MINUTES OF THE 159TH MEETING OF GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 20.03.2026

The 159th meeting of the Genetic Engineering Appraisal Committee (GEAC) of the Ministry of Environment, Forest and Climate Change (MoEF&CC) was held on 20.03.2026 in hybrid mode at Teesta Conference 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

Eleven Members, Dr. H. K. Sharma, Dr. Vinay K. Nandicoori, Dr. U. S. N. Murthy, Dr. J. P. Shukla, Dr. Rekha S. Singhal, Dr. P. Suprasanna, Ms. Shruti Singh, Dr.Geeta Jotwani, Dr. Sanjeev Khosla, Shri V.P. Yadav and Dr. Alka Rao did not attend the 159 th meeting of GEAC.

Decision

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

Action: GEAC Secretariat

Agenda Item No. 2: Confirmation of minutes of the 158th GEAC meeting

Minutes of the 158th 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 158th GEAC meeting.

Action: GEAC Secretariat

Agenda Item No. 3: Action taken report on the decisions taken in the 158th GEAC meeting

Member Secretary, GEAC briefed about the action taken on the decisions at the 158th 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 Expert Committee Recommendations on the proposal of M/s Mahyco Pvt Ltd., Mumbai for environmental release of Bollgard II Roundup Ready Flex (BGII^{TM} RRF^{TM}) cotton incorporating events MON 15985 x MON 88913

The committee was informed that the 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 was initially considered by GEAC in its 145th meeting held on 27.07.2022 under Agenda Item 5.1 and the 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.

GEAC in its 149th meeting held on 17.05.2023 under Agenda Item 5.1, after considering the recommendations of the Expert Committee made the following recommendations:

i. The updated dossier as per above mentioned recommendations be directly submitted to the same Expert Committee; as constituted in 145th GEAC meeting under Chairmanship of Dr. Sanjay Mishra, Co-Chair, GEAC. This Expert Committee shall be responsible for review of updated dossier and further processing of the proposal, including preparation of Risk Assessment and Risk Management (RARM) Report, in accordance with the applicable guidelines/procedures/ SOPs.
ii. The above-mentioned Expert Committee for BG II RRF can seek the additional information, as and when required, directly from the applicant for further processing of the proposal. Chairperson of this Expert Committee may also co-opt other subject experts, as deemed appropriate.
iii. The applicant to deposit 100 grams of the BG II RRF Cotton plant material with the ICAR-National Bureau of Plant Genetic Resources (ICAR-NBPGR) for purposes of future reference and submit the acknowledgement of receipt of plant material by ICAR- NBPGR to the GEAC within 30 days.

The chairman of the expert committee, Dr. Sanjay Kumar Mishra superannuated from the service and one member of the committee, Dr. S.J. Rahman passed away. In view of this and after detailed deliberation on the progress of the work undertaken by the said expert committee, GEAC, in its 155th meeting held on 09.06.2025 under agenda No. 8.1, recommended for reconstitution of expert committee for finalization of RARM plan for this proposal.

The Expert Committee submitted RARM Plan and dossier to the GEAC vide email dated 27.11.2025. The Expert Committee inter-alia recommended that applicant is required to submit event-specific detection protocols for MON 15985 and MON 531 with a validated Limit of Detection (LoD) of 0.01%.; data on Soil Microflora and Soil-Microbe Interaction studies, and for the use of MON 88913 (RRF) as refugia, the data for Compositional Analysis and Sub-chronic feeding studies generated in India.

Recommendations

GEAC deliberated in detail on the recommendations of the Expert Committee, the RARM plan and the dossier. Keeping in view the precautionary principle, the GEAC

recommended that applicant may be advised to generate additional data as recommended by Expert Committee under Indian Conditions, as per extant procedure and in accordance with the extant biosafety guidelines.

Action: GEAC Secretariat

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

5.1 M/s Assam Agricultural University (AAU), Jorhat, Assam to conduct a repeated Event Selection Trial (EST) under confined field conditions of four GE Chickpea (*Cicer arietinum*) lines expressing *cry1Ac* or *cry2Aa* gene (three GE chickpea lines Jimbour 100B, Jimbour 81G and SA-1×100B expressing cry1Ac gene; one GE chickpea line SA-1×72C2 expressing *cry2Aa* gene) for pod borer (*Helicoverpa armigera*) resistance during Rabi 2026

The committee was informed that the proposal submitted by M/s Assam Agricultural University (AAU), Jorhat, Assam to conduct a repeated Event Selection Trial (EST) under confined field conditions of four GE Chickpea (*Cicer arietinum*) lines expressing *cry1Ac* or *cry2Aa* gene (three GE chickpea lines Jimbour 100B, Jimbour 81G and SA-1×100B expressing cry1Ac gene; one GE chickpea line SA-1×72C2 expressing *cry2Aa* gene) for pod borer (*Helicoverpa armigera*) resistance during Rabi 2026 application was previously considered and recommended by GEAC in its 151st GEAC meeting held on 19.12.2023 under Agenda Item 4.3.

The applicant now intends to repeat Event Selection Trial (EST) at two trial site locations viz., Punjab Agricultural University (PAU), Ludhiana and University of Agricultural Sciences (UAS), Dharwad during Rabi 2026

During clarification sought by RCGM regarding reason for resubmission, applicant informed that "*we propose to re-evaluate the same GE chickpea lines expressing cry1Ac and cry2Aa genes, as tested in the EST 2024–2025, for resistance against pod borer in an EST at the same sites viz. PAU, Ludhiana and UAS, Dharwad–during Rabi 2025–2026.*

The results of trial conducted during 2024-2025 were not clear because of late planting due to excessive rainfall in October 2024.

In the proposed trial, the trial locations remain unchanged, and no new events are being introduced. Only minor modifications have been made in the trial design by excluding a few introgressed lines that did not show confirmed expression of trait in the 2024–2025 trial."

The application was considered by RCGM in its 324th meeting held on 10.12.2025. RCGM vide email dated 19.12.2025 have sent the recommendations of its 324th meeting and recommended to GEAC for further consideration.

Recommendations:

GEAC deliberated on the proposal. Based on the recommendation given in 324th RCGM meeting, the proposal of M/s Assam Agricultural University (AAU), Jorhat, Assam to conduct a repeated Event Selection Trial (EST) under confined field

conditions of four GE Chickpea (*Cicer arietinum*) lines expressing *cry1Ac* or *cry2Aa* gene (three GE chickpea lines Jimbour 100B, Jimbour 81G and SA-1×100B expressing *cry1Ac* gene; one GE chickpea line SA-1×72C2 expressing *cry2Aa* gene) for pod borer (*Helicoverpa armigera*) resistance during Rabi 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 324th RCGM Meeting, recommendations and/or conditions stated in RCGM Letter dated 18.12.2025.
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 confined field trials to ensure compliance of prescribed terms and conditions. The permit letter shall, inter-alia, mention the constitution and Terms of Reference of Central Compliance Committee, including 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: RCGM and GEAC Secretariat

Agenda Item No. 6: Applications related to Environmental Approval of clinical trials/ pharmaceuticals / veterinary drugs and Commercial Production

6.1 M/s Greenergy Bio Refineries Pvt. Ltd., Karnataka for commercial production of Ethanol using genetically modified *Saccharomyces cerevisiae* strain SYNERXIA® JADE ADY

The committee was informed that the applicant submitted an application dated 11.08.2025 for commercial production of 900 Lac Litres per annum ethanol using GE *Saccharomyces cerevisiae* strain SYNERXIA® JADE ADY using grain based feedstock at their distillery located in Hanumanhalli Village, Ranibennur Taluk, Dist Haveri, Karnataka. The applicant intends to use the ethanol for biofuel purpose.

The supplier of strain SYNERXIA® JADE ADY is M/s Danisco India Private Limited. The strain SYNERXIA® JADE ADY is genetically engineered for stress tolerance, improved production rates, and endogenous glucoamylase expression.

GEAC in its 153rd GEAC meeting held on 03.10.2024 appraised the Standard Risk Assessment and Risk Management Plan (RARMP) for Environmental Safety for Undertaking Commercial Production of Ethanol Using Genetically Engineered Organisms (GEOs)/Living Modified Organisms (LMOs). Accordingly, applicant vide email dated 19.08.2025 have submitted the RARMP.

The RARMP submitted by M/s Greenergy Bio Refineries Pvt. Ltd., Karnataka was considered and deliberated by RCGM in its 324th meeting dated 10.12.2025. RCGM via email dated 18.12.2025 have sent the letter to GEAC, enclosed with recommendations of its 324th RCGM meeting for further consideration.

Recommendations

GEAC deliberated on the proposal. Based on the recommendations of 324th RCGM meeting and the RARMP recommended by RCGM, the proposal submitted by M/s Greenergy Bio Refineries Pvt. Ltd., Karnataka for commercial production of 900 Lac Litres per annum per annum of ethanol using GE *Saccharomyces cerevisiae* strain SYNERXIA® JADE ADY using grain based feedstock at their distillery located in Hanumanhalli Village, Ranibennur Taluk, Dist Haveri, Karnataka was recommended by the Committee subject to following conditions:

i. The activity shall adhere to the plans proposed in the application and shall comply with the RARM plans as 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 and/or other competent authorities, as applicable.

iii. The applicant shall inform the GEAC Secretariat within 30 days from the date of commencement of production.

iv. The project shall be implemented under the oversight of IBSC.

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

vi. Applicant shall ensure environmentally sound and safe management of any residue/discharge of the production process as per existing laws, rules, and regulations applicable.

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

viii. Records related to the generation, treatment, recycling/reuse, and disposal of waste, effluents, residues, and other by-products arising from the production process shall be properly maintained and submitted to the concerned State Pollution Control Board (SPCB) at regular intervals, twice a year, i.e., on 15th October (for the period April–September) and 15th April (for the period October–March) as per extant procedure.

ix. The approval granted to the application is under the provisions of the *Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms/ Genetically Engineered Organisms or Cells, 1989* (Rules, 1989) notified under the Environment (Protection) Act, 1986. This approval shall not be construed as a substitute for any other statutory approvals, consents, permissions, or compliance with standards/conditions required under any other applicable Acts, Rules, or subordinate legislation, including but not limited to the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981 and the applicant shall obtain all such necessary approvals from the competent authorities, including the State Pollution Control Board, prior to the operation of the project, as applicable.

x. The approval is subject to other statutory clearances.

xi. Appropriate safety measures, including on-site emergency plans, shall be established and implemented to effectively manage any accidents/incidents, in accordance with the following guidelines:

a. Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017
b. Handbook for Institutional Biosafety Committees (IBSCs), Third Revised Edition, September 2020.

xii. Proper care shall be taken for decontamination and disposal of all materials, in accordance with Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017.

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

xiv. Environmental standards shall be maintained in the plant, including the following:

a. Conducting periodic Environmental Audit
b. Maintaining and operating the Effluent Treatment Plant (ETP)/Zero Liquid Discharge (ZLD) system and ensuring compliance with applicable standards, including implementation of an appropriate waste management and disposal strategy

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

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

xvii. For every co-product and by-product generated 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, as required in accordance with the extant statutory provisions.

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

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

Action: GEAC Secretariat

6.2 M/s Greenergy Bio Refineries Pvt. Ltd., Karnataka for commercial production of Ethanol using genetically modified *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY

The committee was informed that the applicant submitted an application dated 11.08.2025 for commercial production of 900 Lac Litres per annum ethanol using GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY using grain based feedstock at their distillery located in Hanumanhalli Village, Ranibennur Taluk, Dist Haveri, Karnataka. The applicant intends to use the ethanol for biofuel purpose.

The supplier of strain SYNERXIA® RUBY G2 ADY is M/s Danisco India Private Limited. The strain SYNERXIA® RUBY G2 ADY is genetically engineered for stress tolerance, improved production rates, and endogenous glucoamylase expression.

GEAC in its 153rd GEAC meeting held on 03.10.2024 appraised the Standard Risk Assessment and Risk Management Plan (RARMP) for Environmental Safety for Undertaking Commercial Production of Ethanol Using Genetically Engineered Organisms (GEOs)/Living Modified Organisms (LMOs). Accordingly, applicant vide email dated 19.08.2025 have submitted the RARMP.

The RARMP submitted by M/s Greenergy Bio Refineries Pvt. Ltd., Karnataka was considered and deliberated by RCGM in its 324th meeting dated 10.12.2025. RCGM via email dated 19.12.2025 have sent the letter to GEAC, enclosed with recommendations of its 324th RCGM meeting for further consideration.

Recommendations

GEAC deliberated on the proposal. Based on the recommendations of 324th RCGM meeting and the RARMP recommended by RCGM, the proposal submitted by M/s Greenergy Bio Refineries Pvt. Ltd., Karnataka for commercial production of 900 Lac Litres per annum per annum of ethanol using GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY using grain based feedstock at their distillery located in Hanumanhalli Village, Ranibennur Taluk, Dist Haveri, Karnataka was recommended by the Committee subject to following conditions:

i. The activity shall adhere to the plans proposed in the application and shall comply with the RARM plans as recommended by GEAC.

ii. 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 and/or other competent authorities, as applicable.

iii. The applicant shall inform the GEAC Secretariat within 30 days from the date of commencement of production.

iv. The project shall be implemented under the oversight of IBSC.

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

vi. Applicant shall ensure environmentally sound and safe management of any residue/discharge of the production process as per existing laws, rules, and regulations applicable.

vii. The applicant shall ensure strict compliance of zero discharge of viable GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY into the environment at any stage including import, transport, storage, production, recovery, handling, and waste management.

viii. Records related to the generation, treatment, recycling/reuse, and disposal of waste, effluents, residues, and other by-products arising from the production process shall be properly maintained and submitted to the concerned State Pollution Control Board (SPCB) at regular intervals, twice a year, i.e., on 15th October (for the period April–September) and 15th April (for the period October–

March) as per extant procedure.

ix. The approval granted to the application is under the provisions of the *Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms/ Genetically Engineered Organisms or Cells, 1989* (Rules, 1989) notified under the Environment (Protection) Act, 1986. This approval shall not be construed as a substitute for any other statutory approvals, consents, permissions, or compliance with standards/conditions required under any other applicable Acts, Rules, or subordinate legislation, including but not limited to the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981 and the applicant shall obtain all such necessary approvals from the competent authorities, including the State Pollution Control Board, prior to the operation of the project, as applicable.

x. The approval is subject to other statutory clearances.

xi. Appropriate safety measures, including on-site emergency plans, shall be established and implemented to effectively manage any accidents/incidents, in accordance with the following guidelines:

    i. Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017

    ii. Handbook for Institutional Biosafety Committees (IBSCs), Third Revised Edition, September 2020.

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

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

xiv. Environmental standards shall be maintained in the plant, including the following:

    a. Conducting periodic Environmental Audit

    b. Maintaining and operating the Effluent Treatment Plant (ETP)/Zero Liquid Discharge (ZLD) system and ensuring compliance with applicable standards, including implementation of an appropriate waste management and disposal strategy.

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

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

xvii. For every co-product and by-product generated 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, as required in accordance with the extant statutory provisions.

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

xix. The approval will be for a limited period of four years, from the date of issue of letter, as per clause 13 of “Rules for The Manufacture, Use, Import, Export and Storage Of Hazardous Micro Organisms/ Genetically Engineered Organisms Or

Cells 1989 (Rules 1989) notified under Environment Protection Act, 1986."

Action: GEAC Secretariat

6.3 M/s Greenergy Bio Refineries Pvt. Ltd., Karnataka for commercial production of Ethanol using genetically modified *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY

The committee was informed that the applicant submitted an application dated 11.08.2025 for commercial production of 900 Lac Litres per annum ethanol using GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY using grain based feedstock at their distillery located in Hanumanhalli Village, Ranibennur Taluk, Dist Haveri, Karnataka. The applicant intends to use the ethanol for biofuel purpose.

The supplier of strain SYNERXIA® SAPPHIRE ADY is M/s Danisco India Private Limited. The strain SYNERXIA® SAPPHIRE ADY is genetically engineered for stress tolerance, improved production rates, and endogenous glucoamylase expression.

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 19.08.2025 have submitted the RARMP.

The RARMP submitted by M/s Greenergy Bio Refineries Pvt. Ltd., Karnataka was considered and deliberated by RCGM in its 324th meeting dated 10.12.2025. RCGM via email dated 18.12.2025 have sent the letter to GEAC, enclosed with recommendations of its 324th RCGM meeting for further consideration.

Recommendations

GEAC deliberated on the proposal. Based on the recommendations of 324th RCGM meeting and the RARMP recommended by RCGM, the proposal submitted by M/s Greenergy Bio Refineries Pvt. Ltd., Karnataka for commercial production of 900 Lac Litres per annum per annum of ethanol using GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY using grain based feedstock at their distillery located in Hanumanhalli Village, Ranibennur Taluk, Dist Haveri, Karnataka was recommended by the Committee subject to following conditions:

i. The activity shall adhere to the plans proposed in the application and activity shall comply with the RARM plans as recommended by GEAC.

ii. 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 and/or other competent authorities, as applicable.

iii. The applicant shall inform the GEAC Secretariat within 30 days from the date of commencement of production.

iv. The project shall be implemented under the oversight of IBSC.

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

vi. Applicant shall ensure environmentally sound and safe management of any

residue/discharge of the production process as per existing laws, rules, and regulations applicable.

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

viii. Records related to the generation, treatment, recycling/reuse, and disposal of waste, effluents, residues, and other by-products arising from the production process shall be properly maintained and submitted to the concerned State Pollution Control Board (SPCB) at regular intervals, twice a year, i.e., on 15th October (for the period April–September) and 15th April (for the period October–March) as per extant procedure.

ix. The approval granted to the application is under the provisions of the *Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms/ Genetically Engineered Organisms or Cells, 1989* (Rules, 1989) notified under the Environment (Protection) Act, 1986. This approval shall not be construed as a substitute for any other statutory approvals, consents, permissions, or compliance with standards/conditions required under any other applicable Acts, Rules, or subordinate legislation, including but not limited to the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981 and the applicant shall obtain all such necessary approvals from the competent authorities, including the State Pollution Control Board, prior to the operation of the project, as applicable.

x. The approval is subject to other statutory clearances.

xi. Appropriate safety measures, including on-site emergency plans, shall be established and implemented to effectively manage any accidents/incidents, in accordance with the following guidelines

    i. Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017
    ii. Handbook for Institutional Biosafety Committees (IBSCs), Third Revised Edition, September 2020.

xii. Proper care shall be taken for decontamination and disposal of all materials, in accordance with Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017.

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

xiv. Environmental standards to be maintained in the plant, including the following:

a. Conducting periodic Environmental Audit

b. Maintaining and operating the Effluent Treatment Plant (ETP)/Zero Liquid Discharge (ZLD) system and ensuring compliance with applicable standards, including implementation of an appropriate waste management and disposal strategy

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

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

xvii. For every co-product and by-product generated 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, as required in accordance with the extant statutory provisions.

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

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

Action: GEAC Secretariat

6.4 M/s Oasis Ethanol Industries Private Limited, Haryana for production of ethanol using genetically modified *Saccharomyces cerevisiae* SYNERXIA® RUBY G2 ADY yeast strain (Active Dry Yeast) using grain based feedstock

The committee was informed that the applicant submitted an application dated 12.11.2025 for commercial production of 1750 Lac Litres per annum ethanol using GE *Saccharomyces cerevisiae* strain SYNERXIA® RUBY G2 ADY using grain based feedstock at their distillery located in Tehsil Sahjadpur, Ambala, HARYANA. The applicant intends to use the ethanol for biofuel purpose.

The supplier of strain SYNERXIA® RUBY G2 ADY is M/s Danisco India Private Limited. The strain will be procured in active dry yeast (ADY) form as ready to use product. The strain SYNERXIA® RUBY G2 ADY is genetically engineered for stress tolerance, improved production rates, and endogenous glucoamylase expression.

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 25.11.2025 have submitted the RARMP.

The RARMP submitted by M/s Oasis Ethanol Industries Private Limited, Haryana was considered and deliberated by RCGM in its 326th meeting dated 07.01.2026. RCGM via email dated 19.01.2026 have sent the letter to GEAC, enclosed with recommendations of its 326th RCGM meeting for further consideration.

Recommendations

GEAC deliberated on the proposal. Based on the recommendations of 326th RCGM meeting and the RARMP recommended by RCGM, the proposal submitted by M/s Oasis Ethanol Industries Private Limited, Haryana for production of 1750 Lac Litres per annum ethanol using genetically modified Saccharomyces cerevisiae SYNERXIA® RUBY G2 ADY yeast strain (Active Dry Yeast) using grain based feedstock at their distillery located in Tehsil Sahjadpur, Ambala, HARYANA. 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® 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 and/or other competent authorities, as applicable

iii. The applicant shall inform the GEAC Secretariat within 30 days from the date of commencement of production.

iv. The project shall be implemented under the oversight of IBSC.

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

vi. Applicant shall ensure environmentally sound and safe management of any residue/discharge of the production process as per existing laws, rules, and regulations applicable.

vii. The applicant shall ensure strict compliance of zero discharge of viable SYNERXIA® RUBY G2 ADY into the environment at any stage including import, transport, storage, production, recovery, handling, and waste management.

viii. Records related to the generation, treatment, recycling/reuse, and disposal of waste, effluents, residues, and other by-products arising from the production process shall be properly maintained and submitted to the concerned State Pollution Control Board (SPCB) at regular intervals, twice a year, i.e., on 15th October (for the period April–September) and 15th April (for the period October–March) as per extant procedure.

ix. The approval granted to the application is under the provisions of the *Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms/ Genetically Engineered Organisms or Cells, 1989* (Rules, 1989) notified under the Environment (Protection) Act, 1986. This approval shall not be construed as a substitute for any other statutory approvals, consents, permissions, or compliance with standards/conditions required under any other applicable Acts, Rules, or subordinate legislation, including but not limited to the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981 and the applicant shall obtain all such necessary approvals from the competent authorities, including the State Pollution Control Board, prior to the operation of the project, as applicable.

x. The approval is subject to other statutory clearances.

xi. Appropriate safety measures, including on-site emergency plans, shall be established and implemented to effectively manage any accidents/incidents, in accordance with the following guidelines

a. Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017

b. Handbook for Institutional Biosafety Committees (IBSCs), Third Revised Edition, September 2020.

xii. Proper care shall be taken for decontamination and disposal of all materials in accordance with Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017.

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

xiv. Environmental standards shall be maintained in the plant, including the following:

i. Conducting periodic Environmental Audit

ii. Maintaining details on Effluent Treatment Plant/ zero liquid discharge and ensuring compliance with relevant standards, including the waste disposal strategy. Maintaining and operating the Effluent Treatment Plant (ETP)/Zero Liquid Discharge (ZLD) system and ensuring compliance with applicable standards, including implementation of an appropriate waste management and disposal strategy

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

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

xvii. For every co-product and by-product generated 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, as required in accordance with the extant statutory provisions.

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

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

Action: GEAC Secretariat

6.5 M/s Oasis Ethanol Industries Private Limited, Haryana for production of ethanol using genetically modified *Saccharomyces cerevisiae* SYNERXIA® SAPPHIRE ADY (GICC03588) yeast strain (Active Dry Yeast) using grain based feedstock

The committee was informed that the applicant submitted an application dated 12.11.2025 for commercial production of 1750 Lac Litres per annum ethanol using GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY using grain based feedstock at their distillery located in Tehsil Sahjadpur, Ambala, HARYANA. The applicant intends to use the ethanol for biofuel purpose.

The supplier of strain SYNERXIA® SAPPHIRE ADY is M/s Danisco India Private Limited. The strain will be procured in active dry yeast (ADY) form as ready to use product. The strain SYNERXIA® SAPPHIRE ADY is genetically engineered for stress tolerance, improved production rates, and endogenous glucoamylase expression.

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 25.11.2025 have submitted the RARMP.

The RARMP submitted by M/s Oasis Ethanol Industries Private Limited, Haryana was considered and deliberated by RCGM in its 326th meeting dated 07.01.2026. RCGM via email dated 19.01.2026 have sent the letter to GEAC, enclosed with recommendations of its 326th RCGM meeting for further consideration.

Recommendation

GEAC deliberated on the proposal. Based on the recommendations of 326th RCGM meeting and the RARMP recommended by RCGM, the proposal submitted by M/s Oasis Ethanol Industries Private Limited, Haryana for production of 1750 Lac Litres per annum ethanol using genetically modified *Saccharomyces cerevisiae* SYNERXIA® SAPPHIRE ADY (GICC03588) yeast strain (Active Dry Yeast) using grain based feedstock at their distillery located in Tehsil Sahjadpur, Ambala, HARYANA. 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® SAPPHIRE ADY (GICC03588) yeast strain (Active Dry Yeast) 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 and/or other competent authorities, as applicable.

iii. The applicant shall inform the GEAC Secretariat within 30 days from the date of commencement of production.

iv. The project shall be implemented under the oversight of IBSC.

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

vi. Applicant shall ensure environmentally sound and safe management of any residue/discharge of the production process as per existing laws, rules, and regulations applicable.

vii. The applicant shall ensure strict compliance of zero discharge of viable GE *Saccharomyces cerevisiae* strain SYNERXIA® SAPPHIRE ADY (GICC03588) yeast strain (Active Dry Yeast) into the environment at any stage including import, transport, storage, production, recovery, handling, and waste management.

viii. Records related to the generation, treatment, recycling/reuse, and disposal of waste, effluents, residues, and other by-products arising from the production process shall be properly maintained and submitted to the concerned State Pollution Control Board (SPCB) at regular intervals, twice a year, i.e., on 15th October (for the period April–September) and 15th April (for the period October–March) as per extant procedure.

ix. The approval granted to the application is under the provisions of the *Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms/ Genetically Engineered Organisms or Cells, 1989* (Rules, 1989) notified under the Environment (Protection) Act, 1986. This approval shall not be construed as a

substitute for any other statutory approvals, consents, permissions, or compliance with standards/conditions required under any other applicable Acts, Rules, or subordinate legislation, including but not limited to the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981 and the applicant shall obtain all such necessary approvals from the competent authorities, including the State Pollution Control Board, prior to the operation of the project, as applicable.

x. The approval is subject to other statutory clearances.

xi. Appropriate safety measures, including on-site emergency plans, shall be established and implemented to effectively manage any accidents/incidents, in accordance with the following guidelines

    i. Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017

    ii. Handbook for Institutional Biosafety Committees (IBSCs), Third Revised Edition, September 2020.

xii. Proper care shall be taken for decontamination and disposal of all materials, in accordance with Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017.

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

xiv. Environmental standards shall be maintained in the plant, including the following:

a. Conducting periodic Environmental Audit

b. Maintaining details on Effluent Treatment Plant/ zero liquid discharge and ensuring compliance with relevant standards, including the waste disposal strategy. Maintaining and operating the Effluent Treatment Plant (ETP)/Zero Liquid Discharge (ZLD) system and ensuring compliance with applicable standards, including implementation of an appropriate waste management and disposal strategy.

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

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

xvii. For every co-product and by-product generated 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, as required in accordance with the extant statutory provisions.

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

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

Action: GEAC Secretariat

Agenda Item No. 7: Applications related to Import/Export

7.1 M/s. Catalysts Bio-Technologies Private Limited, Ghaziabad, for import of Genetically Engineered *Saccharomyces cerevisiae* strain Evolve^{TM} Evergreen yeast for 1G ethanol production

The committee was informed that the applicant submitted an application dated 12.09.2025 for import of Genetically Engineered *Saccharomyces cerevisiae* strain Evolve^{TM} Evergreen yeast for first-generation ethanol production.

The applicants intends to import 1000 Tons of Evolve^{TM} Evergreen dry yeast from Leaf, USA.

The modified strain express glucoamylase, an enzyme capable of hydrolysing starch into glucose units, fermentable by the yeast. The strain also express glyceraldehyde-3-phosphate dehydrogenase while the expression of glycerol-3 phosphate dehydrogenase and glycerol-3-phosphate phosphatase are inhibited allowing the metabolic pathway to be directed towards ethanol production, with a reduction of glycerol production and ethanol yield improvement.

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 15.09.2025.

Applicant vide email dated 19.11.2025 have submitted the Standard RARM which was forwarded to RCGM for consideration. RARM plan was considered in 326th meeting of RCGM held on 07.01.2026. RCGM shared the recommendations to GEAC via email dated 19.01.2026 for further consideration.

Recommendation

GEAC deliberated on the proposal. Taking cognizance of the recommendations of 326th RCGM meeting, committee recommended the proposal of M/s. Catalysts Bio-Technologies Private Limited, Ghaziabad, for import of 1000 Tons of Genetically Engineered Saccharomyces cerevisiae strain Evolve^{TM} Evergreen yeast for 1G ethanol production subject to following conditions:

i. The activity shall adhere to the plans proposed in the application and shall comply with the RARM plans as recommended by GEAC.
ii. Appropriate safety measures, including on-site emergency plans, shall be established and implemented to effectively manage any accidents/incidents, in accordance with the following guidelines:

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 and/or other competent authorities, as applicable.

iv. Applicant shall submit an IBSC-approved Emergency Action Plan for any event of unintentional release of the GE *Saccharomyces cerevisiae* strain Evolve™ Evergreen yeast, prior to 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 with zero discharge of viable GE *Saccharomyces cerevisiae* strain Evolve™ Evergreen yeast into the environment at any stage including import, transportation, storage, access, handling, processing, packing, re-packing, distribution, sale, decontamination, and disposal etc.

vii. Applicant shall ensure that the access to the GE *Saccharomyces cerevisiae* strain Evolve™ Evergreen yeast is restricted, only to trained and experienced persons, as recommended by IBSC. GE *Saccharomyces cerevisiae* strain Evolve™ Evergreen yeast shall be stored securely in the appropriate containers in a locked area until transported. This restriction on access shall apply to all scenarios, including situations where containers containing GE *Saccharomyces cerevisiae* strain Evolve™ Evergreen yeast are temporarily kept in a loading area or are left unattended prior to transport or before 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 Evolve™ Evergreen yeast cultures being transported to detect and prevent any loss of GE *Saccharomyces cerevisiae* strain Evolve™ Evergreen yeast during transport. This must be implemented for all transport events, except in cases where the GE *Saccharomyces cerevisiae* strain Evolve™ Evergreen yeast transport solely occurs within a building. Annual record should be submitted to IBSC.

ix. The packaging of GE *Saccharomyces cerevisiae* strain Evolve™ Evergreen yeast 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 Evolve™ Evergreen yeast 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 Evolve™ Evergreen yeast 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 Evolve™ Evergreen yeast, 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 Evolve™ Evergreen yeast;
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 Evolve™ Evergreen yeast 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

7.2 M/s. Biological E. Limited, Hyderabad, to import HPV monovalent bulks from M/s. JiangSu RecBio Technology Co., Ltd, China, to develop manufacturing process and testing of HPV vaccine

The committee was informed that the applicant intends to import Human Papillomavirus Virus (HPV) monovalent bulk from M/s. JiangSu RecBio Technology Co., Ltd, China to develop Drug Product (DP) manufacturing process and testing of HPV vaccine.

The drug products with different formulations will be tested for toxicity and immunogenicity in animals.

Human Papilloma Virus like particles are expressed in *Hansunella Polymorpha*, which is found to be immunogenic. The VLP is not infectious and do not contain any infectious nucleic acids. No known toxicity and allergenicity. Highly stable on surfaces; resistant to drying and some disinfectants due to non-enveloped nature. The GMO will be used for expression of HPV VLP (Human Papillomavirus Virus-Like Particle). The VLP will be used for immunogenic studies to test their suitability as potential vaccine candidate.

The proposed quantity of import of is as placed below;

Sl No.	HMOs, GMOs/LMOs and product(s) thereof to be exported	Quantity	Type of Pack	Size	Concentration
1.	HPV 6 monovalent bulk	7	Bag	2L	2mg/ml
2.	HPV 11 monovalent bulk	7	Bag	2L	2mg/ml
3.	HPV 16 monovalent bulk	7	Bag	2L	2mg/ml
4.	HPV 18 monovalent bulk	7	Bag	2L	2mg/ml
5.	HPV 31 monovalent bulk	7	Bag	2L	2mg/ml
6.	HPV 33 monovalent bulk	7	Bag	2L	2mg/ml
7.	HPV 45 monovalent bulk	7	Bag	2L	2mg/ml
8.	HPV 52 monovalent bulk	7	Bag	2L	2mg/ml
9.	HPV 58 monovalent bulk	7	Bag	2L	2mg/ml

RCGM vide email dated 23.01.2026 forwarded the application to GEAC for further consideration as the quantity of monovalent bulk is very high, as far as R&D requirements are concerned.

Recommendation

GEAC deliberated on the proposal. Committee noted that vide GSR 616(E) dated 20.09.2006, *Import and Marketing of products derived from Living Modified Organisms (LMOs) as Drugs and Pharmaceuticals in bulk and/or finished formulations where the end product being imported is not a Living Modified Organism are exempted* from Rule 7 to 10 of Rules 1989.

Accordingly, the Committee recommended that the application be returned to RCGM and suggested that RCGM may re-examine the application, taking into account the inputs of CDSCO.

Action: GEAC Secretariat

7.3 M/s. Biocon Limited, Bangalore, to import the Precursor P29 peptide chain (a product derived from E. coli using rDNA technology) from M/s. Hangzhou Bio-bounce Technology Co., Ltd. (Vazyme), China, for developing a scalable process for the manufacturing of r-Semaglutide

The committee was informed that the applicant intends to import Precursor P29 peptide chain (a product derived from E. coli using rDNA technology) from Hangzhou Bio-bounce Technology Co., Ltd. (Vazyme), China to Biocon Limited, Bengaluru.
The applicant has submitted that the proposed laboratory studies are intended to generate high-quality r-Semaglutide (*anti-diabetic medication used for the treatment of type 2 diabetes)* using the precursor P29 peptide chain. The host used for production of P29 is *E. coli*.

The proposed quantity of import is placed below;

Sl No.	HMOs, GMOs/LMOs and product(s) thereof to be exported	Quantity	Type of Pack	Size	Concentration
1.	Precursor P29 peptide	1 x 40.0 Kg = 40.0 Kg	Bag	1.0 Kg/bag 5.0 Kg/bag 10.0 Kg/bag 40.0 Kg/bag	95% (HPLC)

The utilization breakup for 40 Kg of Precursor P29 Peptide is as following;

API qty (kg)	P-29 (kg)	10% extra (kg)	Details
0.5 kg + 0.5 kg	5	5.5	Initial quantity of API required to begin the formulation development. This being an initial scale up batch, considering the failure, additional back up batch (qty. equivalent to 1 kg API) has been considered
6.8 kg	31	34.1	Total quantity required for formulation development studies
Total	36	39.6 ≈ 40 kg	

RCGM vide email dated 23.01.2026 forwarded the application to GEAC for further consideration as the quantity of bulk is very high, as far as R&D requirements are concerned.

Recommendation

GEAC deliberated on the proposal. Committee noted that vide GSR 616(E) dated 20.09.2006, *Import and Marketing of products derived from Living Modified Organisms (LMOs) as Drugs and Pharmaceuticals in bulk and/or finished formulations where the end product being imported is not a Living Modified Organism are exempted* from Rule 7 to 10 of Rules 1989.

Accordingly, the Committee recommended that the application be returned to RCGM and suggested that RCGM may re-examine the application, taking into account the inputs of CDSCO.

Action: GEAC Secretariat

7.4 M/s Perfect day India Pvt. Ltd, Karnataka for import of PDLGB Strain (SPD 1087) from Finland for R&D and Large-Scale Production for Food ingredients / Food supplements in industrial food enzyme production

The applicant submitted an online application 15.11.2025 for Import of the genetically modified strain *Trichoderma reesei* PDLGB (sPD1087) for large scale production of β-lactoglobulin for food use (for Sale to potential Indian manufacturers (client)).

The strain PDLGB (sPD1087) will be procured from VTT Technical Research Centre of Finland and will be supplied to M/s Sterling Biotech, Gujarat for R&D and manufacturing of Bovine Lactoglobulin (LGB) at large scale for food use.

Trichoderma reesei is genetically modified to express β-lactoglobulin identical in amino acid sequence to the native bovine protein.

The applicant intends to import 2500 mL per annum as 10 batches per year (250 ml/ batch).

The applicant vide email dated 27.11.2025 has submitted the Risk Assessment and Risk Management (RARM) Plan for Import of GEO.

Recommendation

The Committee deliberated on the proposal. Taking into consideration, the Order of the Hon'ble High Court of Rajasthan in D.B. Civil Writ (PIL) Petition No. 9095/2019, the Committee recommended that comments may be sought from Food Safety and Standards Authority of India (FSSAI) and Central Insecticides Board & Registration Committee (CIBRC).

The Committee further recommended that FSSAI may examine the matter from a legal perspective. The Committee also recommended seeking inputs from CIBRC regarding the availability of indigenous alternatives.

Action: GEAC Secretariat

Agenda Item No. 8: Additional Items for consideration

8.1 Requirement of Metagenomic Analysis for import of recombinant veterinary vaccine

GEAC in its 156th meeting held on 14.07.2025, deliberated on the application submitted by M/s. Zoetis India Limited, Mumbai for import and marketing of recombinant Bursal Disease-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector veterinary vaccine.

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

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

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

GEAC in its 158th meeting held on 18.12.2025 recommended to consider the matter in its upcoming meeting.

Recommendation

The Committee deliberated in detail on the matter, taking into account the recommendations of RCGM in its 315th and 319th meetings, relevant pharmacopeial monographs, as well as inputs from CDSCO.

Based on the above, the Committee recommended that the requirement of Metagenomic Analysis for the import of recombinant veterinary vaccines need not be made mandatory and may be substituted with the following condition to ensure quality, safety, and regulatory compliance:

> *The applicant shall submit a Certificate of Analysis, including purity and quality parameters, issued by the manufacturer, certifying that the product is free from unacceptable levels of non-target organisms (NTOs) and contaminants, in accordance with applicable regulatory standards.*

Action: GEAC Secretariat

Agenda Item No. 9: Ongoing Applications withheld due to Requirement of Metagenomic Analysis

9.1 M/s Zoetis India Limited, Mumbai for import and marketing of Poulvac Procerta HVT-IBD-ND vaccine for veterinary use only, considered in 147th GEAC meeting held on 18.10.2022, under Agenda item 7.1

9.2 M/s Ceva Polchem Pvt. Ltd., Pune for import and distribution of recombinant vaccine VECTORMUNE FP LT for veterinary use considered in the 149th GEAC meeting held on 17.05.2023 under Agenda Item 7.1

9.3 M/s Virbac Animal Health India Pvt. Ltd., Mumbai submitting IVRI test reports for import and marketing of recombinant vaccine Himmvac Dalguban BBN + Oil Vaccine for veterinary use only, considered in 149th GEAC meeting held on 17.05.2023 under Agenda Item 7.2

9.4 M/s Boehringer Ingelheim India Pvt. Ltd., Mumbai for import of recombinant vaccine Recombitek C8 (Generic Name: Canine DistemperAdenovirus Type 2- Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Live Canarypox Vector, Leptospira Canicola – Grippotyphosa – Icterohaemorrhagiae – Pomona Bacterin) for veterinary use, considered in 150th GEAC meeting held on 10.08.2023, under Agenda Item 6.1

9.5 M/s Virbac Animal Health India Pvt. Ltd., Mumbai submitting IVRI test reports for import and marketing of recombinant vaccine Himmvac Dalguban N + Oil vaccine for veterinary use only, considered in the 144th GEAC meeting held on 22.02.2022, under Agenda 5.11

9.6 M/s Intervet India Pvt. Ltd., Pune submitted for import and marketing of Nobivac Puppy DP Plus recombinant veterinary vaccine, considered in the 145th GEAC meeting of held on 27.07.2022 under Agenda Item 6.5

9.7 M/s Zoetis India Ltd, Mumbai submitting test reports for import and marketing of recombinant veterinary vaccine Poulvac Procerta HVT-IBD, considered in the 142nd GEAC meeting held on 11.05.2021, under Agenda 5.3

9.8 M/s Huvepharma Sea (Pune) Pvt. Ltd for import of recombinant veterinary vaccine Clostridium Perfringens Type A Vaccine, Live Salmonella Vector (Avert NE), considered in 154th GEAC meeting held on 17.04.2025, under Agenda Item 6.1

9.9 M/s Ceva Polchem Pvt. Ltd., Pune to import and distribute recombinant vaccine Cell associated rHVT/ND-H9 LPAI vaccine, Live Frozen (NEWFLEND ND H9), considered by GEAC in its 154th meeting held on 17.04.2025 under Agenda Item 6.2

9.10 M/s Ceva Polchem Pvt. Ltd., Pune to import and distribute recombinant vaccine Marek's Disease-Newcastle Disease vaccine, Serotype 2 & 3, Live Virus, Live Marek's Disease Vector (VECTORMUNE HVT NDV & SB-1), considered in 154th GEAC meeting held on 17.04.2025, under Agenda Item 6.3

Agenda Item No. 10: New Applications withheld due to Requirement of Metagenomic Analysis

10.1 M/s Ceva Polchem Pvt Ltd to import and distribute the recombinant vaccine Avian Encephalomyelitis-Fowl Pox Mycoplasma Gallisepticum Vaccine, Live Virus, Live Fowl Pox Vector Vectormune FP-MG+AE

10.2 M/s Intervet India Pvt. Ltd. for import & marketing of Infectious Laryngotracheitis-Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector (INNOVAX-ND-ILT)

Recommendation

The Committee deliberated on the applications mentioned in Agenda Item No. 9 and 10, in line with the recommendation made under Agenda 8.1 regarding the non-mandatory requirement of Metagenomic Analysis for import of recombinant veterinary vaccines. The Committee recommended that all these applications be deferred at this stage.

The applicants are advised to apply afresh with revised applications/data, in accordance with the recommendations in Agenda 8.1 of this meeting. All other statutory requirements shall remain unchanged and shall be complied with by the applicants.

Accordingly, applicants are suggested to apply afresh with following:

i. Initial 3 batches of the subject vaccine to be certified in ICAR-Indian Veterinary Research Institute (ICAR-IVRI)
ii. Relevant approvals from Department of Animal Husbandry and Dairying, Drug Controller General of India etc. as applicable under the prevailing laws, rules, regulations governing the import of vaccines in India
iii. Certificate of Analysis, including purity and quality parameters, issued by the manufacturer, certifying that the product is free from unacceptable levels of non-target organisms (NTOs) and contaminants, in accordance with applicable regulatory standards.

Action: GEAC Secretariat

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

Annexure 1

List of Participants

Members who participated			
1.	**Shri Amandeep Garg** **Chairman** Additional Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jorbagh, Aliganj, New Delhi- 110003	7.	**Dr. D.K. Yadav** DDG, (Crop Science) Indian Council of Agricultural Research, Krishi Bhawan, New Delhi-110001
2.	**Dr. Nitin K. Jain** **Co-Chair** Scientist–G, Department of Biotechnology, C.G.O Complex, Lodhi Road, New Delhi-110003	8.	**Dr. P.K. Dass** Department of Anatomy, LHMC & Associated Hospitals, New Delhi- 110001
3.	**Sh. Raghu Kumar Kodali** **Vice-Chair** Scientist G, MoEFCC, Indira Paryavaran Bhawan, Jor bagh, Aliganj, New Delhi- 110003	9.	**Dr. J.P. Singh** Plant Protection Adviser (PPA), Directorate of Plant Protection, Quarantine & Storage, NH IV, Faridabad-121001, New Delhi
4.	**Dr. Satish Wate** Former Director, CSIR-National Environmental Engineering Research	10.	**Dr. Rubina Bose** Deputy Drugs Controller, Central Drugs Standard Control

	Institute, Nagpur- 440020		Organization, Ministry of Health and Family Welfare, New Delhi -110002 (Representative of Drugs Controller General of India)
5.	**Dr. Dinkar M. Salunkhe** Director, International Centre for Genetic Engineering and Biotechnology, New Delhi-110067	11.	**Dr. Pronab Dhar** Principal Scientist, ICAR-Indian Veterinary Research Institute (IVRI), Bareilly, Uttar Pr adesh- 243122 (Representative of Dr. Trive ni Dutt, Director, IVRI)
6.	**Dr. Chaitanya Joshi** Director, Gujarat Biotechnology Research Centre, Gandhinagar, Gujarat- 382 011	12.	**Dr. Abhilasha Singh Mathuriya** **Member Secretary,** Scientist D, CS-III Division, Ministry of Environment, Forest and Climate Change, Jorbagh, New Delhi-110003
Members who did not participate			
1.	**Dr. H. K. Sharma** Director, National Institute of Technology, Agartala, Tripura- 799 046	7.	**Ms. Shruti Singh** Joint Secretary, IPR, Department for Promotion of Industry and Internal Trade, Udyog Bhawan, New Delhi ,110011
2.	**Dr. Vinay K. Nandicoori** Director, CSIR-Centre for Cellular & Molecular Biology, Hyderabad - 500 007	8.	**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
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