

Decision taken in the 81st Meeting of the Genetic Engineering Approval Committee held on 22.11.2007

The 81st meeting of the Genetic Engineering Approval Committee (GEAC) was held on 22.11.2007 in the Ministry of Environment and Forests under the Chairmanship of Shri B. S. Parsheera, Additional Secretary, MoEF and Chairman, GEAC.

1.0 Consideration of proposals

Transgenic Crops

1.1 Permission to conduct Multi Location Research Trials (MLRT) of two transgenic cauliflower hybrids namely SCF-8 Bt and SCF-9 Bt containing *cry1Ac* gene during Rabi 2007 submitted by M/s Sungro Seeds Research Ltd., New Delhi.

1.0 The Committee noted that the RCGM in its meeting held on 25.9.2007 has recommended the proposal for MLRT with two transgenic cauliflower hybrids namely SCF-8 Bt and SCF-9 Bt containing *cry1Ac* gene during Rabi 2007 subject to compliance of the following conditions:

- a) For cauliflower seed production, as per India Minimum Seed Certification Standards, an isolation distance of 1600 m and additional physical/biological barriers should be maintained to avoid any pollen flow.
- b) In case of the field trials, the applicant should give an undertaking to the RCGM that the field experiments will be terminated before flowering stage. The company may then maintain an isolation distance of 200 m as proposed in their application. It was noted that proposed isolation distance is in conformity with the Hon'ble Supreme Court directions dated 8.5.2007.

2.0 The GEAC considered the above proposal in light of the recommendations made by the RCGM and in accordance with the Hon'ble Supreme Court directions dated 8.5.2007. After detailed deliberations, the Committee approved conduct of MLRT with Bt cauliflower subject to the following conditions:

- In addition to the conditions stipulated by the RCGM, the applicant should submit a validated event specific test protocol of 0.01 % LOD before undertaking the trials.
- The applicant should submit the name of the lead scientist who would be responsible for conducting the trial.
- MLRT for new events should not be conducted in the farmers' field. MLRT should be undertaken by the Companies/Institutions either in their own premises, research farms, long leased land (minimum of 3 years) or at the SAU/ICAR institutions.

3.0 The GEAC authorized Member Secretary, RCGM to issue the approval letter on receipt of the locations of the field trials and submission of a validated event specific protocol of 0.01%.

1.2 Permission to conduct experimental seed production of four Bt cotton hybrids namely SP 700 B2, SP 503 B2, SP 671 B2, SP 1044 B2 containing *cry1Ac* and *cry2Ab* gene (event MON 15985) in an area of 0.5 acres each in Central and South zones during Kharif 2007 by M/s. Bayer BioSciences Pvt. Ltd., Hyderabad.

1.0 The Committee noted that the GEAC in its meeting held on 22.6.2007 has approved the conduct of MLRT with Bt cotton hybrids namely SP 700 B2, SP 503 B2, SP 671 B2, SP 1044 B2 containing *cry1Ac* and *cry2Ab* gene (event MON 15985) in Central and South zones during kharif 2007.

2.0 After detailed deliberations, the GEAC approved seed production of the above hybrids in an area of 0.5 acre as per the prevailing regulatory procedures and recommendations of the RCGM.

1.3 Permission to conduct trials through All India Co-ordinate Research Project (Vegetable Crops) under ICAR during Kharif -2008, 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.

1.0 The Committee considered the request of the Company for conduct of ICAR trials of 6 Bt brinjal hybrids. The Committee reiterated that the request cannot be considered at this stage as Bt brinjal hybrids developed by the parent company namely M/s Mahyco is still under review.

1.4 Request to revoke the permission for commercial release of Bt cotton hybrid NSC 913 Bt to M/s. Nuziveedu Seeds from the Director of Agriculture, Haryana.

1.0 The Member Secretary, GEAC informed the Committee that Haryana State Agriculture Department has informed that the Bt cotton seeds of NCS 913 Bt developed by M/s. Nuziveedu has shown poor performance. The Department based on complaints received from farmers has conducted an enquiry through a Committee of cotton experts of CCS HAU, Hissar, Joint Director of Agriculture (cotton) and Deputy Director of Agriculture, Fatehabad. Based on the investigation report which found that the quality of seeds supplied by M/s Nuziveedu Seeds Ltd. was not of the desired standard, the sale of NSC 913 Bt seeds have been banned in Haryana.

1.0 Regarding the request of the State Department of Agriculture to withdraw the commercial approval given by the GEAC, the Committee was of the view that the GEAC under Rules, 1989 is mandated to accord approval for environmental release. However, the State Department may restrict the sale of seeds under the relevant acts and regulations.

1.5 Request to issue a certificate confirming to the effect that no GM rice, groundnut and sesame seeds have been permitted in India by Agricultural and Processed Food Products Export Development Authority (APEDA).

1.0 The Committee considered the request received from APEDA for issuing a certificate confirming that no GM rice, groundnut and sesame seeds have been permitted in India. The Member Secretary, GEAC informed that the above request is being made by APEDA in view of the temporary restriction imposed by Russia on import of rice, groundnuts and sesame seeds from India in view of the measures agreed upon between the two sides and the format for quality testing certificate mutually agreed upon. One of the requirements in the certificate is confirmation from Government of India that no GM crops in Rice, groundnuts and sesame seeds exist in India.

2.0 The Committee authorized Member Secretary, GEAC to issue a letter to APEDA confirming that "no GM crops in Rice, groundnuts and sesame seeds exist in commercial production in India".

1.6 Development of detection kits of different Cry 1Ac genes by M/s. Amar Immunodiagnosics Pvt. Ltd.

1.0 The Committee advised the applicant to obtain the requisite accreditation for notification of the laboratory as a referral laboratory.

1.7 Communication received from Deptt. of Agriculture, Govt. of Chhatisgarh, Raipur seeking clarifications regarding conduct of the MLRT on Bt okra hybrid at Durg, Raipur by M/s. Maharashtra Hybrid Seeds Co. Ltd. (Mahyco), Mumbai during Rabi 2007-08 and representation received from M/s Mahyco.

1.0 The Committee considered the communication received from Deptt. of Agriculture, Govt. of Chhatisgarh, Raipur seeking clarifications on whether the MLRT permit issued for Kharif, 2007 for Bt okra would be valid for Rabi 2007 and the response given by DBT.

2.0 The Committee was of the view that approval for Kharif 2007 would imply that sowing should be completed during the Kharif season. However, approval for the field trials would be valid for the entire duration of the crop life cycle even if it spills over to Rabi season. The Committee ratified the communication sent by DBT.

1.8 Consideration of ICMR Guidelines on Food Safety.

1.0 Dr. Vasantha Muthuswamy, Chief (BMS), ICMR made a brief presentation on the ICMR guidelines on food safety. She informed that the draft guidelines has been examined by the Expert members of the RCGM and the Sub Committee constituted by RCGM for review of the toxicity and allergenicity studies to be conducted in GM crops under the Chairmanship of Director, NIN. It was noted that the modifications proposed by the experts have been incorporated in the draft guidelines. The protocols for conducting the food safety assessment developed by the Sub Committee would also form part of the above guidelines. After a brief discussion, it was agreed that the revised guidelines along with the protocols would be posted on the ICMR, DBT and MoEF websites for inviting public comments. Subsequent to review of the stakeholder comments, the revised final draft will be placed for consideration of the RCGM and the GEAC.

1.8 Status of compliance of Hon'ble Supreme Court directions dated 8.5.2007 in GM crop field trials.

1.0 The Member Secretary GEAC informed the Committee that the Petitioners have initiated Contempt of Court proceedings against Chairman, GEAC, Co-Chairman, GEAC and Member Secretary, GEAC and the matter is listed for hearing on 17.1.2008. After detailed deliberations the Committee confirmed that approvals given by the GEAC is in full compliance of the following conditions stipulated by the Hon'ble Supreme Court:

1. All trials should have a lead scientist's name with contact details who would be responsible for all aspects of the trials including regulatory requirements.
2. An isolation distance of 200 m would be maintained during field trials. Since the isolation distance would vary depending on the biology of the crop, the GEAC has prescribed higher isolation distance as per the Indian Minimum Seed Certification Standards where applicable.
3. Prior to bringing out the GM material from the green house for conduct of open field trial the Company should submit a validated event specific test protocol at an LOD of at least 0.01% to detect and confirm that there has been no contamination.

2.0 The status of the field trials and compliance with respect to the Hon'ble Supreme Court order was placed before and noted by the Committee as follows:

Field trials for GM crops expressing new gene events permitted for Kharif 2007				
Company	Crop	Trial	State	Location

Maharashtra Hybrid Seeds Company Ltd.	Bt Rice	MLRT (Initiated in Rabi, 2007 with approval of GEAC)	Gujarat, Maharashtra, West Bengal, Bihar, Jharkhand, Karnataka and Tamil Nadu.	Anand, Bhandara, Rajgad, South 24 Parganas, Midnapur, Gaya, Ranchi, Davangere, Mandya, Tanjore and Coimbatore.
	Bt Okra	MLRT	Maharashtra, Gujarat, Chhattisgarh, Rajasthan, Haryana, Bihar, Uttar Pradesh, Jharkhand, West Bengal, Karnataka, Tamil Nadu.	Jalna, Jalgaon, Vadodara, Durg, Jaipur, Karnal, Gaya, Lucknow, Ranchi, Nadia, Haveri, Coimbatore
Sungro Seeds Research Ltd.	Bt Brinjal	MLRT	Delhi, Haryana, Punjab, Rajasthan, Uttar Pradesh	Allipur, Hamidpur, Sonapat, Ludhiana, Fatehgarh, Jaipur, Basti.
University of Agricultural Sciences, Dharwad	Bt Brinjal	MLRT	Karnataka	UAS Research Stations
Central Potato Research Institute, Shimla	Potato	Strip trials	Himachal Pradesh	Not initiated
Methahelix Life Sciences, Bangalore	Bt Rice	Strip trial	Karnataka	Not initiated
Tamil Nadu Agricultural University. Coimbatore	Bt Brinjal	MLRT	Tamil Nadu	Coimbatore, Periyakulam, Madurai, Killikulam and Palur.
ICRISAT, Patancheru	Groundnut	Contained field experiments	Andhra Pradesh	Not initiated
Bejo Sheetal Seeds Pvt. Ltd, Jalna	Bt Brinjal	Conduct Pollen flow studies	Maharashtra and Uttar Pradesh	Not initiated
	Bt Brinjal	Strip trial/ experimental seed production	Maharashtra	Not initiated
M.s Maharashtra Hybrid Seeds Company Ltd.	Bt Tomato and Bt Rice	Pollen flow study	Maharashtra	Not initiated
Maharashtra Hybrid Seeds Company Ltd.	Bt cotton (Round up Ready flex Cotton).	MLRT	Andhra Pradesh, Karnataka and Tamil Nadu.	Guntur, Ranga Reddy, Haveri, Dharwad, Coimbatore and Salem.
Maharashtra Hybrid	Bt Brinjal	Large scale	Maharashtra, Gujarat,	Rahuri, Parbhani,

Seeds Company Ltd.		field trial	Madhya Pradesh, Karnataka, Tamil Nadu, Punjab, Uttar Pradesh, Haryana, Rajasthan and Jharkhand.	Anand, Jabalpur, Dharwad, Coimbatore, Ludhiana, Varanasi, Hisar. Bikaner, and Ranchi at Institutional / Research farms of ICAR/IIVR.
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3.0 The Member Secretary, GEAC informed that field trials of Bt Brinjal, Bt okra, Bt rice and Bt cotton (RRF) have been initiated only after complying with the Hon'ble Supreme Court order dated 8.5.2007. In respect of other crops, field trials have not been initiated as the applicants were not able to comply with the requirements of 0.01 % LOD or due to non- availability of land for maintaining the prescribed isolation distance.

4.0 The Committee expressed deep concern that the research activities on GM technology in agriculture has practically come to a standstill thereby resulting in delay in the biological research and retarding the progress of the country. Bt cotton experience has confirmed that the GM technology is highly beneficial to farmers. Any delay in the judicial review would have a significant economic impact on the farming community. The Committee advised that the above matter may be brought to the notice of the Hon'ble Supreme Court.

2.0 Additional Items with the permission of the Chair

2.1 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.

1.0 The above proposal was considered in the 80th GEAC meeting held 1.10.2007 wherein it was decided to seek clarification from ICMR. The representative of ICMR informed that the proposal has been considered by the ICMR Technical Committee of Experts for clinical trials in its two meetings and the Committee has recommended continuation of phase-II clinical trials.

2.0 During the deliberations, one of the Experts pointed out that the applicant has not fully complied with the conditions stipulated by the GEAC. The applicant has furnished only the safety data but the efficacy data has not been submitted. Also the number of patients considered for clinical trials in the higher age group is only 32. The representative of ICMR informed that the applicant is conducting a double blind Cohort study and therefore the efficacy data can be provided only after the trials have been completed. The total number of patients to be considered in the cohort study is about 135.

3.0 After detailed deliberations and taking into consideration, the recommendations of the ICMR and its Technical Committee of Experts, the GEAC approved the conduct of phase-II clinical trials in the age group of >2 and <5 years subject to compliance of the conditions stipulated in the approval letters dated 15.5.2006 and 15.6.2006.

2.2 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.

1.0 The Committee noted that the above proposal was considered in the 80th GEAC meeting held on 1.10.2007 wherein it was decided to advise the applicant to submit the full dossier of the drug from the manufacture, translated into English so as to enable the Experts give their comments expeditiously. Representative of ICMR informed that the revised information is in order and the

GEAC may consider approving Phase-III clinical trials with r-adenovirus imported from China. One of the Experts informed that the information furnished in the dossier is neither satisfactory nor adequate to conclude that the drug is safe for conduct phase-III clinical trial. After detailed deliberations, it was decided to refer the proposal to the RCGM for comments.
