

**Minutes of the meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 27.04.2011.**

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The meeting of the GEAC was held on 27.04.2011 in National Agriculture Sciences Centre, Pusa under the chairmanship of Shri M. F. Farooqui, Additional Secretary, MoEF and Chairman, GEAC.

List of participants is annexed.

**Agenda item 1: Consultation with experts and scientist on regulatory process for Genetically Modified Crops as part of Bt brinjal post moratorium follow-up.**

1.0 At the outset, the Chairman welcomed all the experts and thanked them for sparing their valuable time in attending this important meeting. He further informed that the meeting has been convened as a follow-up to the direction given by the Hon'ble Minister to the GEAC in his decision document dated 9.2.2010 while imposing moratorium on Bt Brinjal Event EE-I developed by M/s. Mahyco, TNAU, Coimbatore and UAS, Dharwad.

2.0 To facilitate a focused discussion on the outcome of the public consultation, he requested Dr. Ranjini Warriar, Member-Secretary GEAC to make a brief presentation on the outcome and key concerns that emerged during the public consultations. Dr Warriar in her presentation explained in brief (i) Purpose of this meeting, (ii) Documents Circulated to Members; (iii) Legal and Statutory Requirements; (iv) Facts on Bt. Brinjal development; (v) Process followed by the GEAC; (vi) Process followed in the public consultation; (vii) Summary of key concerns. The following points were noted:

- I. The purpose of this meeting is to deliberate
  - a. key concerns that have emerged as outcome of the public consultation
  - b. need of additional studies to assess the safety of Bt Food Crops
  - c. protocols and procedures to be followed while conducting the additional studies
- II. To a query on why the Inter-Academy Report on GM Crops (updated) was circulated to the Members as it has not been discussed in the GEAC, it was clarified that all post-moratorium analysis document received by the GEAC which include (i) Dr Lou M Gallagher report pertaining to the scope and adequacy of the GEAC toxicology risk assessment; (ii) David A. Andow report on the scope and adequacy of the GEAC environmental risk assessment pertaining to Bt Brinjal, (iii) updated Inter-Academy Report on GM Crops; (iv) Socio-Economic Analysis of Production and Marketing of Brinjal and Ex-ante Assessment of Economic Benefits of Bt Brinjal in India have been circulated for information.
- III. The CEE report contained statements made by 631 stakeholders in the public consultations meeting (both propositions and concerns). The concerns raised by various stakeholders have been studied in detail and broadly categorized under

six categories, viz. general issues, molecular/genetic aspects, health/food and feed safety concerns, environmental concerns, market/trade issues and other issues. Specific comments reflected in the decision document have been further sub-categorized under each category as indicated below:

#### **A. HEALTH/FOOD AND FEED SAFETY CONCERNS**

1. Sub chronic 90 day rat feeding study not adequate
2. Feeding study design flawed to mask statistical differences in laboratory studies
3. Need for long term chronic toxicity studies
4. Concerns about the concept of substantial equivalence
5. Enhanced potential toxins, allergens and anti-nutrients
6. Reduced nutritional value of Bt brinjal/GM food
7. Transfer of novel genes to humans and animals and bacteria
8. Need for human trials
9. Issues related to Ayurveda and Siddha

#### **B. ENVIRONMENTAL CONCERNS**

10. Potential gene transfer to related cultivated and wild species
11. Impact on biodiversity/traditional varieties
12. Impact on non-target organisms
13. Accumulation of residue levels of expressed proteins in agro- ecosystem
14. Risk of becoming weedy/invasive
15. Insect resistance development
16. Environmental risk assessment not in accordance with Cartagena Protocol on Biosafety

#### **C. MOLECULAR /GENETIC ASPECTS**

17. Bt brinjal expresses chimeric gene (fusion of cry 1Ab & cry1ac ). Safety testing has been done only for cry 1 Ac gene
18. Contains gratuitous cassette for antibiotic resistance (*aad* gene encoding spectinomycin/streptomycin resistance) The cassette has a promoter for bacterial expression
19. Use of *Agrobacterium* based transformation system can cause cancerous tumors.
20. Effect of transferring viral sequences to plants, viruses and other organisms (CaMV 35 can activate dominant viruses.
21. Proteomics, transcriptomics (high throughput sequencing), metabolomics, 2D gel electrophoresis required for hazard identification or identifying unintended effects not carried out.

#### **D. MARKET/ TRADE ISSUES**

22. Need for post market surveillance

- 23. Labeling issues
- 24. Impact on organic farming
- 25. Socio economic issues
- 26. Liability issues due to contamination

#### **E. OTHER ISSUES**

- 27. Use of company data/lack of independent studies
- 28. Lack of public consultation in decision making
- 29. Lack of public awareness
- 30. Technology ownerships by the MNCs

#### **F. GENERAL ISSUES**

- 31. General opposition to GM crops
- 32. Need of Bt. Brinjal / Use of Alternative Strategies
- 33. Inefficient regulatory frameworks/mechanisms – Not compliant with Codex and Biosafety Protocol
- 34. Lack of independence in the regulatory agency.

- IV. It was also clarified that the list of concerns presented is only an indicative list but covers key areas of concerns, which need to be addressed by the Committee.

3.0 Subsequent to the presentation, the Chairman, GEAC invited views of the experts on general and specific issues covering the following:

- I. Gaps, if any, in the sub-chronic/acute toxicity studies
- II. Need for long term toxicity studies to assess the impact of Bt brinjal on human health.
- III. Need for profiling techniques/non-targeted approaches to identify unintended effects
- IV. Use of Antibiotic Resistance Marker (ARM) genes in GM food crops
- V. Impact on biodiversity/ traditional varieties due to gene flow
- VI. Crossability with the wild relatives
- VII. Insect Resistance Management Strategies
- VIII. Socio-economic and trade concerns
- IX. Reliability of the company's data/ independent testing.
- X. Lack of independence in the regulatory agency

4.0 The Committee extensively deliberated on the above issues. The following points were noted:

#### **A. General Issues**

- I. On the general issue, many experts were of the view that the Government should give a clear cut direction on whether GM Food is required or not for the country. If the

perception is not clear; it is going to affect ongoing research in public institutions and universities.

## **B. Specific Issues**

On specific issues, three points namely (i) need for additional biosafety studies to assess the safety of cry 1 Ac protein; (ii) acceptance of company data & (iii) the way forward were discussed. Details of the deliberations are summarized below:

### **I. Need for additional biosafety studies to assess the safety of Bt protein**

i On whether additional studies are required to assess the safety of Bt protein, most of the Experts were of the view that the studies prescribed under the current regulatory system and studies conducted with Bt brinjal are adequate. However Dr P M Bhargava, representatives of Department of AYUSH and Dr Ram Vishwakarma, Director, Indian Institute of Integrative Medicine, Jammu were of the view that additional studies may be required.

ii Experts who were of the view that additional studies are not required to assess the safety of Bt protein provided the following justification:

- Given that *cry1Ac* protein has been used extensively in global agriculture and has gone through biosafety clearances in so many countries, there should be no doubt about the safety of the *cry1Ac* gene. Adequate tests have been conducted for Bt Brinjal also. Cry1AC protein in corn has been tested in human and animal for more than 15 years.
- The safety data generated by NIN has been elaborated by experiments carried out within and outside the country that demonstrate (i) Cry1Ac interacts specifically with receptors aminopeptidase and cadherin of pest *Helicoverpa* only; (ii) divergence in the structure of cadherin and aminopeptidase results in lack of activity of Cry1Ac protein. Thus structurally diverse orthologous receptors of human corresponding proteins do not react at all with Cry1Ac; (iv) protein Cry1Ac is degraded in 20 seconds to non toxic molecules at acidic pH (v) specificity is further demonstrated by the observed lack of activity against larvae of *Spodoptera litura* (vi) aminopeptidase of *S.litura* does not interact with Cry1Ac protein.
- No new data or evidence has been established to prove that Bt protein is unsafe or hazardous. Even the reports of international experts are an analysis of the EC-II Report and their main concern is that the GEAC had set a too narrow scope. Their recommendations/ conclusions are based on “indications” or “possibilities”
- Bt technology is best suited and an alternative way to control cryptic borers such as bollworms, which are internal feeders, much like the brinjal fruit and shoot borer.
- Data from CICR has clearly shown reduced application of pesticides in cultivated Bt cotton crop The reduction in insecticide usage from Rs 718 crores in 2004 for lepidopteran caterpillars to Rs 110 crores (Rs 23 crores for

American bollworm) in 2010, can be seen as a spectacular achievement of Bt cotton technology.

- Sizeable quantities of highly toxic insecticides such as carbosulfan, carbofuran, triazophos, metasystox, monocrotophos, phorate, methyl parathion, phosphomidan, dicofol etc which are considered to be extremely hazardous to the environment and which have been severely regulated by the FAO (Food and Agricultural Organization), WHO (World Health Organization) and the UNEP (United Nations Environment Programme) are being used on Brinjal crop. The three organophosphate insecticides (phosphamidon, methyl parathion and monocrotophos) belong to the category of either 'banned or restricted use' in India. But, it is a matter of immense concern that these are regularly used on Brinjal crop just before harvest. All these insecticides are systemic and are translocated into fruits, thus posing immense dangers.
- Bt cotton seed meal is being fed to cattle in India for a number of years now. No authenticated cases of adverse effects on farm animals have been reported so far.
- A large diversity of wild/weedy forms related to brinjal exists in India. Among these, the group comprising *S. incanum-S. insanum* complex is crossable with brinjal under artificial cross-pollination. The amount of crossability varies with genotypes, but successful crosses produce viable hybrids. As Bt is not a dominant gene, it will not result in any fitness advantage even if it is transferred.
- *S. melongena* (brinjal) and *S. incanum-S. insanum* have never been reported as invasive or difficult to eradicate weeds. The probable hybrids existing in nature also do not pose any problems as serious weeds. In our experience of nearly two decades of work on Indian Solanums, we have never found these plants growing in dense populations. They exist as individual plants or sparse populations of 10-15 plants in nature or as sporadic plants around cultivated fields.
- The fear that adoption of Bt brinjal will lead to loss of indigenous diversity of cultivated forms is rather exaggerated. If Bt cotton is any example and Bt brinjal is as successful, we will see numerous seed companies transferring Bt gene into their varieties/hybrids that are already acceptable to the farmers and consumers. While Bt gene would be common among these, the rest of the genome will be as diverse as it is at present.
- About 4,000 accessions of brinjal germ plasm are available in the gene bank with NBPGR. It is the responsibility of public institutions like NBPGR to preserve the natural forms as India is a centre of diversity of not only brinjal but several other crops.

iii Several members also expressed concern about the sustainability of the technology. They opined that the main concern about *cry1Ac* gene is resistance development of the fruit and shoot borer to Bt brinjal, especially because it is a monophagous pest. The transgenic line under consideration does not provide full protection against the target insect pest. Also this insect pest has only one host plant, brinjal. The recommended refugia of 5% would be grossly insufficient to delay resistance significantly. However, globally acknowledged expertise available in the country, and at

CICR can be utilized to devise effective resistance management strategies immediately prior to the release based on stochastic models developed by CICR.

iv Dr P M Bhargava did not support the above views. He opined that the need for additional studies to assess the safety of Bt protein needs to be reviewed in light of new evidences available. He further stated that the objective regarding purpose of the tests, such as where; how; the list of tests needed to be conducted; etc has not been achieved by today's meeting. He suggested that a separate meeting with additional experts may be convened to discuss the list of 39 studies suggested by him in his letter to the Hon'ble Minister for Environment & Forests and to the GEAC. In response, Members were of the view that additional tests if prescribed, should be on the basis of international best practices and experiences. No Utopian protocols only specific for India should be prescribed as raising the bar would increase the affordability cost to farmers. Members were also of the view that studies such as proteomics, transcriptomics, etc. are currently only research tools and do not provide any value addition to the biosafety assessment. Dr Bhargava did not agree with the above views and reiterated emphatically that he was not against the technology but in light of the new evidences and experiences available, there is an urgent need for a scientific debate on the additional studies suggested by him. He opined that during the debate, members who do not agree with the requirement may provide scientific basis and evidence on why a particular study is not required. He suggested that during the next meeting, experts such as Prof. Madhav Gadgil, a socio-economic expert and others may be invited for having a wider opinion on the matter. It was clarified that the meeting notice and relevant papers have been circulated to Prof Gadgil but no response has been received. However, the relevant papers would be resent after contacting Prof Gadgil. Dr Bhargava also requested Member Secretary, GEAC to circulate his letter dated September 2, 2010 eliciting the list of 39 studies required for biosafety assessment. It was clarified that the communication has been circulated and would be resent to all the members.

v Representatives of the Department of AYUSH (Ayurveda, Unani and Medicinal Plant Board) opined that they were participating in this process for the first time and they were enlightened by the discussions and views of the eminent experts. They also informed that discussions with MoEF on concerns pertaining to gene flow and crossibility, etc. have been clarified. While the Department was willing to go along with the views of experts regarding the safety of Bt protein, they were of the view that their concern is limited to the fact that brinjals had a special medicinal advantage in traditional system of medicine. They suggested that compositional comparative analysis of both traditional brinjal and Bt brinjal to ascertain the alteration, if any, in the bioactivities, nutritional and medicinal values as some of the Solanum species are used in the preparation of classical formulations of Indian medicines used in the treatment of neurological and musculo-skeletal disorders. It was further recommended that such studies may be conducted in public sector institutions such as Central Drug Research Institute(CDRI), Lucknow, National Institute of Nutrition (NIN), Indian Institute of Integrated Medicine (IIM) and others.

vi. In response to the above observations, Dr Sesikaran, Director, NIN requested scientists from AYUSH to provide the following information based on which appropriate follow up action to identify and estimate such components in the Bt Brinjal under

consideration will be carried out as additional components of compositional equivalence studies:

- Nature of medicinal properties of brinjal
- The specific varieties which have been documented in literature to have such properties
- the active ingredients / ingredient which have such properties
- Their chemical nature, mode of action clinical indications etc if information is documented
- The standardized methodology to measure these components and / or their active / inactive metabolites which could act as fingerprints for identification
- The methodology for estimation as accepted based on their sensitivity and specificity limits of detection etc

vii Dr Ram Vishwakarma, Director, Indian Institute of Integrated Medicine, Jammu suggested that International Safety Guidelines with no conflict of interest should be strictly followed. He further suggested that international regulatory data is available on the website and needs to be studied by the GEAC to verify whether the protocols and procedures followed to generate biosafety data with Bt brinjal conforms to international practices/scrutiny.

## **II Acceptance of company data**

All members except Dr P M Bhargava agreed that any data generated in accredited GLP laboratories can be accepted as this practice is being followed internationally for release of all products. Dr. Bhargava opined that there is a need for setting up an independent GMO testing facility devoid of conflict of interest and encompassing all the stakeholders for generation of biosafety data for regulatory purposes and data submitted by the company should not be accepted.

## **III Suggestions on Way Forward:**

The following recommendations of Dr G Padmanabhan were supported by many Experts, however, Dr P M Bhargava categorically opposed it:

1. Limited release of Bt seeds to identified farmers under strict expert supervision should be undertaken to evaluate its performance in public space. This would also help in the assessment of its suitability for cooking purposes and as a food item. If it is considered absolutely necessary, this period can also be used to test a couple of parameters: 1. Analysis of alkaloids 2. Chronic toxicity test for 180 days. He further opined that these two tests are needed only to send the message that GEAC is not averse to go the extra-mile to address even remote issues of safety.

5.0 Joint Secretary (seeds) Ministry of Agriculture, supporting the suggestion for limited release also stated that Ministry of Agriculture has initiated several developmental programs to improve food security and awareness. For successful implementation of the

promotional programs GM technology is required. He further suggested that the review should be science based and completed in a time bound manner.

6.0 In his concluding remarks, the Chairman opined that the issues involved are very complex and it may not be possible in one meeting or one sitting, to come to an agreed consensus on what needs to be done, etc. On the issue of whether GM technology is needed or not, he informed that the GEAC is guided by the statement made by the Hon'ble Prime Minister at the Indian Science Congress on January 3, 2010 at Thiruvananthapuram wherein he has categorically stated that "we should pursue all possible leads that biotechnology provides that might increase our food security as we go through climate related stress subject to the condition that the question of safety is given full weightage, with appropriate regulatory control based on strictly scientific criteria".

7.0 The Chairman also opined that due consideration should be given to issues raised by the State Governments and such apprehensions have to be addressed in a transparent manner to ensure public acceptability of the technology. He also pointed out that the current regulatory process is going through a transition period as new initiatives such as the Biotechnology Regulatory Authority of India Bill is under active consideration of the Government. During the interim period, the GEAC will continue its dialogue with experts and take necessary action to strengthen the regulatory framework in India. He requested all experts, as a follow-up to today's meeting, to forward a half-page recommendation on the way forward including the need for additional studies within 7 days. With a view to facilitate scientific debate he further suggested, while recommending additional studies, the experts may also indicate the end point for such studies, its applicability in the biosafety assessment, whether such studies are prescribed by other regulatory agencies and if so what the prescribed protocols are.

8.0 Thanking all the members once again for their active participation, he informed that a second consultative meeting will be convened by the GEAC to discuss the recommendations received from experts and other departments on the requirement for additional biosafety studies.

The meeting ended with a vote of thanks to the Chair and Members.

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