

Decisions taken in the 96th Meeting of the Genetic Engineering Approval Committee (GEAC) held on 9.9.2009

The 96th meeting of the GEAC was held on 9.9.2009 in the Ministry of Environment and Forests (MoEF) under the Chairmanship of Shri B S Parsheera, Special Secretary, MoEF and Chairman, GEAC.

The deliberations/decisions taken in the GEAC meeting in respect of Agenda Items 4 to 7 are as follows:

Agenda Item No. 4: Policy Issue

4.1 Report of the Sub-committee constituted by the GEAC to finalize the list of studies to be conducted by the applicant under BRL-I and BRL-II trials.

4.1.1 Following the adoption of event based approval system and new set of guidelines and SOPs for confined field trials, it became necessary to have a set of information/data requirements for safety assessment of regulated, genetically engineered (GE) plants. Accordingly, a draft guidance document listing out studies to be conducted under BRL-I & II trials was prepared. The document was circulated to the members of RCGM and GEAC and subsequently placed on the website by DBT at <http://www.igmoris.nic.in> and <http://dbtbiosafety.nic.in> for a period of three weeks.

4.1.2 In the GEAC meeting held on 13.5.2009, a Sub-committee under the chairmanship of Prof Arjula R Reddy, Co-Chairman GEAC was constituted to examine the "Guidance document for information/data generation and documentation for safety assessment of GE Plants" Member Secretary, GEAC informed that the guidance document was finalized by the Sub-committee in the meeting held on July 29, 2009. After a brief discussion on the salient features of the recommendations made by the Sub-committee, some members opined that additional time for further review may be provided. It was agreed to consider the matter in the next GEAC meeting scheduled for 14.10.2009. Members were advised to forward their comments, if any, to the Secretariat by September 30, 2009.

4.2 Stocktaking assessment of GM crops which are under various stages field testing.

4.2.1 In accordance with the decision taken in the GEAC meeting held on 8.7.2009, information on the status of GM vegetables under field trials was placed before the Committee. The Committee noted that the status of field trials of GM vegetables is as under:

A. M/s Nunhems India Pvt Ltd:

- (i) Development of transgenic cauliflower expressing RST08-30, 15 events and**
- (ii) Development of transgenic cabbage expressing *cry 1b* and *cry 1c* gene.**

1.0 Nunhems is working on genetically modified (GM) cabbage and cauliflower containing a dual gene construct with two-linked Bt genes *cry1Ba* and *cry1Ca* and a marker gene encoding for phosphinothricin acetyl transferase (PAT). The transformations have been performed in the labs of Nunhems in The Netherlands and the various GM events were imported into India for Elite Event (EE) selection and variety development. The EE selection, variety development and studies for obtaining regulatory approval are being performed within the Public Private Partnership CIMBAA (Collaboration on Insect Management for Brassicas in Asia and Africa). Based on the event selection trials, the company has short listed 4-5 events for further event selection trials under net house conditions. No confined trials under BRL-I have been initiated.

B. M/s Sungro Seeds Research Ltd ,

(i) Development of transgenic cauliflower expressing cry 1Ac gene event CFE 4

1.0 Development of transgenic cauliflower expressing cry 1Ac gene event CFE 4 and seeds of proprietary lines transformed with *Cry1Ac* gene were received from M/s Mahyco in 2003. From June 2004 to March 2005 backcrossing of hybrids and evaluation at greenhouse level was done. Confined field trials for generating bio-efficacy and biosafety data was conducted in 2005 and 2006. As the trials conducted in 2006 were not conclusive due to low target pest infestation, the applicant has repeated the trials in 2008 for generation of the following information:

- a) Evaluation of performance of Bt cauliflower against Diamond back moth (DBM)
- b) Effect of germination, aggressiveness and weediness
- c) Soil rhizospheric studies
- d) Monitoring of occurrence of beneficial and non target insects
- e) Estimation of level of expression of Bt proteins at regular intervals
- f) Generation of Baseline susceptibility data
- e) DNA fingerprinting data of hybrid/ genotype

C. M/s Maharashtra Hybrid Seeds Company Ltd.,

(i) Development of transgenic okra expressing cry Ac gene and

1.0 The *cry1Ac* gene, source *Bacillus thuringiensis* was received from Monsanto and transformation was done at Mahyco laboratory. From 2000 to 2002, backcrossing of hybrids and evaluation at greenhouse level was done. The applicant has conducted pollen flow study and soil microflora study during the limited field trial in 2004. Subsequently, the applicant has conducted confined field trials during 2005, 2006 and 2007 for generation of the following information:

- a. Pollen flow study
- b. Soil microflora study
- c. Effect on target pests
- d. Effect on non-target pests
- e. Soil micro-biota studies
- f. Protein expression studies
- g. Weediness and aggressiveness studies
- h. Molecular characterisation and event ID
- i. Baseline susceptibilities studies

2.0 Trial planting was also done at Jalna to generate material for biosafety studies during 2009. A biosafety package is being generated.

(ii) Development of transgenic tomato expressing cry 2Ab gene.

1.0 Seeds of proprietary lines transformed with *Cry2Ab* gene, source *Bacillus thuringiensis* was received from Monsanto and transformation was done at Mahyco laboratory. RCGM approved the conduct of pollen flow trial on 11th July, 2006. However, due to non-availability of seeds, the applicant requested RCGM to extend the pollen flow permit to Kharif 2007. Meanwhile due to Hon'ble SC order, the applicant was directed to develop LOD of at least 0.01%, before undertaking the trials.

2.0 The company has informed that the *Cry2Ab* tomato project is put on hold for the present due to a change in the company's crop/trait priorities. Further, the company is in the process of developing the LOD protocol. No field trials have been initiated.

D. M/s Avesthagen Pvt. Ltd.

(i) Development of transgenic tomato expressing unedited NAD9.

1.0 The transgenic tomato lines have been developed in Arka Vikas background originally for evaluating male sterility. A sub sample of the population thus generated was found to be deeply pigmented and subsequently analyzed for lycopene content. Lycopene analysis revealed a 250-500% increase in lycopene content as compared to control.

2.0 RCGM in its letter dated 25.08.2008 had requested the company to furnish information on bio-efficacy data generated in laboratory condition, pepsin digestibility, heat, thermal stability, acute oral toxicity data generated on the purified protein and other safety assessment study on the purified protein as per the new protocols being adopted by the RCGM/ GEAC. Only after the requested studies are completed the confined field trials for event selection will be initiated. No field trials have been initiated so far.

E. National Research Centre on Plant Biotechnology, (NRCPB),

(i) Development of transgenic tomato expressing Antisense ACC synthase gene.

1.0 No field trials have been initiated so far. The applicant is in the process of initiating event selection trials.

F. M/s Bejo Sheetal Seeds Pvt. Ltd.

(i) Development of transgenic brinjal expressing cry 1Fa1 (event 142).

1.0 The transgenic brinjal expressing cry 1Fa1 (event 142) was initially developed by Indian Agricultural Research Institute, New Delhi and subsequently transferred to M/s Bejo Sheetal Seeds Pvt. Ltd in 2005 for introgression into the parental lines of the company and conducting biosafety studies as per the regulatory requirement. From 2005 to 2006 backcrossing of hybrids and evaluation at greenhouse level was done. In 2007, LOD protocol for 0.01% was developed and validated by Avesthagen. In 2008 hybrid evaluation in transgenic polyhouse was carried. In 2009, BRL-I trials were initiated at three locations with 2 Bt Brinjal hybrids namely Janak Bt and BSS 793 Bt. The 2009 trials are presently on-going. The applicant has also initiated the following activities:

- Limited seed production of Bt Brinjal hybrids for BRL-II trials .
- Preparation for sub-chronic studies with test material on test animal at NIN, Hyderabad .
- Tests with purified protein for acute oral toxicity, pepsin digestive assay and thermo stability study at NIN, Hyderabad.

G. Central Potato Research Institute.

(i) Development of transgenic potato expressing RB transgenic potato clones

CPRI is working on transgenic potato expressing RB gene. RB gene has been cloned from the wild potato species *Solanum tuberosum*. The transgenic potato developed by CPRI contain two transgenic line (SP951 and SP 904) of US potato cultivar Katahdin and their hybrids derived from the crosses Kufri /Jyoti/Kufri Bahar x SP591/SP904. So far only event selection trials have been carried out.

4.2.2 The Committee noted that only Bt cauliflower, Bt Okra and Bt Brinjal developed by M/s Sungro Seeds Research Ltd, M/s Maharashtra Hybrid Seeds Company Ltd. and M/s Bejo Sheetal Seeds

Pvt. Ltd, respectively, have progressed from the laboratory stage to the confined field trial (BRL-I) phase for generation of biosafety data.

4.2.3 During the deliberations, Member Secretary, RCGM informed the Committee that RCGM is receiving several applications from technology transfer partners for conducting BRL-I trials. He informed that IARI, through technology transfer agreement has transferred the cry 1Fa1 gene (event 142) to five companies of which M/s Bejo Sheetal Seeds Pvt. Ltd, has taken the lead to generate biosafety data for Bt brinjal. Some members opined that if an applicant desires to generate biosafety data independently, he may be permitted to do so. It was however clarified that the GEAC has adopted event based approval mechanism whereby the mandate of the GEAC is to evaluate the biosafety of an 'event'. Additional trials by several technology partners or sub-licensee would not provide any value addition to the safety assessment. Besides, deviating from the event based approval mechanism would put immense pressure on the regulatory agencies. Members also opined that it should be the responsibility of the technology provider to generate the biosafety data. However, in the present case the technology transfer agreement should clearly spell out the modalities and responsibility for generating biosafety data and obtaining the required regulatory approval.

4.2.4 The Committee further advised that a meeting between the technology provider (IARI) and the technology partners who are developing Bt brinjal expressing cry 1Fa1 gene (event 142) may be convened by the Ministry to resolve the above issues

4.3 Recommendation of RCGM regarding the procedure for submission of applications for conduct of field trials of GE crops up to BRL-I level

4.3.2 The GEAC did not accept the suggestion made by the RCGM that applications for conduct of all confined field trials of GE crops may be received and processed by the GEAC Secretariat including issuance of permission letter on the following grounds:

- As per Rules 1989, mandate of the RCGM is to review all R&D activities involving genetically modified Organisms including bringing out manuals of guidelines laying down the procedure and protocols for the trials whereas the mandate of the GEAC is to accord approval for large scale / environmental release. The requirement of approval from the GEAC for BRL-I trials is based on the Hon'ble SC direction. The Ministry has filed an application for amendment of the order.
- The laboratory and green house data is a pre-requisite for consideration of the application for BRL-I trials. The application for BRL-I trials is submitted along with the laboratory and green house trials data to the RCGM. The GEAC can consider the matter only on receipt of the RCGM recommendations.
- With the adoption of the event based approval system, it has been agreed that the applicant may approach the regulatory agencies with a consolidated proposal for conducting BRL-I and BRL-II trials. The guidance document and list of studies to be conducted during BRL-I and BRL-II is under consideration of the GEAC.
- The minutes of the GEAC meeting are approved within three working days and letters of communication regarding GEAC decision are done within four working days.
- Considering that new events with novel traits are under development, the time frame for review of the protocols and procedure may vary. The applicants may therefore be advised to submit their proposal for BRL-I atleast 60 -90 days before they intend to start the trials.

4.4 Discussion on conducting BRL-I trials with direct imported GM seeds by applicants without carrying out R&D work in the country

4.4.1 The Committee after extensive debate on the issue concluded that BRL-I trials with direct imported GM seeds without carrying out R&D work in the country shall not be permitted.

4.4.3 As regards the recent approval given to M/s Pioneer Overseas Corporation to conduct BRL-I trials with imported GM Corn seeds, the Committee opined that the company may be advised to repeat the BRL-I trials with GM seeds developed in the country.

4.5 Constitution of an Appellate Authority to address grievances that can not be resolved by the 'Standing Committee' constituted by the GEAC to review applications for commercial release of Bt cotton hybrids expressing approved events.

4.5.1 The Committee noted that the GEAC meeting held on 13.5.2009 had authorized the Chairman, GEAC and Co-Chairman GEAC to serve as 'Appellate Authority' to address grievances that cannot be resolved by the 'Standing Committee'. The Committee noted that as per the legal advice, it was not technically feasible to create another 'Appellate Authority' as constitution of another AA under the chairmanship of Chairman, GEAC by the MoEF will go against the intent of Section 19 of Rules 1989. However National Environmental Appellate Authority (NEAA), constituted by the Ministry under Section 19 of Rules 1989 can hear appeal against the decision of the 'Standing Committee', created by the GEAC. There is no legal hurdle in this regard.

In light of the above clarifications, the Committee concluded that applicants who are not satisfied with the decision of the 'Standing Committee' may approach NEAA or may represent their grievances in the appropriate court of law.

Agenda item No. 5: Consideration of applications for confined field trials (BRL-1)/seed production /event selection of transgenic crops expressing new genes/events as recommended by the RCGM.

5.1 Permission for seed production on six Bt brinjal varieties namely Malapur local (S Bt (ML(S) Bt); Manjarigota Bt (MG Bt); Udupigulla Bt (UG Bt); Kudachi local Bt (KL Bt); Rabkavi local Bt (RL Bt) and GO112 Bt expressing cry 1Ac gene (Event EE1) at University of Agricultural Sciences (USA), Dharwad for conducting Biosafety Research Level II (BRL-II) trials by M/s University of Agricultural Sciences, Dharwad.

5.1.1 The Committee did not approve the proposal as the request is not in line with the event based approval mechanism adopted by the GEAC.

5.2 Permission to conduct event selection trials for evaluation of vacuolar acid and invertase RNAi- transgenic events namely K.Chipsona-1, K.ChipInv RNAi-2214, K.ChipInv RNAi-2013 K.ChipInv RNAi-2311, K.ChipInv RNAi-2123, K.ChipInv RNAi-2262 K.ChipInv RNAi-2213 K.ChipInv RNAi-2015 for evaluation of reduction in cold-induced sweetening and consequent improvement in chip colour by M/s Central Potato Research Institute, Shimla.

5.2.1 The Committee considered the request of CPRI to conduct "event selection trials" on potato for evaluation of vacuolar acid and invertase RNAi- transgenic events namely K.Chipsona-1, K.ChipInv RNAi-2214, K.ChipInv RNAi-2013 K.ChipInv RNAi-2311, K.ChipInv RNAi-2123, K.ChipInv RNAi-2262

K.ChipInv RNAi-2213 K.ChipInv RNAi-2015 for evaluation of reduction in cold-induced sweetening and consequent improvement in chip colour in ICAR owned plot at Jalandhar, Punjab.

5.2.3 The RCGM has recommended the proposal in its meeting held on 28.7.2009.

5.2.4 The Committee conveyed its 'no objection' to the proposal.

5.3 Permission to conduct event selection trials of marker free rice expressing the *cry 2Ab* gene during Rabi 2009 by M/s Mahyco at Nizamabad, A.P.

5.3.1 The Committee considered the request from M/s Mahyco to conduct event selection trials on marker free 20 Bt Rice events namely 2Bt -1 to 2 Bt -20 expressing *cry 2 Ab gene*. The trials will be conducted at Anand Nagar, Nizamabad, A.P.

5.3.2 The Committee noted that the RCGM has recommended the proposal in its meeting held on 28.7.2009 subject to the condition that the trials should be conducted at the company's own farm or land taken on lease at least for three years. It was pointed out that a policy decision has been taken by the RCGM /GEAC to permit event selection trials only within the institutional research farms and not on lease land in farmer's field.

5.3.4 The Committee conveyed its 'no objection' to the proposal subject to the condition that the event selection trials shall be conducted within the institutional research farms.

5.4 Permission to conduct experimental hybrid seed production of one transgenic cotton hybrid i.e. WS 106 expressing *cry 1F* and *cry 1Ac* proteins (WideStrike TM=*cry 1F* event 281-24-236+*cry1Ac* event 3006-210-23) in one location by M/s Dow Agro Sciences India Pvt. Ltd.

5.4.1 The Committee considered the request of the company for seed production of WideStrike hybrid, WS-106, in 0.5 acres in south zone during Kharif 2009 at one location at their R&D centre for conducting BRL-II trials in Kharif 2010 and other biosafety studies.

5.4.4 The Committee further noted that the RCGM in its 76th meeting held on 02.05.2009 had directed the applicant to provide details of seed produced and status of utilization of the same. The information submitted by the applicant was reviewed by the RCGM in its meeting held on 28.7.2009. RCGM has recommended experimental seed production in an area of 0.5 acres in one location within the institution research farm during kharif 2009. The hybrid seeds will be utilized for conducting BRL-II during Kharif 2010 and other biosafety studies.

5.4.5 The Committee conveyed its 'no objection' to the proposal.

Agenda Item No 6: Other Items

6.1 Permission for Export of Bt cotton hybrid seed to Pakistan and Philippines by M/s Nath Biogene (I) Ltd. Aurangabad.

6.1.1 The Committee considered the request from M/s Nath Biogene (I) Ltd to export Bt cotton hybrid seeds expressing fusion gene (event GFM Cry 1A) as per details given below:

- Export of fifteen G.hirsutum cotton hybrid seeds to M/s Guard Agricultural Research and Services (P) Ltd. Lahore, Pakistan. The proposed shipment will contain 1.5 Kg (100 g x 15) Bt cotton hybrids seeds.

- Export of six G.hirsutum cotton hybrid seeds to Department of Agriculture, Cotton Development Administration, Quezon City, Philippines. The proposed shipment will contain 600 grams. (100 g x 6) of Bt cotton hybrids seeds.

6.1.2 The intended purpose of the export is for conducting multi locational field trials in different agro climatic zone in Pakistan and Philippines. The applicant has submitted 'Biosafety License' from Pakistan Environmental Protection Agency, Islamabad for import of Bt Cotton seeds to Pakistan from India. The applicant has also submitted the 'Plant Quarantine Clearance' from the Department of Agriculture, Bureau of Plant Industry, Manila and Department of Science and Technology, National Committee on Biosafety of the Philippines (NCBP), Republic of Philippines for import of Bt cotton seeds from India to Philippines.

6.1.3 After detailed deliberations, the Committee conveyed it's 'no objection' for export of Bt cotton seeds expressing fusion gene (event GFM Cry 1A)) event to Pakistan and Philippines subject to the following conditions:

1. Approval of the National Competent Authority of Pakistan and Philippines in accordance with the biosafety rules and guidelines of the importing country.
2. Approval from the National Biodiversity Authority, Chennai.

6.2 Representation from National Seed Association of India (NSAL) for Inclusion of State of Orissa as a part of Central zone for the purpose of Bt. cotton cultivation.

6.2.2 The Committee briefly discussed the issues raised by M/s NSAL on whether Bt cotton hybrids approved by the GEAC for central zone prior to the EBAM would be automatically valid for Orissa which has now been included in the central zone for cotton cultivation. As the Bt cotton hybrids were not tested for Orissa, the Committee advised that release of Bt cotton hybrids in the state may be as per the new EBAM. The list of hybrids approved by the GEAC may be forwarded to the State Govt of Orissa for their reference.

Agenda Item No 7: Any other matter with the permission of the Chair.

7.1 Permission for export of transgenic corn seed from M/s Monsanto Research Centre (MRC) Bangalore to M/s Monsanto, USA by M/s Monsanto Holdings Pvt Ltd., New Delhi.

7.1.1 The Committee considered the request from M/s Monsanto to export 5 event lines of transgenic corn seed from Monsanto Research Centre (MRC) Bangalore to Monsanto, St. Louis, USA. It was noted that the transformation vector and plasmids were imported from Monsanto, USA with the approval of the RCGM. The conventional special lines were imported through NBPGR. The transformation work was carried out at Monsanto Research Centre (MRC), Bangalore within the greenhouse. It was further noted that the applicant proposes to export seeds of transgenic corn of 50 grams each from five single-copy events (ZM_B51906; ZM_B51921; ZM_B52050; ZM_B520516 and ZM_B52096) to Monsanto, USA for further event characterization. The transgenic seeds from these plants contain the genes, CP4-EPSPS, which confers resistance to the herbicide glyphosate. The applicant has also submitted a copy of import permit from United States Department of Agriculture.

7.1.2 The Committee conveyed its 'no objection' to the proposal.

The next meeting of the GEAC is scheduled for 14.10.2009.
