Decisions taken in the 108th meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 09.03.2011.

The 108th meeting of the GEAC was held on 09.03.2011 in the Ministry of Environment & Forests under the chairmanship of Shri M. F. Farooqui, Additional Secretary, MoEF and Chairman, GEAC.

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 106th GEAC meeting.

3.1 The Committee noted that decisions taken in the GEAC meeting held on 09.02.2011 have been communicated to the project proponents, concerned government departments and other agencies. On specific issues, the following points were noted:

3.1.1 M/s. Bayer's Biosciences Pvt Ltd. have been advised to submit specific information on the labeling requirements for GM oil in other countries. A note highlighting the labeling requirements under various laws and mandate of various regulatory agencies under the domestic law existing in the country is under preparation.

3.1.2 As regards the brainstorming session to assess the performance of Bt cotton at Nagpur scheduled for March-April 2011, Member Secretary GEAC informed that the matter was discussed with DG, ICAR and Director, CICR, Nagpur wherein it was informed that during March-April there would be no standing cotton crop and therefore organizing the meeting at Nagpur for the purpose of field visit may be futile. The Committee opined that the meeting may be scheduled in New Delhi. It was agreed that the date and venue for the meeting will be communicated in the next meeting.

3.2 The Committee was also informed that Shri Nitish Kumar, Chief Minister, Bihar has indicated that he is opposed to Bt. Maize field trials in the State and permission given for this activity should be withdrawn immediately. On the basis of the request received from the Chief Minister, Bihar, the GEAC decided to withdraw the permission granted to M/s Monsanto India Ltd. for conduct of BRL-II trials for transgenic Maize in Bihar. It was also decided, in future, GEAC may give one month's time to the State Governments to convey their no objection prior to issue of the approval letter for field trials.

Agenda item No.4 : Policy issues

4.1 Discussion on the "Guidance document for information/data generation and documentation for safety assessment of GE Plants" during BRL-I and II trials".

4.1.1 At the outset, the Chairman suggested that the guidance document should be discussed thread bare so as to minimize anomalies or misinterpretation. As the matter is highly technical in nature, he further suggested that discussions can be spread over two to three meetings so as to provide ample time for discussion, further consultations and review of international practices and other available scientific literature which would assist the Committee in arriving at a consensus. He then invited the Member Secretary to briefly introduce the "Guidance Document" subsequent to which page by page review was initiated.

4.1.2 During the deliberations, amendments suggested by the members are summarized below:

1. The Committee opined that Section III page 2, para 2 and para 4 needs to be amended appropriately so as to clearly reflect the following policy decision taken by the GEAC regarding the number of locations, size and period of BRL-I trials and BRL-II trials:

i. BRL-1 trials will be conducted for a minimum of two years in three locations during major crop growing seasons. The BRL-I trials during the second year will be repeated in the same three trial sites as that of the first year BRL-I trials;

ii. The BRL-I trials are limited to an area of one acre per trial site and therefore the maximum cumulative area under BRL-I should not exceed three acres.

iii. BRL-2 trials will be conducted for a minimum of one year during major crop growing seasons at a minimum of eight locations. Additional trials may be called for depending on the agro-climatic zones.

iv. The BRL-II trials are limited to an area not more than 2.5 acres per trial site.

v. The data generated during BRL-1 trials will also be generated during BRL-2 trials;

vi. Additional trials may be called for based on the quality of data generated and /or new scientific evidence.

vii. Applicants may, for the purpose of research or otherwise may conduct BRL-1 / BRL-2 trials for more than the prescribed seasons with the approval of the RCGM/GEAC.

viii. Seed production area should not be spread in more than five locations per zone.

ix. The field trials will be conducted only within the institutional research farm of the Company/ State Agricultural University/ICAR/long leased land (3 years).

2. The Committee also advised that the requirement for BRL-I and BRL-II may be reflected in a tabular form

3. During the deliberations, the issue of BRL-I and BRL-II trials for perennial crops such as the recently approved BRL-I trials for GM rubber wherein the first trial itself would take around 14 years was also discussed. The Committee noted that the "Guidance Document" may not be able to reflect each and every situation and therefore such cases may be dealt on a case-by-case basis. It was agreed that this aspect will be reflected in the 'Guidance Document' under Section-III.

4. In **Section IV check-list 1**, inclusion of the following elements was suggested by one of the experts :

i. **Event characterization/Determination of transformation event integrated into the genome:** The number of copies must be assessed in Southern hybridization analysis with probes directed against every region and open reading of T-DNA (if transformation is by Agrobacterium) and against every Open Reading Frame (ORF) on the plasmid (if transformation is by any method other than Agrobacterium). Appropriate controls for copy number must be included so that multiple tandem insertions of the introduced DNA can be identified.

Some Members argued that event characterization using Real-Time Quantitative PCR will also suffice to find out whether a single T-DNA or partial T-DNA has been integrated into the plant genome. Other members argued that information on the presence of additional fragments may not be necessary as the entire product is evaluated for its safety prior to commercialization.

5. In **Section IV, Check-list 3,** inclusion of the following elements was suggested by one of the experts :

i. In **Point 4** include "non-component ORF" as a sub-point. It was argued that the intergenic regions of the introduced DNA must be assessed to determine if there are any significant ORFs in this DNA. An ORF that can encode for a protein of ~30 amino

acids can be considered to be a significant ORF. All such ORFs must be indicated in the description. After detailed deliberation, in the absence of consensus, the Committee was of the view that this issue will be re-visited once discussion on the 'Guidance Document' is complete.

ii. In **Point 4**, it was agreed to amend sub-point 4 as "Function of each component of the inserted gene construct in the plant and associated eco-system".

6. In **Section IV Check-list 4,** inclusion of the following elements was suggested by one of the experts:

i. "Other ORFs identified on the introduced DNA" should also be tested for homology to known protein toxins and allergens.

As this point is linked to consensus on para 6 (i) above, it was agreed to revisit this issue.

7. In **Section IV check-list 5, sub-point 1**, some members were of the view that data should be provided for at least 5 generations to confirm the stability of the gene trait /RNAi or anti-sense construct whereas some members were of the view that a minimum of three generation is adequate and would vary depending on crop to crop and trait to trait.

8. It was also agreed to reflect the requirement of "Unique Identifier Code" in check-list IV of the 'Guidance Document'.

4.1.3 After detailed deliberations, it was agreed to continue discussion on the 'Guidance Document' from Point-V onwards pertaining to studies that should be undertaken during BRL-I or BRL-II in the next GEAC meeting. During the intersessional period, it was agreed that members would exchange their views on the matter so as to facilitate discussion in the next GEAC meeting with a view to arrive at a consensus to the maximum extent possible.

Agenda Item No 5 : Consideration of applications for confined field trials of transgenic crops (Event selection) as recommended by the RCGM.

5.1 Permission to conduct experimental seed production of 139 transgenic rice (*Oryza sativa*) events by M/s BASF India Ltd, New Delhi.

5.1.1 The Committee considered the request of M/s BASF India Ltd to conduct experimental seed production for event selection trials with 139 transgenic rice events at TNAU, Coimbatore. The Committee noted that the GEAC in its meeting held on 4.10.2010 had accorded approval to conduct event selection trials on 139 events of transgenic rice at TNAU, Coimbatore.

5.1.2 It was further noted that the applicant proposes to transplant about 15-30 individual seedlings of each event in rows. The individual plants will be subsequently checked for construct validation via PCR analysis on dried leaf samples and plants that pass this test will be harvested individually, processed and stored by BASF India till a new round of yield trials is started.

5.1.3 During the deliberations, it was also noted that DBT has issued the approval letter to M/s BASF on 15.2.2010. As per the SC Court direction prior approval of GEAC is required for all activities outside the green house (event selection, BRL-I, seed production) before approval is issued by the RCGM.

5.1.4 After detailed deliberations, the following decisions were taken:

1. The applicant may be requested to clarify (i) why the individual plants are being checked for construct validation via PCR analysis; (ii) whether the individual plants are homozygous lines or they are segregating lines;

2. DBT may be directed to withdraw the approval granted for seed production vide letter No.BT/BS/17/348/2009-PID dated 15.2.2011.

Agenda Item No 6 : Consideration of applications related to Pharmaceuticals

6.1 Permission to import Proteqflu a Vaccine against Equine Influenza in horses from Merial, France and market in India by M/s Pet Express Chennai.

6.1.1 The request from M/s Pet Express to import Proteqflu, Vaccine against Equine Influenza from Merial, France and market in India was considered by the GEAC It was noted that it is a live recombinant Canary Pox Virus Vaccine.

6.1.2 Equine influenza or Horse flu is the disease caused by strains of Influenza A that is enzootic in the horse/equine species. Equine influenza occurs throughout the world and is caused by two main strains of viruses, (i) Equine 1 and (ii) Equine 2. The disease has 100% infection rates in an unvaccinated horse population. The disease has a very short incubation period of 1-3 days. The affected animals show signs of fever, cough, discharge from the nostrils, become depressed and are reluctant to eat or drink for several days. The economic importance of an outbreak of equine influenza in India can have multiple ramifications ranging from the breeding stock and racing fraternity besides having the potential to cripple the armed forces. Early and regular vaccination is the recommended method of control of the disease.

6.1.3 The Expert Members were of the view that Proteqflu has been used extensively since 2000 and no adverse report on the safety or efficacy has been received since its registration. Proteqflu has met the safety requirements based on studies including those performed after administration of a single dose, after administration of overdose, administration of overdose in pregnant mares and after repeated administration of repeated single doses. Several serological and challenge studies have demonstrated the efficacy of Proteqflu in relation to dose-response efficacy, duration of immunity in foals, efficacy under field conditions and field efficacy study in adult horses.

6.1.4 The product has been registered in 31 countries, like, Austria, Belgium, Denmark, France, Germany, Greece, Russia, United Kingdom, South Korea, Sweden, Spain, Malaysia and many more.

6.1.5 After detailed deliberation the Committee approved the import and marketing of the product in India.

Agenda Item No 7 : Other items:

7.1 Need for conducting toxicity and allergenecity tests on purified barnase and barstar proteins from Department of Genetics, University of Delhi South Campus (UDSC), New Delhi.

7.1.1 The Committee noted that the GEAC in its meeting held on 29.9.2010 had accorded approval to conduct BRL-I trials on transgenic mustarded (*Brassica Juncea*) Hybrid DHH-11 *containing barnase, barsar and bar genes* events bn 3.6 (barnase line) and modbs 2.99 (barstar line) at two to three locations along with the crossibility studies and limited seed production.

7.1.2 The Committee noted that UDSC has requested waiver of toxicity and allergenecity tests on purified barnase and barstar proteins on the following grounds:

- The transgenic mustarded (*Brassica Juncea*) Hybrid DHH-11 *contains three genes viz barnase, barsar and bar* out of which barnase and barstar genes have the tissue specific promoter and are expressed only in the tapetum of the anthers.

- The two proteins viz barnase and barstar are present in extremely small quantities only at the tapetum tissue of anthers for a very short period of time i.e. at the anther development

stage when tapetum is fully functional. Both the proteins are not present in any other plant tissue (including edible and non edible) which can be reconfirmed using real-time PCR technique.

- As per the 'Guidelines and Protocols for Safety Assessment of Regulated GE Crops, 2008', acute toxicity testing and other studies with purified proteins needs to be undertaken only if the expressed proteins are present in edible plant parts.

- The waiver request is also in line with the approvals granted by USA, Canada and Australia while approving *Brassica napus* containing similar gene inserts to M/s Aventis (now Bayer Crop Sciences).

- RCGM in its 96th meeting held on 27.12.2010 has recommended that there is no need for conducting food safety studies with purified barnase and barstar proteins, subject to submission of data on expression of the two proteins in various plant parts.

7.1.3 After detailed deliberations, the Committee opined that the requirement for food safety assessment as per the 'Guidelines and Protocols for Safety Assessment of Regulated GE Crops, 2008' cannot be relaxed. Some of the members opined that globally available toxicity and allergenicity tests on purified barnase and barstar using surrogate proteins can be considered. The Committee noted that the GEAC in its meeting held on 09.02.2011 had constituted a sub-committee to look into suggestions received from the industry association regarding streamlining of the regulatory processes. As one of the TOR of the sub-committee was to examine the acceptance of the biosafety data generated in GLP certified laboratories outside the country, it was decided to consider this issue as and when the report of the Sub-committee is received.

7.2 Show-cause Notice issued to M/s Mayhco for planting non-Bt RRF cotton as refugia during BRL-II trials with BG II-RRF cotton hybrids.

7.2.1 As per the decision taken in the GEAC meeting held on 12.1.2011, a 'Show Cause' notice was issued to M/s Mahyco on February, 7, 2011 seeking explanation on why penal action under E(P)A should not be initiated for violations of 'Rules 1989 as well as the status of the ongoing BRL-II field trials with BGII RRF cotton wherein non-Bt RRF cotton has been planted as refugia.

7.2.2 The Committee considered the following response stated by the applicant:

i. Mahyco has complied with all conditions of the permit/s/protocols granted/approved by the authorities.
ii. BRL-II trials with BG-II RRF cotton using non-Bt RRF cotton as refugia was conducted under the supervision of Director CICR as per the protocol approved by him.
iii. The import of cotton seed containing RRF event MON 88913 was done as per existing rules under the Environment (Protection) Act, 1986.
iv. Pollen flow trials for non-Bt with RRF were conducted and the BGIIRRF lines were derived after introgression of RRF trait from the imported cotton seeds.
v. The protocols for BGIIRRF BRL-II trials provided for a 50 meters isolation distance to prevent any possible cross-pollination.
vi. With perfect incineration process no viable transgene and other plant material generated in the trial plot is allowed to survive in the field.
vii. Non-Bt with RRF cotton has been approved for large scale release in USA and Australia since 2004 and 2006 respectively.
viii. The use of non-Bt with RRF for planting in refuge area does not result in environmental release as the same was planted in small area with adequate isolation distance.
ix. In any event, the purpose of refugia has been met by the use of non-Bt with RRF as the same would sustain susceptible bollworm populations.

7.2.3 After detailed deliberations, the Committee opined that, clarifications submitted by the applicant are not satisfactory as it does not justify the planting of non Bt RRF cotton hybrids (Event MON 88913); an event which has not been approved for environmental release. The Committee

reiterated that it is the responsibility of the applicant to ensure that all approvals have been obtained prior to initiating the trials.

7.2.4 In view of the above stated facts, it was decided to (i) issue a warning to M/s. Mahyco stating that any non compliance in future would attract punitive actions under EPA 1986; (ii) data generated during BRL-II trials using non-Bt RRF flex as refuge shall not be considered for regulatory purpose; & (iii) issue a warning to Director, CICR, Nagpur not to recommend protocols with unapproved events for field testing without the prior approval of the GEAC.

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