MINUTES OF THE 155th MEETING OF THE GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 09.06.2025

The 155th meeting of the Genetic Engineering Appraisal Committee (GEAC) of the Ministry of Environment, Forest and Climate Change (MoEF&CC) was held on 09.06.2025 in hybrid mode at Teesta Hall, First Floor, Vayu 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

Three members communicated their inability to attend the 155th meeting of GEAC, na mely Dr. U. S. N. Murthy, Dr. Satish Wate and Dr. P. Suprasanna. Further, Dr. H.K S harma, Dr. Vinay K. Nandicoori, Dr. J.P Shukla, Dr. Chaitanya Joshi, Ms. Shruti Sing h, Dr. Geeta Jotwani, Dr. Sanjeev Khosla, Shri. V.P. Yadav, Mrs. Rubina Rose 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 154th GEAC meeting

Minutes of the 154th 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 154th GEAC meeting.

Action: GEAC Secretariat

Agenda Item No. 3: Action taken report on the decision taken in the 154th GEAC meeting

Member Secretary, GEAC briefed about the action taken on the decisions at the 154th 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 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 applicant has submitted an online application on 16.04.2025 to conduct BRL-II confined field trials of herbicide tolerant transgenic maize (Event NK603) carrying *cp4epsps* gene.

Transgenic maize hybrid event NK603 was developed for herbicide tolerance with *cp4epsps* gene (Event NK603). Linear DNA fragment was used for particle bombardment transformation for expressing *cp4epsps* constitutive protein and a transgenic Event NK603 was identified based on Event Selection Trials and BRL-1 trial. The transgenic maize hybrid with Event NK603 provides tolerance to the non-selective herbicide Glyphosate due to *cp4epsps* gene.

GEAC in its 111th meeting held on 06.07.2011 under Agenda Item 5.14, approved the proposal of M/s Monsanto India Limited, New Delhi to conduct BRL-I trials on maize hybrids namely Hishell & 900M Gold containing Event NK603 during the appropriate seasons during 2011-2013.

BRL-I Confined Field Trial was conducted during 2012-2014. BRL-I (2nd season) confined field trial was conducted on 2013.

The committee in its 130th GEAC meeting held on 11.08.2016 under Agenda item 6.5 recommended the proposal of Ms. Monsanto India Pvt. Ltd to conduct Confined Field Trial BRL-II of transgenic Maize containing Event NK603 at North, Central and South zones for a period of 2 years. However, trial could not be conducted.

On 16th September, 2019 Monsanto India Ltd. amalgamated with Bayer Crop Science Ltd.

Presently, Bayer Crop Science Ltd. has submitted the proposal to renew the GEAC permission no. C-12013/41/2008-CS-III dated 12th September 2016 to conduct BRL-II trials for herbicide tolerant transgenic Maize with event NK603 during Kharif 2025

and/or Rabi 2025-26 and Kharif 2026 at State Agricultural Universities and ICAR institutes under confined field conditions at following 12 proposed trial locations:

i. PAU, Ludhiana
ii. HAU, Hisar
iii. MPUAT, Udaipur
iv. AAU, Anand
v. DWR Jabalpur/JNKVV, Jabalpur/RVSKVV, Gwalior
vi. MPKV, Rahuri
vii. VNMKV, Parbhani
viii. UAS, Dharwad
ix. ANGRAU, Guntur
x. PJTSAU, Hyderabad
xi. TNAU, Coimbatore
xii. RAU, PUSA, Bihar

The applicant vide email dated 04.06.2025 has submitted the NOC obtained from Government of Punjab dated 29.05.2025 for the Kharif season 2025.

Recommendation

After due deliberations on the proposal, and taking cognizance of the concurrence received from Government of Punjab, 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 PAU, Ludhiana for the *Kharif* season 2025 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 a vis their non-transgenic counterparts.

The approval is subject to following conditions:

1) The applicant shall adhere to the conditions and/or recommendations mentioned in concurrence obtained from Government of Punjab vide letter dated 29.05.2025.
2) 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 the Government of India from time to time available at https://ibkp.dbtindia.gov.in/Content/Rules
3) 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.
4) The applicant shall share information regarding name of the trial-in-charge/lead scientist responsible for conduct of trial before start of the trial.
5) 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.

6) 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.
7) The applicant shall ensure 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.
8) 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 Punjab Agricultural University, Ludhiana, Punjab.

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 gene(s) in terms of productivity of the genetically engineered maize lines, germination, weediness, aggressiveness and other parameters.

9) 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 200 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).

10) 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.

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

12) 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.

13) 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.

14) 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.

15) 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.

16) 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.

17) 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.

18) No harvested material, cob or byproduct 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 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.

19) 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.

20) 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.

21) 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.
22) Harvested seed and/or plant material from the confined field 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.
23) 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.
24) 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
25) 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

26) 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.
27) 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
28) Monitoring agencies shall be allowed access, during regular business hours, to inspect the place where regulated genetically engineered plant material is located and to check any records relating to the transportation or use of the genetically engineered plant material in a confined field trial.
29) 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.
30) 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
31) 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.
32) 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.
33) 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 applicant intend to conduct BRL-II confined field trials of insect resistance transgenic maize Event MON89034 and has submitted application on 18.04.2025.

Transgenic maize hybrid is developed for insect resistance against lepidopteran pests carrying *cry1A105* and *cry2Ab2* genes (Event MON89034).

GEAC in its 115th meeting held on 08.02.2012 under Agenda item 5.10 approved the BRL-I Trial proposal submitted by M/s. Monsanto India Ltd., New Delhi with two transgenic maize (Zea mays L.) hybrids namely Hishell & 900 M Gold containing event MON 89034 during 2012-13 and 2013-14.

Accordingly, the applicant conducted BRL-I trial with two hybrids Hishell and 900M Gold with MON89034 event during 2012-2014.

On 16th September, 2019 Monsanto India Ltd. amalgamated with Bayer Crop Science Ltd.

Presently, Bayer Crop Science Ltd. intends to conduct BRL-II trials of insect resistance transgenic maize with event MON89034 during Kharif and /or Rabi of 2025-26 and Kharif 2026 at State Agricultural Universities and ICAR institutes under confined field conditions at following 11 proposed trial locations:

i. PAU, Ludhiana
ii. HAU, Hisar
iii. MPUAT, Udaipur
iv. AAU, Anand
v. DWR Jabalpur/JNKVV, Jabalpur
vi. RVSKVV, Gwalior
vii. MPKV, Rahuri
viii. VNMKV, Parbhani
ix. UAS, Dharwad
x. ANGRAU, Guntur
xi. PJTSAU, Hyderabad

The applicant vide email dated 04.06.2025 submitted the NOC obtained from Government of Punjab dated 29.05.2025 for the Kharif season 2025.

Recommendation

After due deliberations on the proposal, and taking cognizance of the concurrence received from Government of Punjab, the Committee recommended the proposal of M/s Bayer Crop Science Limited, Gurugram, Haryana for conduct of BRL-II Confined Field Trials of insect resistance transgenic maize Event MON89034 containing *cry1A105* and *cry2Ab2* gene at PAU, Ludhiana during the Kharif season 2025 to/for:

i. Study the efficacy of insect protected maize (MON89034) hybrid against target lepidopteran pests.
ii. Monitor occurrence of beneficial and non-target insects 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 a vis* 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 Punjab vide letter dated 29.05.2025.
2) 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.
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 MON89034 expressing *cry1A105* and *cry2Ab2* conferring resistance against

lepidopteran insects along with its conventional counterpart at Punjab Agricultural University, Ludhiana, Punjab.

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.

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 200 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. Insecticides 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 byproduct 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 field 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

4.3 M/s. Rasi Seeds Pvt. Ltd., Salem, Tamil Nadu to conduct BRL-I trials (1st Year and 2nd Year) confined field trials with GE cotton hybrids harbouring event RIRC-304 expressing cry1C gene and breeding stack of events RIRC-304×MON15985 (BGII, expressing *cry1Ac* and *cry2Ab2* genes) for resistance against bollworm complex (*Pectinophora gossypiella, Helicoverpa armigera* and *Spodoptera litura*).

Committee was informed that applicant intends to conduct BRL-I trials (1st Year and 2nd Year) with GE cotton hybrids harbouring event RIRC-304 expressing *cry1C* gene and breeding stack of events RIRC-304xMON15985 (BGII, expressing *cry1Ac* and *cry2Ab2* genes) for resistance against bollworm complex (*Pectinophora gossypiella, Helicoverpa armigera and Spodoptera litura*) during the year 2025-26 and 2026-27 at total 17 trial site locations across central, south and north cotton growing zones viz Firozpur, Bathinda, Fatehabad, Hisar, Junagadh, Khandwa, Khargone, Aurangabad, Amravati, Akola, Salem, Warangal, Medak, Guntur, Raichur, Vepanthattai and Kurnool.

The application was considered by the RCGM in its 305th and 306th meetings held on 05.03.2025 and 19.03.2025, respectively. RCGM vide email dated 23.04.2025 have sent the recommendations of its 305th and 306th meeting and recommended to GEAC for further consideration.

Accordingly, the queries raised after reviewing the proposal by GEAC secretariat were sent to RCGM vide email dated 09.05.2025. RCGM Secretariat vide email dated 15.05.2025 clarified that RCGM, in its 305th meeting held on 05.03.2025 recommended that applicant may submit molecular characterization data as well as food and feed safety studies with pure protein (Acute Oral Toxicity studies, protein

thermal stability, pepsin digestibility assay) of the parent event MON15985 (Bollgard II) of GE cotton breeding stack RIRC-304×MON 15985 within four months.

The committee was informed that the applicant has obtained NOC dated 27.05.2025 from Government of Madhya Pradesh and Punjab. Applicant vide email dated 30.05.2025 submitted the NOC dated 29.05.2025 obtained from Government of Punjab for Confined field trials (BRL-I) (1st& 2nd year) of transgenic cotton hybrids containing the event RIRC-304 and the stacked RIRC 304 X MON 15985 events for the management of cotton bollworms during Kharif season 2025-26 and 2026-27.

Recommendation

Committee deliberated on the recommendation of 305th and 306th meeting of RCGM and NOC received from Govt. of Madhya Pradesh and Punjab and recommended the proposal of M/s. Rasi Seeds P. Ltd., Salem, Tamil Nadu to conduct BRL-I trials (1st Year) during Kharif 2025-2026 with GE cotton hybrids harbouring event RIRC-304 expressing *cry1C* gene and breeding stack of events RIRC-304×MON15985 (BGII, expressing *cry1Ac* and *cry2Ab2* genes) for resistance against bollworm complex (*Pectinophora gossypiella, Helicoverpa armigera* and *Spodoptera litura*) at below mentioned sites :

i. Khandwa, Madhya Pradesh
ii. Firozpur, Punjab
iii. Bathinda, Punjab

The recommendation is subject to following conditions:

i. The applicant shall adhere to the conditions of RCGM letter dated 23.04.2025.
ii. The applicant shall adhere with the conditions and/or recommendations mentioned in concurrence obtained from Government of Madhya Pradesh vide Letter dated 27.05.2025; and Government of Punjab vide Letter dated 29.05.2025.
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 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

4.4 M/s ICAR-National Institute for Plant Biotechnology (NIPB), New Delhi to conduct repeated Event selection Trial (EST-II) under confined field conditions of four GE pigeon-pea (*Cajanus cajan*) lines (Event 7, Event 12, Event 13, and Event 14) expressing *cry2Aa* gene for pod borer resistance (*Helicoverpa armigera*) at ICAR-Indian Agricultural Research Institute (IARI), New Delhi during Kharif 2025-2026.

The proposal of ICAR-National Institute for Plant Biotechnology, New Delhi to conduct Event Selection Trials of ten transgenic pigeon-pea lines expressing *cy2Aa*/ *cry1AcF* genes (*cry2Aa* Lines: Event 7, Event 10, Event 12, Event 13, and Event 14; cry1AcF Lines: Event 19, Event 22, Event 24, Event 25 and Event 26) at IARI, New Delhi during cropping season July, 2022 to April, 2023 was initially approved by GEAC in its 146th meeting held on 25.08.2022 under Agenda Item 5.2.

Presently, the applicant has submitted an application to RCGM to conduct a repeated Event Selection Trial (EST-II) under confined field conditions with four GE pigeon-pea lines (Event 7, Event 12, Event 13 and Event 14) expressing *cry2Aa* gene for pod borer resistance (*Helicoverpa armigera*) at ICAR IARI, New Delhi during Kharif 2025-2026.

The proposal was considered by RCGM in its 307th and 309th meetings held on 02.04.2025 and 30.04.2025, respectively. RCGM vide email dated 15.05.2025 have sent the recommendations of 307th and 309th meeting and recommended to GEAC for further consideration.

In accordance with the recommendations of the 146th GEAC meeting held on 25.08.2022, since this EST has been proposed to be conducted strictly within the

institutional premises and under controlled conditions, the Concurrence/ No Objection Certificate (NOC) from the state Government is not required.

Recommendation

After detailed deliberations, the proposal of ICAR-National Institute for Plant Biotechnology, New Delhi to conduct repeated Event Selection Trials of four GE pigeon-pea lines (Event 7, Event 12, Event 13 and Event 14) expressing *cry2Aa* gene for pod borer resistance (*Helicoverpa armigera*) at ICAR IARI, New Delhi during 2025-2026 was recommended by the committee.

The recommendation is subject to following conditions:

i. The applicant shall adhere to the conditions of RCGM letter dated 15.05.2025.
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 EST to ensure compliance of prescribed terms and conditions. The permit letter shall also mention constitution and objective of Central Compliance Committee.

Action: RCGM & GEAC Secretariat

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

5.1 M/s PPD Pharmaceutical Product Development India Pvt. Ltd., Mumbai for Phase III, randomized, observer-blind, placebo-controlled, multi-centre, multinational study to evaluate the efficacy, immunogenicity, and safety of a Respiratory Syncytial Virus vaccine in infants and toddlers (PEARL).

The committee was informed that the application was initially considered in 151st GEAC meeting held on 19.12.2023 under Agenda item 5.1 wherein it was recommended that the proposal be forwarded to RCGM for scrutiny and comments be requested from Drugs Controller General of India (DCGI), Central Drugs Standard Control Organization (CDSCO) be in regard to processing of the proposal. The application has also been forwarded by DCGI-CDSCO to RCGM for scrutiny.

Accordingly, the application was considered by RCGM and in its 283rd meeting wherein following was recommended:

- *"No biosafety concerns have been observed in the submitted data on molecular characterization, analytical characterization, non-clinical immunogenicity and safety studies in different animal models.*
- *Nodal IBSC (IBSC of JSS, Mysuru) to submit the SOPs w.r.t. the storage, transfer, disposal and decontamination mechanisms of the test item DP vials to RCGM and DCGI-CDSCO."*

In 152nd GEAC meeting held on 29.07.2024 under Agenda item 5.4, the applicant informed that the Nodal IBSC of applicant (IBSC of JSS, Mysuru) is yet to submit SOPs w.r.t. the storage, transfer, disposal and decontamination mechanisms of the test item DP vials to RCGM and DCGI-CDSCO, as recommended in 283rd RCGM meeting. Further, it was also informed that they are yet to obtain approval of DCGI-CDSCO. Accordingly, "*committee directed the applicant to submit, through its Nodal IBSC (IBSC of JSS, Mysuru), SOPs w.r.t. the storage, transfer, disposal and decontamination mechanisms of the test item DP vials to RCGM and DCGI-CDSCO, as recommended in 283rd RCGM meeting. The final recommendation of RCGM, after examination of SOPs provided by applicant, to be submitted to GEAC for consideration of environmental safety aspect of clinical trials of Respiratory Syncytial Virus vaccine, before Phase-III study."*

Applicant vide email dated 23.12.2024 informed that Standard Operating Procedure (SOP) was submitted to RCGM on 18.11.2024.

SOP was considered by RCGM in its 299th meeting held on 11.12.2024 wherein RCGM recommended that *the SOPs submitted by the applicant w.r.t. the storage, transfer, disposal and decontamination mechanisms of the test item DP vials are found to be appropriate. Further, RCGM recommended the Nodal IBSC-JSS Academy of Higher Education & Research, Mysuru to ensure the proper implementation of the submitted SOPs.*

Applicant vide email dated 23.12.2024 have submitted to GEAC the final recommendation of 299th RCGM meeting along with the SOP recommended by RCGM.

GEAC Secretariat has reviewed SOPs and it is observed that the text uses the phrase 'should be/must be' in a suggestive manner, whereas it ought to be expressed in a binding form, such as 'shall be' or 'will be'.

Further, it is observed that:

a. No clear SOP outlining transport temperature control validation during transport.

b. On-site destruction process does not provide site-specific procedures or personnel responsibilities for on-site destruction.
c. Protocol for cleaning spillages of biological or investigational material is missing
d. No Emergency procedures for vial breakage or leakage during handling.
e. PPE types and handling protocols are not specifically described.
f. Material-specific handling protocols on material types (e.g., cold-chain, hazardous IPs, etc.) is missing.

Recommendation

Committee deliberated on the recommendations of 299th RCGM meeting and on SOPs recommended by RCGM for Phase III, randomized, observer-blind, placebo-controlled, multi-centre, multinational study to evaluate the efficacy, immunogenicity, and safety of a Respiratory Syncytial Virus vaccine in infants and toddlers (PEARL) by M/s PPD Pharmaceutical Product Development India Pvt. Ltd., Mumbai. The Committee suggested the applicant to revise and resubmit the SOPs addressing the aforementioned gaps to GEAC secretariat.

Accordingly, the decision on the application was deferred.

Action: GEAC Secretariat

5.2 M/s Oasis Ethanol Industries Private Limited, Haryana for commercial production of Ethanol using genetically modified *Saccharomyces cerevisiae* strain SYNERXIA® JADE ADY.

The committee was informed that the proposal by M/s Oasis Ethanol Industries Private Limited, Haryana for commercial production of Ethanol using genetically modified *Saccharomyces cerevisiae* strain SYNERXIA® JADE ADY was initially considered by GEAC in its 151st meeting on 19.12.2023 under Agenda Item 5.2, wherein the committee recommended the following;

i. After due deliberations, the Committee was of the view that RCGM be requested to prepare a Risk Assessment & Risk Management Plan (RARMP) in respect to environmental safety, that the applicant should comply with, for commercial production of ethanol using genetically modified organisms at the distilleries. The applicant was directed to submit a draft RARMP in respect to environmental safety, for consideration of RCGM.
ii. The Committee also requested RCGM to prepare a standard RARMP pertaining to environmental safety that should be adhered with while undertaking commercial production of ethanol using genetically modified organisms at the distilleries.

iii. Further, the Committee was of the view that for every by-product, obtained during such a commercial production process, that is intended to be utilized/ sold/ marketed/ commercialized or is to be released into the environment; the applicant shall have to obtain separate regulatory approval in accordance with extant statutory provisions.

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). Letter communicating the Standard RARMP was sent to applicant vide letter dated 23.10.2024. The applicant vide email dated 16.12.2024 have submitted the RARMP, which was forwarded to RCGM for consideration.

The RARMP submitted by M/s Oasis Ethanol Industries Private Limited, Haryana was considered in its 306th and 309th RCGM meeting dated 19.03.2025 and 30.04.2025 respectively. RCGM vide email dated 19.05.2025 have sent the recommendations of its 306th and 309th meeting for further consideration by GEAC.

Recommendation

"GEAC deliberated in detail on the co-products and by-products that may be generated during the intended production process, and recommended that, if any such co-product or by-product, is intended to be utilized, sold, marketed, commercialized, or released into the environment—the applicant shall obtain separate approval in accordance with the extant statutory provisions. The GEAC, keeping in view the precautionary principle, recommended that the afore-said recommendation shall also be applicable, to all applicants whose proposals for the import of GE yeast and production of ethanol fuel from GM yeast have been recommended by the Committee in the past four years."

Further, taking cognizance of the recommendations of 306th and 309th RCGM meeting, the RARMP submitted by M/s Oasis Ethanol Industries Private Limited, Haryana for commercial production of Ethanol using genetically modified *Saccharomyces cerevisiae* strain SYNERXIA® JADE ADY 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 SYNERXIA® JADE ADY 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 project should be implemented under the oversight of IBSC.

iv. The applicant shall submit IBSC approved compliance report on RARM plan as approved by GEAC, every 6 months to GEAC Secretariat.

v. 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.

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

vii. 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).

viii. 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.

ix. The approval is subject to other statutory clearances.

x. 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.

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

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

xiii. 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

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

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

xvi. 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.

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

xviii. 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: Applications related to Import/ Export

6.1 M/s Intervet India Pvt. Ltd., Pune for import and marketing of Nobivac Puppy DP Plus recombinant veterinary vaccine.

The committee was informed that the proposal of M/s Intervet India Pvt. Ltd., Pune for import and marketing of Nobivac Puppy DP Plus recombinant vaccine (Generic name: Combined Canine Distemper and Canine Parvovirus Vaccine, Live, Freeze dried vaccine) for veterinary use was initially considered in the 145th meeting of GEAC held on 27.07.2022 under Agenda Item 6.5, wherein committee recommended the proposal for import, subject to the conditions that *"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 151st GEAC held on 19.12.2023 under Agenda Item 6.2 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."

The applicant vide GEAC application dated 03.04.2025 has submitted the Metagenomic analysis certified by GBRC.

The committee was informed that the applicant intends to import and market 2600 vials of 1 dose per year of Nobivac Puppy DP Plus including Solvent from Intervet International B.V. Boxmeer, The Netherlands for veterinary use in India. The applicant intends to use for active immunisation of puppies from 4 weeks of age onwards to prevent clinical signs and mortality of canine distemper virus infection and canine parvovirus infection and to prevent viral excretion following canine distemper virus infection and following canine parvovirus infection.

The metagenomics analysis report identified the expected target viruses Canine distemper virus (CDV) and Canine parvovirus (CPV) from the vaccine samples, along with the expected host genomic content from Vero and A72 cells, confirming the presence of CDV and CPV 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.

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. Nobivac Puppy DP Plus recombinant vaccine), 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.

Action: GEAC Secretariat

6.2 M/s Danisco (India) Pvt. Ltd., Hyderabad, for Import and marketing of SYNERXIA® JADE ADY (Active Dried Yeast) for ethanol production.

The committee was informed that the application submitted by M/s Danisco India Private Limited, Hyderabad for import of 2000 metric ton (2,000,000 Kgs) of SYNERXIA ® JADE ADY (Active Dried Yeast), per annum from USA and its marketing for ethanol production was initially considered in 148th GEAC meeting under Agenda Item 6.1, wherein the committee recommended the proposal subject to the condition that applicant shall ensure strict compliance of zero discharge of viable SYNERXIA ® JADE ADY yeast strain into the environment at any stage including import, transport, storage, handling, management etc.

The Committee also recommended that the firms, whomsoever using the imported genetically modified SYNERXIA ® JADE ADY (Active Dried Yeast) strains, has to obtain separate approval from GEAC for large scale manufacturing in accordance with Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017.

In 151st GEAC meeting held on 19.12.2023 deliberations were held with regard to requirement of developing a Standard RARMP in respect to environmental safety, pertaining to storage, transportation, access, handling, packing, re-packing, distribution, sale, decontamination, and disposal of GMO consignment. Accordingly, RCGM was requested to prepare a standard RARMP for import of GMO consignment.

In 152nd GEAC held on 29.07.2024 under Agenda item 6.4, Committee directed the GEAC secretariat to share the standard RARMP, as and when approved, with all the applicants whose proposals for import of GE yeast have been recommended by the Committee in past four years for compliance henceforward.

GEAC in its 153rd GEAC meeting held on 03.10.2024 appraised the Standard RARMP for import of Genetically Engineered Organisms (GEOs)/Living Modified Organisms (LMOs) for Commercial Production. Letter communicating the Standard RARMP for import was sent to applicant vide letter dated 21.10.2024. Applicant vide email dated 16.12.2024 have submitted the Standard RARMP, which was forwarded to RCGM for consideration.

RARM plan was considered in 304th and 309th meeting of RCGM dated 19.02.2025 and 30.04.2025 respectively. RCGM vide email dated 19.05.2025 have sent the recommendations of its 304th and 309th meeting for further consideration by GEAC.

Recommendation

Taking cognizance of the recommendations of 304th and 309th RCGM meeting, the RARMP submitted by M/s Danisco (India) Pvt. Ltd., Hyderabad, for Import and marketing of SYNERXIA® JADE ADY (Active Dried Yeast) for fuel ethanol production 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. 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.

iii. Applicant shall ensure that the GE *Saccharomyces cerevisiae* strain SYNERXIA ® JADE ADY 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.

iv. Applicant shall submit IBSC approved Emergency Action Plan for an event of unintentional release of GE *Saccharomyces cerevisiae* strain SYNERXIA® JADE ADY, before import.

v. The Applicant shall submit 16s RNA Gene Sequencing and 18s RNA Gene Sequencing Reports for the Initial five batches to detect any adventitious presence of bacteria and yeast except as indicated.

vi. The applicant shall ensure strict compliance of zero discharge of viable GE *Saccharomyces cerevisiae* strain SYNERXIA ® JADE ADY into the environment at any stage including storage, transportation, access, handling, packing, re-packing, distribution, sale, decontamination, and disposal etc.

vii. Applicant shall ensure that the access to the GE *Saccharomyces cerevisiae* strain SYNERXIA ® JADE ADY is restricted, only to trained and experienced persons, as recommended by IBSC. GMOs should be stored securely in the containers in a locked area until transported. This restriction on access applies to all scenarios, including situations where containers containing GE *Saccharomyces cerevisiae* strain SYNERXIA ® JADE ADY are temporarily left for collection in a loading area or are left unattended before undergoing proper decontamination.

viii. Applicant shall ensure that inventory of consignment is maintained and procedures are in place to track and account for all GMOs or the number of primary containers of GE *Saccharomyces cerevisiae* strain SYNERXIA ® JADE ADY cultures being transported to detect and prevent any loss of GE *Saccharomyces cerevisiae* strain SYNERXIA ® JADE ADY during transport. This must be implemented for all transport events, except in cases where the GE *Saccharomyces cerevisiae* strain SYNERXIA ® JADE ADY transport solely occurs within a building. Annual record should be submitted to IBSC.

ix. The packaging of *GE Saccharomyces cerevisiae* strain SYNERXIA ® JADE ADY consignment should be of high quality and robust enough to endure the typical shocks and pressures experienced during transportation, including transfers between different transport units and warehouses, and unpacking from pallets or overpacks for subsequent manual or mechanical handling. The packaging must be designed and sealed in a way that prevents

any loss of contents due to vibrations or changes in temperature, humidity, or pressure that may occur under normal transport conditions.

x. The packaging should include three essential components: a) A primary receptacle, b) a secondary packaging, and c) an outer packaging, with either the secondary or outer packaging being rigid. The primary receptacles must be securely placed within the secondary packaging to prevent breakage, puncture, or leakage during regular transportation. The secondary packaging, must be properly secured within the outer packaging using appropriate cushioning material. Even if there is any leakage from the primary receptacles, it should not compromise the integrity of the cushioning material or the outer packaging.

xi. The storage area shall be checked and maintained at regular intervals to avoid unintentional release of GE *Saccharomyces cerevisiae* strain SYNERXIA ® JADE ADY into the environment and such inspections should be recorded.

xii. For transport, "GENETICALLY MODIFIED MICROORGANISMS" shall be marked on the outer packaging, clearly visible or be reproduced on the outside of the overpack, in a manner capable of notifying any other handler of the material that the item to be transported is, or contains a GMO. Where transport is being undertaken by a service provider then the outermost container must be labelled to clearly show the name, address and contact details of the sender or its authorized person, so that the sender can be contacted in case of loss, damage or misdirection.

xiii. Applicant shall ensure that the transported GE *Saccharomyces cerevisiae* strain SYNERXIA ® JADE ADY shall be accompanied by, instructions on how to decontaminate any material in the event of unintentional release, sufficient volume of effective decontamination agent to decontaminate, appropriate protective clothing for manpower undertaking the decontamination; and supporting instruments necessary to undertake decontamination.

xiv. The transport record shall include, the name of the parent species of the GMO; number of individual containers transported and total amount (volume/weight); expiry date; the mode of transport (e.g. by hand, rail and road, road and air); the name and contact details of the transporter(s) if transport or other service providers are used; the name and contact details of the sender and recipient; date sent.

xv. All containers shall be decontaminated after transport.

xvi. In an event of any unintentional release, applicant shall be responsible for the decontamination of the site, utensils and surroundings etc.

xvii. In case of any escape, unintentional release, spill, leak, or loss of GE *Saccharomyces cerevisiae* strain SYNERXIA ® JADE ADY, including situations where consignment fail to reach the intended recipient, the applicant shall:

a. Promptly initiate efforts to locate and/or retrieve the consignment and take necessary steps to return them to containment or render them nonviable. The exposed area must be immediately decontaminated with an appropriate decontaminating agent effective against the GE *Saccharomyces cerevisiae* strain SYNERXIA ® JADE ADY ;
b. Report such incident to the IBSC within 03 days, to ensure that the IBSC is notified of the occurrence in case of unintentional release.
c. Take necessary measures to mitigate potential risks to the environment and public health, in case of unintentional release.

xviii. Applicant shall ensure to periodically train manpower engaged in the GE *Saccharomyces cerevisiae* strain SYNERXIA ® JADE ADY handling.

xix. IBSC can visit the site and take sample for monitoring the compliance.

xx. IBSC may impose other terms and conditions, as and when required, with the information to this committee.

xxi. A compliance report, along with records of storage, duly approved by IBSC, must be submitted annually to the GEAC.

xxii. The firms (other than the applicant), that intend to use the imported genetically modified SYNERXIA® JADE ADY (Active Dried Yeast) strains, will have to obtain separate approval in accordance with its extant statutory provisions.

xxiii. 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

6.3 M/s Danisco (India) Pvt. Ltd., Hyderabad, for import and marketing of GE *Saccharomyces cerevisiae*strain SYNERXIA® RUBY G2 ADY for fuel ethanol production from grain feedstocks.

The committee was informed that applicant intends to import and market GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY for fuel ethanol production from grain feedstocks SYNERXIA® RUBY G2 ADY is genetically modified for extracellular expression of glucoamylase which produces high levels of ethanol than parental strains and increase the robustness of the strain for fuel ethanol production.

The imported dried yeast SYNERXIA® RUBY G2 ADY will be used in the manufacture of fuel ethanol from grains. The byproduct DDGS will be available for use as an animal feed ingredient in line with the existing practices.

The applicant intends to import 200MT per year of active dry yeast from USA for use in India.

The Standard RARMP for Import of Genetically Engineered Organisms (GEOs)/Living Modified Organisms (LMOs) for Commercial Production as appraised by GEAC in its 153rd meeting held on 03.10.2024 was communicated to the applicant vide email dated 11.02.2025.

The applicant vide email dated 26.03.2025 submitted RARMP which was forwarded to RCGM for consideration. RARM Plan was considered in 310th meeting of RCGM held on 14.05.2025.

RCGM vide email dated 27.05.2025 have sent the recommendations of its 310th meeting dated 14.05.2025 for further consideration by GEAC.

Recommendation

Taking cognizance of the recommendations of 310th RCGM meeting, the RARMP submitted by M/s Danisco (India) Pvt. Ltd., Hyderabad, for import and marketing of GE Yeast SYNERXIA® RUBY G2 ADY for fuel ethanol production from grain feedstocks was recommended by the Committee subject to following conditions:

i. The activity must comply with the RARM plans recommended by GEAC.
ii. 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.
iii. Applicant shall ensure that the GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY 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.
iv. Applicant shall submit IBSC approved Emergency Action Plan for an event of unintentional release of GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY, before import.
v. The Applicant shall submit 16s RNA Gene Sequencing and 18s RNA Gene Sequencing Reports for the Initial five batches to detect any adventitious presence of bacteria and yeast except as indicated.
vi. The applicant shall ensure strict compliance of zero discharge of viable GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY into the environment at any stage including storage, transportation, access, handling, packing, re-packing, distribution, sale, decontamination, and disposal etc.
vii. Applicant shall ensure that the access to the GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY is restricted, only to trained and experienced persons, as recommended by IBSC. GMOs should be stored securely in the containers in a locked area until transported. This restriction

on access applies to all scenarios, including situations where containers containing GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY are temporarily left for collection in a loading area or are left unattended before undergoing proper decontamination.

viii. Applicant shall ensure that inventory of consignment is maintained and procedures are in place to track and account for all GMOs or the number of primary containers of GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY cultures being transported to detect and prevent any loss of GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY during transport. This must be implemented for all transport events, except in cases where the GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY transport solely occurs within a building. Annual record should be submitted to IBSC.

ix. The packaging of *GE Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY consignment should be of high quality and robust enough to endure the typical shocks and pressures experienced during transportation, including transfers between different transport units and warehouses, and unpacking from pallets or overpacks for subsequent manual or mechanical handling. The packaging must be designed and sealed in a way that prevents any loss of contents due to vibrations or changes in temperature, humidity, or pressure that may occur under normal transport conditions.

x. The packaging should include three essential components: a) A primary receptacle, b) a secondary packaging, and c) an outer packaging, with either the secondary or outer packaging being rigid. The primary receptacles must be securely placed within the secondary packaging to prevent breakage, puncture, or leakage during regular transportation. The secondary packaging, must be properly secured within the outer packaging using appropriate cushioning material. Even if there is any leakage from the primary receptacles, it should not compromise the integrity of the cushioning material or the outer packaging.

xi. The storage area shall be checked and maintained at regular intervals to avoid unintentional release of GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY into the environment and such inspections should be recorded.

xii. For transport, "GENETICALLY MODIFIED MICROORGANISMS" shall be marked on the outer packaging, clearly visible or be reproduced on the outside of the overpack, in a manner capable of notifying any other handler of the material that the item to be transported is, or contains a GMO. Where transport is being undertaken by a service provider then the outermost container must be labelled to clearly show the name, address and contact details of the sender or its authorized person, so that the sender can be contacted in case of loss, damage or misdirection.

xiii. Applicant shall ensure that the transported GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY shall be accompanied by, instructions on how to decontaminate any material in the event of unintentional release, sufficient volume of effective decontamination agent to decontaminate, appropriate protective clothing for manpower undertaking the decontamination; and supporting instruments necessary to undertake decontamination.

xiv. The transport record shall include, the name of the parent species of the GMO; number of individual containers transported and total amount (volume/weight); expiry date; the mode of transport (e.g. by hand, rail and road, road and air); the name and contact details of the transporter(s) if transport or other service providers are used; the name and contact details of the sender and recipient; date sent.

xv. All containers shall be decontaminated after transport.

xvi. In an event of any unintentional release, applicant shall be responsible for the decontamination of the site, utensils and surroundings etc.

xvii. In case of any escape, unintentional release, spill, leak, or loss of GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY, including situations where consignment fail to reach the intended recipient, the applicant shall:

a. Promptly initiate efforts to locate and/or retrieve the consignment and take necessary steps to return them to containment or render them nonviable. The exposed area must be immediately decontaminated with an appropriate decontaminating agent effective against the GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY ;
b. Report such incident to the IBSC within 03 days, to ensure that the IBSC is notified of the occurrence in case of unintentional release.
c. Take necessary measures to mitigate potential risks to the environment and public health, in case of unintentional release.

xviii. Applicant shall ensure to periodically train manpower engaged in the GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY handling.

xix. IBSC can visit the site and take sample for monitoring the compliance.

xx. IBSC may impose other terms and conditions, as and when required, with the information to this committee.

xxi. A compliance report, along with records of storage, duly approved by IBSC, must be submitted annually to the GEAC.

xxii. The firms (other than the applicant), that intend to use the imported genetically modified SYNERXIA® RUBY G2 ADY strains, will have to obtain separate approval in accordance with its extant statutory provisions.

xxiii. 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.

xxiv. 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

6.4 M/s Danisco (India) Pvt. Ltd., Hyderabad, for import and marketing of GE Yeast SYNERXIA® SAPPHIRE ADY for fuel ethanol production from grain feedstocks.

The applicant made a presentation before the committee and informed that they intend to import and market of GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY for fuel ethanol production from grain feedstocks. SYNERXIA® SAPPHIRE ADY is genetically modified to express glucoamylase and increase the robustness of the strain for fuel ethanol production.

The imported dried yeast SYNERXIA® SAPPHIRE ADY will be used in the manufacture of fuel ethanol from grains. The byproduct DDGS will be available for use as an animal feed ingredient in line with the existing practices.

The applicant intends to import 200MT per year of active dry yeast from USA for use in India.

The Standard RARMP for Import of Genetically Engineered Organisms (GEOs)/Living Modified Organisms (LMOs) for Commercial Production as appraised by GEAC in its 153rd GEAC meeting held on 03.10.2024 was communicated to the applicant vide email dated 11.02.2025.

The applicant vide email dated 26.03.2025 submitted RARMP which was forwarded to RCGM for consideration. RARM Plan was considered in 310th meeting of RCGM held on 14.05.2025.

RCGM vide email dated 27.05.2025 have sent the recommendations of its 310th meeting dated 14.05.2025 for further consideration by GEAC.

Recommendation

Taking cognizance of the recommendations of 310th RCGM meeting, the RARMP submitted by M/s Danisco (India) Pvt. Ltd., Hyderabad, for import and marketing of GE Yeast *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY for fuel ethanol

production from grain feedstocks was recommended by the Committee subject to following conditions:

i. The activity must comply with the RARM plans recommended by GEAC.
ii. 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.
iii. Applicant shall ensure that the GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY 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.
iv. Applicant shall submit IBSC approved Emergency Action Plan for an event of unintentional release of GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY, before import.
v. The Applicant shall submit 16s RNA Gene Sequencing and 18s RNA Gene Sequencing Reports for the Initial five batches to detect any adventitious presence of bacteria and yeast except as indicated.
vi. The applicant shall ensure strict compliance of zero discharge of viable GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY into the environment at any stage including storage, transportation, access, handling, packing, re-packing, distribution, sale, decontamination, and disposal etc.
vii. Applicant shall ensure that the access to the GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY is restricted, only to trained and experienced persons, as recommended by IBSC. GMOs should be stored securely in the containers in a locked area until transported. This restriction on access applies to all scenarios, including situations where containers containing GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY are temporarily left for collection in a loading area or are left unattended before undergoing proper decontamination.
viii. Applicant shall ensure that inventory of consignment is maintained and procedures are in place to track and account for all GMOs or the number of primary containers of GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY cultures being transported to detect and prevent any loss of GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY during transport. This must be implemented for all transport events, except in cases where the GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY transport solely occurs within a building. Annual record should be submitted to IBSC.
ix. The packaging of *GE Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY consignment should be of high quality and robust enough

to endure the typical shocks and pressures experienced during transportation, including transfers between different transport units and warehouses, and unpacking from pallets or overpacks for subsequent manual or mechanical handling. The packaging must be designed and sealed in a way that prevents any loss of contents due to vibrations or changes in temperature, humidity, or pressure that may occur under normal transport conditions.

x. The packaging should include three essential components: a) A primary receptacle, b) a secondary packaging, and c) an outer packaging, with either the secondary or outer packaging being rigid. The primary receptacles must be securely placed within the secondary packaging to prevent breakage, puncture, or leakage during regular transportation. The secondary packaging, must be properly secured within the outer packaging using appropriate cushioning material. Even if there is any leakage from the primary receptacles, it should not compromise the integrity of the cushioning material or the outer packaging.

xi. The storage area shall be checked and maintained at regular intervals to avoid unintentional release of GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY into the environment and such inspections should be recorded.

xii. For transport, "GENETICALLY MODIFIED MICROORGANISMS" shall be marked on the outer packaging, clearly visible or be reproduced on the outside of the overpack, in a manner capable of notifying any other handler of the material that the item to be transported is, or contains a GMO. Where transport is being undertaken by a service provider then the outermost container must be labelled to clearly show the name, address and contact details of the sender or its authorized person, so that the sender can be contacted in case of loss, damage or misdirection.

xiii. Applicant shall ensure that the transported GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY shall be accompanied by, instructions on how to decontaminate any material in the event of unintentional release, sufficient volume of effective decontamination agent to decontaminate, appropriate protective clothing for manpower undertaking the decontamination; and supporting instruments necessary to undertake decontamination.

xiv. The transport record shall include, the name of the parent species of the GMO; number of individual containers transported and total amount (volume/weight); expiry date; the mode of transport (e.g. by hand, rail and road, road and air); the name and contact details of the transporter(s) if transport or other service providers are used; the name and contact details of the sender and recipient; date sent.

xv. All containers shall be decontaminated after transport.

xvi. In an event of any unintentional release, applicant shall be responsible for the decontamination of the site, utensils and surroundings etc.

xvii. In case of any escape, unintentional release, spill, leak, or loss of GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY, including situations where consignment fail to reach the intended recipient, the applicant shall:

a. Promptly initiate efforts to locate and/or retrieve the consignment and take necessary steps to return them to containment or render them nonviable. The exposed area must be immediately decontaminated with an appropriate decontaminating agent effective against the GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY;
b. Report such incident to the IBSC within 03 days, to ensure that the IBSC is notified of the occurrence in case of unintentional release.
c. Take necessary measures to mitigate potential risks to the environment and public health, in case of unintentional release.

xviii. Applicant shall ensure to periodically train manpower engaged in the GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY handling.

xix. IBSC can visit the site and take sample for monitoring the compliance.

xx. IBSC may impose other terms and conditions, as and when required, with the information to this committee.

xxi. A compliance report, along with records of storage, duly approved by IBSC, must be submitted annually to the GEAC.

xxii. The firms (other than the applicant), that intend to use the imported genetically modified SYNERXIA® SAPPHIRE ADY strains, will have to obtain separate approval in accordance with its extant statutory provisions.

xxiii. 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.

xxiv. 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

7. Additional Items for consideration

7.1 Central Compliance Committee (CCC) for monitoring of Confined Field Trial (CFT) sites of GE plants

Genetically Modified Organisms (GMOs), including Genetically Modified (GM) crops, in India are governed by *"Rules for the Manufacture, Use, Import, Export and Storage of*

Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989" (Rules 1989) notified under the Environment (Protection) Act, 1986.

According to the "*Guidelines for the Monitoring of Confined Field Trials of Regulated GE Plants, 2008*," the Central Compliance Committees (CCCs) are constituted on a case-by-case basis by RCGM/GEAC and are prerequisite for monitoring/ periodic inspection of the progress and compliance of all types of CFTs of regulated GM crops.

The CCCs undertake field visits to CFT sites to ensure compliance with the terms and conditions prescribed by regulatory agencies (RCGM/ GEAC) and also to ensure that the provisions of Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated Genetically Engineered (GE) Plants, 2008 are followed in the confined field trial of regulated GM crops.

Further as per the "*Manual on Monitoring Confined Field Trials of Regulated, Genetically Engineered (GE) Plants, 2015*" released by MoEF&CC, presently, CFTs are monitored by the CCCs constituted by RCGM on recommendations of GEAC.

The current composition of CCC team includes six members:

a) Team leader,
b) Subject-specific experts,
c) Representative of GEAC,
d) Nominee of director of research of concerned state agriculture university,
e) Nominee of the state department of agriculture, and
f) Representative of RCGM.

The important stages for monitoring of CFTs of GE plants from a risk management perspective including planting, the period of crop flowering prior to seed set, harvest or trial termination, and post-harvest restriction period.

RCGM in its 265th meeting held on 23.08.2023, extensively deliberated on the requisite composition of CCC as well as the important stages for monitoring of CFTs from a risk management perspective as per extant regulatory guidelines. Moreover, RCGM in its 275th, 296th and 298th meeting held on 10.01.2024, 30.10.2024, and 27.11.2024 respectively had recommended three reforms including monitoring of CFTs (EST and BRL-I) during harvest or trial termination and post-harvest restriction period and reforms related to online monitoring and compositions of CCC.

In its 300th meeting held on 26.12.2024, RCGM recommended the following to GEAC for further considerations;

i. CCCs constituted by RCGM on recommendations of GEAC will have the following members;

A. *A Team Leader*
B. *Subject-specific expert(s)*
C. *Nominee from State Agricultural University*
D. *Nominee from State Department of Agriculture*
E. *Representative of RCGM or Representative of GRAC depending on availability*

ii. Participation of the CCC is essential for monitoring CFTs at the stage of flowering prior to seed set. For CCC visits at the stage of harvest/termination, participation of the subject-specific expert(s) is not necessary. At the stage of post-harvest restriction, the Nominee of the State Agriculture University, the Nominee of the State Department of Agriculture, and the DBT Nominee of the IBSC will conduct the monitoring

iii. GEAC may deliberate the use of technology and monitoring of trial sites through video conferencing to strengthen the monitoring of trial sites.

Further, in 154th meeting held on 17.04.2025, GEAC was of the view that the agenda 7.2 related to CCCs should be discussed in the next GEAC meeting.

Recommendation

After detailed deliberation, the committee decided to defer the agenda item.

Action: GEAC Secretariat

8. Any other Item with the permission of Chairman

8.1 Reconstitution of Expert Committee for analysis of proposal of M/s Mahyco Private Ltd., Mumbai for environmental release of Bollgard II Roundup Ready Flex (BGIITM RRFTM) cotton incorporating events MON 15985 x MON 88913

The Committee was informed that in accordance with the recommendations made by GEAC in its 145th meeting held on 27.07.2022 under Agenda Item 5.1, Expert Committee, was constituted under the Chairmanship of Dr. Sanjay Kumar Mishra, Scientist-H, Department of Biotechnology (DBT) and Co-chair, GEAC for comprehensive examination of the dossier submitted by applicant as per extant rules/regulations/ guidelines. Report of this Expert Committee was received on 01.12.2023 and was considered by GEAC in its 149th meeting held on 17.05.2023 under Agenda Item 5.1. In its 149th meeting, the Committee decided that the applicant be directed to revise/ update the dossier as per recommendations of Expert Committee and that the updated dossier be directly submitted back to Expert Committee for further evaluation/ processing of the proposal.

Further, in the 151st GEAC Meeting held on 19.12.2023, under Agenda item 8.1, the Status of work undertaken by Expert Committee was discussed. Scientific evaluation of the biosafety dossier for preparation of RARM report was undertaken by the members of Expert Committee, involving continuous engagement with the applicant, and many meetings were convened. The preparation of RARM plan is a complex task. Seeing this, the tenure of the Expert Committee was extended 3 times.
At present, the composition of the committee is as below:

1.	**Dr. Sanjay Kumar Mishra** Scientist H, Department of Biotechnology, New Delhi	Chairman
2.	**Dr. Ashok Kumar Singh** Director, Indian Agricultural Research Institute, New Delhi	Member
3.	**Dr. D. K. Yadav** ADG (Seeds), Crop Science Division, ICAR, New Delhi	Member
4.	**Dr. A. H. Prakash** Project Coordinator (Cotton Improvement) and Head, AICRP on Cotton, ICAR-Central Institute for Cotton Research, Coimbatore	Member
5.	**Dr K. Annapurna** Former Head, Division of Microbiology ICAR-Indian Agricultural Research Institute, New Delhi	Member
6.	**Dr. Nitin K. Jain** Scientist G, Department of Biotechnology, New Delhi	Member
7.	**Dr. S. J. Rahman** Professor & Univ. Head of Entomology, Prof. Jayashankar Telangana State Agri. University, Hyderabad	Member
8.	**Dr. Satish Wate** Former Director, CSIR - National Environmental Engineering Research Institute, Nagpur	Member
9.	**Dr. Madhu Dikshit** Former Director, CSIR-Central Drug Research Institute, Lucknow	Member
10.	**Director** ICAR - National Institute of Agricultural Economics and Policy Research (NIAP), New Delhi	Member
11.	**Dr. Abhilasha Singh Mathuriya** Scientist D, Ministry of Environment, Forests and Climate Change, New Delhi	Member Secretary

The Terms of Reference of the Expert Committee are given below:

a. The Committee shall function in the Ministry of Environment, Forest and Climate Change for comprehensive review of the updated dossier submitted by M/s Mahyco Private Ltd., Mumbai and for further processing of the proposal, including

preparation of Risk Assessment and Risk Management (RARM) Report, in accordance with the applicable guidelines/procedures/ SOPs.

b. The Committee shall function for a period of six months from the date of issue of this notification.
c. The Committee shall submit its recommendations to the Genetic Engineering Appraisal Committee (GEAC).
d. The Chairperson of this Committee may co-opt other members/experts, as necessary.
e. The Committee can seek the additional information, as and when required, directly from the applicant for further processing of the proposal.
f. The Committee shall maintain all classified information as confidential.
g. The non-official members of the Expert Committee will be entitled for TA/DA as per their entitlement as per SR 190 and OM dated 12.4.2017 (p.17/c) of Ministry of Finance and sitting charges of Rs.4000 per day for attending the meeting.

The Committee was informed about the superannuation of Dr. Sanjay Kumar Mishra, Scientist H, Department of Biotechnology, who was serving as the Chair of this Expert Committee. The Committee was further informed about the demise of Dr. S. J. Rahman, a member of the Committee. In light of these developments, the reconstitution of the Expert Committee is required.

Recommendations

After detailed deliberation on the progress of the work undertaken by the expert committee, GEAC recommended the reconstitution of expert committee for finalization of RARM plan for proposal of M/s Mahyco Private Ltd., Mumbai for environmental release of Bollgard II Roundup Ready Flex (BGIITM RRFTM) cotton incorporating events MON 15985 x MON 88913 with following composition:

1.	**Dr. Satish Wate** Former Director, CSIR - National Environmental Engineering Research Institute, Nagpur	Chairman
2.	**Dr. Ashok Kumar Singh** Former Director, Indian Agricultural Research Institute, New Delhi	Member
3.	**Dr. D. K. Yadav** DDG (Seeds), Crop Science Division, ICAR, New Delhi	Member
4.	**Dr. A. H. Prakash** Project Coordinator (Cotton Improvement) and Head, AICRP on Cotton, ICAR-Central Institute for Cotton Research, Coimbatore	Member
5.	**Dr K. Annapurna** Former Head, Division of Microbiology ICAR-Indian Agricultural Research Institute, New Delhi	Member

6.	**Dr. Nitin K. Jain** Scientist G, Department of Biotechnology, New Delhi	Member
7.	**Dr. Chandish Balal** Former Director, ICAR - National Bureau of Agricultural Insect Resources (NBAIR), Bangalore (**Expert from RCGM**)	Member
8.	**Dr. Madhu Dikshit** Former Director, CSIR-Central Drug Research Institute, Lucknow	Member
9.	**Director** ICAR - National Institute of Agricultural Economics and Policy Research (NIAP), New Delhi	Member
10.	**Dr. Abhilasha Singh Mathuriya** Scientist D, Ministry of Environment, Forests and Climate Change, New Delhi	Member Secretary

The Terms of Reference of the Expert Committee are given below:

a. The Committee shall function in the Ministry of Environment, Forest and Climate Change for comprehensive review of the updated dossier submitted by M/s Mahyco Private Ltd., Mumbai and for further processing of the proposal, including preparation of Risk Assessment and Risk Management (RARM) Report, in accordance with the applicable guidelines/procedures/ SOPs.
b. The Committee shall function for a period of six months from the date of issue of notification.
c. The Committee shall submit its recommendations to the Genetic Engineering Appraisal Committee (GEAC).
d. The Chairperson of this Committee may co-opt other members/experts, as necessary.
e. The Committee can seek the additional information, as and when required, directly from the applicant for further processing of the proposal.
f. The Committee shall maintain all classified information as confidential.
g. The non-official members of the Expert Committee will be entitled for TA/DA as per their entitlement as per SR 190 and OM dated 12.4.2017 (p.17/c) of Ministry of Finance and sitting charges of Rs.4000 per day for attending the meeting.

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

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	**6.**	**Dr. P.K. Dass** Department of Anatomy, LHMC & Associated Hospitals, 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	**7.**	**Dr. J.P. Singh** Plant Protection Adviser (PPA), Directorate of Plant Protection, Quarantine & Storage, NH IV, Faridabad-121001, New Delhi
3.	**Dr. Dinkar M. Salunkhe** Director, International Centre for Genetic Engineering and Biotechnology, New Delhi-110067	**8.**	**Dr. Pronab Dhar** Principal Scientist, ICAR-Indian Veterinary Research Institute (IVRI), Bareilly, Uttar Pradesh- 243122 (Representative of Dr. Triveni Dutt, Director, IVRI)
4.	**Dr. Rekha S. Singhal** Professor, Food Technology, Institute of Chemical Technology, Mumbai- 400 019	**9.**	**Dr. Alka Rao** Advisor (Science & Standards & Regulation), FSSAI
5.	**Dr. D.K. Yadav** DDG, (Crop Science) Indian Council of Agricultural Research, Krishi Bhawan, New Delhi-110001	**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 Paryavaran Bhawan, Jorbhagh road, Aliganj, New Delhi – 110003		
Members who did not participate			
1.	**Dr. Satish Wate**	**7.**	**Dr. P. Suprasanna** Scientific Officer H (Retd.),

	Former Director, CSIR-National Environmental Engineering Research Institute, Nagpur- 440020		Biosciences group, BARC, Mumbai-400 085
2.	**Dr. H. K. Sharma** Director, National Institute of Technology, Agartala, Tripura- 799 046	**8.**	**Ms. Shruti Singh** Joint Secretary, IPR, Department for Promotion of Industry and Inter nal Trade, Udyog Bhawan, New De lhi 110011
3.	**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 Famil y Welfare, Ramalingaswami Bhavan, Ansari Nagar, New Delhi—110 029
4.	**Dr. J. P. Shukla** Scientist, CSIR-Advanced Materials and Process Research Institute, Bhopal- 462 026	**10.**	**Dr. Sanjeev Khosla** Director, CSIR- Institute of Microbial Technology, Chandigarh- 160 036
5.	**Dr. U. S. N. Murthy** Director, National Institute of Pharmaceutical Education and Research, Guwahati- 781101	**11.**	**Shri V.P. Yadav** Scientist F, Central Pollution Control Board, Parivesh Bhawan, East Arjun Nagar, Delhi-110 032
6.	**Dr. Chaitanya Joshi** Director, Gujarat Biotechnology Research Centre, Gandhinagar, Gujarat- 382 011	**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)