the science-based multi-disciplinary approach used in food, feed and. environmental safety assessment of GE plants. In this context, a consensus document on molecular characterization of GE plants has been published by OECD. It has been indicated there that the use of the data and information considered may depend on the type of safety assessment being performed as well as characteristics of the product. The document does not provide an exhaustive list of analytical techniques that may be used for molecular characterisation. The examples of analytical techniques are given to serve only to provide a better context for an aspect of molecular characterisation discussed and do not imply that specific techniques are recommended or are necessary in each case, thus clearly emphasising that a case by case approach has to be followed.

Sequencing of risk assessment studies

Taking into consideration the above, the requirements related to biosafety testing of an event, as a prerequisite for obtaining a permit for confined field trials, are typically limited to the following:

0

a detailed description of the GM plant including information about the genetic elements that comprise the construct used to transform the plant;

ii)

information about the parental (i.e., non-GM) plant;

in)

information about the proposed confined field trial site;

the GM plant and for monitoring the same.
This is confirmed by reviewing the requirements for obtaining confined field trial permits from the regulatory authorities in other countries such as Argentina, Australia, Brazil Canada, Mexico, and the United States. The regulatory authorities in these countries have established procedures to permit field evaluation of experimental GM plants that have yet to be assessed for food or environmental safety, precisely because such field trials are necessary to generate the data required to do so. In all cases, however, the emphasis is on implementation of effective management practices that mitigate any persistent environmental impact from the confined field trials. Requiring experimental biosafety testing of GE events before event selection is completed is accepted as both uninformative and financially punitive to both product developers and regulators (who have an obligation to assess all data that, they require). There are, however, no examples of any mandatory experimental testing requirements from any of the regulatory authorities reviewed.

TEC Recommendations

1.
The sequencing of studies provided in the "Guidance for Information/Data Generation and Documentation for Safety Assessment of Regulated, Genetically Engineered (GE) Plants", which is in draft stage, should henceforth be adopted quickly by the RCGM and GEAC. While these guidelines are much more prescriptive, particularly when reviewed against the guidelines by other regulatory authorities, will certainly ensure that all product developers (public and private sector) shall have an advance knowledge of expected requirements for biosafety testing.

2-
The sequencing of studies presented in "Guidance for Information/Data Generation and Documentation for Safety Assessment of Regulated, Genetically Engineered (GE) Plants" should in future be reviewed at regular intervals of no less than three years to ensure that ourguidelies remain consistent with internationally'accepted best practices, and standards. For example, information/data requirements relevant to molecular characterization should be consistent with the OECD Consensus Document on Molecular Characterization of Plants Derived from Modern Biotechnology.

RCGM and GEAC. We note that the present approach for the environmental risk assessment in the guidelines for research in transgenic plants, 1998 is rather broad, whereas there is an urgent need for developing and adopting comprehensive guidelines for the environmental risk assessment by RGGM and GEAC The process for the same be transparent and consultative, involving all stakeholders, and TEC is of the view that it must start immediately,

4.

Since the notification of Rules, 1989, research and development of GE plants in India has increased dramatically. Each of the competent regulatory authorities established under Rules, 1989 is a committee, whose membership is comprised of either volunteers or appointees, all of whom have substantive positions elsewhere. It is felt by us that the efforts by bodies like RCGM and GEAC to undertake risk assessments was perhaps not all thatrigrous even when the volume of work was less than what is the case presently. Therefore, we stronglyrecommend for the establishment of a Risk Assessment Unit (RAU), as also suggested in the "Draft Establishment Plan for the National Biotechnology Regulatory Authority".

Further, the RAU should serve both RCGM and GEAC and be permanently staffed by a multi-disciplinary team of scientists/experts competant enough and responsible for undertaking science-based risk assessments, including but not limited to those required to approve clinical or confined field trials for the experimental GMOs as well as for their commercial release of GMOs (i.e., product specific risk assessments) .The proposed RAU could be transitioned to the Biotechnology Regulatory Authority of India, as and when the BRAI Bill is promulgated by the Parliament.

5.

In addition to establishing the RAU, RCGM and GEAC should immedately establish a roster of qualified scientific experts in relevant disciplines to provide sound scientific advice/information on biosafety issues that could impact on human and animal health as well as the environment The issue concerning conflict of interest should also be addressed while including experienced scientists to the roster.

6.

Although, the safety assessment is completed at step 5 after the GEAC approval and subsequently the GM crops are to be treated in the same

gooa governance practice and as a measure to ensure quality products for the farmers, it is our considered view that the Ministry of Agriculture and Indian Council of Agricultural Research (ICAR) should play an inclusive and rather proactive role in the above stated first three steps, especially to conduct confined field trials (BRLI and II stages). It is suggested that the National Agricultural Research System (NARS) should have assigned responsibility for the conduct of confined field trials for assessing the agronomic performance, an essential requirement for the release of GM varieties/hybrids in accordance with the National Seed Policy as well as National Seed Act. For this, ICAR can make good use of established ' infrastructure under the All India Crop Coordinated Programmes. It is, therefore, advised that a single window system for managing the testing and release of pM varieties/hybrids should be established taking into account: special, considerations involved with GM crops viz. expression levels of inserted proteins, confirmation of the events etc., irrespective whether these are produced by the private or public sector. In this context, the Ministry of Agriculture should consider establishing a high level committee of experts, including socioeconomist, farmers, NGOs and the representative of private sector to review finally for commercial release the cases that are cleared by GEAC,

7.

Once a GM variety/hybrid is released, required post release monitoring mechanism must be put in place to ensure performance based large scale field evaluation and to address specific concerns or the conditions,if any, laid down by the GEAC during the approval process.

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1 Summary of Current Situation in India *1.1*

Background

It is to be noted that the term "open Field trial" is a misnomer in the context of trials of GM crops. This is because although the trial is done in the open field, thus exposing the plants to the natural environment, the GM plants and genetic material being tested are confined to the field trial site using measures to ensure that the genes in pollen or seed do not escape from the trial site (reproductive isolation), that the GE material is not eaten by humans or livestock (material confinement), and that the GE plants and any volunteers arising from the trial are destroyed after the test and do not persist in the environment. Thus, the field trials are referred as "Confined field trials" in case of GM crops and are carefully managed in order to ensure that experimental material remains confined, and no environmental release is permitted so that no adverse effects on the environment and human or animal health are allowed.

. Confined field trials have been adopted by biotechnology regulatory authorities throughout the world as an essential research tool for enabling the biosafety evaluation of experimental, GE plants. Confined field trails also provide an opportunity for product developers to assess the efficacy and agronomic performance of GE plants under realistic environmental conditions, and to produce sufficient, representative plant material for other regulatory testing requirements, such as compositional analyses needed for GE food safety assessment, and livestock feeding trials that may be used on a case-specific basis to demonstrate performance.

It may also be noted that confined field trials are very different from commercial releases. Separate questions, separate review and approval processes are followed in every country for the two steps. The focus in confined field trials is towards ensuring confinement measures, and not asking for elaborate safety data, as the required safety data is actually generated during these trials. On the other hand full risk assessment is undertaken prior to commercial releases.

It has been well established globally that confined field trials can be performed safely and routinely by focusing on material and genetic confinement measures, without any prior requirement of safety data before granting permission by regulatory authorities,

L2 Indian Regulatory System

As indicated earlier, the conduct of confined field trials of genetically engineered (GE) crops is regulated under Rules,1989 notified under the Environment (Protection) Act, 1986 by the Ministry of Environment & Forests (MoEF), Government of India. According to these rules, the Genetic Engineering Appraisal Committee (GEAC) housed in MoEF and the Review Committee on Genetic Manipulation (RCGM) housed in the Department of Biotechnology (DBT), Government of India are empowered to review and approve the applications related to conduct of all biosafety research trials of GE crops and related activities. The regulatory process involves permission from Institutional Biosafety Committee (IBSC), Review Committee on Genetic Manipulation (RCGM) and Genetic Engineering Appraisal Committee (GEAC).

In 1998, DBT had brought out guidelines for research in transgenic plants, which briefly describe the considerations for limited field experiments. In view of the enormous progress made during the next ten

confined field trials and methodical evaluation of the same as indicated below:

i. Guidelines for the Conduct of Confined Field Trials of Regulated, Genetically Engineered (GE) Plants, 2008, ii. Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered (GE) Plants, 2008 iii. Guidelines for the Monitoring of Confined Field Trials of Regulated, GE°Plants, 2008

It has been noted that these guidelines have been developed by a consultative approach by organizing series of consultation with stakeholders and public review by placing on the websites. An elaborate application form has been provided to get relevant information from the applicant about the unmodified species (through biological documents) and its modified GE version (through laboratory experimentation). After technical review successful applicants are issued a permit letter to conduct confined field trials with following conditions/ requirements for compliance and reporting such as (only a broad list is provided)-

i) Restrictions on size and number of confined field trials with a simplified field protocol, storage and transport details, field maps etc,

ii) Records and reporting by applicant

a) Compliance records b) Field trial report c) To provide mandatory information submission - on plating, harvest information submission, accidental release information if any iii) Information on reproductive isolation of confined field trials. v) Disposal of material from confined field trials. vi) Post harvest land use and monitoring.

Standard Operating Procedures (SOPs) have been provided to carry out each activity in CFT of GE material (SOPs on storage, transport, conduct of field trials, harvest and termination and post harvest monitoring). Finally for each of these activities eight recording formats have been provided to the permitted party for compliance and records.

The monitoring of BRL trials is done by Central Compliance Committees (CCC) deputed by RCGM and GEAC for BRL-I and BRL-II trials respectively. Monitoring teams are given the responsibility of determining whether the conduct of a trial is in compliance with the term and conditions of the permit. The monitoring teams are expected to verify implementation of reproductive isolation method, marking of the site locations, matching it with the site identified on the map, documentation inspection including recording formats, storage facility inspection, if any etc. Proforma for monitoring of confined field trials ■ has been provided to CCC for reporting to the regulatory authorities.

2 Relevant Information from other Biotechnology Regulatory Authorities

Biotechnology regulatory authorities in other countries also specify the information required to obtain a permit from the authority to conduct confined field trials in an application format (and any accompanying guidance) prescribed for this purpose. The information required may include the results from a limited number of laboratory or bioinformatics tests, table 1 summarizes this information for some of the other countries (Argentina, Australia, Brazil, Canada, Mexico, and the United States) in comparison with India.

	Argentir	"3 s ^	1 ffl	o	o 'x	NO ^ 00	India
The biology of the unmodified plant species (taken from biology documents, literature)	R	R	R	R	R	N	R
Phenotype of the GE plant	R	■R	R	R	R	R	R
Transformation method used to develop the GE plant (e.g., biolistics, *Agrohacterium,* protoplast fusion)	R	R	R	R	R	R	R
Selection method (used to differentiate transformed from non-transformed plants during regeneration)	R	R	R	R	R	N	R
Construct map & information about source of each genetic element	R	R	R	R	R	R	R
Name of transgenic protein	R	R	R	R	R	N	R
Molecular characterization (e.g., copy number, number of insertion sites etc.)	N	R	N	N	R	N	N
Type of expression of transgenic protein (e.g., constitutive, tissue specific, inducible)	R	R	R	R	R	N	R
Maximum level of expression in edible plant tissues	D	R	N	N	R	N	D
Amino acid sequence homology to known allergens	R	R	N	D	R	N	R
Phenotypic stability over multiple generations	R	R	N	N	R	N	N
Amino acid sequence homology to known toxins	R	R	N	D	R	N	R
Intended or anticipated changes to plant characteristics (based on expected phenotype)	R	R	R	R	R	N	R

R=Required

D=Desirable but not required i.e., provide the data/information is available.

N=Not required

As is apparent from the table above, and as is the case for other national regulatory authorities, only very limited testing of experimental GE plants is undertaken prior to confined field trials. This reflects the fact

'Annex III of Resolution N° 701/1 l:Application for the Authorization of the Experimental Release of Regulated Genetically Modified Plant Organisms (GMPO) - First Phase http://64.76.123.202/site/agregado_de_valor/biotechnology/60-APPLICATIONS/___expaimental/_archivos/ResoIution%20N%C2%B0%20701%201.1.pdf

Application for licence for dealings with a GMO involving intentional release of the GMO into the environment (DIR).http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dirform5-htm. Note: the OGTR will accept applications where relevant data and references are not available (as is often the case with applications for confined field trials) . In these cases, the applicant must include in the application: (a).a statement that the specified information is incomplete or unavailable, as the case may be; and (b).an indication of the significance of the incomplete or unavailable information to the evaluation of the possible risks of the proposal in relation to the health and safety of people and the environment; and (c).a summary of known existing scientific evidence relevant to such evaluation; and (d).applying that summary - an evaluation of the possible risks, based on theoretical approaches and research methods that are generally accepted in the scientific community.

[3] Normative Resolution No. 06 of November 6th, 2008 (http://www.ctnbio.gov.br/index.php/content/view/12856.html)

directive Dir2000-07: Conducting Confined Research Field Trials of Plant with Novel Traits in Canada (http://ww.inspection.gc.ca/plants/plants-with-novel-tra

'Chapter II of the Regulations to the Genetically Modified Organisms Biosafety Law (http://www.cibiogem.gob.mx/eng/Documents/Ing_RLBOGMs_P.pdf)

[6]http://ww'w.aphis.usda.gov/biotechnology/downloads/permit_guidance.pdf

'http://igmoris.nic.ir^iles/Application%20fomi%20for%20cordlned%20fieId%20trials.pdf

under realistic environmental and agronomic conditions.

There are no examples where national regulatory authorities prescribe the exact sequencing of tests to be conducted prior to or during confined field trials. Instead, regulations, rales and guidance are used to describe the type of information that a regulatory authority requires in order to be able to undertake a food safety or environmental risk assessment of a GE event. It is then the responsibility of the product developer to ensure that this information (including the supporting experimental data) is provided to the regulatory authority in each product-specific dossier when the applicant applies for commercial approval of that product. . In many cases, e.g., Argentina, Australia, Canada and the United States, a pre-submission consultation with the regulatory authority is recommended to ensure that there is clear understanding as to what is and is not required in a regulatory submission.

3 TEC Recommendations

1. In the table of requirement of information, the requirement for molecular characterization and that for the phenotypic stability over generations be also made under "desirable" category, whereas presently they are listed under "not required" category.
2, Confined field trials should only be permitted by RCGM/GEAC after careful consideration of submissions that adhere exactly to the "Application for Confined Field Trial" form (see http://igmoris.nic.in/Files/Application%20form%20for%20confmed%20field%20trials.pdf). This form, in combination with the "Guidelines and Standard Operating Procedures for Confined Field Trials of Regulated, Genetically Engineered Plants", clearly specifies the information required by the competent authorities to determine if a confined field trial should be permitted or not. The application form was developed through a transparent, consultative process that included a period for public review and comment. Hence, both the approach and procedure for permitting confined field trials in India have already been peer-reviewed and public-reviewed.

   In summary, the tests that are required prior to obtain a permit for a confined field trial are:

   a. Amino acid sequence homology comparisons to assess the extent to which the transgenic protein is similar in structure to known toxins;
   b. Amino acid sequence homology comparisons to assess the extent to which the transgenic protein is similar in structure to known allergens.

   It is also considered desirable, but is not mandatory, to determine the maximum level of expression of the transgenic protein in the edible portions of the plant.

3. While the TEC is cognizant of the fact that other national regulatory authorities do not prescribe the nature or sequencing of tests that must be conducted during confined field trials, the TEC reiterates its recommendation under TOR a that the sequencing of studies presented in "Guidance for mformation/Data Generation and Documentation for Safety Assessment of Regulated, Genetically Engineered (GE) Plants" should be adopted immediately by RCGM/GEAC, and reviewed at regular intervals of no less than three years to ensure that the guidance remains consistent with internationally accepted best practices and test standards.

..... ,, ,,,.,,,,. .,,,,,,,«,.V|/imjt;it:i(u«i/ *engineered crop/piants is scientifically tenable in the green house conditions and whether it is possible to replicate the conditions for testing under different agro ecological regions and seasons in greenhouse?*

1 **Summary of Current** Situation **in** India

LI Background

Research on plants developed through genetic engineering is initially conducted in greenhouses - which are specialized structures enabling the growth of plants inside a controlled environment. Greenhouses provide optimal and controlled conditions required for growing plants developed in laboratories that are fragile and need to be properly cared for. Greenhouse also enables safe multiplication of initial plants through seed or vegetative propagules. However, any new plant has ultimately to be evaluated in a natural environment outside the greenhouse to enable assessment of performance under actual conditions in which these would be grown by farmers. Greenhouse conditions being controlled and artificial one is unable to predict how a plant will perform when grown outdoors.

Therefore during the course of product development it is an established practice to evaluate the material under field conditions. In case of genetically engineered (GE) plants such field trials are conducted under confined conditions referred to as "confined field trials". Typically, this includes planting the testing material in small plots so that a preliminary phenotypic evaluation can be completed to select the best types for further evaluation. Confined field studies are also crucial in the development of GE crops as they enable researchers to evaluate environmental safety of GE plants and collect biosafety data required by regulatory authorities. In addition, plant material, such as seeds and forage, can be produced using small confined field trials and collected to perform compositional analyses and other tests necessary to demonstrate food safety. The quantity of plant material required for feeding studies such as cattle feeding studies is typically in ten to hundred tonnes. Greenhouse studies cannot be performed at a scale sufficient to comply with these regulatory requirements. Therefore field trials are essential for development and performance/safety assessment of every new agricultural variety.

1.2 Indian Regulatory System

Revised Guidelines for Research in Transgenic Plants, 1998[1] provide detailed guidance for regulatory agencies responsible for overseeing activities undertaken in greenhouse vs. field testing. Detailed guidelines on structure of greenhouse are also provided. Presently, Institutional Biosafety Committees (IBSCs) review the data generated under greenhouse before forwarding applications for confined field trials to RCGM and GEAC. Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered (GE) Plants, 2008[2] are in place for conduct of confined field trials. These are applicable for all types of testing under field conditions including the event selection trials, biosafety research trials, production of material for food and feed testing etc..

2 **Relevant Information from** other Biotechnology Regulatory Authorities

Review of decision documents in other countries[3],[4],[5] reveal that there are no examples in any country where the regulatory decisions have been made only on the basis of greenhouse evaluation. It has

[1] Text available at http://dbtbiosafety.nic.in/
[2] Text available at http://dbtbiosafety.nic.in/
[3] http://www.inspection.gc.ca/piants/plants-with-novel-traits/eng/1300137887237/1300137939635

ivuu ui u,otj uuiiiivauwus IUI uiais ociween iy?z ana. zui i. me permissions granted lor conduct ot confined field trials of new events of GM crops (other than already approved Bt cotton) since 2005 is less than 100 in India[6].

It is also important to take note of a research paper recently published by European scientists[7], wherein an elaborate experiment has been carried out with the objective of analyzing the differences between greenhouse and field from GE wheat. They recorded increased vegetative biomass and seed number and a twofold yield in the GE wheat plant compared with non-GE control plants in the green house. The result was completely reversed in the field where two of the four GE plants showed up to 56% yield reduction and a 40-fold increase of infection with ergot disease *Claviceps purpurea* compared with their control lines in the field experiment while another GE line lost its distinctness from the control line. More of such scientific references are available in literature.

3 TEC Recommendations

The TEC also reviewed the actual physical requirements and processes involved in raising GE crops starting from laboratory initiation to final commercial release, which also includes evaluation and. testing for safety. The following emerged of the discussion:

GE plants are raised through several generations under laboratory and field conditions during the course of evaluation. The first experimental products (transformant stage T_0) and their progeny (TO are extremely fragile and genetically diverse and thus necessarily need to be grown under protection of green house. However, since these plants are ultimately to be grown for agricultural production, they have to be grown in the field at T_2 and subsequent generations for testing their actual field agronomic performance, (for technical justification see Annexure TOR c). •.

The discussions and some presentations also brought to forefront the very fact that it is impossible to simulate field-like conditions for normal crop growth under greenhouse conditions and in fact no amount of manipulation in controlled environment can mimic the extremely complex and dynamic environmental conditions prevailing under natural field situations. This limits the scope of greenhouse as an adequate system for carrying out evaluation of GE plants for all traits. Additional requirement of seed and green material for toxicological studies also further justify growing of GM material under confined natural field conditions.

Taking into consideration, the above facts, the TEC is of the view that a proper evaluation of a genetically engineered plant is scientifically not tenable in a contained greenhouse since it would not be feasible to replicate the conditions prevailing under natural field conditions representing different agroecological regions and growing seasons. Therefore, it advises that confined field testing, as recommended under the present regulatory system, is the right option for a realistic evaluation of any genetically engineered plant to know its suitability for any agronomic trait of economic importance.

http://www.aphis.usda.gov/biotechnology/brs_main.shtm!

http://www.ogtr.gov.au/ [6] Details available at http://www.igmoris.nic.in

Zeller SL, Kaiinina 0, Brunner S, Keller B, Schmid B (2010) Transgene x environment interactions in genetically modified wheat. PLoS ONE 5(7): ell405. doi:10.1371/journal.pone.0011405

1. Summary of Current Situation in India

Field trials do play a critical role in the evaluation and development of new crop varieties and hybrids which help in improving agricultural productivity, alleviate poverty and increase food security. It is to be understood here that the term "Open Field Trial" used in the context of GM crops is a misnomer, being quite distinct from Open Field Trials conducted on non-GM crops. Field trials of GM crops, though conducted in the open field, are actually under physical and biological confinement. Specific measures are adopted to ensure that the seeds or pollen or other propagules from the confined crop do not escape out of the trial site (biological, physical and reproductive isolation), that the GM material is not consumed or used by humans or livestock (material confinement), and that the GM plants and : any volunteers arising at the trial site are destroyed over the following seasons to ensure that the GM plants so tested do not persist in the environment. Hence, GM testing field trials are appropriately referred to as "Confined Field Trials".

Confined Field Trials, therefore, represent the first controlled introduction of GM plants into the environment. This is a distinct activity and serves as link between experiments carried in contained conditions (e.g., laboratories, greenhouses and screen houses) and open field cultivation by the farmers, and ensures safe testing and limited production. The "Guidelines for the Conduct of Confined Field Trials of Regulated, Genetically Engineered Plants" (2008) do provide a well-described overview of what a confined field trial ("open field trial" as per the ToR) is, and what it is used for.

The key characteristics of a Confined Field Trial are as follows:

> It is an experimental activity, conducted prior to the approval for general release.
> It is done on a small scale, typically in an area of less than 1 ha at a given site.
> Access to the field site is restricted only to the authorized personnel.
> Confined field trials are conducted under conditions known to mitigate: •.

Pollen- or seed-mediated dissemination of the experimental plant;

» Persistence of the GM plant or its progeny in the environment, and; •. •■ Introduction of the GM plant or plant products into the human food or livestock feed pathways.

The term "confinement" of a field trial refers to biological and reproductive isolation, including physical isolation and restricted access in an enclosure covered by a proper permanent fencing of 8ft height and locked gates. On a case-by-case basis, specific methods of physical confinement are to be advised to prevent herbivory or the destruction of plant material by foraging animals, or the unauthorized harvest or removal of plant material by humans.

> The measures for confinement are set forth in detail by the Regulatory Authority in the Terms and Conditions of Authorization of the confined trial, and must be strictly followed by the Authorized Party and concerned trial personnel.
> Since the trial is done with plants that are 'regulated', or not yet approved for general release, the Regulatory Authority maintains an oversight of these confined field trials carries required periodic inspections or reports oh the progress and compliance of the

Confined field trials are primarily conducted to evaluate the field responses and biosafety features of specific gene/s comprising events in a crop plant grown in an environment where theGM crop is likely to.be commercially cultivated. The evaluation includes collection of data on identification of the best event, potential biosafety impacts, efficacy of the event and production of seed and other tissue material for further experimentation and analysis. For identification of the desired event among several dozen produced and maintained in the greenhouse as discussed under ToR c, confined field trials are carried out in the selected representative locations of the targeted environment. The collection of such field trial data is a prerequisite for safety assessment of the GM crop under evaluation. Additionally, field trials are carried out to produce sufficient plant material so that the developer can undertake further research to address the information and data requirements for livestock feed and human food safety assessments.

L2Indian Regulatory System

Guidelines for the conduct of confined field trials or regulated GM plants, 2008 are in place for the information requirements and procedures used for permitting the confined field trials by RCGM and GEAC. However, this does not preclude any additional regulatory requirements that may be identified during the review process and imposed by the regulatory authorities. Regarding the review process, the initial assessment of an application for a confined field trial begins at the institutional level itself Based on information generated by the applicant in the laboratory and the greenhouse, the IBSC evaluates the proposal for conducting a field trial and, based on its recommendation, the applicant submits the proposal to RCGM or GEAC.

RCGM is the Competent Authority for Biosafety Research Level I (BRLI) trials. These trials are limited in size to no more than 1 acre (0.4 ha) per trial site subject to a cumulative total of a maximum of 20 acres (8.1 ha) for all locations for each plant species/construct combination per crop season. BRLI trials are conducted for two crop seasons.

GEACis the Competent Authority for Biosafety Research Level II **(BRLD)** trials. These are limited in size to no more than 2.5 acres (1 ha) per trial site and the number of locations to be decided on a case by case basis for each plant species/construct combination per year. As per the requirement, BRL II trials are conducted for one crop season.

The application form for seeking permission for confined field trials includes detailed baseline information about the unmodified plant species, information on GM plant, information on the molecular characterization of the event and gene construct, and information on trial site and the trial protocol.

Following the completed review of applications, which may include comments and advice from other government agencies, institutions or experts on a case by case basis, the authorization of confined field trial is granted by RCGM/GEAC. The permit letter contains detailed terms and conditions under which the authorization is granted including the

uocumenranon ana recording 01 data generated and activities carried out during the trial at each location. These are documented and maintained by the Trial In charge so identified at each location while granting permission.

2. Concerns about the current system of confined field trials in India

2.1. Well defined crop-wise trial protocols exist for testing and evaluation of potential non-GM crop varieties/hybrids for release and notification under the Seed Act 1966 and New Seed Policy 2002 implemented under the Ministry of Agriculture. These trials are carried out under All India Coordinated Research Project (AICRP) by different units of the Indian Council of Agricultural Research (ICAR) and other National Agricultural Research System (NARS) institutions. The first releases of the GM cotton hybrids in 2002 were based on testing under this system in coordination with RCGM/GEAC for ascertaining their safety and agronomic performance before their environmental and commercial release. This system seems to have become lax subsequently with practically no role of ICAR testing system.

TEC is of strong view that delinking of ICAR. testing procedure, that once existed, has led to the release of a large number of Bt cotton hybrids (>1300 hybrids) without proper agronomic evaluation, thus resulting in confusion among farmers.

2.2. Upon scrutiny of the trial documents with the regulatory agencies, it has been noticed that the developers have been allowed to conduct confined field trials even on the farmers' fields taken on lease. This leads to a concern regarding vulnerability of such GM trials to unauthorised access or even possible spread/contamination. Such a situation could have been avoided had there been active involvement of ICAR system, as before, in the release process.

2.3. Apparently little efforts seemed to have been made to harmonize two relevant laws for; i) environmental release of GM crop under EPA (1986) and, ii) release of varieties/hybrids for general cultivation under the Seed Act (1966) or New Seed Policy(2002) of Government of India.

3. **Relevant Information from other Biotechnology Regulatory** Authorities

National regulatory authorities in different countries vary in the level of details provided in regulatory guidance for the management of confined field trials. However, in all cases there are common, mandatory requirements: (1) confined field trials must be reproductively isolated from any of its sexually compatible species; (2) no plant material from the trial site can enter into the food and livestock feed chains without the express permission of the appropriate regulatory authorities; (3) restrictions are placed on how the trial site may be used after the field trial has been harvested; (4) confined field trials must be monitored both by the applicant and the regulatory authority during and after the trial; (5) transport and storage of regulated plant material must be documented and properly managed to ensure that there is no accidental release.

rrugramj wnue in omers it is administered by industry associations (e.g., Crop Life, "Excellence through Stewardship").

4. TEC Recommendations

The "Guidelines for the Conduct of Confined Field Trials of Regulated, Genetically Engineered Plants" (1998) and the associated "Standard Operating Procedures for Confined Field Trials of Regulated, Genetically Engineered Plants" (2008), though quite prescriptive, need further review to ensure the inclusion of those details that were elaborated in 1998 guidelines prior to the adoption of new guidelines in 2008. Also, the procedures used to ensure their implementation and monitoring by RCGM and GEAC need to be strengthened by involving, right from the beginning, the Ministry of Agriculture (Departments of Agriculture & Cooperation, and ICAR) in the conduct, monitoring and evaluation of all confined field trials (BRLI and BRLII). To this end, the TEC recommends the following:

4.1. The RCGM, GEAC and ICAR must work hand-in-hand to conduct the confined field trials atthe specified sites (Recommendation 4.3) as well as improve the quality and timeliness of inspections by qualified monitoring teams. A roster of such monitors,with required expertise needs tobe maintained and updated regularly by these agencies. Also, a schedule of site visits needs to be defined and followed diligently including the maintenance of proper records, duly signed.

4.2. Crop-specific Standard Operating Procedures (SOP) should be developed and made available online. Such SOPs should incorporate, in addition to the existing procedures,!) methods for reproductive isolation of the confined field trial site, ii) schedules for monitoring the field trial during and after the growing season, iii) required duration of post-harvest restrictions on the trial site, and iv) methods for on-site/off-site disposal of regulated plant materials. These procedures should be developed immediately for those crops for which confined field trials are already approved or in the process of approval.

4.3.A system for notification of confined field trial sites located in different agro-ecological zones should be developed by RCGM and GEACin consultation with the ICAR.These sites could include both public and private sectorinstitutions/facilities, meeting the specifiedconditions. However, no trials should be allowed on farmers' fields, leased or otherwise.

4.4. TEC was given to understandthat a provision for sufficient grants has been made in the XII Plan by DBT for an overall improvement of the regulatory system, including conduct and monitoring of confined field trials. The available financial resources should, therefore, be used on priority for strengthening the regulatory system (infrastructure and human resources).

4.5. The TEC is of the view that the GM crops under confined field trials are experimental in nature and are managed by the authorised personnel only. As per specifications, the material is not allowed to be exposed to open environment before, during or after the confined field trial. Therefore, seeking no-objection certificates for

is an existing practice for the Central Variety Releases under the Seed Act being implemented by the Ministry of Agriculture, Government of India.

4.6. Taking into consideration the existence of a system of testing and standard protocols and practices being followed under AICRP, that synchronises in general with the three years of confined field testing in BRL I and BRL II, the two need to be integrated to establish a three year protocol of joint testing of new GM events, so as to address the twin objectives of environmental/biosafety as well as agronomic performance. The agronomic evaluation should be against the best national check, regional check, and the latest released variety/hybrid in the state concerned. For all the new events, the decision of RCGM/GEAC on biosafety and environmental concerns must be the final at either of the testing stages (BRL I or BRL II), irrespective of good agronomic performance of the variety.

4.7. Monitoring for biosafety compliance as well as agronomic performance of each confined trial must be made mandatory, and shall be carried out by GEAC through an inter-ministerial monitoring compliance committees including people drawn from a roster of experts. Apart from centralized monitoring, each confined field trial must be monitored by a "site-specific monitoring committee" comprising a geneticist/plant breeder as leader, a molecular biologist, a pathologist, an entomologist, an agronomist and a physiologist from the same institution responsible for the conduct of such confined trial.

4.8. In cases where an already approved event is incorporated into a new genetic background, after verified for its stability, such variety/hybrid shall be evaluated independently by the AICRP protocol as above for agronomic performance and the expression of the event concerned for a period of two years, as per the existing practice under the New Seed Policy of Government of India.

4.9. Varieties/hybrids evaluated by the above process shall then be approved for general cultivation by a Central GM-Crop Release Committee on par with the Variety Release Committee under the Ministry of Agriculture. For this, the existing ToRs of the Standing Committee under the MOEF could henceforth be part of the ToRs of the Central GM-Crop Release Committee to be served by the MOA, in collaboration with MOEF. This committee shall include-experts from the disciplines concerned including the Crop Project Coordinators/Director, officials of Seed/Crops Divisions of DAC and ICAR, socio-economists, progressive farmers, NGOs and the private sector representatives.

4.10. Once a GM crop variety/hybrid is released, a well-designed case-by-case post release monitoring system must be put in place jointly by the DoAC and ICAR to address specific post-release issues identified during the event approval by GEAC. Such a system should also monitor the long term effects from the point of view of food safety, soil health, environment and agronomic performance, as appropriate, and in our view

4.11. It is further suggested that the Ministry of Agriculture may also consider issuing a separate notification on priority for the general release of GM crops on par with New Seed Policy, while legally ensuring much needed harmonization of both EPA under MoEF and the Seed Act under MoA.

1 **Summary of Current** Situation in India

LI Background

As mentioned earlier procedures for the conduct of confined field trials are intended to accomplish three important goals:
1) preventing the escape from the trial site of novel genes in pollen, seed or other plant parts;
2) preventing GE plant material from being consumed by humans and/or animals; and
3) preventing GE plants from escaping from confinement and establishing and persisting in the environment.

With the achievement of these three goals, novel genes and their products are confined to the field trial site, and their release into the general environment prevented. In order to establish effective procedures to achieve these goals, permitted Parties are required to follow Standard Operating Procedures (SOPs) for the safe transport and storage of GE plant material, for reproductive isolation and material confinement of the GE plants on the field trial site.

Further, it is also important to understand that the process of introgression of a transgene from pollen flow etc.: (referred as contamination from escaped material in the TOR) is not simple and actually occurs in many steps involving several hybrid generations. For such a process to occur the GM crops and their wild relatives must grow within pollen dispersal distance, be sexually compatible, flower at the same time and viable pollen must be delivered to the stigma. Successful fertilization of the embryo must then be followed by zygote and seed formation. Introgression requires the hybrid seed to germinate and the first fjlial generation (Fl) plant to establish and flower in order to further hybridize with members of the recipient population . Fl hybrids must therefore persist for at least one generation and be sufficiently fertile to produce backcross hybrids. Finally, backcross generations must progress to the point at which the transgene is incorporated into the genome of the wild relative. Apart from these biological factors another important element determining the likelihood of such introgression is the occurrence of related species in the area where crop is being grown.

In view of the stringent risk mitigation protocols such as reproductive isolation distance already in place and additional biosafety measures such as post harvest monitoring requirements prescribed during field testing of GM crops, the possibility of contamination, under the existing knowledge sphere on this aspect, is unlikely.

1.2 Indian Regulatory System

It is noted that the concern indicated in the TOR were earlier also raised by the Petitioners in the ongoing PH. At the behest of the Petitioners, the Hon'bie Supreme Court vide Order dated 8.5.2007 and 8.4.2008 laid the requirement of a validated event specific protocol at an LOD of at least 0.01% prior to bringing out the GM material from the green house for conduct of open field trials. As per order of Hon'bie Supreme Court Order, MoEF had set up a sub-committee of subject specific experts and members of

grounds:

1. The objective of requiring detection methods for GE plant material are based on specific needs. Generally these methods are required to ensure purity and segregation of genetic events by researchers and developers; to assure compliance with labeling or other legislation by the food industry; and to verify compliance with legislation or to solve legal disputes that may arise by regulatory authorities.

2. For research materials entering into confined field trials, where there may be tens, or hundreds, of different GE plant events undergoing initial evaluation, it is practically not feasible to consider the development of validated test methods for each event as several events are discarded during the research and development stage itself.

3. In view of the stringent risk mitigation protocols such as reproductive isolation distance already in place and additional biosafety measures such as post harvest monitoring requirements prescribed during field testing of GM crops, the possibility of contamination, under the existing knowledge sphere on this aspect, is relatively unlikely but must still be monitored.

Accordingly, the requirement of an event specific validated protocol is mandatory prior to the commercial release. Further, the level of detection (LOD) of the expressed substance in GM transgenic crop variety be defined based on analytical methods available for the detection of LOD of 0.01% at the time of release.

2 **Relevant Information from other** Biotechnology Regulatory Authorities

No regulatory authorities in countries that routinely permit confined field trials prescribe "validated. protocols and active testing for contamination" in associated with confined field trials at any level. This includes Argentina[1], Australia[2], Brazil[3], Canada[4], China[5], Mexico[6], and the United States[7]. This also applies to countries such as Bangladesh[8], Kenya[9], South Africa[10]and Paraguay.[11] In all of these countries, emphasis is placed on proactively addressing compliance management of confined field trials so that accidental releases from the trial site do not occur. It is not considered feasible or useful to implement off-site monitoring programs based on event-specific diagnostic testing. Instead, it is critical that the risk mitigation practices that are used to confine the field trial are effective and this is where research or "testing" efforts are best applied. There has never been any negative environmental impact reported from any GM field trial in the world.

[1] http://64.76.123.202/site/agregado_de_valor^otechnology/60-APPLICATIONS/___experimental/_archivos/Resolution%20N%C2%B0%20701%2011.pdf
[2] http://www.ogtr.^ov.au/intemet/ogtr/publishing.nsf/Content/dirform5-htm
[3] http://www.ctnbio.gov.br/index.php/content/view/12856.html
[4] http://wvvw.inspection.gcxa/plants/plants-with-novel-traits/applicants/directive-dir2000-07/eng/130447466 .
[5] http://english.biosafety.gov.cn/
[6] http://www.cibiogem.gob.mx/eng/Documents/Ing_RLBOGMs_P.pdf
[7] http://www.aphis.usda.gov/biotechnology/downIoads/permit_,guidance.pdf
[8] ^Bangladesh Biosafety Rules 2012
[9] ^ttp:/Avvftv.biosafetykenyagole/index.php?optipn=com_content&view=article&id=I64:biosafety-contained-use-regula 2011&catid=84&Itemid=498
[10] '^ttp://www.nda.agric.za/doaDev/sideMenuAiosafety/doc/GUIDELINE4WORKwithGOM.pdf
[11] http://www.sobrevivencia.org.py/vl/?tag=comision-nacional-de-bioseguridad-conbio

1. RCGM and GEAC should review the isolation distances that have been established for spatial isolation of confined field trials and the requirement/suitability of additional measures so as to ensure that they follow the best available practices.,

2. DBT, ICAR and MoEF should fund research projects specifically designed to: (1) identify the appropriate spatial isolation distances for plant species that are likely to be studied in the confined field trials possibly in next ten years; (2) identify other effective means of ensuring reproductive isolation of confined field trials.

3. The Laboratories for the testing of contamination be accredited and funded by DBT/MOEF7ICAR and required capacity building be given high priority so that experts could help in proper monitoring.

independent testing laboratory/institution,, **1**

Summary of Current Situation in India

1.1 Background

As per the regulated requirement, the responsibility for demonstrating the safety of any new GM plant lies with the developer of that particular plant. The product developer generates the required data to support the safety of the product according to the guidelines and protocols prescribed by the regulatory authorities. However, the type of tests needed, to assess safety may vary according to particular GM plant being tested and the comparative assessment between, the GM plant, and its non GM counterpart. Therefore, the guidelines are not 100% prescriptive and no regulatory system stipulates a mandatory list of exactly which tests should be done. But at the same time efforts are made to use validated tests protocols with harmonization as per the consensus achieved internationally through the bodies such as WHO, FAO, OECD, CODEX ALIMANTORIOUS, ICH etc. This is also the case for new chemical and • drugs.

A review of the testing requirements for GM plants, as stipulated by RCGM and GEAC (based on the internationally agreed guidance), indicates that the type of facilities required for conducting various biosafety tests do exist in both public and private sector institutions. Several institutions functioning under DBT, ICAR, CSIR and ICMR have the necessary infrastructure and professional capabilities for undertaking various biosafety tests. Further, many of the organizations particularly in the private sector (generally referred as contract research organizations) are accredited by relevant national and international bodies and are engaged in undertaking biosafety tests as per the guidelines and protocols prescribed by regulatory authorities in India as well as other countries such as USA, European Union etc. In fact, these CROs (sometimes 100% EOUs) are one of the major growing segments in Indian biotechnology industry.

DBT in its response to TEC has informed about a study conducted by them to review the availability of testing facilities in national institutions and contract research organizations involved in safety testing of GMOs and analyse constraints/gaps, if any, with respect to regulatory requirements with an objective to prepare an action plan for strengthening testing facilities in the country. The regulatory requirements for

facilities and professional expertise in India for undertaking required tests.

1.2 Indian Regulatory System

The two systems for laboratory accreditation that are currently in use in India and mostly applicable to biosafety and food safety testing of GM crops are: the National Accreditation Board for Testing and , Calibration Laboratories (NABL) and the National Good Laboratory Practices (GLP) Compliance Monitoring Authority. Importantly, both these systems do apply internationally recognized accreditation standard procedures and hence, could be used to have concerned labs accredited.

- Currently, there! is no independent institute for biosafety assessment. Moreover, in view of the muiti . dimensional and muiti disciplinary nature of testing/ data generation needed for biosafety tests, it may not be advisable for a single institution to undertake all biosafety related tests, which may also vary on a case by case basis. Therefore, a network of accredited laboratories has to be created and declared by DBT/MOEF on priority so that these are engaged by the developers for generating required data.

2 Relevant Information from other Biotechnology Regulatory Authorities

A review of regulatory systems in other countries reveals that biosafety tests as per the country's guidelines are conducted in GLP certified labs both in public and private sector. For example, in case of toxicology studies, USEPA accepts the data from tests conducted in GLP labs coordinated by local . quality assurance managers of EPA. The European Food Safety Authority (EFSA) requires that any study carried out on the GMO must comply with OECD principles of Good Laboratory Practices (GLPs) and the report be accompanied by formal statement of quality assurance. Similar procedures are followed in Australia, Brazil, South Africa etc.

There is no example reported from any of the countries regulating development of GM crops, where a single institution is capable of or has been set up to undertake all tests required for safety assessment of GM crops, as per the regulatory requirements.

3 TEC Recommendations

safety assessment of GM crops. However, whereas the private sector laboratories are accredited currently ' under the existing systems, the public sector laboratories are invariably not. Thus, there is an urgent need to strengthen the required infrastructure through needed reforms for both management and funding. These labs are to be adequately funded to create required facilities in order to seek accreditation from organizations such as NABL and National GLP Compliance Monitoring Authority.

In view of the above, TEC recommends that:

1) It will riot be advisable to set up a single institution for all biosafety tests. Instead, a network of laboratories be established by RCGM/GEAC, once these labs get accreditated based on required •international standards.
2) Recognizing the diverse requirements for testing facilities and professional expertise for safety assessment of GM crops, there should be a major human resource development initiative for training in the best institutions, both within, and abroad.
3) GOI may establish an inter-ministerial coordination and monitoring mechanism for taking necessary steps in strengthening/upgrading/funding the public sector labs and for having a regular funding/monitoring mechanism in place.
4) For required public confidence, data be got generated by the inventor mainly in the accreditated labs, whether public or private, for submission of application to the Regulatory Authority.

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The Registrar
Supreme Court of India
New Delhi

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Subject: Final Report of the Technical Expert Committee (TEC) appointed by the Hon'ble Supreme Court in the matter of Writ Petition (Civil) No. 260 (2005) of Aruna Rodrigues vs. Union of India

Dear Sir:

The Technical Expert Committee (TEC) appointed by the Hon'ble Supreme Court in the above matter is herewith submitting its Final Report

The Interim Report that was submitted on October 7, 2012 had been signed by all the five original members of the TEC comprising of Dr. P.S. Chauhan, Prof. P.C. Kesavan, Prof. P.S. Ramakrishnan, Dr. I. Siddiqi, and Dr. B. Sivakumar.

In November 2012, post-Interim Report, a sixth member Dr. R.S, Paroda was appointed to the TEC by the Hon'ble Supreme Court.

One of the TEC members Dr. B. Sivakumar is out of the country since May 15, but has participated in the discussions and deliberations upto that time and in arriving at the recommendations. He has given his consent to the Report and its recommendations.

The TEC members present on the last day of the final meeting of the TEC i.e. June 30,2013 at the Centre for International Cooperation in Science (CICS), Chennai are signing this covering letter.

Dr. R.S. Paroda's contributions are separately attached.

Signed,

1NSA Honorary Senior Scientist
Formerly:
Indian National Science Academy Honorary Scientist
Professor of Ecology, Jawaharlal Nehru University
Founder Director, 6B Pant Inst, of Himalayan Environment & Development
Professor of Botany/Professor,of Ecodevelopment. North-eastern Hill University

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Dated: 30 June, 2013

To

The Honourable Supreme Court. India

Dear Sirs:

I would like to state that 1 have participated in the discussions and deliberations at the meeting of the TEC held at Chennai for the preparation of the Final Report of the TEC being submitted, to the Honourable Supreme Court in the matter of writ petition (Civil) No. 260 (2005) of Aruna Rodrigues vs. Union of India. I am aware of and fully agree with the Final Report and its Recommendations. I hereby authorize Dr. P.S. Chauhan and Dr. Imran Siddiqi to sign the Report on my behalf.

Yours faithfully