

Minutes of the 129th meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 20.06.2016

The 129th meeting of the GEAC was held on June 20, 2016 in the Ministry of Environment, Forest and Climate Change (MoEFCC) under the Chairpersonship of Dr. Amita Prasad, Additional Secretary, MoEFCC and Chairperson, GEAC.

The list of the participants is annexed at Anenxure-1.

Agenda item No.1 : Leave of absence

The Committee granted leave of absence to Dr. Rene Borges and Dr. B. Sesikeran.

Agenda item No.2 : Confirmation of minutes of 128th meeting of the GEAC held on 04.03.2016

The Committee confirmed and accepted the Minutes of the 128th GEAC Meeting circulated to the Members on 08.03.2016

Agenda item No.3 : Action taken report on the decision taken in the 128th GEAC Meeting

The Committee agreed to convene the GEAC meetings once in every 60 days and suggested the secretariat to prepare a tentative schedule for convening the GEAC meetings for next 6 months.

Agenda Item No.4 : **Application related to environmental release**

4.1 Permission for environmental release of transgenic mustard hybrid DMH-11 and parental lines containing events bn 3.6 and modbs 2.99 developed using barnase, barstar and bar genes by M/s. CGMCP, University of Delhi.

The Committee discussed about the application of Centre for Genetic Manipulation and Crop Plants (CGMCP), University of Delhi for environmental release of transgenic mustard hybrid DMH-11 and parental lines containing events bn 3.6 and modbs 2.99 developed using barnase, barstar and bar genes.

The Members noted that the Sub-Committee constituted under the Chairmanship of Dr. K. Veluthambi met on two occasions and after 1st meeting requested CGMCP to address certain queries and to submit a revised dossier addressing queries of Sub-Committee. Subsequently, the Members were informed that a revised dossier has been received and the results obtained through RT-PCR needs to be analyzed by the Sub-Committee and for reviewing the same, the Sub-Committee has requested for an additional duration of one month so that, the Sub-Committee can submit its final recommendations to GEAC.

Further, GEAC has invited two groups of NGO's for presenting their views/ concerns regarding the release of GM mustard in India. Representatives from Consortium of Indian Farmers Association made a presentation to the Members of the Committee and requested for approving GM Mustard in India, as this technology confers additional yield of 30% and also saves huge money through import substitution and also benefit the farmers by providing additional income.

The other group of NGO's represented by Ms. Kavitha Kuruganti couldn't make a presentation due to paucity of time and it was noted that a special meeting as required at later convenient date tentatively during the third week of July 2016, may be convened to hear the concerns/ issues from that group of representatives.

Agenda Item 5 : Applications related to Confined Field Trials of GE crops (Event selection/ BRL-I/ BRL-II Trials)

5.1 Permission to conduct confined field trial for event selection on two transgenic Chickpea events (IPC2 and MP9) harbouring *cry1Ac* gene to study agro-phenological traits of insect resistant transgenic chickpea by ICAR-IIPR.

The application submitted by ICAR-Indian Institute of Pulses Research (IIPR) is deferred as additional data requested by RCGM has not been received. Subsequent to receipt of additional data by RCGM and its evaluation and feedback, the application would be considered by GEAC.

5.2 Request for Event Selection Trial of insect resistant transgenic pigeonpea events (IPC2 & SS5) harbouring *Bt* gene (*cry1Ac* or *cry1Aabc*) developed at ICAR-Indian Institute of Pulses Research, Kanpur

The application submitted by ICAR-Indian Institute of Pulses Research (IIPR) is deferred as additional data requested by RCGM has not been received. Subsequent to receipt of additional data by RCGM and its evaluation and feedback, the application would be considered by GEAC.

5.3 Permission to conduct BRL-2 trials on Glytol® cotton containing GHB 614 event in Central and North zone during 2016, based on the biosafety data generated during BRL-1 trials by Bayer Biosciences Pvt. Ltd.

The Committee noted that RCGM has reviewed the application and also prepared a Risk Assessment and Management Plan (RAMP). The Members opined that Biosafety support Unit (BSU) should also evaluate the Sub-Chronic and Acute Toxicity data generated by the applicant.

The Members deliberated on the issue related to Herbicide Tolerance with respect to stability of this trait and experiences of other countries also to be evaluated regarding issues related to Glyphosate resistance.

Members suggested that a formal communication may be sent from MoEFCC to Director General, ICAR for addressing the issue related to Glyphosate Resistance and suggest a strategy for addressing the same. Members also suggested Dr. S.S.Banga could prepare and submit to GEAC a concept note on recommended dosage of Glyphosate usage per crop/ year- and related issues for further follow up.

Members also suggested that information on potential risks involved in weeds becoming resistant to Glyphosate be also sought from developer. The GEAC approved the conduct of BRL-2 trials on Glytol® cotton containing GHB 614 event in Central and North zone during 2016 with prescribed SOPs.

5.4 Permission for hybrid seed production of wide Strike cotton hybrids during 2016-2017 by M/s Dow Agro Science Pvt. Ltd

The Committee after evaluation of the application submitted by M/s Dow Agro Science Pvt. Ltd accorded permission for hybrid seed production of wide Strike cotton hybrids during 2016-2017 subject to providing clarification by the company on the objective of hybrid seed production.

5.5 Permission to conduct confined field trial BRL-II of transgenic Maize (Zea Mays L) containing Event NK603 at North, Central and South zones by M/s Monsanto.

The Committee noted that RCGM has reviewed the application and also prepared a Risk Assessment and Management Plan (RAMP). The Committee after evaluation of the application submitted by M/s Monsanto Pvt. Ltd accorded permission for conduct of confined field trial of BRL-II of transgenic Maize (Zea Mays L) containing Event NK603 at North, Central and South zones subject to providing clarification on number of herbicide sprays that would be applied per year.

5.6 Permission to conduct second year Biosafety Research Level-I (BRL-I) trial with 2 transgenic maize (Zea mays L.) hybrids containing cry1F, cry1Ab and cp4EPSPSgenes (stacked events of TC1507 x MON 810 x NK 603 (DAS-01570-1 x MON-00810-6 x MON-00603-6) by M/s. Pioneer Hi-Breed Private Limited, Hyderabad.

The Committee after evaluation of the application submitted by Pioneer Hi-Breed Private Limited accorded permission for conduct of second year Biosafety Research Level-I (BRL-I) trial with 2 transgenic maize (Zea mays L.) hybrids containing cry1F, cry1Ab and cp4EPSPSgenes (stacked events of TC1507 x MON 810 x NK 603 (DAS-01570-1 x MON-00810-6 x MON-00603-6) subject to providing clarification on number of herbicide sprays that would be applied per year.

5.7 Permission to conduct event selection trials on marker free transgenic rice (Oryza sativa) on events namely:W1-MF-001 to W1-MF-007; W2-MF-001 to W2-MF-024; 01-MF-001 to 01-MF-011; N1-MF-001 to N1-MF-007; N3-MF-001 to N3-MF-006; N4-MF-001 to N4-MF-008; Y1-MF-001 to Y1-MF-005 carrying genes for abiotic stress tolerance namely drought & salinity and nutrition stress by M/s. Bioseed Research India Pvt. Ltd., Hyderabad

The Committee after evaluation of the application submitted by M/s. Bioseed Research India Pvt. Ltd accorded permission for conduct of event selection trials on marker free transgenic rice (Oryza sativa) on events namely:W1-MF-001 to W1-MF-007; W2-MF-001 to W2-MF-024; 01-MF-001 to 01-MF-011; N1-MF-001 to N1-MF-007; N3-MF-001 to N3-MF-006; N4-MF-001 to N4-MF-008; Y1-MF-001 to Y1-MF-005 carrying genes for abiotic stress tolerance namely drought & salinity and nutrition stress at company's own research farm at Rangareddy/ Hyderabad of Telangana State.

5.8 Permission to conduct event selection trails on transgenic Sugarcane (Saccharum spp.) containing eighteen events namely Co 86032 (DREB2-3, DREB 2-13, DREB 2-14, DREB 2-15, DREB 2-24, HSP70-6, HSP70-8, HSP70-9, HSP70-10, HSP70-22, DREB2+PDH45-2, DREB2+PDH45-3, DREB2+PDH45-4, DREB2+PDH45-5, PDH45-2, PDH45-10, PDH45-20, PDH45-23) at own site by Sugarcane Research Institute, U.P Council of Sugarcane Research (UPCSUR), Shahjahanpur

The application submitted by Sugarcane Research Institute is deferred as additional data requested by RCGM has not been received yet. Subsequent to receipt of additional data by RCGM and its evaluation and feedback, the application would be considered by GEAC

5.9 Permission to conduct confined field trial (Event Selection) in 31 transgenic Rice events expressing cry2Aa2 along with 1 non-transgenic counterpart at company own farm M/s Rasi Seeds Research Farm, Masaipet, Medak Dist, Telangana.

The Committee noted that RCGM has reviewed the application and also prepared a Risk Assessment and Management Plan (RAMP). The Committee after evaluation of the application submitted by Rasi Seeds Research Farm accorded permission for conduct of confined field trial (Event Selection) in 31 transgenic Rice events expressing cryAa2 along with 1 non-transgenic counterpart at company own farm at Masaipet, Medak Dist, Telangana.

6.0 Agenda Item 6: Application related to Export /Import

6.1 Permission for import of Dried Distillers Grains with soluble (DDGS)-Corn from USA by M/s Godrej Agrovet Ltd.

The Committee suggested forwarding the application to RCGM / BSU for its evaluation and feedback. Based on evaluation by RCGM and upon submission of Risk Assessment and Management Plan, the application would be further considered by GEAC. Committee suggested seeking comments also from Department of Animal Husbandry and Dairying (DAH&D), Ministry of Agriculture and Food Safety and Standards Authority of India (FSSAI)

6.2 Permission for Import of GM Soya bean Meal by M/s Sugna Foods.

The Committee suggested forwarding the application to RCGM / BSU for its evaluation and feedback. Based on evaluation by RCGM and upon submission of Risk Assessment and Management Plan, the application would be further considered by GEAC. Committee suggested seeking comments also from Department of Animal Husbandry and Dairying (DAH &D), Ministry of Agriculture and Food Safety and Standards Authority of India (FSSAI)

6.3 Permission for import of DDGS made from GM corn from USA by M/s Baramati agro.

The Committee suggested forwarding the application to RCGM / BSU for its evaluation and feedback. Based on evaluation by RCGM and upon submission of Risk Assessment and Management Plan, the application would be further considered by GEAC. Committee suggested seeking comments also from Department of Animal Husbandry and Dairying (DAH &D), Ministry of Agriculture and Food Safety and Standards Authority of India (FSSAI)

6.4 Permission for import of DDGS made from GM corn from USA by M/s Anmol Feeds Pvt Ltd.

The Committee suggested forwarding the application to RCGM / BSU for its evaluation and feedback. Based on evaluation by RCGM and upon submission of Risk Assessment and Management Plan, the application would be further considered by GEAC. Committee suggested seeking comments also from Department of Animal Husbandry and Dairying (DAH &D), Ministry of Agriculture and Food Safety and Standards Authority of India (FSSAI)

6.5 Permission for import of DDGS made from GM corn from USA by M/s Shanthi Feeds Pvt. Ltd.

The Committee suggested forwarding the application to RCGM / BSU for its evaluation and feedback. Based on evaluation by RCGM and upon submission of Risk Assessment and Management Plan, the application would be further considered by GEAC. Committee suggested seeking comments also from Department of Animal Husbandry and Dairying (DAH &D), Ministry of Agriculture and Food Safety and Standards Authority of India (FSSAI)

6.6 Permission for import of High Oleic Soy oil:- Plenish™ stack genes DP-3Ø5423-1xMONØ4Ø32-6 from USA by M/s Pioneer Hi-Breed Private Limited, Gurgaon

The Committee reviewed the application submitted by M/s Pioneer Hi-Breed Private Limited for import of High Oleic Soy oil:- Plenish™. The Members opined that company may be suggested to get its sample tested with regard to presence of any transgene-encoded protein or transgene DNA in the sample (through use of living modified organism [LMOs]) while processing of high Oleic Soy Oil.

The Committee suggested getting the sample analyzed from any of the following laboratories equipped for testing of GM samples namely:

- I. ICAR-National Bureau of Plant Genetic Resources, New Delhi
- II. Punjab Biotechnology Incubator, Mohali
- III. Export Inspection Agency-Kochi
- IV. DNA Fingerprinting and Transgenic Crop Monitoring Lab, Hyderabad

7.0 Implementation of RTI Order dated 1.4.2016 regarding making public Biosafety Dossiers related to GM mustard and other crops.

The Committee suggested writing to Central Information Commission (CIC) for seeking additional time period of 90 days for taking a decision of making public biosafety dossier document related to GM Mustard.

The Committee suggested that this extension sought from CIC is due to Sub-Committee's requirement of additional duration for evaluation of revised dossier submitted by CGMCP on GM Mustard.

The Committee suggested MoEFCC to make a formal request to CIC seeking additional extension of 90 days for implementation of RTI order dated 01.04.2016 regarding making public biosafety dossier related to GM Mustard.

8.0 Any other item with the permission of Chair.

The Committee discussed issue regarding the No Objection Certificate (NOC) to be issued by State Governments. The Committee opined that adequate information should be provided to State Governments and a clause may also be imposed that decision regarding NOC to be communicated to applicant within 90 days from the date of application and if in the mean

time State Governments doesn't take any appropriate action, the decision should be considered positive by the applicant.

The Committee also suggested that if certain trial sites be notified as GM field testing sites, the issue of NOC could be addressed to a large extent. Members were informed that several meetings and discussions are being convened under the overall guidance of Department of Biotechnology for addressing issues related to NOC for conduct of confined field trials.

The Committee also opined that initiatives for imparting training to State level officers from Department of Agriculture and Scientists/ Staff from State Agricultural Universities be planned and organized by MoEFCC for sensitizing about the regulatory process for conduct of confined field trails as well as on issues related to biosafety and enforcement mechanisms for preventing of illegal seed production as well as for detection of spurious samples through advanced LMO/ GMO testing methods so that they can play a better role in monitoring and also take a informed decision about conduct of confined field trials.

The Committee agreed to engage Dr. Ranjini Warriar, Former Adviser, MoEFCC as an Expert Member for participation in the GEAC meetings in view of her vast experience and expertise in the subject as well as her past association as Member Secretary and Vice-Chair of GEAC for several years.

The meeting ended with a Vote of Thanks to the Chair.
