Decisions taken in the 109th meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 11.05.2011

The 109th meeting of the GEAC was held on 11.05.2011 in the Ministry of Environment & Forests under the chairmanship of Shri M. F. Farooqui, Additional Secretary, MoEF and Chairman, GEAC.

A list of participants is annexed.

The deliberations and decisions taken in the GEAC meeting in respect of Agenda items 3 to 7 are as follows:

Agenda item No. 3 : Action taken report on the decision taken in the 108th GEAC meeting.

3.1 The Committee noted that decisions taken in the GEAC meeting held on 09.03.2011 have been communicated to the project proponents, concerned government departments and other agencies. On specific issues, the following points were noted:

3.1.1 A warning letter was issued to M/s. Mahyco on May 2, 2011 stating that (i) any non compliance in future would attract punitive actions under EPA 1986; (ii) to adopt a resolution through the Mahyco Board of Directors expressing regret and reaffirming that such lapses will not be repeated. The resolution so taken shall be put on the website. (iii) data generated during BRL-II trials using non-Bt RRF flex as refuge shall not be considered for regulatory purpose. Further, Director, CICR, Nagpur has also been directed not to recommend protocols with unapproved events for field testing without the prior approval of the GEAC.

3.1.2 A meeting of the GEAC to consult with experts on regulatory process for Bt Food Crops as part of the post Bt brinjal moratorium follow-up was held on 27.4.2011 at NASC Complex, Pusa New Delhi. In the said meeting all experts were requested to forward a half-page recommendation on the way forward including the need for additional studies within 7 days. It was also agreed that, while prescribing the 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 are the prescribed protocols. Based on the comments received from the expert members, GEAC will decide on the further course of action. Minutes of the meeting will be circulated on approval.

3.1.3 Discussion on the "Guidance Document for information/data generation and documentation for safety assessment of GM plants during BRL-I and II trials" has been deferred to the next meeting due to the long agenda for this meeting.

Agenda item No. 4 : Policy issues

4.1 Presentation by NGOs on specific issues/concerns

4.1.1 Member Secretary, GEAC informed that two industry associations, namely, ABLE and NSAI were given an opportunity to make a presentation on suggestions for improving the regulatory process in its 106th meeting held on 12.1.2011. In response, five NGOs namely, Centre for Sustainable Agriculture, Greenpeace India, Thanal and Kheti Virasat Mission and Ms Aruna Rodrigues, petitioner in the SC PIL on GMOs have requested for an opportunity to present their arguments and concerns on related aspects.

4.1.2 The Committee invited the Civil Society representatives to make a presentation. At the outset, on behalf of the Civil Society, Ms Kavitha Kuruganti , thanked the Committee for giving this opportunity. She further informed that this is the second meeting with the GEAC and the first one under the new Chairperson. She requested the Committee that concerns expressed by them be reflected in the minutes of the GEAC meeting as done in the case of the meeting with the industry association. She also informed that the GEAC should take into consideration alternate strategies such as organic farming, socio economics, farmers' rights, etc. while taking a decision on release of LMOs and if this is not the concerned body, they would like to know to whom these concerns should be addresses.

4.1.3 She further informed that the presentation will cover several issues which have been summarized into four presentations, namely (i) Concerns over dilution of GM regulations by Ramanjaneyulu, Centre for Sustainable Agriculture; (ii) The Indian Regulatory Regime Around Transgenic Crops (Lessons from cotton experience) by Kavitha Kuruganti, Alliance for Sustainable & Holistic Agriculture (ASHA); (iii) Regulation & Risk Assessment (Bt Brinjal Event EE-I Case Study) by Ms Aruna Rodrigues and (iv) GM Field Trials - Contaminating our Food and Nature by Rajesh Krishnan, Greenpeace India.

4.1.4 Issues covered in each of the presentations are summarized below:

1. Presentation on Concerns over dilution of GM regulations by Ramanjaneyulu, Centre for Sustainable Agriculture

i. Event based approval mechanism (EBAM)

The policy decision of the GEAC to follow EBAM based on assumption that 'biosafety profile of an event does not change when it is transferred to other genetic backgrounds of the same crop through back-crossing to develop new hybrids/parents and therefore each of the hybrid with an approved event need not undergo biosafety tests needs to be reviewed on the following grounds:

- Proteomics studies show that the protein compositions (including native proteins) vary
- Post market stability analysis shows that 'Gene expression varies between different genetic backgrounds and it has biosafety implications (in addition to agronomic performance)'
- 'Quantitative levels of Cry1Ac and the seasonal decline in expression differed significantly among the eight commercial Bollgard hybrids tested'
- Choice of parental background appeared to be crucial for sustainable expression of the cry1Ac transgene' (Kranti. et.al 2005)
- Aguilera et.al 2008: A Qualitative Approach for the Assessment of the Genetic Stability of the MON 810 Trait in Commercial Seed Maize Varieties, Food Anal. Methods (2008) 1:252–258

ii. Imports

- Biosafety data should be generated based on the germplasm which would be commercialized only hence imported transgenic germplasm which would be backcrossed at a later date should not be allowed
- Backcrossing with imported germplasm by itself may bring in new problems for e.g. susceptibility to sucking pests with coker lines in case of cotton.

Therefore, biosafety assessment (in addition to agronomic performance) should also consider these things

- Similarly biosafety data on GM foods should be accepted only from the studies done locally.

iii. Acceptance of biosafety data from overseas

- Data from any overseas laboratory should not be accepted as:
  - Regulatory frameworks differs in each country
  - Oversight is not possible,
  - it is important to see that the GM material (plant or animal) used should be produced in the receiving environment.
  - Expression of characters varies with ecological situations. Certain proteins etc which could have detrimental effects which are not seen in temperate climatic conditions may be observed in tropical conditions and may also vary with germplasm.

iv. Deregulation of stacked events and regulatory status of single event parental lines

- Transgenic with stacked genes (in combined construct or separate events) also should undergo the biosafety studies even if the individual events were cleared- as the interactions and cumulative effects could be different
- Similarly, in hybrid transgenics (single or stacked genes) and stacked products the parental lines should undergo biosafety studies as the parents also would be grown in open fields during seed production

v. Pollen flow and gene flow and seed production standards

- Pollen flow studies are necessary as it depends on local ecological conditions, cropping pattern and availability of different pollinator insects
- Gene flow and its consequences should be studies in addition to the pollen flow. Therefore, risk assessment should include consequences of gene flow:
  - to GE crops to wild relatives or other cultivated non-gm varieties
  - impact on non target effects on plants in natural or agricultural ecosystems
  - evolution of new weeds particularly with herbicide resistant canola
  - genetic contamination of crops intended to have a level of purity with regards to market demands, such as organic or intended to be sold in a foreign market that does not tolerate the presence of materials from GE plants
  - possible health effects from genes engineered to produce pharmaceutical or industrial compounds if these plants enter the food or feed supply

vi. Seed production standards cannot be used

- Indian Minimum Seed Standard Certification are based on different parameters
  - as the gene flow from conventional varieties/hybrids may not have serious biosafety consequences
  - tolerable levels are higher up to 5 % depending on types, where as for contamination from gm crops it is from 0.01-0.09 %

2. Presentation on the Indian Regulatory Regime Around Transgenic Crops (Lessons from cotton experience) by Kavitha Kuruganti, Alliance for Sustainable & Holistic Agriculture (ASHA)

i. The Bt cotton approval process is ridden with several gaps such as:

- Legal provisions violated
- Biosafety provisions violated
- Biosafety assessment inadequate
- Need assessment missing
- No periodic review & risk management frameworks.
- Consumer' & Farmers' rights not taken into consideration.

ii. Decision-making, Permissions, Supervision

- From 1998 onwards, there is no involvement of state governments or panchayats, though Agriculture is a State Subject
- No SBCCs and DLCs functional even now
- All approvals happening without any regulatory structures put into place and without the institutions with authority being part of decision-making

iii. Biosafety violations & Illegal operations : Several instances have been brought to the notice of the GEAC

- Cultivation of Navbharat Bt cotton and many other illegal Bt cotton seeds are going on unchecked
- BG II trials have been conducted in an unscientific way & in violation to biosafety norms. These have been well documented by the NGOs.
- Illegal proliferation of RRF cotton seed (MON 1445 event) has not been addressed.
- Use of non-Bt RRF cotton seed use by Mahyco has been let off only with a warning.

iv. Monitoring and Liability:

- No liability regime to check contamination and leakage from field trials.

- Both the applicant and regulator should be made liable.

v. Impact Assessment :

- Not just edible parts should be tested for toxicity or allerginicity as problems could be from any plant part, for e.g. allergies in Bt cotton fields
- Laboratories abroad: While Monsanto has accepted Bt cotton samples mixed up" in the Skin Sensitization Test of May 1998 (allergenicity in a guinea pig model), no test taken up to replace this. There is no indication of anyone ever raising any issue around this. No independent analyses or testing
- Event-Based Approval Mechanism is not rigorous and scientific. CICR study across hybrids indicate a 8-fold variability in the trait-protein expression
- No long term assessment or when claims are made of yield increases (which is not possible in GE), proof of how this is due to GE trait and whether there are sustained yield increases have been conducted. There has been no cumulative assessment of impacts due to introduction of herbicide tolerant trait.
- No realistic assessment of resistance build-up. Resistance management plans are unrealistic and failing on the ground. Introduction of Bt gene in cotton has resulted in changes in pest ecology, and impact on soil. In addition, Bt cotton

requires higher chemical fertiliser use and therefore Bt technology itself is unsustainable for pest management.
- Assessment beyond biosafety is missing.

vi. Assessment framework:

- Why are Bt crop applications entertained when alternatives for pest management exist?
- Assessment is done against another hazardous technology and not against safe, affordable alternatives like NPM
- Bt crops often seen as an integral part of IPM - but they are anti-ethical to fundamental principles of IPM.
- There has been no review of the Bt cotton performance. As per Rules 1989, approval is initially granted for a period of 4 years subsequent to which the applicant is required to renew the approval every two years. In case of Bt cotton, approval was granted for three years and subsequently renewed every two years. However, this provision has been removed. No review has taken place so far including on yield claims.
- There is no system of investigations when complaints are made, for e.g. the animal mortality/morbidity phenomenon has remained uninvestigated so far

vii Farmers' & Consumers' Rights

- Bt cotton seed oil in our food chain. What kind of testing was taken up for this? What about consumer's right to informed choices and labeling?
- Farmers' rights have been impacted. No non-Bt cotton seeds are available in the market. In UAS-Dharwad, non-GM seed stock got apparently contaminated and no seed for organic farmers were available. Exorbitant seed prices & seed monopolies and IPR issues are cropping up in some public sector research? No impact assessment has been taken up beforehand and no comprehensive review so far to address these issues.

3. Regulation & Risk Assessment (Bt Brinjal Event EE-I Case Study) by Ms Aruna Rodrigues

i. Exemplary Regulation Rooted in the Precautionary Principle should be the objective of the GEAC and should address the following issues:

- Do we need the GM crop
- Bio-safety First
- Sceptical Analyses
- Independent Testing & Analyses

ii. On this basis, Monsanto's Bt Brinjal Dossier is demonstrably flawed and therefore must be rejected. Analysis of the Bt brinjal dossier by international experts conclude that Bt brinjal is not safe. The presentation also briefly covered the findings of the international experts pertaining to risk assessment, toxicology, dose-response modelling, etc as given under:

iii. Dr. Lou Gallagher: **Main Findings: 14 & 90 day feeding studies**

"The current food safety studies for Bt brinjal were not conducted in accordance with published standards, did not accurately summarize results, and ignored toxic endpoints

for rats fed Bt brinjal. In particular, rats fed Bt brinjal for 78 out of 90 days (only one dose level)"

- reproductive performance, neurological function, behavioural effects not evaluated
- ovaries at half their normal weight
- enlarged spleens with white blood cell counts at 35 to 40 % higher than normal with elevated eosinophils, indicating immune function changes.
- toxic effects to the liver
- major health problems among test animals were ignored in these reports.
- The single test dose used was lower than recommended by the Indian protocols (in themselves, significantly below international standards)

iv. Prof David Andow analysis on:

Environmental Risk Assessment

- India is the centre of the world's biological diversity in Brinjal. It contains 2500 varieties and 29 wild species (approx) of brinjal.
- The damage due to Fruit and Shoot Borer (FSB) "vastly" overstated (in dossier and EC II report @ 60-70%
- The BFSB is managed effectively by alternative systems of agriculture, IPM.
- Most of the possible environmental risks of Bt brinjal have not been adequately evaluated; this includes risks to local varieties of brinjal and wild relatives, risks to biological diversity, soil health and risk of resistance evolution in BFSB.
- EC-II relied on dubious scientific assumptions, did not focus on realistic environmental concerns, inadequately evaluated some important environmental concerns, and ignored other real environmental concerns.
- Brinjal has considerable valuable genetic diversity in India that could be threatened by gene flow.
- wild and weedy relatives may obtain fitness benefit
- wild relatives suffer reduced genetic diversity
- Contamination of Non-GM due to gene flow
- For purposes of risk assessment it can be assumed that gene flow is high enough to be evolutionary meaningful.

Resistance: "The evolution of resistance to Bt crops is a real risk and is treated as such throughout the world."

- EC-II does not acknowledge the risk of resistance, and the Dossier does not propose effective means to manage it.
- the likelihood of resistance evolving quickly is high. Without any management of resistance evolution, Bt brinjal is projected to fail in 4-12 years.
- secondary pests in Bt brinjal– examined only "cursorily" despite the "common occurrence of secondary pests on Bt crops around the world

Socio economics

- small-scale resource-poor farmers who grow most Brinjal will be at the most risk. (<1ha for all crops)

- because of the way brinjal is used, essential for economic and food security
- 10% of the increase in profitability from Bt brinjal, but are expected to retain 63% of the increase from brinjal IPM
- IPM, other alternative production systems for control of BFSB are being tested, actively used, and promoted in India

v. Doug Gurian-Sherman: Gene flow: Response to EC II

- Mahyco presents virtually no data that assesses the risks of gene flow from Bt brinjal to wild relatives. Several wild relatives of brinjal are found in India and have been shown to be sexually compatible with brinjal. Further, methods to prevent gene flow from crops to wild relatives currently do not exist.
- Gene flow from Bt brinjal to wild relatives, if commercialised, would therefore be virtually certain.

vi. Prof Heinemann: Genomic Analyses:

- The dossier and the subsequent GEAC analysis (ECII) fail to meet fundamental and even routine hazard assessment standards for molecular characterization. Since this is the starting point of any risk assessment, the downstream effects on the analysis can be significant".
- The GEAC cannot conclude from Mahyco's data that there is a single insert – implications for safety, patents /IP
- Profiling techniques/Non-targeted approaches**:** required for hazard identification or identifying unintended effects
- No mention of the Comparator
- The lack of compliance with the Codex "highlights a serious deficiency in the EC-II assessment";
- EC II does not meet the spirit of India's international obligations under the Protocols of the CBD.
- Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and its supporting document the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (2003, CAC/GL 45-2003) for its assessment of potential effects to human health.
- The goal of each safety assessment is to provide assurance, in the light of the best available scientific knowledge, that the food will not cause harm when prepared or consumed according to its intended use, nor should the organism itself cause harm when viable organisms remain in the food" (Codex 2003, paragraph 25).
- "A safety assessment is characterized by an assessment of a whole food or a component thereof relative to the appropriate conventional counterpart:
  - taking into account both intended and unintended effects;
  - identifying new or altered hazards;
  - identifying changes, relevant to human health, in key nutrients."
- "Risk assessment should be carried out in a scientifically sound and transparent manner and can take into account expert advice of, and guidelines developed by relevant international organizations."

vii. Gaps in Risk Assessment identified based on the above analyses:

- Need for Bt brinjal? And proper independent evaluation of BFSB infestation
- Profiling techniques: not done for reasons of cost and time constraints
- Chronic Toxicity: require long term multi-generational feeding studies
- Allergenicity: testing was not Codex compliant
- ERA essentially not done including: evolution of resistance, gene flow & soil toxicity.
- Non-compliance with the CAC and CBD
- Post Market Monitoring of Bt cotton be made mandatory before another GM crop is commercialized

4. GM Field Trials - Contaminating our Food and Nature by Rajesh Krishnan, Greenpeace India

i. Field trials involve open air, deliberate release of GMOs unlike the pharma applications and there are many instances of contamination from field trials (fait accompli (biological or physical seed leakage or mixing up)

ii. There is no Policy Directive being utilised on what crops and which regions need to be strictly kept outside of any kind of transgenic research and release as recommended by the Task Force on Agricultural Biotechnology. Almost all applications for Field trials are permitted without any discretion. GEAC continues to be a Clearing House.

iii. Report of Task Force on Agri-Biotech (headed by M S Swaminathan): Chapter II. Application of Biotechnology in Agriculture - Point 1.6 states:

- Biotech applications, which do not involve transgenics such as biopesticides, biofertilizers and bio-remediation agents, should be accorded high priority. They will help to enforce productivity in organic farming areas
- Transgenic approach should be considered as complimentary and resorted to when other options to achieve the desired objectives are either not available or not feasible
- Transgenic research should not be undertaken in crops/commodities where our international trade may be affected
- Such areas of biotechnological applications, which can reduce employment and impinge on the livelihood of rural families, should be avoided. (4. Choice of Research Problems).

iv. Concerns about the current Field Trial procedures

- Biosafety assessments and open air release happen simultaneously, thereby releasing potentially risky organisms into the environment before any risk assessment is done.
- No review of Biosafety data after the first level of Field trials and before Largescale trials start.
- Field trials are being permitted in ecologically sensitive regions. For eg. Western Ghats
- While Field trials are also used for assessing agronomic benefits, comparisons with best available technology are not done. For ex. transgenic pest resistant crop are not compared with NPM practices.
- Field trial permission for 2 years/season given in one go these days.

- Monitoring is no one's baby, mostly done by the crop developers themselves, a case of conflicting interests.
- Biosafety norms inadequate - no rigorous monitoring of the trials (both for biosafety and for results declared - monitoring committees do not take up random sudden checks etc).
- Although there is a direction from the Supreme Court that GEAC needs to give approvals for all environmental releases of GM crops including field trials, to this date RCGM under DBT gives permission letters. GEAC rubber stamps all RCGM approvals for Field trials.
- Complete absence of a liability regime that will act as a deterrent for violations & contraventions by GM crop developer or even the regulators.
- No assessments of contamination done post the Field Trials.

v. Violations/Bad Practices: examples over the years

- SBCCs not formed in many states like Bihar where FTs have happened. DLCs almost completely absent; SBCCs & DLCs non- functional.
- The local panchayats are not consulted for an informed decision about Field trials.
- Biosafety violations found in field trials - isolation distance not always maintained - Kolhapur maize trial; Guntur Bt okra trial; Jharkhand Bt rice trial; West Bengal trials.
- Regular contamination happening of food/supply chain: Even during Bt cotton field trials (RFSTE findings); later, with Bt brinjal and Bt okra (CSA findings).
- Volunteer plants tested positive in Jharkhand (Gene Campaign's lab testing for Bt rice).
- No destruction of GM material as prescribed.
- Information on trial not given to farmers, Panchayat or State Govt. (in AP, WB, Bihar, Chattisgarh)
- Badly-performing field trials are abandoned ("MEC" findings on BG II trials).
- State Governments complain about not being in the know of field trials (Andhra Pradesh, Karnataka, Chattisgarh, Bihar, West Bengal).
- Bt Rice trial in close proximity to India's richest rice collection in IGKVV….
- Instances of planting before permission is issued has been reported by Andhra Pradesh.
- Data collection is not as per prescribed norms/frequency.
- GM rubber trials have been approved with the same terms and conditions as annual/seasonal crops!!…
- Trials where no monitoring team ever visited…No scientificity to which trials get visited.

vi. Violations: Example from GM Cotton alone

- Bt cotton: RCGM permitted, Field trial produce entered supply chain, State govts objected, laid-down institutional mechanisms missing, Illegal proliferation first, approval later.
- BGII Field Trials: Civil society "MEC" - no information to farmers, state govts, abandoning of badly-performing sites, supply chain contamination, no rigorous monitoring, no liability towards farmers where trials happen.
- Illegal HT cotton proliferation (MON1445): 3 states confirm and GEAC acknowledges
- HT Cotton (MON89013) in RRF Bt cotton trials as refuge: Company as well as CICR has violated Indian law and only a warning has been issued.

vii. Cases of contamination from Field trials

In India:

- Bt Cotton – 1999 onwards
- Bt Okra -2005
- Bt Rice – 2008
- Ht cotton – 2009

Other countries

- LL rice -[USA] -2006
- GM Papaya [Thailand and Taiwan]-2005
- GM Flax [Canada]-2010
- GM Bentgrass [USA] 2003-06
- GM rapeseed [UK] -2003

viii. Consequences of contamination from field trials

- Health – untested potentially risky crops in our food chain. No baseline info to check for the impact of such contamination.
- Environmental – genetic erosion especially in centers of origin and diversity, impacts on the ecosystem.
- Economic [Trade] – Agri exports in peril. Bayer's LL Rice case, 2006 : (In 2005, EU imported 32% of its rice from USA; in 2007, it was only 2.5%; Bayer paid $5.8 mn in just 1 case!)
- Socio economic – Farmers losing their right to keep their farm free from GM,organic farmers at lose, consumer lose their right to have safe, GM free food.

ix. Open trials continue unabated

Rice, Maize, sorghum, mustard, brinjal, okra, cabbage, cauliflower, tomato, groundnut, chickpea, potato, castor, cotton....

x. Containment of contamination from field trials

The only way one can stop transgenic crops from contaminating the regular crops and the wild is by keeping them in contained conditions. It is only a Euphemism in India that Field Trials of upto 2.5 acres per location are called "Confined" and commercial cultivation is called "Environmental Release".

5. Remarks by Shri R Sridhar, THANAL and Convenor, Coalition for a GM-free India.

- By giving clearance to Bt brinjal, the credibility of the GEAC has significantly gone down as top priority is not given to Biosafety. The GEAC should be guided by the directions given by the Minister for Environment & Forests in the decision document dated 9.2.2010 and the report of the Task Force on Agriculture Biotechnology under Prof M S Swaminathan and debate on the additional biosafety tests to be done..
- The GEAC should consult with experts having no conflict of interest and in the next consultative meeting with the experts; the GEAC should include experts having expertise in environmental science, genetic toxicology and socio economics.

- The approval given for GM Rubber BRI-I trials should be immediately withdrawn as the approval conditions issued by DBT is faulty.
- The regulatory agency should not be complacent and should take punitive actions against violators.

6. Demand: In view of the above facts, the NGOs have demanded the following action from the GEAC:

i. Summing up the issue, Ms Kavitha Kuruganti stated that the technology in itself is intrinsically problematic and irreversible as it is a living technology. Using Bt cotton experience in other instances, the GEAC should play a proactive role in strengthening the regulatory mechanism as currently, the GEAC is following a minimalistic approach.

ii. In conclusion, the following demands were made by the NGOs :

- The EC II Report: discredited consequent to the moratorium, is not relevant as a reference document for appraisal any longer
- Bt brinjal biosafety dossier must be rejected
- Risk Assessment & hazard identification: Comprehensive protocols required and gaps remedied
- Independent & autonomous institute of testing & analyses for all studies
- Invite Andow for comprehensive discussions with regulators, scientists and civil society
- Immediate suspension of all GM crop Field trials until:
  - Policy directives are in place and implemented for each field trial & only when a GMO is assessed for its need and shown that alternatives do not exist
  - Ethical and social justification & sustainability requirements to be met at preliminary stage itself
  - New guidelines on risk assessment prior to field trials is in place. The risk assessment should involve biosafety and socioeconomic impact assessments.
  - This risk assessment should be made public and Field trials should be permitted only after all concerns raised by the public on this are answered to their satisfaction.
  - There should be a public consultation at the proposed Field trial location prior to any field trial, where Panchayat Raj Institutions should be involved for exercising their constitutional authority in an informed manner, in addition to state government exercising its authority.
  - Demonstrating adequately the capability to oversee all trials that are permitted, in a scientific, rigorous fashion.
  - An immediate, detailed assessment of all field trial locations in the past to check for contamination - demonstrate that adequate and required testing facilities exist.
  - An Action plan should be created on how to contain if contaminations have already occurred.
  - In case of a contamination detected, there must be liabilities fixed both on the crop developer and those monitoring the trials.
- No more approvals of any GMO for environmental release (incl. for trials) without a comprehensive review of GM cotton experience, lessons to be gleaned from the same (incl. on risk and larger impact assessment), and incorporated into our regulatory regime including liability regimes to be put into place on crop developers & regulators.

4.1.5 Subsequent to the presentation, the Chairman invited comments of the GEAC members. Prof Hegde, National Law School, Bangalore stated that 'conflict of interest' is a very complex issue and the GEAC has been trying to address this issue recently for few months. Biotechnology being a highly technical subject, if opinion of scientists involved in GMO research and development is not considered, then where would the expertise come from? Member Secretary GEAC pointed out that there have been several instances of ransacking the ongoing GM crop trials and often names of certain NGOs have figured in the incident. She opined that such issues also need to be addressed by the civil society as such situations are more likely to lead to contamination of non–GM crops rather than confined field trials conducted with proper isolation distance and post harvest measures. The Committee decided that it needs to examine the issues raised in the presentation separately after going through the issues raised. Ms Kavitha Kuruganti urged that no further decisions should be taken by the GEAC in light of issues raised by her and other representatives of NGOs.

4.1.6 The Chairman thanked the invitees for making the presentation. He informed that the GEAC has no intention to fast track any approval process and decisions of GEAC are based on inputs received from different stakeholder and available scientific facts. He further stated that it is in this context that meetings with the industry associations, experts and NGOs have been convened by the GEAC. He assured that the concerns of the NGOs will be given due consideration while taking a decision along with other available facts as the GEAC has to take a balanced view. 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 others and take necessary action to strengthen the regulatory framework in India.

4.2 Clarifications sought by the Standing Committee on the Event Based Approval Mechanisms for Bt cotton hybrids expressing approved events.

4.2.1 The Member Secretary, GEAC informed that in the 6th meeting of the Standing Committee held on 1st April 2011, to review the Bt cotton applications for the North Zone, the Standing Committee unanimously expressed that ICAR/SAU reports which clearly indicate the details of agronomy traits as well as CLCuV disease tolerance have great significance in view of the problems being faced by the cotton farmers in the country. The Standing Committee decided to appeal to the GEAC to incorporate the requirement of one year field testing in the TOR. Accordingly, the Standing Committee decided to consider the following parameters while considering the applications for the North Zone:

1. Confirmation of gene/event through molecular characterization by the licensor that the gene /s which is being used is one of the approved events (LOC in original)
2. Level of Protein expression in green house and field trials;
3. Morphological Characters of the parents and the hybrids using DUS descriptors as per PPVF&RA guidelines;
4. Bio-efficacy data generated in laboratory conditions;
5. Authorization certificate / No objection Certificate (NOC) from technology provider (in original) in case of sub-licensee;
6. Affidavits duly signed by the Notary on Stamp paper;
7. One year field trial data from concerned SAU/ICAR-AICCIP report on the particular hybrid;
8. Data on tolerance of Bt cotton hybrids to Cotton leaf curl virus in North zone as evaluated by SAU centre in North zone/CICR, Sirsa.
9. The standing committee shall lay down rules and procedure for submission of application and conduct of the meetings.

It was noted that the Standing Committee has added two additional data requirements namely, the need for one year field trial data on agronomic performance and data on tolerance of Bt cotton hybrids to CLCUV in North Zone.

4.2.2 Based on the above criteria, the applications received by the Standing Committee were divided into three categories as given below:

A. Recommended: SAU/ICARN data is available, yield of the hybrid is at par or better than the check, and it is CLCuV disease tolerant.
B. Not Recommended: SAU/ICARN data is available, yield of the hybrid is lower than the check, and it is CLCuV disease tolerant
C. Not considered: SAU/ICARN data not submitted and are requested to submit the same

4.2.3 The matter has been referred to the GEAC as the Standing Committee has forwarded the recommendations along with the list of Bt cotton hybrids approved/not approved for the North Zone for consideration of the GEAC. However, it was informed that another meeting of the Standing Committee was held on 6th May 2011 wherein certain decisions to approved the recommended cases have been taken. It was decided, in the first instance, to obtain the outcome of the Standing Committee meeting held on 6th May 2011.

4.2.4 Discussion on specific issues such as the need for one year field trial data on agronomic performance and data on tolerance of Bt cotton hybrids to CLCUV in North Zone under the EBAM system was deferred due to paucity of time.

Agenda Item 4.3 to 7.3

Discussions on the above agenda items were deferred due to paucity of time. It was decided to consider the agenda items during the next GEAC meeting tentatively scheduled for 8th June 2011.

The meeting ended with a vote of thanks to the chair and members.

****

List of the Members who attended the 109th GEAC meeting held on 11.05.2011

S.No	Name and address
1.	Shri M. F. Farooqui, Additional Secretary, MoEF and Chairman, GEAC.
2.	Dr Arjula R. Reddy, Co Chairman, GEAC & Professor, Department of Plant Sciences, Hyderabad
3.	Dr. Swapan Dutta, DDG (Crop Science), ICAR, New Delhi
4.	Dr. Gorakh Singh, Horticulture Commission, Deptt of Agriculture & Cooperation (DAC), Ministry of Agriculture
5.	Dr. B. M. Khadi, Principal Scientist, UAS, Dharwad
6.	Dr. K. Bangarurajan, Deputy Drugs Controller, FDA Bhawan, New Delhi
7.	Dr. M. Udaya Kumar, Department of Crop Physiology, Univ. of Agricultural Science, Bangalore
8.	Shri Govindraj Hegde, Assistant Professor, NLSIU, Bangalore
9.	Dr R. Warrier, Director, MoEF & Member Secretary, GEAC, New Delhi
10.	Ms Madhu Gupta, Research Officer, MoEF, New Delhi
Special Invitee	
11. .	Dr. P. M. Bhargava, Former Director, CCMB, Hyderabad.
12.	Dr G.V.Ramanjaneyulu, Centre for Sustainable Agriculture, Hyderabad
13.	Mr. Rajesh Krishnan, Greenpeace India
14.	Mr Sridhar. R. THANAL and convener, Coalition for a GM Free India
15.	Ms Aruna Rodrigues, Sunray Harvesters, Petitioner in Supreme Court PIL.
16.	Ms. Kavitha Kuruganti, Alliance for Sustainable & Holistic Agriculture (ASHA)

****