MINUTES OF THE 157TH MEETING OF GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 10.10.2025

The 157th meeting of the Genetic Engineering Appraisal Committee (GEAC) of the Ministry of Environment, Forest and Climate Change (MoEF&CC) was held on 10.10.2025 in hybrid mode at Indus Conference Hall, Ground floor, Jal Block, Indira Paryavaran Bhawan, New Delhi. The meeting was chaired by Shri Amandeep Garg, Additional Secretary, MoEF&CC, Chairperson GEAC. The list of participants is placed at **Annexure 1**.

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

Action: GEAC Secretariat

Agenda Item No. 1: Leave of absence

Members, Dr. U. S. N. Murthy, Dr. P. Suprasanna, Dr. Sanjeev Khosla, Dr. Rekha S Singhal, Dr. J.P Shukla and Dr. J.P Singh communicated their inability to attend the 157th meeting of GEAC. Further, Dr. Vinay K Nandicoori, Ms. Shruti Singh, Dr. Geeta Jotwani, Shri V.P. Yadav, Dr. Rajeev Singh Raghuvanshi 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 156th GEAC meeting

Minutes of the 156th 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 156th GEAC meeting.

Action: GEAC Secretariat

Agenda Item No. 3: Action taken report on the decisions taken in the 156th GEAC meeting

Member Secretary, GEAC briefed about the action taken on the decisions at the 156th meeting of GEAC. The committee was informed that letters communicating GEAC decisions had been issued to applicants, and all other concerned as required.

Decision

The Committee noted the actions taken by the Secretariat.

Action: GEAC Secretariat

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

4.1 M/s University of Delhi South Campus, Delhi to conduct Event Selection Trial (EST) under confined field conditions of five GE *Brassica juncea cv.* Varuna lines (*SynJ 16, SynJ 22, Photo 32, Photo 45 and Photo 62*) expressing *cp4epsps* (5-enolpyruvylshikimate 3-phosphate synthase) and *als* (Acetolactate synthase) genes for glyphosate herbicide resistance at Delhi University Research Farm, Bawana during 2025-2026.

The applicant intends to conduct Event Selection Trial (EST) under confined field conditions of five GE *Brassica juncea cv.* Varuna lines (*Syn.J 16, SynJ 22, Photo 32, Photo 45 and Photo 62*) expressing *cp4epsps* (5-enolpyruvylshikimate 3-phosphate synthase) and als (Acetolactate synthase) genes for glyphosate herbicide resistance at Delhi University Research Farm, Bawana during 2025-2026.

The application was considered by RCGM in its 311th meeting held on 28.05.2025 where in the RCGM recommended the application to conduct above-mentioned event selection trial under confined field conditions during 2025-2026 to GEAC for further consideration. RCGM vide email 09.06.2025 have sent the recommendations of its 311th meeting and application of dossier to GEAC.

Recommendation

Based on the recommendation given in 311th RCGM meeting, the proposal of M/s University of Delhi South Campus, Delhi to conduct Event Selection Trial (EST) under confined field conditions of five GE *Brassica juncea cv.* Varuna lines (*SynJ 16, SynJ 22, Photo 32, Photo 45 and Photo 62*) expressing *cp4epsps* (5-enolpyruvylshikimate 3-phosphate synthase) and *als* (Acetolactate synthase) genes for glyphosate herbicide resistance at Delhi University Research Farm, Bawana during 2025-2026 was recommended by the Committee. The recommendation is subject to following conditions:

i. Applicant shall perform the trials as per extant rules/guidelines/regulations and adhere with the recommendations of 311th RCGM Meeting, recommendations and/or conditions stated in RCGM Letter dated 06.06.2025. Further, the trials should be conducted at insect specific hotspot in the trial sites that are appropriate to evaluate the introduced insect resistant trait in the GE plant.
ii. The applicant shall share details of the trial site as required under part G of the Guidelines and SOPs for Confined Field Trials of regulated GE plants, 2008 including ownership of trial site.
iii. The applicant shall share information regarding confirmed availability of isolation distance, land use and its ownership, before start of the trial.
iv. The applicant shall share information regarding name of the trial-in charge/lead scientist responsible for each trial, as well as expected date of sowing, before start of the trial.

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

Action: GEAC & RCGM Secretariat

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

5.1 M/s BCL Industries Pvt. Ltd, Punjab for commercial production of ethanol using GE *Saccharomyces cerevisiae* strain M24926

The committee was informed that the application submitted by M/s BCL Industries Pvt. Ltd, Punjab for commercial production of ethanol using GE *Saccharomyces cerevisiae* strain M24926 was previously considered by GEAC in its 152nd meeting held on 29.07.2024 under Agenda Item 5.3 wherein, the committee recommended the applicant to prepare and/ or align their respective RARMP's in accordance with the standard Risk Assessment & Risk Management Plan (RARMP) and submit their revised proposals to RCGM for consideration.

The applicant intends to produce 72 million liters per annum of ethanol for gasoline blending at Bathinda, Punjab using GE *Saccharomyces cerevisiae* strain M24926 (Brand Name: Fermboost). The *S. cerevisiae* strain M24926 has been genetically modified to introduce genes encoding for glucoamylase and trehalase enzymes, enabling efficient ethanol production. It was informed that the supplier of *S. cerevisiae* strain M24926 will be M/s Aaditya Finechem Pvt. Ltd, Jaipur.

GEAC in its 153rd GEAC meeting held on 03.10.2024 appraised the Standard Risk Assessment and Risk Management (RARM) Plan for Environmental Safety for Undertaking Commercial Production of Ethanol Using Genetically Engineered Organisms (GEOs)/Living Modified Organisms (LMOs). Letter communicating the Standard RARMP was sent to applicant vide letter dated 18.10.2024. The applicant vide email dated 12.07.2025 have submitted the RARMP, which was forwarded to RCGM for consideration.

The committee was apprised that the RARMP submitted by M/s BCL Industries Pvt. Ltd, Punjab was considered and recommended by RCGM in its 316th meeting dated 20.08.2025. RCGM vide email dated 09.09.2025 have sent the recommendations of its 316th meeting for further consideration by GEAC.

Recommendation

Based on the recommendations of 316th RCGM meeting and the RARMP recommended by RCGM, the proposal submitted by M/s BCL Industries Pvt. Ltd, Punjab for commercial production of 72 million liters per annum of ethanol for gasoline blending at Bathinda, Punjab using GE *Saccharomyces cerevisiae* strain M24926 was recommended by the Committee subject to following conditions:

i. The activity must adhere to the plans proposed in the application and activity must comply with the RARM plans recommended by GEAC.
ii. Applicant shall ensure that the GE *Saccharomyces cerevisiae* strain M24926 is used for the intended application as indicated. In case of different use, except as indicated in the application, applicant shall take separate approval from GEAC.
iii. The 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 M24926 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

5.2 M/s OM Sons Marketing Pvt. Ltd, Punjab for commercial production of ethanol using GE *Saccharomyces cerevisiae* strain M24926

The committee was informed that the application submitted by M/s OM Sons Marketing Pvt. Ltd, Punjab for commercial production of ethanol using GE *Saccharomyces cerevisiae* strain M24926 was previously considered by GEAC in its 152nd meeting held on 29.07.2024 under Agenda Item 5.3 wherein, the committee recommended the applicant to prepare and/ or align their respective RARMP's in accordance with the standard Risk Assessment & Risk Management Plan (RARMP) and submit their revised proposals to RCGM for consideration.

The applicant intends to produce 61 million liters per annum of ethanol for gasoline blending at Bathinda, Punjab using GE *Saccharomyces cerevisiae* strain M24926 (Brand Name: Fermboost). The *S. cerevisiae* strain M24926 has been genetically modified to introduce genes encoding for glucoamylase and trehalase enzymes, enabling efficient ethanol production. It was informed that the supplier of *S. cerevisiae* strain M24926 will be M/s Aaditya Finechem Pvt. Ltd, Jaipur.

GEAC in its 153rd GEAC meeting held on 03.10.2024 appraised the Standard Risk Assessment and Risk Management (RARM) Plan for Environmental Safety for Undertaking Commercial Production of Ethanol Using Genetically Engineered Organisms (GEOs)/Living Modified Organisms (LMOs). Letter communicating the Standard RARMP was sent to applicant vide letter dated 18.10.2024. The applicant vide email dated 14.07.2025 have submitted the RARMP, which was forwarded to RCGM for consideration.

The committee was apprised that the RARMP submitted by M/s OM Sons Marketing Pvt. Ltd, Punjab was considered by RCGM in its 316th meeting dated 20.08.2025. RCGM vide email dated 09.09.2025 have sent the recommendations of its 316th meeting for further consideration by GEAC.

<u>Recommendation</u>

Committee deliberated on the proposal. Based on the recommendations of 316th RCGM meeting and the RARMP recommended by RCGM, the proposal submitted by M/s OM Sons Marketing Pvt. Ltd, Punjab for commercial production of 61 million liters per annum ethanol using GE *Saccharomyces cerevisiae* strain M24926 for gasoline blending at Bathinda, Punjab was recommended by the Committee subject to following conditions:

i. The activity must adhere to the plans proposed in the application and activity must comply with the RARM plans recommended by GEAC.
ii. Applicant shall ensure that the GE *Saccharomyces cerevisiae* strain M24926 is used for the intended application as indicated. In case of different use,

except as indicated in the application, applicant shall take separate approval from GEAC.

iii. The 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 M24926 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

5.3 M/s Pancarbo Greenfuels Pvt. Ltd, Punjab for commercial production of ethanol using GE *Saccharomyces cerevisiae* strain M24926

The committee was informed that the application submitted by M/s Pancarbo Greenfuels Pvt. Ltd, Punjab for commercial production of ethanol using GE *Saccharomyces cerevisiae* strain M24926 was previously considered by GEAC in its 152nd meeting held on 29.07.2024 under Agenda Item 5.3 wherein, the committee recommended the applicant to prepare and/ or align their respective RARMP's in accordance with the standard Risk Assessment & Risk Management Plan (RARMP) and submit their revised proposals to RCGM for consideration.

The applicant intends to produce 53 million liters per annum of ethanol for gasoline blending using GE *Saccharomyces cerevisiae* strain M24926 (Brand Name: Fermboost) at Bathinda, Punjab. The *S. cerevisiae* strain M24926 has been genetically modified to introduce genes encoding for glucoamylase and trehalase enzymes, enabling efficient ethanol production. It was informed that the supplier of *S. cerevisiae* strain M24926 will be M/s Aaditya Finechem Pvt. Ltd, Jaipur.

GEAC in its 153rd GEAC meeting held on 03.10.2024 appraised the Standard Risk Assessment and Risk Management (RARM) Plan for Environmental Safety for Undertaking Commercial Production of Ethanol Using Genetically Engineered Organisms (GEOs)/Living Modified Organisms (LMOs). Letter communicating the Standard RARMP was sent to applicant vide letter dated 18.10.2024. The applicant vide email dated 05.07.2025 have submitted the RARMP, which was forwarded to RCGM for consideration.

The committee was apprised that the RARMP submitted by M/s Pancarbo Greenfuels Pvt. Ltd, Punjab was considered by RCGM in its 316th meeting dated 20.08.2025. RCGM vide email dated 09.09.2025 have sent the recommendations of its 316th meeting for further consideration by GEAC.

Recommendation

Taking cognizance of the recommendations of 316th RCGM meeting and the RARMP recommended by RCGM, the proposal submitted by M/s Pancarbo Greenfuels Pvt. Ltd, Punjab for commercial production of 53 million liters per annum of ethanol for gasoline blending using GE *Saccharomyces cerevisiae* strain M24926 at Bathinda, Punjab was recommended by the Committee subject to following conditions:

i. The activity must adhere to the plans proposed in the application and activity must comply with the RARM plans recommended by GEAC.
ii. Applicant shall ensure that the GE *Saccharomyces cerevisiae* strain M24926 is used for the intended application as indicated. In case of different use, except as indicated in the application, applicant shall take separate approval from GEAC.
iii. The 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 M24926 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

5.4 M/s Globus Spirits Ltd, West Bengal for commercial production of ethanol using GE *Saccharomyces cerevisiae* strain MeJi797- Innova Force ADY

The committee was informed that the applicant submitted an application dated 07.01.2025 for commercial production of 66000KL per annum of ethanol using GE *Saccharomyces cerevisiae* strain MeJi797 (*amgPS* gene, *amyJA126PE096* gene) in fermentation facility at West Bengal Plant. The applicant intends to use the ethanol for biofuel purpose.

The committee was informed that the supplier of GE *Saccharomyces cerevisiae* strain MeJi797 (*amgPS* gene, *amyJA126PE096* gene) will be M/s Novozymes South Asia Pvt. Ltd., Bangalore.

GEAC in its 153rd GEAC meeting held on 03.10.2024 appraised the Standard Risk Assessment and Risk Management (RARM) Plan for Environmental Safety for Undertaking Commercial Production of Ethanol Using Genetically Engineered Organisms (GEOs)/Living Modified Organisms (LMOs). Accordingly, Applicant vide email dated 10.01.2025 was directed to submit the Standard RARMP. The applicant vide email dated 29.01.2025 have submitted the RARMP, which was forwarded to RCGM for consideration.

The RARMP submitted by M/s Globus Spirits Ltd, West Bengal was considered by RCGM in its 314th and 316th meeting dated 09.07.2025 and 20.08.2025 respectively. RCGM vide email dated 09.09.2025 have sent the recommendations of its 314th and 316th meeting for further consideration by GEAC.

Recommendation

Based on the recommendations of 316th RCGM meeting and the RARMP recommended by RCGM, the proposal submitted by M/s Globus Spirits Ltd, West Bengal for commercial production of 66000KL per annum of ethanol using GE *Saccharomyces cerevisiae* strain MeJi797- Innova Force ADY for biofuel purpose at West Bengal 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 MeJi797 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 MeJi797 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.

viii. 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 Novozymes South Asia Pvt. Ltd, Bangalore for import, storage, transportation and marketing of GE active dried yeast strain Innova Apex ADY for ethanol production.

The committee was informed that the application submitted by M/s Novozymes South Asia Pvt. Ltd, Bangalore for import, storage, transportation and marketing of GE active dried yeast strain Innova Apex ADY for ethanol production was previously considered by GEAC in its 152nd meeting held on 29.07.2024 under Agenda Item 6.4.

The applicants intends to import 100 tonnes per annum of GE Innova Apex ADY (strain S1077-H06) active dried yeast, from USA.

The committee in its 152nd GEAC meeting recommended that upon appraisal of standard RARMP by GEAC, the GEAC secretariat shall provide the applicant with the standard RARMP and further directed the applicant to prepare and/ or align their respective RARMP in accordance with the standard RARMP and submit their revised proposals for all three strains of GE yeast [namely, Innova Apex (strain S1077-H06), Cellerity S 1.0 (CIBTS1260-J132-F3) and strain MeJi797 (amgPS gene, amyJA126PE096)] to RCGM for consideration.

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. The applicant vide email dated 26.11.2024 submitted the RARMP to RCGM.

The committee was apprised that the RARMP submitted by M/s Novozymes South Asia Pvt. Ltd, Bangalore was considered by RCGM in its 299th, 314th and 316th meeting dated 11.12.2024, 09.07.2025 and 20.08.2025 respectively and recommended RARMP for import of 100 tonnes per annum. RCGM vide email dated 09.09.2025 have sent the recommendations of its 299th, 314th and 316th meeting for further consideration by GEAC.

Recommendation

Taking cognizance of the recommendations of 316th RCGM meeting, committee recommended the proposal of M/s Novozymes South Asia Pvt. Ltd, Bangalore for import of 100 tonnes per annum GE Innova Apex ADY (strain S1077-H06) from USA and its distribution for ethanol production 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 Innova Apex ADY (strain S1077-H06) 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 Innova Apex ADY (strain S1077-H06), 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 Innova Apex ADY (strain S1077-H06) 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 Innova Apex ADY (strain S1077-H06) 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 Innova Apex ADY (strain S1077-H06) 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 Innova Apex ADY (strain S1077-H06) cultures being transported to detect and prevent any loss of GE Innova Apex ADY (strain S1077-H06) during transport. This must be implemented for all transport events, except in cases where the GE Innova Apex ADY (strain S1077-H06) transport solely occurs within a building. Annual record should be submitted to IBSC.
ix. The packaging of GE Innova Apex ADY (strain S1077-H06) 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 Innova Apex ADY (strain S1077-H06) 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 Innova Apex ADY (strain S1077-H06) 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 Innova Apex ADY (strain S1077-H06), 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 Innova Apex ADY (strain S1077-H06);

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 Innova Apex ADY (strain S1077-H06) 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 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

6.2 M/s Novozymes South Asia Pvt. Ltd., Bangalore for import and commercialization of *S. cerevisiae* strain MeJi797 (amgPS gene amyJA126PE096 gene) for ethanol production

The committee was informed that the applicant intends to import and market genetically modified *S. cerevisiae* strain MeJi797 (amgPS gene, amyJA126PE096 gene) for ethanol production.

The applicants intends to import 100 tonnes, per annum, of *S. cerevisiae* strain MeJi797, from USA.

The application was initially recommended by GEAC in its 144th meeting held on 22.02.2022 under Agenda Item 5.7. Accordingly, permit letter dated 11.04.2022 was issued after the approval of Competent Authority allowing for import of 1000 Kgs of *S. cerevisiae* strain MeJi797 per annum from USA, as per quantity requested then.

GEAC in its 151st meeting held on 19.12.2023 under Agenda Item 6.1 considered the request made by applicant to increase the quantity of import of *S. cerevisiae* strain MeJi797 from 1000 Kgs to 2000 metric ton (2,000,000 Kgs) per annum for its marketing for ethanol production wherein committee recommended the following;

i. *The applicant was directed to submit a draft RARMP in this regard, for consideration of RCGM.*

ii. *In respect of earlier permit granted vide letter dated 11.04.2022 in accordance with the recommendations of 144th GEAC for import of 1000 Kgs of S. cerevisiae strain MeJi797, the applicant has been directed to provide a detailed plan of marketing and distribution of S. cerevisiae strain MeJi797 being imported. This shall include details of present and prospective tie-ups with buyers/ purchasers of imported S. cerevisiae strain for the quantum of utilization per annum.*

iii. *Further, the applicant has been directed to provide details of stored quantity and supplied quantity (to buyers/ purchasers) of S. cerevisiae strain MeJi797 that is imported, per annum, as per the permit letter dated 11.04.2022.*

Further, GEAC in its 152nd meeting held on 29.07.2024 under Agenda item 6.4 while deliberating another application regarding import submitted by M/s Novozymes South Asia Pvt. Ltd., Bangalore, the committee directed the applicant to provide a detailed plan of marketing & distribution as well as details of stored quantity and supplied quantity of *S. cerevisiae* strain MeJi797 in accordance with the recommendations in it's 151st meeting. The applicant vide email dated 10.09.2024 submitted the response regarding Plan of marketing & distribution, storage, and supplied quantity of strain *S. cerevisiae* strain MeJi797.

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. The applicant vide email dated 26.11.2024 submitted the RARMP to RCGM.

The committee was apprised that the RARMP submitted by M/s Novozymes South Asia Pvt. Ltd, Bangalore was considered by RCGM in its 299th, 314th and 316th meeting dated 11.12.2024, 09.07.2025 and 20.08.2025 respectively and recommended RARMP for import of 100 tonnes per annum. RCGM vide email dated 09.09.2025 have sent the recommendations of its 299th, 314th and 316th meeting for further consideration by GEAC.

<u>Recommendation</u>

Taking cognizance of the recommendations of 316th RCGM meeting, committee recommended the proposal of M/s Novozymes South Asia Pvt. Ltd, Bangalore for import of 100 tonnes per annum *Saccharomyces cerevisiae* strain MeJi797 from USA and its distribution for ethanol production 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 *Saccharomyces cerevisiae* strain MeJi797 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 *Saccharomyces cerevisiae* strain MeJi797, 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 *Saccharomyces cerevisiae* strain MeJi797 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 *Saccharomyces cerevisiae* strain MeJi797 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 *Saccharomyces cerevisiae* strain MeJi797 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 *Saccharomyces cerevisiae* strain MeJi797 cultures being transported to detect and prevent any loss of *Saccharomyces cerevisiae* strain MeJi797 during transport. This must be implemented for all transport events, except in cases where the *Saccharomyces cerevisiae* strain MeJi797 transport solely occurs within a building. Annual record should be submitted to IBSC.

ix. The packaging of *Saccharomyces cerevisiae* strain MeJi797 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 *Saccharomyces cerevisiae* strain MeJi797 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 *Saccharomyces cerevisiae* strain MeJi797 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 *Saccharomyces cerevisiae* strain MeJi797, 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 *Saccharomyces cerevisiae* strain MeJi797;
  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 *Saccharomyces cerevisiae* strain MeJi797 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 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 Praj Industries Ltd, Pune for import of GE *Saccharomyces cerevisiae* strain CelluX™4 for ethanol production

The committee was informed that the application submitted by M/s Praj Industries Ltd, Pune for import of GE *Saccharomyces cerevisae* strain CelluX™4 for ethanol production was previously considered in 152nd GEAC held on 29.07.2024 under Agenda Item 6.5, wherein the committee directed the applicant to prepare and/ or align their respective RARMP in accordance with the standard RARMP and submit their revised proposal to RCGM for consideration.

The applicant intends to import 10 MT, per annum, of GM yeast CelluX™4 Active dry yeast from M/s Leaf, USA and supply it to M/s Bharat Petroleum Corporation Limited (BPCL) 2G ethanol plant located in Bargarh, Odisha. The modified strain CelluX 4 is able to ferment hexose sugars and the pentose sugar D-xylose into ethanol in lignocellulose hydrolysates.

GEAC in its 153rd GEAC meeting held on 03.10.2024 appraised Standard Risk Assessment and Risk Management (RARM) Plan for Import of Genetically Engineered Organisms (GEOs)/Living Modified Organisms (LMOs) for Commercial Production. Letter communicating the Standard RARMP was sent to applicant vide letter dated 18.10.2024.

Applicant vide email dated 14.11.2024 have submitted the Standard RARM which was forwarded to RCGM for consideration. RARM plan was considered in 298th and 302nd meetings of RCGM held on 27.11.2024 and 22.01.2025, respectively. RCGM shared the recommendations to GEAC via email dated 07.02.2025 for further consideration.

The application was then considered by GEAC in its 154th meeting held on 17.04.2025 under Agenda Item 6.7. During deliberations, it was mentioned that the documents were examined by GEAC secretariat and it was observed that information regarding Standard Operating Procedures (SOPs) for corrective actions in case of spillage; An emergency plan for post accidental spillage including potential impact of spills into water bodies (e.g., ponds, lakes); a detailed on-site emergency plan for cleaning of spillages are missing.

The committee in its 154th GEAC meeting recommended the applicant to submit below mentioned missing information from the RARM Plan to the RCGM:

i. Standard Operating Procedures (SOPs) for corrective actions in case of spillage.
ii. An emergency plan for post-accidental spillage including potential impact of spills into water bodies.
iii. A detailed on-site emergency plan for cleaning of spillages.

Applicant vide email dated 26.05.2025 submitted the revised RARMP along with additional documents which was forwarded to RCGM for consideration.

The committee was apprised that the RARMP submitted by M/s Praj Industries Ltd, Pune was considered by RCGM in its 312th and 314th meeting dated 11.06.2025 and 09.07.2025 respectively. RCGM vide email dated 05.08.2025 have sent the recommendations of its 312th and 314th meeting for further consideration by GEAC.

Recommendation

The Committee deliberated on the RARMP submitted by the applicant in accordance with recommendations of 152nd GEAC meeting and recommended by RCGM. Taking cognizance of the recommendations of 312th and 314th RCGM meeting, committee recommended the proposal of M/s Praj Industries Ltd, Pune for import of 10 MT per annum *Saccharomyces cerevisiae* strain CelluX™4 from USA and its distribution for ethanol production 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 *Saccharomyces cerevisiae* strain CelluX™4 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 *Saccharomyces cerevisiae* strain CelluX™4, 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 *Saccharomyces cerevisiae* strain CelluX™4 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 *Saccharomyces cerevisiae* strain CelluX™4 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 *Saccharomyces cerevisiae* strain CelluX™4 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 *Saccharomyces cerevisiae* strain CelluX™4 cultures being transported to detect and prevent any loss of *Saccharomyces cerevisiae* strain CelluX™4 during transport. This must be implemented for all transport events, except in cases where the *Saccharomyces cerevisiae* strain CelluX™4 transport solely occurs within a building. Annual record should be submitted to IBSC.

ix. The packaging of *Saccharomyces cerevisiae* strain CelluX™4 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 *Saccharomyces cerevisiae* strain CelluX™4 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 *Saccharomyces cerevisiae* strain CelluX™4 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 *Saccharomyces cerevisiae* strain CelluX™4, 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 *Saccharomyces cerevisiae* strain CelluX™4;
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 *Saccharomyces cerevisiae* strain CelluX™4 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 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. 7: Additional Items for consideration

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

The committee was informed that the proposal submitted by M/s Bayer Crop Science Limited, Gurugram, Haryana for conduct of BRL-II confined field trials of insect resistance transgenic maize (Zea mays L.) Event MON89034 containing *cry1A105* and *cry2Ab2* gene was considered by GEAC in its 155th meeting (09.06.2025), under Agenda Item No. 4.2, wherein committee recommended the application for BRL-II trial at PAU, Ludhiana during the Kharif season 2025.

In accordance with the recommendations of 155th GEAC, Central Compliance Committee (CCC) was constituted vide this Ministry's OM dated 11.09.2025 and further revised on 15.09.2025 with the following composition;

1	**Dr SN Sudhakara Babu** Former Principal Scientist, ICAR-Indian Institute of Oilseeds Research, Hyderabad	Team Leader
2	**Dr Bhupender Kumar** Sr. Scientist ICAR- Indian Institute of Maize Research, Ludhiana	Member
3	**Dr. S. Subramanian,** Principal Scientist, Division of Entomology, ICAR – Indian Agricultural Research Institute, New Delhi	Member
4	**Dr. Nithin K Jain,** Scientist 'G', Department of Biotechnology Representative of RCGM, DBT	Member
5	Nominee of Director of Research of concerned State Agriculture University (PAU, Ludhiana)	Member
6	Nominee of the concerned State Department of Agriculture, Punjab	Member
7	**Dr. Abhilasha Singh Mathuriya** Scientist D, CS-III Division, MoEFCC	Member Covenor

CCC visit was conducted on 18.09.2025 and the committee made the following observations;

"Feedback on the SOP maintained

- *All SOPs for conduct of trial in field and documentation was satisfactory.*
- *Border trap rows were of African tall variety –Flowering is synchronous*

Recommended corrective actions

- *Suggested to erect bird net for the trial area.*

Any other pertinent details/ observations

- *The trial is conducted with one replication in strip block design.*
- *Representative of nominees of State Dept of Agriculture, Director of Res, PAU also participated along with other CCC members".*

Recommendation

The committee noted the observations of the CCC visit and the report submitted by Central Compliance Committee. As per the CCC's recommended corrective action, applicant is advised to comply erection of bird net for the trial site and reply with photographs.

Committee was of view that the trial must be conducted with triplicate replication at all other proposed trial locations to ensure generation of robust and scientifically/ statistically valid data.

Action: GEAC Secretariat

Agenda Item No. 8: Information Items

8.1 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 proposal submitted by M/s Bayer Crop Science Limited, Gurugram, Haryana to conduct BRL-II confined field trials of herbicide tolerant transgenic maize (Event NK603) carrying *cp4epsps* gene was previously considered by GEAC in its 155th meeting held on 09.06.2025, under Agenda Item 4.1, wherein committee recommended the proposal subject to conditions at PAU, Ludhiana for the Kharif season 2025. Accordingly, GEAC secretariat issued permit letter dated 26.06.2025.

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

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

Decision

The Committee noted the actions taken by the Secretariat.

8.2 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 proposal submitted by M/s Bayer Crop Science Limited, Gurugram, Haryana for conduct of BRL-II confined field trials of insect resistance transgenic maize (Zea mays L.) Event MON89034 containing *cry1A105* and *cry2Ab2* gene was considered by GEAC in its 155th meeting (09.06.2025), Ag No. 4.2, wherein committee recommended the application for BRL-II trial at PAU, Ludhiana during the Kharif season 2025.

Applicant vide email dated 03.07.2025 submitted NOC dated 19.06.2025 issued by Government of Haryana. Further, applicant vide email dated 30.07.2025 submitted the NOC dated 29.07.2025 issued by Government of Andhra Pradesh and sought permission for conduct of BRL-II trials.

Taking cognizance of interim procedures adopted in 154th GEAC meeting under Agenda Item 8.1, decisions taken by GEAC in its 155th meeting and concurrence received from Government of Haryana and Government of Andhra Pradesh, GEAC secretariat issued permit letters dated 29.09.2025 for conduct of BRL-II trials at (i) CCS, Haryana Agricultural University (HAU) Hisar/Regional Research Station Karnal and (ii) ANGRAU, Lam, Guntur during the Kharif season 2025 subject to conditions as stipulated in the 155th GEAC under Agenda item No. 4.2.

Decision

The Committee noted the actions taken by the Secretariat.

8.3 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 RIRC304 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*).

The proposal by M/s. Rasi Seeds Pvt. Ltd., Salem, Tamil Nadu was previously considered by GEAC in its 155th meeting held on 09.06.2025 under Agenda Item 4.3, wherein committee recommended the 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 subject to conditions:

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

Accordingly, email was sent to RCGM on 23.06.2025 to issue permit letter. Applicant vide email dated 24.06.2025 submitted the NOC dated 12.06.2025 from Government of Haryana. Further, applicant vide email dated 24.06.2025 submitted the NOC dated 21.06.2025 received from Government of Andhra Pradesh.

Taking cognizance of interim procedures adopted in 154th GEAC meeting under Agenda Item 8.1, decisions made by GEAC in its 155th meeting and concurrence obtained from Government of Haryana and Government of Andhra Pradesh, GEAC secretariat communicated RCGM to issue permit letter vide email dated 18.07.2025. Accordingly, RCGM vide email dated 23.07.2025 issued addendum to the permit letter issued earlier for following three trial locations;

i. CCS HAU, Hisar, Haryana
ii. Kurnul, Andhra Pradesh
iii. ANGRAU, LAM, Guntur, Andhra Pradesh

Decision

The Committee noted the actions taken by the Secretariat.

The meeting ended with a vote of thanks to the Chair, Co-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	7.	**Dr. Chaitanya Joshi** Director, Gujarat Biotechnology Research Centre, Gandhinagar, Gujarat- 382 011
2.	**Dr. Nitin K. Jain** Scientist–G and Member Secretary RCGM, Department of Biotechnology, C.G.O Complex, Lodhi Road, New Delhi-110003	8.	**Dr. D.K. Yadav** DDG, (Crop Science) Indian Council of Agricultural Research, Krishi Bhawan, New Delhi-110001
3.	**Sh. Raghu Kumar Kodali** Scientist G, MoEFCC MoEFCC, Indira Paryavaran Bhawan, Jorbagh road, Aliganj, New Delhi- 110003	9.	**Dr. P.K. Dass** Department of Anatomy, LHMC & Assoc iated Hospitals, New Delhi- 110001
4.	**Dr. Satish Wate** Former Director, CSIR-National E nvironmental Engineering Resear ch Institute, Nagpur- 440020	10.	**Dr. Pronab Dhar** Principal Scientist, ICAR-Indian Veterin ary Research Institute (IVRI), Bareilly, U ttar Pradesh- 243122 (Representative of Dr. Triveni Dutt, Director, IVRI)
5.	**Dr. H. K. Sharma** Director, National Institute of Technology, Agartala, Tripura- 799 046	11.	**Dr. Alka Rao** Advisor (Science & Standards & Regulation), FSSAI
6.	**Dr. Dinkar M. Salunkhe** Director, International Centre for Genetic Engineering and Biotechnology, New Delhi-110067	12.	**Dr. Abhilasha Singh Mathuriya** Member Secretary, Scientist D, CS-III Division, Ministry of Environment, Forest and Climate Change, Jorbagh, New Delhi-110003
Officer from the Ministry			
1.	**Ms. Jaspreet Kaur** Deputy Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jorbhagh road, Aliganj, New Delhi – 110003		
Special Invitee			
1.	**Dr SN Sudhakara Babu**		

	Former Principal Scientist, ICAR-Indian Institute of Oilseeds Research, Hyderabad		
Members who did not participate			
1.	**Dr. Vinay K. Nandicoori** Director, CSIR-Centre for Cellular & Molecular Biology, Hyderabad - 500 007	**7.**	**Dr. Geeta Jotwani** Scientist G, Indian Council of Medical Research (ICMR), Ministry of Health and Family Welfare, Ramalingaswami Bhavan, Ansari Nagar, New Delhi—110 029
2.	**Dr. U. S. N. Murthy** Director, National Institute of Pharmaceutical Education and Research, Guwahati- 781101	**8.**	**Dr. Sanjeev Khosla** Director, CSIR- Institute of Microbial Technology, Chandigarh- 160 036
3.	**Dr. J. P. Shukla** Scientist, CSIR-Advanced Materials and Process Research Institute, Bhopal- 462 026	**9.**	**Dr. J.P. Singh** Plant Protection Adviser (PPA), Directorate of Plant Protection, Quarantine & Storage, NH IV, Faridabad-121001, New Delhi
4.	**Dr. Rekha S. Singhal** Professor, Food Technology, Institute of Chemical Technology, Mumbai- 400 019	**10.**	**Shri V.P. Yadav** Scientist F, Central Pollution Control Board, Parivesh Bhawan, East Arjun Nagar, Delhi-110 032
5.	**Dr. P. Suprasanna** Scientific Officer H (Retd.), Biosciences group, BARC, Mumbai-400 085	**11.**	**Dr. Rajeev Singh Raghuvanshi** Drugs Controller General of India Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, FDA Bhavan, ITO, Kotla Road, New Delhi -110002
6.	**Ms. Shruti Singh** Joint Secretary, IPR, Department for Promotion of Industry and Internal Trade, Udyog Bhawan, New Delhi 110011		

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