Minutes of the 2nd meeting of the Expert Committee on Bt brinjal held on 3.07.2007

The second meeting of the Expert Committee on Bt brinjal was held on 3.7.2007 under the Chairmanship of Dr. C. R. Babu, former Pro-Vice Chancellor, Delhi University in the Ministry of Environment & Forests, New Delhi.

At the outset, Dr. Ranjini Warrier, Director, MoEF informed the Committee that Dr. Deepak Pental, Vice Chancellor, Delhi University and Chairman of the Expert Committee on Bt brinjal has intimated that being an active researcher in the area of transgenics and due to his busy schedule with the DU admission process he will not be in a position to Chair the meeting of the Expert Committee on Bt brinjal. Dr. Warrier proposed that Dr. C. R. Babu, in view of his experience and being the senior most member of the Committee may be requested to Chair the second meeting of the Expert Committee on Bt brinjal. The Committee endorsed the proposal made by Director, MoEF.

Dr. C. R. Babu thanked the Ministry of Environment & Forests and the Committee for entrusting the responsibility of such a complex issue. He stated that the issue related to development and release of transgenic crops especially food crops is highly controversial as there are two schools of thoughts which would never merge even if the debate continues for a century. He was of the view, the aim of the Committee should be to see how to narrow the gap between the two groups so that the benefits of science and technology are available to the society. He initiated the meeting by inviting Dr. R. Warrier to give a brief background on the mandate of the Expert Committee and the latest development in respect of the Hon'ble Supreme Court ruling.

Dr. Warrier informed the Committee that M/s Mahyco has produced transgenic brinjal plants with cry1Ac gene from *Bacillus thuringiensis* tolerant to the fruit and shoot borer, one of the major pests which attack the brinjal crop throughout its life cycle. Bt Brinjal developed by M/s Mahyco is the first GM food crop under evaluation for release in India but it is also the first GM eggplant to be released globally. GEAC had posted the biosafety data generated by M/s Mahyco on its website for public comments. In accordance with the decision taken in the GEAC meeting held on 1.6.2006, MoEF has set up an Expert-Committee to review the feedback received on Bt brinjal proposal submitted by M/s Mahyco.

The terms of reference of the Expert-Committee is as follows:

a) To evaluate comments received from the various stakeholders vis-à-vis the biosafety data generated by the Company and available scientific /technical data/literature from studies conducted by various national and international institutions.
b) Suggest additional studies (if any) to be conducted.
c) To evaluate the adequacy of the protocol proposed for LST and recommend additional safeguards (if any).
d) Recommend protocol for socio economic studies.
e) Any other recommendation on related aspects.

The first meeting of the Expert-Committee on Bt brinjal was held on September 25, 2006 wherein it was decided that representatives of MoEF and DBT would compile the representations received from various stakeholders and submit a summary of the issues raised for consideration of the Expert-Committee in the second meeting.

In view of the Hon'ble Supreme Court Direction dated 29.09.2006 wherein the GEAC was directed not to accord any approval till further directions are issued on the matter, the second meeting of the Expert Committee was deferred. Vide Order dated 08.05.2007, the above direction has been amended to the extent that the GEAC may accord approval for commercial release of Bt cotton hybrids expressing approved gene events such as *cry 1Ac* (MON 531 event), *cry 1Ac and cry 2Ab* (MON 15985), *cry 1Ac* (event 1) and *cry 1Ab + cry 1Ac* GFM. Further, the Hon'ble Supreme Court has also

permitted conduct of field trials of GM crops expressing new gene events subject to the following conditions:

1. All trials should have a lead scientist's name with contact details who would be responsible for all aspects of the trials including regulatory requirements.
2. An isolation distance of 200 m would be maintained during field trials.
3. Prior to bringing out the GM material from the green house for conduct of open field trial the Company should submit a validated event specific test protocol at an LOD of at least 0.01% to detect and confirm that there has been no contamination.

In light of the above Order, this second meeting of Expert Committee has now been convened. She also informed that the following documents have been complied for facilitating the discussions. These documents were also circulated to the members in advance.

1. Overview of the biosafety regulatory framework in India
2. Summary of development of Bt brinjal and biosafety assessments
3. Summary of representations/concerns raised by the stakeholders
4. Response received from members and other experts
5. Other relevant issues

After a brief discussion on the implications of the Hon'ble SC directions dated 8.5.2007, the Chairman invited each member to present their preliminary views on the major issues that need to be addressed while taking a view on the proposal for conduct of large scale field trials of Bt brinjal developed by M/s Mahyco. He further requested the Committee to consider point wise the comments received from the stakeholders. Summary of the stakeholder comments and response of the Committee is annexed at **Annexure I** to this document. Lastly, he requested the Committee to list out the additional biosafety studies that need to be generated before the product is considered for commercial release.

Conclusions and Recommendations

A. The Committee concluded that the biosafety data generated by the Applicant is in accordance with the protocol and procedures stipulated by the regulatory agency. However, Bt brinjal being the first GM food crop to be released in India and the first to be released globally, the Committee was of the view that a cautious step by step approach needs to be taken. While the data generated by the Applicant concludes that the Bt brinjal is safe and equivalent to its non Bt counterpart, the Committee was of the opinion that more independent studies especially with respect to toxicity assay in NABL accredited laboratories may be required to re-affirm the findings made in the earlier studies. The Committee further opined that the short term data generated on the environmental safety and socio economic aspects needs to be further substantiated with additional trials / tests to explicitly conclude the benefits from Bt brinjal and superiority of the technology with respect to existing technologies especially the available methods for pest management and pesticide reduction.

The Committee is, therefore, of the opinion that large scale field trials may be allowed subject to the conditions mentioned below:

a) All field trials should be conducted in the research farm under the control of ICAR/IIVR. The trial should be carried out under the direct supervision of Director, IIVR.

b) All field trials should strictly comply with the Hon'ble Supreme Court direction dated 8.5.2007 which directs:

- All trials should have a lead scientist's name with contact details who would be responsible for all aspects of the trials including regulatory requirements.
- An isolation distance of 200 m would be maintained during field trials.
- Prior to bringing out the GM material from the green house for conduct of open field trial

the Company should submit a validated event specific test protocol at an LOD of at least 0.01% to detect and confirm that there has been no contamination.

B. The Committee further recommends conduct of the following studies during large scale trials:

i. Field trials for assessing the environmental safety and agronomic advantage of Bt brinjal needs to be repeated at a minimum of **10-11** locations to represent different agro climatic zones for two seasons. The protocols for the trials would be finalized by RCGM in consultation with Director, IIVR.

ii. The pollen flow would be recorded during the field trials every 10 m up to 200 m in one trial plot at a minimum of 6 locations representing different agro climatic zones for a period of two years. The pollen flow study should be conducted with a minimum of around 100 standing plants, planted at an interval of 75x50 cm spacing.

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

iv. As per the directions issued by RCGM baseline susceptibility data needs to be generated for at least three pests - Fruit and Shoot borer (*Leucinodes orbonalis*), Gram caterpillar/fruit borer (*Helicoverpa armigera*) and Stem borer (*Euzophera perticella*), over a minimum of two years (two seasons). The Committee noted that baseline susceptibility data for stem borer have not been generated. The Committee advised that the same may be conducted during the two year field trials.

v. The Cry1Ac protein expression levels were assessed every 30 days and not every 15 days as prescribed by RCGM through the crop cycle. The Committee recommends the study be repeated in accordance with the procedure prescribed by RCGM.

vi. *Soil impact assessment study* should include tests on the counts related to Rhizobium in the soil of Bt and normal plots and for the presence/absence of Cry1Ac protein at different depths (up to one metre) in the soil at one location. The changes in fertility and impact on next crop may also be recorded. In other words carry over effects of residues of Bt brinjal should be investigated.

vii. Bt brinjal being a food crop, a flavour analysis of Bt and non-Bt fruits may be included as an additional parameter and this study may be undertaken at CFTRI.

viii. The Company to review if the highest MIC95 value should be kept for monitoring rather than the average for the target pest vis-à-vis Cry1Ac protein expression levels.

ix. The Food / Feed Safety assessment should include foliage toxicity study in Goats.

x. The skin sensitization test of transgenic material in guinea pigs as laid down in the DBT guidelines has not been taken up. The Committee recommended the study may be conducted.

xi. Additional toxicity / allergenicity / compositional / nutritional studies as recommended by Director, NIN after examining the raw data on food and feed safety generated by the Applicant.

xii. Detailed socio economic study as prescribed by a three member Sub Committee comprising of Dr. S. Parasuraman, Director, TISS, Mumbai, Dr. M.N. Murthy, Director, IEG and Dr. Mathura Rai, Director, IIVR, Varanasi.

xiii. Analysis of fruit dry matter to determine differences in yield from the agronomic trials in respect of Bt and check entries.

Results from all studies must be reviewed along with the socio economic study to decide on the introduction of Bt brinjal in India.

****

Annexure-I

Response of the Expert Committee on Bt brinjal with respect to comments received from stakeholders

1. ENVIRONMENTAL ISSUES:

a. Comments on Pollen flow studies

1. The pollen flow studies with regard to Bt Brinjal were done in two locations during 2002. The one year study taken up is grossly inadequate to understand the potential contamination of and transfer to other species from Bt Brinjal and such studies require at least 5 years in different locations to understand the potential impacts.

2. The Mahyco presentation itself talks about brinjal being cross-pollinated to an extent as high as 48% and 'is often classified as a cross-pollinated crop'.

3. The pollen flow studies done in the case of Bt Brinjal do not assess the distance traveled by the transgene though the objective states so. The counting of spiny seedlings from the non-spiny Pusa Kranti brinjal variety's progeny also does not indicate outcrossing percentage of the transgene. It only measures the outcrossing of other traits and not the transgenic trait, which is of utmost concern.

4. Pollen travel distance was concluded as 20 meters and outcrossing percentage as 1.5% to 2.7% based on this protocol with serious shortcomings. These results are highly undependable, both because the protocol is faulty and because the results are inconsistent with known information on such outcrossing. This outcrossing will obviously be a combined result of several factors, including the fact that insect load and activity itself might be low in a given situation [like the company's campus]. This insect activity could also vary across kharif and rabi seasons. Therefore, what comes out of the limited testing by Mahyco in its campuses cannot obviously be generalized to all brinjal-growing situations in the country.

5. In the protocol adopted here [concentric rings of Pusa Kranthi non-spiny hybrid around the Bt Brinjal plot], the movement of pollen gets effected drastically by the pollen load / density, micro-climate, physical hindrances etc. created by the crop (Pusa Kranti) taken around in concentric rings. As we all know, this is one of the factors always considered in modifying / reducing the isolation distances in seed production programs. This pollen load and density will also be affected by the size of the Bt Brinjal block in the middle. It is not clear from the data provided by the company how big the transgenic brinjal plot was in the middle.

6. The study only looks at the potential transfer from one cultivated variety to another. It does not look at a whole set of issues related to potential transfer to wild and other related varieties and the subsequent impact on the eco-systems that are present for each of these varieties.

7. There is no data or study of pollen viability which is also an important factor to consider, talking about outcrossing and insect pollination.

8. Does GEAC or the company have data on all the related species to brinjal, wild and otherwise and where these exist? Do they have data on the eco-systems of such areas? Have they done any tests to understand the potential impacts of Bt Brinjal on such varieties and their eco-systems?

9. The pollen flow studies should actively look at exceptional pollination events, since India is a centre of origin for brinjal.

10. There is no data on other methods of propagation including seed spillage etc. The weediness tests [and test for volunteers] are completely inadequate and even one volunteer is a potential source of cross-pollination later on. The company-adopted protocol is obviously faulty, inapplicable to real growing conditions and has not obviously tested for transfer to wild varieties and the possibility of Bt Brinjal conferring an advantage to them.

11. The extent of pollen flow also depends on the pollen load and also on the insect activity in the area. The 2 studies conducted at Rannebennur and Jalna are only conclusive of pollen flow in those locations and this data cannot be extrapolated for the whole country.

Response of the Expert Committee with respect to comments on Pollen flow studies:

The Committee made the following observations in respect of trials conducted by the Applicant:

1. Pollen flow experiments were carried out according to approved protocols in 2 locations. The pollen flow studies did assess the distance traveled by the transgene, by assessing the distance traveled by pollen from transgenic plants. This also allowed estimation of outcrossing frequencies for the experimental plots.

2. The pollen flow study protocols followed were standard protocols approved by the regulatory authority. Experimental details, including field design, dimensions, layout and area under the transgenic crop were submitted to the authority at the time of application for permission to conduct the trials.

3. Pollen flow studies were conducted to establish the pollen behavior in Bt brinjal and to show if it is any different than non-Bt brinjal. Weediness studies were conducted and reported to the authorities.

4. These studies indicated that Bt brinjal does not show any weediness characteristic and behave in a similar fashion as any cultivated non-Bt brinjal.

The Committee concluded that the data generated for one season at two locations is not adequate to estimate the extent of pollen flow and outcrossing ability of the Bt brinjal. The Committee was of the view that the pollen flow studies should be conducted for a period of at least 3 years. As the applicant has conducted the pollen flow studies for one season the Committee recommended that the pollen flow studies repeated for another two years at a minimum of 6 locations in different zones. The pollen flow studies should be conducted with a minimum of 100 standing plants in a plot size of 75X50 sqm. The pollen flow should be estimated at every 10 meters up to 200 meters.

With respect to wild species of Solanum and their habitats, most of the species of Solanum are introduced from S. America and are naturalized in India. These are weedy and found in disturbed habitats such as roadsides, vacant lands, agricultural fields and forest fringes. These species are not components of natural ecosystem but are confined to ruderale communities. Consequently, it is meaningless to investigate the impact of pollen flow of eco system however, it is necessary to assess the pollen flow on the weedy species of Solanum found in ruderale communities.

b. Comments on Centre of Origin

1. No GM crop has ever been released in its country of origin so far anywhere in the world. The overwhelming concerns about a Centre of Origin relate to environmental, agricultural, socio-cultural and IPR issues which have to be given a serious consideration by the regulators.

2. Even more seriously is that India contains wild and weedy species of brinjal. There are landraces, weedy forms and allied wild species in India although the evolutionary relationships and classification are not well understood. GE contamination could reach these wild and

weedy forms. Once in these populations, it cannot be eradicated. In addition, the GE trait in Bt brinjal is insect resistance.

3. No studies on the effects of the presence of the Cry 1Ac gene in wild varieties have been done so far. The surety of gene flow along with the absence of the knowledge on the impacts of the insertion of such genes in the wild varieties creates a dangerous situation.

Response of the Expert Committee with respect to comments on Centre of Origin:

1. The exact origin of *S. melongena* is uncertain. There are reports that suggest, South America as the Centre of Origin of the species of the genus Solanum, to which both potato (*S. tuberosum*) and brinjal (*S. melongena*) belong. It probably originated from the African wild species *S. incanum. S. melongena* was first domesticated in SE China, and taken to the Mediterranean region during the Arab conquests in the 7th century. There are also reports that the brinjal originated in Indo-Burma region (Hawkes et al., 1979). Experiments conducted three decades ago confirmed that the pollen-mediated transfer to *Solanum* species such as *S. insanum, s. incanum and S. integrifolium* was possible (Rao, 1979). However, the Bt genes will not confer any fitness advantage to these species because insect pests are rarely found on these species. If brinjal was mentioned in ancient Indian literature, it only indicates that it was domesticated, having been introduced into India, a long time ago and this in itself is not an evidence of its origin in India. There is no doubt that India has contributed to its diversification through domestication and breeding. India may be a secondary centre of diversity while Africa is the preliminary centre of diversity. It may be noted that *S. Melongena* does not occur in wild and is not weedy like other species of genus.

2. The Bt gene used in Bt brinjal confers no advantage to recipient plants in terms of aggressiveness or growth characteristics. No instances of natural interspecific hybridization with wild species have been reported for cultivated brinjal. However, investigations are necessary on the invasiveness of transgenic brinjal and on the natural hybridization between Bt brinjal shown in kitchen garden/ agricultural fields and the weedy species of Solanum found in and around the Bt brinjal growing sites.

The Committee concluded that outcrossing studies should be conducted under complete confined condition at one location at IIVR, Varanasi. The ability to cross with *Solanium iIncanum* and the properties of weediness and invasiveness of Bt brinjal should be assessed.

c. Comments on Soil Impact Studies

1. There are several serious shortcomings with the protocol adopted for the soil analyses related to Bt Brinjal cultivation.

2. The soil impact studies have not been conducted to capture cumulative effects over several years of Bt Brinjal cultivation and have only analysed impacts for one season in each zone.

3. The physiological and molecular aspects were not studied in different treatments in these soil analysis tests. Similarly accumulation of toxin through the leaf litter was not taken up, as the soil samples were collected on pre-harvest days. The toxin persistence in the soil seems unestimated.

4. To estimate the impact of Bt toxin on soil microorganisms involves isolation and enumeration of micro-biota and study of biochemical characteristics for utilization of certain chemicals (or) compounds (or) production of metabolites by their physiological characteristics. Enzyme studies and finally the molecular behaviour of the genes responsible for particular characteristics have to be understood for changes.

5. The study results did not reveal the following: what are the lethal levels of toxins to kill the test invertebrates? What are the actual toxin levels in the soil in the pre-harvest and post-harvest seasons of Bt and non-Bt crops? What are the changes in enzymatic and physiological behaviour in soil biota? What are the genetic modifications that took place affecting the functions of the microbes?

6. It is not clear what the plot sizes for the study of soil invertebrates are, when the company took up the study in the two years [while one was on the campus, the other was during limited field trials, we are made to understand]. The reliability of data from a study like this depends a lot on the plot sizes used because insects and other invertebrates can readily move in and out of small areas. There is little chance of detecting any effects when the plots are small.

7. From other studies that looked at soil invertebrates, especially from Bt eggplant crop, it can only be concluded that the impact on non-target invertebrates is not well understood.

8. It is also apparent that no comparison has been made with plots which grew non-Bt Brinjal.

9. The method of using insect bio-assays for measuring toxin levels in soil samples is unreliable. How do we know that the baseline susceptibility of the larvae chosen is not low? Other methods have to be adopted that would measure the toxin level as well as persistence.

10. Finally, what tests have been conducted to assess the impacts of Bt Brinjal cultivation on the next crop – its growth, disease incidence, yields etc., - for medium and long term impacts in a cumulative sense, due to alterations in soil conditions which cannot be captured over just one season?

11. Since conclusive experimental evidence is available to indicate that root exudates from GM crops perceptibly alter the soil microflora profile (Vadakattu & Watson, 2004) it is disturbing that no data has been generated on this very crucial aspect, which can substantially alter the inherent fertility status of the soil in which these crops are grown. The long-term effects of such changes can vastly affect the productive capacity of soils in which these crops are grown. Such data must have been provided to eliminate any doubt on the possible adverse effect of root exudates on soil's inherent fertility status.

Response of the Expert Committee with respect to comments on soil impact studies:

1. Soil studies have been conducted over two seasons and 8 locations covering different agro-climactic zones of the country. These studies analysed root-zone and non-root-zone, as well as pre- and post-harvest soil samples.

2. Bt protein has been assessed in soil at regular intervals during the crop growing season in the rhizosphere and non-rhizosphere zones from plots where Bt plants and control plants were cultivated, as well as after the crop was removed from the field (30 days before crop planting to 60 days after crop harvest, sampling done every 30 days). The protein was undetectable at all time-points in the study indicating that the levels of protein in soil, if any, were below the detection levels. The reported half life of Cry1Ac protein is 9.3 to 40 days depending on the soil types.

3. Non-target effects have been analysed for soil microflora and invertebrates. Bt protein estimation in soil samples have indicated no variation observed in the microbial populations of Bt and non-Bt brinjal soil samples tested indicating that Bt protein has no effect on soil microflora.

4. Baseline susceptibility was not part of soil analysis but was carried out for the assessment of resistance, if any, existing in the population of target insects.

5. Plot design and other details were submitted to the authorities at the time of application for permission to carry out soil studies. All soil studies, except for one location, were carried out during multi-location field trials. One study was conducted on a company-owned field.

6. All soil samples from Bt plots were compared with samples from adjoining non-Bt plots in the same trial field.

7. Insect bioassays and ELISA are widely accepted methods for estimation of Bt protein in soil. Laboratory populations of the insect larvae were used for the bioassays, and ELISA for detection of Bt protein in the soil. Both methods showed no detectable Bt protein in all samples tested.

8. Multi-location field trials of Bt brinjal at 17 locations over two years showed no effects on subsequent crop cultivation.

9. Root-zone and non-root zone samples were analyzed at all locations where soil impact studies were conducted. No differences in soil microbiota and invertebrate populations were observed.

The Committee concluded, though the data generated for two seasons indicate that there is no variation in the presence of soil microflora and invertebrates, it is advisable that the studies may be repeated to include tests on the counts related to Rhizobium in the soil of Bt and normal plots and for the presence/absence of Cry1Ac protein at different depths (up to one metre) in the soil at one location. The changes in fertility and impact on next crop may also be recorded. The protocol for the studies may be designed in consultation with IIVR and approved by RCGM. The impact of Bt brinjal on AFM and earthworms in soils should be assessed. Many of the non target insects' larval phases are completed in the soil. The impact of Bt brinjal on these insects should also be assessed.

2. HEALTH ISSUES (COMMENTS ON FOOD SAFETY ASSESSMENT):

a. Observations on whether the tests were conducted as per the DBT guidelines

1. The DBT guidelines for sub-chronic oral toxicity study on goats for 90 days specify that Indian ***Barberi*** breed should be used whereas ***Osmanabaadi*** breed was used in the experiments for Bt Brinjal.

2. The skin sensitization test of transgenic material in guinea pigs as laid down in the DBT guidelines has not been taken up.

3. Sub-chronic oral toxicity of leaves of transgenic plants on male rabbits prescribed in DBT guidelines was not tested.

4. The allergenicity of the protein extract from transgenic brinjal was carried out in *Brown Norway* rats and not in *rabbits* or *guinea pigs* as suggested in DBT guidelines.

5. DBT guidelines prescribe ***in vitro*** and ***in vivo*** immunological assays for the detection of reactogenic antibodies in the test sera. ***In vivo*** assays (PCA and PK tests) were not done.
6. The DBT guidelines state that the characteristics of the donor organisms, of the vectors used, of the transgenic inserts and of the transgenic plants are required to be generated.

Response of the Expert Committee in respect of observations on whether the tests were conducted as per the DBT guidelines:

1. The Barberi breed is popular in urban areas of Delhi, western Uttar Pradesh and Haryana. Attempts to popularize the breed in southern region have not been successful as the animal did not adapt to the agroclimatic regions. The Osmanabadi or Deccan breed of goats is available in the southern region, mostly in Maharashtra, Andhra Pradesh and Karnataka. The breed also meets most of the criteria of Barberi and is well adapted to the agroclimatic conditions in the southern parts of the peninsula. As per the Universities Federation for Animal Welfare, the choice of breed for experimentation in case of goat and sheep is dictated by climatic conditions and availability. In this case Osmanabadi was selected as the study was to be carried out in Bangalore city located in extreme south of the country. In compliance to the later part of the guidelines pertaining to the study, the goats were procured from a single source, the Goat Research Station, Osmanabad to ensure standard genetic background and maintenance of health barrier. The study was conducted by Advinus Therapeutics, Bangalore, a NABL accredited laboratory. Both barberi and osmanabadi breed are stall bred and therefore the experiment conducted with osmanabadi breed is scientifically acceptable.

2. The skin sensitization test of transgenic material in guinea pigs as laid down in the DBT guidelines has not been taken up. The Committee recommended that the study may be conducted.

3. As per the guidelines of DBT only sub-chronic oral toxicity in male rabbit is mandatory. However, the company carried out this study by including additionally female rabbit as one of the treatments. All required parameters as per the DBT guidelines were assessed separately for both male and female rabbits.

4. The protocol for testing allergenicity with Brown Norway rat is a recognized model for allergenicity studies and superior to the rabbits or guinea pigs models. Therefore, no additional study with guine pig or rabbit model is necessary.

5. Characteristics of the donor organism, vectors and inserts have been submitted to the regulatory authorities.

b. Observations on toxicity, allergenicity/ irritation tests:

1. The report on Sub-Chronic Oral Toxicity Tests on Spraque Dawley rats for 90 days given in summary by the laboratory and the company raises the following questions:

   i) The reports say that "there were isolated instances of necropsy findings" isolated is how many? Clarification on 'isolated' is missing.
   ii) The incidence of 'pathological lesions' ... 'being extremely small' needs further explanation.
   iii) They conclude that it is not dose-dependent when apparently only one dose of 1000 mg was used. The three doses of 250, 500 and 1000 mg/kilo of body weight were used only in the dose-ranging study of 14 days and not the main study of 90 days as per the report. It is not clear how the main study report [of 90 days] then concluded that it is not dose-dependent.

   Unless the raw data is examined and the full report is seen, it is not possible to arrive at meaningful conclusions regarding the safety of the product.

2. The report on Sub-Chronic Oral Toxicity Study on Goats for 90 days that, statistically significant changes were found in the haematological as well as the clinical 'parameters. But despite this, they are not considered to be of physiological significance. In the absence of raw

data, including the range of control values, it is difficult to further comment on this aspect on the safety or otherwise of the product.

3. The reported significant difference in the hay consumption of the transgenic Bt Brinjal fed group is also of concern.

4. It is claimed that several toxicity, irritation and feeding tests have been taken up to prove the safety of Bt Brinjal. However, no feedback is possible on the tests since no data has been shared, other than the protocols being shared.

5. All that the studies cover are possible acute and sub-chronic [90 days] effects. These tests do not look at long term sub-lethal effects, multi-generational effects, reproductive health effects due to organ damage or effects on growth etc. etc. It is very important that GEAC do not take a decision on a food crop, that too a vegetable crop, without such long term studies.

6. The acute oral toxicity test of transgenic brinjal result summary on page 28 of the first document put up on the MoEF website says that the control group was gavaged with non-transgenic cotton seed and not non-Bt brinjal. This is either a typographical error or the fact that the company supplies "set result summary" for various crops, whether Bt Cotton or Bt Brinjal.

7. Similarly, feeding tests as in the case of the feeding tests on goats consisted of feeding the animals "with a concentrate of which 12.5% was test seed and the concentrate itself will be 10% of the total feed", whereas Bt brinjal could be fed directly in large quantities [and not just "test seed"] to cattle/livestock especially when there is surplus production and when there is dumping at market yards due to excess production. The cow feeding tests for instance were done with "a total mixed diet where all diets will have the same inclusion level of test/control substance or part of the concentration mixture" with around 2 kgs of fresh transgenic brinjals. When there is dumping in market yards, the consumption could be much higher than this. What tests have been done keeping in mind the worst possible scenario in real life and keeping in mind long term impacts?

8. As has been pointed out earlier in the sheep mortality fact finding reports, feeding tests have not been done against sheep [but on goats which are known to be hardier animals] and against real life open grazing conditions. The real feeding conditions also include the fact that they are grazed in open fields, with different parts of the plant consumed, possibly in combination with some pesticide sprays. The other possibility, as in the case of Bt Cotton, there could be misunderstanding amongst farmers that no sprays are required for the transgenic crop and therefore, grazing on the crop is much more safer.

9. In the Primary Skin Irritation test done on rabbits, it is not clear what the "test article" was. The animals seem to have been treated with the transgenic vegetable, with two checks of non-transgenic brinjal and untreated check. However, past investigations into the health problems with Bt Cotton have shown that the cotton fibre of the Bt Cotton plant could be inducing the allergic reactions. Similarly, a Filipino study on Bt Maize showed that the pollen could be the allergy-causing agent. How then does a study on the vegetable conclude that workers who work in the Bt Brinjal fields will not be affected [especially given the fact that the reports from various states out that workers are having skin allergy problems while working in bt cotton fields]?

10 In the sub-chronic oral toxicity test on rats, it is reported that "There were isolated instances of necropsy findings such as reddening of lungs, dilated kidney pelvis, distended uterus and abscess in salivary gland. The gross pathological changes observed during necropsy were confirmed histologically. The abscess noted grossly in salivary gland was confirmed histologically. Lungs reddening noted at necropsy in four animals, was identified as acute congestion. The incidence of pathological lesions being extremely small, and not dose

dependent, was not considered to be of toxicological significance" . These findings need more explanation and these could indeed be the 'early warnings' that a precautionary approach requires. The GEAC should ask independent research bodies to conduct the test, with longer periods to find out if this is a finding that requires serious attention.

10. Similar are findings related to haematology, clinical chemistry etc., in the case of goat feeding and rabbit feeding studies which can be understood better only if all findings in terms of tabulated numbers are presented.

11. There are serious limitations to current allergy testing procedures for GMO proteins. For example, recent results in Australia revealed that a protein previously consumed safely in beans had become immunogenic (similar to allergic reaction) when engineered into GMO peas. The immunogenicity of the GMO peas would not have been detected by currently used tests. Therefore, new allergy tests, and careful, long-term tests, are needed to assure the safety of Bt brinjal. The pea immunology test is very important because it formally proves that the assumptions underlying the 'event based' approval process are fundamentally wrong. In this test, the Australians also used a latest testing procedure and this paper is annexed to this letter.

Response of the Expert Committee with respect to observations on toxicity, allergenicity / irritation tests:

1. The allergenicity testing protocols were approved by the regulatory authority before the studies were carried out.

2. The isolated instances of necropsy refers to the random occurrence of abnormalities found in the animals used for the studies and are in no way related to the administration of the Bt brinjal test material. In this particular study, more such instances were observed in the control groups of animals (7/20) than in the animals treated with Bt brinjal (2/20).

3. Regarding the pathological lesions, the entire sentence in the report is: "The incidence of pathological lesions being extremely small, and not dose dependent, was not considered to be of toxicological significance." (p.21). The numbers of animals showing pathological instances are as follows: No treatment, 3/20; Non-transgenic brinjal, 4/20; Non-transgenic commercial check, 5/20; Transgenic brinjal, 2/20. (Appendix C1, p.89)

4. The dose study conducted prior to the main study is a normally accepted practice to determine what dose of the test material is to be used in the main study.

5. The haematological differences were found in the non-brinjal fed group (normal diet) when compared to the brinjal fed groups, and not between the non-transgenic brinjal treated group and Bt brinjal treated groups.

6. There was a marginal decrease in hay consumption by male goats in the Bt brinjal fed group in week 11 of the study. This was considered not to be of physiological significance.

7. Sub-chronic 90-day animal studies are widely accepted as standard tests for food and feed safety.

8. The Committee expressed concern at the 'typographical error' in the report submitted by Intox. The Committee requested MoEF/DBT to verify whether Intox is a NABL accredited laboratory and if not the Institute needs to be audited through an agency such as NIN.

9. Bt brinjal and control brinjal **fruits** (not test seeds) in quantities of 500 grams were fed daily to the goats in the sub-chronic 90-day goat study. It is not clear what concentrate is referred

to. Two kg of fresh Bt brinjal was considered by the independent testing institution, GB Pant University of Agriculture and Technology, to be appropriate.

10. Goats are closely related to sheep, and a sub-chronic 90-day feeding study was completed on this species.

11. The test article was Bt brinjal powder compared to non-Bt brinjal powder. The reports of Bt cotton inducing allergies/ sheep death in AP etc. are unsubstantiated.

The Committee requested Director, NIN to examine the raw data and clarify whether any variations/ anomalies observed in the toxicicity and allergencity studies submitted by the applicant are statistically acceptable variations or abnormalities arising of Bt gene. The Committee further requested Director NIN to indicate whether there is a need to repeat or conduct additional food safety test and while doing so he may take into consideration the gaps between the Biosafety Guidelines of 1998 prescribed by DBT and the Codex guidelines.

c. Comments on Health Impact:

1. Though cry1Ac gene was earlier considered generally innocuous, recent published evidence indicates that cry1Ac protein from *Bacillus thuringiensis* 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 *in vivo* 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.

2. Recent reports on CaMV 35S (Myhre et al, 2006) note that promoter gene expression in human enterocyte-like cells might have GE food implications.

3. 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.

4. The *Agrobacterium tumefaciens* 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.

5. The Cry toxins from Bt are known to be allergens and immunogens. The antibiotic-resistant marker genes [aad and nptII genes] bring their own serious concerns with regard to the safety of the product. The nptII gene confers resistance to antibiotics like kanamycin and neomycin. The aad gene confers resistance to streptomycin and spectinomycin. Further, the aad gene is under the control of a bacterial promoter. Both genes and DNA can theoretically get transferred into bacteria and cause antibiotic resistance. In a country which depends on antibiotics like streptomycin in its healthcare, this could be a dangerous development.

6. Similarly, use of the CaMV 35 S [cauliflower mosaic virus] promoter, used in creating Bt Brinjal is a matter of concern. Published research shows that the 35S promoter can initiate transcriptional activity in human cells, despite the promoter being a plant-specific one. The cauliflower mosaic virus (CaMV) has similarities with the human hepatitis B virus. As all genomes of living species contain dormant viruses, there is a potential for the CaMV promoter to reactivate them raising concerns related to cancers.

Response of the Expert Committee with respect to comments on health impact:

1. Extensive biosafety studies conducted worldwide for more than a decade have concluded with *cry1Ac* and *nptII* gene products are safe.
2. The *aad* gene is not expressed in plants. Moreover, there are no reports that soil bacteria have taken up DNA from crop plants, whether transgenic or otherwise (reviewed in UK government's GM science review, www.gmsciencedebate.org.uk/report/default.htm).
3. There is no relationship between an antibiotic-resistance marker gene used in plants and antibiotic resistance in humans. The marker gene is used in research to help researchers distinguish a new plant variety from related plants. When the plants are exposed to the target antibiotic in the laboratory, the new plant variety will continue to grow, unaffected by the antibiotic, allowing the researcher to identify and select for plants that have the desired trait.
4. An antibiotic-resistance marker gene is not an antibiotic. It produces a protein that allows only plants containing the marker gene to grow in the presence of a specific antibiotic. This protein is broken down in the digestive tract. Therefore, the marker gene product cannot function in the human body. It cannot inactivate antibiotics and the likelihood of an antibiotic resistant gene being transferred from food to bacteria in the human gut is negligible.
5. Cauliflower mosaic virus is very commonly present in cabbages and cauliflowers sold in the market. Historically human beings have been consuming CaMV and its 35S promoter at levels that are over 10,000 times greater than those in uninfected transgenic plants A typical infected cauliflower cell contains around 100,000 copies of the virus and its genome. The suggestion that CaMV 35S promoter could be transferred from plants to green algae, yeast, *Escherichia coli* and human cells is untenable on the grounds that such a transfer had not occurred even though, throughout history, humans had consumed huge quantities of the CaMV 35S promoter. The Hepatitis B and CaMV viruses never replicate in the same cells; CaMV replicates in plants and hepatitis B in animals.

d. Comments on Food Cooking and Protein Estimation studies:

1. The company claims that studies have been done on protein estimation in cooked transgenic brinjal and reports that the Bt protein was undetectable cooked fruits and that the Cry1Ac protein rapidly degrades upon cooking.

2. Whether the company or the GEAC have data on how many different ways brinjal is consumed in different parts of the country, by different communities. What does this data say?

3. The claim that the protein was undetectable and that it degrades rapidly is questionable. While it cannot be detected in its soluble form, what has happened to its breakdown products is important. What are the effects of such products?

4. Cooking studies should take into account complex food matrices and not just raw seed or fruit or vegetable in isolation. In the Cooking Studies and Protein Estimation, the company has tested for the Cry1Ac protein but has not checked for the metabolites. While the ELISA test might show negative for the protein, it does not account for the complex food matrix situations, as the Starlink Corn case has demonstrated.

Response of the Expert Committee with respect to comments on Food Cooking and Protein Estimation studies:

The common popular methods of cooking brinjal include roasting, steaming and shallow- or deep-frying. The presence of Bt protein was tested for in common brinjal cooked in all the popular ways. All methods showed that the Bt protein is non-detectable by ELISA within one minute of cooking. In the digestive system the Bt protein breaks down into common amino acids which are part of normal

diet. Further, the *Cry 1Ac* protein has been tested extensively in various digestive assays internationally and is found to be safe.

3. AGRONOMIC ISSUES:

a. Comments on Mahyco's Agronomic trials:

1. To critically understand Genotype Environment-Pest interactions, at least three years' data is required (over the same season) and not just two or three crops grown in a year. This is because the pest incidence is seasonal and is highly influenced by the environment.

2. The trials cannot be termed as Multi-locational trials since each hybrid has been tested at the most at two locations.

3. Further, the trials for each specific hybrid were not continued in the subsequent year in the same location whereas such trials should be with the same hybrid, in the same location for at least three years.

4. Similarly, consistent data over at least three years on insect susceptibility/resistance and efficacy of the method as per ICAR norms is required to arrive at any meaningful conclusions.

5. Data provided by Mahyco on non-target pests is only for one season and one centre. It should be from all the centres, over seasons.

6. Trials are not compared with best agronomic and pest management practices already existing (IPM, NPM, organic). Available data generated by institutions like Indian Institute of Horticulture Research, Tamil Nadu Agricultural University, Anand Agricultural University, Centre for World for Solidarity/Centre for Sustainable Agriculture clearly show that other efficient pest management practices are possible. Therefore, the best available management practices should be the check for testing Bt Brinjal's efficacy.

7. There are some important questions unanswered on the data parameters, listed below:

    - % damage of terminal buds and shoot damage is an important parameter that needs to be assessed.
    - toxicity and efficacy of the technology on the first instar larvae of Fruit & Shoot Borer (FSB) is something that needs to be clearly assessed.
    - data on little leaf incidence is to be generated and reported
    - plant population at the time of harvest is important
    - all the trials should also take up entomological evaluation in addition to agronomic evaluation. Wherever the plant population is low or the trials are not reported, the reasons for that should be indicated and assessed.
    - In some cases, pest incidence (of FSB) is below ETL even in control plot.
    - Some data like 80 larvae/plant is exaggerated and unbelievable
    - ETL across locations is highly variable (CD and CV should be mentioned and data needs to be analysed statistically).

8. In Mahyco's trials conducted in 11 locations, data have been presented only from 9 locations. The data from Hissar and Alwar are not presented.

9. In Kharif 2005, permission had been accorded for 15 trials. However, data for only 3 hybrids from six locations has been presented. How is this accounted for or justified is not clear.

10. No statistical analysis has been done in reports by the company. Without statistical analysis no meaningful conclusions can be drawn.

11. Data on the number of (pesticide) sprays, quantity of fertilizer used and the type of fertilizers used for the different treatments are not available.

12. No information on the plant population at the time of harvest is available. This is extremely crucial for a reliable statistical scrutiny.

13. It is not clear who has taken the count of various pests, insects, diseases etc., from the trial plots and who has supervised data collection from the farmers' fields.

14. Data have not been presented along the checks and the non-Bt counterparts. Selective presentation of data is noticed.

15. The variation in yields across locations is very high and it is not clear whether the same management practices were used across locations for drawing any conclusions.

16. While permitting limited field trials, the DBT asked for the evaluation of field infestation levels of Fruit and Shoot borer (*Leucinodes orbonalis*), Gram caterpillar/fruit borer (*Helicoverpa armigera*) and Stem borer (*Euzophera p*erticella). However, details of the evaluation carried out are not available for any meaningful conclusion. This should have been presented for all the treatments for various pests for any such conclusion to be drawn.

17. As per information available, baseline susceptibility data was generated only for one pest [*Leucinodes*] for one year [2004] even though the DBT's permission letter given to the company for conducting multi-locational trials in 2004 as well as 2005 requires the company to generate such data for at least three pests - Fruit and Shoot borer (*Leucinodes orbonalis*), Gram caterpillar/fruit borer (*Helicoverpa armigera*) and Stem borer (*Euzophera perticella*), over a minimum of two years (two seasons).

18. The DBT has asked the company to assess the Cry1Ac protein expression levels once every 15 days in their permission letter. This has not been meticulously followed.

19. Data on the economics of pesticide use, the cost-benefit ratio, as required to be generated from all trial locations as per the DBT's permission letter in 2005 is not available. In the absence of such data, no valid and dependable conclusion can be drawn on the efficacy of Bt brinjal.

20. It is not clear how the agronomic trials were conducted in Kharif 2004 and Kharif 2005 by the company. For each hybrid, multi-locational trials were conducted for only one year, in two locations only, based on which fruit damage and average fruit damage is being reported to be dramatically different between the Bt and non-Bt brinjal plots.

21. What was the protocol adopted for the company's trials? Did it compare the Bt Brinjal with other alternatives like IPM, NPM, organic etc.? Who oversaw the data generated by the company, for each location and what were their monitoring findings?

22. The agronomic performance overseen through the ICAR trials has misleading data and conclusions. This is unreliable since the data has not been statistically analysed. Even the data

presented by Mahyco from its own limited field trials in farmers' fields shows a 7-fold variability in yields per hectare, across hybrids and a 2.5-fold variability within a hybrid. This skews the averages quite a bit.

Response of the Expert Committee with respect to comments on Mahyco's agronomic trials:

1. Mahyco conducted multi-location field trials at 17 locations over the same season for two years (K-2004 and K-2005) to understand genotype-environment-pest interaction. These interactions were also studied and reported in field trials at two locations during K-2002, prior to the multi-location trials.

2. In addition to the company-managed MLTs, ICAR trials with each of the eight Mahyco Bt hybrids were conducted at 11 locations over 2 seasons.

3. Data on baseline susceptibility of the target insect pest was generated consecutively for two years in 2004-05 & 2005-06. Brinjal fruit and shoot borer, (*Leucinodes orbonalis*), infested fruits were collected from fields. There were a total of twenty nine locations which included nine populations collected from RCGM Bt brinjal trial locations in Kharif 2004, six populations from RCGM Bt brinjal trials in Kharif 2005 and fourteen populations during 2004-'05.

4. Studies on non-target insect pests were carried out over 2 years of multi-location field trials at all sites (17 locations). Data generated on non-target insect pests has been submitted to the regulatory authorities.

5. Data on percent shoot damage was recorded during the MLTs and submitted to the regulators. Data on damage caused by brinjal fruit and shoot borer (BFSB) to shoots and fruits was recorded and submitted.

6. Efficacy of the Bt brinjal technology on different BFSB larval stages, including first instar larvae, was established in laboratory assays as it is not possible to conduct the study under field conditions. Bt brinjal was found to be efficient in controlling first instar BFSB larvae.

7. Data on brinjal little leaf incidence has been generated and reported.

8. Plant population at the time of harvest has been recorded and data has been submitted to the regulators.

9. Entomological evaluation for both target and non-target insects has been taken up and reported during all the field trials conducted by Mahyco. Data generated from all the field trial locations has been submitted to the regulatory authorities.

10. An isolated instance of 80 larvae/plant was observed and recorded only at one location during the multi-location field trials. As per the report, the mean larvae count per plant vary between 3.47 to 20.79 larvae / plant in non Bt plants. The highest count was observed at Kurnool (22 larvae/ plant). In Bt plant it varied from 0.32 to 5.27 plant.

11. The ETL was fixed at 5% shoot damage and 10% fruit damage. Statistical analysis of the data generated during field trials was undertaken as part of the standard field evaluation procedure.

12. Mahyco conducted multilocation field trials at 11 locations during K-2004-05 (Jalandhar, Alwar, Mirzapur, Bhopal, Ahmadnagar, Pune, Solapur, Kurnool, Tumkur, Dharwad and Dharmapuri). Hissar was not in the list of proposed and/or approved locations. Mahyco did

not conduct a trial there during the K-04 season. Data generated at all 11 locations were submitted to the regulatory authorities.

13. In Kharif 2005, permission was sought by Mahyco for 15 locations. However RCGM permitted trials only at six locations.

14. Data on number of pesticides sprays used, quantity and type of fertilizers used were recorded. Pesticide spray data was submitted to the regulatory authority.

15. Data recording on various aspects of the field trials was done by Mahyco field trial coordinators who are full-time employees of Mahyco.

16. Data generated on Bt brinjal have been presented in comparison with the non-Bt counterparts and non-Bt checks.

17. As per the approved protocols, local agronomic management practices were followed. Bt brinjal, their non-Bt counterparts and checks were subjected to similar management practices at the same location.

18. Since the primary objective of the study is to assess the efficacy of the technology, evaluation of field infestation levels of Fruit and Shoot borer (*Leucinodes orbonalis*), Gram caterpillar/fruit borer (*Helicoverpa armigera*) and Stem borer (*Euzophera p*erticella) have been conducted. Insect data was recorded for all treatments laid out in the field trials.

19. Baseline susceptibility data were generated on brinjal fruit and shoot borer (*Leucinodes orbonalis*) over two seasons (2004 and 2005). Extensive multi-year data for baseline susceptibility of *Helicoverpa armigera* for Cry1Ac is available. It was noted that baseline susceptibility for Stem borer (*Euzophera perticella*) has not been carried out.

20. Cry1Ac protein expression levels were assessed every 30 days and not every 15 days as prescribed by DBT through the crop cycle.

21. Only limited data on savings in usage of pesticides and yield advantage with respect to Bt brinjal over their non-Bt counterparts were recorded and submitted to the regulatory authorities during MLT. More data on the economic aspects of Bt brinjal need to be generated.

22. Multi-location trials conducted by Mahyco were monitored by MEC constituted by RCGM. Statistical analysis of the data generated has been presented before the MEC.

The Committee concluded that additional trials for agronomic evaluation need to be conducted by an independent agency such as IIVR. The Committee recommended the agronomic evaluation be conducted at 10 agro climatic zones under the direct control and supervision of Director, IIVR, Varanasi.

b. Comments on the ICAR-supervised field trials:

1. The agronomic trials data presented by the company from its trials has to be read along with the ICAR-supervised All India Coordinated Research Project - Vegetable Cultivation (AICRP) results on Bt Brinjal, which are part of the regulatory requirements. From the data presented in the AICRP annual report for 2005-06, there is not much promise for Bt Brinjal.

2. Further, even in the AICRP data, a critical statistical analysis will present a reliable picture of the actual situation. For example, the fruit borer infestation figures between centres like

Varanasi and Hyderabad show a great variation and only statistical analysis will help to evolve a better picture.

3. In the ICAR trials, there is high variation and the results are erratic. No meaningful conclusions can be drawn on the performance as data is very insufficient.

4. Unfortunately, even with the best of efforts, information on the AICRP Bt Brinjal trials in 2004 would not available and these trials are not even reflected in the AICRP Annual Report, which is intriguing. Further, Mahyco's presentation to the GEAC does not have any data from the ICAR supervised trials.

5. All ICAR trials are paid up trials, no independent assessment was made. There is a serious and objectionable conflict of interest in this. Our own investigations reveal that many of the scientists involved in such trials are also not adequately trained on biosafety issues and testing protocols.

6. The agronomic trials conducted by ICAR was for two years for the first set of five hybrids and for one year for another 3 Bt Brinjal hybrids. However, data from the first year of trials is not available in public domain and no intelligent feedback can be provided without information on the protocols used and the complete set of data generated.

Response of the Expert Committee with respect to ICAR trials:

Taking into consideration the presentation and clarification submitted by Director, IIVR, the Committee concluded that:

1. ICAR trials are statistically designed trials and scientists of the Institute have adequate experience in conducting the trials.

2. ICAR trials have been conducted for a period of two years during 2005 and 2006 and results of the trials conclude that Bt technology is effective in controlling fruit and shoot borer.

3. ICAR trials are required to be conducted for a period of 2 to 3 seasons. On conclusion of the study, the report is directly submitted to the regulators.

4. ICAR trials are independent trials as the study is conducted and managed by ICAR scientists with no involvement of Company representative (except for providing seedlings).

5. The variation in insect mortality between the centres is quite a common phenomena and may be due to variation in natural infestation of the target insect and different climatic and soil factors. The differential level of infestation between hybrids is due to specific genotypic character or differential level of expression of target gene.

4. SOCIO ECONOMIC ASPECTS

a. Comments on Socio Economic Issues:

1. There is no need for Bt Brinjal to be introduced. This is not something that farmers have demanded and almost all major farmers' organizations of the country have already rejected the proposal of entry of Bt Brinjal even if it is in the form of field trials and seed production, whether in the public sector or in the private sector. There is no crisis in the production of brinjal and it is absolutely false that the company's data claims that there are upto 80 sprays of pesticides on brinjal crop. For the consumers, there is absolutely no benefit with Bt Brinjal but only a set of problems and dangers presented. All major consumer organizations of the

country have already rejected the idea of Bt Brinjal. If despite the lack of need and demand, Bt Brinjal is permitted for field trials and seed production, what guarantee is GEAC is giving to us that this is indeed safe? What liability-fixing mechanisms exist to hold each individual member of GEAC accountable for these kinds of decisions taken?

2. There are other issues on which Brinjal farmers need intervention & support. Are the GEAC and concerned government ministries and departments giving any guarantee to farmers that they will procure the crop and stabilize prices with Minimum Support Price and guaranteed procurement to ensure a fair price to farmers? If not, what real benefits will accrue to farmers?

3. What guarantee are GEAC and the individual members who represent ministries that are mandated to protect consumer interests giving that consumer rights and choices will be upheld even after the entry of Bt Brinjal, if approved? Will labelling work for distinguishing between Bt and non-Bt Brinjal in our markets and haats? What choices are being left to consumers of the country who want to remain GM-free in their consumption and how will their fundamental right to safe food be upheld?

4. If Bt Brinjal is for reducing pesticide usage, then it has to be noted that Bt Brinjal has been compared with only conventionally-grown brinjal. This completely ignores the rich experience that exists within the Indian Council of Agricultural Research [ICAR] on Integrated Pest Management on brinjal, that too with non-chemical approaches. It also ignores the fact that there is vast experience with NPM and organic approaches which farmers have been successfully using for years now on a large scale. Does GEAC have data on such experience and does the Committee know how Bt Brinjal compares with such experience?

5. Brinjal has great socio-cultural significance in the country. Does the GEAC or the company have adequate information/data on such aspects and what the impact of Bt Brinjal would be on such socio-cultural dimensions?

6. Preliminary socio-economic studies were conducted by academic institutions. Publications and reports generated by these researchers have been submitted to the regulatory authority.

7. Brinjal is also used in Ayurveda for its medicinal properties. Does GEAC or the company have data on this and about what Bt Brinjal's impacts on the efficacy of such medicines would be?

8. Coming to the "biosafety tests" that have been conducted on Bt Brinjal – it is repeated again through this letter that no independent studies have been taken up to test the biosafety of Bt Brinjal. The entire regulatory mechanism is relying on the developers of the product to come back to the regulators and actually report that something is indeed wrong with the process or product! This is of course impossible to happen and the past history with biotech corporations shows that companies like Monsanto have willfully suppressed information evolved through own investigations on harmful effects of GM crops. There is completely unacceptable conflict of interest in this matter and GEAC should therefore not take any decisions based on this set of studies and findings.

9. It is obvious from all the tests that they were done in great haste, to appease the regulatory requirements rather than to genuinely test for any potential adverse impacts, especially in the medium and long term. Very important tests including the effect of Bt toxin combined with pesticides [combination effect] was not taken up anywhere whereas this would be the reality of cultivation practices even with GM technology! In addition, there is of course the whole area of "unintended consequences" where the regulators and others do not even know the right questions to ask!

10. There seems to be the presence of a Mahyco member of staff at all times during the interviews which completely invalidates any findings of this survey.

11. Where is research on consumer acceptance, consumer willingness to pay for non-GM premiums, on potential effects of markets on farmers etc.? Where is research on socio-economic impacts vis-à-vis successfully established ecological alternatives?

12. Where is research on the implications of IPRs on farmers' rights, economics, control over the technology, legal implications and so on, in the socio-economic impact assessment?

13. Rights of farmers and consumers who wish to be GM-free: What protection and guarantee is GEAC going to provide for farmers and consumers of this country who have a right to be GM-free and their Right to Safe Food?

Response of the Expert Committee with respect to socio economic aspects:

The Committee concluded that the socio economic data generated for Bt brinjal is not adequate to establish the need / superiority of the Bt technology with respect to other conventional techniques available. The Committee recommended that a three member Sub Committee comprising of Dr. S. Parasuraman, Director, TISS, Mumbai, Dr. M.N. Murthy, Professor of Economics, IEG, New Delhi and Dr. Mathura Rai, Director, IIVR, Varanasi be constituted to prescribe a protocol for conduct of socio economic studies and mechanism for evaluation of the data generated from the context of issues projected by the stakeholders.

b. Comments on Other Issues:

1. It not certain whether the testing laboratories follow Good Laboratory Practice (GLP) procedures and whether they are accredited. It is also not clear how testing materials were ascertained and whether they are authentic. The laboratories undertaking the test must ensure their authenticity by independently getting them analyzed.

2. The committee was constrained to some extent since the details of the experiments [protocol, full data, statistical evaluation etc.] were unavailable to critically examine the issues involved. In fact, in many instances only the summary of reported work carried out was available.

Response of Expert Committee with respect to comments on other issues:

1. **F**ood safety studies are conducted in public institutions and various government accredited laboratories such as Indian Veterinary Research Institute, Izatnagar, National Diary Research Institute, Karnal, Indian Toxicological Research Institute, Lucknow, Avian Research Institute, Rae Bareilly, Central Institute for Fish and Aquaculture, Mumbai, Advinus Ltd, Bangalore and Intox, Pune. Advinus Ltd, Bangalore is a NABL accredited laboratories. Intox, Pune is an ISO accredited laboratory. The Committee also expressed concern regarding the validity / authenticity of the reports submitted by a reputed Institution such as Intox. The Committee sought clarification on whether Intox is an NABL accredited laboratory. If it is not, the Committee recommended that the same may be audited by NIN. Based on the audited report, it may be decided whether the study conducted at the institution needs to be repeated at a NABL accredited lab.

2. The raw data are available for review by any person who wants to examine in the presence of any representative authorized by the GEAC.

****