

**MINUTES OF THE 147th MEETING OF THE GENETIC ENGINEERING
APPRAISAL COMMITTEE HELD ON 18.10.2022**

The 147th meeting of the Genetic Engineering Appraisal Committee (GEAC) of the Ministry of Environment, Forest and Climate Change (MoEF&CC) was held on 18.10.2022 in hybrid mode at Narmada Conference Hall, Ground Floor, Jal Block, Indira Paryavaran Bhawan, New Delhi. The meeting was chaired by Shri Naresh Pal Gangwar, Additional Secretary, MoEF&CC. The list of participants is placed at **Annexure 1**.

At the outset, Chairperson, GEAC welcomed all the members and requested the Member Secretary to start the discussion on agenda items.

Agenda Item No. 1: Leave of absence

Seven members communicated their inability to attend the 147th meeting of GEAC, namely Dr. Vinay K. Nandicoori, Dr. P. K. Dass, Dr. Sanjeev Khosla, Dr. Dinkar M. Salunkhe, Dr. H. K. Sharma, Dr. J.P. Shukla and Dr. P. Suprasanna. Further, 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 146th GEAC meeting

Minutes of the 146th GEAC meeting were circulated to all the members for comments and minutes were suitably amended to incorporate comments received from the members

Decision:

Members confirmed the minutes of the 146th GEAC meeting.

Action: GEAC Secretariat

Agenda Item No. 3: Action taken report on the decision taken in the 146th GEAC meeting

Member Secretary, GEAC briefed about the action taken on the decisions at the 146th 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

<u>Agenda Item No. 4: Applications related to Environmental release</u>
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4.1 M/s Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi South Campus, New Delhi for permission for environmental release of transgenic mustard hybrid DMH -11 and parental lines bn 3.6 and modbs 2.99 containing barnase, barstar and bar genes.
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The Committee was informed that in 146th meeting of GEAC held on 25.08.2022, an Expert Committee was constituted for examining evidence about impact of transgenic mustard on honey bees and other pollinators in order to assess the need for conducting field demonstration studies on honey bees and other pollinators. Accordingly, two meetings of the Expert Committee were held on 23.09.2022 and 30.09.2022. The Sub-Committee submitted its report to the GEAC Secretariat on 08.10.2022.

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

“Based on the examination of scientific evidences available globally, and as per the recommendations of concerned ministries, it seems unlikely that the bar, barnase, and barstar system will pose an adverse impact on honey bees and other pollinators. Therefore, the Committee was of the view that GEAC may consider the environmental release of GE mustard and further evaluation to be carried out as per ICAR guidelines for release and notification.

However, to generate scientific evidences in Indian agro-climatic situation and also as a precautionary mechanism, the Expert Committee suggests that the field demonstration studies with respect to the effect of GE mustard on honey bees and other pollinators, as recommended in the 136th GEAC meeting, may also be conducted post-environmental release, simultaneously by the applicant, within two years under supervision of ICAR and the report be submitted to the 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.

Recommendations:

After due deliberations on the report of the Expert-Committee, as well as comments received from DBT and DARE, the Committee recommended the following:

- I. The environmental release of genetically engineered mustard parental lines bn 3.6 carrying *barnase* and *bar* genes, and modbs 2.99 containing *barstar* and *bar* genes, so that these events can be used for developing new parental lines and hybrids under supervision of ICAR.
- II. The environmental release of mustard hybrid DMH-11 for its seed production and testing as per existing ICAR guidelines and other extant rules/regulations prior to commercial release.
- III. Further, to generate scientific evidences in Indian agro-climatic situation and also as a precautionary mechanism, the field demonstration studies with respect to the effect of GE mustard on honey bees and other pollinators, as recommended in the 136th GEAC meeting, shall also be conducted post-environmental release, simultaneously by the applicant, within two years under supervision of ICAR, as per ICAR guidelines and other extant rules/guidelines/regulations and the report be submitted to the GEAC.

These recommendations are subject to the following conditions:

- I. The approval is for a limited period of four years from the date of issue of approval letter as per clause 13 of Rules 1989 and is renewable for two years at a time based on compliance report.
- II. 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 is authorized to constitute the Committee.
- III. Applicant shall deposit 100 grams each of approved hybrids as well as their parental lines with the ICAR-National Bureau of Plant Genetic Resources (ICAR-NBPGR) and communicate the same to GEAC within 30 days of issue of this clearance letter for purposes of future reference in case of trade, traceability and dispute on account of ownership.
- IV. The applicant shall provide detailed step-by-step testing procedures for identifying approved event in the transgenic hybrids (bar, barnase and barstar) and parental lines, to the GEAC within 30 days from the receipt of approval letter.
- V. Applicant shall develop and deposit the DNA fingerprints of the approved Transgenic Mustard varieties within 30 days from the receipt of approval letter to the ICAR-NBPGR.
- VI. Usage of any formulation of herbicide is recommended only under controlled and specified conditions exclusively for hybrid seed production after obtaining label claim and approval from Central Insecticide Board & Registration Committee (CIB&RC).
- VII. Usage of any formulation of herbicide is not permitted for cultivation in the farmer's field under any situation and such use would require the necessary permission as per the procedures and protocols of safety assessment of insecticides/ herbicides by CIB&RC. Any such use in the farmer's field without due approval from CIB&RC would attract appropriate legal action under Central Insecticides Act 1968 and Rules 1971, EP Act 1986 and the Rules made there under.
- VIII. Commercial use of DMH-11 hybrid shall be subject to Seed Act 1966 and related rules and regulations, its amendments and Gazette notifications from time to time as applicable.

- IX. The applicant shall prepare and submit the annual/seasonal reports on acreage, yield and states/ regions where the transgenic mustard is sown during the approval period to the GEAC.
- X. It is mandatory that all seed packets of GE mustard Hybrid DMH-11 and subsequent hybrids derived from the technology should be appropriately labelled indicating the contents including the name of the transgenes, physical and genetic purity of the seeds etc. Each packet should also contain detailed description for use including sowing pattern, pest management, suitability of agro-climatic conditions etc. in English, Hindi and vernacular language.
- XI. All efforts should be made by applicant and licensees to undertake an awareness and education programme interlaid through development and distribution of educational material on GE Mustard Hybrid DMH-11 for farmers, dealers and others.
- XII. Indian Council of Agricultural Research (ICAR) would be the authorized agency to accord necessary permissions for development of any other *Brassica juncea* hybrids resulting from events approved and their descendants, provided the intended use is similar. However, all hybrids released using this technology shall also be regulated under Seed Act 1966 and related rules and regulations, its amendments and Gazette notification from time to time as applicable. ICAR shall also ensure the following conditions prior to release of any new hybrids:
- Confirmation of events through molecular characterization to be submitted from accredited lab, in original, as notified for the purpose.
 - Data on level of transgenes (Barnase, Barstar and Bar) expression in the events/ hybrids at seedling stage from accredited lab, in original, as notified for the purpose.
 - Morphological characters using Distinctiveness, Uniformity and Stability (DUS) descriptors as per Protection of Plant Varieties and Farmers Rights Act, (PPVFRA) guidelines for the hybrids.
 - Source of germplasm/ pedigree and biotech traits must be provided with self-declaration by the applicant.
 - Affidavit on the ownership of hybrid/ variety/ events.
 - Performance trial report including agronomic parameters, yield with coefficient of variation (CV) and critical difference (CD), pest & disease reaction etc. as per ICAR guidelines.
- XIII. If at any time, the applicant or the responsible parties become aware of any information regarding risk to the environment, or risk to animal or human health, that could result from release of these materials in India, or elsewhere, the applicant must immediately provide in writing such information to regulatory bodies.

- XIV. The approval may be revoked under Rule 13(2) of Rules, 1989, if any evidences regarding harmful effects of the approved GE mustard, such as damage to the environment, nature or health as could not be envisaged when the approval was given comes under notice of GEAC and on noncompliance of any condition stipulated by GEAC.
- XV. MoEF&CC/ GEAC may prescribe any additional conditions/ requirements or constitute any Sub-Committees or commission any studies if felt appropriate during the period of approval.
- XVI. The recommendations are subject to other statutory clearances, as applicable, including the clearance from FSSAI.

Action: GEAC Secretariat

Agenda Item No. 5: Applications related to Confined Field Trials of GE crops (Event Selection/ BRL-I/ BRL-II Trials)

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

The Committee was informed that this application was considered and recommended in 146th meeting of GEAC held on 25.08.2022 for two trial sites, namely, ICAR-CPRI Headquarters, Shimla and ICAR-CPRI regional station, Kufri based on the No Objection Certificate (NOC) for conducting BRL-I trials of GE potato clonal hybrid KJ66 from the Government of Himachal Pradesh, and recommendations of 231st meeting of Review Committee on Genetic Manipulation (RCGM), vide Letter No. BT/IBKP/081/2020 dated 10.05.2022.

The applicant has now obtained No Objection Certificate (NOC) for conducting BRL-I trials of GE potato clonal hybrid KJ66 from the Government of Meghalaya also, and accordingly has proposed to conduct BRL-I trials during 2022 at ICAR-CPRI regional station, Shillong.

Recommendation:

The proposal of M/s ICAR-Central Potato Research Institute (CPRI), Shimla seeking permission to also conduct BRL-I trials of GE potato clonal hybrid KJ66 (non-GE potato cv. Kufri Jyoti x GE potato Event KatSP951 cv. Katahdin) expressing *RB gene* derived from Wild Mexican diploid potato (*Solanum bulbocastanum*) during 2022 at ICAR-CPRI regional station, Shillong was recommended by the committee subject to the conditions as stipulated in minutes of 146th GEAC Meeting under Agenda Item No. 5.1.

The Review Committee on Genetic Manipulation (RCGM) may issue the permit letter and monitor confined field trials to ensure compliance of prescribed terms and conditions.

Action: RCGM & GEAC Secretariat

5.2 National Agri-Food Biotechnology Institute (NABI), Mohali for Event Selection Trials of five GE Banana lines expressing OsNAS1 or OsNAS2 genes.

The applicant made a presentation before the Committee and informed that they intend to conduct Event Selection Trials of five GE banana lines (*Musa* sp. cv. Grand Naine) expressing OsNAS1 or OsNAS2 gene involved in Nicotianamine biosynthesis pathway for Iron bio fortification. Three GE lines expressing OsNAS1 gene driven by Ubiquitin promoter are NRQIGN53-'19/15, BAQIGN53-'19/84 and BAQIGN53-'19/74. Two GE Lines expressing OsNAS2 gene driven by Ubiquitin promoter are NRQIGN68-'20/47 and NRQIGN68-'20/36.

Event selection trials are proposed to be conducted at five trial site locations viz., National Agri-Food Biotechnology Institute, Mohali; ICAR- National Research Centre for Banana, Tiruchirappalli; Tamil Nadu Agriculture University, Coimbatore; Navsari Agriculture University, Navsari; and Sarat Chandra Sinha College of Agriculture, Dhubri Campus, Assam.

This application was considered and recommended by RCGM in its 222nd meeting held on 23.12.2021, vide its Letter No. BT/IBKP/468/2021 dated 21.01.2022.

Recommendation:

Based on the recommendation of RCGM, the proposal of National Agri-Food Biotechnology Institute (NABI), Mohali to conduct Event Selection Trials of five GE Banana lines expressing OsNAS1 or OsNAS2 genes involved in Nicotianamine biosynthesis pathway during cropping season 2022 to 2024 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/468/2021 dated 21.01.2022.

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

Action: RCGM & GEAC Secretariat

5.3 National Agri-Food Biotechnology Institute (NABI), Mohali for Event Selection Trials of twenty GE Banana lines expressing Apsy2a or NEN-DXS2 genes.

The applicant made a presentation before the Committee and informed that that they intend to conduct Event Selection Trials of twenty GE banana lines (*Musa* sp. cv. Grand Naine) expressing Apsy2a or NEN-DXS2 gene involved in carotenoid biosynthesis pathway for Pro-Vitamin A bio fortification. Twelve GE lines expressing Apsy2a gene driven by Ubiquitin promoter are NABI-GN440, NABI-GN423, NRQP34-'19/01, NRQP34-'19/02, NRQP34-'19/03, NRQP34-'19/05, NRQP34-'19/07, NRQP34-'19/08, NRQP34-'19/10, NRQP34-'19/11, NRQP34-'19/12 and NRQP34-'19/13. Three GE lines expressing Apsy2a gene driven by ACO promoter are NABI-GN321, NABI-GN346, NABI-GN416. Five GE lines expressing *NEN-DXS2* gene driven by *Ubiquitin* promoter are NABI-GN544, NABI-GN545, NABI-GN547, NABI-GN552, NABI-GN553.

Event selection trials are proposed to be conducted at five trial sites namely National Agri-Food Biotechnology Institute, Mohali; ICAR-National Research Centre for Banana, Tiruchirappalli; Tamil Nadu Agriculture University, Coimbatore; Navsari Agriculture University, Navsari; and Sarat Chandra Sinha College of Agriculture AAU, Dhubri, Assam.

This application was considered and recommended by RCGM in its 222nd meeting held on 23.12.2021, vide its Letter No. BT/IBKP/468/2021 dated 21.01.2022.

Recommendation:

Based on the recommendation of RCGM, the proposal of National Agri-Food Biotechnology Institute (NABI), Mohali to conduct Event Selection Trials of twenty GE banana lines expressing Apsy2a or NEN-DXS2 gene involved in carotenoid biosynthesis pathway during cropping season 2022 to 2024 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/468/2021 dated 21.01.2022.

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

Action: RCGM & GEAC Secretariat

5.4 M/s Bioseed Research India, Hyderabad for Event Selection Trials of twenty-five GE Cotton lines expressing Cry2Ai gene.

The application for conduct of Event Selection Trial of twenty-five GE cotton lines expressing cry2Ai gene for resistance to Pink Bollworm was withdrawn by the applicant.

5.5 M/s Bioseed Research India, Hyderabad for Event Selection Trials of ten GE cotton lines expressing Cry2Ai gene.

The applicant made a presentation before the Committee and informed that they intend to conduct Event Selection Trial of ten GE cotton lines (BioCot130-1, BioCot130-2, BioCot130-3, BioCot130-4, BioCot130-5, BioCot130-6, BioCot130-7, BioCot130-8, BioCot130-9, and BioCot130-10) expressing cry2Ai gene at two trial sites owned by company in Hyderabad, Telangana and Jalna, Maharashtra to evaluate resistance against Pink Bollworm during Kharif 2023 season.

This application was considered and recommended by RCGM in its 197th meeting held on 07.01.2021, vide Letter No. BT/IBKP/068/2020 dated 03.02.2021.

Recommendation:

Based on the recommendation of RCGM, the proposal of M/s Bioseed Research India, Hyderabad to conduct Event Selection Trials of ten GE cotton lines expressing cry2Ai gene at two trial sites owned by company in Hyderabad, Telangana and Jalna,

Maharashtra to evaluate resistance against Pink Bollworm during Kharif season 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/IBKP/068/2020 dated 03.02.2021.

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

Action: RCGM & GEAC Secretariat

5.6 M/s Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi South Campus, New Delhi for Event Selection Trials of a GE Mustard line developed by antisense suppression of fad2 gene.

The applicant informed the Committee that they intend to conduct event selection trial of GE Mustard line, containing event-HO 3.18, developed by antisense suppression of fad2 gene for high oleic and low linoleic content, at Delhi University, Field Research station in Bawana during cropping season Rabi 2023.

This application was considered and recommended by RCGM in its 216th meeting held on 30.09.2021, vide Letter No. BT/IBKP/024/2019 dated 29.11.2021.

Recommendation:

Based on the recommendation of RCGM, the proposal of M/s Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi South Campus, New Delhi to conduct Event Selection Trials of a GE Mustard line containing event-HO 3.18, developed by antisense suppression of fad2, at Delhi University, Field Research station in Bawana during cropping season Rabi 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/IBKP/024/2019 dated 29.11.2021.

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

Action: RCGM & GEAC Secretariat

5.7 M/s Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi South Campus, New Delhi for Event Selection Trials of a GE Mustard line expressing BjMYB28 gene.

The applicant informed the Committee that they intend to conduct event selection trial of GE Mustard line C3/15 expressing BjMYB28 (RNAi) gene for low glucosinolate content at Delhi University farm station, Bawana during cropping season Rabi 2023.

This application was considered and recommended by RCGM in its 216th meeting held on 30.09.2021, vide Letter No. BT/IBKP/024/2019 dated 29.11.2021.

Recommendation:

Based on the recommendation of RCGM, the proposal of M/s Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi South Campus, New Delhi to conduct Event Selection Trials of GE Mustard line C3/15 expressing BjMYB28 (RNAi) gene for low glucosinolate content at Delhi University farm station, Bawana during cropping season Rabi 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/IBKP/024/2019 dated 29.11.2021.

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

Action: RCGM & GEAC Secretariat

5.8 M/s Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi South Campus, New Delhi for Event Selection Trials of twenty-two GE Mustard lines expressing WRI1 and/or DGAT1 genes.

The applicant informed the Committee that they intend to conduct event selection trial of twenty-two GE Mustard lines expressing WRI1 and/or DGAT1 genes (Fifteen lines viz. WRI 1 – 7, WRI 1 – 13 , WRI 1 – 20, WRI 1 – 38, WRI 1 – 39, WRI 1 – 41, WRI 1 – 42, WRI 1 – 43, DGAT1- 7, DGAT1- 10, DGAT1- 22, DGAT1- 23, DGAT1- 27, DGAT1- 39 and DC- 4 from Rabi 2019, and seven lines WRI 1-1, WRI 1 – 21, WRI 1 – 34, DC- 1, DC- 7, DC- 8 and DC-15) for high oil content at Delhi University farm station, Bawana during cropping season Rabi 2023.

This application was considered and recommended by RCGM in its 216th meeting held on 30.09.2021, vide Letter No. BT/IBKP/024/2019 dated 29.11.2021

Recommendation:

Based on the recommendation of RCGM, the proposal of M/s Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi South Campus, New Delhi to conduct Event Selection Trials of twenty-two GE Mustard lines expressing WRI1 and/or DGAT1 genes for high oil content at Delhi University farm station, Bawana during cropping season Rabi 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/IBKP/024/2019 dated 29.11.2021.

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

Action: RCGM & GEAC Secretariat

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

The applicant made a presentation before the Committee and informed that they intend to conduct event selection trial of two GE rubber (*Hevea brasiliensis*) lines, Os1 and Os2, expressing *osmotin* gene derived from tobacco to confer Biotic /abiotic stress tolerance. This trial is proposed to be conducted at Sarutari Research farm, RRS,

Guwahati for 15 years during cropping season 2023-2038 (15 years) since Rubber plant has long gestation period of around 6-7 years.

It was also informed to the Committee that *Osmotin* is a stress responsive multifunctional protein belonging to PR-5 protein family, providing osmotolerance to plants. Its gene expression pattern indicates that its transcription can be activated by several factors like sodium chloride, desiccation, ethylene, wounding, abscisic acid, tobacco mosaic virus, fungi and UV light. Using in vitro assay, it has been also demonstrated that osmotin has antifungal activity against a variety of fungi, including *Phytophthora candida*, *Neurospora crassa* etc.

This application was considered and recommended by RCGM in its 239th meeting of held on 24.08.2022, vide Letter No. BT/IBKP/533/2021 dated 30.09.2022.

Recommendation:

Based on the recommendation of RCGM, the proposal of M/s Rubber Research Institute of India, Kottayam to conduct Event Selection Trials of two GE rubber lines expressing *osmotin* gene derived from tobacco to confer Biotic /abiotic stress tolerance at Sarutari Research farm, RRS, Guwahati during cropping season 2023-2038 (15 years) 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 BT/IBKP/533/2021 dated 30.09.2022.

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

Action: RCGM & GEAC Secretariat

Agenda Item No. 6: Applications related to Environmental Approval for Commercial Production

6.1 M/s Danisco India Private Limited, Hyderabad for production of ethanol using SYNERXIA® JADE ADY Yeast.

The applicant made a presentation before the Committee and informed that they intend to import and perform pilot testing of GM Yeast strain “SYNERXIA® JADE ADY” for ethanol production using grain-based fermentation technology. It is proposed to undertake pilot studies at 100+ liters scale at CSIR-Institute of Microbial Technology (IMTECH), Chandigarh in BSL-1 compliant facility for manufacture of ethanol from the grains, with an aim to obtain permission for marketing of SYNERXIA® JADE ADY in India. The genetic modifications in SYNERXIA® JADE ADY include deletions, over expression of a native gene, and insertion of gene for extracellular expression.

It was informed that SYNERXIA® JADE ADY will be imported from USA as active dry yeast (ADY).

Recommendation:

After detailed deliberations, the Committee was of the view that the applicant shall be directed to submit additional information with respect to appropriate regulatory approvals granted by other countries, GMO characteristics as identified by regulatory authorities in other countries, documentary evidence of Generally Recognized As Safe (GRAS) designation granted to SYNERXIA® JADE ADY by the exporting country, and detailed information on biosafety aspects.

Action: GEAC Secretariat

Agenda Item No. 7: Applications related to Import/Export**7.1 M/s Zoetis India Limited, Mumbai for import and marketing of Poulvac Procerta HVT-IBD-ND vaccine for veterinary use only.**

The applicant made a presentation before the Committee and informed that they intend to import and market Bursal Disease-Marek's Disease-Newcastle Disease Vaccine Serotype 3, Live Marek's Disease Vector (Brand Name: Poulvac Procerta HVT-IBD-ND) vaccine for veterinary use.

The active ingredients of HVT-IBD-ND contains cassettes that express the VP2 gene derived from strain F52/70 and the F gene from a lentogenic Newcastle strain (D26-76) inserted into the herpes virus of turkeys (HVT) backbone expressing both genomes. Herpesvirus Turkey (HVT) – containing a VP2 gene of infectious bursal disease virus (IBDV) and the fusion (F) protein of a lentogenic strain of Newcastle disease virus (NDV) inserted into the HVT genome. This product has been shown to be effective for the vaccination of healthy one-day old chickens and 18- to 19-day-old embryonated chicken eggs against standard infectious bursal disease, and Marek's and Newcastle diseases.

The applicant intends to import 13434 units of 4000 doses and 18575 units of 2000 doses, per annum, from USA.

Recommendation:

The committee recommended the proposal of M/s Zoetis India Limited, Mumbai for import of Bursal Disease-Marek's Disease-Newcastle Disease Vaccine Serotype 3, Live Marek's Disease Vector (Brand Name: Poulvac Procerta HVT-IBD-ND) vaccine 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), including its metagenomics analysis for verification of purity of the target event/organisms and to check the presence of non-target event/organisms.
- ii. Obtain relevant approvals from Department of Animal Husbandry and Dairying, Drug Controller General of India etc. as per existing laws, rules, regulations as applicable.
- iii. The final data certified by IVRI to be presented before the GEAC for final approval, before it is marketed in the country.

Action: GEAC Secretariat

7.2 M/s Zoetis India Limited, Mumbai for import and marketing of Frunevetmab (Brand Name: SOLENSIA) solution for veterinary use only.

The applicant made a presentation before the Committee and informed that they intend to import and market Frunevetmab solution for Injection (7mg/ml). Frunevetmab is a felinised monoclonal antibody used in cats for the treatment of pain associated with osteoarthritis (OA). The active substance of Solensia, frunevetmab, is a monoclonal antibody (mAb) specifically targeting nerve growth factor (NGF).

Frunevetmab is produced using standard biopharmaceutical techniques. The secreted product, from a genetically engineered Chinese Hamster Ovary cell line, is a disulphide-linked, glycosylated, tetramer consisting of 2 identical 457 amino acid heavy gamma chains (feline IgG1) and 2 identical 217 amino acid kappa light chains. Frunevetmab is synthetically derived and both the heavy chain “NV-02-HC” cDNA and the light chain “NV-02-LC” cDNA is of known amino acid sequences. Frunevetmab binds NGF with high affinity, is a potent inhibitor of NGF activity and does not recruit complement.

The product is proposed to be administered as a single subcutaneous injection monthly, at a minimum dose of 1 mg/kg bodyweight (bw). A single-strength injection (7 mg/ml) will be packaged in 1 ml vial. The applicant intends to import 1200 vials of Frunevetmab solution for Injection 7mg/ml, per annum, from Belgium.

Recommendation:

After detailed deliberations, the Committee was of the view that the applicant shall be directed to obtain permission from the Drug Controller General of India (DCGI).

Action: GEAC Secretariat

7.3 M/s Zoetis India Limited, Mumbai submitting IVRI test reports for import and marketing of lokivetmab (Brand name: CYTOPOINT) solution for veterinary use only.

The applicant made a presentation before the Committee and informed that the application for import and marketing of Lokivetmab Solution for Injection (10mg/ml, 20mg/ml and 40mg/ml) for veterinary use was recommended in the 144th meeting of GEAC held on 22.02.2022 subject to the conditions “i. Initial 3 batches of the subject vaccine to be certified in ICAR-Indian Veterinary Research Institute (ICAR-IVRI), ii. Obtain relevant approvals from Department of Animal Husbandry and Dairying, Drug Controller General of India etc. as per existing Indian laws applicable for import of vaccines. iii. The final data certified by IVRI to be presented before the GEAC for final approval, before it is marketed in the country.”

Accordingly, the applicant has obtained NOC from Department of Animal Husbandry, and Dairying, vide Letter No. K-11053/47/2021/LH-Part I, for marketing of Lokivetmab Solution for Injection (10mg/ml, 20mg/ml and 40mg/ml). ICAR-IVRI vide Letter No. STD/QC/VT/Zoetis/2022-23 dated 28.7.2022 informed M/s Zoetis India Limited, Mumbai that testing/analysis of Lokivetmab, Frunevetmab, Bedinvetmab cannot be done at ICAR-IVRI since they are not vaccine/diagnostic. The applicant also informed that no such testing facility are available at National Institute of Virology, Pune and National Institute of Biologicals (NIB), Noida.

Recommendation:

After detailed deliberations, the Committee was of the view that the applicant shall be directed to obtain permission from the Drug Controller General of India (DCGI).

Action: GEAC Secretariat

7.4 M/s Danisco India Private Limited, Hyderabad for import and marketing of SYNERXIA® JADE ADY (Active Dried Yeast) for ethanol production.

The applicant made a presentation before the Committee and informed that they intend to import of GM Yeast strain “SYNERXIA® JADE ADY” for marketing for use in fuel ethanol production from grain based feedstocks. The genetic modifications in SYNERXIA® JADE ADY include deletions, over expression of a native gene, and insertion of gene for extracellular expression. It was informed that upto 2000 MT of GM yeast, per annum, will be imported from USA as active dry yeast (ADY).

Recommendations:

The proposal of M/s Danisco India Private Limited, Hyderabad for import and marketing of SYNERXIA® JADE ADY (Active Dried Yeast) for ethanol production was not recommended by the Committee. Applicant was asked to submit additional information as stated in Agenda 6.1.

Action: GEAC Secretariat

Agenda Item No. 8: Information Items

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

M/s Bioseed Research India, Hyderabad submitted for permission for 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 to be conducted at five locations, namely, Janwada, Jalna, Akola, Junagadh, and Hisar (located in four states Telangana, Maharashtra, Gujarat, and Haryana).

RCGM recommended this proposal to GEAC in its 224th meeting held on 20.01.2022, vide Letter No. BT/IBKP/068/2020 dated 08.02.2022.

Taking view of the decision taken in 146th GEAC that if the proposed confined field trial sites are other than Notified Field Trial Sites (NFTS), GEAC Secretariat will send a formal communication to the Additional Chief Secretary/Principal Secretary (Agriculture) of the concerned States/UTs requesting them to communicate their views/comments, if any, within 60 days. Subsequently, the concerned State/UT(s) ACS/PS (Agriculture) or their nominee will be invited as Special Invitee in the corresponding GEAC Meeting wherein the application will be considered for deliberation.

Accordingly, communication has been sent by the Secretariat to the concerned States requesting their views/comments within the stipulated time period.

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	8. 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	9. Shri V.P. Yadav Scientist F Central Pollution Control Board Parivesh Bhawan, East Arjun Nagar, Delhi-110 032
3. Ms. Rita Khanna Advisor, MoEFCC Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jorbagh road, Aliganj, New Delhi- 110003	10. Dr. Chaitanya Joshi Director, Gujarat Biotechnology Research Centre, Gandhinagar, Gujarat- 382 011
4. Dr. Satyendra Kumar Director, CS-III Division Ministry of Environment, Forest and Climate Change, Jorbagh, New Delhi-110003	11. Dr. Rekha S. Singhal Professor, Food Technology, Institute of Chemical Technology, Mumbai- 400 019
5. Dr. Nitin K. Jain Scientist-F and Member Secretary RCGM Department of Biotechnology, C. G. O, Complex, Lodhi Road, New Delhi-110003	12. Dr. D.K. Yadav ADG (Seed), Crop Science Division Indian Council of Agricultural Research, Krishi Bhawan, New Delhi- 110001
6. Dr. S. J. Rahman, Principal Scientist & Univ. Head of Entomology, Prof. Jayashankar Telangana State Agri. University, Hyderabad-500 030	13. Ms. Nilanjana Mukherjee (Representative of Ms. Shruti Singh , Joint Secretary, IPR, Department for Promotion of Industry and Internal Trade, Udyog Bhawan, New Delhi 110011)
7. Dr. U. S. N. Murthy Director, National Institute of Pharmaceutical Education and Research, Guwahati- 781 101	14. Dr. J.P. Singh Plant Protection Adviser(PPA), Directorate of Plant Protection, Quarantine & Storage, NH IV, Faridabad-121001. New Delhi

Members who did not participate		
1.	Dr. P. Suprasanna Scientific Officer H (Retd.) Biosciences group BARC, Mumbai-400085	5.
		Dr. P.K. Dass Department of Anatomy LHMC & Associated hospitals, New Delhi- 110 001
2.	Dr. Vinay K. Nandicoori Director, CSIR-Centre for Cellular & Molecular Biology, Hyderabad - 500 007	6.
		Dr. H. K. Sharma Director, National Institute of Technology, Agartala, Tripura- 799 046
3.	Dr. J. P. Shukla Scientist, CSIR-Advanced Materials and Process Research Institute, Bhopal- 462 026	7.
		Dr. Sanjeev Khosla Director, CSIR-Institute of Microbial Technology, Chandigarh- 160 036
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	8.
		Dr. Dinkar M. Salunkhe Director, International Centre for Genetic Engineering and Biotechnology New Delhi-110 067
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	