MINUTES OF THE 154th MEETING OF THE GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 17.04.2025

The 154th meeting of the Genetic Engineering Appraisal Committee (GEAC) of the Ministry of Environment, Forest and Climate Change (MoEF&CC) was held on 17.04.2025 in hybrid mode at Satluj Hall, Ground Floor, Jal Block, Indira Paryavaran Bhawan, New Delhi. The meeting was chaired by Shri Amandeep Garg, Additional Secretary, MoEF&CC. 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

Four members communicated their inability to attend the 154th meeting of GEAC, namely Dr. Dinakar M. Salunke, Dr Sanjay Mishra, Satish Wate and Dr. J. P. Singh. Further, Dr. H.K. Sharma, Dr. Vinay K Nandicoori, Dr. J.P. Shukla, Dr. P. Suprasanna, Ms. Shruti Singh, Dr. Geeta Jotwani, Shri V.P Yadav and Dr. Alkao Rao did not attend the meeting.

Decision:

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

Action: GEAC Secretariat

Agenda Item No. 2: Confirmation of minutes of the 153rd GEAC meeting

Minutes of the 153rd 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 153rd GEAC meeting.

Action: GEAC Secretariat

Agenda Item N o. 3: Action taken report on the decision taken in the 153rd GEAC meeting

Member Secretary, GEAC briefed about the action taken on the decisions at the 153rd meeting of GEAC. The committee was informed that letters communicating GEAC decisions had been issued to applicants as required.

Decision:

The Committee noted the actions taken by the Secretariat.

Action: GEAC Secretariat

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

4.1 M/s Bioseed Research India, Hyderabad for BRL-I (1st year) trial of GE cotton hybrids carrying Event BioCotX24A1 expressing *cry8Ea1* (X24A1DM) gene.

The application was initially considered in 152nd meeting dated 29.07.2024. Applicant informed that they intend to conduct BRL-I (1st year) Confined field trial of GE cotton hybrids carrying Event BioCotX24A1 expressing cry8Ea1(X24A1DM) gene for resistance against Pink Bollworm (*Pectinophora gossypiella*). The trials are proposed to be conducted at 16 locations, situated in North, South & Central Zone, namely- 1) Panghal, Hisar; 2) Mathela, Khandwa; 3) Sala, Dhar; 4) Ambadgaon, Jalna; 5) Kukonda, Rangareddy; 6) CCS HAU, Hisar; 7) Bathinda Station, PAU, Ludhiana; 8) JAU, Junagadh; 9) NAU, Navsari; 10) MPKV, Rahuri; 11) PDKV, Akola; 12) RVSKVV, Gwalior; 13) UAS, Raichur; 14) ANGRAU, Guntur; 15) SKRAU, Bikaner; and 16) Yadgir, Karnataka.

The application was considered by RCGM and has been recommended in its 282nd meeting held on 18.04.2024 and 288th meeting held on 10.07.2024.

Applicant obtained NOC/concurrence for conduct of proposed trials from Government of Haryana, Andhra Pradesh, Karnataka, Madhya Pradesh and Punjab.

In 152nd GEAC Meeting, applicant submitted that the trials will not be taken up in North Zone for Kharif 2024 sowing season as the time, favorable for sowing, is over.

Based on the recommendation(s) of RCGM and NOC received from Govt.(s), GEAC in its 152nd meeting dated 29.07.2024 recommended proposal at following locations:

i. Mathela, Khandwa, M.P.
ii. Sala, Dhar, M.P.
iii. RVSKVV, Gwalior, M.P.
iv. UAS, Raichur, Karnataka
v. Yadgir, Karnataka
vi. ANGRAU, Guntur, A.P.

The applicant vide email dated 04.04.2025 and 16.04.2025 informed that they have obtained concurrence from Government of Punjab, Haryana and Gujarat.

Recommendation:

Based on the recommendation of 282nd and 288th meeting of RCGM and NOC received from Govt. of Haryana, Punjab and Gujarat; the proposal of M/s Bioseed Research India, Hyderabad to conduct BRL-I (1st year) trial of GE cotton hybrids carrying Event BioCotX24A1 expressing cry8Ea1 (X24A1DM) gene, at below mentioned five sites, to

evaluate resistance against Pink Bollworm during Kharif season 2025-2026 was recommended by the Committee:

i. CCSHAU, Hisar, Haryana
ii. Panghal, Hisar, Haryana
iii. Bathinda Station, PAU Ludhiana, Punjab
iv. JAU, Junagadh, Gujarat
v. NAU, Navsari, Gujarat

The recommendation is subject to following conditions:

i. The applicant shall adhere with the conditions and/or recommendations as per RCGM Letter dated 29.04.2024 and 19.07.2024, along with the RARM Plan enclosed therewith.
ii. The applicant shall adhere with the conditions and/or recommendations mentioned in concurrence obtained from Government of Haryana vide Letter dated 12.04.2024; Government of Punjab vide Letter dated 10.02.2025; Government of Gujarat vide Letter dated 16.04.2025
iii. The BRL-I confined field trials should be conducted at insect specific hotspot in the trial sites that are appropriate to evaluate the introduced insect resistant trait in the GE plant.
iv. The applicant shall share details of the trial site as required under part G of the Guidelines and SOPs for Confined Field Trials of regulated GE plants, 2008 including ownership of trial site.
v. The applicant shall share information regarding confirmed availability of isolation distance, land use and its ownership, before start of the trial.
vi. The applicant shall share information regarding name of the trial-in-charge/lead scientist responsible for each trial, as well as expected date of sowing, before start of the trial.
vii. Upon successful completion of intended BRL-I confined field trials, the findings/ report of these BRL-I trials should be reviewed by RCGM in consonance with the findings/ report of Event Selection Trials under confined field conditions of GE cotton lines expressing cry8Ea1 (X24A1DM) gene which are intended to be undertaken by applicant during Kharif 2025-2026 growing season. Accordingly, the furtherance, if any, of these BRL-I confined field trials should be taken into consideration by RCGM.

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

Action: GEAC & RCGM Secretariat

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

5.1 M/s Venkateshwara Hatcheries Pvt. Ltd., Pune for NOC for manufacturing and marketing of Newcastle Disease Vaccine Inactivated (Lasota and Genotype 7) and Newcastle Disease Vaccine inactivated (Lasota and Genotype 13) for commercial use.

The applicant made a presentation before the committee and informed that they intend to manufacture and market Newcastle Disease Vaccine Inactivated (Lasota and Genotype 7) and Newcastle Disease Vaccine inactivated (Lasota and Genotype 13) for commercial use.

The applicant has initially submitted the application in DCGI, wherein the Form 46 received from DCGI office regarding product permission contains a clause to obtain NOC from GEAC before marketing the products.

The applicant intends to produce 300 million doses per annum of Newcastle Disease Vaccine Inactivated (Lasota+Genotype 7) and Newcastle Disease Vaccine Inactivated (Lasota+Genotype 13) at Ventri Biologicals, Pune for immunization of chicken for protection against circulating NDV types.

The committee was informed that the applicant has mentioned in the application that the vaccines do not contain any recombinant strains and are manufactured by propagating individual whole virus strains in embryonated chicken eggs.

Recommendation:

After due deliberations, the committee was of view that DCGI may reexamine the necessity of NOC from GEAC in the matter.

Action: GEAC Secretariat

5.2 M/s Buttar Biofuels Pvt. Ltd, Chandigarh for commercial production of ethanol using GE *Saccharomyces cerevisiae* strain M24926.

The committee was informed that the proposal of M/s Buttar Biofuels Pvt. Ltd, Chandigarh for commercial production of ethanol using GE *Saccharomyces cerevisiae* strain M24926 was previously considered by GEAC in its 149th and 152nd meeting.

Applicant intend to produce 60 MT ethanol per annum using GE *Saccharomyces cerevisiae* strain M24926 (Brand Name: Fermboost) at production facility at Amritsar, Punjab for gasoline blending. The Strain M24926 is genetically modified to introduce genes encoding for glucoamylase and trehalase enzymes for enabling efficient ethanol production. The supplier of strain M24926 is Lallemand's distributor M/s Aaditya Finechem Pvt. Ltd, Jaipur.

It was informed that in the 149th GEAC meeting, information was sought by the committee regarding Environmental Risk Management and Safety Plan (ERMP), on site/

off site plan emergency plan, waste management plan and Details of IBSC and their regulatory approvals. Applicant submitted the requisite details vide their letter dated 28.12. 2023. The various plans received from applicant was forwarded to RCGM for concurrence.

In 152nd GEAC meeting committee recommended the applicant to prepare and/ or align their respective ERMP's in accordance with the standard Risk Assessment & Risk Management Plan (RARMP) and submit their revised proposals to RCGM for consideration. GEAC in its 153rd GEAC meeting held on 03.10.2024 appraised the Standard Risk Assessment and Risk Management (RARM) Plan for Environmental Safety for Undertaking Commercial Production of Ethanol Using Genetically Engineered Organisms (GEOs)/Living Modified Organisms (LMOs). Letter communicating the Standard RARMP was sent to applicant vide letter dated 21.10.2024. The applicant vide email dated 28.10.2024 have submitted the RARMP, which was forwarded to RCGM for consideration. The RARMP submitted by M/s Buttar Biofuels Pvt. Ltd, Chandigarh was considered and deliberated in its 297th and 299th RCGM meeting dated 13.11.2024 and 11.12.2024 respectively.

RCGM via email dated 03.02.2025 have sent the letter to GEAC, enclosed with recommendations of its 297th and 299th RCGM meeting for further consideration. Further, RCGM has mentioned in the letter that if desired appropriate procedure/mechanism for monitoring of storage facility may be laid out by GEAC.

Recommendation:

Taking cognizance of the recommendations of 297th and 299th RCGM meeting, the RARMP submitted by M/s Buttar Biofuels Pvt. Ltd, Chandigarh for commercial production of ethanol using GE *Saccharomyces cerevisiae* strain M24926 was recommended by the Committee subject to following conditions:

i. The activity must adhere to the plans proposed in the application and activity must comply with the RARM plans recommended by GEAC.
ii. Applicant shall ensure that the *GE Saccharomyces cerevisiae* strain M24926 is used for the intended application as indicated. In case of different use, except as indicated in the application, applicant shall take separate approval from GEAC.
iii. The project should be implemented under the oversight of IBSC.
iv. The applicant shall submit IBSC approved compliance report on RARM plan as approved by GEAC, every 6 months to GEAC Secretariat.
v. It is obligated to ensure environmentally sound and safe management of any residue/discharge of the production process as per existing laws, rules, regulations applicable.
vi. The applicant shall ensure strict compliance of zero discharge of viable GE Saccharomyces cerevisiae strain M24926 into the environment at any stage including import, transport, storage, production, recovery, handling, management etc.

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

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

ix. The approval is subject to other statutory clearances.

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

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

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

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

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

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

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

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

Action: GEAC Secretariat

5.3 M/s Bharat Petroleum Corporation Limited, Greater Noida (U.P.) for commercial production of ethanol GE *Saccharomyces cerevisiae* strain CelluX4.

The application submitted by M/s. Bharat Petroleum Corporation Limited (BPCL), Greater Noida (U.P.) for production of 2G ethanol was previously considered by GEAC in its 152nd meeting, wherein, the committee directed applicant to prepare and/or align their respective RARMP's in accordance with the standard RARMP and submit their revised proposals to RCGM for consideration.

GEAC in its 153rd GEAC meeting held on 03.10.2024 appraised the Standard RARMP for Environmental Safety for Undertaking Commercial Production of Ethanol Using Genetically Engineered Organisms (GEOs)/Living Modified Organisms (LMOs). Letter communicating the Standard RARMP was sent to applicant vide letter dated 16.10.2024. Accordingly, the applicant vide email dated 22.10.2024 have submitted the RARMP which was forwarded to RCGM for consideration.

The RARMP submitted by M/s BPCL, Greater Noida (U.P.) was considered and deliberated by RCGM in its 296th and 299th meeting dated 30.10.2024 and 11.12.2024 respectively. RCGM in its 299th meeting recommended to forward the revised RARMP for production of 100KL Per Day of 2G ethanol to GEAC for further consideration. RCGM vide email dated 03.02.2025 shared the recommendations of the meetings.

Recommendation:

In cognizance with recommendations of 296th and 299th RCGM meeting, the proposal and RARMP submitted by M/s Bharat Petroleum Corporation Limited, Greater Noida (U.P.) for commercial production of ethanol GE *Saccharomyces cerevisiae* strain CelluX4 was recommended by the Committee, subject to the 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 CelluX4 is used for the intended application as indicated. In case of different use, except as indicated in the application, applicant shall take separate approval from GEAC.
iii. The project should be implemented under the oversight of IBSC.
iv. The applicant shall submit IBSC approved compliance report on RARM plan as approved by GEAC, every 6 months to GEAC Secretariat.
v. It is obligated to ensure environmentally sound and safe management of any residue/discharge of the production process as per existing laws, rules, regulations applicable.
vi. The applicant shall ensure strict compliance of zero discharge of viable GE *Saccharomyces cerevisiae* strain CelluX4 into the environment at any stage including import, transport, storage, production, recovery, handling, management etc.
vii. The records of generation, treatment, recycle/reuse and disposal of related to production process shall be maintained and submitted to concerned SPCB at regular intervals of twice in a year, on 15th October (for April-September) and 15th April (for October to March).
viii. The clearance granted to the project/activity is strictly under the provisions of the EIA Notification 2006 and its subsequent amendments. It does not

tantamount/construe to approvals/consent/permissions etc. required to be obtained or standards/conditions to be followed under any other Acts/ Rules/ Subordinate legislations, etc., as may be applicable to the project. The applicant shall obtain necessary permission as mandated under the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981, as applicable from time to time, from the State Pollution Control Board, prior to construction & operation of the project.

ix. The approval is subject to other statutory clearances.

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

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

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

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

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

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

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

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

Action: GEAC Secretariat

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

6.1 M/s Huvepharma Sea (Pune) Pvt. Ltd for import of recombinant veterinary vaccine *Clostridium Perfringens* Type A Vaccine, Live Salmonella Vector (Avert NE).

The applicant made a presentation before the committee and informed that they intend to import recombinant veterinary vaccine *Clostridium Perfringens* Type A Vaccine, Live *Salmonella* Vector (Avert NE).

The application was initially submitted to CDSCO dated 26.04.2024 for clearance, wherein the CDSCO have requested the applicant to provide clearance obtained from GEAC.

The host microorganism referred as Recombinant Attenuated *Salmonella* Vaccine (RASV) strain 12341 has been genetically modified to introduce recombinant plasmid, pG8R220. The donor DNA sequences PlcC and NetB toxin is from *Clostridium perfringens*. The genes for PlcC and GST-NetB were cloned into the vector plasmid pYA3681 resulting in the expression plasmid pG8R220.

The applicant intends to import up to 100,00,000 doses of *Clostridium Perfringens* Type A Vaccine, Live *Salmonella* Vector per annum for use in chickens one day of age or older for active immunization against *Clostridium perfringens* type A, the causative agent of necrotic enteritis for use in India.

Recommendation:

The committee recommended the proposal of M/s Huvepharma Sea (Pune) Pvt. Ltd for import of 100,00,000 doses per annum of recombinant veterinary vaccine *Clostridium Perfringens* Type A Vaccine, Live *Salmonella* Vector (Avert NE) for veterinary use subject to the following conditions:

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

Action: GEAC Secretariat

6.2 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).

The applicant made a presentation before the committee and informed that they intend to import and distribute recombinant vaccine Cell associated rHVT/ND-H9 LPAI

vaccine, Live Frozen (NEWFLEND ND H9) capable of inducing an immune response against NDV and H9 LPAIV in poultry.

NEWFLEND ND H9 is a recombinant veterinary vaccine with rHVT/ND/H9 event. It is a genetically engineered FC-126 HVT strain with the F glycoprotein encoding gene of the lentogenic Sato strain of NDV and the synthetic constructed H9 haemagglutinin gene of LPAIV (Low Pathogenic Avian Influenza Virus). This recombinant vaccine is intended to use in active immunisation of 18 day-old embryonated chicken eggs or one-day-old chicks against Newcastle disease virus (NDV) and H9 subtype of Low Pathogenic Avian Influenza virus (LPAIV-H9) to reduce clinical signs, lesions and virus shedding.

The applicant intends to import and distribute 20 million doses of vaccines per annum from Ceva-Phylaxia Veterinary Biologicals Co. Ltd., Hungary.

Recommendation:

The committee recommended the proposal of 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) for veterinary use subject to the following conditions:

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

Action: GEAC Secretariat

6.3 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).

The applicant made a presentation before the committee and informed that they intend 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) for poultry.

VECTORMUNE HVT NDV & SB-1 is a recombinant veterinary vaccine with two vial presentation containing rHVT/NDV. One vial of rHVT/NDV is mixed with one vial of

SB-1 at the time of vaccination. The vaccine after reconstitution contains rHVT/NDV Mareks Disease-Newcastle Disease vaccine, Serotype 3, Live Virus, Live Mareks Disease Vector (Vectormune HVT NDV) fraction and non LMO SB-1 (Serotype 2) fraction. This recombinant vaccine is intended to use in vaccination of healthy one-day-old chicks or in 18 to 19 day-old embryonated chicken eggs as an aid in the prevention of Newcastle disease and very virulent Marek's disease.

The applicant intends to import and distribute 27,000 vials per annum of VECTORMUNE HVT NDV & SB-1 from Ceva Animal Health LLC, USA.

The application was initially considered in the 125th GEAC meeting held on 11.12.2015 and 130th meeting held on 11.08.2016, wherein the committee recommended the import and marketing of VECTORMUNE HVT NDV & SB-1 vaccine.

The committee was informed that applicant vide email dated 26.11.2024 informed that as manufacturer decided to change the product from combined one vial to two vials for harmonization, this product was not imported till date.

Recommendation:

The committee recommended the proposal of 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) for veterinary use subject to the following conditions:

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

Action: GEAC Secretariat

6.4 M/s Centaur Pharmaceuticals Pvt. Ltd., Pune for import of Zein F4000C-Pharmaceutical Grade for use in pharmaceuticals dosage formulation.

The committee was informed that the Application for import of Zein F4000C-Pharmaceutical Grade for use in pharmaceuticals dosage formulation was previously considered in the 148th GEAC meeting, wherein the committee recommended the import

of 150kg Zein F4000C-Pharmaceutical Grade, per annum for use in pharmaceuticals dosage formulation "Pyridostigmine Bromide 180mg Tablets" subject to twelve conditions. The product, Zein F 4000C Pharmaceutical Grade, is derived from genetically modified Zea mays (Maize/Corn).

The applicant was directed to submit Environmental Risk Management and Safety Plan (ERMP) within 3 months, after approval to this Ministry. In accordance with the stipulated conditions, applicant submitted the ERMP, which was forwarded to RCGM. The applicant has requested via email dated 24.09.2024 to consider the application for import of 175kg of Zein F 4000C Pharmaceutical Grade from Flo Chemical Corporation, USA.

The applicant vide email dated 11.04.2025 informed that they have discontinued purchasing Zein protein 4000C (GMO) and no further import will be done for this material, and requested to close the application.

Recommendation:

The committee noted the withdrawal of application by M/s Centaur Pharmaceuticals Pvt. Ltd., Pune for import of Zein F4000C-Pharmaceutical Grade for use in pharmaceuticals dosage formulation.

Action: GEAC Secretariat

6.5 M/s Aaditya Finechem Pvt. Ltd, Jaipur for import of GE *Saccharomyces cerevisiae* strain M24926 and its distribution for ethanol production.

The application submitted by M/s Aaditya Finechem Pvt. Ltd, Jaipur for import of 200 MT of GE *Saccharomyces cerevisiae* strain M24926 (Brand Name: Fermboost), per annum, from Brazil and its marketing for ethanol production was initially considered in 149th GEAC Meeting held on 17.05.2023 and 150th GEAC meeting held on 10.08.2023. The application was recommended in 150th GEAC meeting held on 10.08.2023.

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

In 152nd GEAC meeting held on 29.07.2024, under Agenda item 6.3, the applicant made a presentation before the Committee and informed that they intend to import 2000 MT per annum of GE *S. cerevisiae* strain M24926 (Brand Name: Fermboost) from Canada and distribute/market it for ethanol production. The committee recommended that upon appraisal of standard RARMP by GEAC, the GEAC secretariat shall provide all the

concerned applicants with the standard RARMP and further directed the applicant to prepare and/ or align their respective RARMP in accordance with the standard RARMP and submit their revised proposal to RCGM for consideration.

GEAC in its 153rd GEAC meeting held on 03.10.2024 appraised the Standard RARMP for Import of Genetically Engineered Organisms (GEOs)/Living Modified Organisms (LMOs) for Commercial Production. Letter communicating the Standard RARMP for import was sent to applicant vide letter dated 21.10.2024. Applicant vide email dated 28.10.2024 have submitted the Standard RARMP, which was forwarded to RCGM for consideration.

RARM plan was considered in 297th and 299th meeting of RCGM dated 13.11.2024 and 11.12.2024 respectively

RCGM vide email dated 16.01.2025 have sent the recommendations of its 297th and 299th meeting dated 13.11.2024 and 11.12.2024 respectively for further consideration by GEAC.

Recommendation:

The Committee deliberated on the RARMP submitted by the applicant in accordance with recommendations of 152nd GEAC meeting. Taking cognizance of the recommendations of 297th and 299th RCGM meeting, committee recommended the proposal of M/s Aaditya Finechem Pvt. Ltd, Jaipur for import of 2000 MT per annum GE *Saccharomyces cerevisiae* strain M24926 from Canada and its distribution for ethanol production subject to following conditions.

i. The activity must adhere to the plans proposed in the application and activity must comply with the RARM plans recommended by GEAC.
ii. Appropriate safety measures, including on-site emergency plans, must be in place to manage any accidents as per:
    a. *Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017.*
    b. *Handbook for Institutional Biosafety Committees (IBSCs), Third Revised Edition, September 2020.*
iii. Applicant shall ensure that the GE *Saccharomyces cerevisiae* strain M24926 is used for the intended application as indicated. In case of different use, except as indicated in the application, applicant shall take separate approval from GEAC.
iv. Applicant shall submit IBSC approved Emergency Action Plan for an event of unintentional release of GE *Saccharomyces cerevisiae* strain M24926, before import.
v. The Applicant shall submit 16s RNA Gene Sequencing and 18s RNA Gene Sequencing Reports for the Initial five batches to detect any adventitious presence of bacteria and yeast except as indicated.
vi. The applicant shall ensure strict compliance of zero discharge of viable GE *Saccharomyces cerevisiae* strain M24926 into the environment at any stage

	including storage, transportation, access, handling, packing, re-packing, distribution, sale, decontamination, and disposal etc.
vii.	Applicant shall ensure that the access to the GE *Saccharomyces cerevisiae* strain M24926 is restricted, only to trained and experienced persons, as recommended by IBSC. GMOs should be stored securely in the containers in a locked area until transported. This restriction on access applies to all scenarios, including situations where containers containing GE *Saccharomyces cerevisiae* strain M24926 are temporarily left for collection in a loading area or are left unattended before undergoing proper decontamination.
viii.	Applicant shall ensure that inventory of consignment is maintained and procedures are in place to track and account for all GMOs or the number of primary containers of GE *Saccharomyces cerevisiae* strain M24926 cultures being transported to detect and prevent any loss of GE *Saccharomyces cerevisiae* strain M24926 during transport. This must be implemented for all transport events, except in cases where the GE *Saccharomyces cerevisiae* strain M24926 transport solely occurs within a building. Annual record should be submitted to IBSC.
ix.	The packaging of GE *Saccharomyces cerevisiae* strain M24926 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 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 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, 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 non-viable. The exposed area must be immediately decontaminated with an appropriate decontaminating agent effective against the GE *Saccharomyces cerevisiae* strain M24926;

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 M24926 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

6.6 M/s Virbac Animal Health India Pvt. Ltd., Mumbai for import and marketing of recombinant vaccine Himmvac Dalguban BBN + Oil Vaccine for veterinary use only.

The Committee was informed that the proposal of M/s Virbac Animal Health India Pvt. Ltd., Mumbai for import and marketing of Himmvac Dalguban BBN + Oil vaccine [Generic Name: Combined Newcastle Disease (KBNP-C4152R2L) & Avian infectious Bronchitis (M41 Strain and KM91 Strain), Inactivated Oil Vaccine] for veterinary use was previously considered and recommended in 149th GEAC meeting held on 17.05.2023, wherein the following was recommended:

"*The committee directed the applicant to get the metagenomics analysis of the subject vaccine certified by Gujarat Biotechnology Research Centre (GBRC), Gujarat for verification of purity of the target event/ organisms and to check the presence of non-target*

event/organisms. The final data certified by GBRC to be presented before the GEAC for final approval, before it is marketed in the country. The Committee also directed the applicant to inform the quantity, per annum, of the subject vaccine to be imported in the country as the same has not been indicated in the GEAC application submitted to the Secretariat."

The committee was informed that the applicant has submitted the Metagenomic analysis of the vaccine certified by GBRC vide email dated 04.02.2025. The committee further noted the quantity to be imported 3,000 units per annum provided by the applicant.

The Metagenomic analysis study revealed *that most reads were attributable to the host Galgal genome, followed by sequences associated with the target virus (NDV + AIB). Notably, a presence of Cutibacterium spp., Escherichia coli, Chlamydia spp., were detected in the vaccine.*

Recommendation:

After due deliberations on the GBRC certified Metagenomic analysis report, the Committee was of the view that the comments may be solicited from Animal Husbandry Commissioner, DAHD; ICAR - Indian Veterinary Research Institute (IVRI), Bareilly; ICAR - National Institute of Veterinary Epidemiology and Disease Informatics (NIVEDI), Bengaluru; and ICMR-National Institute of Virology (NIV), Pune in respect of following:

i. The prevalence in India of the Non-Target Organisms (NTOs) detected in the subject veterinary recombinant vaccine (i.e. Himmvac Dalguban BBN + Oil Vaccine), as per Metagenomic analysis report certified by GBRC, with a view to identify if the NTOs detected are novel or are prevalent in the country.
ii. In case the NTOs detected in the vaccines are prevalent or not, in India, the probable risks that identified NTOs can pose in Indian context.
iii. The threshold/ permissible level of presence of Non-Target Organisms, which can be permitted in the veterinary vaccines being imported in India.

Action: GEAC Secretariat

6.7 M/s Praj Industries Ltd, Pune for import of GE *Saccharomyces cerevisiae* strain CelluX4 for ethanol production.

The committee was informed that the proposal submitted by M/s Praj Industries Ltd, Pune for import of GE *Saccharomyces cerevisiae* strain CelluX4 for ethanol production was previously considered in 152nd GEAC held on 29.07.2024 under Agenda Item 6.5, wherein the committee directed the applicant to prepare and/or align their respective RARMP in accordance with the standard RARMP and submit their revised proposal to RCGM for consideration. The applicant intends to import 10 MT, per annum, of GE *Saccharomyces cerevisiae* CelluX4 Active dry yeast from M/s Leaf, USA and supply it

to M/s Bharat Petroleum Corporation Limited (BPCL) 2G ethanol plant located in Bargarh, Odisha.

The modified strain CelluX4 is able to ferment hexose sugars and the pentose sugar D-xylose into ethanol in lignocellulose hydrolysates.

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

Applicant vide email dated 14.11.2024 have submitted the Standard RARMP which was forwarded to RCGM for consideration.

RARM plan was considered in 298th and 302nd meetings of RCGM held on 27.11.2024 and 22.01.2025, respectively. RCGM has shared the recommendations to GEAC via email dated 07.02.2025 for further consideration, which were examined by GEAC secretariat and it was observed that information regarding which were examined by GEAC secretariat and it was observed that information regarding Standard Operating Procedures (SOPs) for corrective actions in case of spillage; An emergency plan for post-accidental spillage including potential impact of spills into water bodies (e.g., ponds, lakes); a detailed on-site emergency plan for cleaning of spillages are missing.

Recommendation:

Committee deliberated on the recommendations of 298th and 302nd RCGM meeting, and on the RARMP submitted by M/s Praj Industries Ltd., Pune, for the import of GE *Saccharomyces cerevisiae* strain CelluX4 for ethanol production. The Committee suggested the applicant to submit below mentioned missing information from the RARM Plan to the RCGM:

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

Accordingly, the decision on the application was deferred till the recommendations from the RCGM on the above-mentioned points are received.

Action: GEAC Secretariat

6.8 M/s Virbac Animal Health India Pvt. Ltd., Mumbai for import and marketing of recombinant vaccine Himmvac Dalguban N + Oil vaccine for veterinary use only.

The committee was informed that the proposal for import and marketing of Ranikhet Disease Vaccine, Inactivated, NDV-KBNP-C4152R2L Strain (Trade name: Himmvac

Dalguban N + Oil vaccine) for veterinary use by M/s Virbac Animal Health India Pvt. Ltd., Mumbai was initially considered in the 144th meeting of GEAC held on 22.02.2022, wherein the proposal was recommended for import only subject to the following conditions;

i. *Initial 3 batches of the subject vaccine to be certified in ICAR-Indian Veterinary Research Institute (ICAR-IVRI) or Chaudhary Charan Singh National Institute of Animal Health (CCSNIAH), Uttar Pradesh (as notified by Ministry of Health and Family Welfare);*
ii. *Obtain relevant approvals from Department of Animal Husbandry and Dairying, Drug Controller General of India etc. as per existing Indian laws applicable for import of vaccines;*
iii. *The final data certified by IVRI/CCSNIAH to be presented before the GEAC for final approval, before it is marketed in the country.*

Subsequently in 150th meeting of GEAC held on 10.08.2023, the committee was informed that the applicant had submitted the ICAR-IVRI certified test batch reports vide Letter No. STD/QC/VT/Virbac/2023-24/89 dated 06.07.2023; the NOC obtained from Department of Animal Husbandry and Dairying vide Letter No. K-11053/47/2021-LH-Part I dated 24.03.2022; permission in Form 45 under Drugs and Cosmetics Act obtained from Drugs Controller General (India) vide Letter No. 12- 08/Virbac/2021/VD dated 02.05.2022. The following was recommended to the applicant:

"The committee directed the applicant to get the metagenomics analysis of the subject vaccine certified by Gujarat Biotechnology Research Centre (GBRC), Gujarat for verification of purity of the target event/organisms and to check the presence of non-target event/organisms. The final data certified by GBRC to be presented before the GEAC for final approval, before it is marketed in the country.

The Committee also directed the applicant to inform the quantity, per annum, of the subject vaccine to be imported in the country as the same has not been indicated in the GEAC application submitted to the Secretariat."

The committee was informed that the applicant vide email dated 04.02.2025 has submitted the Metagenomic analysis of the vaccine certified by GBRC. The quantity to be imported 9000 units per annum is provided by the applicant.

The Metagenomics study revealed that most reads were attributable to the host *Galgal* genome, followed by sequences associated with the target virus (NDV+AIB). Notably, *Cutibacterium spp., Escherichia coli, Campylobacter coli, Chlamydia spp. and Caudovirales, Circovirus were detected in the vaccine.*

Recommendation:

After due deliberations on the GBRC certified Metagenomic analysis report, the Committee was of the view that the comments may be solicited from Animal Husbandry Commissioner, DAHD; ICAR - Indian Veterinary Research Institute (IVRI), Bareilly;

ICAR - National Institute of Veterinary Epidemiology and Disease Informatics (NIVEDI), Bengaluru; and ICMR-National Institute of Virology (NIV), Pune in respect of following:

i. The prevalence in India of the Non-Target Organisms (NTOs) detected in the subject veterinary recombinant vaccine (i.e. Himmvac Dalguban N+ Oil vaccine), as per Metagenomic analysis report certified by GBRC, with a view to identify if the NTOs detected are novel or are prevalent in the country.
ii. In case the NTOs detected in the vaccines are prevalent or not, in India, the probable risks that identified NTOs can pose in Indian context.
iii. The threshold/ permissible level of presence of Non-Target Organisms, which can be permitted in the veterinary vaccines being imported in India.

Action: GEAC Secretariat

Agenda Item No. 7: Additional Items for consideration

7.1 The request submitted by NABI, Mohali for extension of validity of two permit letters (No. BT/IBKP/468/2021 dated 23.12.2022) issued for the conduct of Event Selection Trials (ESTs) of GE banana lines under confined field conditions during 2023-24 conducted by National Agri-Food Biotechnology Institute, Mohali, at two trial site locations, namely: i) Sarat Chandra Sinha College of Agriculture AAU, Dhubri, Assam, and ii) National Agri-Food Biotechnology Institute (NABI), Mohali till June, 2025.

Letter No. BT/IBKP/468/2021 dated 10.12.2024, received from RCGM regarding the request submitted by National Agri-Food Biotechnology Institute (NABI), Mohali for extension of validity of two permit letters (No. BT/IBKP/468/2021 dated 23.12.2022) issued for the conduct of Event Selection Trials (ESTs) of GE banana lines under confined field conditions during 2023-24 conducted by National Agri-Food Biotechnology Institute, Mohali, at two trial site locations, namely: i) Sarat Chandra Sinha College of Agriculture AAU, Dhubri, Assam ii) National Agri-Food Biotechnology Institute (NABI), Mohali till June, 2025.

i. Five GE banana lines expressing OsNASI gene (three GE lines viz., NRQIGN53-'19/15, NRQIGN53-'19/23 and NRQIGN53-'19/10) or OsNAS2 gene (two GE lines expressing viz., NRQIGN68-'20/47 and NRQIGN68-'20/36) for iron biofortification (IBKP UAC: NATTOFEB0220).
ii. Twenty GE banana lines expressing Apsy2a gene (twelve GE lines expressing Apsy2a gene driven by Ubiquitin promoter viz., NABI-GN440, NABI-GN423, NRQP34-'19/01, NRQP34-'19/02, NRQP34-'19/03, NRQP34-'19/05, NRQP34-'19/07, NRQP34-'19/08, NRQP34-'19/10. NRQP34-'19/11, NRQP34-'19/12 and NRQP34-'19/13; three GE lines expressing Apsy2a gene driven by ACO promoter viz., NABI- GN321, NABI-GN346, NABI-GN416) or NEN-DXS2 gene (five GE lines

expressing NEN-DXS2 gene driven by Ubiquitin promoter viz. NABI-GN544, NABI-GN545, NABI-GN549, NABI-GN552, NABI- GN553) for Pro-Vitamin A biofortification. (IBKP UAC: NATTOPVA0220).

The application was considered by GEAC in its 147th meeting on 18.10.2022 under agenda item 5.2 and 5.3 wherein the committee recommended the proposals. Accordingly, RCGM was directed to issue the permit letters.

Two different RCGM permit letter(s) No. BT/IBKP/468/2021 dated 23.12.2022 were issued to National Agri-Food Biotechnology Institute, Mohali, to conduct the two above-mentioned ESTs under confined field conditions during 2023-24 at five trial locations namely;

1) National Agri-Food Biotechnology Institute (NABI), Mohali
2) ICAR-National Research Centre for Banana (NRCB), Tiruchirappalli
3) Navsari Agriculture University (NAU), Navsari, Gujarat
4) Sarat Chandra Sinha College of Agriculture (SCSCA), AAU, Dhubri, Assam
5) Tamil Nadu Agricultural University (TNAU), Coimbatore

Furthermore, RCGM issued Addendum No. BT/MBKP/468/2021 dated 17.07.2023 and 19.07.2023 to replace two GE banana lines for iron biofortification and one GE banana line for Pro-Vitamin A biofortification, respectively to the permit letter(s).

The applicant via email to RCGM dated 20.11.2024 have informed that the trials were planted as per appropriate planting season for these locations (except at TNAU). The Central Compliance Committee has also visited all four trial sites. The trials at ICAR-NRCB, Trichy and Fruit Research Station, Gandevi, Navsari were harvested in August, 2024 and November 2024 respectively. However, the trials at SCSCA, AAU, Dhubri and NABI, Mohali shall be completed only in January/February, 2025 and April/May, 2025, respectively. The applicant has requested for extension of the validity of permit letters till the year 2025 for the conduct of ESTs of GE banana lines under confined field conditions at two trial site locations namely: 1) Sarat Chandra Sinha College of Agriculture AAU. Dhubri, Assam and 2) National Agri-Food Biotechnology Institute (NABI), Mohali.

The matter was considered in the 298th RCGM meeting held on 27.11.2024 wherein the RCGM recommended that the request submitted by NABI, Mohali for extension of validity of two permit letters (Nos. BT/IBKP/468/2021 dated 23.12.2022) till June 2025 may be granted and the application to be forwarded to GEAC for consideration.

RCGM vide Letter No. BT/IBKP/468/2021 dated 10.12.2024, forwarded the recommendation of 298th RCGM meeting and requested to consider above request in the next GEAC meeting for appropriate decision.

Recommendation:

In cognizance with recommendation of 298th RCGM meeting, the request submitted by NABI, Mohali for extension of validity of two permit letters (No. BT/IBKP/468/2021 dated 23.12.2022) issued for the conduct of Event Selection Trials (ESTs) of GE banana lines under confined field conditions during 2023-24 conducted by National Agri-Food Biotechnology Institute, Mohali, at two trial site locations, namely: i) Sarat Chandra Sinha College of Agriculture AAU, Dhubri, Assam, and ii) National Agri-Food Biotechnology Institute (NABI), Mohali till June, 2025 was recommended by the committee.

Action: GEAC Secretariat

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

Genetically Modified Organisms (GMOs), including Genetically Modified (GM) crops, in India are governed by "Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989" (Rules 1989) notified under the Environment (Protection) Act, 1986.

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

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

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

The current composition of CCC team includes six members:

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

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

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

In its 300th meeting held on 26.12.2024, RCGM gave recommendations on the proposed reforms of CCCs to GEAC for deliberation.

Recommendation:

After detailed deliberation, the Committee was of the view that the agenda should be discussed in the next GEAC meeting.

Action: GEAC Secretariat

Agenda Item No. 8: Any Other Item with the Permission of the Chairman

8.1 Applications related to concurrence from State government for Confined Field Trials of GE crops (BRL-I/ BRL-II Trials)

The Committee was informed that pursuant to the Hon'ble Supreme Court Order dated 01.05.2006 in the Aruna Rodrigues & Ors. vs UoI & Ors. Case (WP (C) 260/2005), the field trials of Genetically Modified Organisms (GMOs) including GE Crops are conducted only with the approval of the GEAC.

The GEAC in its 111th meeting held on 06.07.2011 took a decision to seek No Objection Certificate (NOC) from the State Government(s) before according permission for conducting Confined Field Trails.

It was further informed that in its 146th meeting dated 25.08.2022, after detailed deliberations, the GEAC decided to exempt the requirement of NOC from the State Government(s) for conducting Event Selections Trials, as previously recommended in 130th GEAC meeting held on 11.08.2016, since they are conducted strictly within the institutional premises and under controlled conditions.

For other Confined Field Trials, including BRL-I and BRL-II trials, the Committee decided that:

i. If the proposed confined field trial site is a Notified Field Trial Site (NFTS) as per GEAC approved proposal for establishment of NFTS for conducting confined field trials of GE Crops in its 140th meeting held on 28.07.2020, then in such

instances, the proposals for confined field trials will be considered by GEAC without any requirement of NOC from the State/UT Government(s).

ii. If the proposed confined field trial sites are other than Notified Field Trial Sites (NFTS), GEAC Secretariat will send a formal communication to the Additional Chief Secretary/Principal Secretary (Agriculture) of the States/UTs where the proposed confined field trial sites of each application are situated, requesting them to communicate their views/comments, if any, within 60 days of receipt of GEAC Secretariat letter. After 60 days, GEAC Secretariat will invite concerned State(s)/UT(s) Additional Chief Secretary/Principal Secretary (Agriculture) or their nominee as a Special Invitee and consider the application for detailed deliberations regarding recommendation of confined field trials based on views/comments, if any, received from the State/UT Government(s).

Deliberation

The Committee extensively deliberated on the persistent challenges faced by applicants in securing concurrence from State Governments for conducting Biosafety Research Level-I (BRL-I), and BRL-II trials.

The Committee noted that, at present, GEAC considers the recommendations of RCGM on the application, along with details of the trial sites recommended by RCGM and the concurrence issued by the concerned State Government, for granting final approval.

Committee noted that, despite obtaining technical clearances from the RCGM and the GEAC, applicants often face challenges in initiating confined field trials due to procedural delays in obtaining the requisite concurrence from the respective State Governments. Such delays, particularly when they coincide with season-specific sowing windows, can jeopardize the timely initiation of field trials and adversely impact the overall research timeline and biosafety data generation process, which are critical for regulatory evaluation. Further, even after receipt of concurrence from the State Governments, applicants have to wait for the convening of next GEAC meeting and the approval of GEAC, before they start the trial.

Recommendation

The Committee recognized the need to streamline the approval process for confined field trials without compromising regulatory oversight or biosafety. To address procedural delays, particularly those related to the timely receipt of concurrence from the concerned State Governments, the Committee recommended an interim procedural mechanism for applications that have already been approved by both the RCGM and the GEAC, and where trial sites have been duly recommended by the RCGM. In such cases, if the State Government's concurrence is received subsequent to GEAC's approval, the applicant may submit the same directly to the GEAC Secretariat. Upon administrative review of the concurrence by the Secretariat, and with the approval of the Chairman, GEAC, the Secretariat may request the RCGM to issue the formal permit letter to the applicant. The details of such approvals and actions taken shall be placed before the GEAC in its subsequent meeting for information and record.

Action: GEAC Secretariat

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

Annexure 1

List of Participants

Members who participated			
1.	**Shri Amandeep Garg** Additional Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jorbagh road, Aliganj, New Delhi- 110003	**7.**	**Dr. P.K. Dass** Department of Anatomy, LHMC & As sociated Hospitals, New Delhi- 110 001
2.	**Dr. D.K. Yadav** ADG (Seed), Crop Science Division, Indian Council of Agricultural Research, Krishi Bhawan, New Delhi-110001	**8.**	**Dr. Rubina Bose** Deputy Drugs Controller, Central Drugs Standard Control Org anization, Ministry of Health and Fa mily Welfare, FDA Bhavan, ITO, Kotl a Road, New Delhi -110002 (Represe ntative of Drugs Controller General o f India)
3.	**Dr. Pronab Dhar** Principal Scientist, ICAR-Indian Veterinary Research Institute (IVRI), Bareilly, Uttar Pradesh- 243122 (Representative of Dr. Triveni Dutt, Director, IVRI)	**9.**	**Dr. Rekha S. Singhal** Professor, Food Technology, Institute of Chemical Technology, Mumbai- 400 019
4.	**Dr. U. S. N. Murthy** Director, National Institute of Pharmaceutical E ducation and Research, Guwahati- 781101	**10.**	**Dr. Chaitanya Joshi** Director, Gujarat Biotechnology Research Centre, Gandhinagar, Gujarat- 382 011
5.	**Dr. Sanjeev Khosla** Director, CSIR- Institute of Microbial Technolog y, Chandigarh- 160 036	**11.**	**Dr. Abhilasha Singh Mathuriya** Member Secretary, Scientist D, CS-III Division, Ministry of Environment, Forest and Climate Change, Jorbagh, New Delhi-110003
6.	**Dr. Nitin K. Jain** Scientist–G and Member Secretary RCGM, Department of Biotechnology, C.G.O Complex, Lodhi Road, New Delhi-110003		
Officer from the Ministry			
1.	**Ms. Jaspreet Kaur** Deputy Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jorbhagh road, Aliganj, New Delhi – 110003		

Members who did not participate			
1.	**Dr. Sanjay Kumar Mishra** Scientist H, Department of Biotechnology, Block 2 CGO Complex, Lodhi Road, New Delhi - 110 003	**7.**	**Dr. Dinkar M. Salunkhe** Director, International Centre for Genetic Engineering and Biotechnology, New Delhi-110 067
2.	**Dr. Vinay K. Nandicoori** Director, CSIR-Centre for Cellular & Molecular Biology, Hyderabad - 500 007	**8.**	**Ms. Shruti Singh** Joint Secretary, IPR, Department for Promotion of Industry and Inte rnal Trade, Udyog Bhawan, New D elhi 110011
3.	**Dr. J. P. Shukla** Scientist, CSIR-Advanced Materials and Process Research Institute, Bhopal- 462 026	**9.**	**Dr. H. K. Sharma** Director, National Institute of Technology, Agartala, Tripura- 799 046
4.	**Dr. Satish Wate** Former Director, CSIR-National Environmental Engineering Research Institute, Nagpur- 440020	**10.**	**Shri V.P. Yadav** Scientist F, Central Pollution Control Board, Parivesh Bhawan, East Arjun Nagar, Delhi-110 032
5.	**Dr. Alka Rao** Principal Scientist, Protein Science and Engineering & Adjunct Associate Professor, GNR Protein Centre, CSIR-Institute of Microbial Technology (CSIR-IMTECH), Sector 39-A, Chandigarh-160036	**11.**	**Dr. P. Suprasanna** Scientific Officer H (Retd.), Biosciences group, BARC, Mumbai-400 085
6.	**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	**12.**	**Dr. J.P. Singh** Plant Protection Adviser (PPA), Directorate of Plant Protection, Quarantine & Storage, NH IV, Faridabad-121001. New Delhi