

MINUTES OF THE 151st MEETING OF THE GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 19.12.2023

The 151st meeting of the Genetic Engineering Appraisal Committee (GEAC) of the Ministry of Environment, Forest and Climate Change (MoEF&CC) was held on 19.12.2023 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 and requested the Member Secretary to start the discussion on agenda items.

Agenda Item No. 1: Leave of absence

Four members, namely, Dr. Sanjeev Khosla, Dr. Rekha Singhal, Dr. P. Suprasanna and D. U.S.N. Murthy communicated their inability to attend the 151st meeting of GEAC. Further, Dr. Vinay K. Nandicoori, Ms. Shruti Singh, Dr. Dinkar M. Salunkhe, Dr. J.P. Shukla and Dr. H. K. Sharma did not attend the meeting.

Decision:

Leave of absence was granted to Members who communicated their inability to attend the meeting. Absence of members who did attend the meeting was noted.

Action: GEAC Secretariat

Agenda Item No. 2: Confirmation of minutes of the 150th GEAC meeting

Member Secretary, GEAC mentioned the minutes of the 150th GEAC meeting and requested the Members to provide comments, if any. Members were further requested to confirm the minutes.

Decision:

Members confirmed the minutes of the 150th GEAC meeting.

Action: GEAC Secretariat

Agenda Item No. 3: Action taken report on the decision taken in the 150th GEAC meeting

Member Secretary, GEAC briefed about the action taken on the decisions at the 150th meeting of GEAC. He informed that letters communicating GEAC decisions had been issued to applicants and concerned State Government(s).

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 Rallis India Ltd., Bangalore for replacing earlier recommended two GE cotton breeding stacks, MLS2154 x MLS4301 x MLS2531 and MLS2154 x MLS4301, with a new GE cotton breeding stack MLS4301 x MLS2531 expressing *cry1F* and *synthetic epsps* genes for conducting BRL-1 trials (1st Year and 2nd Year).

The applicant made a presentation before the Committee and informed that their proposal was initially recommended in 145th GEAC meeting held on 27.07.2022 under Agenda Item 4.1 for conduct of trials with two GE cotton breeding stacks (MLS2154 x MLS4301x MLS2531 and MLS2154 x MLS4301) during 2022-23 and 2023-24 growing season at following two locations based on the concurrence received from Government(s) of Karnataka & Haryana:

- i. University of Agricultural Sciences, Dharwad, Karnataka; University of Agricultural Sciences, Raichur, Karnataka.
- ii. Chaudhary Charan Singh Haryana Agricultural University, Hisar, Haryana.

The applicant informed that aforesaid trials have not been conducted for 2022-23 and 2023-24 cropping season. It is now proposed to conduct trials with a new GE cotton breeding stack viz. MLS4301 X MLS2531 expressing *cry1F* and synthetic EPSPS genes instead of earlier recommended two GE cotton breeding stacks, MLS2154 x MLS4301 x MLS2531 and MLS2154 x MLS4301.

It was informed that this revised proposal was considered by RCGM in its 261st meeting held on 28.06.2023, based upon which the proposal was considered by GEAC in its 150th meeting held on 10.08.2023 under Agenda Item 4.5. The GEAC in its 150th meeting was of the view that the RCGM be requested to further clarify its aforementioned 261st recommendations with regard to the new proposed GE cotton breeding stack MLS4301x MLS2531.

Accordingly, RCGM in its 267th meeting held on 20.09.2023 provided its clarification, vide Letter No. BT/IBKP/223/2020 dated 11.10.2023, as below:

*“Since individual parent event(s) of the breeding stack (MLS4301 x MLS2531) were subjected to and selected from already conducted event selection trials, a separate event selection trial is not required for breeding stacks containing selected (elite) events. Therefore, GEAC may consider the request submitted by M/s Rallis India Limited, Karnataka to replace earlier two GE cotton breeding stacks (MLS2154 x MLS4301 x MLS2531 and MLS2154 x MLS4301) expressing *cry1Ac*, *cry1F* and *synthetic epsps* genes with a new GE cotton breeding stack (MLS4301 x MLS2531) expressing *cry1F* and *synthetic epsps* genes for conducting BRL-I trials (1st Year and 2nd Year) to evaluate resistance against *Helicoverpa armigera* and *Spodoptera litura* and tolerance to herbicide glyphosate at two trial locations in the state of Haryana and/or Karnataka.”*

The applicant informed the Committee that they now propose to conduct trials with GE cotton breeding stack (MLS4301 x MLS2531) during 2024-26 cropping seasons only in Karnataka.

The Committee noted that permission for conduct of BRL-I trials recommended in its 145th meeting under Agenda Item 4.1 was based on the concurrence provided by Government of Karnataka vide Letter No. FEE 42 ENV 2019 dated 08.08.2022. The Committee also noted that change now proposed for conduct of BRL-I trials during 2024-26 cropping seasons is only in respect of GE cotton breeding stack which, as per 267th RCGM recommendations, can be considered given that individual parent event(s) of the breeding stack (MLS4301 x MLS2531) were subjected to and selected from already conducted event selection trials. No other scientific/ technical changes have been proposed in the conduct of trials during 2024-26 cropping seasons in Karnataka.

Recommendation:

1. Taking cognizance of recommendations of RCGM in its 267th meeting held on 20.09.2023, vide Letter No. BT/IBKP/223/2020 dated 11.10.2023, the Committee recommended the request of M/s Rallis India Ltd., Bangalore for replacing earlier two GE cotton breeding stacks, MLS2154 x MLS4301 x MLS2531 and MLS2154 x MLS4301, with a new GE cotton breeding stack MLS4301 x MLS2531 expressing *cry1F* and synthetic *epsps* genes for conducting BRL-1 trials (1st Year and 2nd Year) subject to the following conditions:
 - i. The applicant shall adhere with the conditions and/ or recommendations of 204th, 261st and 267th RCGM in this regard (Letter No. BT/IBKP/223/2020 dated 03.05.2021 and 20.09.2023), and conduct additional studies on micro-organisms as per existing protocols.
 - ii. The use of herbicide glyphosate shall be as per the limit permitted by Central Insecticide Board and Registration Committee (CIB&RC). The applicant shall intimate the CIB&RC- Directorate of Plant Protection, Quarantine & Storage about use of Glyphosate.
 - iii. The BRL-I confined field trials should be conducted at insect specific hotpot 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, before start of the trial.
 - 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 lead scientist responsible for each trial, as well as expected date of sowing, before start of the trial.
2. The Committee recommended conduct of BRL-1 trials (1st Year and 2nd Year) of GE cotton breeding stack MLS4301 x MLS2531 expressing *cry1F* and *synthetic epsps* genes during cropping seasons 2024-26 in Karnataka, taking into consideration earlier concurrence provided by Government of Karnataka vide Letter No. FEE 42 ENV 2019 dated 08.08.2022.

3. Further, the Committee directed the applicant to provide information, regarding the confined field trial sites in Karnataka, prior to the commencement of trials to Review Committee on Genetic Manipulation (RCGM) under intimation to GEAC.
4. The Committee authorized RCGM to consider changes, if any, in confined field trial sites within a State which is already recommended by GEAC and in cropping season duration (in case trials could not take place as per cropping season stipulated by GEAC); for instant application under intimation to GEAC.

RCGM to 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 ICAR-Central Potato Research Institute, Shimla for BRL-I trials of GE Potato clonal hybrid K66 expressing RB gene.

The Committee was informed that the application of ICAR-CPRI to conduct BRL-I trial of GE potato clonal hybrid KJ66 expressing RB gene at seven regional stations of CPRI, namely, Shimla (Himachal Pradesh), Jalandhar (Punjab), Gwalior (Madhya Pradesh), Kufri (Himachal Pradesh), Modipuram (Uttar Pradesh), Shillong (Meghalaya), and Ooty (Tamil Nadu) has earlier been considered in 146th and 147th GEAC Meetings. Based on the concurrence received for conduct of trials from Government(s) of Meghalaya and Himachal Pradesh, this application was recommended by GEAC as below:

- i. Recommended for conduct of trials at ICAR-CPRI stations, Shimla and Kufri in 146th GEAC meeting held on 25.08.2022 under Agenda Item 5.1.
- ii. Recommended for conduct of trials at ICAR-CPRI regional station, Shillong in 147th GEAC meeting 18.10.2022 under Agenda Item 5.1.

It was informed that applicant vide letter dated 06.06.2023 requested intervention of GEAC Secretariat in seeking views/ comments from the remaining four states (namely, Punjab, Madhya Pradesh, Uttar Pradesh, and Tamil Nadu), in accordance with the decision taken in 146th GEAC meeting under Agenda Item 7.4, so as to enable conduct of BRL-I trials at remaining four CPRI regional stations situated in Jalandhar, Gwalior, Modipuram, and Ooty. Accordingly, GEAC secretariat vide letter dated 26.06.2023 requested the Additional Chief Secretary/ Principal Secretary (Agriculture) to provide their views/ comments on the application within 60 days. However, no response was received from any of the four States. As per the aforesaid decision taken in 146th GEAC meeting, after the stipulated time was over GEAC Secretariat, vide Letter dated 14.12.2023, invited Additional Chief Secretary/ Principal Secretary (Agriculture) of the four States to participate in the 151st GEAC meeting and put forth their views.

Representatives from all four States participated in the meeting and provided their remarks as below:

- a. Dr. R. S. Sikarwar, Scientist, Rajmata Vijayaraje Scindia Krishi Vishwavidyalaya (RVSKVV), Gwalior, Madhya Pradesh participated in-person whereas Ms. Rashmi Varghese, Deputy Director, Department of Agriculture & Farmer's Welfare, Govt. of M.P. participated virtually. Clarity was sought on the requirement/ procedure for seeking comments from State Governments and on notified field trial sites.
- b. Dr. Vijay Bahadur Dwivedi, Joint Director (Vegetables) and Dr. Vineet Kumar, Deputy Director (Meerut Division) from Department of Horticulture & Food Processing, Govt. of U.P. participated virtually and in-person, respectively. It was informed that this application shall be taken up by the Horticulture Department of the State since it is a food crop, and that the comments will be provided in due course.
- c. Additional Director, Horticulture Department, Govt. of Tamil Nadu informed that their Government has been apprised about the matter and accordingly, the application is still under consideration by them.
- d. Representative from Directorate of Environment & Climate Change, Govt. of Punjab participated in the meeting and informed that their Department has not received the letter seeking comments. It was informed that the matter will be taken up with the concerned Department of Agriculture.

Member Secretary, GEAC referring to the decision taken by Committee in 146th GEAC meeting under Agenda Item 7.4, apprised all the representatives of the State Governments that the extant procedure being followed, while considering applications for conduct of BRL-I & II confined field trials of GM crops, involves seeking views/ comments from the concerned State Government(s) where the field trial sites are situated. Upon obtaining concurrence from State Governments, the GEAC considers the conduct of confined field trials in those respective States. In case the State Government(s) do not respond or communicate their non-concurrence with appropriate reasoning, the GEAC invites the Additional Chief Secretary/ Principal Secretary (Agriculture) of the State Government(s), or their nominee, to the GEAC meeting in order to deliberate on the application, while taking into consideration their remarks. It was informed to the State Government(s) representatives that this interactive procedure with State Government(s) have been established to take into consideration the remarks of State Government(s) while considering the applications for conduct of BRL-I & II confined field trials of GM crops.

Recommendation:

The Committee noted that concurrence has already been received from Government(s) of Himachal Pradesh and Meghalaya for the instant application. The comments/ views from other four State Government(s) where confined field trial sites are proposed (namely, Punjab, Madhya Pradesh, Uttar Pradesh, and Tamil Nadu) were sought in June, 2023 and have been awaited since.

However, taking into consideration the remarks of representatives from these four State Government(s); the Committee was of the view that additional time of 30 days be provided, within which the States must communicate their views/comments, if

any, on the proposal. After the stipulated time, the Additional Chief Secretary/Principal Secretary (Agriculture) of concerned States or their nominee will again be invited in the GEAC meeting wherein the proposal for conduct of trials at the proposed sites will be considered by the Committee for a decision.

The Committee directed GEAC Secretariat to share the letter dated 26.06.2023 and 12.14.2023 earlier sent by them to the State Government(s) with the representatives which participated in this meeting in order to expedite the process of obtaining comments/ views of the State Government(s).

The Committee also directed the applicant to contact the concerned State Government(s) and provide information/ clarification, if any, desired by them in order to expedite the process of seeking views/ comments of State Government(s).

Action: GEAC Secretariat

4.3 Assam Agricultural University, Jorhat, Assam for Event Selection Trials of four GE Chickpea lines expressing cry1Ac or cry2Aa gene.

The applicant made a presentation before the Committee and informed that it is proposed to conduct confined field trial for Event Selection with four GE Chickpea (*Cicer arietinum*) lines expressing *cry1Ac* or *cry2Aa* gene to evaluate resistance to Gram pod borer (*Helicoverpa armigera*) pest at two locations, namely, Punjab Agricultural University (PAU), Ludhiana and University of Agricultural Sciences (UAS), Dharwad. Of the four GE chickpea lines being subjected to trials, two GE chickpea lines-100B and 81G, express *cry1Ac* gene while two GE chickpea lines- 80C and 72C2, express *cry2Aa* gene.

This application was considered and recommended by RCGM in its 270th meeting held on 01.11.2023, vide Letter No. Letter No. BT/IBKP/313/2020 dated 01.12.2023.

Recommendation:

Based on the recommendation of RCGM, the proposal of Assam Agricultural University, Jorhat, Assam to conduct Event Selection Trials under confined conditions with four GE Chickpea lines (100B, 81G, 80C and 72C2) expressing *cry1Ac* or *cry2Aa* gene conferring resistance against Gram pod borer (*Helicoverpa armigera*) during cropping season 2024-2025 was recommended by the Committee subject to the condition that applicant will perform the trials as per extant rules/guidelines/regulations; and will adhere with the RARM Plan, recommendations and/or conditions of RCGM as per its Letter No. BT/IBKP/313/2020 dated 01.12.2023. Further, the trials should be conducted at insect specific hotpot in the trial sites that are appropriate to evaluate the introduced insect resistant trait in the GE plant.

The Committee authorized RCGM to consider changes, if any, in confined field trial sites and in cropping season duration (in case trials could not take place as per cropping season stipulated by GEAC) for instant application under intimation to GEAC.

RCGM to 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 BeejSheetal Research Private Limited, Maharashtra for BRL-II trials of two Bt Brinjal hybrids expressing *Cry1Fa1* gene.

The applicant made a presentation before the Committee and informed that the proposal of M/s BeejSheetal Research Private Limited, Maharashtra for conduct of BRL-II trials with two Bt Brinjal Hybrids, namely, Janak & BSS-793, expressing *Cry1Fa1* gene (gene event 142) has earlier been considered and recommended by GEAC as below:

- i. In 121st meeting held on 18.07.2014, GEAC recommended for conduct of trials at seven locations namely Maharashtra, Gujarat, Punjab, Haryana, Uttar Pradesh, New Delhi and Andhra Pradesh subject to condition that they obtain NOC from concerned States.
- ii. GEAC also approved inclusion of two additional locations, viz. Assam and Telangana, for the conduct of these BRL-II trials (placed before the Committee for information in 130th meeting held on 11.08.2016).

Applicant informed that they could only obtain NOC from Government of Delhi for duration appropriate for Brinjal's growing season. Accordingly, they conducted BRL-II trials at ICAR-India Agricultural Research Institute (IARI), New Delhi during 2016-17.

It was further informed that in order to conduct BRL-II trials in 2-3 more locations situated in different agro-climatic zones, applicant submitted application to GEAC. Subsequently, GEAC in its 139th meeting held on 19.05.2020 recommended conduct of these BRL-II trials in 8 States (viz. Madhya Pradesh, Karnataka, Bihar, Chhattisgarh, Jharkhand, Tamil Nadu, Odisha and West Bengal) during seasons 2020-23 subject to the condition that they receive NOC from concerned States.

The applicant informed the Committee that they want to repeat the BRL-II trials and accordingly has submitted instant proposal to conduct BRL-II trials with two Bt Brinjal Hybrids, namely, Janak & BSS-793, expressing *Cry1Fa1* gene (gene event 142) during cropping season 2024-26 in five States namely, Delhi, Haryana, Uttar Pradesh, Karnataka and Assam.

Recommendation:

In accordance with the decision taken in 146th meeting of GEAC held on 25.08.2022 under Agenda Item 7.4, the Committee directed the GEAC Secretariat to send a formal

communication to the Additional Chief Secretary/Principal Secretary (Agriculture) of the five concerned States (namely, Delhi, Haryana, Uttar Pradesh, Karnataka and Assam) where confined field trial sites are proposed, seeking their views/comments within the stipulated time, and subsequently invite them to the GEAC meeting wherein the proposal will be considered for deliberation.

The Committee also directed the applicant to contact the concerned State Government(s) and provide information/ clarification, if any, desired by them in order to expedite the process of seeking views/ comments of State Government(s).

Action: GEAC Secretariat

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

5.1 M/s 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 proposal is to conduct randomized, observer-blind, placebo-controlled, multi-centre, multinational Phase III clinical trials [VAD00004] to evaluate the efficacy, immunogenicity, and safety of Respiratory syncytial virus (RSV) NS2/1313/I1314L vaccine in infants and toddlers. The vaccine will be administered in 6300 subjects, intranasally using a nasal administration device and is intended to provide active immunization for prevention of RSV disease in infants from 6 to <22 months of age.

The investigational vaccine is Sanofi's RSVt vaccine which is based on the same viral construct (i.e., Δ NS2/ Δ 1313/I1314L) as the US NIH RSV vaccine; however, the vaccines differ in formulation and mode of administration (i.e., nasal spray versus drops). The US NIH live-attenuated RSV vaccine is developed by deleting the gene encoding the RSV IFN / apoptosis antagonist NS2 protein. Deletion of the NS2 gene (Δ NS2) attenuates the virus by decreasing pathogenicity and enhancing immunogenicity. This vaccine additionally contains a genetically stabilized attenuating and temperature sensitivity mutation in the L protein (codon deletion Δ 1313), as well as a missense mutation I1314L that prevents a de-attenuating mutation that otherwise can occur at position 1314).

Recommendation:

The Committee was of the view that the proposal of M/s PPD Pharmaceutical Product Development India Pvt. Ltd., Mumbai for conduct of a randomized, observer-blind, placebo-controlled, multi-centre, multinational Phase III clinical trials [VAD00004] to evaluate the efficacy, immunogenicity, and safety of Respiratory syncytial virus (RSV)

NS2/1313/I1314L vaccine be forwarded to Review Committee on Genetic Manipulation (RCGM) for scrutiny. Further, the Drugs Controller General of India, Central Drugs Standard Control Organization (CDSCO) is also requested to share its comments in regard to processing of the proposal.

Action: GEAC Secretariat

5.2 M/s Oasis Ethanol Industries Private Limited, Haryana for commercial production of Ethanol using genetically modified *Saccharomyces cerevisiae* strain SYNERXIA® JADE ADY.

The applicant made a presentation before the Committee and informed that they propose to undertake commercial production of ethanol using genetically modified *Saccharomyces cerevisiae* strain, SYNERXIA® JADE ADY at their distillery located in Tehsil Sahjadpur, Ambala, Haryana.

It was informed that the *S. cerevisiae* strain SYNERXIA® JADE ADY intended to be used for production of ethanol for fuel blending using grain-based feedstock, has been recommended for import and marketing by GEAC in its 148th meeting held on 31.01.2023. In the said GEAC meeting under Agenda Item 6.1, proposal of M/s Danisco India Private Limited (DIPL), Hyderabad for import of 2000 metric ton (2,000,000 Kgs) of SYNERXIA® JADE ADY (Active Dried Yeast), per annum from USA and its marketing for ethanol production was recommended by the Committee subject to condition that the firms, whomsoever using the imported genetically modified SYNERXIA® JADE ADY (Active Dried Yeast) strains, has to obtain separate approval from GEAC for large scale production.

The Committee deliberated on the requirement of developing a standard Risk Assessment & Risk Management Plan in respect to environmental safety, for considering proposals related to large scale/ commercial production of ethanol using genetically modified organisms at the distilleries.

Recommendation:

1. After due deliberations, the Committee was of the view that RCGM be requested to prepare a Risk Assessment & Risk Management Plan (RARMP) in respect to environmental safety, that the applicant should comply with, for commercial production of ethanol using genetically modified organisms at the distilleries. The applicant was directed to submit a draft RARMP in respect to environmental safety, for consideration of RCGM.
2. The Committee also requested RCGM to prepare a standard RARMP pertaining to environmental safety that should be adhered with while undertaking commercial production of ethanol using genetically modified organisms at the distilleries.

3. Further, the Committee was of the view that for every by-product, obtained during such a commercial production process, that is intended to be utilized/ sold/ marketed/ commercialized or is to be released into the environment; the applicant shall have to obtain separate regulatory approval as required by the extant laws/ rules/ regulations.

Action: GEAC Secretariat

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

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

The applicant made a presentation before the Committee and informed that they intend to import and market genetically modified *S. cerevisiae* strain MeJi797 (amgPS gene, amyJA126PE096 gene) for ethanol production. It was informed that this *S. cerevisiae* strain MeJi797 was recommended for import and marketing by GEAC in its 144th meeting held on 22.02.2022 under Agenda Item 5.7. Accordingly, permit letter dated 11.04.2022 was issued after the approval of Competent Authority allowing for import of 1000 Kgs of *S. cerevisiae* strain MeJi797 per annum from USA, as per quantity requested then. The applicant now intends to increase the quantity of import of *S. cerevisiae* strain MeJi797 from 1000 Kgs to 2000 metric ton (2,000,000 Kgs) per annum for its marketing for ethanol production.

The applicant further submitted that no import of *S. cerevisiae* strain MeJi797 has been done, in accordance with the permit letter issued by GEAC Secretariat on 11.04.2022.

Recommendation:

1. After due deliberations, the Committee was of the view that RCGM be requested to prepare a Risk Assessment & Risk Management Plan 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. The applicant was directed to submit a draft RARMP in this regard, for consideration of RCGM.
2. The Committee also requested RCGM to prepare a standard RARMP pertaining to storage, transportation, access, handling, packing, re-packing, distribution, sale, decontamination, and disposal of GMO consignment imported for the purpose of commercial production.
3. In respect of earlier permit granted vide letter dated 11.04.2022 in accordance with the recommendations of 144th GEAC for import of 1000 Kgs of *S. cerevisiae* strain MeJi797, the applicant has been directed to

provide a detailed plan of marketing and distribution of *S. cerevisiae* strain MeJi797 being imported. This shall include details of present and prospective tie-ups with buyers/ purchasers of imported *S. cerevisiae* strain for the quantum of utilization per annum.

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

Action: GEAC Secretariat

6.2 M/s Intervet India Pvt. Ltd., Pune submitted for import and marketing of Nobivac Puppy DP Plus recombinant veterinary vaccine.

The Committee was informed that the proposal of M/s Intervet India Pvt. Ltd., Pune for import and marketing of Nobivac Puppy DP Plus recombinant vaccine (Generic name: Combined Canine Distemper and Canine Parvovirus Vaccine, Live, Freeze dried vaccine) for veterinary use was initially considered in the 145th meeting of GEAC held on 27.07.2022 under Agenda Item 6.5, wherein this proposal was recommended by the Committee for import, subject to the conditions that “*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.*”

The Committee was informed that the applicant has submitted the ICAR-IVRI certified test batch reports received vide Letter No. STD/QC/VT/Intervet/2023-24/ dated 08.06.2023; and the NOC received from Department of Animal Husbandry and Dairying vide Letter No. K-11053/47/2021-LH-Part I dated 12.04.2022.

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.

The Committee also suggested that more laboratories/ centres be identified which can undertake metagenomics analysis in the country.

Action: GEAC Secretariat

Agenda Item No. 7: Additional Items for consideration

7.1 Matter pertaining to requirements for import of alfalfa hay from USA.

The Committee was informed that the matter pertaining to requirements for import of alfalfa hay from USA was initially considered in the 146th meeting of GEAC held on 25.08.2022 under Agenda Item 8.1. Recommendations of 146th GEAC were sent to DA&FW, vide Letter dated 15.09.2022, after the approval of the Competent Authority.

It was informed that subsequent to 146th GEAC Meeting, the Food Safety and Standards Authority of India (FSSAI) vide Letter dated 08.05.2023 conveyed the following:

- i. FSSAI was asked to scientifically examine import of GM feed (alfalfa hay) for its use as cattle feed.
- ii. Scientific Panel (SP) on Genetically Modified Organisms (GMOs) & Foods took note of the scientific literature available in different research journals, reports and the material available on the website of different organizations, including detailed studies.
- iii. SP is of opinion that GM alfalfa (herbicide tolerant) can be considered as a livestock safe feed as is Non-GM alfalfa feed. However, this opinion is based only on the secondary data, i.e. available scientific literature.
- iv. Observations of SP along with detailed note may be put up to GEAC for suggesting the way forward.

Further, FSSAI vide its Letter dated 11.09.2023, informed DA&FW that safety assessment of GM alfalfa feed was carried out by SP and that animal feed is not in the mandate of Food Safety and Standards Act (FSSA) 2006 and that any approval for GM crop is recommended by GEAC. Taking cognizance of FSSAI's letter dated 11.09.2023, DA&FW vide letter dated 10.10.2023 requested that issue regarding regulation of alfalfa hay be sorted amongst GEAC & FSSAI.

In this regard, the Committee was apprised that presently the matters related to GM food/ GMOs intended for food use are governed by Rules 1989 as well as Food Safety and Standards Act (FSSA) 2006. As per Rule 11 (Permission and Approval for Food Stuffs) of Rules, 1989: *"Food stuffs, ingredients in food stuffs and additives including processing aids containing or consisting of genetically engineered organisms or cells, shall not be produced, sold, imported or used except with the approval of the Genetic Engineering Appraisal Committee"*.

It was informed that after the enactment of FSSA 2006; the definition of Food under Section 3 (j) of FSSA, 2006 also includes Genetically Modified Food. Ministry of Environment, Forest & Climate Change (MoEF&CC) vide Gazette Notification dated 23.08.2007 exempted *"Food stuff, ingredients in food stuff and additives including processing aids derived from Living Modified Organisms where the end product is not a Living Modified Organism"* from the purview of Rule 11 of Rules, 1989. However,

Ministry of Health, Family & Welfare (MoH&FW) requested that since FSSAI had not framed rules/ regulations for GM food under the FSSA 2006, the GEAC may continue to process the applications relating GM food stuffs under Rules 1989. As per Hon'ble Supreme Court Order dated 11.08.2017 in W.P. No.173/ 2006 and W.P. No. 11/ 2008, FSSAI was directed to frame regulations in connection with genetically engineered and modified food.

The Committee was further informed that amendments have been proposed to FSSA 2006. FSSAI has accepted the suggestion as proposed by MoEF&CC in respect of Draft Amendment FSSA Bill 2020:

- i. Genetically modified "or engineered" feed to be included in definition of feed.
- ii. It shall be the duty of the Food Authority to regulate and monitor manufacture, processing, distribution, sale, export and import of feed, including genetically modified or engineered feed.
- iii. The Food Authority shall be responsible for health safety assessment of food or feed consisting of, containing or derived from GMOs in order to protect human and animal health.

The Committee comprehensively deliberated on extant regulations governing use of genetically modified food and feed in India at present. Regulation of feed, as envisaged, under amendments proposed to FSSA was also discussed.

Recommendation:

1. After due deliberations, the Committee was of the view that 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; whereas the health safety aspect of genetically modified food as well as the products derived from processing thereof intended for direct use for human consumption shall be regulated by FSSAI as per provisions of Food Safety and Standards Act 2006, as amended time to time. For regulation of genetically modified food and products derived thereof:
 - a. 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.
 - b. FSSAI will be the regulatory body granting permission in respect of health safety aspects, taking into consideration environmental safety assessment carried out by GEAC.
2. The environmental safety aspect of any genetically modified feed 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; whereas the health safety aspect of genetically modified feed as well as the products derived from processing thereof intended for direct use for animal consumption shall be regulated by FSSAI as per provisions of Food Safety and Standards Act (FSSA)

2006, if the amendments, as proposed, to FSSA 2006 are passed by the Parliament. For regulation of genetically modified feed and products derived thereof:

- a. 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 (if the amendments, as proposed, to FSSA 2006 are passed by the Parliament and feed gets covered under the mandate of this act).
 - b. FSSAI will be the regulatory body granting permission in respect of health safety aspects, taking into consideration environmental safety assessment carried out by GEAC (if the amendments, as proposed, to FSSA 2006 are passed by the Parliament and feed gets covered under the mandate of this act).
3. In respect of matter pertaining to import of alfalfa hay from USA, the Committee noted that health safety aspect of alfalfa hay has been examined by Scientific Panel on GMO & Food and they have stated that GM alfalfa hay can be considered as livestock safe feed as per secondary data available. The Committee was of the opinion that FSSAI/ MoH&FW shall forward these findings/ examination of Scientific Panel on GMO & Food directly to DA&FW.
 4. The Committee decided that environmental safety aspect of alfalfa hay be examined by RCGM and their recommendation in this regard shall be submitted to GEAC for consideration.
 5. 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 and, if applicable, apprise about it to the concerned Ministry/ Department. The FSSAI/ Scientific Panel (SP) on GMO & Food shall undertake the health safety assessment of genetically modified feed and, if applicable, apprise about it to the concerned Ministry/ Department.

Action: GEAC Secretariat

Agenda Item No. 8: Information Items

8.1 Status of work undertaken by Expert Committee, constituted as per recommendations of 145th and 149th meetings of GEAC, for proposal of M/s Mahyco Private Ltd., Mumbai for environmental release of Bollgard II Roundup Ready Flex (BGIITM RRFTM) cotton incorporating events MON 15985 x MON 88913.

The Committee was informed that in accordance with the recommendations made by GEAC in its 145th meeting held on 27.07.2022 under Agenda Item 5.1, Expert Committee, was constituted under the Chairmanship of Dr. Sanjay Kumar Mishra, Scientist-H, Department of Biotechnology (DBT) and Co-chair, GEAC for

comprehensive examination of the dossier submitted by applicant as per extant rules/ regulations/ guidelines. Report of this Expert Committee was received on 01.12.2023 and was considered by GEAC in its 149th meeting held on 17.05.2023 under Agenda Item 5.1. In its 149th meeting, the Committee decided that the applicant be directed to revise/ update the dossier as per recommendations of Expert Committee and that the updated dossier be directly submitted back to Expert Committee for further evaluation/ processing of the proposal.

The tenure of Expert Committee constituted under the Chairmanship of Dr. Sanjay Kumar Mishra was extended vide order dated 09.06.2023 for six months in accordance with the recommendations of 149th GEAC meeting with following terms of reference:

- a. The Committee shall function in the Ministry of Environment, Forest and Climate Change for comprehensive review of the updated dossier submitted by M/s Mahyco Private Ltd., Mumbai and for further processing of the proposal, including preparation of Risk Assessment and Risk Management (RARM) Report, in accordance with the applicable guidelines/procedures/ SOPs.
- b. The Committee shall submit its recommendations to the Genetic Engineering Appraisal Committee (GEAC).
- c. The Chairperson of this Committee may co-opt other members/experts, as necessary.
- d. The Committee can seek the additional information, as and when required, directly from the applicant for further processing of the proposal.

The GEAC was apprised about the work undertaken by the Expert Committee after 149th GEAC Meeting. It was informed that the revised/ updated dossier, as per the recommendations of the Expert Committee was submitted by the applicant on 26.06.2023, after which the dossier was circulated for review of Expert Committee members on 28.06.2023. Subsequently, a meeting of this Expert Committee was held on 14.07.2023 wherein it was recommended that:

1. Applicant be directed to further elaborate socio-economic aspects of the dossier.
2. Applicant be directed to provide information which is missing or not clear in dossier.
3. With regard to preparation of RARM Plan, it was recommended:
 - i. Applicant to prepare zero draft of RARM Plan.
 - ii. Zero draft of RARM Plan to be submitted to RCGM for review.
 - iii. Subsequently, the RARM Plan (incorporating suggestions of RCGM) shall be considered by the Expert Committee.

In accordance with the recommendation of Expert Committee, applicant submitted the revised dossier and zero draft of RARM Plan on 05.09.2023, which was then forwarded to RCGM Secretariat for review & further action on 06.09.2023. The RARM Plan was comprehensively reviewed by RCGM over four meetings as below:

- a. 267th meeting held on 20.09.2023
- b. 269th meeting held on 18.10.2023
- c. 272nd meeting held on 29.11.2023
- d. 273rd meeting held on 13.12.2023

Member Secretary, RCGM informed that the approved recommendations of 273rd meeting of RCGM held on 13.12.2023 have been forwarded to the Member Secretary, Expert Committee on 18.12.2023.

Henceforth, the Expert Committee shall review the draft RARM Plan received from RCGM and submit final draft of RARM Plan & report to GEAC for further consideration.

Recommendation:

The Committee noted the progress of work done in respect of processing the proposal of M/s Mahyco Private Ltd., Mumbai for environmental release of Bollgard II Roundup Ready Flex (BGII RRF) cotton incorporating events MON 15985 x MON 88913.

Further, the Committee decided to extend the tenure of the Expert Committee constituted under the Chairmanship of Dr. Sanjay K. Mishra, Co-Chair, DBT for six months.

Action: GEAC Secretariat

Agenda Item No. 9: Any other Item with the permission of the Chairman

9.1 Recommendations of 265th meeting of RCGM in regard to composition of Central Compliance Committee (CCC) and important stages for monitoring of confined field trials of GE plants.

Member Secretary, RCGM mentioned that RCGM in its 265th meeting held on 23.08.2023 deliberated on the subject of composition of Central Compliance Committee (CCC) and important stages for monitoring of confined field trials of GE plants. These 265th recommendations of RCGM were forwarded to GEAC for further consideration vide Letter No. PID-15011(12)/3/2021-PPB-DBT dated 11.10.2023.

GEAC Secretariat to examine 265th recommendations of RCGM in regard to composition of Central Compliance Committee (CCC) and important stages for monitoring of confined field trials of GE plants.

Action: GEAC Secretariat

9.2 Request of Indian Council of Agricultural Research (ICAR), New Delhi in regard to proposal for establishing identified institutes as Notified Field Trial Sites (NFTSs).

The matter pertaining to establishment of Notified Field Trial Sites (NFTS) was mentioned. It was informed that the GEAC in its 149th meeting held on 17.05.2023 considered this matter under Agenda Item 8.2 wherein 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 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.

Member Secretary, RCGM informed that the proposal for establishment of NFTS is currently under consideration of ICAR. Representative of ICAR informed that they are reaching out to the State Governments, seeking a way forward in this matter.

Recommendation:

In accordance with the decision taken by GEAC in its 149th meeting held on 17.05.2023 under Agenda Item 8.2, the Committee requested ICAR/ DBT to provide the list of Institutions/ Agricultural Universities recommended by the Expert Committee for establishment as Notified Field Trial Sites (NFTSs) as per the 'Proposal for Establishment of Notified Field Trial Sites to conduct Confined Field Trials of GE Crops' noted by GEAC in its 140th meeting. Subsequent to this, the Chairman, GEAC in Ministry of Environment, Forest, and Climate Change may accordingly send a formal communication to the concerned State/ UT Government(s), where NFTSs are proposed to be established, in order to seek their one-time concurrence/ views/ comments.

Further, ICAR/ DBT shall pursue with the concerned State Government(s) to take forward the process of establishment of NFTSs in accordance with the 'Proposal for Establishment of Notified Field Trial Sites to conduct Confined Field Trials of GE Crops'.

Action: GEAC Secretariat

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

Annexure 1**List of Participants**

Members who participated	
1. Shri Naresh Pal Gangwar Additional Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jorbagh road, Aliganj, New Delhi- 110003	9. Shri V.P. Yadav Scientist F Central Pollution Control Board Parivesh Bhawan, East Arjun Nagar, Delhi-110 032
2. Dr. Sanjay Kumar Mishra Scientist H, Department of Biotechnology, Block 2, CGO Complex, Lodhi Road New Delhi - 110 003	10. Dr. Nitin K. Jain Scientist-G & Member Secretary RCGM, Department of Biotechnology, C. G. O, Complex, Lodhi Road, New Delhi-110003
3. Dr. Satyendra Kumar Director, CS-III Division Ministry of Environment, Forest and Climate Change, Jorbagh, New Delhi-110003	11. Dr. Chaitanya Joshi Director, Gujarat Biotechnology Research Centre, Gandhinagar, Gujarat- 382 011
4. Dr. D.K. Yadav ADG (Seed), Crop Science Division Indian Council of Agricultural Research, Krishi Bhawan, New Delhi-110001	12. Dr. P.K. Dass Department of Anatomy LHMC & Associated Hospitals, New Delhi- 110 001
5. Dr. Alka Rao Principal Scientist, Protein Science and Engineering & Adjunct Associate Prof., GNR Protein Centre, CSIR-Institute of Microbial Technology (CSIR-IMTECH), Sector 39-A, Chandigarh-160036	13. Dr. J.P. Singh Plant Protection Adviser (PPA), Directorate of Plant Protection, Quarantine & Storage, NH IV, Faridabad-121001.
6. Dr. S. J. Rahman Principal Scientist & Univ. Head of Entomology, Prof. Jayashankar Telangana State Agri. University, Hyderabad-500 030	14. Shri Sunil Kumar Bakshi Head, Regulation, Food Safety and Standards Authority of India, FDA Bhawan, Kotla, New Delhi - 110002
7. Dr. Pronab Dhar Principal Scientist, ICAR-Indian Veterinary Research Institute (IVRI), Bareilly, Uttar Pradesh- 243122 (Representative of Dr. Triveni Dutt, Director, IVRI)	15. Dr. Satish Wate Former Director CSIR-National Environmental Engineering Research Institute Nagpur- 440020

8.	Dr. Geeta Jotwani Scientist G Indian Council of Medical Research (ICMR) Ministry of Health and Family Welfare Ramalingaswami Bhavan, Ansari Nagar, New Delhi—110029	16.	Dr. Rubina Bose Deputy Drugs Controller (India), Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, FDA Bhawan, Kotla Road, New Delhi -110002 (Representative of Dr.V.G. Somani, Drugs Controller General of India)
Members who did not participate			
1.	Dr. P. Suprasanna Scientific Officer H (Retd.) Biosciences group BARC, Mumbai-400085	6.	Ms. Shruti Singh Joint Secretary, IPR, Department for Promotion of Industry and Internal Trade, Udyog Bhawan, New Delhi 110011
2.	Dr. Vinay K. Nandicoori Director, CSIR-Centre for Cellular & Molecular Biology, Hyderabad - 500 007	7.	Dr. H. K. Sharma Director, National Institute of Technology, Agartala, Tripura- 799 046
3.	Dr. J. P. Shukla Scientist, CSIR-Advanced Materials and Process Research Institute, Bhopal- 462 026	8.	Dr. U. S. N. Murthy Director, National Institute of Pharmaceutical Education and Research, Guwahati- 781 101
4.	Dr. Sanjeev Khosla Director, CSIR-Institute of Microbial Technology, Chandigarh- 160 036	9.	Dr. Rekha S. Singhal Professor, Food Technology, Institute of Chemical Technology, Mumbai- 400 019
5.	Dr. Dinkar M. Salunkhe Director, International Centre for Genetic Engineering and Biotechnology New Delhi-110 067		
Special Invitee			
1.	Dr. Vineet Kumar Deputy Director Meerut Division Directorate of Horticulture & Food Processing, Govt. of U.P.	4.	Dr. R. S. Sikarwar Scientist, Rajmata Vijayaraje Scindia Krishi Vishwavidyalaya (RVSKVV), Gwalior, Madhya Pradesh
2.	Dr. Vijay Bahadur Dwivedi Joint Director (Vegetables) Department of Horticulture & Food Processing, Govt. of U.P.	5.	Ms. Rashmi Varghese Deputy Director, Department of Agriculture & Farmer's Welfare, Govt. of M.P
3.	Additional Director Horticulture Department, Govt. of Tamil Nadu	6.	Representative from Directorate of Environment & Climate Change, Govt. of Punjab

Officer from the Ministry

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| 1. | Dr. Abhilasha Singh Mathuriya
Scientist D, CS-III Division, Ministry of Environment, Forest and Climate Change,
Jorbagh, New Delhi-110003 |
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