

Decisions taken in the 80th Meeting of the Genetic Engineering Approval Committee held on 1.10.2007

The 80th meeting of the Genetically Engineering Approval Committee (GEAC) was held on 1.10.2007 in the Ministry of Environment and Forests under the Chairmanship of Shri B. S. Parsheera, Additional Secretary, MoEF and Chairman, GEAC.

3.0 Action taken report

1.0 The Member Secretary, GEAC informed the Committee that decisions taken in the meeting held on 8.8.2007 have been communicated to the project proponents, concerned government departments and other agencies. Details of action taken were placed before and noted by the Committee.

2.0 The Committee further considered the communication received from Dr. Mathura Rai, Director, IIVR, Varanasi regarding the progress made in the large scale field trials of Bt Brinjal and briefly discussed the constraints in conducting the pollen flow studies in the IIVR/ICAR institutions due to non availability of land. It was noted that 240 acres (approx 100 ha) of land per location is required for conducting pollen flow studies. The Committee considered the two options suggested by Director IIVR viz; (i) either reduce the number of locations from 6 to 3 or (ii) redesign the protocol for pollen flow studies. The expert members were of the view that 2-3 locations are adequate for assessing the pollen flow. The committee therefore recommended that pollen flow studies may be conducted at a minimum of 3 locations in different agro-climatic zones within the institution research farm of the Company or long leased land (minimum of 3 years lease) or SAU research farms under the supervision of Director IIVR.

3.0 The Committee also took note of the clarifications forwarded by Member Secretary, RCGM to Dr. Mathura Rai in response to the representation from M/s Greenpeace and endorsed the same. The Committee requested Member Secretary GEAC to issue a communication in this regard to Director IIVR.

4.0 The representative of Ministry of Food processing and Industry informed the Committee that the department does not have adequate expertise to evaluate the adverse impact on health (if any) arising from LMOs and products thereof. The Committee clarified that import of GM food / seeds which can propagate in the environment would require prior approval of GEAC. In case of processed food, the mandate would fall under the purview of Food Safety and Standard Act, 2006 which is being implemented by the Ministry of Health and Family Welfare. In response to a query raised by the representative of Ministry of Food processing and Industry regarding the mechanism for evaluating the food safety in processed food it was clarified that if the product is approved for human consumption in the country of origin, food-feed safety dossier generated in the country of origin may form the basis for initial evaluation. The Committee requested Member Secretary GEAC to forward a copy of the Gazette notification (S.O. 1519(E) dated 11.9.2007) exempting food/ food stuffs/ ingredients derived from LMO where the end product is not an LMO from the purview of the GEAC to the concerned ministries/ department along with a brief note on the same.

5.0 Member Secretary GEAC further informed that in Writ Petition (Civil) No. 115/2004 filed by M/s Gene Campaign vs UoI, the Hon'ble Supreme Court has advised that the suggestions made by the Petitioner regarding improvement in the regulatory system as well as names of Experts to be consulted may be forwarded to the appropriate authority. The Committee opined that DBT is in the process of setting up the NBRA and modality for implementation of the same is under active consideration of the Govt. Therefore, suggestions made by the Petitioner including names of some of the members who may be consulted in the formulation of a robust regulatory mechanism, may be forwarded to DBT for consideration to incorporate in the NBRA regulatory mechanism, as considered appropriate.

Agenda Item No 4: Consideration of New Proposals

A. Pharmaceuticals

4.1 Permission for Manufacture and marketing of FMD (Foot and Mouth disease) vaccine by M/s Biovet Private Ltd. Bangalore.

4.1.1 The Committee noted that the present application dated 4.6.2007 is for manufacture and marketing of FMD (Foot and Mouth disease) vaccine by M/s Biovet Private Ltd. The FMD vaccine virus strains will be procured from IVRI (Project Directorate, FMD, IVRI, Mukteshwar) under the technology transfer agreement with NRDC. The Committee further noted that though the product is not genetically engineered, the virus used in Foot and Mouth disease vaccine (virus called serotype and subtype) comes under Risk **group III** which is highly infectious. The proposal has been referred to the GEAC as Rules, 1989 is applicable for both GMOs as well as HMOs.

4.1.2 After detailed deliberations and taking into consideration the recommendations received from ICMR and DBT, the Committee approved the above proposal.

B. Reconsideration Cases

4.2 Permission for import to conduct Phase III Clinical trials with r-adenovirus p 53 (rAdp53) in the treatment for newly diagnosed unresectable squamous cell carcinoma of head and neck from China by M/s Intas Biopharmaceuticals Ltd.

4.2.1 The Committee noted that the above proposal was considered in the 79th GEAC meeting held on 8.8.2007 wherein it was decided to await comments of the experts before the proposal is considered for phase – III clinical trials in India. The Committee noted that the experts have recommended that there is a need to obtain full dossier of the drug from the manufacture, translated into English and all the data submitted in the dossier should be as per Schedule 'Y' requirement, which is to be reviewed by the expert group for the appropriateness of the study before import of drug for phase-III study is considered. The Committee directed the applicant to submit the requisite information for further consideration and taking a final view.

4.3 Permission for manufacture of indigenously developed Human Immunodeficiency Viral (HIV) antigens p24, gp120 and gp41 for diagnostic kit development by M/s. Sudershan Biotech Ltd.

4.3.1 The Committee noted that the above proposal was considered in the 79th GEAC meeting held 8.8.2007 wherein it was decided to await comments of the Experts. Based on the recommendations of DCGI, ICMR and DBT, the Committee approved the manufacture of indigenously developed Human Immunodeficiency Viral (HIV) antigens p24, gp120 and gp41 for diagnostic kit development by M/s. Sudershan Biotech Ltd.

4.4 Permission for import and conduct of phase II clinical trials of Chimerivax tm – JE in children of descending age from USA by M/s Quintiles Research (India) Pvt. Ltd.

4.4.1 The above proposal was considered in the 79th GEAC meeting held 8.8.2007 wherein it was decided to await comments of the Experts. The Committee considered the comments received from DBT, ICMR and the Expert Group on JE vaccine. It was noted that in the meeting of the Expert Group held on 13.9.2007, the experts had sought certain clarifications. From the ICMR communication, it was not clear if the required information has been submitted by the applicant. The Committee decided to seek clarification from ICMR in the first instance and request ICMR to forward the

clarifications to the GEAC. The Committee further authorized Chairman GEAC to take appropriate decision based on the clarifications received from ICMR.

C. Transgenic crops

4.5 Permission to conduct Large Scale trials on Bt Brinjal hybrids SBJ 1 Bt, SBJ 2 Bt SBJ 4 Bt, SBJ 6 Bt, SBJ 7 Bt and SBJ 8 Bt expressing cry 1Ac gene by M/s Sungro Seeds Research Ltd. Delhi.

4.5.1 The Committee considered the request from M/s Sungro Seeds Research Ltd. for Large Scale trials of Six Bt Brinjal hybrids namely **SBJ 1 Bt, SBJ 2 Bt SBJ 4 Bt, SBJ 6 Bt, SBJ 7 Bt and SBJ 8 Bt** expressing cry 1Ac gene. Transgenic seeds of Bt. brinjal event developed by M/s Mahyco were transferred to Sungro Seeds Ltd. vide transfer clearance letter no. BT/BS/17112/2003-PID dated 8.12.2003 for introgression into their genotypes by traditional back crossing method.

4.5.2 The Committee was of the view that the Bt brinjal hybrids developed by the parent company namely M/s Mahyco is still under review and therefore the present request cannot be considered at this stage.

4.6 Permission to conduct confined Multi Location Research Trial (MLRT) on 2 Bt cabbage hybrids namely SCB-3 Bt and SCB-7 Bt expressing cry1Ac gene by conducting Multi Location Research Trial (MLRT) during Rabi 2007 by M/s. Sungro Seeds Research Ltd., New Delhi

4.6.1 The Committee noted that the Hon'ble Supreme Court directions dated 8.5.200, in respect of field trials of GM crops with new events was specific to the 24 items approved by the GEAC during 1.5.2006 to 22.9.2006. The transgenic crops approved for MLRT during this period includes rice, okra, groundnut, potato, tomato, brinjal, castor, cauliflower, mustard and cotton. As Bt cabbage is not listed in the 24 items approved by the GEAC during 1.5.2006 to 22.9.2006, the request for MLRT cannot be considered without informing the Hon'ble Supreme Court. The Member Secretary GEAC informed the Committee that an application for modification of the Court orders dated 8.5.2007 has been filed by the UoI. As the applicant has completed the requisite regulatory testing and evaluation process, the Committee opined that subject to the outcome of the Hon'ble Supreme Court decision, the proposal for MLRT with Bt cabbage may be approved subject to the following conditions:

1. The applicant should submit to the RCGM/GEAC the name of the Lead Scientist responsible for the trials before undertaking the trials.
2. The applicant should submit to the RCGM/GEAC an event specific test protocol duly validated/verified by ICGEB, New Delhi / NBRI, Lucknow or any other accredited laboratory before undertaking the trials.
3. An isolation distance of minimum 200 m shall be maintained. In cases where the Seed Standards Certification mandates a larger isolation distance, the same shall be maintained.
4. The MLRT shall not be conducted in farmers' field. MLRT should be undertaken by the Companies/Institutions either in their own premises, research farms, long leased land (a minimum of three years lease) or at the SAU/ICAR institutions.

4.7 Permission to conduct contained limited field research trial (strip trial) with transgenic tomato (cv. Pusa. Ruby) expressing antisense ACC synthase gene at the IARI, New Delhi during Rabi season (Oct.-2007 to April-2008) by National Research Centre on Plant Biotechnology, IARI, New Delhi.

4.7.1 The Committee considered the above proposal and noted that the RCGM in its meeting held on 3.9.2007 has recommended the **strip trial** with transgenic tomato subject to the following conditions-

- 1 Strip trials, for new events should be undertaken by the Companies/ Institutions in their own premises/ research farms. In accordance with the Hon'ble Supreme Court directions an isolation distance of 200 m should be maintained
- 2- The applicant should submit a validated event specific test protocol before undertaking the trials.

4.7.2 After detailed deliberations the GEAC approved the request for strip trials subject to the following conditions:

1. The applicant should submit to the RCGM/GEAC the name of the Lead Scientist responsible for the trials before undertaking the trials.
2. The applicant should submit to the RCGM/GEAC an event specific test protocol duly validated/ verified by ICGEB, New Delhi / NBRI, Lucknow or any other accredited laboratory before undertaking the trials.
3. An isolation distance of minimum 200 m shall be maintained. In cases where the Seed Standards Certification mandates a larger isolation distance, the same shall be maintained.
4. The Strip trials shall not be conducted in farmers' field. Strip trials should be undertaken by the Companies/Institutions in their own premises or research farms.

5.0 Other Items

5.1 Permission for commercial release of Bt cotton hybrids namely 113 Bt and 302 Bt expressing cry 1 Ac gene (MON- 531) in the South zone by M/s Bioseed Research India Pvt. Ltd.

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5.2 Permission for commercial release ACH 21-1 expressing cry 1 Ac gene (MON- 531) in the Central zone by M/s Ajeet Seeds Ltd.

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5.3 Permission to conduct Strip trial of 40 F1 Bt cotton hybrids namely TPHCN07-011 to TPHCN07-050 under contained open field condition at RJ Biotech's Research farm by M/s. RJ Biotech, Aurangabad.

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5.4 Permission to conduct Strip trial 56 BG-1 hybrids (HXH) and 4 hybrids (HXB) containing cry1Ac (Event MON 531) and 9 BG-II hybrids (HXH) and 1 (HXB) containing cryX (cry1Ac & cry2Ab) (Event MON 15985) at own R&D Farm Gundlapochampally, via Hakimpet Medchal, R.R.Dist. Andhra Pradesh during Kharif-2007 in South zone by M/s. Amar Bio-Tech Ltd., Hyderabad.

1.0 The Committee considered agenda items at 5.1 to 5.4 pertaining to commercial release / strip trials of Bt cotton hybrids with approved gene events. The Member Secretary RCGM informed the Committee that the above applications were inadvertently missed out and only considered in the recently held RCGM meeting. The Committee noted that the proposals for commercial release and strip trials have completed the requisite regulatory testing and evaluation process. The MEC and RCGM have recommended the proposals. The GEAC therefore approved the above proposals. As the sowing season for cotton is over in all three zones, it was further decided that the approval would be valid for Kharif 2008 only.

5.5 Permission for extension of the period for conducting replicated confined Multi-Location Research Trial (MLRT) on Bt rice hybrid containing *cry1Ac* gene from Kharif 2007 to Rabi 2007 and to generate the biosafety data by M/s. Maharashtra Hybrid Seeds Company Limited, Mumbai.

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5.6 Permission to extension of the period for conducting contained limited field research trial (strip trial) on RB-transgenic potato lines (SP-951) from kharif-2007 to Rabi-2007 by Central Potato Research Institute, Shimla.

1.0 The Committee noted that in respect of agenda item No. 5.5 and 5.6, the GEAC in its earlier meeting had approved the proposal for conduct of MLRT with Bt rice by M/s Mahyco and transgenic potato by CPRI during Kharif, 2007. Since, the applicants were unable to undertake the trials during Kharif, 2007, approval has been requested for conducting the trials during Rabi 2007. Trials for potato will, however be conducted at Modipuram (Modinagar) instead of Shimla. The RCGM in its meeting held on 03.09.2007 has agreed with the above request. The GEAC conveyed its no objection for conducting the trials in Rabi 2007.

5.7 Representation received from M/s Metahelix Life Science, Bangalore regarding the GEAC decision with respect to the proposal for large scale field trials of Bt cotton hybrids developed by the Company.

1.0 The Committee took note of the representations received from M/s Metahelix and was of the view that further action can be taken by the Committee only after receipt of complete biosafety dossier and further directions from the Hon'ble Supreme Court.

List of participants who attended the GEAC meeting on 1.10.2007

S.No.	Name and Designation
1.	Shri B. S. Parsheera , Chairman, GEAC
2.	Shri A. K. Goyal , Vice chairman, GEAC
3.	Dr. K. K. Tripathi , Adviser, DBT, New Delhi.
4.	Dr. P. Anand Kumar , Principal Scientist, NRCPT, New Delhi
5.	Dr. K. C. Jain , Deputy Director General (Crop Science) ICAR, Krishi Bhavan
6.	Dr. B. K. Chaudhari , SEE & I/C Treat Lab, CPCB, Delhi
7.	Shri S. B. Dongre , Director, MoFPI, New Delhi.
8.	Dr. R. Warriar , Director, MoEF and Member-Secretary, GEAC
9.	Dr. M. Hota , Additional Director, MoEF.
10.	Ms. Madhu Gupta , RO, MoEF