MINUTES OF THE 158TH MEETING OF GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 18.12.2025

The 158th meeting of the Genetic Engineering Appraisal Committee (GEAC) of the Ministry of Environment, Forest and Climate Change (MoEF&CC) was held on 18.12.2025 in hybrid mode at Sutlej Hall, Ground floor, Jal Block, Indira Paryavaran Bhawan, New Delhi.

Owing to the unavailability of the Chairperson, GEAC, the Chairperson requested the Co-Chairperson to chair the meeting, which was consented to. Accordingly, the meeting was chaired by Dr. Nitin K. Jain, Scientist–G, Department of Biotechnology (DBT), Co-Chairperson, GEAC. The list of participants is placed at Annexure 1.

At the outset, Co-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

MembersDr. U. S. N. Murthy, Dr.Rekha S. Singhal, Dr. D.K. Yadav, Dr. P.K. Dass and Dr.Alka Rao communicated their inability to attend the 158th meeting of GEAC. Further, Shri Amandeep Garg, Dr. Vinay K. Nandicoori,Dr. J. P. Shukla, Dr. P. Suprasanna, Ms. Shruti Singh, Dr.GeetaJotwani, Dr. Sanjeev Khosla, and Shri V.P. Yadav 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 157th GEAC meeting

Minutes of the 157th 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 157th GEAC meeting.

Action: GEAC Secretariat

Agenda Item No. 3: Action taken report on the decisions taken in the 157th GEAC meeting

Member Secretary, GEAC briefed about the action taken on the decisions at the 157th meeting of GEAC. The committee was informed that letters communicating GEAC decisions had been issued to applicants, and all other concerned 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 Bayer Crop Science Limited, Gurugram, Haryana for conduct of BRL-II confined field trials of herbicide tolerant transgenic maize (*Zea mays L.*) Event NK603 containing *cp4epsps* gene

The committee was informed that the proposal submitted by M/s Bayer Crop Science Limited, Gurugram, Haryana to conduct BRL-II confined field trials of herbicide tolerant transgenic maize (Event NK603) carrying *cp4epsps* gene was previously considered by GEAC in its 155th meeting held on 09.06.2025 wherein committee recommended the proposal subject to conditions at PAU, Ludhiana for the *Kharif* season 2025. Accordingly, GEAC secretariat issued permit letter dated 26.06.2025.

Applicant vide email dated 03.07.2025 submitted NOC dated 19.06.2025 issued by Government of Haryana and sought permission for conduct of BRL-II at Haryana.

Taking cognizance of interim procedures adopted in 154th GEAC meeting under Agenda Item 8.1, decisions taken by GEAC in its 155th meeting and concurrence received from Government of Haryana, GEAC secretariat issued permit letter dated 29.09.2025 for conduct of BRL-II trials at CCS, Haryana Agricultural University (HAU) Hisar/Regional Research Station Karnal during the *Kharif* season 2025 subject to conditions as stipulated in the 155th GEAC under Agenda item No. 4.1. Further, in the 157th GEAC held on 10.10.2025, the committee was informed about the action taken by GEAC Secretariat.

Applicant vide email dated 10.10.2025 submitted the NOC dated 08.10.2025 issued by Government of Karnataka and sought permission for conduct BRL-II trials during the *Rabi* 2025-26 season at UAS, Dharwad, Karnataka.

Recommendations

After due deliberations on the proposal, and taking cognizance of the concurrence received from Government of Karnataka, the Committee

recommended the proposal of M/s Bayer Crop Science Limited, Gurugram, Haryana for conduct of BRL-II Confined Field Trials of herbicide tolerant transgenic maize Event NK603 containing *cp4epsps* gene at University of Agricultural Sciences (UAS), Dharwad, Karnataka, during the *Rabi* season 2025–26 to/for:

i. Study the weed control efficacy of herbicide tolerant maize hybrids (Event NK603) with application of Glyphosate K salt.
ii. Monitor occurrence of beneficial insects and insect pests on transgenic maize hybrids and their non-transgenic counterparts and checks.
iii. Comparative assessment of soil ecosystem, weediness, morphology & phenotypic characters of transgenic corn and its conventional counterpart hybrids.
iv. Study the level of expression of candidate proteins expressed by the inserted genes in plant tissues at regular intervals during the growing season / trial period at selected locations.
v. Comparison of agronomic benefits of transgenic corn vis avis their non-transgenic counterparts.

The approval is subject to following conditions:

1) The applicant shall adhere with the conditions and/or recommendations mentioned in concurrence obtained from Government of Karnataka vide letter dated 08.10.2025.
2) The applicant shall prepare a comprehensive Risk Assessment and Risk Management (RARM) Plan and submit the same to the GEAC prior to the sowing, along with all earlier RCGMapproved RARM plans, copies of approved test protocols, and relevant regulatory approvals.
3) The trials are to be conducted as per the Guidelines 2008, the Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017 and Revised Guidelines for Research in transgenic plants, guidelines for confined field trials and other food and feed safety assessment of GE crops adopted by of the Government of India from time to time and available at https://ibkp.dbtindia.gov.in/Content/Rules.
4) The applicant shall conduct detailed safety assessment studies for generation of data as per the regulatory requirements given in Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016; Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2008; Protocol for Food and Feed Safety Assessment of GE crops, 2008; Guidelines for the conduct of confined field trials of regulated, GE plants in India, 2008; and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, GE Plants, 2008.
5) The applicant shall share information regarding name of the trial-in-charge/lead scientist responsible for conduct of trial before start of the trial.
6) The applicant shall provide complete information and detailed map of the

confined field trial site as per the "Guidelines for the conduct of confined field trials of regulated, GE plants in India, 2008 and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, GE Plants, 2008" (collectively referred as Guidelines 2008) to the Member-Secretary, GEAC/ RCGM/ State Department of Agriculture/ State Agriculture Universities/ District Authorities and other field functionaries preferably 7 working days before sowing/planting and positively within 7 working days after sowing/planting on the trial site.

The following items shall be included on each map of a field trial site:

i. Trial-in-Charge's name and contact details
ii. Permit number from the regulatory authority
iii. Legal or descriptive land location (name of the village, taluka, district, state or university)
iv. Accurate distances to physical landmarks or surrounding landmarks such as telephone poles, fences, alleys, roads, or steel poles.
v. Total area planted with the regulated material, including negative controls and any border or guard rows when used (hectares or square meters)
vi. Label all fields within the isolation area by the common name of the crop
vii. Indicate any fields of the same/related crops that fall within, or border on, the isolation area
viii. Include any natural ecosystems adjacent to the trial site (natural habitats, waterways, gardens, orchards, forests, woodlots, and hedgerows), wherever reasonable
ix. Planting date
x. Compass directions, with North at the top of the page

7) The applicant shall ensure that genetically engineered seed and/or plant material for planting is transported in clearly identified, secure containers and kept separate from other seed and/or plant material. All packing material, shipping containers, and any other material accompanying the genetically engineered plant material shall be treated or disposed of in such a manner so as to prevent the dissemination and establishment of this material or any progeny plants.
8) The applicant shall insure that a signboard at the trial site with the above information, along with the field trial layout, must be erected till post-harvest land use restriction has been completed.
9) Trial Protocol: While conducting the BRL-II trials under confined field condition, the applicant/trial-in-charge are directed to follow the trial specifications as detailed below:

    i. The BRL-II trial under confined field conditions shall be conducted with herbicide tolerant transgenic maize Event NK603 containing *cp4epsps* gene along with its conventional counterpart at UAS,

Dharwad, Karnataka.

ii. The applicant is advised to submit the following to GEAC positively within 7 days after sowing/planting on the trial site;

   a. GPS coordinates of each trial site location
   b. List of hybrids for each trial location
   c. Treatments included in the field trial, and
   d. Trial site map

iii. Appropriate national and local checks, and spacing are to be included for comparison of the efficacy of the genes in terms of productivity of the genetically engineered maize lines, germination, weediness, aggressiveness and other parameters.

iv. Trial must be conducted with triplicate replication at the proposed trial location to ensure generation of robust and scientifically/ statistically valid data.

10) Trial size and reproductive Isolation:

i. The experimental area should not be more than 2.5 acre per trial location.

ii. The applicant/trial-in-charge shall further plant a minimum of 10 meters (containing at least five trapper rows) of non-transgenic maize variety(ies)/hybrid(s) counterpart(s) around the periphery of the outer transgenic maize plant rows all around the plot. It is to be ensured that the maize plants in the border rows flower concurrently with the plants in the confined field trial. If any of the trial plants flower before the onset of flowering of pollen trap row plants, or if any of the trial plants have not completed flowering after the pollen trap row plants have completed this stage, a breach of border row isolation will have occurred. All plants within the border row area must be disposed of in the same manner as the regulated trial plants. The border row area will be subject to the same conditions of post-harvest land use restriction and monitoring as the trial site proper.

iii. To prevent the establishment and spread of regulated GE plants within the environment, the regulated GE plants within a confined field trial must be reproductively isolated from sexually compatible plant species in proximity to the trial site. An isolation distance of 200 meters from the periphery of the nearest row of GE maize would be maintained all around the experimental plot. The applicant/trial-in-charge would not plant any sexually compatible or prohibited plant within 200 meters of isolation distance. It is to be ensured that the conditions for reproductive isolation of all trial plants are met during both the current growing season and the post-harvest restriction period of the next growing season(s) as per

the Guidelines 2008.

iv. If additional confined field trial(s) conducted concurrently at the trial location, the minimum isolation distance prescribed for the crop must be maintained from the periphery of the outer border row plants all around the trial site of each nearby confined field trial.

v. Any progeny plant that arises on the trial site after completion of the trial must be eliminated and disposed as per the Guidelines 2008.

vi. The applicant should take precautionary steps to avoid the possibility of spread of seeds by birds.

vii. Herbicides to be used in the trial are required to be registered in India for use for maize (or to be used for the experimental purpose only with necessary permission as per the procedures and protocols of safety assessment of insecticides/ herbicides by CIB&RC under Central Insecticides Act 1968, and rules and regulations thereunder).

11) Records and reporting:

i. Records, including pre- and post-harvest site monitoring, activities related to trial site compliance (including subcontracts), cleaning of equipment, transportation, disposition and storage of all surplus and harvested seed and plant material, shall be maintained and shall be made available to RCGM/GEAC, Central Compliance Committee (CCC) or the designated monitoring agencies upon request. Mandatory recording formats are referenced in the RCGM/GEAC Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated Genetically Engineered Plants, 2008: Transport, Storage, Management, Harvest or Termination and Post-Harvest Management and can be downloaded from https://ibkp.dbtindia.gov.in/Content/Rules.

ii. The applicant shall submit a field trial report through the trial-in-charge to GEAC within three months after termination/harvest of the confined field trial. The field trial report must summarize the completed trial, including methods, observations, data and analysis of any effects of the trial plants on other plants, non-target organisms, or the environment.

12) GEAC Secretariat shall constitute Central Compliance Committee (CCC) with the approval of Chairman GEAC, and ensure monitoring of the trial.

13) Applicant shall inform and submit records to GEAC within 7 working days of planting at a trial site about record of planting with a confined field trial permit number, the amount of material planted, the planting date, the transportation of plant material to the trial site, the cleaning of any equipment used during planting, and the disposition of any surplus plant material remaining after planting, along with the relevant photographs with cardinal directions, date and time to be indicated on each photograph

capturing complete trial area covering all corners of the trial site, physical markers (such as flag), fencing of the trial site, notice board, and border rows, preferably marked with treatments and replications.

14) The applicant would provide three photographs of the experimental site, taken from a distance sufficient to indicate the transgenic plots in a single photograph with cardinal directions, date and time. These photographs should preferably capture the trial area covering all corners of the trial site, physical markers (such as flag), fencing of the trial site, notice board, border rows, treatments and replications. Such photographs would be taken at three intervals during the season to document the start of the experiments (planting), the mid way of the experiments (Flowering) and the end of the experiments (harvest/termination). These photographs would be submitted along with the field trial report at the conclusion of the experiments.

15) The record of Harvest/Termination shall be prepared for each confined field trial site and shall document the date and method of harvest, the quantity of harvested material, the disposition of any harvested materials, the cleaning of any equipment used during harvest, and the method of destruction of any residual plant material on the trial site. This record must be verified and signed by Chairman of the CCC, or any nominee of RCGM/GEAC/SAU authorized by RCGM/GEAC during the conduct of a trial site inspection during harvest, or within 15 days of the completion of harvest.

16) The applicant/trial-in-charge shall notify GEAC positively within 24 hours of discovery of any incident involving an accidental or unauthorized escape like spillage, theft, encroachment by unauthorized persons, vandalization etc. of regulated GE plant material during transportation, storage within a contained facility, or during any other activity associated with the conduct of a confined field trial. As per the Guidelines 2008, any breach of the authorized terms and conditions of reproductive isolation shall be considered an accidental release and subject to risk assessment and management, if any, is to be carried out at the cost of the applicant.

17) In the case of accidental release or spillage of genetically engineered plant material during transport, recoverable seeds or seedlings shall be collected and rendered non- viable and disposed of, the site shall be marked and monitored, and a notification shall be immediately provided to GEAC. Any plants arising from unrecoverable seeds or seedlings must be rendered non-viable and disposed of before flowering.

18) In the event that the plants undergoing confined field trial testing exhibit any characteristics substantially different from those known for the host plant species (i.e., its non-GE counterpart, or anticipated and listed in the application), or suffers any unusual occurrence, the applicant/trial-in-charge shall notify GEAC within five (5) days of such observations.

19) No harvested material, cob or by product from a confined field trial, under any circumstances, shall be used as human food or livestock feed. No seed or other plant material from the confined field trial to be enter the food or

feed chains. Seed or other plant material harvested from confined trials authorized by GEAC to be retained for future research work and must be disposed of by a method given in the Guidelines 2008 (e.g., dry heat, steam heat, incineration, deep burial, chemical treatment, or crushing or burying on the trial site). Progeny from any confined field trial cannot be retained for future planting without prior written authorization from GEAC, and this must be specifically requested in the field trial application.

20) The trial-in-charge or his/her designate must monitor the trial site at least ONCE EVERY TWO WEEKS from the time of planting until the time of harvest of the trial. This monitoring has to be recorded in a bound book provided by the Permitted Party as per the formats given in the Guidelines 2008. The record of spatial isolation will be used to document all monitoring and field activities needed to demonstrate reproductive isolation of the trial site. The growth and stage of any prohibited plant found within the isolation distance of the trial site should be recorded during monitoring.

21) Members of the CCC, monitoring teams of SAUs or any other authorized party by RCGM/GEAC have the authority to inspect confined field trial sites at the time of planting, during the growing, harvesting season, and the period of post-harvest land use restriction for compliance with the terms and conditions of authorization. Monitoring agencies also have the authority to inspect contained facilities that may be used for the storage of regulated genetically engineered plant material. The trial-in-charge or Facility- in-Charge (for storage facilities) as appropriate, may accompany the monitoring teams on inspections; however, the coordination of such activities is the responsibility of the Permitted Party. The applicant should incorporate the suggestions/recommendations of CCC Team during its visit to the BRL-II confined field trial.

22) In addition to ensuring reproductive isolation of the field trial site during the growing season of the confined field trial, it is also necessary to prevent the establishment of any progeny plants at the field trial site during post-harvest period. The following precautions be implemented during this period of subsequent growing season, effective from the date of final harvesting.

    i. The area under restriction must be monitored during the post-harvest period to ensure that any prohibited plants (volunteers or sexually compatible species) are destroyed prior to flowering.
    ii. No plants of the same or a sexually compatible species may be planted in the restricted area during the post-harvest period.
    iii. Land use of the restricted area must be compatible with requirements for monitoring and removal of prohibited plants. No plants that could interfere with monitoring for prohibited plants can be planted.
    iv. The restricted area is normally limited to the area of the trial site, if border rows were used as an alternative method of reproductive

isolation, and does not include the surrounding isolation area. However, if a breach of reproductive isolation occurred during the performance of the confined field trial, the restricted area will include the trial site and the surrounding isolation area.

23) Harvested seed and/or plant material from the confined trial may only be retained if requested in the application and previously authorized by RCGM/GEAC. Any harvested seed and/or plant material must be clearly labelled, securely transported, and stored separately from other seed and/or plant material.
24) A record of harvest documenting the date and method of harvest, the amount of harvested materials, the disposition of harvested materials, the cleaning of any equipment used during harvest, and the method of destruction of any residual plant material on the trial site, shall be prepared by the applicant for verification and signature by monitoring agency. This harvest inspection shall occur either during harvest or within 15 days of the completion of harvest.
25) Any equipment or tools used during planting shall be cleaned on the trial site prior to movement off the site in order to remove residual plant material. Surplus seed, transplants, or other plant material remaining after planting, or recovered during the cleaning of equipment, shall be rendered non-viable and disposed of using a method acceptable to GEAC such as: dry heat, steam heat, incineration, crushing, deep burial to one meter on the trial site, or chemical treatment.
26) The applicant shall maintain adequate records of all confined field trials, including pre- and post-harvest site monitoring, activities related to trial site compliance (including subcontracts), cleaning of equipment, transportation, and disposition and storage of all surplus and harvested seed and plant material.
27) The applicant/trial-in-charge shall notify GEAC in writing at least 15 days in advance of planting any plant species on the trial site during the post-harvest period.
28) The applicant shall submit a report summarizing the completed trial, including observations and data, methods of observation, and analysis of any deleterious effects on plants, non-target organisms, or the environment, to GEAC within six months after the termination of the confined field trial.
29) Monitoring agencies shall be allowed access, during regular business hours, to the place where regulated genetically engineered plant material is located and to any records relating to the transportation or use of the genetically engineered plant material in a confined field trial.
30) If a chemical treatment is used on the trial site that requires a time until safe entry, a sign must be posted at the access to the trial indicating the date and time of spraying as well as the time until safe entry as per extant statutory provisions. This condition is intended to protect the health and safety of monitoring agencies.

31) The applicant would keep full account of the genetically engineered materials and seeds, if any, set in the GE plants. All materials after experimentation, including the seeds of the crop under trial from the trapper rows, would be fully accounted for, and the information would be documented and preserved in a bound book that would be available to the Government when requested for. The harvested crop from the border rows and leftover plant and plant parts from the entire experimental plot shall be destroyed by burning after completion of the experiment, in the presence of the local authority.
32) Only authorized personnel would be allowed to visit the experimental plot. Persons visiting the experimental plot shall enter the name, designation and purpose of visiting the experimental plot in a bound book which should be made available to the Government when requested for.
33) The applicant would extend full cooperation to the authorized personnel of the GEAC/ RCGM/CCC/ State Government Officials/ State Agriculture University or their nominee to inspect the experimental sites and to have access, for official use only, the experimental results of the above.
34) The Applicant is hereby directed to convey to the Member Secretary, GEAC within 15 days after the receipt of this permission an unequivocal acceptance of the above conditions along with the information asked for as above. In case, the Permitted Party does not intend to conduct the BRL-II under confined field conditions, the same must also be intimated in writing to the GEAC Secretariat.

Action: GEAC Secretariat

4.2 M/s Bayer Crop Science Limited, Gurugram, Haryana for conduct of BRL- II confined field trials of insect resistance transgenic maize (*Zea mays L.*) Event MON89034 containing *cry1A105* and *cry2Ab2* gene

The committee was informed that the proposal submitted by M/s Bayer Crop Science Limited, Gurugram, Haryana for conduct of BRL-II confined field trials of insect resistance transgenic maize (Zea mays L.) Event MON89034 containing *cry1A105* and *cry2Ab2* gene was considered by GEAC in its 155th meeting held on 09.06.2025, wherein committee recommended the application for BRL-II trial at PAU, Ludhiana during the *Kharif* season 2025.

The Committee was further informed that, during Secretariat scrutiny, the applicant, vide email dated 06.01.2025, submitted a response to Query No. (viii) related to the BRL-II application for Event MON89034, inter alia stating that the BRL-II trials permitted earlier were for the breeding stack Event MON89034 × NK603, which is the product intended for commercial release, and that the present proposal pertains to BRL-II confined field trials of the individual component Event MON89034, intended to support the stacked product from an individual component environmental risk assessment perspective.

The applicant informed that the Stack events (MON 89034 X NK 603) are already approved for BRL-II trials by GEAC in its 104th meeting dated 15.11.2010 under Agenda No. 5.5, 105th meeting held on 08.12.2010 under Agenda No. 5.1 and, in its 112th meeting dated 21.09.2011 under Agenda No. 5.20.

The Committee further noted that subsequent to the above recommendation, the Department of Biotechnology (DBT) has issued the Guidelines on Genetically Engineered Plants Containing Stacked Events, 2025, which lay down specific provisions applicable to genetically engineered plants containing stacked events.

Recommendations

The Committee noted that applicant has informed that Event MON89034 is not intended for commercialization as a standalone event, and the breeding stack Event MON89034 × NK603, which is the product intended for commercial release, are already approved for BRL-II trials by GEAC in past and that the present proposal pertains to BRL-II confined field trials of the individual component Event MON89034, intended to support the stacked product from an individual component environmental risk assessment perspective.

Accordingly, after deliberation Committee recommended that RCGM be requested to review the proposal in light of Guidelines on Genetically Engineered Plants Containing Stacked Events, 2025 and submit its recommendations to GEAC.

Action: GEAC Secretariat

Agenda Item No. 5: Applications related to Environmental Approval of clinical trials/ pharmaceuticals / veterinary drugs and Commercial Production

5.1 M/s Dhanuka Soya Pvt Ltd, Madhya Pradesh for commercial production of ethanol using GE *Saccharomyces cerevisiae* Strain M24926

The committee was informed that the applicant submitted an application dated 06.10.2024 for commercial production of ethanol using GE *Saccharomyces cerevisiae* strain M24926 (Brand Name: Fermboost). The applicant intends to use the ethanol for biofuel purpose.

The Strain M24926 is genetically modified to introduce genes encoding for glucoamylase and trehalase enzymes for enabling efficient ethanol production. The supplier of strain M24926 is Lallemand's distributor M/s Aaditya FinechemPvt. Ltd, Jaipur.

GEAC in its 153rd GEAC meeting held on 03.10.2024 appraised the Standard Risk Assessment and Risk Management (RARM) Plan for Environmental Safety

for Undertaking Commercial Production of Ethanol Using Genetically Engineered Organisms (GEOs)/Living Modified Organisms (LMOs). Accordingly, Applicant vide email dated 13.11.2024 was directed to submit the Standard RARMP. The applicant vide email dated 05.08.2025 have submitted the RARMP.

The RARMP submitted by M/s Dhanuka Soya Pvt Ltd, Madhya Pradesh was considered and recommended by RCGM in its 321st meeting dated 29.10.2025. RCGM via email dated 18.11.2025 have sent the letter to GEAC, enclosed with recommendations of its 321st RCGM meeting for further consideration.

Recommendations

Based on the recommendations of 321st RCGM meeting and the RARMP recommended by RCGM, the proposal submitted by M/s Dhanuka Soya Pvt Ltd, Madhya Pradesh for commercial production of 127.5 million liters per annum of ethanol for gasoline blending at Neemuch, Madhya Pradesh using GE *Saccharomyces cerevisiae* strain M24926 (Brand name: Fermboost) was recommended by the Committee subject to following conditions:

i. The activity must adhere to the plans proposed in the application and activity must comply with the RARM plans recommended by GEAC.
ii. Applicant shall ensure that the GE *Saccharomyces cerevisiae* strain M24926 is used for the intended application as indicated. In case of different use, except as indicated in the application, applicant shall take separate approval from GEAC.
iii. The applicant shall inform the GEAC Secretariat within 30 days from the date of commencement of production.
iv. The project should be implemented under the oversight of IBSC.
v. The applicant shall submit IBSC approved compliance report on RARM plan as approved by GEAC, every 6 months to GEAC Secretariat.
vi. It is obligated to ensure environmentally sound and safe management of any residue/discharge of the production process as per existing laws, rules, and regulations applicable.
vii. The applicant shall ensure strict compliance of zero discharge of viable GE *Saccharomyces cerevisiae* strain M24926 into the environment at any stage including import, transport, storage, production, recovery, handling, management etc.
viii. The records of generation, treatment, recycle/reuse and disposal of related to production process shall be maintained and submitted to concerned SPCB at regular intervals of twice in a year, on 15th October (for April-September) and 15th April (for October to March).
ix. The clearance granted to the project/activity is strictly under the provisions of the EIA Notification 2006 and its subsequent amendments. It does not tantamount/construe to approvals/consent/permissions etc. required to be obtained or standards/conditions to be followed under any other Acts/ Rules/ Subordinate legislations, etc., as may be applicable to

the project. The applicant shall obtain necessary permission as mandated under the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981, as applicable from time to time, from the State Pollution Control Board, prior to construction & operation of the project.

x. The approval is subject to other statutory clearances.

xi. Appropriate safety measures, including on-site emergency plans, must be in place to manage any accidents as per:
   a. Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017
   b. Handbook for Institutional Biosafety Committees (IBSCs), Third Revised Edition, September 2020.

xii. Proper care must be taken for decontamination and disposal to the environment in accordance with Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017.

xiii. Accidents, if any, must be reported to GEAC and necessary corrective actions to be taken without delay.

xiv. Environmental standards to be maintained in the plant, include:
   a. Conducting an Environmental Audit
   b. Maintaining details on Effluent Treatment Plant/ zero liquid discharge and ensuring compliance with relevant standards, including the waste disposal strategy.

xv. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.

xvi. The Ministry reserves the right to stipulate additional conditions if found necessary. The applicant, in a time bound manner, shall implement these conditions.

xvii. For every co-product and by-product produced during process, which is included in the present application, intended to be utilized /sold/marketed/commercialized or is to be released into the environment, applicant shall obtain separate approval in accordance with the extant statutory provisions.

xviii. GEAC Secretariat shall monitor and ensure compliance of the stipulated conditions. The applicant shall extend full cooperation to the officer (s) of the GEAC Secretariat by furnishing the requisite data / information/monitoring reports.

xix. The approval will be for a limited period of four years from the date of issue of letter, as per clause 13 of "Rules for The Manufacture, Use, Import, Export and Storage Of Hazardous Micro Organisms/ Genetically Engineered Organisms Or Cells 1989 (Rules 1989) notified under Environment Protection Act, 1986."

Action: GEAC Secretariat

5.2 M/s Dhanuka Biotech Pvt Ltd, Madhya Pradesh for commercial

production of ethanol using GE *Saccharomyces cerevisiae* Strain M24926

The committee was informed that the applicant submitted an application dated 06.10.2024 for commercial production of ethanol using GE *Saccharomyces cerevisiae* strain M24926 (Brand Name: Fermboost). The applicant intends to use the ethanol for biofuel purpose.

The Strain M24926 is genetically modified to introduce genes encoding for glucoamylase and trehalase enzymes for enabling efficient ethanol production. The supplier of strain M24926 is Lallemand's distributor M/s Aaditya Finechem Pvt. Ltd, Jaipur.

GEAC in its 153rd GEAC meeting held on 03.10.2024 appraised the Standard Risk Assessment and Risk Management (RARM) Plan for Environmental Safety for Undertaking Commercial Production of Ethanol Using Genetically Engineered Organisms (GEOs)/Living Modified Organisms (LMOs). Accordingly, Applicant vide email dated 13.11.2024 was directed to submit the Standard RARMP. The applicant vide email dated 06.08.2025 have submitted the RARMP.

The RARMP submitted by M/s Dhanuka Biotech Pvt Ltd, Madhya Pradesh was considered and deliberated by RCGM in its 321st meeting dated 29.10.2025. RCGM via email dated 18.11.2025 have sent the letter to GEAC, enclosed with recommendations of its 321st RCGM meeting for further consideration.

Recommendations

Based on the recommendations of 321st RCGM meeting and the RARMP recommended by RCGM, the proposal submitted by M/s Dhanuka Biotech Pvt Ltd, Madhya Pradesh for commercial production of 97.5 million liters per annum of ethanol for gasoline blending at Neemuch, Madhya Pradesh using GE *Saccharomyces cerevisiae* strain M24926 (Brand name: Fermboost) was recommended by the Committee subject to following conditions:

i. The activity must adhere to the plans proposed in the application and activity must comply with the RARM plans recommended by GEAC.
ii. Applicant shall ensure that the GE *Saccharomyces cerevisiae* strain M24926 is used for the intended application as indicated. In case of different use, except as indicated in the application, applicant shall take separate approval from GEAC.
iii. The applicant shall inform the GEAC Secretariat within 30 days from the date of commencement of production.
iv. The project should be implemented under the oversight of IBSC.
v. The applicant shall submit IBSC approved compliance report on RARM plan as approved by GEAC, every 6 months to GEAC Secretariat.
vi. It is obligated to ensure environmentally sound and safe management of any residue/discharge of the production process as per existing laws,

rules, and regulations applicable.

vii. The applicant shall ensure strict compliance of zero discharge of viable GE *Saccharomyces cerevisiae* strain M24926 into the environment at any stage including import, transport, storage, production, recovery, handling, management etc.

viii. The records of generation, treatment, recycle/reuse and disposal of related to production process shall be maintained and submitted to concerned SPCB at regular intervals of twice in a year, on 15th October (for April-September) and 15th April (for October to March).

ix. The clearance granted to the project/activity is strictly under the provisions of the EIA Notification 2006 and its subsequent amendments. It does not tantamount/construe to approvals/consent/permissions etc. required to be obtained or standards/conditions to be followed under any other Acts/ Rules/ Subordinate legislations, etc., as may be applicable to the project. The applicant shall obtain necessary permission as mandated under the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981, as applicable from time to time, from the State Pollution Control Board, prior to construction & operation of the project.

x. The approval is subject to other statutory clearances.

xi. Appropriate safety measures, including on-site emergency plans, must be in place to manage any accidents as per:
   a. Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017
   b. Handbook for Institutional Biosafety Committees (IBSCs), Third Revised Edition, September 2020.

xii. Proper care must be taken for decontamination and disposal to the environment in accordance with Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017.

xiii. Accidents, if any, must be reported to GEAC and necessary corrective actions to be taken without delay.

xiv. Environmental standards to be maintained in the plant, include:
   a. Conducting an Environmental Audit
   b. Maintaining details on Effluent Treatment Plant/ zero liquid discharge and ensuring compliance with relevant standards, including the waste disposal strategy.

xv. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.

xvi. The Ministry reserves the right to stipulate additional conditions if found necessary. The applicant, in a time bound manner, shall implement these conditions.

xvii. For every co-product and by-product produced during process, which is included in the present application, intended to be utilized /sold/marketed/commercialized or is to be released into the environment, applicant shall obtain separate approval in accordance with the extant statutory provisions.

xviii. GEAC Secretariat shall monitor and ensure compliance of the stipulated conditions. The applicant shall extend full cooperation to the officer (s) of the GEAC Secretariat by furnishing the requisite data / information/monitoring reports.

xix. The approval will be for a limited period of four years from the date of issue of letter, as per clause 13 of "Rules for The Manufacture, Use, Import, Export and Storage Of Hazardous Micro Organisms/ Genetically Engineered Organisms Or Cells 1989 (Rules 1989) notified under Environment Protection Act, 1986."

Action: GEAC Secretariat

Agenda Item No. 6 : Additional Items for consideration

6.1 Requirement of Metagenomic Analysis for import of recombinant veterinary vaccine

GEAC in its 156th meeting held on 14.07.2025, deliberated on the application submitted by M/s. Zoetis India Limited, Mumbai for import and marketing of recombinant Bursal Disease-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector veterinary vaccine. The Committee recommended that the RCGM may examine the aspects of Metagenomic Analysis for import of recombinant veterinary vaccines, including the identification of acceptable non-target organisms (NTOs) and their threshold limits, and provide appropriate recommendations in this regard.

The requirement was considered by RCGM in its 315th and 319th meeting held on 06.08.2025 and 01.10.2025 respectively. RCGM recommended that the *"requirements for the import and marketing of recombinant vaccines should be based on the testing requirements as mentioned in the pharmacopeial monographs; and also, on the basis of history of approval in the well-regulated global market."*

RCGM vide email dated 28.10.2025 sent the recommendations of its 315th and 319th meeting to GEAC.

Recommendations

Committee recommended to consider this matter in upcoming GEAC meeting.

Action: GEAC Secretariat

The meeting ended with a vote of thanks to the Co-Chair and all the Members.

Annexure 1

List of Participants

Members who participated			
1.	**Dr. Nitin K. Jain** Scientist–G, Department of Biotechnology, C.G.O Complex, Lodhi Road, New Delhi-110003 (As Chairman)	**6.**	**Dr. Chaitanya Joshi** Director, Gujarat Biotechnology Research Centre, Gandhinagar, Gujarat- 382 011
2.	**Sh. Raghu Kumar Kodali** Scientist G, MoEFCC MoEFCC, Indira Paryavaran Bhawan, Jorbagh road, Aliganj, New Delhi- 110003	**7.**	**Dr. J.P. Singh** Plant Protection Adviser (PPA), Directorate of Plant Protection, Quarantine & Storage, NH IV, Faridabad-121001, New Delhi
3.	**Dr. Satish Wate** Former Director, CSIR-National Environmental Engineering Research Institute, Nagpur-440020	**8.**	**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)
4.	**Dr. H. K. Sharma** Director, National Institute of Technology, Agartala, Tripura- 799 046	**9.**	**Dr. Pronab Dhar** Principal Scientist, ICAR-Indian Veterinary Research Institute (IVRI), Bareilly, Uttar Pradesh- 243122 (Representative of Dr.TriveniDutt, Director, IVRI)
5.	**Dr. Dinkar M. Salunkhe** Director, International Centre for Genetic Engineering and Biotechnology, New Delhi-110067	**10.**	**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 ParyavaranBhawan, Jorbhagh road, Aliganj, New Delhi – 110003		

Members who did not participate			
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. Vinay K. Nandicoori** Director, CSIR-Centre for Cellular & Molecular Biology, Hyderabad - 500 007	**9.**	**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. U. S. N. Murthy** Director, National Institute of Pharmaceutical Education and Research, Guwahati- 781101	**10.**	**Dr. Sanjeev Khosla** Director, CSIR- Institute of Microbial Technology, Chandigarh- 160 036
4.	**Dr. J. P. Shukla** Scientist, CSIR-Advanced Materials and Process Research Institute, Bhopal- 462 026	**11.**	**Dr. P.K. Dass** Department of Anatomy, LHMC & Associated Hospitals, New Delhi- 110001
5.	**Dr. Rekha S. Singhal** Professor, Food Technology, Institute of Chemical Technology, Mumbai- 400 019	**12.**	**Shri V.P. Yadav** Scientist F, Central Pollution Control Board, Parivesh Bhawan, East Arjun Nagar, Delhi-110 032
6.	**Dr. P. Suprasanna** Scientific Officer H (Retd.), Biosciences group, BARC, Mumbai-400 085	**13.**	**Dr. Alka Rao** Advisor (Science & Standards & Regulation), FSSAI
7.	**Ms. Shruti Singh** Joint Secretary, IPR, Department for Promotion of Industry and Internal Trade, Udyog Bhawan, New Delhi ,110011		

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