

MINUTES OF THE 149th MEETING OF THE GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 17.05.2023

The 149th meeting of the Genetic Engineering Appraisal Committee (GEAC) of the Ministry of Environment, Forest and Climate Change (MoEF&CC) was held on 17.05.2023 in hybrid mode at Indus 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

Two members, Dr. Nitin K. Jain and Dr. P. Suprasanna communicated their inability to attend the 149th meeting of GEAC. Dr. Vinay K. Nandicoori, Ms. Shruti Singh, Dr. Dinkar M. Salunkhe, Dr. J.P. Shukla and Dr. Geeta Jotwani 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 148th GEAC meeting

Minutes of the 148th GEAC meeting were circulated to all the members for comments and were suitably amended to incorporate comments received. Member Secretary, GEAC mentioned these minutes and requested the Members to provide comments, if any. The Committee agreed that the third condition "*The BRL-1 confined field trials should be conducted at the biodiversity hotspot locations in the State*", mentioned in the decision under Agenda Item 4.1 of 148th GEAC meeting, be further specified and accordingly should be read as "*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*". Members were further requested to confirm the minutes.

Decision:

Members noted the amendment in the minutes and with that confirmed the minutes of the 148th GEAC meeting.

Action: GEAC Secretariat

Agenda Item No. 3: Action taken report on the decision taken in the 148th GEAC meeting

Member Secretary, GEAC briefed about the action taken on the decisions at the 148th meeting of GEAC. He informed that letters communicating GEAC decisions had been issued to applicants.

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 trial (1st Year) of GE cotton hybrids containing Event 18L-5-3 expressing cry2Ai gene.

The Committee was informed that the application was considered in the 148th GEAC meeting held on 31.01.2023 and that the BRL-I trials (1 st year) of GE cotton hybrids containing Event 18L-5-3 expressing cry2Ai gene for resistance against Pink Bollworm are proposed to be conducted at following five locations as per the information provided by RCGM Secretariat vide Letter No. BT/IBKP/068/2020 dated 08.02.2022 and email dated 24.04.2023:

- a. Janwada (Telangana): Bioseed Research India, Plot No. 234, B Block, Kavuri Hills, Phase II, Hyderabad – 500033, Telangana
- b. Jalna (Maharashtra): Bioseed Research India, Plot No. 12, C-4, N-1, CIDCO, Aurangabad – 401301, Maharashtra
- c. Akola (Maharashtra): Dr Panjabrao Deshmukh Krishi Vidyapeeth, Akola – 444104, Maharashtra
- d. Junagadh (Gujarat): Junagadh Agricultural University, Junagadh – 362001, Gujarat
- e. Barwala-Hisar (Haryana): Research Station, M/s. Bioseed Research India, Village – Panghal, Barwala-Hansi Road, Hisar – 124121, Haryana

The Committee was informed about the chronology with regard to processing of the proposal. Taking cognizance of decision taken in 146th GEAC meeting held on 25.08.2022 regarding requirement of views/ comments from the concerned State Government(s), OM dated 12.10.2022 was sent to the concerned States to communicate their views/comments within 60 days. Further, the concerned States were invited vide OM dated 24.01.2023 for participation in the 148th meeting of GEAC for consideration of the proposal. However, the meeting was attended only by representative of Government of Telangana who sought additional time to provide their views. Views were received from Government of Haryana, conveying no objection for conduct of trials vide Memo No. 721/ADO (Seed) dated 17.11.2022.

The GEAC in its 148th meeting approved the proposal for conduct of trials at Hisar, Haryana site whereas additional time of 30 days was given to other three States vide OM dated 23.02.2023. The Committee also noted that for approval given under Agenda Item 4.1 of 148th GEAC meeting, one of the conditions stipulated for conduct of these trials at Haryana, i.e. third condition “The BRL-1 confined field trials should be conducted at the biodiversity hotspot locations in the State” needs to be further specified in regard to biodiversity hotspot locations. Accordingly, the Committee was of the view that this specific condition should be re-framed as “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.”

It was also informed that the Government of Telangana vide Letter dated 14.03.2023 requested for additional time of 45 days to communicate their views. To this, GEAC Secretariat requested Government of Telangana to provide their views latest by

20.04.2023. Furthermore, Government of Telangana vide Letter dated 16.05.2023 stated that they've decided not to take up the trial during 2023-24 cropping season.

Government of Gujarat vide Letter dated 06.03.2023 communicated that the proposal is not found acceptable by them without citing any reason. No comments have been received from Government of Maharashtra yet.

The Committee was informed that all the four concerned States invited for the 149th GEAC meeting vide Letter dated 03.05.2023 for the consideration of the proposal.

Sri Hanumant K Zendage, Special Commissioner of Agriculture, Government of Telangana participated virtually in the 149th meeting and informed that Telangana Government, in order to provide their views on the proposal, constituted an Expert Committee which has given its report. It was further informed that the Government of Telangana is in the process of evaluating all the published material available on the issue of the Genetically Modified (GM) crops. Accordingly, the Government of Telangana has decided not to take up the trial during year 2023-24 cropping season and that a view on it will be taken after more detailed analysis.

Based on the responses received from concerned State Governments, the Committee was of the view that capacity building activities, such as series of sensitization workshops or conferences, may be taken up with the Agriculture Department of the State/ UTs Government(s) in order to apprise them with various aspects of GM crops including, biosafety framework, regulatory procedure for development, Global status of its use, etc.; thereby enabling them in informed decision making.

Recommendation:

Taking cognizance of the response of the concerned State Governments, namely, Government of Telangana, Gujarat, and Maharashtra; the Committee recommended that communication be sent from Chairperson, GEAC to the Additional Chief Secretary/ Principal Secretary, Agriculture Department of these States as below:

- i. Government of Telangana be requested to cite the reason for not taking up the trials for the 2023-24 cropping season.
- ii. Government of Gujarat be requested to cite the reason for not finding the proposal acceptable.
- iii. Government of Maharashtra be requested again to provide their views/ comments along with appropriate reasoning within 30 days. In case no response is received from them within the stipulated time, the GEAC will make appropriate recommendation in this matter.

The Committee further suggested that Department of Biotechnology (DBT), Indian Council of Agricultural Research (ICAR), and Ministry of Agriculture may jointly organize capacity building activities with regard to GM crops for apprising the State/ UT Government(s) about the technology involved and regulatory framework in place for evaluation of these GM crops; thereby enabling informed decision making by the State/ UT Government(s).

Action: GEAC Secretariat

4.2 M/s Ajeet Seeds Pvt. Ltd., Aurangabad for Event Selection Trial of Bt brinjal events expressing cryIAc gene (AJTCryIAc /pASPL818).

The applicant made a detailed presentation before the Committee. The Committee was informed that M/s Ajeet Seeds Pvt. Ltd., Aurangabad intends to conduct Event Selection Trial (under confined field conditions) for four Bt brinjal events (ASPL-101, ASPL-103, ASPL-104 and ASPL-110) expressing cry1Ac gene (AJTCry1ac/pASPL818) conferring resistance against Lepidopteran pests (*Leucinodes orbonalis* and *Helicoverpa armigera*) causing Brinjal Fruit and Shoot Borer. The trial is proposed to be conducted at the applicant's farm (Gut No. 74) at Hanumantgaon, Post: Solegaon, Tq. Gangapur, Dist: Aurangabad-431133. The objective of these trials is to select the best transgenic Bt Brinjal event(s), and to evaluate agronomic and morphological traits of Bt brinjal events; vis-à-vis non-Bt Brinjal under confined field conditions.

This application was considered and recommended by the Review Committee on Genetic Manipulation (RCGM) in its 184th meeting held on 04.06.2020, vide Letter No. BT/BS/17/67/2002-PID dated 16.07.2020.

Recommendation:

Based on the recommendation of RCGM, the proposal of M/s Ajeet Seeds Pvt. Ltd., Aurangabad to conduct Event Selection Trials of four Bt Brinjal events (ASPL-101, ASPL-103, ASPL-104 and ASPL-110) expressing cry1Ac gene (AJTCry1ac/pASPL818) conferring resistance against Lepidopteran pests (*Leucinodes orbonalis* and *Helicoverpa armigera*) during Kharif cropping season of 2023 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/BS/17/67/2002-PID dated 16.07.2020. 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 letter and monitor confined field trials to ensure compliance of prescribed terms and conditions.

Action: GEAC & RCGM Secretariat

Agenda Item No. 5: Applications related to Environmental Release of GE crops

5.1 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 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 was initially considered in the 145th

meeting of GEAC held on 27.07.2022 under Agenda Item 5.1 wherein it was decided that an Expert Committee be constituted under the Chairmanship of Dr. Sanjay Kumar Mishra, Co-Chair, GEAC for detailed review of the dossier submitted by the applicant for environmental release of BGII RRF. Accordingly, the Expert Committee was constituted vide OM dated 22.08.2022 and its report has been submitted to the GEAC secretariat on 01.12.2022 through email.

The Committee reviewed the report submitted by the Expert-Committee constituted under the Chairmanship of Dr. Sanjay K Mishra. The recommendations were:

"The developer should be suggested to revise their overall claim in the dossier in respect of efficacy of BGII RRF hybrids against the target pests, bollworm complex and Spodoptera litura, specifying the lepidopteran insects against which the BGII RRF hybrid are effective. Also, socio-economic analysis need to be revised.

The specific remarks of the committee may be forwarded to the developer for improvisation of the dossier with respect to depiction of the data and re-submit to GEAC".

Members were invited to put forth their comments on the aforementioned recommendations submitted by the Expert Committee. The members were in agreement of the recommendations submitted by the Expert Committee.

Recommendation:

After considering the recommendations of the Expert Committee, the GEAC made the following recommendations:

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

Action: GEAC Secretariat

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

6.1 M/s Aaditya Finechem Pvt. Ltd., Jaipur for import of genetically modified *Saccharomyces cerevisiae* strain M24926 for ethanol production.

The applicant made a detailed presentation before the Committee and informed that M/s Aaditya Finechem Pvt. Ltd., Jaipur proposes to import and market genetically modified *Saccharomyces cerevisiae* strain M24926 (Brand Name: Fermboost) for production of ethanol from grain. The *S. cerevisiae* strain M24926 has been genetically modified to introduce synthetic genes encoding for glucoamylase and trehalase enzymes, enabling efficient ethanol production. The enzymes present in Strain M24926 are well characterized and are not associated with pathogenicity, toxicity or antibiotic resistance. Technology used for the strain development ensures that only the target DNA is inserted in the Strain, while negating any possibility of transferring DNA from the donor to the strain. The applicant intends to import up to 1000 MT of *S. cerevisiae* strain M24926 per annum from Brazil.

It was further informed that during the distillation stage of ethanol production process, Strain M24926 will be subject to temperature stress that exceeds their tolerance, resulting in inactivation/ death of individual yeast cells and denaturing of the enzymes. Accordingly, at the end of the ethanol production process, Strain M24926 will be completely inactivated.

The Committee deliberated upon utility of the trehalase enzyme in the bioethanol production process and periodic metagenomic studies conducted at the end of the ethanol production process after the yeast strain is inactivated.

Recommendation:

After deliberations, the proposal of M/s Aaditya Finechem Pvt. Ltd., Jaipur for import of 200 metric ton (200, 000 Kgs) of *Saccharomyces cerevisiae* strain M24926 (Brand Name: Fermboost), per annum, from Brazil and its marketing for ethanol production was recommended by the Committee subject to the following conditions:

- i. The applicant shall provide additional information with regard to metagenomic studies, if any conducted in the countries where the *S. cerevisiae* M24926 strain is commercially approved, in order to evaluate recurrence of genetic material from the effluent/ solid waste discharged at the end of the production process; and role of trehalase enzyme in biofuel production pathway. The information shall be submitted for the consideration of the GEAC prior to import of *Saccharomyces cerevisiae* strain M24926.
- ii. The applicant shall ensure strict compliance of zero discharge of viable *Saccharomyces cerevisiae* strain M24926 into the environment at any stage including import, transport, storage, handling, management etc.
- iii. The firms, whomsoever using the imported genetically modified *Saccharomyces cerevisiae* strain M24926 has to obtain separate approval from GEAC for large scale manufacturing in accordance with Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017.

- iv. The applicant shall ensure that the firms, whomsoever using the *Saccharomyces cerevisiae* strain M24926 for commercial production of ethanol, undertake metagenomics studies in order to evaluate recurrence of genetic material from the effluent/ solid waste discharged at the end of the production process.

Action: GEAC Secretariat

6.2 M/s Buttar Biofuels Private Limited, Chandigarh for import of genetically modified *Saccharomyces cerevisiae* strain M24926 for ethanol production.

The applicant made a presentation before the Committee and informed that M/s Buttar Biofuels Private Limited, Chandigarh intends to import *Saccharomyces cerevisiae* strain M24926 (Brand Name: Fermboost) for commercial production of ethanol. The *S. cerevisiae* strain M24926 has been genetically modified to introduce genes encoding for glucoamylase and trehalase enzymes, enabling efficient ethanol production. The applicant intends to import up to 60 MT of *S. cerevisiae* strain M24926 per annum from Brazil.

The applicant informed that they will be utilizing the *S. cerevisiae* strain M24926, imported in India by M/s Aaditya Finechem Pvt. Ltd., Jaipur for the first time as per Agenda Item 6.1 of this meeting above, for the commercial production of ethanol at their biofuel plant. M/s Buttar Biofuels Private Limited, Chandigarh is the end user of *S. cerevisiae* strain M24926 while M/s Aaditya Finechem Pvt. Ltd., Jaipur will be the PAN India supplier of the *S. cerevisiae* strain M24926.

Recommendation:

After deliberations, the Committee directed the applicant to submit Environmental Risk Management and Safety Plan (ERMP), on site/ off site plan emergency plan, waste management plan with regard to commercial production of ethanol using *S. cerevisiae* strain M24926. Further, the applicant shall also submit details of Institutional BioSafety Committee (IBSC) and regulatory approvals, if any, obtained from IBSC, in accordance with Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells Rules 1989.

Action: GEAC Secretariat

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

7.1 M/s Ceva Polchem Pvt. Ltd., Pune for import and distribution of recombinant vaccine VECTORMUNE FP LT for veterinary use.

The applicant made a presentation before the Committee and informed that M/s Ceva Polchem Pvt. Ltd., Pune intends to import and distribute recombinant veterinary vaccine, namely, Vectormune FP LT (Generic Name: Fowl Pox-Laryngotracheitis Vaccine, Live Fowl Pox Vector, Freeze-dried) for use in chickens. The applicant intends to import around 20,000 vials of this veterinary vaccine, per annum, manufactured by M/s Ceva Animal Health LLC, (M/S Biomune Co) Lenexa US.

It was informed that in Vectormune® FP, LT Live freeze-dried vaccine, the Fowl Pox virus (FPV) has been genetically modified to express key protective Infectious Laryngotracheitis (ILT) virus antigens. The recombinant FPV Cutter strain expresses protective antigens of ILT virus strains 632 and NS175, thereby enabling the active immunization of chickens against fowl pox virus and laryngotracheitis. The vaccine is recommended for use through subcutaneous or in ovo route in healthy one week old chicks or older or in 18 to 19 day-old embryonated chicken eggs followed by a boost vaccination at 7 days of age as an aid in the prevention of fowl pox and laryngotracheitis.

The Committee deliberated upon the requirement of metagenomic analysis of the subject vaccine to verify purity of the target event/organisms and to check the presence of non-target event/organisms. Representative of ICAR-Indian Veterinary Research Institute (ICAR-IVRI) nominated by Director, IVRI who is a Member of GEAC informed that IVRI performs only efficacy tests of the veterinary vaccine and not their metagenomic analysis. Dr. Chaitanya Joshi, Director, Gujarat Biotechnology Research Centre (GBRC) who is also Member of the Committee informed that GBRC has the facility to perform metagenomic analysis of the vaccine.

Recommendation:

The committee recommended the proposal of M/s Ceva Polchem Private Limited, Pune for import of Vectormune FP LT (Generic Name: Fowl Pox-Laryngotracheitis Vaccine, Live Fowl Pox Vector, Freeze-dried) for veterinary use subject to the following conditions:

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

Action: GEAC Secretariat

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

The Committee was informed that the proposal of M/s Virbac Animal Health India Pvt. Ltd., Mumbai for import and marketing of Himmvac Dalguban BBN Plus Live Vaccine [Generic Name: Combined Newcastle Disease (KBNP-C4152R2L) & Avian Infectious Bronchitis (M41 Strain and & KM91 Strain), Inactivated Oil Vaccine] for veterinary use was initially considered in the 144th meeting of GEAC held on 22.02.2022 under Agenda Item 5.12, 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/Virbac/2022-23 dated 08.02.2023; the NOC received from Department of Animal Husbandry and Dairying vide Letter No. K-11057/47/2021-LH-Part I dated 22.03.2023; permission in Form 45 under Drugs and Cosmetics Act obtained from Drugs Controller General (India) vide Letter No. 12-38/Virbac/2021/VD dated 05.05.2022.

The Committee deliberated upon the requirement of metagenomic analysis of the subject vaccine to verify purity of the target event/organisms and to check the presence of non-target event/organisms. Representative of ICAR-Indian Veterinary Research Institute (ICAR-IVRI) nominated by Director, IVRI who is a Member of GEAC informed that IVRI performs only efficacy tests of the veterinary vaccine and not their metagenomic analysis. Dr. Chaitanya Joshi, Director, Gujarat Biotechnology Research Centre (GBRC) who is also Member of the Committee informed that GBRC has the facility to perform metagenomic analysis of the vaccine.

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 it is marketed in the country

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

Action: GEAC Secretariat

Agenda Item No. 8: Additional Items for consideration

8.1 Discussion on regulation of Genetically Modified foods in India.

The Committee was informed that, in its 134th meeting held on 21.03.2018, it deliberated on the applications related to import of GM Soyabean grain and crude/processed/partially processed oil derived from Genetically Modified (GM) Soybean /Canola under Agenda Item 6.1-6.9 wherein the following recommendation was made “i) Applications for import of oil may be transferred to FSSAI; ii) For considering proposals for bulk import of GM grains for processing, these may be forwarded to RCGM for preparing RARM to be considered by a Subcommittee of GEAC, before it is considered by the committee; iii) FSSAI may expedite putting in place requisite guidelines and policy on labelling at the earliest.”

In accordance with the abovementioned GEAC recommendation, the approval of GEAC from environmental safety angle is required for processing of all GM grains/seeds. This decision was taken in pursuance of the Hon'ble Supreme Court order dated 11.08.2017 in matters related to Writ Petition No. 173/2006 and Writ Petition No. 11/2008, directing the Food Safety and Standards Authority of India (FSSAI) for framing of relevant guidelines and regulations in connection with genetically engineered and modified food under Section 22 of FSS Act, 2006, and placing it for consideration by the Parliament.

However, the framing of relevant guidelines and regulations in connection to GM Food are still pending. Meanwhile, the Committee was informed, that Food Safety and Standards Authority of India (FSSAI) vide its Order No. 1-1764/ FSSAI/ Imports/ 2018(Part-1) dated 21.08.2020 took a decision that every consignment of imported food products listed in its Annexure-I shall be accompanied with a Non-GM origin cum GM free certificate issued by Competent National Authority of the exporting country. Further, FSSAI vide its Order No. 1-1764/ FSSAI/ Imports/ 2018(Part-1) dated 12.10.2020 clarified that the said order is applicable only to food crops listed in its Annexure-I and not to processed food products in general. Subsequently, FSSAI vide its Order No. 1764/ FSSAI/ Imports/2019 (Part-1) dated 08.02.2021 stated that the tolerance limit for adventitious presence (AP) of GMOs at 1% is permissible in imported food crop consignments as listed in Annexure-I of the order dated 21.08.2020.

Recommendation:

- i. The Committee noted the permissible tolerance limit for adventitious presence (AP) of GMOs at 1% in the imported food crop consignment as stated by FSSAI vide Order No. 1764/ FSSAI/ Imports/ 2019 (Part-1) dated 08.02.2021.
- ii. Taking cognizance of aforementioned FSSAI order dated 08.02.2021, in all such instances of import of food crops with permissible adventitious presence of 1 % GMOs the Committee further suggested that the FSSAI may also consider that the GMOs which are adventitiously present in the imported food crop consignments that can also be used as seeds or other plant propagating material (cultivation), contain or are derived from, gene event(s) which are approved for use by a Competent National Regulatory Authority.

- iii. Further, the Committee reiterated the decision taken in 134th GEAC meeting held on 21.03.2018 that for considering proposals for bulk import of GM grains for processing, approval of GEAC is required prior to final approval of FSSAI in this regard. Such proposals may be forwarded to RCGM for preparing RARM to be considered by a Sub-committee of GEAC, before it is considered by the GEAC itself.

Action: GEAC Secretariat

8.2 Indian Council of Agricultural Research (ICAR), New Delhi submitted proposal for establishing identified institutes as Notified Field Trial Sites (NFTS).

The Committee was informed that the 'Proposal for Establishment of Notified Field Trial Sites (NFTS) to conduct Confined Field Trials of GE Crops' submitted by DBT was recommended by the GEAC in its 140th meeting held on 28.07.2020 under Agenda Item 7.2 subject to the following conditions:

- i. *"The committee noted the proposal shared by Department of Biotechnology on the Notified Field Trial Sites and suggested that a one-time approval for 5 years may be sought from the respective State Governments.*
- ii. *ICAR is the premier National Institute for agricultural research, including research involving genetic engineering technologies. The purpose of GE technologies in agricultural research is to ensure food security by developing plants with desirable traits such as tolerance to drought/flood/salinity/pests/weeds; higher yield etc. Hence, a scheme for setting up NFTS may be formulated and SFC/EFC approval may be sought by the Department of Biotechnology and/or Ministry of Agriculture and Farmers' welfare.*
- iii. *The committee suggested the Department of Biotechnology to include ground water quality assessment component in the proposal of establishing NFTS."*

In 146th GEAC Meeting held on 25.08.2022 a decision was taken under Agenda Item No. 7.4 that if the proposed confined field trial site is a Notified Field Trial Site (NFTS) as per GEAC approved proposal for establishment of NFTS for conducting confined field trials of GE Crops in its 140th meeting held on 28.07.2020, then in such instances, the proposals for confined field trials will be considered by GEAC without taking any views/comments from the State/UT Government(s).

Indian Council of Agricultural Research has informed that a committee has been constituted by them under the Chairmanship of Dr. B. S. Dhillon, Vice Chancellor, Punjab Agriculture University to define the modalities of implementation of proposal as submitted by DBT and recommended by GEAC for Establishment of National Network on Notified Field Trial Sites (NNNFTS) for Biotechnology Research and Development. This Committee constituted by ICAR has identified 42 Institutions (ICAR Institutes and State Agricultural Universities) across different agro-climatic zones for establishment and operation of NFTS for testing the genetic engineered events. The ICAR has submitted the proposal to the GEAC for recommendation of the 42 Institutes to be designated as NFTS to enable ICAR/DBT for further process of inviting

expression of interest for conduct the trials and find out the modalities to get these sites exempted from seeking views/ comments from the states.

The Committee was informed that as per the proposal noted by GEAC in its 140th meeting, approval & monitoring mechanism for NFTS is as below:

- i. RCGM/ GEAC shall constitute an Expert Committee for assessing suitability of proposed site.
- ii. The constituted Committee shall inspect the proposed site and submit the report to State Agriculture Department and RCGM/ GEAC.
- iii. Expert Committee to approve NFTS and recommend financial support for establishing each NFTS, based on site visit.
- iv. Composition of this Expert Committee will be:
 - a. Chairman (a senior expert in plant Breeding and Genetics familiar with the requirements of conducting CFTs of GE crops)
 - b. Nominee of GEAC
 - c. Nominee of RCGM
 - d. Nominee of ICAR
 - e. Nominee of Ministry of Agriculture
 - f. Nominees from state departments of agriculture (from respective states, the applications for establish/ certification of CFTs are under consideration)
 - g. Three subject specific experts

Recommendation:

The Committee noted the institute sites proposed to be designated as Notified Field Trial Sites (NFTS) by ICAR.

In cognizance of the decision taken in 140th GEAC Meeting held on 28.07.2020 with regard to proposal of DBT for establishment of Notified Field Trial Sites (NFTSs) to conduct confined field trials of GE Crops, the Committee 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 aforementioned proposal. Further, 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 recommended in 140th GEAC meeting.

The Committee was of the view that after fulfilling all the requirements for designating the sites approved by the above-mentioned Expert Committee as NFTSs in accordance with the proposal of establishment of NFTSs recommended in 140th GEAC Meeting, the GEAC shall give final recommendation regarding notification of these NFTSs.

Action: GEAC & RCGM Secretariat

Agenda Item No. 9: Information Items

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

RCGM, in its 224th meeting held on 20.01.2022, recommended 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 for resistance against Pink Bollworm during Kharif season at five trial locations, namely, Janwada, Jalna, Akola, Junagadh, and Hisar located in four states (Telangana, Maharashtra, Gujarat, and Haryana) to GEAC vide Letter No. BT/IBKP/068/2020 dated 08.02.2022.

Based on the comments received by Government of Haryana, vide Memo No. 721/ADO (Seed) dated 17.11.2022, the GEAC in its 148th meeting held on 31.01.2023 granted permission to conduct the proposed trials at Hisar, Haryana whereas the proposal for conduct of trials at remaining four locations, namely, Janwada, Jalna, Akola, Junagadh (located in Gujarat, Telangana, and Maharashtra) will be deliberated upon in the 149th GEAC Meeting under Agenda Item No. 4.1.

Further, it is to inform that RCGM vide its email dated 22.03.2023 forwarded its recommendation of 244th meeting held on 02.11.2022 for inclusion of following five additional locations, thereby making it a total of 10 locations, for conduct of BRL-I 1st year trial of GE cotton hybrids containing Event 18L-5-3 expressing cry2Ai gene by M/s. Bioseed Research India, Hyderabad:

- i. Madhya Pradesh- College of Agriculture Khandwa, Rajmata Vijayraje Scindia Krishi Vishwavidyalaya (RVRKVV), Gwalior- 474002.
- ii. Telangana- Professor Jayshankar Telangana State Agriculture University, Hyderabad- 500030.
- iii. Haryana- CCS Haryana Agriculture University, Hisar- 125004.
- iv. Punjab- Regional Research Station, Punjab Agricultural University, Bhatinda- 151005.
- v. Rajasthan- Agriculture Research Station, S. K. Rajasthan Agriculture University, Sriganganagar/ Bikaner- 334006.

Taking cognizance of decision taken in 146th GEAC meeting regarding requirement of views/ comments from the concerned State Government(s), OM dated 03.05.2023 has been sent by the GEAC Secretariat to the concerned States wherein additional trial sites are located, namely, Madhya Pradesh, Haryana, Punjab, Rajasthan and Telangana requesting them to communicate their views/comments within 60 days.

9.2 ICAR-National Institute for Plant Biotechnology, New Delhi to conduct Event Selection Trials of ten transgenic pigeon pea lines expressing Cry2Aa/ Cry1AcF genes.

RCGM in its 199th meeting held on 04.02.2021, recommended the proposal of ICAR-National Institute for Plant Biotechnology, New Delhi to conduct Event Selection Trials of ten transgenic pigeon pea lines expressing Cry2Aa/ Cry1AcF genes at IARI, New Delhi.

Based on the recommendation of RCGM and No Objection Certificate (NOC) granted for conducting Event Selection Trials at IARI, New Delhi by the Government NCT of Delhi vide Letter No. F(1)/NOC of GE/JDA/2021-22/1482 dated 22.07.2022; the GEAC in its 146th meeting held on 25.08.2022 granted permission to conduct trials during cropping season July, 2022 to April, 2023 and requested RCGM to issue the permit letters and monitor confined field trials to ensure compliance of prescribed terms and conditions. Accordingly, RCGM Secretariat issued the permit letter on 31.10.2022 stating that the permit is valid for the appropriate season 2022-23 only. Since pigeon pea is a Kharif crop (growing season June-April) and the permit letter was issued in October 2022, the trials could not be conducted for the growing season 2022-2023. RCGM Secretariat vide email dated 16.02.2023 forwarded the request of the applicant to grant an extension for conducting event selection trial in the upcoming season i.e., June 2023 - April 2024.

Accordingly, the GEAC Secretariat, vide OM dated 17.04.2023 has requested RCGM Secretariat to issue the permit for conduct of Event Selection Trials for the growing season June 2023 - April 2024 while all other remarks/ stipulated conditions in 146th GEAC decision remains the same.

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

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	10. Dr. Satish Wate Former Director CSIR-National Environmental Engineering Research Institute Nagpur- 440020
2. Dr. Sanjay Kumar Mishra Scientist H, Department of Biotechnology, Block 2 CGO Complex, Lodhi Road New Delhi - 110 003	11. Shri V.P. Yadav Scientist F Central Pollution Control Board Parivesh Bhawan, East Arjun Nagar, Delhi-110 032
3. Dr. Satyendra Kumar Director, CS-III Division Ministry of Environment, Forest and Climate Change, Jorbagh, New Delhi-110003	12. 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	13. 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 Professor, GNR Protein Centre, CSIR-Institute of Microbial Technology (CSIR-IMTECH), Sector 39-A, Chandigarh-160036	14. Dr. H. K. Sharma Director, National Institute of Technology, Agartala, Tripura- 799 046
6. Dr. S. J. Rahman, Principal Scientist & Univ. Head of Entomology, Prof. Jayashankar Telangana State Agri. University, Hyderabad-500 030	15. Dr. Sanjeev Khosla Director, CSIR-Institute of Microbial Technology, Chandigarh- 160 036
7. Dr. C. Madhan Mohan and Dr. Pronab Dhar Principal Scientist, ICAR-Indian Veterinary Research Institute (IVRI), Bareilly, Uttar Pradesh- 243122 (Representative of Dr. Triveni Dutt, Director, IVRI	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)
8.	Dr. J.P. Singh Plant Protection Adviser (PPA), Directorate of Plant Protection, Quarantine & Storage, NH IV, Faridabad-121001. New Delhi	17.	Dr. U. S. N. Murthy Director, National Institute of Pharmaceutical Education and Research, Guwahati- 781 101
9.	Dr. Rekha S. Singhal Professor, Food Technology, Institute of Chemical Technology, Mumbai- 400 019	18.	Shri Sunil Kumar Bakshi Head, Regulation, Food Safety and Standards Authority of India, FDA Bhawan, Kotla, New Delhi - 110002
Members who did not participate			
1.	Dr. P. Suprasanna Scientific Officer H (Retd.) Biosciences group BARC, Mumbai-400085	5.	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	6.	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	7.	Dr. Nitin K. Jain Scientist-F and Member Secretary RCGM, Department of Biotechnology, C. G. O, Complex, Lodhi Road, New Delhi-110003
4.	Dr. Geeta Jotwani Scientist G Indian Council of Medical Research (ICMR) Ministry of Health and Family Welfare Ramalingaswami Bhavan, Ansari Nagar, New Delhi—110029		
Special Invitee			
1.	Sri Hanumant K Zendage IAS Special commissioner of Agriculture, Government of Telangana		

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		
-----------	---	--	--