MINUTES OF THE 152nd MEETING OF THE GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 29.07.2024

The 152nd meeting of the Genetic Engineering Appraisal Committee (GEAC) of the Ministry of Environment, Forest and Climate Change (MoEF&CC) was held on 29.07.2024 in hybrid mode at Narmada Conference Hall, Ground Floor, Jal Block, Indira Paryavaran Bhawan, New Delhi. The meeting was chaired by Shri Naresh Pal Gangwar, Additional Secretary, MoEF&CC. The list of participants is placed at **Annexure 1**.

At the outset, Chairperson, GEAC welcomed all the members. The Committee expressed its condolences on sudden demise of one of its Members, Dr. S.J. Rahman and acknowledged his contributions. Committee was of view to co-opt another expert of same domain in place of Dr. Rahman. Member Secretary was requested to begin the discussion on agenda items.

Action: GEAC Secretariat

Agenda Item No. 1: Leave of absence

Three members communicated their inability to attend the 152nd meeting of GEAC, namely Dr. Satish Wate, Dr. P. Suprasanna, and Shri V.P. Yadav. Further, Ms. Shruti Singh, Dr. Dinkar M. Salunkhe, Dr. Vinay K. Nandicoori, Dr. Alka Rao, Dr. H. K. Sharma, and Dr. J. P. Shukla 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 151st GEAC meeting

Under agenda item 7.1 of 151st GEAC meeting, following has been recommended with regard to regulation of Genetically Modified (GM) food:

- "*Environmental safety aspect of any genetically modified food as well as the products derived from processing thereof shall be regulated by GEAC as per provisions of Rules 1989, as amended time to time;*
- *For regulation of genetically modified food and products derived thereof, GEAC will be the regulatory body granting permission in respect of environmental safety aspects, and such permissions shall be subject to clearance/permission of FSSAI.*"

In respect of recommendation made under agenda item 7.1 of 151st GEAC meeting, elucidation was given that exemption has been granted to '*Food stuffs, ingredients in food stuffs and additives including processing aids derived from Living Modified Organisms where the end product is not a Living Modified Organism*' from Rule 11 of Rules 1989 vide gazette notification dated 23.08.2007. Accordingly, GEAC will be implementing its role, in respect of regulation of GM food from environmental safety

angle, taking into account the aforesaid exemption granted in 2007. Members were requested to provide comments, if any.

Decision:
Members noted the elucidation in the minutes and confirmed the minutes of the 151st GEAC meeting.

Action: GEAC Secretariat

Agenda Item No. 3: Action taken report on the decision taken in the 151st GEAC meeting

The Committee was briefed about the action taken on the decisions at the 151st meeting of GEAC. Member Secretary informed that letters communicating GEAC decisions had been issued to applicants, concerned States and Ministries/ Departments/committees, 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 applicant made a presentation before the Committee and 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 sixteen locations in total situated in North Zone, South & Central Zone, namely- 1) Panghal, Hisar; 2) Mathela, Khandwa; 3) Sala, Dhar; 4) Ambadgaon, Jalna; 5) Kukonda, Rangareddy; 6) CCS HAU, Hisar; 7) 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.

It was further informed that applicant has obtained concurrence for conduct of proposed trials from four State Government(s), namely, Government of Andhra Pradesh vide Letter dated 22.05.2024; Government of Karnataka vide Letter dated 14.06.2024; Government of Madhya Pradesh vide Letter dated 08.04.2024 and 18.07.2024; and Government of Punjab vide Letter dated 13.03.2024. The Committee was informed that the Ghosli village trial site was indicated in the NOC issued by

Government of Madhya Pradesh which is not same as the trial site information provided by applicant.

Applicant submitted that they have requested Government of Madhya Pradesh for the necessary changes, with regard to trial site, in the letter dated 18.07.2024 issued by them. Further, the applicant submitted that the trials will not be taken up in North Zone (Punjab) for Kharif 2024 sowing season as the time, favourable for sowing, is over.

The applicant also submitted that during 2023-2024 they undertook trials of GE cotton hybrids carrying Event BioCotX24A1 expressing cry8Ea1(X24A1DM) gene within contained conditions (laboratory and/or greenhouse), on the basis of which the gene event BioCotX24A1 expressing cry8Ea1(X24A1DM) is proposed for BRL-I trials during 2024 growing season.

Recommendation:

Based on the recommendation(s) of 282nd & 288th RCGM meeting and NOC received from Govt.(s) of Andhra Pradesh, Karnataka, and Madhya Pradesh; 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 sites, to evaluate resistance against Pink Bollworm during Kharif season 2024-2026 was recommended by the Committee:

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 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 Government of Andhra Pradesh vide Letter dated 22.05.2024; Government of Karnataka vide Letter dated 14.06.2024; Government of Madhya Pradesh vide Letter dated 08.04.2024 and 18.07.2024.
iii. The BRL-I confined field trials at the trial site (Mathela, Khandwa) situated in Madhya Pradesh, as informed by the applicant, shall be commenced only after the receipt of revised concurrence from Government of Madhya Pradesh.
iv. 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.
v. 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.

vi. The applicant shall share information regarding confirmed availability of isolation distance, land use and its ownership, before start of the trial.
vii. 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.
viii. 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 three GE cotton lines expressing cry8Ea1 (X24A1DM) gene which are intended to be undertaken by applicant during Kharif 2024 growing season. Accordingly, the furtherance, if any, of these BRL-I confined field trials in 2025 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

4.2 M/s Ajeet Seeds Pvt. Ltd, Aurangabad for event selection trial under confined field conditions of five GE Cotton lines expressing cry2Aa gene.

The applicant made a presentation before the Committee and informed that they intend to conduct Event Selection Trial under confined field conditions of five GE Cotton lines (ASCOT101, ASCOT102, ASCOT103, ASCOT104 and ASCOT105) expressing cry2Aa gene conferring resistance against Pink Bollworm (*Pectinophora gossypiella*) and American bollworm (*Helicoverpa armigera*) at the applicant owned trial site at the Bhendala Farm, Aurangabad, Maharashtra during Kharif cropping season 2024.

This application was considered and recommended by RCGM in its 276th meeting held on 24.01.2024 and 279th meeting held on 06.03.2024.

Recommendation:

Based on the recommendation of 276th and 279th RCGM, the proposal of M/s Ajeet Seeds Pvt. Ltd, Aurangabad to conduct event selection trial under confined field conditions of five GE Cotton lines (ASCOT101, ASCOT102, ASCOT103, ASCOT104 and ASCOT105) expressing cry2Aa gene during Kharif cropping season 2024-2025 was recommended by the Committee subject to the condition that applicant shall perform the trials as per extant rules/guidelines/regulations and will adhere with the recommendations of 276th and 279th RCGM Meeting, recommendations and/or conditions stated in RCGM Letters dated 01.02.2024 and 08.04.2024 along with the RARM Plan provided therewith. Further, the trials should be conducted at insect specific hotspot in the trial sites that are appropriate to evaluate the introduced insect resistant trait in the GE plant.

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

4.3 M/s Ajeet Seeds Pvt. Ltd, Aurangabad for event selection trial under confined field conditions of seven GE Cotton lines expressing modified cry1Ac (ISRD1508) containing gut binding peptide.

The applicant made a presentation before the Committee and informed that they intend to conduct event selection trials under confined field conditions of seven GE Cotton lines (ASCOT201, ASCOT202, ASCOT203, ASCOT204, ASCOT205, ASCOT206 and ASCOT207) expressing modified Cry1Ac(ISRD1508) gene containing gut binding peptide to confer resistance against Pink bollworm (*Pectinophora gossypiella*), American bollworm (*Helicoverpa armigera*) and other Lepidopteran pests of cotton. These trials are intended to be conducted at applicant owned trial site at Hanumantgaon Farm, Aurangabad, Maharashtra during Kharif cropping season 2024-2025.

This application was considered and recommended by RCGM in its 282nd meeting held on 18.04.2024.

Recommendation:

Based on the recommendation of 282nd RCGM, the proposal of M/s Ajeet Seeds Pvt. Ltd, Aurangabad to conduct event selection trial under confined field conditions of seven GE Cotton lines (ASCOT201, ASCOT202, ASCOT203, ASCOT204, ASCOT205, ASCOT206 and ASCOT207) expressing modified Cry1Ac(ISRD1508) gene containing gut binding peptide during Kharif cropping season 2024-25 was recommended by the Committee subject to the condition that applicant shall perform the trials as per extant rules/guidelines/regulations and will adhere with the recommendations of 282nd RCGM Meeting, recommendations and/or conditions stated in RCGM Letter dated 29.04.2024 along with the RARM Plan provided therewith. Further, the trials should be conducted at insect specific hotspot in the trial sites that are appropriate to evaluate the introduced insect resistant trait in the GE plant.

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

4.4 M/s. Bioseed Research India, Hyderabad for event selection trial under confined field conditions of three GE cotton lines expressing cry8Ea1 (X24A1DM) gene.

The applicant made a presentation before the Committee and informed that they intend to conduct Event Selection Trials under confined field conditions of three GE cotton lines (BioCotx24A1, BioCotx24A2, and BioCotx24A3) expressing cry8Ea1 gene (X24A1DM) conferring resistance against Pink bollworm, during Kharif 2024 growing season at three company owned trial locations situated in 1) Jalna, Maharashtra; 2) Hanumangarh, Rajasthan; and 3) Siddipet, Telangana.

This application was considered and recommended by RCGM in its 273rd meeting held on 13.12.2023 and 287th meeting held on 26.06.2024.

Recommendation:

Based on the recommendations of 273rd and 287th RCGM meeting, the proposal of M/s. Bioseed Research India, Hyderabad to conduct event selection trial under confined field conditions of three GE cotton lines expressing cry8Ea1 (X24A1DM) gene during Kharif cropping season 2024-2025 was recommended by the Committee subject to the condition that applicant shall perform the trials as per extant rules/guidelines/regulations and will adhere with the recommendations of 273rd & 287th RCGM Meeting, recommendations and/or conditions stated in RCGM Letter dated 21.12.2023 and 10.07.2024. Further, the trials should be conducted at insect specific hotspot in the trial sites that are appropriate to evaluate the introduced insect resistant trait in the GE plant.

RCGM to provide RARM Plan to the applicant which shall be adhered with for the conduct of trials.

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 Laurus Bio Pvt. Ltd, Bangalore for commercial production of following products using GE *Escherichia coli*:

i. **Recombinant Keratin 1 Protein for non-therapeutic purpose**
ii. **Recombinant Keratin 2 Protein for non-therapeutic purpose**
iii. **Recombinant Elastin Protein for non-therapeutic purpose**

iv. Recombinant Collagen 1 Protein for non-therapeutic purpose
v. Recombinant Collagen 2 Protein for non-therapeutic purpose
vi. Recombinant bovine Beta-Lactoglobulin protein for non-therapeutic purpose

The applicant made a presentation before the Committee and informed that they intend to undertake commercial production of six recombinant proteins (namely, Keratin 1, Keratin 2, Elastin, Collagen 1, Collagen 2, and bovine Beta-lactoglobulin) using GE *Escherichia coli* for non-therapeutic purpose.

The recombinant proteins Keratin 1, Keratin 2, Elastin, Collagen 1, and Collagen 2 are intended for use in cosmetic industry. The recombinant protein bovine Beta-Lactoglobulin is intended for use in food and cell culture industry. The *Escherichia coli* K12 Strain has been genetically modified to incorporate synthetic bioengineered genes (~15-20 copies) enabling production of corresponding recombinant proteins. The applicant submitted that the technology for production of recombinant keratin protein using GE *E. coli* strains has been developed in USA. The applicant, with due permission of their IBSC, imported the permissible quantity of GE *Escherichia coli* strains (producing recombinant proteins) from USA, for scale-up process development studies and curated the process parameters for biomanufacturing (at scale greater than 100 litres).

The applicant submitted the GE *Escherichia coli* strains do not contain any antibiotic marker, and accordingly no antibiotics will be utilized in fermenters during production of silk protein. The applicant's commercial production facilities are GMP certified. Further, it was submitted that the material produced at the commercial level will be shipped back to USA, and will not be marketed in India.

The applicant intends to manufacture approximately 50 - 100 Kg of pure Keratin 1, Keratin 2, elastin, and collagen 2 recombinant proteins per annum. They intend to manufacture 2000-4000 Kg of pure collagen 1 and bovine Beta-lactoglobulin recombinant proteins per annum.

Recommendation:

The proposal of M/s Laurus Bio Pvt. Ltd, Bangalore for commercial production of six recombinant proteins (namely, Keratin 1, Keratin 2, Elastin, Collagen 1, Collagen 2 and bovine Beta-Lactoglobulin) using GE *Escherichia coli* strains for non-therapeutic purpose was recommended by the Committee subject to following conditions:

i. The applicant shall submit to RCGM the draft Risk Assessment and Risk Management Plan, in respect of environmental safety, which should be duly approved by IBSC.
ii. The commercial production shall commence only upon approval of Risk Assessment and Risk Management Plan by GEAC
iii. The applicant shall also submit details of relevant regulatory approvals, obtained in country of export, for GE *Escherichia coli* strains which they intend

to use for commercial production, to GEAC before undertaking commercial production.

iv. The applicant shall submit an undertaking that GE *Escherichia coli* strain does not contain any antibiotic marker, and accordingly no antibiotics will be utilized in fermenters during production of any of the recombinant proteins.

v. The project should be implemented under the oversight of IBSC of the applicant with regular annual reports to RCGM.

vi. The applicant shall submit IBSC approved compliance report on RARM plan (as approved by GEAC), every 6 months to GEAC Secretariat and concerned Regional Office of this Ministry.

vii. 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.

viii. The applicant shall ensure strict compliance of zero discharge of viable GE *Escherichia coli* strains into the environment at any stage including import transport, storage, handling, production, recovery, export, management etc.

ix. The records of generation, treatment, recycle/reuse and disposal of waste, 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).

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

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

xii. The Regional Office of this Ministry shall ensure compliance of the stipulated conditions. The project authorities should extend full cooperation to the officer (s) of the Regional Office by furnishing the requisite data / information/monitoring reports.

xiii. 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.

xiv. The approval is subject to other statutory clearances.

Action: GEAC Secretariat

5.2 M/s Laurus Bio Pvt. Ltd, Bangalore for commercial production of recombinant silk protein using GE *Pichia pastoris* for nontherapeutic purpose.

The applicant made a presentation before the Committee and informed that they intend to produce recombinant silk protein using GE *Pichia pastoris* strain. The

produced protein is intended to be utilized for industrial/manufacturing applications in cosmetic (personal care) industry.

Recombinant Silk Protein is a synthetic bioengineered version of silk protein, produced from *Pichia pastoris* strains as an extracellular protein. The silk sequence is derived from *Argiope bruennichi* Major *Ampullate Spidroin*. DNA encoding the target silk protein was synthetically made and extracellularly expressed in Pichia.

The technology for production of recombinant silk protein expressed in GE *P. pastoris* strain has been developed in USA. The applicant, with due permission of their IBSC, imported the GE *Pichia pastoris* strains (producing recombinant proteins) from USA, for scale-up process development studies and curated the process parameters for biomanufacturing (at scale greater than 100 litres). The applicant submitted the GE *P. pastoris* does not contain any antibiotic marker, and accordingly no antibiotics will be utilized in fermenters during production of silk protein. The applicant's commercial production facilities are GMP certified.

Further, it was submitted that the material produced at the commercial level will be shipped back to USA. The applicant intends to manufacture approximately 50-100 Kg of silk protein per annum, and will not be marketed in India.

Recommendation:

The proposal of M/s Laurus Bio Pvt. Ltd, Bangalore for commercial production of recombinant silk protein using GE *Pichia pastoris* for nontherapeutic purpose was recommended by the Committee subject to following conditions:

i. The applicant shall submit to RCGM, the draft Risk Assessment and Risk Management Plan, in respect of environmental safety, which should be duly approved by IBSC.
ii. The commercial production shall commence only upon approval of Risk Assessment and Risk Management Plan by GEAC.
iii. The applicant shall also submit details of relevant regulatory approvals, obtained in country of export, for GE *P. pastoris* strains which they intend to use for commercial production, to GEAC before undertaking commercial production.
iv. The applicant shall submit an undertaking that GE *P. pastoris* strain does not contain any antibiotic marker, and accordingly no antibiotics will be utilized in fermenters during production of recombinant silk protein.
v. The project should be implemented under the oversight of IBSC of the applicant with regular annual reports to RCGM.
vi. The applicant shall submit IBSC approved compliance report on RARM plan (approved by GEAC), every 6 months to GEAC Secretariat and concerned Regional Office of this Ministry.
vii. 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.

viii. The applicant shall ensure strict compliance of zero discharge of viable GE *Pichia pastoris* strains into the environment at any stage including import transport, storage, handling, production, recovery, export, management etc.

ix. The records of generation, treatment, recycle/reuse and disposal of waste 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).

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

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

xii. The Regional Office of this Ministry shall ensure compliance of the stipulated conditions. The project authorities should extend full cooperation to the officer (s) of the Regional Office by furnishing the requisite data / information/monitoring reports.

xiii. 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.

xiv. The approval is subject to other statutory clearances.

Action: GEAC Secretariat

5.3

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

ii. **M/s Oasis Ethanol Industries Pvt. Ltd, Haryana for commercial production of ethanol using GE *Saccharomyces cerevisiae* strain M24926**

iii. **M/s Muzaffarpur Biofuels Pvt. Ltd, Bihar for commercial production of ethanol using GE *Saccharomyces cerevisiae* strain M24926**

iv. **M/s Chandrika Power Pvt. Ltd, Bihar for commercial production of ethanol using GE *Saccharomyces cerevisiae* strain M24926**

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

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

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

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

All the applicants made presentation before the Committee and informed that they intend to produce ethanol using GE *Saccharomyces cerevisiae* strain M24926 (Brand Name: Fermboost). The *S. cerevisiae* strain M24926 has been genetically modified to introduce genes encoding for glucoamylase and trehalase enzymes, enabling efficient ethanol production. It was informed that the supplier of *S. cerevisiae* strain M24926 for all the eight firms will be M/s Aaditya Finechem Pvt. Ltd, Jaipur.

The Committee was apprised that in the its previous meeting held on 19.12.2023 deliberations were held with regard to requirement of developing a standard Risk Assessment & Risk Management Plan (RARMP) in respect to environmental safety, for considering proposals related to large scale/ commercial production of ethanol using genetically modified organisms at the distilleries. Accordingly, RCGM was requested to prepare a standard RARMP pertaining to environmental safety while undertaking commercial production of ethanol using genetically modified organisms at the distilleries.

Member Secretary, RCGM apprised that the RCGM has deliberated and nearly finalized the standard RARMP. The RARMP, as approved by RCGM, will be submitted for consideration of GEAC shortly.

Recommendation:

The Committee was of the view that the applications for commercial production of ethanol using genetically modified yeast should be considered after development of standard Risk Assessment & Risk Management Plan (RARMP) in respect of environmental safety. Accordingly, the decision on the applications was deferred till the time standard RARMP is not finalized.

Upon appraisal of standard RARMP by GEAC, the GEAC secretariat shall provide all the concerned applicants with the standard RARMP.

Subsequently, the applicants are directed to prepare and/ or align their respective RARMP's in accordance with the standard RARMP and submit their revised proposals to RCGM for consideration.

Action: GEAC Secretariat

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

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

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

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

The applicant made a presentation before the Committee and informed that the Nodal IBSC of applicant (IBSC of JSS, Mysuru) is yet to submit SOPs w.r.t. the storage, transfer, disposal and decontamination mechanisms of the test item DP vials to RCGM and DCGI-CDSCO, as recommended in 283rd RCGM meeting. Further, it was also informed that they are yet to obtain approval of DCGI-CDSCO.

Recommendation:

The Committee directed the applicant to submit, through its Nodal IBSC (IBSC of JSS, Mysuru), SOPs w.r.t. the storage, transfer, disposal and decontamination mechanisms of the test item DP vials to RCGM and DCGI-CDSCO, as recommended in 283rd RCGM meeting.

The final recommendation of RCGM, after examination of SOPs provided by applicant, to be submitted to GEAC for consideration of environmental safety aspect of clinical trials of Respiratory Syncytial Virus vaccine, before Phase-III study.

Action: GEAC Secretariat

5.5 M/s Praj Industries Ltd, Pune for production of lactic acid and lactide using GE *Pichia kudriavzevii* strain PMCC/Y/107.

The applicant made a presentation before the Committee and informed that they intend to produce L-lactic acid from sugar-based feedstocks using genetically engineered strain of *Pichia Kudriavzevii* strain PMCC/Y/107. Lactic acid produced will be further converted to lactide and Polylactic Acid with the intend to develop bioplastics.

The applicant imported genetically modified *Pichia kudriavzevii* strain PMCC/Y/105 from Finland with approval of IBSC (meeting dated 27.05.2022). *Pichia Kudriavzevii* strain PMCC/Y/107 has been derived from PMCC/Y/105 by successful R&D undertaken by applicant.

The applicant informed that production will be undertaken at applicant's demonstration scale plant in Jejuri, Pune. The applicant intends to produce a maximum of 140 MT/year of L-lactic acid (88 % w/w) and 100 MT/year of lactide. The lactic acid & lactide will be supplied to compounders involved in sampling/ production of bioplastics.

Recommendation:

The proposal of M/s Praj Industries Ltd, Pune for commercial production of lactic acid and lactide using GE *Pichia kudriavzevii* strain PMCC/Y/107 was recommended by the Committee subject to following conditions:

i. The applicant will submit to RCGM draft Risk Assessment and Risk Management Plan, in respect of environmental safety, which should be duly approved by IBSC.
ii. The commercial production shall commence only upon approval of Risk Assessment and Risk Management Plan by GEAC.
iii. The applicant shall also submit details of relevant regulatory approvals, obtained in country of export, for GE *Pichia kudriavzevii* strain which they imported, to GEAC before undertaking commercial production.
iv. The project should be implemented under the oversight of IBSC of the applicant with regular annual reports to RCGM.
v. The applicant shall submit IBSC approved compliance report on RARM plan (approved by GEAC, every 6 months to and GEAC Secretariat and concerned Regional Office of this Ministry.
vi. 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.
vii. The applicant shall ensure strict compliance of zero discharge of viable GE *Pichia kudriavzevii* strain PMCC/Y/107 into the environment at any stage including import, transport, storage, production, recovery, handling, management etc.
viii. 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).
ix. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.
x. The Ministry reserves the right to stipulate additional conditions if found necessary. The Company, in a time bound manner, shall implement these conditions.
xi. The Regional Office of this Ministry shall ensure compliance of the stipulated conditions. The project authorities should extend full cooperation to the officer (s) of the Regional Office by furnishing the requisite data / information/monitoring reports.
xii. 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.

xiii. The approval is subject to other statutory clearances.

Action: GEAC Secretariat

5.6 M/s Praj Industries Ltd, Pune for production of 2,3 Butanediol using GE *Saccharomyces cerevisae*.

The applicant made a presentation before the Committee and informed that they intend to produce 2,3 Butanediol (2,3 BDO) from sugar-based feedstocks like molasses using GE *Saccharomyces cerevisiae* strain YA1245-1.

The 2,3 BDO produced is intended to be used for catalytic conversion to 1,3 Butadiene and Methyl Ethyl Ketone (MEK). The 1,3 Butadiene produced is intended to be supplied for sampling purpose to rubber companies manufacturing tyres while Methyl Ethyl Ketone (MEK) is intended for industrial utilization – as a solvent in the printing inks.

The production will be conducted at 1 KL scale fermentor followed by down-stream processing to evaluate technology performance at Praj Matrix-R&D Center in Pune. The maximum production of 2,3 BDO is expected to be ~500 L/year.

Recommendation:

The proposal of M/s Praj Industries Ltd, Pune production of 2,3 Butanediol using GE *Saccharomyces cerevisiae* strain YA1245-1 was recommended by the Committee subject to following conditions:

i. The applicant shall submit to RCGM draft Risk Assessment and Risk Management Plan, in respect of environmental safety, which should be duly approved by IBSC.
ii. The commercial production shall commence only upon approval of Risk Assessment and Risk Management Plan by GEAC.
iii. The project should be implemented under the oversight of IBSC of the applicant with regular annual reports to RCGM.
iv. The applicant shall submit IBSC approved compliance report on RARM plan (as approved by GEAC, every 6 months to and GEAC Secretariat and concerned Regional Office of this Ministry.
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 *Pichia kudriavzevii* strain PMCC/Y/107 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 Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.

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

x. The Regional Office of this Ministry shall ensure compliance of the stipulated conditions. The project authorities should extend full cooperation to the officer (s) of the Regional Office by furnishing the requisite data / information/monitoring reports.

xi. 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.

xii. The approval is subject to other statutory clearances.

Action: GEAC Secretariat

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

The applicant made a presentation before the Committee and informed that they intend to produce ethanol using GE *S. cerevisiae* strain CelluX4 at their upcoming biorefinery at Bargarh, Odisha. The modified strain CelluX 4 is able to ferment hexose sugars and the pentose sugar D-xylose into ethanol in lignocellulose hydrolysates

The applicant informed that they intend to get commissioned their birefinary plant in Odisha by August' 2024. The plant is designed to process 430 MT/day of biomass (on dry basis) into ethanol. Ethanol produced from the plant will be 100 KLPD. The GM *S. cerevisiae* strain CelluX4 required for the production of ethanol is approximately 9 MT/annum. The GE *S. cerevisiae* strain CelluX4 will be supplied to biorefinery by M/s Praj Industries Ltd., Pune.

The Committee was apprised that in the its previous meeting held on 19.12.2023 deliberations were held with regard to requirement of developing a standard Risk Assessment & Risk Management Plan (RARMP) in respect to environmental safety, for considering proposals related to large scale/ commercial production of ethanol using genetically modified organisms at the distilleries. Accordingly, RCGM was requested to prepare a standard RARMP pertaining to environmental safety while undertaking commercial production of ethanol using genetically modified organisms at the distilleries.

Member Secretary, RCGM apprised that the RCGM has deliberated and nearly finalized the standard RARMP. The RARMP, as approved by RCGM, will be submitted for consideration of GEAC shortly.

Recommendation:

The Committee was of the view that the application for commercial production of ethanol using GE *S. cerevisiae* strain CelluX4 should be considered after development of standard Risk Assessment & Risk Management Plan (RARMP) in respect of environmental safety. Accordingly, the decision on the application was deferred till the time standard RARMP is not finalized.

Upon appraisal of standard RARMP by GEAC, the GEAC secretariat shall provide the applicant with the standard RARMP.

Subsequently, the applicant is directed to prepare and/ or align their respective RARMP in accordance with the standard RARMP and submit their revised proposal to RCGM for consideration.

Action: GEAC Secretariat

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

6.1. M/s Ceva Polchem Pvt. Ltd, Pune submitting test reports for import and distribution of recombinant veterinary vaccine Vectormune FP LT.

The Committee was informed that the proposal of M/s Ceva Polchem Pvt. Ltd, Pune for import and marketing of Vectormune FP LT recombinant veterinary vaccine (trade name: Fowl PoxLaryngotracheitis Vaccine, Live Fowl Pox Vector, Freeze-dried) was initially considered in the 149th meeting of GEAC wherein the Committee recommended the proposal for import only subject to three conditions.

In accordance with the stipulated conditions, applicant has submitted the ICAR-IVRI certified test batch reports and the NOC received from DAHD.

Director, GBRC, one of the committee member informed that in the metagenomic analysis of the recombinant veterinary vaccine sample submitted by applicant, non-target organisms, have been detected upto a certain level. The Committee deliberated regarding prevalence of identified non-target organisms in the vaccine and the threshold/ permissible level upto which non-target organisms can be allowed in the veterinary 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. Vectormune FP LT), as per metagenomic analysis report certified by GBRC, with a view to identify if the NTOs detected are novel or are prevalent in the country.
ii. In case the NTOs detected in the vaccines are prevalent or not, in India, the probable risks that identified NTOs can pose in Indian context.
iii. The threshold/ permissible level of presence of Non-Target Organisms, which can be permitted in the veterinary vaccines being imported in India.

Action: GEAC Secretariat

6.2 M/s Zoetis India Ltd, Mumbai submitting test reports for import and marketing of recombinant veterinary vaccine Poulvac Procerta HVT-IBD.

The Committee was informed that the proposal of M/s Zoetis India Ltd, Mumbai for import and marketing of Poulvac Procerta HVT-IBD (trade name: Bursal Disease-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector) recombinant veterinary vaccine was initially considered in the 142nd meeting of GEAC wherein the Committee recommended the proposal for import subject to following conditions:

i. *"initial 3 batches of the subject vaccine to be certified in ICAR-Indian Veterinary Research Institute (ICAR-IVRI)*
ii. *obtain relevant approvals from Department of Animal Husbandry and Dairying, Drug Controller General of India etc. as per existing Indian laws applicable for import of vaccines.*
iii. *The final data certified by IVRI to be presented before the GEAC for final approval, before it is marketed in the country*"

In accordance with the stipulated conditions, applicant has submitted the ICAR-IVRI certified test batch reports, and the NOC received from DAHD.

The Committee took cognizance of its earlier decision in such similar applications, wherein applicant has been asked to get the metagenomics analysis of the subject vaccine be certified by Gujarat Biotechnology Research Centre (GBRC), Gujarat.

Recommendation:

After deliberations, 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 the subject vaccine is marketed in the country.

Action: GEAC Secretariat

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

The applicant made a presentation before the Committee and informed that they intend to import 2000 MT per annum of GE *S. cerevisae* strain M24926 (Brand Name: Fermboost) from Canada and distribute/ market it for ethanol production. Their proposal for import of *S. cerevisiae* strain M24926, per annum, from Brazil was initially considered and recommended in 149th and 150th GEAC meetings. Additionally, the applicant informed that they intend to import the same GE yeast from Canada as well.

The Committee was apprised that in the 151st GEAC meeting held on 19.12.2023 deliberations were held with regard to requirement of developing a standard Risk Assessment & Risk Management Plan (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.

Member Secretary, RCGM apprised that the RCGM has deliberated and nearly finalized the standard RARMP. The RARMP, as approved by RCGM, will be submitted for consideration of GEAC shortly.

Recommendation:

The Committee was of the view that the application for import of GE *Saccharomyces cerevisae* strain M24926 should be considered after development of standard Risk Assessment & Risk Management Plan (RARMP) in respect of environmental safety. Accordingly, the decision on the application was deferred till the time standard RARMP is not finalized.

Upon appraisal of standard RARMP by GEAC, the GEAC secretariat shall provide the applicant with the standard RARMP.

Subsequently, the applicant is directed to prepare and/ or align their respective RARMP in accordance with the standard RARMP and submit their revised proposal to RCGM for consideration.

Action: GEAC Secretariat

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

The applicant made a presentation before the Committee and informed that they intend to import GE *S. cerevisiae* strain Innova Apex (strain S1077-H06). They intend to import 2000 MT, per annum, of GE Innova Apex active dried yeast, from USA.

The Committee was informed that in its 144th and 148th meetings the applicant was granted permission for import of two other GE *S. cerevisiae* strains, namely, strain – Cellerity S 1.0 (CIBTS1260-J132-F3) and strain MeJi797 (amgPS gene,

amyJA126PE096) gene. It was also informed that in its 151st meeting, the applicant was directed to provide a detailed plan of marketing & distribution as well as details of stored quantity and supplied quantity of *S. cerevisiae* strain MeJi797. The information, as directed in the 151st GEAC meeting, has not yet been submitted by the applicant.

It was also informed that in 151st GEAC deliberations were held with regard to requirement of developing a standard Risk Assessment & Risk Management Plan (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.

Member Secretary, RCGM apprised that the RCGM has deliberated and nearly finalized the standard RARMP. The RARMP, as approved by RCGM, will be submitted for consideration of GEAC shortly.

The Committee deliberated upon all the previous proposals for import of GE yeast submitted by this applicant as well as other applicants in past four years.

Recommendation:

The Committee was of the view that the application for import of GE *S. cerevisiae* strain Innova Apex (strain S1077-H06) should be considered after development of standard Risk Assessment & Risk Management Plan (RARMP) in respect of environmental safety. Accordingly, the decision on the application was deferred till the time standard RARMP is not finalized.

Upon appraisal of standard RARMP by GEAC, the GEAC secretariat shall provide the applicant with the standard RARMP.

Subsequently, the applicant is directed to prepare and/ or align their respective RARMP in accordance with the standard RARMP and submit their revised proposals for all three strains of GE yeast [namely, Innova Apex (strain S1077-H06), Cellerity S 1.0 (CIBTS1260-J132-F3) and strain MeJi797 (amgPS gene, amyJA126PE096)] to RCGM for consideration. Further, committee directed the applicant to provide a detailed plan of marketing & distribution as well as details of stored quantity and supplied quantity of *S. cerevisiae* strain MeJi797 in accordance with the recommendations in its 151st meeting.

The Committee also directed the GEAC secretariat to share the standard RARMP, as and when approved, with all the applicants whose proposals for import of GE yeast have been recommended by the Committee in past four years for compliance henceforward.

Action: GEAC Secretariat

6.5 M/s Praj Industries Ltd, Pune for import of GE *S. cerevisae* strain CelluX4 for ethanol production.

The applicant made a presentation before the Committee and informed that they intend to import 10 MT, per annum, of CelluX4 Active dry yeast from USA and supply it to M/s Bharat Petroleum Corporation Limited (BPCL) 2G ethanol plant located in Bargarh, Odisha.

The Committee was apprised that in the its previous meeting held on 19.12.2023 deliberations were held with regard to requirement of developing a standard Risk Assessment & Risk Management Plan (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.

Member Secretary, RCGM apprised that the RCGM has deliberated and nearly finalized the standard RARMP. The RARMP, as approved by RCGM, will be submitted for consideration of GEAC shortly.

Recommendation:

The Committee was of the view that the application for import of GE *S. cerevisae* strain CelluX4 should be considered after development of standard Risk Assessment & Risk Management Plan (RARMP) in respect of environmental safety. Accordingly, the decision on the application was deferred till the time standard RARMP is not finalized.

Upon appraisal of standard RARMP by GEAC, the GEAC secretariat shall provide the applicant with the standard RARMP.

Subsequently, the applicant is directed to prepare and/ or align their respective RARMP in accordance with the standard RARMP and submit their revised proposal to RCGM for consideration.

Action: GEAC Secretariat

6.6 M/s Arvind Limited, Ahmedabad for import of GMOs (*Escherichia coli, Pseudomonas putida and Pseudomonas fluorescens*) producing natural pigments and its utilization for fermentation and dyeing.

The applicant made a presentation before the Committee and informed that they intend to import approximately 5mL of GM Microorganisms (*Escherichia coli, Pseudomonas putida and Pseudomonas fluorescens*) producing natural pigments from UK to carry out initial screening of pigments at small scale. The imported GMOs will be grown at small scale (1 – 5 liters) in shake flasks and fermenters and used to dye fabrics and tested for colour fastness. The work will be conducted at BS level -1 and fermentation will be performed in a closed loop system.

The Committee was informed that the proposal of M/s Arvind Limited, Ahmedabad for import of GM Microorganisms (*Escherichia coli, Pseudomonas putida and Pseudomonas fluorescens*) producing natural pigments was initially recommended in the 141st GEAC meeting subject to the three conditions.

i. *"The firm M/s Arvind Limited, Ahmedabad will constitute Institutional Biosafety Committee;*
ii. *The import should be conducted under the oversight of IBSC of the applicant and inform Review Committee on Genetic Manipulation (RCGM), Department of Biotechnology.*
iii. *For large scale production of dye derived from Genetically Modified Organisms, the applicant is requested to apply to GEAC in Form IIA for further consideration, along with the recommendation of IBSC."*

The applicant submitted that owing to Covid pandemic situation in 2020, no import of GMOs was done, vide the permit granted in 141st GEAC meeting. It was also informed that the applicant is yet to constitute an IBSC as recommended in 141st GEAC.

Recommendation:

Considering that the applicant intends to import GMOs for Research & Development purpose only, the Committee directed that the application shall be referred to RCGM for consideration and appropriate decision.

The Committee directed the applicant to constitute the IBSC and subsequently submit this application, as per the relevant form, to RCGM for consideration.

Action: GEAC Secretariat

Agenda Item No. 7: Additional Items for consideration

7.1 Andhra Pradesh State Sericulture Research and Development Institute (APSSRDI), Hindupur submitting report of Phase I multilocational field trials (2015-2017) on transgenic BmNPV resistant silkworm for consideration of subsequent Phase II multi-locational field trials.

The applicant made a presentation before the Committee and informed that research on development of transgenic *Bm*NPV resistant silkworm has been undertaken by Centre for DNA Fingerprinting and Diagnostics (CDFD), Hyderabad. Transgenic silkworms resistant to *Bm*NPV infection have been produced using the technique of piggyBac mediated germline transgenesis. The *Bm*NPV virus resistant property in the Nistari genetic background has been successfully transferred to a commercial high yielding, diapausing, baculovirus susceptible, CSR2 silkworm strain through marker assisted repeated backcross strategy at APSSRDI, Hindupur. Transgenic silkworm hybrids have been developed by crossing transgenic lines with various commercial breeds of India suitable for various Agro-climatic zones.

The Phase I multi-locational field trials were conducted in 2016-2017 with permission from RCGM in association with Central Silk Board at its institutions (CSRTI at Mysore, Behrampore, and Pampore) and APSSRDI, Hindupur.

Presently, the applicant intends to undertake Phase II multi-locational field trials at 4 selected silkworm rearing places/ sites at farmers premises in association with Central Silk Board and Karnataka State Sericulture Research and Development Institute (KSSRDI). The identified trial sites include stations of APSSRDI, CSRTI Mysore, and KSSRDI, Bengaluru. The applicant submitted that silkworms are highly domesticated insects and always reared under contained conditions since they can't survive outdoor. F1 hybrids of GE silkworm used for commercial silk production are not reproduced further as the cocoons are boiled for silk reeling.

The application has been considered by RCGM in its 268th and 274th meetings wherein following was recommended:

i. *"Applicant to ensure that the same farmers' fields (silkworm rearing units) which were identified and inspected by the Site Inspection Committee in 2019 would be utilized for the multi-location trials in the current phase.*
ii. *Conducting the feed safety studies, efficacy and safety studies of GE silkworm as deliberated in 173rd RCGM meeting held on 01.07.2019.*
iii. *The pointwise action points suggested by the Site Inspection Committee to be considered while taking up multi-location trials.*
iv. *APSSRDI to submit revised action plan for preparedness by the project partners to conduct contained trials within the farmers' premises, in case of deviation, if any, in the current context."*

Dr. Gowda, sericulture expert, informed the Committee that the silk produced from transgenic silkworms does contain any part of the foreign protein. Accordingly, the probability of the silk, produced from transgenic silkworms, causing any sort of allergenicity in humans is almost negligible.

Recommendation:

The proposal of Andhra Pradesh State Sericulture Research and Development Institute (APSSRDI), Hindupur for conducting Phase II multi-locational field trials on transgenic BmNPV resistant silkworm was recommended by the Committee subject to following conditions:

i. The applicant shall adhere with the recommendations of 268th and 274th RCGM meetings (vide Letter dated 08.04.2024).
ii. The applicant shall adhere with the Guidelines and Standard Operating Procedures for Research on Genetically Engineered Insects, 2023.
iii. The applicant shall submit Risk Assessment and Risk Management (RARM) Plan and on-site Emergency Plan to RCGM for consideration.
iv. RCGM to monitor field trials to ensure compliance of prescribed terms and conditions by constituting a Site Monitoring Committee. The composition of the Site Monitoring Committee shall include representatives of GEAC, RCGM, & State Government as well as subject matter experts. The Site Monitoring Committee shall visit the trial sites (i.e. silkworm rearing units in farmer's field), at least once during rearing season, to ensure compliance of prescribed terms and conditions.

Action: GEAC Secretariat

7.2 Matter pertaining to requirements for import of alfalfa hay from USA

The Committee was informed that the matter regarding import of alfalfa hay for purpose of animal feed has earlier been considered in its 146th and 151st meetings at length in the 151st meeting of GEAC held on 19.12.2023 under Agenda Item 7.1, regulatory roles of FSSAI and GEAC in regulation of genetically modified food/ feed and products derived thereof was elucidated. It was reiterated that till the time genetically modified feed is not covered under the mandate of FSSA 2006; GEAC shall undertake the environmental safety assessment of genetically modified feed while the FSSAI/ Scientific Panel (SP) on GMO & Food shall undertake the health safety assessment of genetically modified feed.

In 151st GEAC meeting, it was informed that Scientific Panel (SP) on Genetically Modified Organisms (GMOs) & Foods of FSSAI is of opinion that GM alfalfa (herbicide tolerant) can be considered as a livestock safe feed as is Non-GM alfalfa feed. Further, with regard to environmental safety aspect of alfalfa hay, the application was referred to RCGM for examination.

The biosafety dossier pertaining to import of alfalfa hay from USA was considered in the 286th meeting of RCGM wherein the following was recommended:

"*Based on the information provided by USDA, which was forwarded to RCGM by PP Division II, MoAFW, GE alfalfa hay containing any of the three GE events mentioned above (Events J101 and J163, Event KK179, and Bioheuris's alfalfa modified for resistance to acetolactate synthase (ALS) inhibitor herbicides) may be considered based on scientific basis for deregulation by USDA, where, risk due to GE alfalfa hay was found negligible.*"

The Members were requested to provide their comments, if any, on the biosafety dossier pertaining to GE alfalfa hay received from USA.

Recommendation:

Taking cognizance of the recommendations of 286th RCGM as well as of the opinion of Scientific Panel (SP) on Genetically Modified Organisms (GMOs) & Foods of FSSAI considered in 151st GEAC meeting, with regard to alfalfa hay, the Committee recommended the import of alfalfa hay from USA. The recommendation is subject to other statutory clearances.

Action: GEAC Secretariat

7.3 M/s Bioseed Research India, Hyderabad for BRL-I trial (1st Year) of GE cotton hybrids containing Event 18L-5-3 expressing cry2Ai gene.

The Committee was informed that the proposal of M/s Bioseed Research India to conduct BRL-I trial (1st year) of GE cotton hybrids containing Event 18L-5-3 expressing *cry2Ai* gene conferring resistance against Pink Bollworm during Kharif season 2023-24 has earlier been considered in 148th, 149th and 150th meetings of GEAC.

Applicant proposes to conduct of BRL-I trial (1st Year) of GE cotton hybrids containing Event 18L-5-3 expressing cry2Ai gene at following 10 sites located in 7 States:

i. Haryana (Barwala-Hisar): Research Station, M/s. Bioseed Research India, (owned by the applicant's organization).
ii. Haryana (Hisar): CCS Haryana Agriculture University.
iii. Gujarat (Junagadh): Junagadh Agricultural University.
iv. Telangana (Janwada): M/s Bioseed Research India, Hyderabad (owned by the applicant's organization).
v. Telangana (Hyderabad): Professor Jayshankar Telangana State Agriculture, University.
vi. Maharashtra (Akola): Dr Panjabrao Deshmukh Krishi Vidyapeeth, Akola.
vii. Maharashtra (Jalna): Bioseed Research India, Aurangabad (owned by the applicant's organization)
viii. Madhya Pradesh (Gwalior): College of Agriculture Khandwa, Rajmata Vijayraje, Scindia Krishi Vishwavidyalaya (RVSKVV).
ix. Punjab (Bhatinda): Regional Research Station, Punjab Agricultural University.
x. Rajasthan (Sriganganagar/ Bikaner): Agriculture Research Station, S. K. Rajasthan Agriculture University.

In accordance with the concurrence received from Govt. of Haryana & MP, and recommendations of 148th and 159th GEAC meetings, BRL-I trials (1st year) were conducted at 3 sites located in Haryana & MP during the growing season 2023.

Subsequently, the applicant obtained NOC from the Govt. of Punjab vide Letter dated 13.03.2024 & Govt. of Gujarat vide Letter dated 03.02.2024. As per the NOC received from Govt. of Gujarat, the applicant has obtained permission to conduct trials at two sites, namely, Junagadh Agricultural University & also additionally at Navsari Agricultural University.

Applicant vide email dated 14.03.2024 requested that since the sowing of cotton in north zone (Punjab) will start in mid-April, the consent of GEAC for conduct of BRL-I trials in Gujarat & Punjab during growing season 2024 may be communicated to RCGM to enable issuance of permit letter.

Given the precedence that the said proposal had already been recommended for conduct of trials in Haryana & MP by GEAC during cropping season 2023 and that NOC from the concerned State Govt.(s) has been received, the request of applicant for conduct of BRL-I trials during Kharif 2024 growing season was considered with the permission from Chairperson, GEAC at following three additional sites:

i. Gujarat (Junagadh): Cotton research station, Junagadh Agricultural University.
ii. Gujarat (Surat): Main cotton research station, Navsari Agricultural University.
iii. Punjab (Bhatinda): Regional Research Station, Punjab Agricultural University.

It was informed that as per prevailing practice, RCGM was requested to issue the permit letter for conduct of BRL-I trial (1st Year) of GE cotton hybrids containing Event 18L-5-3 expressing *cry2Ai* gene at above mentioned three trials in Gujarat and Punjab for Kharif 2024 season as per following:

i. The conduct of trials will be subject to the same remarks/conditions that were stipulated by the GEAC in its 148th meeting under Agenda Item 4.1 and 150th GEAC meeting under Agenda Item 7.2.
ii. The change in the minutes of 148th GEAC meeting that were confirmed in 149th GEAC meeting held on 17.05.2023 under Agenda Item No. 2.
iii. The conduct of trials will be subject to the remarks/conditions, if any, stipulated by Government of Gujarat vide Letter dated 03.02.2024 and Government of Punjab vide Letter dated 13.03.2024.

Recommendation:

The Committee concurred with the permission granted to M/s Bioseed Research India, Hyderabad for conduct of BRL-I trial (1st year) of GE cotton hybrids containing Event 18L-5-3 expressing cry2Ai gene at three trial sites in Gujarat and Punjab (Junagadh, Surat, and Bhatinda) during Kharif 2024 season as per following:

i. The conduct of trials will be subject to the same remarks/conditions that were stipulated by the GEAC in its 148th meeting under Agenda Item 4.1 and 150th GEAC meeting under Agenda Item 7.2.
ii. The change in the minutes of 148th GEAC meeting that were confirmed in 149th GEAC meeting held on 17.05.2023 under Agenda Item No. 2.
iii. The conduct of trials will be subject to the remarks/conditions, if any, stipulated by Government of Gujarat vide Letter dated 03.02.2024 and Government of Punjab vide Letter dated 13.03.2024.

Action: GEAC Secretariat

7.4 M/s Pioneer Hi-Bred Private Limited, Hyderabad for further extension of permission to store transgenic maize seeds expressing TC1507×MON810 and MON810 gene events.

The committee was informed that the proposal of M/s Pioneer Hi-Bred Private Limited, Hyderabad for extension of permission to store transgenic maize seeds expressing TC1507×MON810 and MON810 gene events has earlier been considered in 142nd and 146th GEAC meetings.

In 142nd meeting of GEAC, the extension of permission was granted to store the TC1507×MON810 and MON810 transgenic maize seeds till November 2021, based on recommendations of 194th RCGM meeting. In 146th meeting of GEAC, extended till November 2023, based on recommendations of 226th RCGM meeting.

For the instant application, RCGM in its 285th meeting has recommended that TC1507×MON810 and MON810 transgenic maize seeds may be stored, as per the inventory, for two more years till December 2025 for any possible future use in BRL trials. The stored quantity of transgenic maize hybrids viz. P3501Y and 30B07Y expressing event MON810 is 4.25 Kg and 5 Kg, respectively. The quantity of transgenic maize hybrids viz. P3501YH and 30B07YH expressing stacked events TC1507 x MON810 is 5.595 Kg and 4.835 Kg, respectively.

Recommendation:

Based on the recommendation of 285th RCGM, the proposal of M/s Pioneer Hi-Bred Private Limited, Hyderabad for extension of permission to store the TC1507×MON810 and MON810 transgenic maize seeds till December 2025, as per below inventory, was recommended by the Committee:

Name of the hybrid	Event(s) expressed	Quantity being stored
P3501YH	TC1507 x MON810	5.595 Kg
30B07YH	TC1507 x MON810	4.835 Kg
P3501Y	MON810	4.250 Kg
30B07Y	MON810	5.000 Kg

Action: GEAC Secretariat

7.5 Review status of proposal for establishing identified institutes as Notified Field Trial Sites (NFTSs).

The Committee was informed that the matter pertaining to establishment of Notified Field Trial Sites (NFTSs) has earlier been considered by GEAC in its 140th, 149th, and 151st meetings. In 149th GEAC meeting dated 17.05.2023 it was decided that RCGM shall constitute an Expert Committee for assessing suitability of the ICAR proposed sites to be designated as NFTSs, in accordance with the Approval & Monitoring Mechanism of NFTS laid out in the proposal of DBT (recommended by GEAC in 140th meeting) for establishment of Notified Field Trial Sites (NFTSs) to conduct confined field trials of GE Crops. Further, it was also decided that ICAR may fulfil the requirements for designating the sites which are found suitable by the aforementioned Expert Committee as NFTSs, as per the proposal for establishment of NFTSs.

It was also informed that ICAR has identified 42 institutions (ICAR Institutes and State Agricultural Universities) across different agro-climatic zones for establishment and operation of NFTS for confined field trials of GM crops which have been considered by GEAC in its 149th meeting.

ADG (Seed), ICAR informed the Committee that out of 42 identified institutions, 38 institutions have given their consent for establishment as NFTSs. The 3 institutions have denied, and accordingly, ICAR is pursuing those institutions and also finding suitable alternative locations. Upon finalization of the institutions, MoEFCC/ MoAFW may write to the concerned State/ UT Government(s), where NFTSs are proposed to be established, in order to seek their one-time concurrence/ views/ comments. The scheme for setting up the Notified Field Trial Sites (NFTSs) to be formulated in the form of Expenditure Finance Committee (EFC) proposal. The approval of EFC for setting up NFTSs will be sought DBT and/or DAFW.

Recommendation:

The Committee was of the view that the process of seeking one-time concurrence from State Government(s) where Notified Field Trial Sites (NFTSs) are proposed to be established and formulation of Expenditure Finance Committee (EFC) proposal for setting up NFTSs can be taken up parallelly.
It was also suggested that a nodal institute may identified which will cater to requirements of other institutes which are proposed to be established as NFTSs. The funds enabling setting up of NFTSs may be sent to that nodal institute which will further distribute it to other institutes.

Action: GEAC Secretariat

Agenda Item No. 8: Information Items

8.1 Recommendation received from 281st RCGM meeting regarding preparation of Risk Assessment & Risk Management Plan.

The application of M/s Novozymes South Asia Pvt. Ltd., Bangalore for import and commercialization of *S. cerevisiae* strain MeJi797 (amgPS gene amyJA126PE096 gene) was considered in 151st GEAC meeting and as per the recommendations made therein RCGM was requested to prepare a Risk Assessment & Risk Management Plan (RARMP) in respect of storage, transportation, access, handling, packing, re-packing, distribution, sale, decontamination, and disposal of GMO consignment imported for the purpose of commercial production. RCGM was also requested to prepare a standard for all such applications. In this regard, applicant was directed to submit a draft RARMP for consideration of RCGM. The applicant was also directed to provide further details w.r.t. storage and distribution of *S. cerevisiae strain* MeJi797.

The application was considered by RCGM in its 281st meeting wherein RCGM has recommended to requested GEAC to direct M/s Novozymes South Asia Pvt. Ltd., Bangalore to provide the protocol, duly approved by its IBSC, for import of *S. cerevisiae* strain MeJi797 for ethanol production, from the point of origin, packaging, transport and receiving at port of entry in India and subsequent transport to the factory in India. RCGM Secretariat also requested GEAC to direct IBSC of M/s Novozymes South Asia Pvt. Ltd., Bangalore to submit a draft RARMP considering all possible risks related to storage, transportation, access, handling, packing, repacking, distribution, sale, decontamination, and disposal of GMO consignment imported for the purpose of commercial production.

In accordance with 281st RCGM recommendations, Letter dated 09.05.2024 was sent to M/s Novozymes South Asia Pvt. Ltd., Bangalore requesting them to provide requisite information to RCGM.

8.2 M/s. Nath Bio-Genes (India) Limited, Aurangabad for repeating event selection trial under confined field conditions of fourteen GE cotton lines expressing cry1Ac-II and cry1Fa1 genes.

The proposal of M/s. Nath Bio-Genes (India) Limited, Aurangabad, Maharashtra to conduct event selection trial (EST) under confined field conditions of 14 GE cotton lines (viz., NBIL-CS-1, NBIL-CS-2, NBIL-CS-3, NBIL-CS-4, NBIL-CS-5, NBIL-CS-6, NBIL-CS-7, NBIL-CS-8, NBIL-C-1253, NBIL-C-1158, NBIL-C-1155, NBIL-C-1160, NBIL-C-1249, NBIL-C-1316) expressing *cry1Ac-II* and *cry1Fa1* genes to confer resistance against *Helicoverpa armigera* and *Pectinophora gossypiella*, at applicants' own R&D farm in Isarwadi, Aurangabad was recommended by GEAC in its 150th meeting.

Upon approval of these GEAC recommendations, RCGM issued the permit letter on 06.10.2023 for conduct of these EST at applicant owned trial location in Isarwadi, Aurangabad during Kharif 2023-24.

Subsequent to issuance of permit letter, the EST under confined field conditions of 14 GE cotton lines was sown on 11.10.2023 and has been harvested/ terminated on 10.05.2024.

A Central Compliance Committee (CCC) was constituted for monitoring of these trials on 07.02.2024. The CCC undertook its trial site visit and submitted its inspection report to RCGM which was considered in their 280th meeting held on 20.03.2024.

The applicant has requested to repeat the event selection trial of 14 GE Cotton lines again during Kharif 2024-25 at its own R&D farm in Isarwadi, Aurangabad due to following reasons:

- *"After completion of the existing EST (Kharif 2023-24), there would be very little time left to apply for BRL-I and get the approvals (from GEAC and RCGM) well in time for planting the BRL-I trials at multiple locations. Planting BRL trials at the right time assume greater importance.*
- *Due to extended cold weather conditions during 2023-24 winter season, the intensity/ severity of Pink Bollworm incidence (and cotton ball damage thereof) was rather low. Consequently, our data generated (for Pink Bollworm damage in particular) does not show distinct differences between the New Events and the Checks."*

This request of applicant to repeat EST has been considered by RCGM in its 283rd meeting and further recommended to GEAC for vetting/ approval and issuance of permit letter.

Taking cognizance of 280th and 283rd RCGM recommendations, letter dated 14.06.2024 has been issued to RCGM secretariat requesting them to issue the permit letter to repeat the EST during Kharif 2024-25 at applicants' own R&D farm in Isarwadi, Aurangabad subject to fulfilment of following four conditions:

i. Applicant will comply with recommendations/ deliberations of 283rd RCGM meeting.
ii. Applicant will provide undertaking stating they will comply with all the regulatory guidelines/ SOPs issued for conduct of field trials as well as conditions

prescribed by both GEAC & RCGM for initial EST permit for Kharif 2023-24 (150th meeting of GEAC, 260th meeting of RCGM).

iii. Taking cognizance of the inspection report of CCC (pl. refer para 5 above), the applicant may also be directed to ensure that all the confinement measures are well in place before the sowing/ commencement of the trial and intimate the same to RCGM Sectt.

iv. The RCGM Sectt. may ensure that trials are commenced only after applicant submits declaration that all appropriate measures of confinement have been taken as per the guidelines/ SOPs/ conditions prescribed in permit letter/ recommendations of CCC inspection report of 12.03.2024 site visit.

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

Annexure 1

List of Participants

Members who participated			
1.	**Shri Naresh Pal Gangwar** Additional Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jorbagh road, Aliganj, New Delhi- 110003	**8.**	**Dr. Sanjeev Khosla** Director, CSIR- Institute of Microbial Technology, Chandigarh- 160 036
2.	**Dr. Sanjay Kumar Mishra** Scientist H, Department of Biotechnology, Block 2 CGO Complex, Lodhi Road, New Delhi - 110 003	**9.**	**Dr. Nitin K. Jain** Scientist–G and Member Secretary RCGM, Department of Biotechnology, C.G.O Complex, Lodhi Road, New Delhi-110003
3.	**Dr. Satyendra Kumar** Director, Ministry of Environment, Forest and Climate Change, Jorbagh, New Delhi-110003	**10.**	**Dr. J.P. Singh** Plant Protection Adviser (PPA), Directorate of Plant Protection, Quarantine & Storage, NH IV, Faridabad-121001. New Delhi
4.	**Dr. D.K. Yadav** ADG (Seed), Crop Science Division, Indian Council of Agricultural Research, Krishi Bhawan, New Delhi-110001	**11.**	**Dr. P.K. Dass** Department of Anatomy, LHMC & Associated Hospitals, New Delhi- 110 001
5.	**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. Rubina Bose** Deputy Drugs Controller, Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, FDA Bhavan, ITO, Kotla Road, New Delhi - 110002 (Representative of Drugs Controller General of India)
6.	**Dr. Pronab Dhar** Principal Scientist, ICAR-Indian Veterinary Research Institute (IVRI), Bareilly, Uttar Pradesh- 243122 (Representative of Dr. Triveni Dutt, Director, IVRI)	**13.**	**Dr. Rekha S. Singhal** Professor, Food Technology, Institute of Chemical Technology, Mumbai- 400 019
7.	**Dr. U. S. N. Murthy** Director, National Institute of Pharmaceutical Education and Research, Guwahati- 781101	**14.**	**Dr. Chaitanya Joshi** Director, Gujarat Biotechnology Research Centre, Gandhinagar, Gujarat- 382 011

Members who did not participate			
1.	**Dr. P. Suprasanna** Scientific Officer H (Retd.), Biosciences group, BARC, Mumbai-400 085	**6.**	**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	**7.**	**Ms. Shruti Singh** Joint Secretary, IPR, Department for Promotion of Industry and Internal Trade, Udyog Bhawan, New Delhi 110011
3.	**Dr. J. P. Shukla** Scientist, CSIR-Advanced Materials and Process Research Institute, Bhopal- 462 026	**8.**	**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	**9.**	**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		
Special Invitee			
1.	**Dr. Manjunath Gowda** Professor and Head, Department of Sericulture, University of Agricultural Sciences, Gandhi Krishi Vignana Kendra (GKVK), Bangalore-65		
Officer from the Ministry			
1.	**Dr. Abhilasha Singh Mathuriya** Scientist D, CS-III Division, Ministry of Environment, Forest and Climate Change, Jorbagh, New Delhi-110003		