MINUTES OF THE 156TH MEETING OF GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 14.07.2025

The 156th meeting of the Genetic Engineering Appraisal Committee (GEAC) of the Ministry of Environment, Forest and Climate Change (MoEF&CC) was held on 14.07.2025 in hybrid mode at Sutlej Hall, Ground Floor, Jal Block, Indira Paryavaran Bhawan, New Delhi. The meeting was chaired by Shri Amandeep Garg, Additional Secretary, MoEF&CC, Chairperson GEAC. The list of participants is placed at **Annexure 1**.

At the outset, Chairperson, GEAC welcomed all the members. Member Secretary was requested to begin the discussion on agenda items.

Action: GEAC Secretariat

Agenda Item No. 1: Leave of absence

Members, Dr. H. K. Sharma, and Dr. Rekha S. Singhal, communicated their inability to attend the 156th meeting of GEAC. Further, Ms. Shruti Singh, Dr. Vinay K. Nandicoori, Dr. Geeta Jotwani, Dr. J. P. Shukla, Dr. Sanjeev Khosla, Dr. Triveni Dutt, and Dr. P. Suprasanna did not attend the meeting.

Decision:
Absence of members who could not attend the meeting was noted.

Action: GEAC Secretariat

Agenda Item No. 2: Confirmation of minutes of the 155th GEAC meeting

Minutes of the 155th GEAC meeting were circulated to all the members for comments and minutes were suitably amended to incorporate the comments received from the members.

Decision:
Members confirmed the minutes of the 155th GEAC meeting.

Action: GEAC Secretariat

Agenda Item No. 3: Action taken report on the decisions taken in the 155th GEAC meeting

Member Secretary, GEAC briefed about the action taken on the decisions at the 155th meeting of GEAC. The committee was informed that letters communicating GEAC decisions had been issued to applicants as required.

Decision:

The Committee noted the actions taken by the Secretariat.

Action: GEAC Secretariat

Agenda Item No. 4: Applications related to Confined Field Trials of GE crops (Event Selection/ BRL-I/ BRL-II Trials)

4.1 M/s Ajeet Seeds Pvt. Ltd., Aurangabad to conduct Event Selection Trial (EST) under confined field conditions of four stacked GE cotton (*Gossypium hirsutum*) lines *viz.*, ASCOT-I02xASCOT-201, ASCOT-I02xASCOT-205, ASCOT-I05xASCOT-201 and ASCOT-I05xASCOT-205 expressing *cry2Aa* and modified *cry1Ac* (ISRD1508) genes for protection against Pink bollworm (*Pectinophora gossypiella*), American bollworm (*Helicoverpa armigera*) and other Lepidopteran pests of cotton during *Kharif* 2025.

Committee was informed that applicant intends to conduct EST under confined field conditions of four stacked GE cotton (*Gossypium hirsutum*) lines *viz.*, ASCOT-I02xASCOT-201, ASCOT-I02xASCOT-205, ASCOT-I05xASCOT-201 and ASCOT-I05xASCOT-205 expressing *cry2Aa* and modified *cry1Ac* (ISRD1508) genes for protection against Pink bollworm (*Pectinophora gossypiella*), American bollworm (*Helicoverpa armigera*) and other Lepidopteran pests of cotton during *Kharif* 2025 at own trial site location of Ajeet Seeds Pvt. Ltd., Hanumantgaon Farm (HF), Aurangabad, Maharashtra.

The application was considered by RCGM in its 308th meeting held on 16.04.2025. RCGM via email dated 06.06.2025 have sent the recommendations of its 308th meeting and recommended to GEAC for further consideration. Further, RCGM via email dated 09.06.2025 sent the Form D3 of the concerned application.

Recommendation

Based on the recommendation of 308th RCGM, the proposal of M/s Ajeet Seeds Pvt. Ltd, Aurangabad to conduct event selection trial under confined field conditions of four stacked GE cotton (*Gossypium hirsutum*) lines *viz.*, ASCOT-I02xASCOT-201, ASCOT-I02xASCOT-205, ASCOT-I05xASCOT-201 and ASCOT-I05xASCOT-205 expressing *cry2Aa* and modified *cry1Ac* (ISRD1508) genes for protection against Pink bollworm (*Pectinophora gossypiella*), American bollworm (*Helicoverpa armigera*) and other Lepidopteran pests of cotton at own trial site location of Ajeet Seeds Pvt. Ltd., Hanumantgaon Farm (HF), Aurangabad, Maharashtra during *Kharif* 2025 was recommended by the Committee.

The recommendation is subject to following conditions:

i. Applicant shall perform the trials as per extant rules/guidelines/regulations and adhere with the recommendations of 308th RCGM Meeting, recommendations and/or conditions stated in RCGM Letter dated 05.06.2025. Further, the trials should be conducted at insect specific hotspot in the trial sites that are appropriate to evaluate the introduced insect resistant trait in the GE plant.
ii. The applicant shall share details of the trial site as required under part G of the Guidelines and SOPs for Confined Field Trials of regulated GE plants, 2008 including ownership of trial site.
iii. The applicant shall share information regarding confirmed availability of isolation distance, land use and its ownership, before start of the trial.
iv. The applicant shall share information regarding name of the trial-in charge/lead scientist responsible for each trial, as well as expected date of sowing, before start of the trial.

RCGM may issue the permit letters and monitor confined field trials to ensure compliance of prescribed terms and conditions. The permit letter shall mention regarding constitution and objective of Central Compliance Committee, as well as participation of State Government representative therein. The permit letter, for confined field trial site, to be issued under intimation to the concerned State Government.

Action: GEAC & RCGM Secretariat

4.2 M/s Ankur Seeds Private Limited, Nagpur, Maharashtra to conduct Biosafety Research Level-I (BRL-I) 1st year trial of two GE cotton hybrids containing Event NBRI-PGK-519 expressing m*cy1EC* and two GE cotton breeding stack hybrids containing Event NBRI-PGK-519xMON15985 expressing m*cry1EC*, *cry1Ac* and *cry2Ab* genes for resistance against Pink bollworm (*Pectinophora gossypiella*), American bollworm (*Helicoverpa armigera*) and Spotted bollworm (*Earias sp.*) during *Kharif* 2025.

Committee was informed that applicant intends to conduct Biosafety Research Level-I (BRL-I) 1st year trial of two GE cotton hybrids containing Event NBRI-PGK-519 expressing *mcry1EC* and two GE cotton breeding stack hybrids containing Event NBRI-PGK-519xMON15985 expressing *mcry1EC*, *cry1Ac* and *cry2Ab* genes for resistance against Pink bollworm (*Pectinophora gossypiella*), American bollworm (*Helicoverpa armigera*) and Spotted bollworm (*Earias sp.)* on company's long leased land during Kharif 2025 at following six trial sites;

i. Khargone, Madhya Pradesh
ii. Dharwad, Karnataka
iii. Guntur, Andhra Pradesh

iv. Jalgaon, Maharashtra
v. Buldana, Maharashtra
vi. Nagpur, Maharashtra

The application was considered by RCGM in its 311th meeting held on 28.05.2025. RCGM vide email dated 16.06.2025 have sent the recommendations of its 311th meeting and recommended to GEAC for further consideration.

The applicant vide email 01.07.2025 has submitted NOC dated 01.07.2025 from Madhya Pradesh and vide email dated 07.07.2025 have submitted NOC dated 05.07.2025 from Andhra Pradesh.

Recommendation

Committee deliberated on the recommendation of 311th meeting of RCGM and NOC received from Govt. of Madhya Pradesh and Andhra Pradesh and recommended the proposal of M/s Ankur Seeds Private Limited, Nagpur, Maharashtra to conduct Biosafety Research Level-I (BRL-I) 1st year trial of two GE cotton hybrids containing Event NBRI-PGK-519 expressing m*cy1EC* and two GE cotton breeding stack hybrids containing Event NBRI-PGK-519xMON15985 expressing m*cry1EC*, *cry1Ac* and *cry2Ab* genes for resistance against Pink bollworm (*Pectinophora gossypiella*), American bollworm (*Helicoverpa armigera*) and Spotted bollworm (*Earias sp.*) during *Kharif* 2025 at below mentioned sites:

i. Khargone, Madhya Pradesh
ii. Guntur, Andhra Pradesh

The recommendation is subject to following conditions:

i. The applicant shall adhere to the conditions of RCGM letter dated 16.06.2025.
ii. The applicant shall adhere with the conditions and/or recommendations mentioned in concurrence obtained from Government of Madhya Pradesh vide Letter dated 01.07.2025; and Government of Andhra Pradesh vide Letter dated 05.07.2025.
iii. The BRL-I confined field trials should be conducted at insect specific hotspot in the trial sites that are appropriate to evaluate the introduced insect resistant trait in the GE plant.
iv. The applicant shall share details of the trial site as required under part G of the Guidelines and SOPs for Confined Field Trials of regulated GE plants, 2008 including ownership of trial site.
v. The applicant shall share information regarding confirmed availability of isolation distance, land use and its ownership, before start of the trial.

vi. The applicant shall share information regarding name of the trial-in charge/lead scientist responsible for each trial, as well as expected date of sowing, before start of the trial.

vii. Upon successful completion of intended BRL-I 1st year confined field trials, the findings/ report of these BRL-I trials should be reviewed by RCGM in consonance with the findings/ report of Event Selection Trials under confined field conditions. Accordingly, the furtherance, if any, of these BRL-I confined field trials should be taken into consideration by RCGM.

RCGM may issue the permit letters and monitor confined field trials to ensure compliance of prescribed terms and conditions. The permit letter shall also mention constitution and objective of Central Compliance Committee, as well as participation of State Government(s) representative therein. The permit letter, for every confined field trial site, to be issued under intimation to the concerned State Government.

Action: GEAC & RCGM Secretariat

Agenda Item No. 5: Applications related to Import/ Export

5.1 M/s Zoetis India Limited, Mumbai for import and marketing of recombinant veterinary vaccine Poulvac Procerta HVT-IBD.

The application submitted by M/s Zoetis India Limited, Mumbai for import and marketing of Bursal Disease-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector (Brand Name: POULVAC PROCERTA HVT-IBD) was initially considered in the 142nd meeting of GEAC held on 11.05.2021 under Agenda item 5.3 wherein the Committee recommended the proposal for import subject to following conditions:

i. *initial 3 batches of the subject vaccine to be certified in ICAR-Indian Veterinary Research Institute (ICAR-IVRI)*

ii. *obtain relevant approvals from Department of Animal Husbandry and Dairying, Drug Controller General of India etc. as per existing Indian laws applicable for import of vaccines.*

iii. *The final data certified by IVRI to be presented before the GEAC for final approval, before it is marketed in the country.*

In accordance with the stipulated conditions, applicant submitted the ICAR-IVRI certified test batch reports, and the NOC received from DAHD which was considered in 152nd GEAC meeting held on 29.07.2024 under Agenda item 6.2 committee wherein the committee recommended the applicant "*to get the metagenomics analysis of the subject vaccine certified by Gujarat Biotechnology Research Centre (GBRC), Gujarat for verification of purity of the target event/organisms and to check the presence of non-target event/organisms. The final data certified by GBRC to be*

presented before the GEAC for final approval, before the subject vaccine is marketed in the country."

Presently the applicant vide GEAC application dated 24.03.2025 has submitted the Metagenomics Analysis Report certified by GBRC.

Email dated 05.05.2025 sent to applicant regarding queries from GEAC Secretariat. Applicant vide email dated 13.06.2025 have informed that the quantity of import per annum is 20,000 vials.

The applicant intends to import from USA and use in India for vaccination of healthy chickens as an aid in preventing infectious bursal disease and Marek's disease. It has been recommended for subcutaneous injection of one-day-old chickens or in ovo vaccination of 18-to 19-day-old embryonated chicken eggs.

The metagenomics analysis report identified the expected target viruses Meleagrid herpesvirus (HVT), Newcastle disease virus (NDV) and VP2 gene of Infectious bursal disease virus (IBDV) from the vaccine samples, along with the expected Gallus *gallus* host genome, confirming the presence of HVT, NDV and IBDV in the RNA and DNA libraries. Notably a presence of *Cutibacterium spp., Malassezia osloensis, Micrococcus* spp., were detected in the vaccine in minimal proportions i.e., ≤ 0.01 percent.

During the meeting, divergent views were expressed by committee members on the benefits of Metagenomic Analysis for import of vaccines. GEAC also felt that there is a need for expert opinion on acceptable NTOs and their acceptable threshold limits.

Recommendation

After due deliberations on the GBRC certified Metagenomic analysis report, the Committee was of the view that the comments may be solicited from Animal Husbandry Commissioner, DAHD; ICAR - Indian Veterinary Research Institute (IVRI), Bareilly; ICAR - National Institute of Veterinary Epidemiology and Disease Informatics (NIVEDI), Bengaluru; and ICMR-National Institute of Virology (NIV), Pune in respect of following:

i. The prevalence in India of the Non-Target Organisms (NTOs) detected in the subject veterinary recombinant vaccine (i.e. POULVAC PROCERTA HVT-IBD), as per Metagenomic analysis report certified by GBRC, with a view to identify if the NTOs detected are novel or are prevalent in the country.
ii. In case the NTOs detected in the vaccines are prevalent or not, in India, the probable risks that identified NTOs can pose in Indian context.
iii. The threshold/ permissible level of presence of Non-Target Organisms, which can be permitted in the veterinary vaccines being imported in India.

Further, the Committee recommended that the RCGM may examine the aspects of Metagenomic Analysis for imports of recombinant veterinary vaccines, including the identification of acceptable non-target organisms (NTOs) and their threshold limits, and provide appropriate recommendations in this regard.

Action: GEAC Secretariat

Agenda Item No. 6 : Additional Items for consideration

6.1 Review status of the preparation of guidelines for import of GM animal feed including DDGS

Distiller's Dried Grains with Solubles (DDGS) is a co-product of grain-based ethanol production, primarily using maize, sorghum, or rice, with yeast strains (*Saccharomyces cerevisiae*) and enzymes like glucoamylases to convert starch into ethanol. It is rich in protein and energy, making it a valuable feed ingredient for cattle, swine, poultry, and aquaculture. Globally, it is widely used for enhances animal health, performance, and food product quality which create strong demand in the feed industry. To improve yield and DDGS quality, producers are using genetically modified (GM) crops and yeast. So, DDGS produced using genetically modified crops and yeast are categorized as GM feed.

Since DDGS is derived from GM crops and yeast, a safety assessment is needed to ensure it does not pose risks to animal health, human food safety through the consumption of animal products, or the environment, and to confirm its nutritional equivalence to conventional DDGS. So, regulating the DDGS derived from GM crops and yeast gains priority during import and marketing in India.

The Committee was informed that, at present, two kinds of applications are pending or expected for consideration by GEAC in coming days

i. Applications for import of DDGS using GM substrates and/or GM yeast, and
ii. Applications related to DDGS produced in India using GM substrates and/or GM yeast**.**

With increasing number of applications related to import of DDGS made from GM corn from USA, GEAC in its 131st meeting dated 13.01.2017, recommended to constitute a sub-committee to prepare draft guideline with a prescribed application form under the chairmanship of Prof. K. Veluthambi, Co-chair, GEAC. In 134th meeting dated 21.03.2018, GEAC accepted the draft guidelines on DDGS prepared by sub-committee.

On 25.07.2018, GEAC received an application seeking permission for import of horse feed containing GM soybean.

After detailed deliberations the members felt that it would not be appropriate to have different forms for different products of animal feed. It was agreed to have a uniform proforma and procedure for dealing with applications related to import of animal feed including DDGS. Accordingly, the Committee reiterated their decision made under Agenda Item No. 6.1 to constitute a Sub-committee under the Chairpersonship of Dr. Lalitha Gowda, Former Chief Scientist, CFTRI and Member, GEAC.

In 138th GEAC meeting dated 11.11.2019, the sub-committee shared the below mentioned draft documents. GEAC sought comments inputs from all the members on the draft guidelines for further consideration.

i. Procedures for handling applications on import of animal feed containing or derived from genetically modified organisms (GMOs)/ living modified organisms (LMOs)
ii. Application Form
iii. Production, processes, uses and safety of Dried Distillers Grains with Solubles (DDGS) for animal feed.

Dr. Lalitha Gowda, Chairperson, Sub-Committee, Former Chief Scientist, CFTRI and Member, GEAC presented the recommendations of the sub-committee before GEAC. After detailed deliberation, considering that the sub-committee constituted earlier under the chairpersonship of Dr. Lalitha Gowda had prepared the initial draft documents related to the import of animal feed containing or derived from GMOs/LMOs, including DDGS, several years ago, the Committee recognized the need for updating of these documents in the light of subsequent scientific advances and extant regulatory framework.

Recommendation

The Committee recommended that the sub-committee to update the previously prepared draft documents so as to incorporate subsequent scientific advances and changes in extant regulatory framework.

Action: GEAC Secretariat

Annexure 1

List of Participants

Members who participated			
1.	**Shri Amandeep Garg** Additional Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jorbagh road, Aliganj, New Delhi- 110003	**8.**	**Dr. D.K. Yadav** DDG, (Crop Science) Indian Council of Agricultural Research, Krishi Bhawan, New Delhi-110001
2.	**Dr. Nitin K. Jain** Scientist–G and Member Secretary RCGM, Department of Biotechnology, C.G.O Complex, Lodhi Road, New Delhi-110003	**9.**	**Dr. P.K. Dass** Department of Anatomy, LHMC & A ssociated Hospitals, New Delhi- 110001
3.	**Sh. Raghu Kumar Kodali** Scientist G, MoEFCC MoEFCC, Indira Paryavaran Bhawan, Jorbagh road, Aliganj, New Delhi- 110003	**10.**	**Dr. J.P. Singh** Plant Protection Adviser (PPA), Directorate of Plant Protection, Quarantine & Storage, NH IV, Faridabad-121001, New Delhi
4.	**Dr. Satish Wate** Former Director, CSIR-National E nvironmental Engineering Resear ch Institute, Nagpur- 440020	**11.**	**Shri V.P. Yadav** Scientist F, Central Pollution Control Board, Parivesh Bhawan, East Arjun Nagar, Delhi-110 032
5.	**Dr. Dinkar M. Salunkhe** Director, International Centre for Genetic Engineering and Biotechnology, New Delhi-110067	**12.**	**Dr. Rubina Bose** Deputy Drugs Controller, Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, FDA Bhavan, ITO, Kotla Road, New Delhi -110002 (Representative of Drugs Controller General of India)
6.	**Dr. U. S. N. Murthy** Director, National Institute of Pharmaceutic al Education and Research, Guwahati- 781101	**13.**	**Dr. Alka Rao** Advisor (Science & Standards & Reg ulation), FSSAI
7.	**Dr. Chaitanya Joshi** Director, Gujarat Biotechnology Research Centre, Gandhinagar, Gujarat- 382 011	**14.**	**Dr. Abhilasha Singh Mathuriya** Member Secretary, Scientist D, CS-III Division, Ministry of Environment, Forest and Climate Change, Jorbagh, New Delhi-110003
Officer from the Ministry			

1.	**Ms. Jaspreet Kaur** Deputy Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jorbhagh road, Aliganj, New Delhi – 110003

Special Invitee	
1.	**Dr. Lalita R. Gowda** Former Chief Scientist, CSIR-Central Food Technology Research Institute (CFTRI), Mysore

Members who did not participate			
1.	**Dr. H. K. Sharma** Director, National Institute of Technology, Agartala, Tripura- 799 046	**6.**	**Ms. Shruti Singh** Joint Secretary, IPR, Department for Promotion of Industry and Internal Trade, Udyog Bhawan, New Delhi 110011
2.	**Dr. Vinay K. Nandicoori** Director, CSIR-Centre for Cellular & Molecular Biology, Hyderabad - 500 007	**7.**	**Dr. Geeta Jotwani** Scientist G, Indian Council of Medical Research (ICMR), Ministry of Health and Family Welfare, Ramalingaswami Bhavan, Ansari Nagar, New Delhi—110 029
3.	**Dr. J. P. Shukla** Scientist, CSIR-Advanced Materials and Process Research Institute, Bhopal- 462 026	**8.**	**Dr. Sanjeev Khosla** Director, CSIR- Institute of Microbial Technology, Chandigarh- 160 036
4.	**Dr. Rekha S. Singhal** Professor, Food Technology, Institute of Chemical Technology, Mumbai- 400 019	**9.**	**Dr. Triveni Dutt** Director, ICAR-Indian Veterinary Research Institute, Bareilly (UP) - 243122
5.	**Dr. P. Suprasanna** Scientific Officer H (Retd.), Biosciences group, BARC, Mumbai-400 085		

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