MINUTES OF THE 150th MEETING OF THE GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 10.08.2023

The 150th meeting of the Genetic Engineering Appraisal Committee (GEAC) of the Ministry of Environment, Forest and Climate Change (MoEF&CC) was held on 10.08.2023 in hybrid mode at Teesta Conference Hall, First Floor, Vayu 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

Six members communicated their inability to attend the 150th meeting of GEAC, namely Dr. Satish Wate, Dr. Rekha Singhal, Dr. Nitin K. Jain, Dr. P. Suprasanna, Dr. Vinay K. Nandicoori and Dr. Sunil Bakshi. Further, Dr. U.S.N. Murthy, Ms. Shruti Singh, Dr. Dinkar M. Salunkhe, Dr. J.P. Shukla, Dr. Chaitanya Joshi, Dr. H. K. Sharma, 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 149th GEAC meeting

Minutes of the 149th 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 final comments, if any. The Committee was also informed that the trade name of veterinary vaccine considered for import and marketing under Agenda Item 7.2 of 149th GEAC meeting has been inadvertently mentioned as “Himmvac Dalguban BBN Plus Live Vaccine” in the minutes of 149th meeting. The brand name “Himmvac Dalguban BBN Plus Live Vaccine”, wherever mentioned under Agenda Item 7.2 in the minutes of 149th meeting, is to be read as “Himmvac Dalguban BBN Plus Oil Vaccine”. Members were further requested to confirm the minutes.

Decision:
Members noted the amendment in the minutes and confirmed the minutes of the 149th GEAC meeting.

Action: GEAC Secretariat

Agenda Item No. 3: Action taken report on the decision taken in the 149th GEAC meeting

Member Secretary, GEAC briefed about the action taken on the decisions at the 149th meeting of GEAC. He informed that letters communicating GEAC decisions had been issued to applicants, concerned States and Ministries/ Departments, 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 Nath Bio-Genes (India) Limited, Aurangabad for Event Selection Trial of fourteen GE cotton lines expressing *cry1Ac-II* and *cry1Fa1* genes.

The Committee was informed that M/s Nath Bio-Genes (India) Limited, Aurangabad intends to conduct Event Selection Trial (under confined conditions) of fourteen GE cotton lines expressing cry1Ac-II and cry1Fa1 genes conferring insect resistance during Kharif season. The fourteen GE cotton lines that will be subjected to the proposed trials are expressing events 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. Of these events, six are independent events while eight (NBIL-CS-1, NBIL-CS-2, NBIL-CS-3, NBIL-CS-4, NBIL-CS-5, NBILCS-6, NBIL-CS-7, NBIL-CS-8) are stacked events.

The trial is proposed to be conducted at the applicant's own R&D farm situated in Isarwadi, Aurangabad, Maharashtra. The primary objective of the proposed trial is to select Bt-transgenic events/stacks among fourteen new events/stacks that encode *Cry1Ac* and *Cry1Fa1* under various regulatory elements that offer enhanced tolerance to the damages inflicted by American Bollworm (*Helicoverpa armigera*), Pink Bollworm (*Pectinophora gossypiella*) and Spotted Bollworm (*Earias vittella*).

This application was recommended by the Review Committee on Genetic Manipulation (RCGM) in its 260th meeting held on 14.06.2023 vide their Letter No. BT/IBKP/521/2021 dated 21.06.2023.

The applicant informed the Committee that they propose to conduct the trials during Kharif 2023 cropping season itself.

Recommendation:

Based on the recommendations of RCGM, the proposal of M/s Nath Bio-Genes (India) Limited, Aurangabad to conduct Event Selection Trial (under confined conditions) of fourteen GE cotton lines (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, NBILC-1155, NBIL-C-1160, NBIL-C-1249, NBIL-C-1316) expressing *cry1Ac-II* and *cry1Fa1* genes conferring insect resistance during Kharif 2023 cropping season 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/521/2021 dated 21.06.2023. 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

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

The Committee was informed that the proposal of M/s Ajeet Seeds Pvt. Ltd., Aurangabad to conduct Event Selection Trial for four Bt brinjal events (ASPL-101, ASPL-103, ASPL-104 and ASPL-110) expressing *cry1Ac* gene (AJTCry1ac/pASPL818) conferring resistance against Lepidopteran was recommended in 149th GEAC Meeting held on 17.05.2023 under Agenda Item 4.2 for conduct of trials during Kharif 2023 cropping season at applicant's farm (Gut No. 74) at Hanumantgaon, Post: Solegaon, Tq. Gangapur, Dist: Aurangabad-431133.

Subsequently, the applicant requested that the aforementioned trials be also conducted at an additional site, viz., ICAR-Indian Agricultural Research Institute (IARI), New Delhi. This request of applicant to add a trial site was recommended by RCGM in its 259th meeting held on 31.05.2023 vide their Letter No. BT/IBKP/040/2019 dated 15.06.2023.

The applicant vide email dated 08.08.2023 has informed that the application for conduct of trials at additional site stands withdrawn for 2023 cropping season given that trial is in progress at trial site located in Maharashtra and the Kharif plantation season for the current year has passed.

Recommendation:

Committee considered the request of the applicant.

4.3 M/s Rubber Research Institute of India, Kottayam for Event Selection Trials of two GE rubber lines expressing *osmotin* gene.

The Committee was informed that the proposal of M/s Rubber Research Institute of India, Kottayam to conduct Event Selection Trials for two GE rubber (*Hevea brasiliensis*) lines, Os1 and Os2, expressing *osmotin* gene derived from tobacco to confer Biotic /abiotic stress tolerance was initially recommended in 147th meeting of GEAC held on 18.10.2022 under Agenda Item 5.9 for conduct of trials during cropping season 2023-2038 (15 years) at Sarutari Research farm, RRS, Guwahati.

Subsequently, applicant has requested that the trial location be changed from Sarutari Research farm, RRS, Guwahati to Taranagar Research Farm, Regional Research Station, Agartala, Tripura. The applicant has also received concurrence from Government of Tripura for the conduct of these trials vide their Letter No. F.15-210/TW/SP/CM's/RM/2021(Part)/76463-66 dated 04.02.2023. This request of applicant to change the trial site was recommended by RCGM in its 259th meeting held on 31.05.2023 vide their Letter No. BT/IBKP/533/2021 dated 15.06.2023.

The applicant informed that they propose to conduct the trials during cropping season 2024 -2039 (15 years) cropping season.

Recommendation:

Based on the recommendations of RCGM, the proposal of M/s Rubber Research Institute of India, Kottayam to change the trial site from Sarutari Research farm, RRS, Guwahati to Taranagar Research Farm, Regional Research Station, Agartala, Tripura for conduct of Event Selection Trials (under confined conditions) of two GE rubber lines, Os1 and Os2, expressing *osmotin* gene to confer biotic /abiotic stress tolerance for 15 years during cropping season 2024 - 2039 (15 years) was recommended by the Committee subject to the same conditions/ recommendations as stipulated by GEAC in its 147th meeting. Further, it was recommended that the applicant shall perform the trials as per extant rules/guidelines/regulations; and will adhere with the recommendations of RCGM vide its Letter No. BT/IBKP/533/2021 dated 15.06.2023 and that of Government of Tripura vide its Letter No. F.15-210/ TW/ SP/ CM's/ RM/ 2021(Part)/76463-66 dated 04.02.2023.

RCGM may issue the permit letter and monitor confined field trials to ensure compliance of prescribed terms and conditions.

Action: GEAC & RCGM Secretariat

4.4 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 has been considered under Agenda Item 4.1 in 148th and 149th meetings of GEAC, held on 31.01.2023 and 17.05.2023, respectively. Further, the Member Secretary informed the Committee about the chronology with regard to the consideration of the proposal.

The proposal was recommended by RCGM in its 224th meeting held on 20.01.2022 for conduct of trials at below mentioned five locations vide their Letter No. BT/IBKP/068/2020 dated 08.02.2022:

i. Haryana (Barwala-Hisar): Research Station, M/s. Bioseed Research India, Village – Panghal, Barwala-Hansi Road, Hisar – 124121, Haryana (owned by the applicant's organization).

ii. Gujarat (Junagadh): Junagadh Agricultural University, Junagadh – 362001, Gujarat.
iii. Telangana (Janwada): Bioseed Research India, Plot No. 234, B Block, Kavuri Hills, Phase II, Hyderabad – 500033, Telangana (owned by the applicant's organization).
iv. Maharashtra (Akola): Dr Panjabrao Deshmukh Krishi Vidyapeeth, Akola – 444104, Maharashtra.
v. Maharashtra (Jalna): Bioseed Research India, Plot No. 12, C-4, N-1, CIDCO, Aurangabad – 401301, Maharashtra (owned by the applicant's organization).

Taking cognizance of the decision taken in the 146th GEAC meeting regarding concurrence to be obtained from the concerned State Government(s), OM dated 12.10.2022 was sent to the four concerned States, namely, Telangana, Maharashtra, Gujarat, and Haryana, requesting them to communicate their views/comments within 60 days. The applicant obtained concurrence to conduct BRL-I trials from the Government of Haryana, vide Memo No. 721/ADO (Seed) dated 17.11.2022. The concerned States were also invited for the 148th meeting of GEAC for consideration of the proposal. Among the four States, only the representative of Government of Telangana attended the 148th GEAC meeting and sought additional time to arrive at some consensus decision with regard to grant of NOC for the proposal. Accordingly, GEAC in its 148th meeting recommended the proposal for conduct of trial at Hisar, Haryana site while also decided to give additional time of 30 days to the three States namely, Telangana, Gujarat, and Maharashtra to communicate their views/comments. The recommendations of the 148th GEAC Meeting were communicated to the concerned States vide OM dated 23.02.2023. Subsequently, all the four concerned States were invited for the 149th GEAC meeting vide OM dated 03.05.2023 however, only representative from Government of Telangana attended the meeting.

The proposal was considered in the 149th meeting wherein the Committee was informed that:

i. Government of Telangana vide Letter dated 16.05.2023 has stated that they've decided not to take up the trial during 2023-24 cropping season.
ii. Government of Gujarat vide Letter dated 06.03.20323 communicated that the proposal is not found acceptable by them without citing any reason.
iii. No comments have been received from Government of Maharashtra yet.

Taking cognizance of the response of the concerned State Governments, the GEAC in its 149th meeting 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 recommendations of 149th GEAC meeting were communicated to the concerned States vide D.O. Letter dated 08.06.2023. Further, all the four concerned States have been invited to attend the 150th GEAC Meeting vide OM dated 04.08.2023.

Shri Anoop Kumar, Additional Chief Secretary, Agriculture and Shri Vaibhav Shinde from Government of Maharashtra attended the 150th GEAC meeting in virtual mode and informed the Committee that the proposal is under consideration and told the Committee that the views of the Government of Maharashtra with regard to the proposed trials will be communicated within fifteen days.

Further, the Committee was informed that Shri M. Raghunandan Rao, APC & Secretary to Government, Agriculture & Co-operation Department, Government of Telangana has sought leave of absence for 150th GEAC meeting vide their D.O No.2807/Agri.III/A1/2022 dated 09.08.2023. In respect of recommendations of 149th GEAC meeting, no response have been received from Governments of Telangana and Gujarat.

Recommendation:

In respect of Governments of Telangana and Gujarat, the Committee recommended that:

i. Government of Telangana be requested to cite the reason for not taking up the trials for the 2023-24 cropping season within thirty days. In case no response is received from them within the stipulated time, it will be considered that no comments/ views are to be put forth by the State Government in this regard and appropriate recommendation may accordingly be made by the Committee.
ii. Government of Gujarat be requested to cite the reason for not finding the proposal acceptable within thirty days. In case no response is received from them within the stipulated time, it will be considered that no comments/ views are to be put forth by the State Government in this regard and appropriate recommendation may accordingly be made by the Committee.

Further, the Committee was of the view that a separate meeting; under the Chairpersonship of Chairman, GEAC; be convened with the concerned State/UT Government(s) in order to understand non-communication of the response.

Action: GEAC Secretariat

4.5 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 Committee was informed that the proposal of M/s Rallis India Limited, Karnataka to conduct BRL-I trials (1st Year and 2nd Year) with two GE cotton breeding stacks (MLS2154 x MLS4301x MLS2531 and MLS2154 x MLS4301) was recommended by GEAC in its 145th meeting held on 27.07.2022 under Agenda Item 4.1 for conduct of trials during Kharif 2022-23 and 2023-24 cropping season at two locations amongst the proposed sites, namely, University of Agricultural Sciences, Dharwad, Karnataka; University of Agricultural Sciences, Raichur, Karnataka; and Chaudhary Charan Singh Haryana Agricultural University, Hisar, Haryana per year.

The applicant made a presentation before the Committee and informed that the trials were not conducted for the 2022-23 cropping season. It was further informed that for the Kharif 2023-24 cropping season, they propose to conduct trials with a new GE cotton breeding stack viz. MLS4301 X MLS2531 (*cry1F* X synthetic *EPSPS*) instead of two GE cotton breeding stacks, MLS2154 x MLS4301 x MLS2531 and MLS2154 x MLS4301, that were earlier recommended by both RCGM and GEAC since other deregulated gene events expressing Cry1Ac gene are already available in the market.

It was informed that the request of 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 for conducting BRL-1 trials (1st Year and 2nd Year) was considered by RCGM in its 261st meeting held on 28.06.2023 wherein the following was recommended:

i. *"In case, the applicant intends to develop stacked GE cotton line(s) containing one or more deregulated event(s) in future, all biosafety studies pertaining to a stacked line containing unapproved events will be applicable.*
ii. *Location of trial sites to conduct confined field trials needs to be distinct agroecological regions to represent the range of environmental conditions under which the plant varieties would be expected to be grown. Therefore, the two confined field trial locations which are around 5 km apart will not be considered as two different trial locations."*

Recommendation:

Taking into consideration the recommendations made by RCGM in its 261st meeting held on 28.06.2023 with regard to the proposal of 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 Committee was of the view that the RCGM be requested to further clarify the aforementioned recommendations

made by them with regard to the new proposed GE cotton breeding stack MLS4301 x MLS2531.

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 IQVIA RDS (India) Private Limited, Bangalore for Phase 3 clinical trial to investigate the safety and immunogenicity of a dengue tetravalent vaccine (live, attenuated) (TDV) administered subcutaneously to healthy subjects aged 4 to 60 years in India.

The Committee was informed that the proposal of M/s IQVIA RDS (India) Private Limited, Bangalore for conduct of a Randomized, Double-Blind, Placebo Controlled, Phase 3 Clinical Trial in order to investigate the safety and immunogenicity of Takeda's Dengue Tetravalent Vaccine (Live, attenuated) (TDV) was considered in 148th meeting of GEAC held on 31.01.2023 wherein the Committee recommended that the proposal be forwarded to RCGM for scrutiny. Further, it was recommended that the Drugs Controller General of India, Central Drugs Standard Control Organization (CDSCO) be also requested to share their comments in regard to processing of the proposal.

The applicant made a presentation before the Committee and informed that in accordance with the recommendations of 148th GEAC Meeting, the proposal was considered by RCGM in its 255th meeting held on 05.04.2023 under Agenda Item 5.3.1 wherein RCGM recommended that "*the RCGM Secretariat to communicate the summary document of the RCGM observations on the Biosafety related aspects of the Takeda- DEN-302 vaccine candidate to the GEAC, on the application for environmental approval of clinical trials for Takeda – DEN 302 submitted by M/s IQVIA RDS Pvt. Ltd., Bangalore for GEAC clearance to conduct the clinical trial in India*". As per this summary document provided by RCGM Secretariat, it is concluded that based on the attenuation status of the host, consistent genetic stability data of all the four TDVs throughout the cell culture and viral passages in the product development process, amount of process related impurities, testing of adventitious agents at different steps of production, stability data and data of non-clinical evaluations in in-vitro and in mosquitoes, mice, rabbits and nonhuman primates; *no specific safety concerns have been observed*.

The Committee was informed that comments were sought from CDSCO in accordance with the recommendations of 148th GEAC meeting. As per the comments of CDSCO received vide email dated 17.07.2023 it is informed that the application of M/s IQVIA RDS (India) Pvt. Ltd., Bangalore for grant of permission to conduct Phase III clinical trial of Tetravalent Dengue Vaccine (Live, Attenuated) is under review by CDSCO.

Further, the applicant and representative of CDSCO participating in the meeting informed the Committee that the proposal has also been reviewed by Subject Expert

Committee (Vaccince) constituted by CDSCO to review proposals and advice Drugs Controller General (India) in matters for Biologicals. This Subject Expert Committee in its meeting held on 16.05.2023 recommended for grant of permission to M/s IQVIA RDS (India) Private Limited, Bangalore to conduct Phase III clinical trial of Dengue Tetravalent Vaccine (live, attenuated) (DEN-302) after submission of revised Phase III clinical trial protocol removing blood withdrawal at visit 3 (Day 30). The Subject Expert Committee accordingly recommended that the firm should submit revised Phase III clinical trial protocol to CDSCO. The applicant informed that the revised protocol amendment with the recommended changes by Subject Expert Committee have been already submitted to CDSCO on 28.06.2023.

Recommendation:

Based on the comments of CDSCO and recommendations of RCGM, the Committee recommended the proposal of M/s IQVIA RDS (India) Private Limited, Bangalore for conduct of a Randomized, Double-Blind, Placebo Controlled, Phase 3 Clinical Trial in order to investigate the safety and immunogenicity of Takeda's Dengue Tetravalent Vaccine (Live, attenuated) subject to the approval of CDSCO and following conditions:

i. The Phase 3 Clinical Trials shall be conducted in accordance with extant rules/ regulations/ guidelines/ standard operating procedures, as applicable, including Environmental Protection Act 1986, Drugs and Cosmetics Act (1940) and its related schedule Y, chapter, Drugs and Cosmetics Rules (1945); Indian Good Clinical Practice Guideline (2001) and their amendments.
ii. Applicant shall submit all information regarding trials in the formats for clinical trial protocols, informed consent forms, ethics committee (EC) approval templates and a format for serious adverse event (SAE) reporting to this committee in accordance with the Drugs and Cosmetics Act (1940), Drugs and Cosmetics Rules (1945) and its amendments.
iii. The applicant shall submit the details of registered and functional Institutional BioSafety Committee (IBSC) and recommendations obtained from IBSC, in accordance with Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells Rules 1989. The IBSC recommendations should not be older than 12 months.
iv. Applicant shall submit IBSC approved Risk Assessment and Risk Management (RARM) Plan for the storage, transportation, access, handling, packing, re-packing, distribution, administration, sale, decontamination, and disposal of Takeda's Dengue Tetravalent Vaccine (Live, attenuated) before trial.
v. Applicant shall submit IBSC approved Emergency Action Plan for an event of unintentional release of Takeda's Dengue Tetravalent Vaccine (Live, attenuated).
vi. The applicant shall ensure strict compliance of zero discharge of Takeda's Dengue Tetravalent Vaccine (Live, attenuated) into the environment at any stage of its utilization including import, transport, storage, administration, management etc.
vii. Applicant shall ensure that the access to the Takeda's Dengue Tetravalent Vaccine (Live, attenuated) is restricted, only to trained and experienced persons, as recommended by IBSC.

viii. The storage area shall be checked and maintained at regular intervals to avoid unintentional release of Takeda's Dengue Tetravalent Vaccine (Live, attenuated) into the environment and such inspections should be recorded.

ix. In an event of any unintentional release, applicant shall be responsible for the decontamination of the site, utensils, wearables and surroundings etc.

x. In case of any escape, unintentional release, spill, leak, or loss of Takeda's Dengue Tetravalent Vaccine (Live, attenuated), the applicant shall:
   a. Make arrangements to immediately decontaminate with an appropriate decontaminating agent effective against the Takeda's Dengue Tetravalent Vaccine (Live, attenuated);
   b. Report such incident to the IBSC within 03 days, to ensure that the IBSC is notified of the occurrence in case of unintentional release of Takeda's Dengue Tetravalent Vaccine (Live, attenuated).
   c. Take necessary measures to mitigate potential risks to the environment and public health, in case of unintentional release of Takeda's Dengue Tetravalent Vaccine (Live, attenuated).

xi. Applicant shall ensure to periodically train manpower engaged in the GMO handling.

xii. IBSC can visit the site and take sample for monitoring the compliance.

xiii. IBSC may impose other terms and conditions, as and when required, with the information to this committee.

xiv. The recommendation is subject to other statutory clearances, as applicable.

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

Action: GEAC Secretariat

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

6.1 M/s Boehringer Ingelheim India Pvt. Ltd., Mumbai for import of recombinant vaccine Recombitek C8 (Generic Name: Canine Distemper-Adenovirus Type 2- Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Live Canarypox Vector, Leptospira Canicola –Grippotyphosa – Icterohaemorrhagiae – Pomona Bacterin) for veterinary use.

The applicant made a presentation before the Committee and informed that M/s Boehringer Ingelheim India Pvt. Ltd., Mumbai intends to import recombinant vaccine, Recombitek C8, for veterinary use. This product has shown to be effective for the vaccination of healthy dogs 9 weeks of age or older. The freeze-dried component of Recombitek C8 contains Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Live Canarypox Vector. The diluent of Recombitek C8 contains *Leptospira canicola*, *L. grippotyphosa*, *L. icterohaemorrhagiae*, and *L. pomona* bacterin. It was informed that the product is primarily effective against disease caused by Canine distemper virus in dogs.

The applicant intends to import 1,50,000 doses of Recombitek C8 per annum from M/s Boehringer Ingelheim Animal Health USA.

Recommendation:

The committee recommended the proposal of M/s Boehringer Ingelheim India Pvt. Ltd., Mumbai for import 1,50,000 doses per annum of recombinant vaccine Recombitek C8 (Generic Name: Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Live Canarypox Vector, Leptospira Canicola-–Grippotyphosa – Icterohaemorrhagiae – Pomona Bacterin) 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. Applicant to 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.

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

Action: GEAC Secretariat

6.2 M/s Virbac Animal Health India Pvt. Ltd., Mumbai submitting IVRI test reports for import and marketing of recombinant vaccine Himmvac Dalguban N + 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 Ranikhet Disease Vaccine, Inactivated, NDVKBNPC4152R2L Strain (Trade name: Himmvac Dalguban N + Oil vaccine) was initially considered in the 144th meeting of GEAC held on 22.02.2022 under Agenda Item 5.11, wherein this proposal was recommended by the Committee for import only subject to the following conditions that "*i) Initial 3 batches of the subject vaccine to be certified in ICAR-Indian Veterinary Research Institute (ICAR-IVRI) or Chaudhary Charan Singh National Institute of Animal Health (CCSNIAH), Uttar Pradesh (as notified by Ministry of Health and Family Welfare); ii) Obtain relevant approvals from Department of Animal Husbandry and Dairying, Drug Controller General of India etc. as per existing Indian laws applicable for import of vaccines; iii) The final data certified by*

IVRI/ CCSNIAH to be presented before the GEAC for final approval, before it is marketed in the country."

The Committee was informed that the applicant has submitted the ICAR-IVRI certified test batch reports vide Letter No. STD/QC/VT/Virbac/2023-24/89 dated 06.07.2023; the NOC obtained from Department of Animal Husbandry and Dairying vide Letter No. K-11053/47/2021-LH-Part I dated 24.03.2022; permission in Form 45 under Drugs and Cosmetics Act obtained from Drugs Controller General (India) vide Letter No. 12-08/Virbac/2021/VD dated 02.05.2022.

The Committee deliberated upon the requirement of metagenomics analysis of the subject vaccine to verify purity of the target event/organisms and to check the presence of non-target event/organisms. The same was also deliberated in detail in the previous (149th) meeting of GEAC held 17.05.2023.

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

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

The Committee was informed that 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 considered in 149th GEAC Meeting held on 17.05.2023 under Agenda Item 6.1 wherein the Committee recommended this proposal subject to four conditions, one of which was that 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. It was further recommended by the Committee that this information shall be submitted for the consideration of the GEAC prior to import of *S. cerevisiae* strain M24926.

The Committee noted the information submitted by the applicant with regard to the studies demonstrating inactivation of the S. cerevisiae M24926 strain under the specific conditions in the effluent/solid waste discharged at the end of the production process. The applicant has submitted that the results of these studies support the

conclusion that the genetically modified *S. cerevisiae* Strain M24926 is fully inactivated post-fermentation by distillation and other processes in fuel ethanol facilities. The Committee noted the information submitted by the applicant with regard to the role of trehalase enzyme in biofuel production pathway. It was informed that trehalose sugar is generally produced when the yeast experiences stress, however, trehalose sugar cannot be fermented into ethanol. Trehalase enzyme catalyzes the conversion of trehalose (produced during stressful conditions) into glucose which is then fermented into ethanol.

Recommendation:

The Committee noted the additional information submitted by the applicant in accordance with recommendations of 149th GEAC meeting. The Committee recommended 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. The approval is subject to other statutory clearances and Chapter 4 of Regulations and Guidelines on Biosafety of Recombinant DNA Research & Biocontainment 2017, conditions stipulated by GEAC in its 149th meeting under Agenda Item 6.1, and following conditions:

i. Applicant shall ensure that the GMO is used for the intended application as indicated. In case of different use, except as indicated in the application, applicant shall take separate approval from GEAC.
ii. The applicant shall submit the details of registered and functional Institutional BioSafety Committee (IBSC) and recommendations obtained from IBSC, in accordance with Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells Rules 1989. The IBSC recommendations should not be older than 12 months.
iii. Applicant shall submit IBSC approved Risk Assessment and Risk Management (RARM) Plan for the storage, transportation, access, handling, packing, re-packing, distribution, sale, decontamination, and disposal of GMO consignment before import.
iv. Applicant shall submit IBSC approved Emergency Action Plan for an event of unintentional release of GMOs, before import.
v. The Applicant shall submit 16s RNA Gene Sequencing and 18s RNA Gene Sequencing Reports for the Initial five batches to detect any adventitious presence of bacteria and yeast except as indicated.
vi. The applicant shall ensure strict compliance of zero discharge of viable GMO into the environment at any stage including storage, transportation, access, handling, packing, re-packing, distribution, sale, decontamination, and disposal etc.
vii. Applicant shall ensure that the access to the GMOs is restricted, only to trained and experienced persons, as recommended by IBSC. GMOs should be stored securely in the containers in a locked area until transported. This restriction on access applies to all scenarios, including situations where containers containing GMOs are temporarily left for collection in a loading area or are left unattended before undergoing proper decontamination.

viii. Applicant shall ensure that inventory of consignment is maintained and procedures are in place to track and account for all GMOs or the number of primary containers of GMO cultures being transported to detect and prevent any loss of GMOs during transport. This must be implemented for all transport events, except in cases where the GMO transport solely occurs within a building. Annual record should be submitted to IBSC.

ix. The packaging of GMO consignment should be of high quality and robust enough to endure the typical shocks and pressures experienced during transportation, including transfers between different transport units and warehouses, and unpacking from pallets or overpacks for subsequent manual or mechanical handling. The packaging must be designed and sealed in a way that prevents any loss of contents due to vibrations or changes in temperature, humidity, or pressure that may occur under normal transport conditions.

x. The packaging should include three essential components: a) A primary receptacle, b) a secondary packaging, and c) an outer packaging, with either the secondary or outer packaging being rigid. The primary receptacles must be securely placed within the secondary packaging to prevent breakage, puncture, or leakage during regular transportation. The secondary packaging, must be properly secured within the outer packaging using appropriate cushioning material. Even if there is any leakage from the primary receptacles, it should not compromise the integrity of the cushioning material or the outer packaging.

xi. The storage area shall be checked and maintained at regular intervals to avoid unintentional release of GMO into the environment and such inspections should be recorded.

xii. For transport, "GENETICALLY MODIFIED MICROORGANISMS" shall be marked on the outer packaging, clearly visible or be reproduced on the outside of the overpack, in a manner capable of notifying any other handler of the material that the item to be transported is, or contains a GMO. Where transport is being undertaken by a service provider then the outermost container must be labelled to clearly show the name, address and contact details of the sender or its authorized person, so that the sender can be contacted in case of loss, damage or misdirection.

xiii. Applicant shall ensure that the transported GMO shall be accompanied by, instructions on how to decontaminate any material in the event of unintentional release, sufficient volume of effective decontamination agent to decontaminate, appropriate protective clothing for manpower undertaking the decontamination; and supporting instruments necessary to undertake decontamination.

xiv. The transport record shall include, the name of the parent species of the GMO; the genetic modification(s); number of individual containers transported and total amount (volume/weight); expiry date; the mode of transport (e.g. by hand, rail and road, road and air); the name and contact details of the transporter(s) if transport or other service providers are used; the name and contact details of the sender and recipient; date sent.

xv. All containers shall be decontaminated after transport.

xvi. In an event of any unintentional release, applicant shall be responsible for the decontamination of the site, utensils and surroundings etc.

xvii. In case of any escape, unintentional release, spill, leak, or loss of GMOs, including situations where GMOs fail to reach the intended recipient, the applicant shall:

a. promptly initiate efforts to locate and/or retrieve the GMOs and take necessary steps to return them to containment or render them non-viable. The exposed area must be immediately decontaminated with an appropriate decontaminating agent effective against the GMOs;
b. report such incident to the IBSC within 03 days, to ensure that the IBSC is notified of the occurrence in case of unintentional release of GMO.
c. take necessary measures to mitigate potential risks to the environment and public health, in case of unintentional release of GMO.

xviii. Applicant shall ensure to periodically train manpower engaged in the GMO handling.

xix. IBSC can visit the site and take sample for monitoring the compliance.

xx. IBSC may impose other terms and conditions, as and when required, with the information to this committee.

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

Action: GEAC Secretariat

Agenda Item No. 7: Additional Items for consideration

7.1 Report of Post Release Monitoring Committee (PRMC) on Genetically Engineered (GE) mustard hybrid DMH 11 and its parental Lines, developed by Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi South Campus for the growing season 2022-23.

The Committee was informed that the environmental release of GE mustard hybrid DMH -11 and its parental lines bn 3.6 and modbs 2.99 containing *barnase*, *barstar* and *bar* genes developed by CGMCP, University of Delhi was recommended by GEAC in its 147th meeting held on 18.10.2022 subject to 16 conditions as stipulated in the minutes of meeting under Agenda Item No. 4.1. One of the conditions stipulated by GEAC for environmental release of GM mustard was that during the period of approval, a Post Release Monitoring Committee (PRMC) would be constituted by GEAC consisting of 2 subject matter external experts and a nominee each from RCGM and GEAC; and PRMC will visit the growing sites of the approved biological material(s) at least once during each season and submit their report to GEAC on the matters of compliance. Chairperson, GEAC was authorized to constitute the PRMC.

It was informed that the PRMC for GE mustard was constituted with the permission of Chairman, GEAC vide OM dated 10.11.2023 in accordance with the recommendations of 147th meeting of GEAC. As stated in its terms of reference, the

PRMC visited all the GE mustard growing sites for the growing season 2022-23 from 18.02.2023 - 06.03.2023 for post-environmental release monitoring.

Dr. P. K. Chakrabarty, Formerly ADG (Plant Protection & Biosafety), Indian Council of Agricultural Research and Chairman, PRMC made a presentation before the Committee informing about the observations made by PRMC during their visit and recommendations of the PRMC for the growing season 2022-23. The composition of PRMC was informed to be as below:

S. No.	Name	Designation
1.	**Dr. P.K. Chakrabarty** Former Member, ASRB and Assistant Director General (Plant Protection and Biosafety), Indian Council of Agricultural Research	Chairman
2.	**Dr. Neelam S. Sangwan** Professor (Biochemistry), Dean Research & Dean, School of Interdisciplinary and Applied Sciences (SIAS), Central University of Haryana, Mahendragarh, Haryana	Member (Representative RCGM)
3.	**Dr. S.J. Rahman** Professor & Univ. Head of Entomology, Agricultural Research Institute (ARI), Prof. Jayashankar Telangana State Agri. University, Rajendranagar, Hyderabad	Member (Representative GEAC)
4.	**Dr. (Mrs) V. Celia Chalam** Principal Scientist, ICAR- National Bureau of Plant Genetic Resources, New Delhi	Member (Subject Expert)
5.	**Prof. Harish Sharma** Former PI, ICAR-AICRP Honeybees and pollinators and Principal Scientist (Apiculture), Dr YSPUH&F, Solan.	Member (Subject Expert)
6.	**Dr. S. Subramanian** Principal Scientist, Division of Entomology, ICAR-Indian Agricultural Research Institute, New Delhi	Member Convener
Co-Opted Members (Site Specific)		
7.	**Dr. B. Arun** Assistant Professor, Department of Genetics and Plant Breeding, Institute of Agricultural Sciences, Banaras Hindu University, Varanasi	Member co-opted for Varanasi site
8.	**Dr. A.R. Sharma** Director Research, RLBCAU, Jhansi, Uttar Pradesh	Member co-opted for Jhansi site
9.	**Dr. H.P. Meghwal** Asst. Professor and PI, AICRP-HB&P, Agricultural Research Station, Kota, Agricultural University Kota, Ummedganj Kota, Rajasthan.	Member co-opted for Bharatpur site

10.	**Prof. Manjit Kaur Sangha** Professor, Plant Biochemistry and Head of Division, PAU Ludhiana	Member co-opted for Ludhiana site.

It was informed that the ICAR- Directorate of Rapeseed-Mustard Research, Bharatpur obtained seeds of GE mustard hybrid DMH 11 from University of Delhi on 28.10.2022 after the permit letter for environmental release of GE mustard hybrid DMH -11 and its parental lines was issued by GEAC Secretariat on 25.10.2022 upon approval of the Competent Authority. These seeds were distributed to the following six ICAR-AICRP-RM centres for conducting ICAR-AICRP-RM initial hybrid trial (IHT) on hybrid DMH-11:

i. ICAR-Directorate of Rapeseed-Mustard Research (ICAR-DRMR), Bharatpur, Rajasthan.
ii. Rani Lakshmi Bai Central Agricultural University (RLBCAU), Jhansi, Uttar Pradesh.
iii. Institute of Agricultural Sciences (IASc), Banaras Hindu University (BHU), Varanasi, Uttar Pradesh.
iv. Punjab Agricultural University (PAU), Ludhiana, Punjab.
v. Chandra Shekhar Azad University of Agriculture & Technology (CSAUA&T), Kanpur, Uttar Pradesh.
vi. Division of Genetics, ICAR-Indian Agricultural Research Institute (ICAR-IARI), New Delhi.

Each of the above six ICAR-DRMR mandated centres were provided seeds of GE mustard hybrid DMH-11 along with other entries as check (50 g seed of each entry) to each centre in coded form to conduct Initial Hybrid Trial (IHT) for agronomic traits and yield evaluation as per criteria laid down for such trials in proceedings of 29th Annual Group Meeting (AGM) of ICAR-AICRP-RM.

In addition to the ICAR-AICRP-RM IHT trials conducted at above mentioned six centres, field demonstration of DMH-11 was undertaken by ICAR-DRMR at Bharatpur. Further, University of Delhi undertook seed multiplication of the parental lines and hybrid DMH-11 seed production at its farm station at Bawana during the growing season 2022-23.

The PRMC visited all the above mentioned GE mustard growing sites for the growing season 2022-23 from 18.02.2023- 06.03.2023 for post-environmental release monitoring.

As informed by the Chairman, PRMC; key observations of PRMC at the ICAR-AICRPRM sites are summarized as below:

i. Agronomic practices at each site were followed as per ICAR-AICRP-RM recommendations.
ii. The condition of the crop in general at all the six centers of ICAR-AICRP-RM growing sites looked good with a robust crop stand.
iii. There was good seed set across all the entries at all the six locations indicating that there had been good activity of honeybees and pollinators on all the entries including GE mustard hybrid.

iv. Required observations as per the trial design were being recorded at all the sites.

Key observations of PRMC at the field demonstration undertaken at ICAR-DRMR, Bharatpur site are summarized as below:

i. The demonstration plot had a robust crop-stand with profuse pod formation and uniformly filled siliques.
ii. Two boxes of honeybees (Apis mellifera) with 8 frames each were kept at the two ends of the demonstration plot confined within the secure nets in 5x3x3m. The boxes were kept at 10% flowering stage at the centre of each netted area. This was to ensure that honeybees had access to flowers of GE mustard hybrid DMH 11 within the confines of the net.
iii. The honey was harvested from the beehives just before the flowering stage was over.
iv. The robust pod setting and well-filled silique apparently showed that pollination and fertilization of flowers and seed setting remained unaffected.

Key observations of PRMC at the seed multiplication and station trial undertaken at University of Delhi, Farm Station at Bawana are summarized as below:

i. Small scale multiplication of the seed of hybrid DMH-11 and its parental lines Varuna bn 3.6 (MS-A line) and EH-2 modbs 2.99 (RF-R line) was undertaken.
ii. An isolation distance of 50 meters as required for hybrid seed production in mustard was maintained.
iii. A station trial (not part of the ICAR-AICRP-RM trials) on the performance of hybrid DMH-11 and 8 other entries that include both hybrids, the national check variety Kranti and Varuna was laid.
iv. Experimental design of the station trial was as per of the IHT of ICARAICRP-RM. Standard agronomic practices were followed.
v. The crop condition was observed to be good across the entries. All the 9 entries were at pod-setting/seed-filling stage. A normal seed set was observed across all the entries.

Further, the recommendations of PRMC are as below:

i. Systematic trials for honeybees and pollinators as per the protocol approved by ICAR and GEAC could not be laid by ICAR-DRMR, Bharatpur last year due to the limited time available following the approval of permission to lay the field trial of GM mustard hybrid for post-release monitoring purposes by GEAC on 25.10.2022 and further directions not to sow after 03.11.2022. However, the observations on honeybee visits and activities appeared to have remained normal as was evident from the well-developed siliques. The honeybee colony kept under the caged condition stored honey which was harvested by the concerned apiculturist.
ii. For next season onwards, separate trials in the prescribed format by ICARAICRP (Honeybees & Pollinators) as approved by GEAC may be laid out in at least two locations as advised by the GEAC. These trials could be laid out in collaboration with ICAR-AICRP Directorate of Honeybees and Pollinators, New Delhi systematically.

Recommendation:

The Committee noted the observations and recommendations of Post Release Monitoring Committee (PRMC) on Genetically Engineered (GE) mustard hybrid DMH 11 and its parental Lines, developed by Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi South Campus for the growing season 2022-23.

Action: GEAC Secretariat

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

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 has been considered under Agenda Item 4.1 in 148th and 149th meetings of GEAC, held on 31.01.2023 and 17.05.2023, respectively. The proposal was recommended by RCGM in its 224th meeting held on 20.01.2022 for conduct of trials at below mentioned five locations vide their Letter No. BT/IBKP/068/2020 dated 08.02.2022:

i. Haryana (Barwala-Hisar): Research Station, M/s. Bioseed Research India, Village – Panghal, Barwala-Hansi Road, Hisar – 124121, Haryana (owned by the applicant's organization).
ii. Gujarat (Junagadh): Junagadh Agricultural University, Junagadh – 362001, Gujarat.
iii. Telangana (Janwada): M/s Bioseed Research India, Plot No. 234, B Block, Kavuri Hills, Phase II, Hyderabad – 500033, Telangana (owned by the applicant's organization).
iv. Maharashtra (Akola): Dr Panjabrao Deshmukh Krishi Vidyapeeth, Akola – 444104, Maharashtra.
v. Maharashtra (Jalna): Bioseed Research India, Plot No. 12, C-4, N-1, CIDCO, Aurangabad – 401301, Maharashtra (owned by the applicant's organization).

The proposal with regard to the conduct of the trials at each of the five aforementioned sites was considered and deliberated by the Committee under Agenda Item 4.4 of this meeting.

It was further informed that RCGM in its 244th meeting held on 02.11.2022 considered the request of applicant and recommended inclusion of five additional trail locations for conduct of stated as below, thereby making a total of ten locations for conduct of BRL-I trial (1st year) of GE cotton hybrids containing Event 18L-5-3 expressing cry2Ai gene:

i. Haryana (Hisar): CCS Haryana Agriculture University, Hisar- 125004.
ii. Madhya Pradesh (Gwalior): College of Agriculture Khandwa, Rajmata Vijayraje Scindia Krishi Vishwavidyalaya (RVRKVV), Gwalior- 474002.
iii. Telangana (Hyderabad): Professor Jayshankar Telangana State Agriculture University, Hyderabad- 500030.

iv. Punjab (Bhatinda): Regional Research Station, Punjab Agricultural University, Bhatinda- 151005.
v. Rajasthan (Sriganganagar/ Bikaner): Agriculture Research Station, S. K. Rajasthan Agriculture University, Sriganganagar/ Bikaner- 334006.

As per extant practice in accordance with recommendation of 146th GEAC meeting, comments were sought by the GEAC Secretariat from the five concerned States for additional trials sites vide OM dated 03.05.2023. In this regard, it was informed that concurrence has been received only from Government(s) of Haryana and Madhya Pradesh for the additional trial sites. Government of Haryana vide email dated 25.05.2023 informed that the earlier consent given vide Memo No. 721/ADO (Seed) dated 17.11.2022 is to be considered. Government of Madhya Pradesh (MP) has communicated their concurrence for the conduct of trials vide Letter No. 48/2023/FWAD dated 25.05.2023. No comments have been received from Government(s) of Rajasthan and Punjab. Government of Telangana vide Letter dated 16.05.2023 informed that they've decided not to take up the trial during 2023-24 cropping season. In accordance with the recommendations of 149th GEAC Meeting, Government of Telangana vide Letter dated 08.06.2023 was requested to cite the reason for not taking up the trials for the 2023-24 cropping season. However, no comments were received from Government of Telangana. All the five concerned States for additional trial sites were invited to attend the 150th meeting of GEAC vide OM dated 04.8.2023. However, representatives from none of these States were present in the 150th GEAC meeting.

The Committee was further informed that subsequent to the receipt of concurrence from Government(s) of Haryana and Madhya Pradesh, the applicant vide email dated 26.05.2023 requested that an early recommendation from GEAC will enable sowing of proposed BRL-I trials for the Kharif 2023 season at two additional sites CCS HAU, Haryana and College of Agriculture Khandwa, RVRKVV, Gwalior, MP in addition to the site (applicant's own research station at Hisar, Haryana) that was already recommended by GEAC in its 148th meeting. Taking cognizance of the fact that the proposed BRL-I trials trial were already considered & deliberated by the Committee in its 148th Meeting held on 31.01.2023, and that the proposal has also been recommended by GEAC for conduct of trials in Hisar, Haryana (applicant's research station); the request of applicant for conduct of BRL-I trials during Kharif 2023 growing season was considered with the permission from Chairperson, GEAC at two additional sites, namely, CCS HAU, Haryana and College of Agriculture Khandwa, RVRKVV, Gwalior subject to the same conditions that were stipulated by the GEAC in its 148th meeting.

It was informed that as per prevailing practice and decision taken in 148th GEAC meeting under Agenda Item 4.1; RCGM was requested to issue the permit letter 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 below mentioned two trial sites subject to the same conditions as those stipulated in 148th GEAC Meeting:

i. Haryana- CCS Haryana Agriculture University (HAU), Hisar- 125004.
ii. Madhya Pradesh- College of Agriculture Khandwa, Rajmata Vijayraje Scindia Krishi Vishwavidyalaya (RVRKVV), Gwalior- 474002.

Recommendation:

After deliberations on 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 at five additional sites, as recommended by RCGM in its 244th meeting held on 02.11.2022, the Committee recommended the following:

i. As recommended under Agenda Item 4.4 of this meeting earlier, Government of Telangana be requested to cite the reason for not taking up the trials for the 2023-24 cropping season within thirty days. In case no response is received from them within the stipulated time, it will be considered that no comments/ views are to be put forth by the State Government in this regard and appropriate recommendation may accordingly be made by the Committee.
ii. Government of Punjab and Rajasthan be again requested to provide their views/ comments on the proposal within thirty days. In case no response is received from them within the stipulated time, it will be considered that no comments/ views are to be put forth by the State Government in this regard and appropriate recommendation may accordingly be made by the Committee.
iii. 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 below mentioned two trial sites subject to the same conditions as those stipulated in 148th GEAC Meeting:
    a. Haryana- CCS Haryana Agriculture University (HAU), Hisar- 125004.
    b. Madhya Pradesh- College of Agriculture Khandwa, Rajmata Vijayraje Scindia Krishi Vishwavidyalaya (RVRKVV), Gwalior- 474002.

Action: GEAC Secretariat

Agenda Item No. 8: Information Items

8.1 M/s ICAR-Central Potato Research Institute, Shimla to conduct BRL-I trials of GE Potato clonal hybrid K66 expressing RB gene.

RCGM in its in its 231st meeting held on 28.04.2022, vide their Letter No. BT/ IBKP/ 081/ 2020 dated 10.05.2022, recommended to GEAC the proposal of ICAR-CPRI to conduct BRL-I trial of GE potato clonal hybrid KJ66 expressing RB gene at seven regional stations of the CPRI, namely, Shimla (Himachal Pradesh), Jalandhar (Punjab), Gwalior (Madhya Pradesh), Kufri (Himachal Pradesh), Modipuram (Uttar Pradesh), Shillong (Meghalaya), and Ooty (Tamil Nadu).

The applicant obtained concurrence for conduct of trials from Government(s) of Meghalaya and Himachal Pradesh and accordingly the subject application was considered and 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.

Taking cognizance of the decision taken by GEAC in 146th GEAC meeting under Agenda Item 7.4 to seek comments/ views from concerned States, applicant vide letter dated 06.06.2023 has requested intervention of GEAC Secretariat in seeking views/ comments from the remaining concerned states (namely, Punjab, Madhya Pradesh, Uttar Pradesh, and Tamil Nadu), in accordance with the decision taken in 146th GEAC meeting, so as to enable conduct of BRL-I trials at remaining four CPRI regional stations situated in Jalandhar, Gwalior, Modipuram, and Ooty.

Accordingly, letter dated 26.06.2023 has been sent by GEAC Secretariat seeking views/ comments from the concerned States.

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	**7.**	**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	**8.**	**Shri V.P. Yadav** Scientist F, Central Pollution Control Board, Parivesh Bhawan, East Arjun Nagar, Delhi-110 032
3.	**Dr. Satyendra Kumar** Director, Ministry of Environment, Forest and Climate Change, Jorbagh, New Delhi-110003	**9.**	**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	**10.**	**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 3 9-A, Chandigarh-160036	**11.**	**Dr. S. J. Rahman,** Principal Scientist & Univ. Head of Entomology, Prof. Jayashankar Telangana State Agriculture University, Hyderabad- -500 030
6.	**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)	**12.**	**Dr. Rubina Bose** Deputy Drugs Controller (India), Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, FDA Bhavan, ITO, 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-400 085	**8.**	**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	**9.**	**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	**10.**	**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—110 029	**11.**	**Dr. Rekha S. Singhal** Professor, Food Technology, Institute of Chemical Technology, Mumbai- 400 019
5.	**Dr. U. S. N. Murthy** Director, National Institute of Pharmaceutical Education and Research, Guwahati- 781 101	**12.**	**Shri Sunil Kumar Bakshi** Head, Regulation, Food Safety an d Standards Authority of India, FDA Bhawan, Kotla, New Delhi - 110002
6.	**Dr. Chaitanya Joshi** Director, Gujarat Biotechnology Research Centre, Gandhinagar, Gujarat- 382 011	**13.**	**Dr. H. K. Sharma** Director, National Institute of Technology, Agartala, Tripura- 799 046
7.	**Dr. Satish Wate** Former Director, CSIR-National Environmental Engineering Research Institute, Nagpur- 440020		
Special Invitee			
1.	**Sri Anoop Kumar** Additional Chief Secretary-Agriculture, Government of Maharashtra	**3.**	**Dr. P. K. Chakrabarty** Formerly ADG (Plant Protection & Biosafety), Indian Council of Agricultural Research, Ministry of Agriculture and Farmer's Welfare, New Delhi
2.	**Shri Vaibhav Shinde** Nominee of ACS Agriculture, Government of Maharashtra		
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		