MINUTES OF THE 146th MEETING OF THE GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 25.08.2022

The 146th meeting of the Genetic Engineering Appraisal Committee (GEAC) of the Ministry of Environment, Forest and Climate Change (MoEF&CC) was held on 25.08.2022 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, Shri Naresh Pal Gangwar, Chairperson, GEAC welcomed all the members and requested the Member Secretary, Dr. Satyendra Kumar, to start the discussion on agenda items.

Agenda Item No. 1: Leave of absence

Two members communicated their inability to attend the 146th meeting of GEAC, namely Dr. Vinay K. Nandicoori and Dr. P. Suprasanna. Further, Ms. Shruti Singh 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 145th GEAC meeting

Minutes of the 145th GEAC meeting held on 27.07.2022 were circulated to all the members for comments and minutes were suitably amended to incorporate the comments received from the members. The Committee agreed that the compliance condition "The applicant shall adhere with the conditions and recommendations as per RCGM Letter No. BT/IBKP/223/2020 dated 03.05.2021, and conduct additional studies on micro-organisms as per existing protocols" mentioned in the decisions for Agenda Item No. 4.1 and 4.2 in the minutes of 145th meeting of GEAC may be read as "The applicant shall adhere with the conditions and recommendations as per RCGM Letter No. BT/IBKP/223/2020 dated 03.05.2021."

Decision:
Members noted the amendment in the minutes of the 145th GEAC meeting and confirmed the same.

Action: GEAC Secretariat

Agenda Item No. 3: Action taken report on the decision taken in the 144th GEAC meeting

Member Secretary, GEAC briefed about the action taken on the decisions at the 145th meeting of GEAC. He informed that letters communicating GEAC decisions had been issued to applicants.

Decision:
The Committee noted the actions taken by the Secretariat.

Action: GEAC Secretariat

Agenda Item No. 4: Applications related to Commercial/ Environmental release

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.

The Committee noted that the application 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 was initially recommended by GEAC in its 133rd meeting held on 11.05.2017 with certain terms and conditions for further approval by the Competent Authority. However, the application was referred back to GEAC for its re-examination pursuant to receipt of several representations both in support and against after the 133rd meeting of GEAC held on 11.05.2017.

In 134th meeting of GEAC held on 21.03.2018, the applicant was advised to undertake field demonstration of GM Mustard in an area of 5 acres at 2-3 different locations with a view to generate additional data on honey bees and other pollinators and honey, and on soil microbial diversity.

In 136th meeting of GEAC held on 20.09.2018, the Committee:

i. Granted approval for conduct of field demonstration studies on honey bees and other pollinators at two locations up to 5 acres in each location namely PAU, Ludhiana and IARI, New Delhi.
ii. Exempted soil microflora studies as these were already done during BRL-I and BRL-II trials.
iii. Approved the request of applicant for conduct of two field studies to assess hybrid seed efficiency and for maintenance of male sterile barnase line bn 3.6.

Further, GEAC extended the permission to conduct field demonstration studies two times, for the seasons 2019-20 and 2020-21.

The letter dated 10.05.2022 was received from Prof. Deepak Pental, Former Professor of Genetics and Vice Chancellor, University of Delhi with a request to reconsider the recommendation of 133rd GEAC meeting regarding environmental release of transgenic mustard hybrid DMH -11 and parental lines bn 3.6 and modbs 2.99 containing barnase, barstar and bar genes. In this regard, comments were sought from Department of Biotechnology (DBT) and Department of Agricultural Research and Education (DARE) on the letter dated 10.05.2022 received from Prof. Deepak Pental. Both DBT and DARE were of the view that the GEAC may consider its recommendations of the 133rd meeting on the environmental release of GM mustard. Prof. Deepak Pental was requested to present the case in 146th GEAC meeting.

Prof. Deepak Pental made a detailed presentation on the proposal and informed the committee that:

i. The average mustard yield increased from 481 kg/hectare in 1961 to around 1.3 tonnes/hectare at present due to the efforts of Indian breeders. Most of the yield increase has been through pure line breeding. Further increases require the deployment of hybrids.

ii. The GE-based hybrid seed production system developed in mustard by CGMCP uses three transgenes – *barnase* (for male sterility), *barstar* (for restoration of male fertility), and *bar* (confers resistance to herbicide phosphinothricin – commercial name Basta). Event Var bn 3.6 contains the *bar* and *barnase* genes and is male sterile. Event EH-2 modbs 2.99 contains the *bar* and the *barstar* genes and restores fertility. The resultant first hybrid DMH-11 contains all three genes i.e., *bar, barnase*, and *barstar*.

iii. The three genes used in mustard i.e., *bar, barnase,* and *barstar*, had been earlier deployed in rapeseed (*Brassica napus*) also called Canola, a sister crop of mustard, for hybrid seed production by the original developers of the technology. The transgenic lines and their hybrids were cleared for environmental release in Canada in 1996, in the USA in 2002, and in Australia in 2003 after a thorough examination by the regulatory authorities of these countries.

iv. Biosafety Research Level (BRL) I and II trials for the two events Var bn 3.6, EH-2 modbs 2.99, and hybrid DMH-11 were carried out by the ICAR and food safety studies by ICMR institutions, with funding from BIRAC, as per the prescribed guidelines of the Govt. of India for field testing, and food safety, and environmental safety.

v. BRL trials conducted over three growing seasons demonstrated that the phenotypic, reproductive, and survival biology characteristics were similar in transgenic mustard lines as compared to their non-transgenic counterparts. No differences in the weediness potential of transgenic lines were observed as compared to their non-transgenic comparators. On average, hybrid DMH-11 showed a 28% yield increase over the mega variety Varuna.

The Committee was informed by Prof. Deepak Pental that CGMCP undertook a detailed analysis of published literature and regulatory decisions in other countries concerning the honey bees. It was informed that:

i. Regulatory decisions published by the USA, Canada, and Australia indicate that no conditions have been imposed at the time of environmental release and authorization for the cultivation of *B. napus* containing the three similar genes, deployed in GE mustard.

ii. A study by the Ministry of Rural Department - Australia on the impact of GM Canola on honey exports showed that the pollen present in the honey after filtration does not contain more than 0.2 % pollen, which is well below the 1% threshold of pollen by weight, above which honey derived from GM Crops would need to be labelled.

iii. Most of the studies on the GE crops grown worldwide have concluded that the transgenic proteins in the released crops do not pose any threat to honey bee foraging or brooding. However, most studies have been on transgenic crops containing insecticidal cry genes from *Bacillus thuringiensis*. In a review paper 'Assessing the Environmental Safety of Transgenic Plants: Honey Bees as a Case Study (Ricroch et al. 2017. Advances in Botanical Research ISSN 0065-2296) based on an analysis of the findings of 64 published papers on the subject, the authors concluded that '*the studied Cry proteins, RNAi or herbicide tolerance proteins do not negatively affect the survival of honey bees and have no potential sublethal effect in controlled laboratory conditions or in field/semifield trials.*'

iv. A study (Pierre et al. 2003. Entomologia Experimentalis et Applicata 108:159) carried out on honey bees feeding on field-grown Basta resistant rapeseed containing the pat gene, showed no difference in the bee behaviour and foraging activity on the transgenic and non-transgenic plants. The bar gene used in GE mustard encodes the same protein as the pat gene (phosphinothricin acetyltransferase). The PAT and the BAR proteins are functionally equivalent and have been shown to have similar substrate specificity, therefore, the two proteins are equally safe.

v. Another study (Huang et al. 2004. J. Eco. Entomol 97:1517) on the impacts of transgenic canola pollen on the survival and development of worker honey bees has concluded that 'transgenic canola pollen does not have adverse effects on honey bee development and that the use of transgenic canola does not pose any threat to honey bees'.

vi. A study from China has reported *Bacillus amyloliquefaciens* to be the most prevalent bacterial species in the 'Honey stomach' of the honey bee *Apis mellifera* –the bacteria from which the *barnase* and *barstar* genes have been sourced for developing GE rapeseed and mustard lines.

vii. The biosafety studies carried out by CGMCP on GE mustard include observations on the effect of GM mustard on beneficial insects including honey bees. The data were recorded during the BRL-1 and BRL-II trials conducted over three growing seasons (2010-11, 2011-12, and 2014-15) at multiple locations. The data showed that the visitation of bees to the transgenic lines and their non-transgenic comparators is similar.

viii. The male-sterile lines had seed set equivalent to their normal comparator lines indicating that the honey bees frequent the GE male sterile (MS) and restorer (RF) lines, and their normal comparator lines without any preference or discrimination.

ix. The expression studies carried out by the developers have shown that the pollen of the two GE parents and the hybrid transgenic lines does not contain any *Barnase* or the *Barstar* protein. Only the *Bar* protein is present in the pollen of the barstar line EH-2 modbs 2.99 and hybrid DMH-11 at very low levels. In the hybrid DMH-11 which will be grown in the farmers' fields, the detectable level of the *Bar* protein is ~0.26 ug/mg of total protein - which is very low. Such low levels of the *Bar* protein in the pollen are not going to have any effect on bee foraging or on the quality of honey produced as the bar protein has a history of safe use and is demonstrated to have no toxic or allergenic properties.

CGMCP submitted to the Committee that no additional studies are required and requested to consider environmental release of transgenic mustard lines and hybrid DMH 11, and grant permission for:

i. Growing and multiplication of mustard (*B. juncea*) parental lines containing event bn 3.6 (*bar::barnase* genes) and event modbs 2.99 (*bar::barstar* genes) for hybrid seed production.

ii. Producing seed of mustard hybrid DMH-11 using the parental lines Varuna bn 3.6 and EH-2 modbs 2.99 for cultivation by the farmers.

iii. Use of the two events - bn 3.6 and modbs 2.99 for introgressing the *bar::barnase* and *bar::barstar* genes into new sets of parental lines to develop the next generation of hybrids with higher yields, disease resistance, and quality traits.

Decision:

The Committee deliberated on the proposal and decided to constitute an Expert Committee under GEAC for examining the claim of CGMCP, University of Delhi in respect of availability of adequate evidence about impact of transgenic mustard on honey bees and other pollinators based on the comments received from DBT and DARE in order to assess the need for conducting field demonstration studies on honey bees and other pollinators.

It was decided that the composition of this Expert Committee under GEAC will be the same as that decided in 145th GEAC for examining the dossier for environmental release of Bollgard II Roundup Ready Flex Cotton. Further, it was also decided to co-opt two more expert members in this Expert Committee under GEAC, namely, Dr. K. C. Bansal and Dr. S. J. Rahman.

Accordingly, the final composition of this Expert Committee under GEAC, for examining the claim of CGMCP, University of Delhi in respect of availability of adequate evidence about impact of transgenic mustard on honey bees and other pollinators to assess the need for conducting field demonstration studies on honey bees and other pollinators, 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, will be as below:

i.	**Dr. Sanjay Kumar Mishra** Scientist H, Department of Biotechnology	Chairman
ii.	**Dr. Ashok Kumar Singh** Director, Indian Agricultural Research Institute	Member
iii.	**Dr. D. K. Yadav** ADG(Seeds), Crop Science Division, ICAR	Member
iv.	**Dr. A. H. Prakash** Project Coordinator (Cotton Improvement) and Head, AICRP on Cotton ICAR-Central Institute for Cotton Research	Member
v.	**Dr K. Annapurna** Former Head, Division of Microbiology ICAR-Indian Agricultural Research Institute	Member
vi.	**Dr. Nitin K. Jain** Scientist F, Department of Biotechnology	Member
vii.	**Dr. S. J. Rahman** Senior Professor & Univ. Head of Entomology, Department of Entomology: College of Agriculture, Prof. Jayashankar Telangana State Agricultural University (PJTSAU)	Member
viii.	**Dr. K. C. Bansal** Secretary, National Academy of Agricultural Sciences	Member
ix.	**Dr. Abhilasha Singh Mathuriya** Scientist D, Ministry of Environment, Forests and Climate Change	Member Secretary

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 applicant made a detailed presentation before the Committee. The Committee was informed that ICAR-Central Potato Research Institute (CPRI), Shimla intends to 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*) to evaluate resistance to late blight pathogen *Phytophthora infestans* during 2022 at seven regional stations of the CPRI viz. Shimla, Jalandhar, Gwalior, Kufri, Modipuram, Shillong, and Ooty.

This application was considered and recommended by the Review Committee on Genetic Manipulation (RCGM) in its 231st meeting held on 28.04.2022, vide RCGM Letter No. BT/IBKP/081/2020 dated 10.05.2022.

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

Decision:

The proposal of M/s ICAR-Central Potato Research Institute (CPRI), Shimla seeking permission to 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 Headquarters, Shimla and ICAR-CPRI regional station, Kufri was recommended by the committee subject to the following conditions:

i. The applicant shall fulfill all the conditions as stipulated in RCGM Letter No. BT/IBKP/081/2020 dated 10.05.2022.
ii. The applicant shall adhere with the conditions and/or recommendations as per RCGM Letter No. BT/IBKP/081/2020 dated 10.05.2022, RARM Plan shared by RCGM, and Government of Himachal Pradesh Letter No. STE(BT)/Tech (8)/2002-475 dated 20.06.2022.
iii. The applicant shall share details of the trial site as required under part G of the Guidelines and SOPs for Confined Field Trials of regulated GE plants, 2008 including ownership of trial site.
iv. The BRL-I confined field trial sites proposed by the applicant should be biodiversity hotspot.
v. The applicant shall share information regarding confirmed availability of isolation distance, as prescribed in the Risk Assessment and Risk Management Plan prepared by RCGM, before the start of the trial.
vi. The applicant shall share information regarding name of the lead scientist responsible for each trial, as well as expected date of sowing, before the start of the trial.
vii. The results of the field trials will also be shared with State Biodiversity Board and local panchayat Biodiversity Management Committees.

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

Action: RCGM & GEAC Secretariat

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

The applicant made a detailed presentation before the committee. The committee was informed that ICAR-National Institute for Plant Biotechnology, New Delhi intends to conduct Event Selection Trials (EST) of ten transgenic pigeon pea lines expressing *Cry2Aa / Cry1AcF* gene (*Cry2Aa* Lines: Event 7, Event 10, Event 12, Event 13, and Event 14; *Cry1AcF* Lines: Event 19, Event 22, Event 24, Event 25 and Event 26) at IARI, New Delhi during cropping season July, 2022 to April, 2023.

This application was considered and recommended by the Review Committee on Genetic Manipulation (RCGM) in its 199th meeting held on 04.02.2021, vide Letter No. BT/IBKP/347/2020 dated 25.02.2021.

The applicant has obtained No Objection Certificate (NOC) for conducting Event Selection Trials from the Government NCT of Delhi vide Letter No. F(1)/NOC of GE/JDA/2021-22/1482 dated 22.07.2022.

Decision:

The proposal of National Institute for Plant Biotechnology, New Delhi to conduct Event Selection Trials of ten transgenic pigeon pea lines expressing *Cry2Aa/ Cry1AcF* genes (*Cry2Aa* Lines: Event 7, Event 10, Event 12, Event 13, and Event 14; *Cry1AcF* Lines: Event 19, Event 22, Event 24, Event 25 and Event 26) at IARI, New Delhi during cropping season July, 2022 to April, 2023 was recommended subject to the condition that applicant will perform the trials as per extant rules/guidelines/regulations as well as RARM Plan shared by RCGM; and will adhere with the recommendations of Government of NCT of Delhi Letter No. F(1)/NOC of GE/JDA/2021-22/1482 dated 22.07.2022 and RCGM Letter No. BT/IBKP/347/2020 dated 25.02.2021.

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

Action: RCGM & GEAC Secretariat

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

6.1 M/s Boehringer Ingelheim India Private Ltd., Mumbai for marketing of Prevexxion RN recombinant veterinary vaccine.

The applicant made a detailed presentation before the Committee. The Committee was informed that the proposal was initially considered in 139th meeting of GEAC and re-considered in 140th meeting of GEAC held on 28.07.2020 wherein the import of Marek's Disease Vaccine, Serotype 1, Live Herpesvirus Chimera (Prevexxion RN) veterinary vaccine from USA was recommended 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) 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 submitted test reports of 3 batches issued by ICAR-IVRI vide Letter F.STD/QC/VT/2021-22 dated 12.07.2021, NOC from the Department of Animal Husbandry and Dairying vide Letter No. K-11057/47/2021-LH-Part I dated 22.03.2022, and Permit Letter No. 12-02/Boehringer/19-VD dated 10.05.2022 from the Drugs Controller General (India), CDSCO for import of the subject vaccine.

Decision:

After deliberations, the proposal of M/s Boehringer Ingelheim India Private Ltd., Mumbai for import of 1,00,000 vials per annum, of Marek's Disease Vaccine, Serotype 1, Live Herpesvirus Chimera (Prevexxion RN) recombinant veterinary vaccine for marketing in the country was recommended by the committee as per batch test reports issued by ICAR-IVRI *vide* Letter F.STD/QC/VT/2021-22 dated 12.07.2021, NOC from the Department of Animal Husbandry and Dairying vide Letter No. K-11057/47/2021-LH-Part I dated 22.03.2022, and Permit Letter No. 12-02/Boehringer/19-VD dated 10.05.2022 from the Drugs Controller General (India), CDSCO.

Action: GEAC Secretariat

6.2 M/s Boehringer Ingelheim India Private Ltd., Mumbai for marketing of Vaxxitek HVT+IBD+ND recombinant veterinary vaccine.

The applicant made a detailed presentation before the Committee. The Committee was informed that the proposal was initially considered in 144th meeting of GEAC held on 22.02.2022 wherein the import of Bursal Disease-Marek's Disease-Newcastle Disease Vaccine, serotype 3, Live Marek's Disease Vector (Vaxxitek HVT+IBD+ND) recombinant veterinary vaccine from USA was recommended 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) 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 submitted test reports of 3 batches issued by ICAR-IVRI vide Letter No. F.STD/QC/VT/2021-22 dated 23.11.2021, NOC from the Department of Animal Husbandry and Dairying vide Letter No. K-11057/47/2021-LH-Part I dated 22.03.2022, and Permit Letter No. 12-18/Boehringer/2020-VD dated 29.06.2022 from the Drugs Controller General (India), CDSCO for import of the subject vaccine.

Decision:

After deliberations, the proposal of M/s Boehringer Ingelheim India Private Ltd., Mumbai for import of 10,000 vials per annum, of Bursal Disease-Marek's Disease-Newcastle Disease Vaccine, serotype 3, Live Marek's Disease Vector (Vaxxitek HVT+IBD+ND) recombinant veterinary vaccine for marketing in the country was

recommended by the Committee as per batch test reports issued by ICAR-IVRI vide Letter No. F.STD/QC/VT/2021-22 dated 23.11.2021, NOC from the Department of Animal Husbandry and Dairying vide Letter No. K-11057/47/2021-LH-Part I dated 22.03.2022, and Permit Letter No. 12-18/Boehringer/2020-VD dated 29.06.2022 from the Drugs Controller General (India), CDSCO.

Action: GEAC Secretariat

Agenda Item No. 7: Additional Items for consideration

7.1 M/s Pioneer Hi-Bred Private Limited, Hyderabad for extension of permission to store the TC1507×MON810 and MON810 transgenic maize seeds.

The applicant made a detailed presentation before the Committee. The Committee was informed that in 142nd meeting of GEAC held on 11.05.2021, the extension of permission was granted to store the TC1507×MON810 and MON810 transgenic maize seeds till November 2021, based on the earlier recommendations of RCGM. This application was considered and recommended by the Review Committee on Genetic Manipulation (RCGM) in its 226th meeting held on 17.02.2022, vide Letter No. BBT/IBKP/031/2019 dated 04.03.2022.

It was informed that the applicant intends to store the transgenic seeds till November 2023 for any possible future use in BRL trials. The stored quantity of transgenic maize hybrids viz. 30B07Y and P3501Y expressing event MON-00810-6 (MON810) is 5 Kg each. The quantity of transgenic maize hybrids viz. 30B07YH and P3501YH expressing stacked events DAS-01507-1 (TC1507) x MON-00810-6 (MON810) – 5.435 Kg and 6.195 Kg, respectively.

Decision:

Based on the recommendation of RCGM vide Letter No. BBT/IBKP/031/2019 dated 04.03.2022, the proposal of M/s Pioneer Hi-Bred Private Limited, Hyderabad for extension of permission to store the TC1507×MON810 and MON810 transgenic maize seeds till November 2023, as per below inventory, was recommended by the Committee.

Name of the hybrid	Event(s) expressed	Quantity being stored
P3501YH	TC1507 x MON810	6.195 Kg
30B07YH	TC1507 x MON810	5.435 Kg
P3501Y	MON810	5.000 Kg
30B07Y	MON810	5.000 Kg

Action: GEAC Secretariat

7.2 M/s Dow AgroSciences India Private Limited, Hyderabad for extension of per mission to store the TC1507 transgenic maize seeds.

The applicant made a detailed presentation before the Committee. The Committee was informed that in 142nd meeting of GEAC held on 11.05.2021, the extension of permission was granted to store the TC1507 transgenic maize seeds till November 2021 was granted, based on earlier recommendations of RCGM. This application was considered and recommended by the Review Committee on Genetic Manipulation (RCGM) in its 226th meeting held on 17.02.2022, vide Letter No. BBT/IBKP/041/2019 dated 04.03.2022.

It was informed that the applicant intends to store the transgenic seeds till November 2023 for any possible future use in BRL trials. The stored quantity of transgenic maize hybrids viz. TC-1 and TC-3 expressing event DAS-01507-1 (TC1507) is 18.172 Kg and 16.885 Kg, respectively.

Decision:

Based on the recommendation of RCGM vide Letter No. BBT/IBKP/041/2019 dated 04.03.2022, the proposal of M/s Dow AgroSciences India Private Limited, Hyderabad for extension of permission to store the TC1507 transgenic maize seeds till November 2023, as per below inventory, was recommended by the Committee.

Name of the hybrid	Event(s) expressed	Quantity being stored
TC-1	TC1507	18.172 Kg
TC-3	TC1507	16.885 Kg

Action: GEAC Secretariat

7.3 M/s International Health Management Associates (IHMA), Gurugram for No Objection Certificate (NOC) to access bacterial isolates for routine in vitro surveillance studies.

The applicant made a detailed presentation before the Committee. The Committee was informed that the applicant intends to access 18,000 microorganisms from human clinical samples in India and export it to USA and Europe for routine *in-vitro* surveillance studies, and has approached GEAC based on the directions of National Biodiversity Authority (NBA), Chennai.

It was further informed that in August 2020, the proposal of M/s IHMA Europe submitted to NBA for accessing 15,000 microorganisms from human blood samples was accepted by the competent authority of NBA and an agreement was signed in March 2021 granting approval for four years. Subsequently, it was learned by NBA that Human Microbiome is highly regulated and applicants have to obtain the approval of Indian Council for Medical Research, Ministry of Health and Family Welfare. Approval granted to IHMA, Europe has been revoked by NBA. Further, NBA referred the case to an Expert Committee constituted under the Chairpersonship of Joint Secretary, Department of Health and Research, MH&FW along with members from the DBT, CCMB, CDFD. The Expert Committee decided that NBA shall instruct the applicant to provide the approvals of the (i) Institutional Ethics Committee of the Hospitals of the (ii) Institutional Biosafety Committee (iii) Health Ministry Screening Committee of the Ministry of Health and Family Welfare, (iv) Genetic Engineering Appraisal Committee of MoEF&CC.

The applicant has submitted that the proposal does not involve in any large-scale use of hazardous microorganisms/ recombinants in industrial production and does not have any in-house research program for the development of newer antibiotics for profit-making with the proposed bacterial isolates to be collected during the study period. The bacterial isolates are being accessed for non-commercial laboratory testing.

Decision:

After detailed deliberations, the Committee was of the view that the claim made by applicant in respect of non-hazardous nature of accessed microorganisms should be ascertained by Indian Council for Medical Research (ICMR), Ministry of Health and Family Welfare. Further in case the claim made by the applicant is sustained by ICMR, there would be no requirement of GEAC approval and NBA may be informed accordingly. In case ICMR does not concur with the claim made by applicant regarding non-hazardous nature of accessed microorganisms, the matter may be taken up in the GEAC meeting. ICMR may also be requested to forward its comments in regard to processing of the application, if needed.

Action: GEAC Secretariat

7.4 Discussion on No Objection Certificate (NOC) from State Governments for conduct of confined field trials.

The Committee was informed that pursuant to the Hon'ble Supreme Court Order dated 01.05.2006 in the Aruna Rodrigues & Ors. vs UoI & Ors. Case, the field trials of Genetically Modified Organisms (GMOs) including GE Crops are conducted only with the approval of the GEAC.

The GEAC in its 111th meeting held on 06.07.2011 took a decision to seek NOC from the State Government(s) before according permission for conducting Confined Field Trails. Subsequently, in the 130th GEAC meeting held on 11.08.2016 it was decided that a maximum period of 90 days should be given to State Governments to give their consent for conduct of confined field trials failing which it should be deemed to be considered as agreed. In the same GEAC meeting (11.08.2016), it was also decided that since Event Selection Trials (ESTs) are conducted strictly within the institutional premises, the clause of NOC to be removed for approvals given to applicants for conduct of event selection trials.

However, since 2020, the GEAC consider the proposals of Confined Field Trials of various GM crops only after obtaining NOC from the concerned State Governments.

It was further informed that the proposal placed by Department of Biotechnology for establishment of Notified Field Trial Sites (NFTS) to conduct confined field trials of GE Crops was recommended by GEAC in its 140th meeting held on 28.07.2020.

Decision:

After detailed deliberations, the committee decided to exempt the requirement of NOC from the State Government(s) for conducting Event Selections Trials, as previously recommended in 130th GEAC meeting held on 11.08.2016, since they are conducted strictly within the institutional premises and under controlled conditions.

For other Confined Field Trials, including BRL-I and BRL-II trials, the Committee decided that:

i. If the proposed confined field trial site is a Notified Field Trial Site (NFTS) as per GEAC approved proposal for establishment of NFTS for conducting confined field trials of GE Crops in its 140th meeting held on 28.07.2020, then in such instances, the proposals for confined field trials will be considered by GEAC with out any requirement of NOC from the State/UT Government(s).
ii. 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 States/UTs where the proposed confined field trial sites of each application are situated, requesting them to communicate their views/comments, if any, within 60 days of receipt of GEAC Secretariat letter. After 60 days, GEAC Secretariat will invite concerned State(s)/UT(s) Additional Chief Secretary/Principal Secretary (Agriculture) or their nominee as a Special Invitee and consider the application for detailed deliberations regarding recommendation of confined field trials based on views/ comments, if any, received from the State/UT Government(s).

Action: GEAC Secretariat

Agenda Item No. 8: Any other Item with the permission of the Chairman

8.1 Clarification regarding requirement for import of alfalfa hay from USA.

The Committee was informed that a letter has been received from Plant Protection Division, Department of Agriculture and Farmers Welfare (DA&FW). The DA&FW is in receipt of request from USA for export of alfalfa hay for the purpose of animal feed to India.

Food Safety and Standards Authority of India (FSSAI), vide its Order No. 1-1764/FSSAI/Imports/2018(Part-1) dated 21.08.2020, has decided that every consignment of imported food products mentioned in its Annexure-I shall be accompanied with a Non-GM origin cum GM free certificate issued by Competent National Authority of the exporting country. The Annexure-I of the said FSSAI order specifies 24 food products, one of which is Alfalfa.

DA&FW approached FSSAI and has obtained official clarification from FSSAI that the Non-GM origin cum GM free certificate as per FSSAI order dated 21.08.2020 is not required if alfalfa hay is being imported for animal feed purpose. DA&FW has sought official clarification from GEAC to further proceed in granting market access of this commodity to USA

Decision:

After detailed deliberations, the Committee was of the view that the following comments may be provided to Department of Agriculture and Farmers Welfare (DA&FW):

i. As per Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/ Genetically Engineered Organisms or Cells, 1989 (Rules 1989); GEAC is responsible for recommending proposals for import of any hazardous microorganisms or genetically engineered organisms/substances or cells only.

ii. If alfalfa hay being imported does not contain any Genetically Modified Organisms (GMOs) or is derived from GMOs, then the Rules, 1989 are not applicable.

iii. If alfalfa hay being imported contains any GMOs or is derived from GMOs, then taking cognizance of the Hon'ble Supreme Court judgement dated 11.08.2017 for W.P. (C) No. 173/2006, such proposals for import of substances containing GMOs or derived from GMOs cells for the purpose of animal feed has forwarded to Food Safety and Standards Authority of India (FSSAI) for necessary action.

Action: GEAC Secretariat

The meeting ended with a vote of thanks to the Chair, Co-Chair, Vice-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	**11.**	**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	**12.**	**Dr. P.K. Dass** Department of Anatomy LHMC & Associated hospitals New Delhi- 110 001
3.	**Ms. Rita Khanna** Advisor, MoEFCC Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jorbagh road, Aliganj, New Delhi- 110003	**13.**	**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	**14.**	**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	**15.**	**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	**16.**	**Dr. Geeta Jotwani** Scientist G Indian Council of Medical Research (ICMR) Ministry of Health and Family Welfare Ramalingaswami Bhavan, Ansari Nagar, New Delhi—110029
7.	**Dr. H. K. Sharma** Director, National Institute of Technology, Agartala, Tripura- 799 046	**17.**	**Dr. Dinkar M. Salunkhe** Director, International Centre for Genetic Engineering and Biotechnology New Delhi-110 067

8.	**Shri V.P. Yadav** Scientist F Central Pollution Control Board Parivesh Bhawan, East Arjun Nagar, Delhi-110 032	**18.**	**Dr. Sanjeev Khosla** Director, CSIR-Institute of Microbial Technology, Chandigarh- 160 036
9.	**Dr. J. P. Shukla** Scientist, CSIR-Advanced Materials and Process Research Institute, Bhopal- 462 026	**19.**	**Sh. Subhash Chand** Joint Director (Chemistry), Secretariat of Central Insecticides Board & Registration Committee (CIB&RC), Directorate of Plant Protection, Quarantine &Storage (Representative of Dr. J.P. Singh, Plant Protection Adviser(PPA) Directorate of Plant Protection, Quarantine & Storage, NH IV, Faridabad-121001. New Delhi)
10.	**Dr. U. S. N. Murthy** Director, National Institute of Pharmaceutical Education and Research, Guwahati- 781 101		
	Member who did not participate		
1.	**Dr. P. Suprasanna** Scientific Officer H (Retd.) Biosciences group BARC, Mumbai-400085	**2.**	**Ms. Shruti Singh** Joint Secretary, IPR, Department for Promotion of Industry and Internal Trade, Udyog Bhawan, New Delhi 110011
3.	**Dr. Vinay K. Nandicoori** Director, CSIR-Centre for Cellular & Molecular Biology, Hyderabad - 500 007		
	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		