RESPONSE TO THE EXPERT COMMITTEE (EC2) ON BT BRINJAL

The following is a response from Kavitha Kuruganti, Kheti Virasat Mission on the EC2 report on Bt Brinjal, as per the call put out by the Hon'ble Minister for Environment & Forests, Govt of India, on October 15th 2009, seeking public feedback.

The responses have been divided into 4 distinct sections as below:

I. **ISSUES WITH THE EXPERT COMMITTEE: IS THIS WHAT THE NATION SHOULD BE ASKED TO RESPOND TO?**

II. **GENERAL RESPONSE TO EC2 REPORT & IMPACT ASSESSMENT OF BT BRINJAL**

III. **SPECIFIC RESPONSES TO EC2 REPORT**

IV. **OTHER VERY IMPORTANT AND FUNDAMENTAL ISSUES:** These include issues like availability of alternatives, pest management and pesticide-related issues with Brinjal, experiences from Bt Cotton, issues around IPRs and farmers' rights, around Indian Systems of Medicine, around consumer choices and labeling, around Event-based approval system and around Liability/Redressal/Remediation regimes.

I. ISSUES WITH THE EXPERT COMMITTEE: IS THIS WHAT THE NATION SHOULD BE ASKED TO RESPOND TO?

The Expert Committee Chairperson, in at least two media interviews (Tehelka and CNN-IBN), expressed the need for more safety tests and long term studies even though the report does not indicate any such views that he holds. There has been at least one more media report based on interviews with expert committee members (Down to Earth, "How Bt Brinjal was Cleared" http://www.downtoearth.org.in/full6.asp?foldername=20091231&filename=news&sec_id=4&sid=3), which further confirms our understanding of the "rigging" of the EC2 report.

This is apart from whether he came under "tremendous pressure" to approve Bt Brinjal or not!

Further, there is the issue of conflicting interest and objectionable presence of several EC2 members in this process. All of this makes it very apparent that the EC2 was designed to approve Bt Brinjal. Attached are two different notes on this matter (Annexure 1 is a note on how the Terms of Reference were changed for the EC2 without any apparent processes and about the objectionable presence of several members in the EC2; Annexure 2 is a letter written by scores of organizations and individuals across India to the Prime Minister of India, seeking the withdrawal of the rigged Expert Committee report).

The original Terms of Reference for the Sub-Committee on Bt Brinjal as per the January 2009 GEAC meeting minutes have been changed quite substantially for the constitution of the EC2. No processes have been run to allow for such changes in the mandate and this in itself makes the EC2 process void.

II. SOME GENERAL RESPONSES TO THE EC2 REPORT

The EC2 report is unscientific in its facts and approach and resolutely determined to clear Bt Brinjal and this is apparent almost throughout the report. Just the fact that 16 scientists have

apparently gone through thousands of pages of biosafety data without a single adverse comment is really amazing!

1.0 To point out to a few major problems to highlight this aspect (lack of scientific rigour in EC2), one can point out to the references that the EC2 cites – some of these are from 1976 (point 1.2.2 on Page 7), 1982 (point 1.2.7. on Page 10) etc.

2.0 The EC2 outright falsified findings saying that "no statistically significant changes have been observed in the parameters tested" in the Food/Feed Safety tests (Page 59, Point 5.3. and Issue 9 of EC2 report). This is simply not true and the crop developer's own reports do show that there have been statistically significant changes.

3.0 The EC2 ignores much evidence on Horizontal Gene Transfer when it says on Page 55 under Issue 2 that "It has been well established that the probability of transfer of transgenic from GM plant material to bacteria (including that normally inhabit stomach and intestine) is unlikely because of series of well established barriers". There are numerous scientific studies that show that HGT is a phenomenon found to occur in several instances and a list of references for such studies is attached (Annexure 3: Horizontal Gene Transfer studies).

4.0 At least four members (that is 25% of the members) of the EC2 were also members of Expert Committee I which put out several recommendations in 2007. For no sound scientific reason proffered, the EC2 concluded that the tests recommended by EC1 are not needed as per the "newly adopted guidelines" in India. It should be remembered that these tests recommended by EC1 were not part of the guidelines present at that time either and the EC1 however saw a merit in recommending certain things. The EC2's unscientific attitude is reflected in this illustration.

5.0 The statement in the EC report (A1 in table in Annexure 1) on page 66 says: *"The cry1Ac gene inserted in Bt brinjal event EE-1 has been constructed by combining the first 1398 nucleotides of the cry1Ab gene (corresponding to amino acids 1 to 466) (Fischhoff et. al., 1987) with nucleotides number 1399 to 3534 of the cry1Ac gene (corresponding to amino acids 467 to 1178). The resultant protein encoded by this gene is 99.4% identical to native Cry1Ac from Bacillus thuringiensis sub sp. kurstaki. This difference of 0.6% is attributed to the difference in presence of **one** amino acid at position 766 i.e. serine in place of leucine".*

Simple calculations done by molecular biologists show that if indeed the difference between native Cry1Ac and the chimeric gene in Bt Brinjal is 0.6%, then the number of amino acid differences is **seven and not one**! If the EC2, with its collective scientific capabilities can go wrong on a simple fact like this, it is unclear how it can be trusted to take up a scientific evaluation of the safety of Bt Brinjal!

6.0 **The EC2 ignored several other points that were brought up** (Annexure 4: Compilation of health-biosafety related issues submitted to the EC2) – many points with regard to studies that are needed, problems with protocols of studies that were taken up as well as problems with analysis and interpretations of data generated have been ignored by EC2. It is not clear whether it is because of hasty processes run or whether it is a determined approach to ignore feedback that has been sent to the regulators.

7.0 The EC2 report in many places talks about "history of safe use" (of cry1Ac or antibiotic resistance genes or GM crops like Bt Cotton etc.) without citing any scientific study that concludes that there is indeed a "history of safe use". **On what scientific basis is the EC2 claiming such "history of safe use"?**

8.0 It is very apparent from the EC2 report, wherein **compliance to guidelines is mentioned and commended at least twenty times in the report**, that the EC2 made its main mandate the verification of compliance to guidelines rather than actually scientifically evaluate whether Bt Brinjal is safe. This is unacceptable and is certainly not the mandate given to the EC2 when it was set up. Even as this country is going through a debate on the current regulatory regime and its (in)adequacy, there is no point in an Expert Committee checking on compliance. Several of these members were in fact instrumental in designing the protocols and permitting the crop developer to take up unscientific studies and the very constitution of the EC2 once again came in the way of scientific, independent evaluation of protocols, data generated etc.!

9.0 The EC2 at several places in its **report refers to regulatory authorities elsewhere** accepting something or the other (page 32, 55, 69, 78 etc.) and invokes the example of USA, Canada, Australia etc. What is apparent is that the EC2 wants to make a note of these regulatory decisions from these countries which have allowed GM crops but ignore the regulatory decisions of many other countries or even the regulatory guidelines from countries like Norway, for example. This is very selective and opportunistic on the part of the EC2.

10.0 While the **85th meeting of the GEAC** clearly asks the ICMR representative who concurred with Dr Bhargava on the need for long term tests to look into incorporation of at least three more aspects of assessment (need for extensive DNA fingerprinting and proteomic study; Study of possible interaction with the commonly used drugs (especially pro biotic interferences and Reproductive interference) into guidelines, these are outright rejected in the current analysis by EC2, even though Dr Vasantha Muthuswamy is supposed to have concurred with Dr Bhargava in 2008! She was part of the EC2 too. What has changed in between is unclear.

11.0 The EC2's assessment of Bt Brinjal relies in many places on some **studies on Cry1Ac protein whereas Bt Brinjal has a chimeric protein**. The EC2 brings down safety issues to just one or two genes (that too a wrong one) whereas the latest research in this area is pointing to the process of Genetic Engineering itself.

12.0 The EC2 was privy to information from Large Scale Trials and some other studies and this **information was not put out in the public domain until November 17th 2009**. Procedurally, this does not augur well for transparent evaluation and only raises a finger of suspicion over such hasty and secret functioning.

13.0 Any complacency centred around **"Protocols approved by RCGM"** is indeed an issue and that is the reason why the constitution of the Expert Committee was being objected to by many civil society groups. If the EC2 members are RCGM members who have earlier cleared various protocols for Mahyco, they would obviously defend these rather than take the scientific points on board. The issue raised by Dr Judy Carman about the size of study and control groups of animals in terms of number of animals being too low, not permitting any statistical significance calculations scientifically possible is a good illustration for this. The EC2 did not respond to this point even though this would make all the difference in what a study might actually throw up.

14.0 **Not all studies were done by accredited laboratories** and that is what the ECI report also pointed out (Page 17) – Advinus Therapeutics, Bangalore is a NABL accredited laboratory. INTOX, Pune is an ISO accredited lab and NIN was asked to do an audit of this lab since it is not a NABL accredited lab. Central Institute of Fisheries Education is not an NABL accredited lab. Rallis India Bangalore is not listed in the NABL directory. Vimta Labs, Central Avian Research Institute, IICT, GB Pant University of Agriculture & Technology etc.,

also need to be seen if they are NABL-accredited. This is an issue that has been taken cognizance of by the Expert Committee 1. It is not rational that the EC2 members, given the kind of overlap that exists in members between the two committees, ignore this valid point made by EC1, which was in the first instance a concern raised by civil society taken on board.

15.0 The **new guidelines in India** have been adopted by the regulators, after receiving support from USAID for this recasting of guidelines. It is obvious that American business interests have a stake in the new guidelines adopted in India and the adoption of the principle of substantial equivalence formally for the first time in India through these guidelines is being questioned by many scientists. Checking for compliance with these guidelines reeks of vested and conflicting interests given that USAID played a part in Bt Brinjal development as well as in evolving the new guidelines.

16.0 **Event based approval system**: It has been pointed out time and again that an event-based approval system that India had embraced, is unscientific and unsound both from a biosafety point of view as well as from an agronomic point of view with new norms that have been adopted recently. The inter-cultivar variability in the protein expressions and other parameters is reason enough to treat each cultivar as a separate GMO. Further, some of the Bt Brinjal hybrids and the Bt Brinjal varieties from the public sector bodies did not even undergo proper agronomic evaluation even as they are being recommended for release by the EC2 and GEAC. This effectively implies that experimentation will take place at the expense of poor farmers, during the period of commercial cultivation! Bt Cotton has valuable lessons to teach on this front where the trials did not comprehensively address various issues and approvals were given hastily in 2002.

17.0 **Backcrossing time and process**: Effective and good backcrossing in breeding requires at least 4-5 years even with the use of modern-day techniques like Marker Assisted Backcrossing, coupled with 'shuttle breeding' etc. which can speed up the processes a bit. With Bt Brinjal, in the case of Mahyco's hybrids as well as public sector Bt Brinjal varieties in the ABSPII project, it is apparent that such time required has not been spent on backcrossing. In fact, pollen flow studies were taken up in 2002, when backcrossing programme was initiated, with Mahyco's Bt Brinjal hybrids! Similarly, while the Material Transfer Agreement with Tamil Nadu Agriculture University was signed in 2005 (between Mahyco and TNAU), the field testing in MLRTs commenced in 2007 itself! This is extremely unscientific and unacceptable – this story was earlier apparent with Bt Cotton too and it is only now that scientists are acknowledging that many of the new diseases being seen with Bt Cotton in Vidarbha and other places (*lalya* disease or bronze wilt etc.) is connected to the original American blood still remaining from the Coker 312 parental line and its particular susceptibilities now affecting Indian farmers. It is found that no regulatory body or Expert Committee has so far looked into this issue in depth and verified this to ensure that farmers don't end up paying the price for such scientific frauds.

III. SPECIFIC RESPONSES TO EC2 REPORT CONTENT

The following points are responses related to biosafety or lack of it, its assessment as well as a few other issues that arise from certain statements made in the EC2 report which have a relevance to the overall assessment of Bt Brinjal, its need, its implications etc. (beyond biosafety too). Several points being raised in these specific responses are a reflection on the state of the regulatory regime in India.

1. The EC2 says (Page 17) that RCGM's 40th meeting discussed in detail on April 25th, 2006 the data generated by Mahyco; however, it is apparent from the EC1 recommendations, finalized in 2007 that no detailed analysis of the raw data ever took place. The EC1 in

fact had asked the Director of National Institute of Nutrition to go through the raw data and as per information obtained under Right To Information, it is apparent that he had looked at the reports of only three studies rather than all the toxicity and allergenicity studies. It is not apparent that this EC2 has studied the raw data either, as they seem to have ignored differences between Bt and non-Bt Brinjal as reflected in different studies.

2. ECI's recommendations in July 2007 were put out with at least 25% of the members of EC2 being part of EC1 also. These recommendations include comments on studies done in non-NABL accredited laboratories, about Bt Brinjal having to be compared with other pest management options available etc. etc. It therefore requires strong scientific rationale to be provided if the EC2 is discounting the suggestions made by EC1. This is not apparent in the EC2 report however.

3. **Table 1.1: Insecticides recommended for FSB**: As per CIBRC website, lindane, cypermethrin, endosulfan, cypermethrin 10%, chlorpyrifos 20% EC, carbaryl and cypermethrin+quinalphos are recommended as per legal registration. Neem seed kernel extract also. The 15 listed in EC2 report are wrong/illegal to be cited and used and if others are recommending these other pesticides, it is not acceptable and requires regulatory action. (http://www.cibrc.nic.in/searchbycropname1.asp).

4. **1.2.6.: Non-target organisms like Parasitoids and predator species getting affected by pesticides used to control FSB** – While it is good to see studies (even if from 1987) cited on unintended impacts on non-target organisms, it is obvious that pesticides and their registration did not capture such impacts. In such a case, it becomes all the more pertinent to ask what studies have been done to look at Bt Brinjal and these parasitoids and impacts on such parasitoids and predator species?

5. **1.2.7.: Genetic Improvement by conventional techniques**: This section too is unscientific and opportunistic, citing a paper from 1982. (a) This ignores that pest management need not be brought down to FSB-tolerant cultivars alone, therefore justifying the entry of Bt Brinjal! (b) In any case, FSB-tolerant cultivars have been evolved/released in the recent past even from Tamil Nadu Agriculture University. (c) Further, this point of the EC2 report ignores that genetic improvement is possible through other techniques too like Marker Assisted Selection. (d) Finally, a paper present on the GEAC website called "Centre of Origin, Inter-relationship, and crossability in Solanum melongena" by Dr Major Singh, IIVR cites De Candolle (1886) and Prain (1903) thus: *"While some taxonomists think that S. melongena has not been found wild, others feel that S. insanum Roxb. and S. incanum Linn., which are wild taxa and considered to be distinct species, are really varieties of S. melongena (De Candolle, 1886: Prain, 1903). De Candolle (1886) and Prain (1903) reported that S. incanum and S. insanum are varieties of S. melongena and not distinct species. This view also gets strongly supported from inter-crossability to produce fertile hybrids and coexistence of S. melongena, S.incanum and S.insanum in different habitats".* If that was the case, then the EC2 point 1.2.7. is not strictly true. The regulators need to first collect data on FSB resistant cultivars evolved in various research centres in the past decade or so and it is apparent that the EC2 did not put in this effort.

6. **1.2.8.: Alternate strategies**: This section fails to mention that alternatives are available. It conveniently talks about non-sustainability of FSB control in future, ignoring the fact that the same would apply to Bt Brinjal too, sooner or later!

7. **1.2.8.: Alternate strategies**: The EC2 report says that adoption of transgenic crops with Cry proteins has given excellent results in maize and cotton and that a 'similar

approach in brinjal is expected to provide substantial benefits to farmers'. The EC2 fails to provide references for making this statement since findings from independent studies show a very mixed picture. It also makes the mistake of equating maize and cotton (a crop where the produce mostly goes into industrial uses and a fibre crop resp.) with Brinjal, an edible crop. Importantly, it fails to recognize latest reports on resistance in these very crops that it claims have given excellent results. (Annexure 5: Tabashnik, 2009 coverage).

8. **1.3. Development of Bt Brinjal by M/S Mahyco**: The EC2 conveniently ignores an important point being made by independent analysts and others that the gene used in bt Brinjal is **NOT** cry1Ac. The fact that it is the same that was used in Bollgard Bt Cotton is also not justification to call it Cry1Ac or to make it more acceptable. There are many unresolved and uninvestigated issues with Bt Cotton too and this is all the more reason not to accept Bt Brinjal with the same gene. The Cry1Ac in Bt Brinjal is claimed to be "similar" in structure and activity to the one found in nature and in commercial microbial formulations and this is not true or scientific.

9. **Page 11: 1.3.:** Bt k formulations not having deleterious effects on non-target organisms including humans is not true. There have been records of negative effects with external sprays too. Further, even the external sprays are not recommended as safe, going by the instructions on such formulations in the market.

10. **Page 12 (point on Bt Brinjal and IPM)**: "Contributes to and provides the foundation for an IPM strategy", says the EC2 report. This is once again a faulty and unscientific understanding of Integrated Pest Management. See Annexure 6 for a note on how Bt crops are a violation of the principles of IPM and sustainable pest management approaches.

11. **Page 12: Chronology of Bt Brinjal development**: In 2002, the backcrossing began, after importing the plasmid from Monsanto in 2000. However, the pollen flow studies were also taken up in 2002 in two locations. How is this possible? Even with some techniques like Marker Assisted Backcrossing, at least three to five years and ideally five years, are required for true back-crossing. How can toxicity studies and allergenicity tests be undertaken without the backcrossing being completed properly in 2003 and 2004? It is only now that the scientists in Indian NARS are acknowledging how the backcrossing programme was not as good as it should have been in the case of Bt Cotton. What is the lesson learnt is not clear and obviously "experts" in the regulatory system are not paying attention to these issues.

12. Page 13 refers to **Studies by the "technology provider"** – so, is the technology provider Monsanto in this case? If that is the case, the IPR implications have to be studied further. It should also be remembered that the studies being cited are on Cry1Ac (not the chimeric gene) and also do not constitute independent research. Nor are these peer-reviewed studies. The EC2 did not also mention which countries did not accept and allow certain products despite the regulatory authorities getting the studies cited here. ***The whole point is not to just accept the reports of the crop developer or technology provider but to take up independent research and analysis, which is sorely missing at this point of time.***

13. **Page 14**: The public sector varieties have not been tried out in Large Scale Trials; they have finished the confined field trials in 2007 and 2008. **This puts into question the event-based approval system adopted in India**. It is obvious that no data exists on these Bt Brinjal varieties and their agronomic performance in a simple protocol that

compares the Bt Brinjal variety with its isogenic counterpart and with the other best pest management options available, even though the Bt Brinjal varieties developed in the USAID-funded consortium project ABSPII are being recommended for release in India.

14. **Section II: Review of regulatory compliance (pp 15-29)** – Around 15-16 pages of the Expert Committee report has focused on this whereas **this does not make Bt Brinjal safe just by virtue of compliance to guidelines – this cannot constitute safety evaluation and this is only a convenient deviation from the original terms of reference for a Bt Brinjal Sub Committee announced in January 2009**. Further, even within this exercise, compliance with regulatory conditions stipulated by GEAC in the permit letter for LST is a wrong thing to do; the checking of compliance should have been against EC1's recommendations.

15. **Page 15, Table 2.1**: The plasmid pMON10518 was imported by Mahyco in March 2000 – It is not clear what the terms and conditions for this are, since this will determine the future of the public sector varieties being touted as the humanitarian side to this PPP effort. It will also determine the IPR issues around Mahyco's Bt Brinjal hybrids, pricing issues etc.

16. **PAGE 15: Table 2.1 – list of regulatory approvals for tests**: There are some questions with regard to permissions given and tests conducted here. For instance, the permission for sub-chronic feeding studies for 90 days in rabbits and goats was given on August 8th 2005 and preparation of feed concentrate for the feeding study happened on 22/12/2005 and 13/2/2006. It is not clear when sowing and harvesting would have taken place and whether fresh test material was supplied to the animals or not. The impact in the study could vary depending on the test material as well as time of harvest to time of diet preparation.

17. **Page 16, Table 2.1**: 2007 and 2008: Experimental seed production permissions were provided to the company thrice (Aug 2007, January 2008 and June 2008) – Why was this done, even without the completion of large scale trials? How is this seed accounted for by the company? Has the GEAC verified the physical availability of these seeds and the biosafety compliance with respect to these stocks?

18. **Page 16, Table 2.1**: "19. Recommendation of RCGM with respect to 90 days goat feeding study with Bt brinjal leaf expressing *cry1Ac* gene. 12/ 81/ 2006-CS-II Feb 06, 2008" – what is this referring to? If this was a permission from RCGM asking the company to take up the foliage feeding study also, then, the decision not to take up such studies came too soon after and the exact reason why this study was dropped is unclear. If this is a letter to Mahyco from RCGM that they need not take up the study as decided in earlier GEAC meetings and by the EC1, where the RCGM promptly communicated a decision from the January 2008 GEAC meeting, then the issue remains that the "conclusions" on Bt Cotton and animal morbidity/mortality by the GEAC are not scientific, based on any investigation nor is it a closed story (Annexure 9).

19. **Page 17: Compliance with 1998 guidelines:** Like Dr Bhargava had already pointed out elsewhere, the issue is not about compliance to existing guidelines – this is a scientific evaluation which can and should question the earlier and existing guidelines too.

20. **Page 17: Point 2.2** – the fact that the RCGM did not do its job in its 40th meeting is already proven by the ECI comments and therefore, to repeat something that is known to be untrue will not make it true, in terms of compliance to 1998 guidelines.

21. **Page 18 has an excerpt from the EC1 recommendation:** "The EC-I further opined that the short term data generated on the environmental safety and socio economic aspects needs to be further substantiated with additional trials/tests to explicitly conclude the benefits from Bt brinjal and *superiority of the technology with respect to existing technologies especially the available methods for pest management and pesticide reduction".* The EC1 came up with this in clear response to a point being raised by civil society groups and some scientists right from the beginning about the variety of alternative pest management practices available for farmers that are ecological, sustainable, affordable and farmer-controlled. This clearly requires Bt Brinjal to have been compared to other pest management methods and not necessarily chemical pesticide treated plots. This did not happen with Bt Brinjal assessment to this day. Table 2.2, points a. and b. conveniently ignore this fact and claim compliance!

22. **Page 19: Table 2.2 a**: Objective is to have an "independent assessment" by IIVR, an ICAR institution? How can this be possible, if IIVR is involved and why choose an ABSPII consortium partner if that is the objective?

23. At least three hybrids, MHB 11 Bt, MHB 39 Bt and MHB 99 Bt have not undergone second year MLRT trials (as apparent from Table 2.1 on Page 15; no trials took place in 2006-07, as is known to some activists who are following the various developments on the GM crops front in India and no permissions are visible in this table either or in the chronology explained on Pages 13-14 of EC2 report); However, Table 4.1. on Page 52 claims that these trials took place in 2006-07. It appears to be a case of the EC2 being more loyal than the King!

24. **Page 20. Point c of table 2.2 on Pollen Flow**: "Sufficient information is available on the biology of brinjal", says the last column as EC2's view. This information shows that brinjal is "an often cross-pollinated crop", with outcrossing ranging between 2 to 48% in brinjal varieties in India. The EC2 then goes on to say in the last column against point c. of Table 2.2. that the "results are in conformity with earlier information supplied by the applicant and available literature". These two don't match and it is not clear how the EC2 reconciled this difference in favour of Mahyco (which claimed 1.46% to 2.7% in its pollen flow study, with IIVR reporting a 0.14% to 0.85% outcrossing in its pollen flow studies in the past two years)! This obviously shows a lot of variance to available literature.

25. **Page 20: Point d of table 2.2: Crossability studies from *melongena* to *incanum*** – EC2 says that these "are in conformity with available literature". However, this is in variance with some literature quoted by Dr Major Singh of IIVR in another paper put up on the GEAC website. Once again, the EC2 reconciled the difference in findings in favour of Mahyco in the current instance. Further, there are studies from TNAU which show crossability with other local species and this has not even been studied in the IIVR crossability studies nor does the EC2 make any reference to such knowledge existing within the NARS.

26. **Data on Aggressive and weediness, on baseline susceptibility** etc., was put up only recently and needs to be studied along with data from large scale trials etc.

27. **Page 22, Point g on Soil Impact Assessment**: The EC1 had clearly said that "Impact on the next crop may be recorded" – this was obviously not done and the EC2 is still ready to conclude that the study is in compliance with stipulated conditions!!

28. **Page 22**: "No cry1Ac was detected in the soil samples" – this contradicts what is known and what the available literature says about this protein and it is interesting to note that the EC2 is ready to accept this finding as is without wondering if something was wrong with the methodology adopted or with the finding itself.

29. **Page 22: Point f: Flavour analysis NOT done by CFTRI** – the response that the recently adopted guidelines do not require such a study is a faulty argument and nullifies the very process taken up earlier.

30. **Page 23, Point i: Foliage studies with goats**: GEAC deciding to dispense with this study is not based on any new investigations and is in fact based on falsified information (Refer to Annexure 9 for more information on this). Therefore, this justification is not tenable and the EC2's readiness to rationalize this on these grounds arouses suspicions.

31. **Page 23: Point j:** Dispensing with the skin sensitization test is not on scientific grounds but only on an argument that recent guidelines do not need it! This kind of selective arguments with regard to suggestions of the earlier Committee are not acceptable – picking up some points and negating some has no scientific basis.

32. **Page 23: Point k:** The NIN director looked at only 3 studies, as per data obtained under Right To Information. Even here, he raised questions that remain unanswered. This is certainly non-compliance on the part of regulators themselves, leave alone the crop developer!

33. **Page 24**: Socio-economic impact assessment of Bt Brinjal - the NCAP study is yet to come in. In fact, the GEAC deciding to clear Bt Brinjal before this study has been finalized is indeed very hasty and unjustifiable.

34. **Page 25, Point 2.4.:** Compliance with the 2008 guidelines. The recasting of these guidelines has been supported by USAID in India and the only apparent reason why this would have been done is to benefit American business interests and not to protect Indians, their health and environment from risks associated with GMOs.

35. **Checklist Point 8 of the new 2008 guidelines**: Assessment of possible allergenicity – the EC2 says "Not applicable as the Bt protein is neither known to be allergenic nor has sequence homology with any known allergen" – this is a very faulty premise for not testing since there could be novel proteins (not necessarily the Bt protein) through the GE process and that is what Prescott et al (2005) show with GM peas shows; there is also scientific literature that shows that the Bt protein could be as potent as the Cholera toxin.

36. **Page 29** – Conclusions at the end of the section on Compliance to Guidelines says, "Since everything is as per guidelines, no additional studies need to be prescribed for safety assessment"…This is absolutely unscientific and does not form part of a scientific evaluation process.

37. **SECTION III – review of bt brinjal biosafety assessment dossier**: Given that the EC2 ignored the points raised by the Director NIN from his earlier analysis of three studies on Bt Brinjal and given that there is no evidence of even a single point raised

now on the biosafety data of Mahyco, there can only be one conclusion – that this Expert Committee did not look at the raw data from the biosafety dossiers of Bt Brinjal. Otherwise, how can there be a scientific evaluation of 1000 PLUS pages by 16 scientists, without a single point being raised, unless there has been no review of such data or unless there is something very fishy!

38. **Page 30: Point 3.1.2.:** not clear what the last line means: "transformation method was a modified method developed at Mahyco". If that's the case, are there any implications for any of the studies being cited being irrelevant for this new transformation method?

39. **Page 30-31: 3.1.3. – description of Cry1Ac gene and protein**: (a) This section ignores the fact that Bt Brinjal does not have the Cry1Ac gene but a chimeric gene. (b) It further ignores scientific evidence that the Bt protoxin is known to bind to (mucosal surface) surface protein in mammalian intestine too (Vazquez-Padron et al, 2000). (c) Finally, this section ignores the fact that it is not just individual genes in a transgene that are a cause for concern in r-DNA technology but the process of genetic engineering itself and transgenic expression of non-native proteins that are a potential cause for concern ("Diversity in translational and post-translational modification pathways between species could potentially lead to discrete changes in the molecular architecture of the expressed protein and subsequent cellular function and antigenicity…These investigations, however, demonstrate that transgenic expression of non-native proteins in plants may lead to the synthesis of structural variants with altered immunogenicity." – Prescott et al, 2005).

40. **Page 31: "**For Cry proteins to be active, it requires alkaline conditions", says the EC2 report: Vazquez-Padron et al (2000) have shown that binding of protoxin to mucosal surface in mammalian gut happened too.

41. **Page 31**: on CaMV 35S promoter and alpha subunit of the *beta-conglycinin* gene of soybean: The EC2 says that "both the regulatory sequences introduced into EE1 event are not capable of causing any disease" – There is at least one published paper in the Lancet that questions this in addition to a published paper where recombination between viral genes in GM plants and infecting viruses has been demonstrated (Wintermantel and Schloez, 1996).

42. **Page 32: nptII gene and aad gene**: the concern is not just with the expression of these genes in the plant but with the possibility of Horizontal Gene Transfer and therefore, the response of the EC2 is inadequate.

43. **Page 33: Point 3.1.5 – Expression of Cry1Ac protein and its quantification**: "The levels of Cry1Ac protein were found to vary between 5 to 47 ppm in shoots and fruits", notes the EC2 report. "Mean molt inhibitory concentration (MIC95 for *Leucinodes orbonalis* has been calculated to be 0.059 ppm for Cry1Ac"*.* In May 2007, the Director, Department of Animal Husbandry (AHD), Andhra Pradesh, sent a letter to the GEAC (ref: No 3531/Epid/2006.dated 9/5/2007), where he reported : "*the Bt protein levels detected in the samples of Bt cotton bolls and leaves sent for analysis to different laboratories was recorded as 5 microgram/gm. This level is within the tolerable range which is said to be "5-10 microgram/gm"*. On this basis, it justified that this level of protein expression in Bt Cotton is tolerable for sheep/goats. In such a case, this clearly shows that the Bt protein far exceeds the "tolerable range" in Bt Brinjal. (Annexure 7 is a letter based on the letter of the Director-AHD, GoAP)

44. **Page 33: Conclusions**: "The EC-II opined that the insect resistance trait is stably integrated in the brinjal genome and there is no evidence or likelihood of genetic

instability". This is a faulty argument since the genetic instability in Bt Brinjal is not about integration of the Bt gene. The crop developer might be interested in that aspect alone but regulators should obviously go beyond this as several studies point to this aspect.

45. **Page 34: Point 3.2.1: Crossability studies:** There are many studies from India which are centred around inter-specific hybrids which also provide an indication of crossability. Nishio *et al*. (1984) observed that crossing *S. melongena* with *S. incanum*, *S. macrocarpon*, *S. integrifolium*, *S. gilo* and *S. nodiflorum* was compatible. The *S. viarum* has been utilized in breeding experiments involving brinjal (*S. melongena*) and viable interspecific hybrids have been realized (Nandakumar, 1983). Nasrallah *et al*. (1963) found that *S. melongena* was crossed with *S. gilo* and *S.indicum*, the F_1's of these crosses were highly sterile and *S. melongena* was not able to be crossed with *S. mammosum* and *S. ciliatum*. *S. melongena* cultivar could cross easily with *S. incanum* and *S. integrifolium*. It gave hybrids with *S. gilo* and *S. indicum* when used as a female parent (Rao, 1968). Anis (1994) reported that the cross *S. melongena* x *S. incanum* yielded seedless fruits. The per cent survival of the hybrid *S. incanum* x *S. melongena* was better than the parents. Preneetha (2002) evaluated the interspecific F_1 hybrids (EP 45 x *S. viarum*, EP 65 x *S. viarum*, CO 2 x *S. viarum* and MDU 1 x *S. viarum*) and found that the F_1 hybrid plants resembled their corresponding female parents morphologically. The IIVR crossability studies however report findings that are in variance with this existing knowledge. **The IIVR crossability study did not use *S. viarum* species or *insanum* at all and there are issues of serious concern with the design of the crossability study itself, as prescribed by the EC1 with a focus on *S indicum*.**

    The Crossability Study b/w *S melongena and S indicum* that was taken up by IIVR further cites the following in its report: *"Rao (1979) carried out a comprehensive survey of inter -specific hybrids of Solanum. Ten species were chosen: S. melongena, S. melongena var. insanum, S. incanum, S integrifolium, S. gilo, S. zuccagnium, S. xanthocarpum, S. indicum, S. sisymbrifolium and S khasianum. Crosses were attempted in all possible combinations. The results are summarized in Table 1 (No Table 1 is in the report however!). Out of 90 pos sible combinations, there was no fruit set in 47, and only parthenocarpic fruits in four. In the remaining 39 crosses which resulted in fruit set, only 24 gave rise to plants which reached the flowering stage".*

46. **Page 35: Outcrossing**: Wide range of outcrossing is acknowledged based on available literature (2 to 48% outcrossing) by the EC2. However, the results of the pollen flow studies are at great variance with this knowledge and the EC2 did not deem it fit for further investigation. The crop developer's pollen flow studies were taken up even as back-crossing programme was underway! In Brinjal, literature shows that 60-70% fruit setting happens through pollination by insects while 30-40% is by selfing. Insect activity is therefore a predominant variable and it is not clear whether this has been factored in into the pollen flow studies taken up on Bt Brinjal.

47. Further, it is pointed out that Bt brinjal pollen traveled to a maximum distance of 30 meters and that **there has been 0.14% to 2.7% outcrossing as per Mahyco's pollen flow studies. EC2 classifies this as "limited outcrossing"! What is limited outcrossing in a country of smallholdings?** Isolation distance and changed planting time is being suggested to minimize outcrossing – who is liable for this? How can small farmers maintain isolation, that too in vegetable plots which themselves are very small, usually leased?

48. **Page 36**: "Further, the EC-II opined that even if there is a very small influx of pollen originating from Bt brinjal varieties, it is not of any consequence, as the Bt protein has been extensively tested for its safety to the environment and food/feed and thus pollen transfer to other cultivated brinjal would not pose any safety risk". This is not an acceptable stand – the EC2 cannot decide on the rights of people who want to remain GM-Free like this! The Bt protein testing that they are referring to is of Cry1Ac and not the chimeric gene used in Bt Brinjal.

49. **Page 36: Horizontal Gene Transfer:** "Horizontal gene transfer from plants to animals (including humans) or microorganisms is extremely unlikely; Similarly, gene transfer from brinjal, or any other plant, to microorganisms is extremely unlikely", says the EC2 report. This is simply not true (Annexure 3) and this kind of a superficial response without any scientific basis and testing especially in the current instance of Bt Brinjal is not acceptable.

50. **Page 37: Aggressiveness studies**: Did they happen during MLRTs or Large Scale Trials? There might be a difference depending on this given how many plants were actually planted per plot in the first instance.

51. **3.2.3.: Impact on non-target organisms and Specificity of Cry proteins**: No in-vitro studies have been taken up with Bt Brinjal, especially at the highest levels of Bt protein expression from this GMO. Further, this analysis once again is a reductionist analysis centred around only Cry1Ac and refuses to acknowledge that other changes in the plant could also result in unpredictable impacts.

52. **Page 38-Table 3.1: Laboratory based eco-toxicology experiments**: It appears that a surrogate protein has been used in all the studies cited in the table and that itself can make these studies invalid. Further, the EC2 says that "No adverse effects were found at the above levels, which are significantly higher than that would be present in the fields" – this is not true since the protein levels in Bt Brinjal are supposed to reach upto 47 ppm!

53. **Page 40: Soil impact studies** – Despite the EC1's recommendation, **no study has been taken up on subsequent crop impact to this day**. (Page 3 of EC1 report: The changes in fertility and impact on next crop may also be recorded. In other words carry over effects of residues of Bt brinjal should be investigated). Further, the soil impacts studies in 2007 and 2008 were taken up by Mahyco and not IIVR!

54. **On absence of detection of Bt protein and such findings from these Bt Brinjal**-related studies, the EC2 observes that findings are in agreement with numerous studies that have shown only target pest impacts and no other impacts. These findings are in fact at great variance with findings from numerous other studies including a recent IARI study with Bt Cotton in India. It is not possible to agree with a finding that says "No Cry1Ac protein was detected in any soil samples". There must be something seriously wrong with the methodology if that were the case! This contradicts numerous other findings!

55. **Page 40 – last para** – The EC2 says: *"It was further noted that cry1Ac gene has been derived from a common soil bacterium and therefore it is expected that soil microorganisms are already exposed to these proteins within the environment".* This is a very unscientific statement since Bt as an organism is certainly present in the soil, but the protein is not in constant expression; and our farm soils certainly do not have Bt as a

protein that is being expressed by GM plants on a large scale. To even equate all these in a superficial, unscientific way is unacceptable on the part of the EC2.

56. **Page 41: "Large scale cultivation of Bt Cotton since 2002 without any toxic effects reconfirms that Cry1Ac protein has no deleterious effect on soil microflora", argues the EC2 report!** On what basis is this being concluded? What studies have been done to show that there are no toxic effects from such large scale cultivation? What about the IARI and UAS-Dharwad experimental studies which do show impacts of Bt Cotton on soil?

57. **Box 3.3 on Possible accumulation and persistence of Bt protein in soil**: Half life in different studies cited here is reported to run into several days - 9.3 days to 40 days depending on the soils and incorporation of plant material etc. If this is the case from available literature, how come there has been no detection of Bt protein in the Bt Brinjal studies conducted by the company and IIVR?

58. **Point 3.3. on Page 43: Food and Feed Safety Assessment**: An Independent Expert Committee (October 2006) noted the following on the genes and vector used in Bt Brinjal. "Though *Cry1Ac* gene was earlier considered generally innocuous, recent published evidence indicates that Cry1Ac protein from *Bacillus thurengiensis* is a potent systemic and mucosal adjuvant as potent as the cholera toxin which enhances mostly serum and intestinal IgG antibody responses specifically at the large intestine (Vazquez et al, 1999). Also another study (Vazquez-Padron et al, 2000) demonstrates the possible interaction *invivo* of Cry proteins with animal bowel. According to Moreno-Fierros et al (2000), caution needs to be exercised while using Cry-containing plants and plant products for human use. Recent reports on *CaMV 35S* (Myhre et al, 2006) note that promoter gene expression in human enterocyte-like cells might have GE food implications. Regarding the *aad* gene used in developing Bt Brinjal [streptomycin resistant gene], this Committee notes that according to the EFSA, this is a potentially dangerous marker to animals and human beings and should not be used in the case of GM plants used as food. The *Agrobacterium tumefaciens* medium was used for the transformation process of development of Bt Brinjal. Strains of agrobacterium were earlier implicated in incidence of bronze wilt in cotton in the US (McGraw, 2000). It is not clear whether its potential impacts have been studied carefully in this case".

59. **Page 43, Point 3.3.1. Toxicity and allergenicity of purified Cry1Ac protein**: All such evidence is irrelevant in the current instance as Bt Brinjal has a chimeric protein. The references are from 1993, 1996 and 1999 while the allergen database could have increased subsequently. Further, while a positive finding of homology may indicate allergenicity, a negative finding may not be a useful indicator of safety! This approach of individual genes and citing safety studies around them is completely inadequate since several studies with GM foods with these genes incorporated into them have shown numerous adverse impacts.

60. **nptII protein**: The half life in simulated intestinal fluids from a 1993 study cited by EC2 is two to five minutes. Can we conclude that there is no safety implication from this, with this information? Further, the implications from HGT of the gene cannot be ruled out.

61. **Page 45: Point 3.3.2.:** Toxicity and allergenicity of Bt Brinjal: Acute oral toxicity test: "proteins that are non-toxic by the oral route are not expected to be toxic by the dermal or pulmonary route". This is something that is routinely used in biosafety dossiers by crop developers, their sponsors (ABSPII, for example) and even "Expert Committees". However, the example of Ricin, a phytotoxin in castor, is worth mentioning here as an

illustration to the contrary. Toxicity of Ricin differed with the route of challenge in experimental studies and the most lethal was the inhalation route, compared to other methods of exposure routes. The toxicity of ricin by the oral route is reported to be several orders lower than by pulmonary or injected routes[1].

62. **Point 3.3.2.:** the sub-chronic oral toxicity study in Sprague Dawley rats is described as "This study provided information on the possible health hazards likely to arise from repeated exposure ***over a relatively limited period of time***". This is an interesting description and admission about this study since the EC2 is also arguing that sub-chronic studies are long enough! Prof Seralini however pointed out to: "Circling disorder and diarrhea were noticed only in the Bt brinjal group, males and females. Moreover liver weight as well as relative liver to body weight ratio decreased in the dose range study in females, by 13% apparently significantly. For the rats fed Bt brinjal water consumption was 8-21% more than the non Bt brinjal group for some periods".

63. **Page 46: Point 3.3.3.: Alkaloid content:** "Alkaloid profile of Bt and non-Bt is the same with not much appreciable variation in their relative abundances", states the EC2 report. Prof Seralini has calculated that the difference is upto 237% and no statistical significance tests have been conducted. The EC2 is however not hesistant to classify this as "not much appreciable variation" and this is unscientific.

64. **Page 47: Detailed compositional analysis**: The EC2 report says that the control substance was collected from 'near-isogenic line': what does that mean, near-isogenic line?

65. **Page 47: Feeding studies on Rabbits**: "It was concluded based on the health, growth and physio-pathological parameters analysed during the experiment that *there were no significant differences* between the groups fed with Bt brinjal containing *cry1Ac* gene and control non-Bt brinjal fruit". However, this is not the conclusion in the study. As per Report of Study No. 4418/05, dated 14/7/2006, as contained in Volume 3 of Bt Brinjal biosafety dossiers on the GEAC website:

    "6. Haemotology: There were no changes observed in between Control Non Bt Brinjal (G2) and transgenic Bt Brinjal containing Cry1Ac gene (G3) groups except for an incidental but not biologically significant reduction in platelet count in G3 males at interim blood sampling and ***significant increase*** *in Hct, reduced MCHC in G3 males and increased prothrombin time in G3 females at terminal blood sampling".*

    "7. Clinical Chemistry: There were no changes observed in between Control Non Bt Brinjal (G2) and transgenic Bt Brinjal containing Cry1Ac gene (G3) groups except for an incidental but not biologically significant increase in albumin, and total bilirubin in G3 males and increased total bilirubin, lactose dehydrogenase in G3 females at interim blood sampling and ***significant increase*** *in the AST, ALT, Total Billirubin and Sodium levels in G3 males and increased total bilirubin and decreased glucose levels in G3 females at terminal blood sampling".*

    G3 group in this study is Bt Brinjal-fed animals' group and the results by the admission of the crop developer itself are the above whereas the EC2 chooses to falsify the findings by saying that "there were no significant differences between the groups".

[1] Gill, D.M. (1982) Bacterial toxins: a table of lethal amounts. Microbiol. Rev. 46, 86

These differences are discounted by the study scientists as thus: *"these changes are considered incidental and not related to transgenic Bt Brinjal feeding since the changes were **marginal** and of no biological significance".* **Beyond this, no rationale is available or provided and the explanation provided by EC2 on Page 59 under Issue 9 is simply not applicable here.** Bt Brinjal cannot be considered safe just because the EC2 concludes so without any scientific basis, falsifying even the findings of the crop developer!

66. **Page 48: Goats study – sub-chronic 90 days study** – "It was concluded based on the health, growth and physio-pathological parameters analysed during the experiment that there were no significant differences between the groups fed with Bt brinjal containing *cry1Ac* gene and control non-Bt brinjal fruit", says the EC2 yet again. However, the conclusions from the study are different and interpretations highly questionable (like above).

    Report of Study No. 4417/05 (page 17 of 131), contained in Vol. 4 of the Biosafety Dossier of Bt Brinjal on the GEAC website has the following: *"There was significant difference in the hay consumption of the transgenic Bt Brinjal and control non-Bt Brinjal fed groups and the control normal diet group except for incidence of lower hay consumption in G3 group males as compared to G2 group during week 11. The change is considered to be marginal and considered to be of no physiological significance"*!

    Haemotology: *"There was no significant difference in the haemotological parameters between the transgenic Bt Brinjal and control non-Bt Brinjal fed groups **except** for incidental change in the value of prothrombin in G3 group males at termination".*

    The prothrombin time for G3 group was 21.47 seconds with the difference with control groups being statistically significant but justified as being within the range of historical control values (prothrombin time – 11.8 and 21.6 seconds). **The results could easily have been OUTSIDE this range and one can only guess how the crop developer would have justified the statistically significant changes even in this case.**

    Clinical chemistry parameters: *"There were no significant differences in the clinical chemistry parameters between transgenic Bt Brinjal and control non-Bt Brinjal fed groups **except** for incidental changes in the values of total bilirubin and alkaline phosphatase in G3 group males at termination".*

67. In fact, the EC1 on page 12 of its report refers to mentions that "Two kg of fresh Bt brinjal was considered by the independent testing institution, GB Pant University of Agriculture and Technology, to be appropriate". This is however not reflected in the protocols.

68. **Page 49 Conclusions**: The EC2 conclusion on "lack of toxicity in animal feeding studies" is questionable since the data is actually showing findings that require further investigation if not an outright rejection of Bt Brinjal!

69. **Page 49 conclusion:** "The detailed compositional analysis confirms that Bt brinjal is substantially equivalent to its non-Bt counterpart, as no significant differences were observed in any of the components". This is questionable since no qualitative compositional analysis has been taken up in the first instance.

70. **Page 51: Table 4.1: field trials conducted with Bt Brinjal in India** – This table has incorrect information on three Mahyco Bt Brinjal hybrids having undergone MLRTs with

ICAR in 2006-07. The date of transplanting is not normal and might not have captured peak pest load on the crop.

71. **Page 52: Point 4.2.1.: Efficacy of the intended Trait:** The results are presented through simple averages and standard deviation. No statistical analysis beyond this was done. Further, the fruit yield in Bt Brinjal is reported to be 335.69 q/ha (+/- 39.36 q/ha) and for non-Bt Brinjal, it is reported to be 287.28 a/ha (+/-28.93 q/ha). However, there are several practicing farmers and scientists who are reporting that their normal yields are in the range of what is being reported for Bt Brinjal! This brings to the fore a question being asked repeatedly – where is the need for Bt Brinjal?

72. **Page 52: Efficacy of intended trait: Fruit damage in bt hybrids** – "The cumulative fruit damage during these trials in Bt brinjal hybrids, their non-Bt counterparts and checks was 8.15%, 26.10% and 25.02% respectively. "The mean cumulative fruit damage in Bt hybrids ranged from 6.28% to 10.04%, whereas the range for non-Bt hybrids and checks was 23.52% to 30.36%", reports the EC2. If that is the case, the yield difference if at all should be only around 16.5% to 20%?? However, the next point on Agronomic Performance records this: "The mean increase in marketable yield of Bt hybrids over their non-Bt counterparts and checks was 71% and 97%, respectively".

73. **Page 52: Economics of Bt Brinjal** – The pesticides cost projections are based on ETLs and chemical spray recommendations. The numbers projected here are very unscientific since if the same trial was done with different pest management options, including non-chemical IPM and NPM, the economics would be vastly different!

74. **Page 53: Estimated economic benefit due to increased marketable yield**: on what basis was this calculated? Which year's price and why? Does this take into account a glut in the market?

75. **Page 55: Antibiotic resistance**: Reviews by regulatory authorities worldwide will not be readily applicable here – one, because of antibiotic resistance as a prevalent problem that health workers are already contending with in India, as compared to situation in other countries; two, consumption patterns of food being different in India where highly processed foods are not consumed and in the case of Bt Brinjal, it could be consumed in numerous ways that are more or less involve direct consumption.

76. **Antibiotic resistance**: the issue is not that of these nptII and aad genes making anti-biotics ineffective because of the enzyme that they produce being in low quantities from Bt Brinjal but that of horizontal gene transfer. Without even studying such a transfer in the case of Bt Brinjal, how can any conclusions be drawn, based on what studies?

77. **Page 56: Claim that crops containing antibiotic resistant genes have a history of safe use for more than two decades** – The EC2 has to show scientific proof of "history of safe use" before claiming so. Which studies have shown this? How do we know that the various problems that let us say the Americans are experiencing, are not in some way linked to GM foods?

78. **Page 56: "Point 5.2. Environmental Safety"** – Centre of Origin issue is yet to be resolved, says EC2. However, authorities concerned about plant biodiversity in the country are not questioning the existing knowledge around Centre of Origin and seem to have firm evidence on India being the Centre of Origin for Brinjal. This issue needs to be resolved scientifically and not just cursorily by an EC2 with two agriculture scientists in it who are both Bt Brinjal developers. The concern in any case is that of our existing

diversity being impacted by Bt Brinjal and there are no contentions on the fact that India is a Centre of Diversity for brinjal.

79. **Gene flow to wild relatives**: this cannot be ruled out – not from existing evidence and not from IIVR's study either. Also, the studies done with such crossability studies left out some species which have shown themselves compatible in other studies (for example, in TNAU).

80. The impacts of contamination cannot be measured only in terms of Cry1Ac trait conferring advantage to the wild relatives….Will there be no other changes with the gene transfer occurring? Is there scientific evidence for this that no other changes are to be expected? Also, is it true that no lepidopteran pests occur on the wild species? Amongst the related species, *S incanum* is known to have higher FSB infestation than others and is not devoid of pest infestation as stated by the EC2.

81. **Issue 4: Effect on Non-target Organisms:** Only the EC2 was privy to additional data. Data has been put out in public domain only later and this is being studied.

82. **Page 58: Cooking studies** (Point 5.3. Food/Feed Safety): This does not address the fact that further metabolites have not been tested for and that there could be other forms of consumption of Bt Brinjal, which do not require cooking. The response also looks at Cry1Ac. This also does not explore whether the harm from a GM food like Bt Brinjal limited to Cry1Ac or newer unpredictable proteins too?

83. **Page 58: No long term assessment of chronic effects** – The need for long term studies has been discounted on faulty grounds. The EC2, as in many other places in the report, talks of Cry1Ac being safe; however, the protein and gene in Bt Brinjal is not Cry1Ac, to begin with. There is NO history of safe use of Bt proteins either. Further, 90 days of a rat's age is just 3 months out of 36 months, which is $1/12^{th}$ of its lifetime. This certainly cannot be equal to 21-25 years of human life. Finally, many chronic health effects that we know today from various contaminants, have not been captured in acute effects' assessments and there is a lesson to be learnt there.

84. **Issue 9, Page 59: Differences found in toxicity studies** that have been ignored – The argument that if the values and data are within normal physiological range, that the product is still safe is questionable. "In the animal feeding studies conducted with Bt brinjal, no statistically significant changes have been observed in the parameters tested" is an outright false statement. A latest scientific study (Spiroux et al, 2009) elaborates on what is wrong with the current analysis and interpretation with results from toxicity tests and that should be read as a response to the EC2's comments on this aspect (Annexure 8 – "A comparison of the effects of three GM Corn varieties on mammalian health", 2009). Points 64 and 65 in this note have already addressed the issue of how EC2 is discounting statistically significant differences, even though the crop developer's data and reports contain the same.

85. **Point 5.4. OTHER ISSUES - "Issue No. 10 – Impact on Organic Farming**" – the EC2's lack of knowledge on the subject is showing starkly. Pest management does not rely totally on botanical extracts in Organic Farming as the EC2 seems to think. Even within that limited understanding, we can show an equal number of studies which show efficacy of organic methods too – whose word should prevail? Therefore, this whole section does not merit any response. Further, the callous response towards organic farmers who wish to remain organic is unacceptable. Why should the onus be on them when the problem is arising from somewhere else?

86. **Issue 11: Acceptance of data submitted by Mahyco** – ECI has already made a point on how some of the labs are not NABL accredited labs. There is no reason why the EC2 should go back on that point, given that at least four members, Dr Sesikeran, Dr Anand Kumar, Dr Mathura Rai and Dr Ranjini Warrier were common to both Expert Committees (25% of the members). In fact, Dr Sesikeran had written to the GEAC questioning the lack of authentification of test material, before the actual experiments were taken up. Samples being archived or not archived cannot be verified now.

87. **Issue 12: Adequacy of information/data generated by Mahyco: Page 61** – The response of the EC2 is completely unscientific and inadequate in this context. While on the one hand, India is supposed to have a case-by-case approval system, this response indicates that Bt Brinjal is not being decided on its own merit but on a pre-decided unscientific notion about Biotechnology, for public sector institutions in particular. The EC2 seems to have forgotten that biotechnology is not just transgenics and not symbolized by Bt Brinjal either. The EC2 should appreciate that this evaluation is not about biotechnology and its need in India but about Bt Brinjal and its safety.

    Information obtained under Right To Information shows that the NIN Director sent some comments to GEAC on October 4th 2007. He looked at only three studies: 90 days oral toxicity study (18 different comments but no specific recommendations), Acute Oral Toxicity Test (13 comments) and Allergenicity study (3 comments, on the Rallis study). For all the three studies, one of the things he pointed out was that **characterization/ authentification of the test article provided by the sponsor did not happen.** This is obviously something that cannot be retro-fitted into the tests that have already taken place and it is surprising that the EC2, which has the same NIN Director as a Member did not make any mention of his earlier findings and observations while addressing this Issue 12 or anywhere else!

88. **Section VI: Page 62 – Conclusions and Recommendations** – "Chronic toxicity studies are warranted only if any toxic effects are observed in acute or sub-chronic studies. Since no toxic effects were seen in acute and sub-chronic studies, there is no need and justification for any chronic or long term studies for evaluating the safety of Bt brinjal event EE-1" – this is a faulty and unscientific argument. Chronic effects need not show up in acute studies.

V. OTHER VERY IMPORTANT AND FUNDAMENTAL ISSUES

There are many issues that had not been mandated to be debated by the EC2 which need to be resolved and should have been, at least by the apex regulatory body before it cleared Bt Brinjal for India. After all, our regulatory regime is supposed to have enshrined the Precautionary Principle as a cornerstone by virtue of India being a signatory to the Cartagena Biosafety Protocol. This approach is technically and legally valid in the case of technologies such as GMOs in our food and farming. Some of these issues are discussed below, left untouched or even ignored despite evidence, by the EC2 and the GEAC.

i. **Pest management and pesticide-related issues** with Brinjal – Most brinjal cultivators in India are not cultivators with intensive farming practices and the pesticide use claims on Brinjal being to an extent of 84 sprays (that too, data from Bangladesh!) is very exaggerated. True, in those pockets where vegetable cultivation is in an intensive fashion, there may be numerous sprays of pesticides to control the

FSB and this kind of high pesticide usage obviously has implications for the ecology, farm economics and on other fronts like health. However, exaggerated projections of pesticide use should not form the basis for decision-making. It should be recalled that before the advent of Bt Cotton, the rationale applied was that around 55% of India's pesticide consumption was on Cotton crop alone and that pest management strategies like Bt Cotton were essential to bring down insecticide usage being targeted at the bollworm complex. Claims were made at that time that 60% of the pesticide usage on cotton was to control the bollworm complex. Bt Cotton was proffered as a solution and if projections were right, India's pesticide consumption should have come down by at least 35%. However, the figures of pesticide consumption do not reflect this either in volume and value. The same arguments are being offered for justifying Bt Brinjal and claims of high pesticide usage which are being projected as the average for all Brinjal farmers across the country are highly questionable.

ii. **Alternatives available for pest management in Brinjal**: there are highly successful, sustainable, affordable and farmer-controlled pest management alternatives available for pest control in Brinjal and these alternative practices are in fact holistic and do not necessarily tackle pests in a linear, reductionist fashion, pest by pest. When such alternatives exist both within the NARS system and with practicing farmers, there is really no need for Bt Brinjal as a solution. As the Supreme Court nominee to GEAC had recommended, the GM option should be picked up only in the absence of alternatives to a given problem. It is also apparent that Bt Brinjal is being compared in various studies against chemical pesticides and being projected as highly beneficial to farmers – the framework of analysis itself is obviously very faulty here, comparing one evil with the other so to speak. The Government of India should show the political will of extending and supporting alternative (alternative to GM seeds and synthetic pesticides) ecological technologies to farmers for sustainable livelihoods, as is being done in a government-supported programme called Community Managed Sustainable Agriculture in the state of Andhra Pradesh on lakhs of acres. Annexure 10 has details on such alternatives.

iii. **Experiences with Bt Cotton have many lessons to be learnt**: The Bt Cotton cultivation experience in India over the past eight years has many valuable lessons to teach policy makers, regulators, farmers and consumers of the country, if we choose to pick them up in pursuit of sustainable development objectives. (a) It has been shown time and again that the Bt technology is unpredictable and the very mixed results over years, locations and hybrids are there for everyone to see. In those places where results have been good, deeper analysis points to good seed source (germplasm into which the Bt gene has been backcrossed), good monsoon years, higher inputs in the form of water and nutrients etc. The technology has failed in many areas which are resource-poor in terms of soils, irrigation as well as farmers' ability to provide inputs. (b) Pest and disease ecology has changed in cotton in unpredictable ways. Secondary pests are emerging into major pests in several places. (c) Impacts on soil are being observed and reported by farmers and there is increased use of chemical fertilizers; a senior agriculture scientist of India had predicted that with even a 6% expansion of GM crop land in the country, there would be a doubling of chemical fertilizer demand and this brings its own problems including that of public financing of an unsustainable input. (d) Stress intolerance is found to be higher on Bt Cotton than on other non-GM cultivars. This has implications for risks and vulnerabilities of our resource-poor farmers. (e) Bt Cotton has left its impacts on animals which have grazed on the crop residues in different parts of the country including from consumption of Bt Cotton seed cake etc. Animals

have either died or fallen sick after consuming Bt Cotton and this phenomenon though acknowledged by some officials, has not been investigated scientifically and systematically by concerned agencies to this day (Annexure 9 is a paper on Bt Cotton and animal morbidity/mortality phenomenon). (f) Agricultural workers have also reported allergies after working in Bt Cotton fields and media and NGO reports exist from different states about this phenomenon which is also uninvestigated to this day. (g) On the regulatory front, Bt Cotton has repeatedly showcased the regulatory incapabilities of India, right from the time that illegal proliferation of unapproved Bt Cotton was first noticed in 2001. Regulatory failures were not just on the biosafety front but in terms of monitoring, reviewing, transparent and scientific decision making and so on. (h) State governments also found out through the tough way that there are no legal mechanisms available to them to regulate seed marketing, seed advertising, seed pricing and for liability and redressal for failures. All the above points are still pending, so to speak and would raise their ugly head in the case of Bt Brinjal too. It is very unwise to move into an edible crop, that too a first-of-its-kind in the world and an unneeded product to boot, without learning lessons from the Bt Cotton experience.

iv. **IPRs on Bt Brinjal and farmers' rights**: Even without any legally protected rights in the case of Bt Cotton, state governments and farmers and even Indian seed companies had to contend with the monopolistic behaviour of MNCs like Monsanto and their Indian partner as most other seed varieties got edged out of the market, as farmers lost their own seed stocks rapidly and as prices were fixed at exorbitant levels leading to many farmers getting into deeper distress and even committing suicides. The issues are going to get murkier with Bt Brinjal including an outright violation of farmers' rights over their germplasm and so on. The technology of Bt Brinjal supposedly belongs to Monsanto, as references here and there reveal. Mahyco is also supposed to have obtained a patent on the "Event" EE1 in Bt Brinjal. Further, public sector universities have parted with their germplasm, with the initial varieties obviously belonging to some farming community or the other, to develop Bt Brinjal varieties in a consortium project called ABSPII. In all of this, it is not clear who has the authority to regulate seed sales, pricing and royalty issues, who is claiming ownership and how on the germplasm that belongs to farmers that the public sector then developed into Bt Brinjal varieties and it is not clear who owns the Bt Brinjal varieties!! Annexure 11 is an article on these complicated issues and serious concerns around seed monopolies, violation of farmers' rights and rapid erosion of seed stocks with farmers etc., are yet to be addressed in any meaningful way by policy makers or regulators.

v. **Bt Brinjal and Indian Systems of Medicine**: Brinjal and related species are used extensively in Ayurveda and other Indian Systems of Medicine. Despite several efforts to get the regulators to look at a more comprehensive impact assessment regime, various stakeholders have failed to get the regulators to take this matter seriously. No impact assessment has been taken up to understand the implications and impacts of Bt Brinjal on Indian Systems of Medicine and this is a matter of grave concern. This could have implications not just in terms of a medicine becoming ineffective but potentially even toxic!

vi. **Bt Brinjal and rights of farmers who wish to remain GM-Free and/or organic**: The onus of remaining GM-Free and/or organic is obviously not with the ones who wish to be so since the origin of the problem lies with decision-making elsewhere. Any approval given to Bt Brinjal cultivation in the country will potentially violate the rights of those farmers who want to be GM-Free and/or organic and no

attention has been paid in the regulatory decision-making processes to issues such as this so far. The EC2 has callously asked such farmers to follow isolation distances etc., but it is not clear why the burden should fall on these farmers who have chosen sustainable pathways of development.

vii. **Rights of states which wish to remain GM-Free:** There are several state governments, which as per the policies adopted at the state level, wish to ban and disallow Bt Brinjal in their respective states. However, there are many practical issues to be addressed as borders with other states are porous and seeds can travel from one place to the other. As per the Constitution of India, Agriculture and Health are state subjects and any decision at the Centre that allows Bt Brinjal anywhere in India violates the authority and rights of those states which choose to remain Bt Brinjal-free.

viii. **Consumer rights and choices violated:** If Bt Brinjal is approved in India, the rights of consumers to choose what they would like to consume would be violated irreversibly. This is simply not acceptable. On the other hand, a labeling regime is practically impossible to implement for a vegetable crop in a country like India and is no solution for this problem.

ix. **No Liability, Redressal and Remediation regime in place**: Even as GEAC cleared Bt Brinjal for commercial cultivation in the country, it should be noted that no liability, redressal and remediation regime exists in India. Who is to be accountable, by what mechanism, for how much and in what conditions, for things going wrong? It is unconceivable that the regulators have cleared an edible GM crop with the Bt gene in it without resolving this basic issue and putting a sound liability, redressal and remediation regime in place.

GIVEN ALL THE ABOVE, IT IS IMPERATIVE THAT THE GOVERNMENT WITHDRAW THE BT BRINJAL EC2 REPORT AND REJECT ANY APPLICATION FOR COMMERCIALISATION OF BT BRINJAL IN INDIA. IN FACT, THE ABOVE FACTS POINT TOWARDS AN URGENT NEED TO STOP ALL OPEN AIR TRIALS OF GM CROPS IN THIS COUNTRY AND TO A NEED TO CREATE A DEMOCRATIC, TRANSPARENT AND SCIENTIFIC PROCESSES DRIVEN WITH A VISION FOR SUSTAINABLE DEVELOPMENT THROUGH WHICH REAL, LASTING SOLUTIONS CAN BE ESTABLISHED IN INDIAN FARMING AND FOOD SYSTEMS. SUCH PROCESSES SHOULD LEAD TO COMMUNITY-CENTRED AND COMMUNITY-LED SUSTAINABLE AGRICULTURE SYSTEMS, WITH APPROPRIATE SUPPORT STRUCTURES AND SYSTEMS CREATED BY THE GOVERNMENT.

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AS SEPARATE ANNEXURES, OTHER REFERENCES AND MATERIALS RELATED TO SUSTAINABLE ALTERNATIVES, ON HORIZONTAL GENE TRANSFER, ON CROSSABILITY, ON GENETIC INSTABILITY IN TRANSGENICS ETC., ARE BEING PROVIDED.

NEWS STORIES ON THE EXPERT COMMITTEE, ITS PROCESSES AND STORIES AROUND INTERVIEWS WITH EC2 CHAIR/MEMBERS:

1. **"Bt brinjal clearance ignored dissenters?"**
   http://www.gmwatch.org/index.php?option=com_content&view=article&id=11670:bt-brinjal-clearance-ignored-dissenters

2. **"Green Signal for Bt Brinjal"**
   http://www.downtoearth.org.in/full6.asp?foldername=20090215&filename=news&sec_id=4&sid=20

3. **"Bt Brinjals in markets near you"** (Audio recording of Dr. Bhargava's interview with Down To Earth) : http://www.downtoearth.org.in/bt_brinjals.asp

4. **"How Bt Brinjal was cleared" – Down to Earth article on the EC2**

http://www.downtoearth.org.in/full6.asp?foldername=20091231&filename=news&sec_id=4&sid=3

5. **"Bt Brinjal tests inadequate – How safe is it"**

http://ibnlive.in.com/news/bt-brinjal-tests-inadequate-how-safe-is-it/106477-3.html

6. **"Controversy continues over Bt Brinjal approval"**

http://ibnlive.in.com/news/controversy-continues-over-bt-brinjal-approval/106190-3.html

7. **"New twist of controversy over commercial release of Bt Brinjal"**

http://beta.thehindu.com/news/national/article60225.ece