

## **MINUTES OF THE 160<sup>TH</sup> MEETING OF GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 29.05.2026**

The 160<sup>th</sup> 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 Godavari Conference Hall, 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. Satish Wate, Ms. Shruti Singh, Dr. Dinkar M. Salunkhe, Dr. Geeta Jotwani, Dr. J. P. Shukla, Dr. Sanjeev Khosla, Dr. U. S. N. Murthy, Dr. P.K. Dass, Dr. Rekha S. Singhal, Shri V.P. Yadav and Dr. P. Suprasannadid not attend the 160<sup>th</sup> 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 159<sup>th</sup> GEAC meeting**

Minutes of the 159<sup>th</sup> GEAC meeting were circulated to all the members for comments and minutes were suitably amended to incorporate the comments received from the members.

The Committee was informed that, under Agenda Item 7.1 of the 159<sup>th</sup> GEAC meeting pertaining to the application of M/s. Catalysts Bio-Technologies Private Limited, Ghaziabad, for import of Genetically Engineered *Saccharomyces cerevisiae* strain Evolve™ Evergreen yeast for 1G ethanol production, the text under Recommendation (iii) may be read as: “*Applicant shall ensure that the GE Saccharomyces cerevisiae strain Evolve™ Evergreen 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*” instead of “*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.*”

### **Decision**

Members noted the correction and confirmed the minutes of the 159<sup>th</sup> GEAC meeting.

**Action: GEAC Secretariat**

**Agenda Item No. 3: Action taken report on the decisions taken in the 159<sup>th</sup> GEAC meeting**

Member Secretary, GEAC briefed about the action taken on the decisions at the 159<sup>th</sup> 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 Ajeet Seeds Pvt. Ltd., Aurangabad, Maharashtra, for Confined Field trial (EST) for GE cotton breeding stack events viz. ASCOT-101 X Mon15985, ASCOT-102X Mon15985 and ASCOT-105 X Mon15985 (ASCOT-101, ASCOT-102 and ASCOT-105 expressing *Cry2Aa*; Mon15985 expressing *Cry1Ac* and *Cry2Ab*) for protection against Cotton bollworm complex during Kharif-2026**

The proposal submitted by M/s Ajeet Seeds Pvt. Ltd., Aurangabad, Maharashtra seeking permission to conduct Event Selection Trial (EST) under confined field conditions of three GE cotton (*Gossypium hirsutum*) breeding stack hybrids (F1) of events viz., ASCOT-101×MON15985, ASCOT-102×MON15985 and ASCOT-105×MON15985 expressing *cry2Aa* (ASCOT-101, ASCOT-102, ASCOT-105), *cry1Ac* and *cry2Ab* (MON15985) genes for protection against Pink bollworm (*Pectinophora gossypiella*), American bollworm (*Helicoverpa armigera*) and Spotted bollworm (*Earias sp.*), pests of cotton at own trial site location in Hanumantgaon Farm, Aurangabad, Maharashtra, during Kharif 2026.

The proposal was considered and deliberated upon during the 330<sup>th</sup> meeting of the Review Committee on Genetic Manipulation (RCGM) held on 03.03.2026. Subsequently, the RCGM, vide its letter dated 16.03.2026, forwarded the recommendations of the 330<sup>th</sup> meeting and recommended the proposal to the GEAC for further consideration.

**Recommendations**

After detailed deliberations, the proposal of M/s Ajeet Seeds Pvt. Ltd., Aurangabad, Maharashtra to conduct Event Selection Trial (EST) under confined field conditions of three GE cotton (*Gossypium hirsutum*) breeding stack hybrids (F1) of events viz., ASCOT-101×MON15985, ASCOT-102×MON15985 and ASCOT-105×MON15985 expressing *cry2Aa* (ASCOT-101, ASCOT-102, ASCOT-105), *cry1Ac* and *cry2Ab* (MON15985) genes for protection against Pink bollworm (*Pectinophora gossypiella*), American bollworm (*Helicoverpa armigera*) and Spotted bollworm (*Earias sp.*), pests

of cotton at own trial site location in Hanumantgaon Farm, Aurangabad, Maharashtra, during Kharif 2026 was recommended by the committee.

The recommendation is subject to following conditions:

- i. The applicant shall adhere to the conditions of RCGM letter dated 16.03.2026.
- ii. The applicant shall submit details of the trial site as per Guidelines and SOPs for Confined Field Trials of regulated GE plants.
- iii. RCGM may issue the permit letter and monitor EST to ensure compliance of prescribed terms and conditions.

**Action: GEAC Secretariat**

**4.2 M/s. Rasi Seeds Pvt. Ltd, Salem, Tamil Nadu to conduct the BRL-I 2<sup>nd</sup> year trial of GE cotton hybrids harbouring event RIRC-304 expressing *cry1C* gene and GE Cotton breeding stack of events RIRC-304×MON15985 expressing *cry1C*, *cry1Ac* and *cry2Ab2* genes for resistance against bollworm complex at six trial site locations during Kharif-2026**

The proposal submitted by M/s Rasi Seeds Pvt. Ltd, Salem, Tamil Nadu seeking permission to conduct the BRL-I 2<sup>nd</sup> year trial of GE cotton hybrids harbouring event RIRC-304 expressing *cry1C* gene and GE Cotton breeding stack of events RIRC-304×MON15985 expressing *cry1C*, *cry1Ac* and *cry2Ab2* genes for resistance against bollworm complex ((i.e., *Pectinophora gossypiella*, *Helicoverpa armigera* and *Spodoptera litura*)) at six trial site locations viz., i) Nihal Khera, Firozpur, Punjab; ii) PAU, Bathinda, Punjab; iii) RVSKVV, Khandwa, Madhya Pradesh; iv) CCSHAU Hisar, Haryana; v) ANGRAU, Guntur, Andhra Pradesh; and vi) Kurnool, Andhra Pradesh during Kharif-2026.

The proposal was recommended for the BRL-I 1<sup>st</sup> year trial by GEAC in its 155<sup>th</sup> Meeting dated 09.06.2025 under Agenda item 4.3.

The proposal was considered and deliberated upon during the 333<sup>rd</sup> meeting of the Review Committee on Genetic Manipulation (RCGM) held on 15.04.2026. Subsequently, the RCGM, vide its letter dated 24.04.2026, forwarded the recommendations of the 333<sup>rd</sup> meeting and recommended the proposal to the GEAC for further consideration, subject to the conditions mentioned below:

- i. *The applicant to submit the complete consolidated report of the BRL-I 1st year trial for all trial sites within three months from the date of trial termination.*
- ii. *RCGM, on review of the BRL-I 1st year trial report, if any deficiencies are identified or additional biosafety studies are observed to be required, the applicant shall incorporate and address the same during the BRL-I 2nd year trial, as directed.*
- iii. *The applicant to submit BRL-I 2nd year report upon completion of the trial in due course. However, RCGM will review the BRL-I 2nd year report only after satisfactory review of the BRL-I 1st year trial report.*

The applicant has submitted No Objection Certificates (NOCs) from the State Governments of Punjab, Haryana, Madhya Pradesh, Andhra Pradesh, Telangana, and Karnataka for the conduct of the BRL-I 2<sup>nd</sup> year trials.

### **Recommendations**

Committee deliberated on the recommendation of 333<sup>rd</sup> meeting of RCGM and NOC received from the State Governments of Punjab, Haryana, Madhya Pradesh, Andhra Pradesh, Telangana, and Karnataka and recommended the proposal of M/s. Rasi Seeds P. Ltd., Salem, Tamil Nadu to conduct BRL-I trials (2<sup>nd</sup> Year) during Kharif 2026 with the GE cotton hybrids harbouring event RIRC-304 expressing *cry1C* gene and GE Cotton breeding stack of events RIRC-304×MON15985 expressing *cry1C*, *cry1Ac* and *cry2Ab2* genes for resistance against bollworm complex (i.e., *Pectinophora gossypiella*, *Helicoverpa armigera* and *Spodoptera litura*) at below mentioned sites :

- i. Nihal Khera, Ferozpur, Punjab;
- ii. PAU, Bathinda, Punjab;
- iii. RVSKVV, Khandwa, Madhya Pradesh;
- iv. CCSHAU Hisar, Haryana;
- v. ANGRAU, Guntur, Andhra Pradesh; and
- vi. Kurnool, Andhra Pradesh

The recommendation is subject to following conditions:

- i. The applicant shall adhere to the conditions of RCGM letter dated 24.04.2026:
  - a. *The applicant to submit the complete consolidated report of the BRL-I 1st year trial for all trial sites within three months from the date of trial termination.*
  - b. *RCGM, on review of the BRL-I 1st year trial report, if any deficiencies are identified or additional biosafety studies are observed to be required, the applicant shall incorporate and address the same during the BRL-I 2nd year trial, as directed.*
  - c. *The applicant to submit BRL-I 2nd year report upon completion of the trial in due course. However, RCGM will review the BRL-I 2nd year report only after satisfactory review of the BRL-I 1st year trial report.*
- ii. The applicant shall adhere with the conditions and/or recommendations mentioned in concurrence obtained from State Governments of Punjab, Haryana, Madhya Pradesh, Andhra Pradesh, Telangana.
- iii. The BRL-I (2<sup>nd</sup> year) confined field trials should be conducted to evaluate the introduced insect resistant trait in the GE plant.
- iv. The applicant shall share details of the trial site as per the Guidelines and SOPs for Confined Field Trials of regulated GE plants, 2008.

RCGM may issue the permit letters and monitor confined field trials to ensure compliance of prescribed terms and conditions. The permit letter, for every confined field trial site, to be issued under intimation to the concerned State Government.

**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. Grainspan Nutrients Private Limited, Gujarat for commercial production of bioethanol using GE *Saccharomyces cerevisiae* strain MeJi797 (Innova Force ADY) and use of by-product DDGS and CO<sub>2</sub>**

The applicant submitted an application and RARMP dated 13.01.2026 seeking approval for the commercial production of 3.83 crore litres per annum of bioethanol (not for consumption), 27,330 MTPA of DDGS for feed, and 1,732 MT of CO<sub>2</sub> for industrial use, using the genetically engineered (GE) *Saccharomyces cerevisiae* strain MeJi797 (Active Dried Yeast – Innova Force ADY) at its production facility located in Ahmedabad, Gujarat.

The GE *Saccharomyces cerevisiae* strain MeJi797 has been genetically modified for up-regulation of the starch hydrolytic pathway through the expression of alpha amylase (*Rhizomucor pusillus*) and glucoamylase (*Pycnopus sanguineus*). The supplier of the strain MeJi797 is M/s. Novozymes South Asia Private limited which has obtained approval from the GEAC in its 157<sup>th</sup> meeting held on 10.10.2025 for import and sale of the said GE yeast strain in India.

GEAC in its 153<sup>rd</sup> GEAC meeting held on 03.10.2024 appraised the Standard Risk Assessment and Risk Management (RARMP) Plan for Environmental Safety for Undertaking Commercial Production of Ethanol Using Genetically Engineered Organisms (GEOs)/Living Modified Organisms (LMOs).

The RARMP submitted by M/s. Grainspan Nutrients Private Limited, Gujarat, was considered and deliberated upon by the RCGM in its 334<sup>th</sup> meeting held on 29.04.2026. Subsequently, the RCGM, vide email dated 14.05.2026, forwarded its recommendations along with the proceedings of the 334<sup>th</sup> RCGM meeting to the GEAC for further consideration.

During the presentation, the applicant informed the Committee that it proposes to undertake pilot-scale studies using the genetically engineered (GE) *Saccharomyces cerevisiae* strain MeJi797 (Active Dried Yeast – Innova Force ADY) at its production facility in Ahmedabad, Gujarat. Applicant further stated that only on successful completion of the pilot studies, the applicant intends to initiate commercial-scale production.

The applicant further submitted that all products generated during the pilot studies including DDGS shall be disposed of in an appropriate manner, and no product shall be sold, distributed, or utilized.

With regard to commercial production, the applicant stated that Dried Distillers Grains with Solubles (DDGS), a by-product of the process, shall be utilized as fuel within the facility and shall not be sold or distributed.

**Recommendations:**

GEAC deliberated on the proposal. Based on the recommendations of 334<sup>th</sup> RCGM meeting and the RARMP recommended by RCGM, GEAC recommended the proposal submitted by M/s. Grainspan Nutrients Private Limited, Gujarat for commercial production of 3.83 crore litres per annum of bioethanol (not for human consumption), using genetically engineered (GE) *Saccharomyces cerevisiae* strain MeJi797 (Active Dried Yeast – Innova Force ADY) at its production facility located in Ahmedabad, 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 MeJi797 (Active Dried Yeast – Innova Force 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. Dried Distillers Grains with Solubles (DDGS), a by-product of the process, shall be utilized as fuel within the facility and shall not be sold or distributed.
- v. For every co-product and by-product including DDGS 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.
- vi. The project shall be implemented under the oversight of IBSC.
- vii. The applicant shall submit IBSC approved compliance report on RARM plan as approved by GEAC, every 6 months to GEAC Secretariat.
- viii. Applicant shall ensure environmentally sound and safe management of any residue/discharge of the production process as per existing laws, rules, and regulations applicable.
- ix. The applicant shall ensure strict compliance of zero discharge of viable GE *Saccharomyces cerevisiae* strain MeJi797 (Active Dried Yeast – Innova Force ADY) into the environment at any stage including import, transport, storage, production, recovery, handling, and waste management.
- x. 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 15<sup>th</sup>

October (for the period April–September) and 15th April (for the period October–March) as per extant procedure.

- xi. 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.
- xii. The approval is subject to other statutory clearances.
- xiii. 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.
- xiv. Proper care shall be taken for decontamination and disposal of all materials, in accordance with Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017.
- xv. Accidents, if any, shall be reported to GEAC and necessary corrective actions shall be taken without delay.
- xvi. Environmental standards shall be maintained in the plant, including the following:
  - i. Conducting periodic Environmental Audit
  - ii. 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
- xvii. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.
- xviii. The Ministry reserves the right to stipulate additional conditions, if deemed necessary. The applicant, in a time bound manner, shall implement these conditions.
- xix. 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.

- xx. 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 Sterling Biotech Pvt Ltd, Gujarat, for Commercial Production of Food-grade  $\beta$ -Lactoglobulin ( $\beta$ -LGB) Using GE *Trichoderma reesei* PDLGB (sPD1087)**

The applicant submitted an application dated 05.12.2025 seeking approval for the large scale production of approximately 2500 Metric ton per annum of  $\beta$ -Lactoglobulin ( $\beta$ -LGB) by using GE *Trichoderma reesei* PDLGB (sPD1087) (classified as Risk Group 1) at Payal Industrial Park, Pakhajan, Taluka Vagra, District Bharuch, Gujarat for food and nutraceutical applications.

The inserted DNA in strain PDLGB (sPD1087) comprises the codon-optimized *Bos taurus*  $\beta$ -LGB gene for enhanced expression in fungal systems. Expression is driven by the inducible *cbh1* promoter for high-level production, and the construct does not contain any antibiotic resistance markers, with selection achieved through auxotrophic complementation.

M/s. Perfect Day India Pvt. Ltd., Bangalore, had earlier imported *T. reesei* PDLGB (sPD1087) in small quantities for research and development purposes in compliance with DBT OM No. BT/BS/17/635/2015-PID dated 17.01.2020. For large-scale import and commercial sale to customers like M/s. Sterling Biotech, the company has submitted an application to the GEAC seeking approval, which was considered in 159<sup>th</sup> GEAC Meeting under Agenda Item 7.4. Following was recommended by the GEAC:

*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.*

**Recommendations:**

The Committee deliberated on the proposal in detail and following decisions are taken:

- i. Considering that genetically modified (GM) food falls under the regulatory mandate of FSSAI under the Food Safety and Standards Act, 2006, the Committee directed the applicant to seek comments/inputs from FSSAI regarding the safety and regulatory status of the proposed product for human consumption and inputs regarding the availability of indigenous alternatives shall be sought from CIBRC.
- ii. Considering that the application of the supplier, M/s. Perfect Day India Pvt. Ltd., for large-scale import and commercial supply of the GE strain *Trichoderma reesei* PDLGB (sPD1087) is currently under consideration of the GEAC, the Committee decided to return the present proposal of M/s. Sterling Biotech Pvt with a request to resubmit the application along with the requisite documents.

**Action: GEAC Secretariat**

#### **Agenda Item No. 6: Applications related to Import/Export**

##### **6.1 M/s Danisco (India) Pvt. Ltd., Hyderabad for import and marketing of eBOOST® GTX - GE (active dry yeast) *S. cerevisiae* FS0436 (GICC003626) for fuel ethanol production from grain feedstocks**

The applicant submitted an application dated 20.12.2025 seeking approval for the import and marketing of eBOOST® GTX, a genetically engineered (GE) active dry yeast strain *Saccharomyces cerevisiae* FS0436 (GICC003626), for ethanol production from the United States. The applicant proposes to import 200 MT per annum. However, the intended import quantity during the first year is 20 MT.

eBOOST® GTX has been genetically engineered for extracellular expression of the glucoamylase gene derived from *Punctularia strigosozonata*. The expressed glucoamylase facilitates hydrolysis of starch in the fermentation medium into fermentable sugars, which are subsequently converted into fuel ethanol by eBOOST® GTX.

The Risk Assessment and Risk Management (RARM) Plan submitted by M/s Danisco (India) Pvt. Ltd., Hyderabad, was considered and deliberated upon by the RCGM in its 330<sup>th</sup> meeting held on 03.03.2026. Subsequently, the RCGM, vide email dated 17.03.2026, forwarded its recommendations along with the proceedings of the 330<sup>th</sup> RCGM meeting to the GEAC for further consideration.

#### **Recommendations**

GEAC deliberated on the proposal. Taking cognizance of the recommendations of 330<sup>th</sup> RCGM meeting, committee recommended the proposal of M/s Danisco (India) Pvt. Ltd., Hyderabad, for import of **200 MT per annum** of eBOOST® GTX, a genetically engineered (GE) active dry yeast strain *Saccharomyces cerevisiae* FS0436 (GICC003626), from the United States, for 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 eBOOST® GTX, a genetically engineered (GE) active dry yeast strain *Saccharomyces cerevisiae* FS0436 (GICC003626) 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 eBOOST® GTX, a genetically engineered (GE) active dry yeast strain *Saccharomyces cerevisiae* FS0436 (GICC003626), 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 spillage of viable eBOOST® GTX, a genetically engineered (GE) active dry yeast strain *Saccharomyces cerevisiae* FS0436 (GICC003626) 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 eBOOST® GTX, a genetically engineered (GE) active dry yeast strain *Saccharomyces cerevisiae* FS0436 (GICC003626) is restricted, only to trained and experienced persons, as recommended by IBSC. GE *Saccharomyces cerevisiae* strain FS0436 (GICC003626) 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 FS0436 (GICC003626) 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 FS0436 (GICC003626) yeast cultures being transported to detect and prevent any loss of GE *Saccharomyces cerevisiae* strain FS0436 (GICC003626) yeast during transport. This must be implemented for all transport events, except in cases where the GE *Saccharomyces cerevisiae* strain FS0436 (GICC003626) yeast transport solely occurs within a building. Annual track record should be submitted to IBSC.
- ix. The packaging of GE *Saccharomyces cerevisiae* strain FS0436 (GICC003626) 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 FS0436 (GICC003626) 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 FS0436 (GICC003626) 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 FS0436 (GICC003626) 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 FS0436 (GICC003626) yeast;
    - b. Report such incident to the State Biotechnology Co-Ordination Committee (SBCC), District Level Committee (DLC) and IBSC immediately, to notify 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 FS0436 (GICC003626) 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**

**6.2 M/s Lallemand India Pvt. Limited for import of Genetically Modified *Saccharomyces cerevisiae* yeast Strain M24926 (Fermboost) and its Distribution for Commercial Production of Ethanol**

The applicant submitted an application dated 14.05.2025 seeking approval for the import and distribution of Genetically Modified *Saccharomyces cerevisiae* yeast Strain M24926 (Fermboost) for commercial production of ethanol from Canada or Brazil. The applicant proposes to import 2,000 MT per annum, with an initial requirement of 16 MT per month for ethanol producers.

The strain M24926 has been genetically modified to express synthetic glucoamylase and trehalase genes derived from *Rasamsonia emersonii* and *Neurospora crassa*, respectively, for hydrolysis of starch and trehalose into glucose. The glucoamylase enzyme also contains the alpha-mating factor secretion signal from native *S. cerevisiae*.

The Risk Assessment and Risk Management (RARM) Plan submitted by M/s Lallemand India Pvt. Limited was considered and deliberated upon by the RCGM in its 330<sup>th</sup> meeting held on 03.03.2026. Subsequently, the RCGM, vide email dated 18.03.2026, forwarded its recommendations along with the proceedings of the 330<sup>th</sup> RCGM meeting to the GEAC for further consideration.

**Recommendations**

GEAC deliberated on the proposal. Taking cognizance of the recommendations of 330<sup>th</sup> RCGM meeting, committee recommended the proposal of M/s Lallemand India Pvt. Limited, for import of **2,000 MT per annum** of Genetically Modified *Saccharomyces cerevisiae* yeast Strain M24926 (Fermboost) from Canada or Brazil, for commercial production of ethanol, 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 Genetically Modified *Saccharomyces cerevisiae* yeast Strain M24926 (Fermboost) 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 Genetically Modified *Saccharomyces cerevisiae* yeast Strain M24926 (Fermboost), 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 spillage of viable Genetically Modified *Saccharomyces cerevisiae* yeast Strain M24926 (Fermboost) 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 Genetically Modified *Saccharomyces cerevisiae* yeast Strain M24926 (Fermboost) is restricted, only to trained and experienced persons, as recommended by IBSC. GE *Saccharomyces cerevisiae* strain M24926 (Fermboost) 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 M24926 (Fermboost) 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 M24926 (Fermboost) yeast cultures being transported to detect and prevent any loss of GE *Saccharomyces cerevisiae* strain M24926 (Fermboost) yeast during transport. This must be implemented for all transport events, except in cases where the GE *Saccharomyces cerevisiae* strain M24926 (Fermboost) yeast transport solely occurs within a building. Annual track record should be submitted to IBSC.
- ix. The packaging of GE *Saccharomyces cerevisiae* strain M24926 (Fermboost) 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 M24926 (Fermboost) 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 M24926 (Fermboost) 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 M24926 (Fermboost) 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 M24926 (Fermboost) yeast;
  - b. Report such incident to the State Biotechnology Co-Ordination Committee (SBCC), District Level Committee (DLC) and IBSC immediately, to notify 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 M24926 (Fermboost) 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**

**6.3 M/s Lallemand India Pvt. Limited on RARMP submitted for import of Genetically Modified *Saccharomyces cerevisiae* yeast Strain M34604 (Brand name: Fermboost ME) and its Distribution for Commercial Production of Ethanol**

The applicant submitted an application dated 02.12.2025 seeking approval for the import and distribution of Genetically Modified *Saccharomyces cerevisiae* yeast Strain M34604 (Brand name: Fermboost ME), from Canada for commercial production of ethanol. The applicant proposes to import 2,000 MT per annum, with an initial requirement of 16 MT per month for end users.

The strain M34604 has been genetically modified to express synthetic and codon optimized *pyruvate decarboxylase (PDC)* gene from the bacterium *Zymomonas mobilis*. Under anaerobic conditions in *Saccharomyces*, *PDC* catalyses the decarboxylation of pyruvate to acetaldehyde, a key step in fermentation pathway leading to ethanol production.

The Risk Assessment and Risk Management (RARM) Plan submitted by M/s Lallemand India Pvt Limited was considered and deliberated upon by the RCGM in its 330<sup>th</sup> meeting held on 03.03.2026. Subsequently, the RCGM, vide email dated 18.03.2026, forwarded its recommendations along with the proceedings of the 330<sup>th</sup> RCGM meeting to the GEAC for further consideration.

**Recommendations**

GEAC deliberated on the proposal. Taking cognizance of the recommendations of 330<sup>th</sup> RCGM meeting, committee recommended the proposal of M/s Lallemand India Pvt. Limited, for import of **2,000 MT per annum** of Genetically Modified *Saccharomyces cerevisiae* yeast Strain M34604 (Brand name: Fermboost ME), from Canada for commercial production of ethanol, 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 Genetically Modified *Saccharomyces cerevisiae* yeast Strain M34604 (Brand name: Fermboost ME) 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 Genetically Modified *Saccharomyces cerevisiae* yeast Strain M34604 (Brand name: Fermboost ME), 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 spillage of viable Genetically Modified *Saccharomyces cerevisiae* yeast Strain M34604 (Brand name: Fermboost ME) 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 Genetically Modified *Saccharomyces cerevisiae* yeast Strain M34604 (Brand name: Fermboost ME) is restricted, only to trained and experienced persons, as recommended by IBSC. GE *Saccharomyces cerevisiae* strain M34604 (Brand name: Fermboost ME) 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 M34604 (Brand name: Fermboost ME) 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 M34604 (Brand name: Fermboost ME) yeast cultures being transported to detect and prevent any loss of GE *Saccharomyces cerevisiae* strain M34604 (Brand name: Fermboost ME) yeast during transport. This must be implemented for all transport events, except in cases where the GE *Saccharomyces cerevisiae* strain M34604 (Brand name: Fermboost ME) yeast transport solely occurs within a building. Annual track record should be submitted to IBSC.
- ix. The packaging of GE *Saccharomyces cerevisiae* strain M34604 (Brand name: Fermboost ME) 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 M34604 (Brand name: Fermboost ME) 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 M34604 (Brand name: Fermboost ME) 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 M34604 (Brand name: Fermboost ME) 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 M34604 (Brand name: Fermboost ME) yeast;
  - b. Report such incident to the State Biotechnology Co-Ordination Committee (SBCC), District Level Committee (DLC) and IBSC immediately, to notify 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 M34604 (Brand name: Fermboost ME) 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**

**6.4 M/s Indian Immunologicals Limited (IIL) for import of Live Attenuated Genetically Modified African Swine Fever Vaccine (AVAC ASF LIVE) from Vietnam for Regulatory Testing and Evaluation in India**

The applicant submitted an application dated 25.02.2026 seeking approval for the import of 300 vials of Live Attenuated Genetically Modified African Swine Fever Vaccine (AVAC ASF LIVE) from Vietnam for regulatory testing and evaluation in India.

The highly virulent ASF virus strain was genetically modified through homologous recombination technology by deletion of six genes segments, namely MGF360-12L, MGF360-13L, MGF360-14L, MGF505-1R, MGF505-2R, and MGF505-3R, belonging to the MGF360 and MGF505 gene groups, resulting in the attenuated ASF-G-ΔMGF vaccine virus strain. This genetic modification results in an attenuated virus capable of limited replication in the host while retaining its immunogenic properties.

The vaccine is formulated as a freeze-dried (lyophilized) preparation and is intended for reconstitution prior to administration. It is designed for active immunization of healthy pigs to induce protective immune responses against circulating virulent ASFV strains.

**Recommendations**

Committee deliberated that AVAC ASF LIVE Attenuated vaccine is derived from highly virulent ASF virus strain falling in Risk Group IV category. After detailed deliberations, committee was of the view that the application may be referred to RCGM for examination.

**Action: GEAC Secretariat**

**Agenda Item No. 7: Applications related to import deferred due to requirement of Metagenomic Analysis in 159th GEAC**

**7.1 M/s Zoetis India Limited, Mumbai for import and marketing of Bursal Disease-Marek's Disease-Newcastle Disease Vaccine Serotype 3, Live Marek's Disease Vector (Poulvac Procerta HVT-IBD-ND) for vaccination of chickens**

The application submitted by M/s Zoetis India Limited, Mumbai for import of Bursal Disease-Marek's Disease-Newcastle Disease Vaccine Serotype 3, Live Marek's Disease Vector (Brand Name: Poulvac Procerta HVT-IBD-ND) vaccine for veterinary.

The applicant intends to import and market 13434 units of 4000 doses and 18575 units of 2000 doses from USA for vaccination of healthy one-day old chickens and 18- to 19-day-old embryonated chicken eggs against standard infectious Bursal disease, and Marek's and Newcastle diseases in India.

The application was previously considered by GEAC in its 147<sup>th</sup> meeting held on 18.10.2022, under Agenda item 7.1, wherein the committee recommended the proposal subject to the following conditions:

- i. *Initial 3 batches of the subject vaccine to be certified in ICAR-Indian Veterinary Research Institute (ICAR-IVRI), including its metagenomics analysis for verification of purity of the target event/organisms and to check the presence of non-target event/organisms.*
- ii. *Obtain relevant approvals from Department of Animal Husbandry and Dairying, Drug Controller General of India etc. as per existing laws, rules, regulations as applicable.*
- iii. *The final data certified by IVRI to be presented before the GEAC for final approval, before it is marketed in the country.*

The applicant vide GEAC application dated 18.03.2025 has submitted with ICAR-IVRI Test report, NOC obtained from DAHD and Metagenomics Analysis Report certified by GBRC.

The application was reconsidered under Agenda Item 9.1 during the 159<sup>th</sup> GEAC meeting held on 20 March 2026, the Committee recommended that Metagenomic Analysis shall not be mandatory for the import of recombinant veterinary vaccines. The recommendations of the 159<sup>th</sup> GEAC meeting were communicated to the applicant vide letter No. F. No. C-12013/37/2022-CS-III dated 13.04.2026.

As per the recommendations, 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.*

Presently, the applicant resubmitted as per 159<sup>th</sup> GEAC recommendation the application on 24.04.2026.

**Recommendations**

The committee had an extensive discussion and noted that the applicant has submitted certificate of analysis including purity and quality parameters issued by manufacture, certifying that the product is free from unacceptable levels of non-target organisms (NTOs) and contaminants, in accordance with applicable regulatory standards. However, as few members has raised biosecurity concerns and suggested that further examination may be required before importing the Bursal Disease-Marek's Disease-Newcastle Disease Vaccine Serotype 3, Live Marek's Disease Vector (Poulvac Procerta HVT-IBD-ND) vaccine for chickens.

Therefore, the committee has decided to forward the application along with the above mentioned certificates for inputs/comments from the Central Drugs Standard Control Organization (CDSCO) and based on the inputs received from CDSCO, GEAC Secretariat will take a view on the application.

**Action: GEAC Secretariat**

**Agenda Item No. 8: Additional Items for consideration**

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

## Annexure 1

### List of Participants

<b>Members who participated</b>	
<b>1 Shri Amandeep Garg</b> <b>Chairman</b> Additional Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jorbagh, Aliganj, New Delhi- 110003	<b>7 Dr. D.K. Yadav</b> ADG, (Crop Science) Indian Council of Agricultural Research, Krishi Bhawan, New Delhi-110001
<b>2 Dr. Nitin K. Jain</b> <b>Co-Chair</b> Scientist-G, Department of Biotechnology, C.G.O Complex, Lodhi Road, New Delhi-110003	<b>8 Dr. J.P. Singh</b> Plant Protection Adviser (PPA), Directorate of Plant Protection, Quarantine & Storage, NH IV, Faridabad-121001, New Delhi
<b>3 Sh. Tarun Kumar Kathula</b> <b>Vice-Chair</b> Scientist G, MoEFCC, Indira Paryavaran Bhawan, Jor bagh, Aliganj, New Delhi- 110003	<b>9 Dr. Rubina Bose</b> Deputy Drugs Controller, Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, New Delhi -110002 (Representative of Drugs Controller General of India)
<b>4 Dr. H. K. Sharma</b> Former Director, National Institute of Technology, Agartala, Tripura- 799 046	<b>10 Dr. Vinay K. Nandicoori</b> Director, CSIR-Centre for Cellular & Molecular Biology, Hyderabad - 500 007
<b>5 Dr. Chaitanya Joshi</b> Director, Gujarat Biotechnology Research Centre, Gandhinagar, Gujarat- 382 011	<b>11 Dr. Alka Rao</b> Advisor, Advisor (S&S&R) Food Safety and Standards Authority of India (FSSAI) New Delhi
<b>6 Dr. P. Dhar,</b> Representative of Director, ICAR-Indian Veterinary Research Institute, Bareilly (UP) – 243122	<b>12 Dr. Abhilasha Singh Mathuriya</b> <b>Member Secretary,</b> Scientist D, CS-III Division, Ministry of Environment, Forest and Climate Change, Jor bagh, New Delhi-110003
<b>Members who did not participate</b>	
<b>1 Dr. Satish Wate</b> Former Director, CSIR-National Environmental Engineering Research Institute, Nagpur- 440020	<b>7 Ms. Shruti Singh</b> Joint Secretary, IPR, Department for Promotion of Industry and Internal Trade, Udyog Bhawan, New Delhi ,110011
<b>2 Dr. Dinkar M. Salunkhe</b>	<b>8 Dr. Geeta Jotwani</b> Scientist G, Indian Council of Medical Research

	Former Director, International Centre for Genetic Engineering and Biotechnology, New Delhi-110067		(ICMR), Ministry of Health and Family Welfare, Ramalingaswami Bhavan, Ansari Nagar, New Delhi—110 029
<b>3</b>	<b>Dr. J. P. Shukla</b> Scientist, CSIR-Advanced Materials and Process Research Institute, Bhopal-462 026	<b>9</b>	<b>Dr. Sanjeev Khosla</b> Director, CSIR- Institute of Microbial Technology, Chandigarh- 160 036
<b>4</b>	<b>Dr. U. S. N. Murthy</b> Director, National Institute of Pharmaceutical Education and Research, Guwahati-781101	<b>10</b>	<b>Dr. P.K. Dass</b> Department of Anatomy, LHMC & Associated Hospitals, New Delhi-110001
<b>5</b>	<b>Dr. Rekha S. Singhal</b> Professor, Food Technology, Institute of Chemical Technology, Mumbai- 400 019	<b>11</b>	<b>Shri V.P. Yadav</b> Scientist F, Central Pollution Control Board, Parivesh Bhawan, East Arjun Nagar, Delhi-110 032
<b>6</b>	<b>Dr. P. Suprasanna</b> Scientific Officer H (Retd.), Biosciences group, BARC, Mumbai-400 085		

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