## MINUTES OF THE 148<sup>th</sup> MEETING OF THE GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 31.01.2023

The 148<sup>th</sup> meeting of the Genetic Engineering Appraisal Committee (GEAC) of the Ministry of Environment, Forest and Climate Change (MoEF&CC) was held on 31.01.2023 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 also informed that four members have been co-opted in the Committee, namely, Drugs Controller General of India (DCGI); Director, ICAR-Institute of Veterinary Research Institute (IVRI); CEO, Food Safety and Standards Authority of India (FSSAI); and Dr. Alka Rao, Principal Scientist, CSIR-Institute of Microbial Technology (IMTECH). However, nomination of Shri Sunil Kumar Bakshi, Head Regulation has been received as a representative of FSSAI. After brief introductions, the Member Secretary, GEAC was requested to start the discussion on agenda items.

### Agenda Item No. 1: Leave of absence

Six members communicated their inability to attend the 148<sup>th</sup> meeting of GEAC, namely Dr. Vinay K. Nandicoori, Dr. Alka Rao, Dr. P. Suprasanna, Dr. Rekha Singhal, Dr. J. P. Singh, and Shri Sunil Kumar Bakshi. Further, Ms. Shruti Singh, Dr. Dinkar M. Salunkhe, Dr. J.P. Shukla and Dr. Geeta Jotwani did not attend the meeting.

#### **Decision:**

Absence of members who could not attend the meeting was noted.

**Action: GEAC Secretariat** 

### Agenda Item No. 2: Confirmation of minutes of the 147th GEAC meeting

Member Secretary, GEAC mentioned the minutes of the 147<sup>th</sup> GEAC meeting and requested the Members to provide comments, if any. Members were further requested to confirm the minutes.

### **Decision:**

Members confirmed the minutes of the 147<sup>th</sup> GEAC meeting.

### Agenda Item No. 3: Action taken report on the decision taken in the 147th GEAC meeting

Member Secretary, GEAC briefed about the action taken on the decisions at the 147<sup>th</sup> meeting of GEAC. He informed that letters communicating GEAC decisions had been issued to applicants.

### **Decision:**

The Committee noted the actions taken by the Secretariat.

**Action: GEAC Secretariat** 

Agenda Item No. 4: Applications related to Confined Field Trials of GE crops (Event Selection/ BRL-I/ BRL-II Trials)

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

The Committee was informed that the applicant intends to conduct BRL-I trial (1st year) of GE cotton hybrids containing Event 18L-5-3 expressing cry2Ai gene for resistance against Pink Bollworm during Kharif season 2023 at five locations, namely, Janwada (Telangana), Jalna (Maharashtra), Akola (Maharashtra), Junagadh (Gujarat), and Hisar (Haryana). This application was considered and recommended by RCGM in its 224<sup>th</sup> meeting held on 20.01.2022, vide Letter No. BT/IBKP/068/2020 dated 08.02.2022.

Taking cognizance of decision taken at Agenda item 7.4 of 146<sup>th</sup> GEAC meeting held on 25.08.2022 regarding requirement of NOCs from the concerned State Government(s), OM dated 12.10.2022 was sent to the concerned States, namely, Gujarat, Haryana, Maharashtra, and Telangana requesting them to communicate their views/comments within 60 days. The same was also placed for information before the Committee in 147<sup>th</sup> GEAC meeting under Agenda Item No. 8.1.

The applicant has obtained NOC to conduct BRL-I trials from the Government of Haryana, vide Memo No. 721/ADO (Seed) dated 17.11.2022. The comments/views from other concerned State Government(s) were not received on the proposal within the stipulated time. Further, the concerned States were invited vide OM dated 24.01.2023 for participation in the 148<sup>th</sup> meeting of GEAC for consideration of the proposal.

The Committee was informed that in view of the OM dated 24.01.2023, only Government of Telangana has nominated Sri Hanumant K Zendage IAS, Special commissioner of Agriculture for in-person participation in the meeting.

The applicant made a detailed presentation before the Committee. The Committee was informed that the Event 18L-5-3 expressing cry2Ai gene was selected given its consistent performance in in-vitro & in-planta bio-assays as well as in event selection trials conducted in Kharif 2019. Hybrids containing Event 18L-5-3 are being proposed for testing in 1<sup>st</sup> year of confined field trials (BRL-1) at the following locations:

- a. Janwada, Hyderabad, Telangana
- b. Jalna, Maharashtra
- c. Barwala, Hissar, Haryana
- d. Akola (SAU), Maharashtra
- e. Junagadh (SAU), Gujarat

Agronomic evaluation/ studies planned during BRL-I trial (1st year) are as below:

- a. Damage to fruiting bodies as result of PBW infestation
- b. Number of PBW larvae recovered per 5 plants/entry
- c. Protein expression and detection studies at plant level
- d. Seed cotton yield
- e. Boll number, weight, size and shape
- f. Total duration of crop
- g. Plant height and architecture

Biosafety evaluation/studies planned during BRL-I trial (1st year) are as below:

- a. Acute oral safety in rats & mice
- b. Dermal irritation study in rabbits
- c. Subchronic 90-day feeding study in rats
- d. Baseline susceptibility study
- e. Compositional studies
- f. Protein expression studies
- g. Studies on target and non-target organisms
- h. Inter- and intra-specific crossability study
- i. Weediness and aggressiveness studies
- j. Study on soil microrganisms and soil fauna

The representative of Government of Telangana, Sri Hanumant K Zendage, informed that the proposal for conduct of BRL-I trials is under consideration by the State Government of Telangana. Before any decision/view is taken with regard to conduct of confined trials in Telangana, consent of Higher/ Competent Authorities within the State Government is required. Accordingly, the Government of Telangana sought additional time to arrive at some consensus decision in this regard.

### **Decision:**

Based on the recommendation of RCGM and NOC received from Government of Haryana, the proposal of M/s Bioseed Research India, Hyderabad to conduct BRL-I trial (1st Year) of GE cotton hybrids containing Event 18L-5-3 expressing cry2Ai gene for resistance against Pink Bollworm during Kharif season 2023 at Hisar, Haryana was recommended by the Committee subject to the following conditions:

i. The applicant shall adhere with the conditions and/or recommendations as per RCGM Letter No. BT/IBKP/068/2020 dated 08.02.2022 and Government of Haryana Memo No. 721/ADO (Seed) dated 17.11.2022.

- ii. 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.
- iii. The BRL-1 confined field trials should be conducted at the biodiversity hotspot locations in the State.
- iv. The applicant shall share information regarding confirmed availability of isolation distance, land use and its ownership, before the start of the trial.
- v. 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.
- vi. The results of the field trials will also be shared with State Biodiversity Board and local panchayat Biodiversity Management Committees.

Further, taking into consideration the remarks of Special commissioner of Agriculture, Government of Telangana in cognizance to decision taken in 146<sup>th</sup> GEAC meeting held on 25.08.2022; the Committee was of the view that additional time of 30 days be given to the concerned States where the proposed confined field trial sites are situated, namely, Telangana, Gujarat, and Maharashtra in order to communicate their views/comments, if any, on the proposal. After the stipulated time, the Additional Chief Secretary/Principal Secretary (Agriculture) of concerned States or their nominee will be invited in the next/ 149<sup>th</sup> GEAC meeting wherein the proposal for conduct of trials at the proposed sites will be taken up for consideration by the Committee.

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: GEAC & RCGM 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 applicant made a detailed presentation before the Committee. The Committee was informed that the applicant intends to conduct 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).

The vaccine under investigation, TDV, consists of 1 molecularly-characterized, attenuated dengue serotype 2 virus strain, plus 3 recombinant dengue virus strains expressing surface antigens corresponding to dengue serotypes 1, 3 and 4. The dengue serotype 2 strain (TDV-2)

is based upon the attenuated laboratory-derived DENV-2 virus strain, originally isolated at Mahidol University, Bangkok, Thailand and generated by 53 serial passages in primary dog kidney (PDK) cells (DENV-2 PDK-53). The recombinant strains were engineered by substituting the structural genes, premembrane (prM) and envelope (E), of TDV-2 with the prM and E genes from the DENV-1 16007, DENV-3 16562 or DENV-4 1036 virus strains, respectively.

Data from completed phase 1 and phase 2 clinical trials in humans have shown satisfactory reactogenicity, safety and immunogenicity profiles for Takeda's TDV in healthy adults in non-endemic areas as well as in healthy adults and children in endemic areas in Asia and Latin America. Further, it was also informed that the level of TDV viremia observed in clinical trials is lower than the level required for DENV transmission to mosquitoes. Magnitude of viremia is similar for attenuated TDV and TDV with a reversion. During clinical observations, it was observed that a fraction (~30%) of the subjects immunized with TDV develop viremia post vaccination (mostly TDV-2), however, viremia levels is 1000X lower than the minimum to infect mosquitos.

The purpose of phase 3 clinical trial is to generate immunogenicity and safety data in the Indian population with a view of supporting future licensure of TDV in India.

The TDV will be administered as 2 doses, given 3 months apart, to participants/ subjects aged 4 to 60 years in India through subcutaneous route. A placebo has been chosen to maintain the double-blind trial design in the absence of a suitable active comparator for the age-range in this trial population. The placebo is normal saline (0.9% sodium chloride [saline] solution) for injection. The trial duration will be approximately 270 days (9 months) for each subject.

### **Decision:**

After due deliberations, the Committee was of the view 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) be forwarded to Review Committee on Genetic Manipulation (RCGM) for scrutiny. Further, the Drugs Controller General of India, Central Drugs Standard Control Organization (CDSCO) is also requested to share its comments in regard to processing of the proposal.

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

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

The Committee was informed that the application for import and pilot testing of genetically modified *Saccharomyces cerevisiae* GPY10138 strain (active dry yeast, trade name: SYNERXIA JADE ADY) for fuel ethanol production using grain-based fermentation technology was initially considered in the 147<sup>th</sup> meeting of GEAC held on 18.10.2022 wherein the applicant was 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. Further, the applicant in Letter dated 29.11.2022 has withdrawn the application for pilot testing indicating that adequate information regarding safe use of SYNERXIA JADE ADY is already available. Accordingly, the applicant intends to import and market SYNERXIA JADE ADY to ethanol manufacturing plants.

The applicant made a detailed presentation before the Committee. The Committee was informed that SYNERXIA® JADE ADY has been evaluated for biosafety aspects by US Environmental Protection Agency (US EPA), and was granted an approval through Microbial Commercial Activity Notice (MCAN) bearing reference number J-21-0010 on 03 May, 2021. As per framework for GRAS designation, specified by US FDA, companies have the option of conducting an expert assessment to determine whether an ingredient can be considered as GRAS. Accordingly, M/s Danisco India Private Limited (DIPL), a subsidiary company of IFF, has secured a third-party opinion from Dr. Michael W. Pariza, an internationally recognized expert in GRAS, who has confirmed that *Saccharomyces cerevisiae* GPY10138 strain is safe to use.

The applicant also informed that Dried Distillers Grains Soluble (DDGS), a by-product of ethanol productions, will be available for use as an animal feed ingredient in line with the existing practices. Fermentation and distillation process for production of ethanol production effectively ensures that yeast (*Saccharomyces cerevisiae*) cells are destroyed in the process itself. Yeast is killed at high temperatures as distillation occurs at temperature of 100-102° Celsius for 5-10 minutes. The inactivation of *S. cerevisiae* GPY 10138 has been compared with the wild type parental strain FerMax TM Gold (FG) and it was observed that the yeast strain is inactivated in heating for one minute at 70° C indicating that there is no live yeast in the residual left biomass after distillation.

### **Decision:**

After detailed deliberations, the proposal of M/s Danisco India Private Limited, Hyderabad for import of 2000 metric ton (2, 000, 000 Kgs) of SYNERXIA ® JADE ADY (Active Dried Yeast), per annum from USA and its marketing for ethanol production was recommended by the Committee subject to the condition that applicant shall ensure strict compliance of zero discharge of viable SYNERXIA ® JADE ADY yeast strain into the environment at any stage including import, transport, storage, handling, management etc.

The Committee also recommended that the firms, whomsoever using the imported genetically modified SYNERXIA ® JADE ADY (Active Dried Yeast) strains, has to obtain separate approval from GEAC for large scale manufacturing in accordance with Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017.

**Action: GEAC Secretariat** 

6.2 M/s Novozymes South Asia Pvt. Ltd., Bangalore for import and commercialization of Active dried yeast – Cellerity S 1.0 for the production of 2G bioethanol.

The applicant made a presentation before the Committee and informed that the genetically modified active dried yeast, Cellerity S 1.0, strain name is CIBTS1260-J132-F3 which is intended for import from USA can co-ferment both xylose and cellulose to ethanol with fast utilization of xylose, thereby enabling efficient conversion of biomass to 2G bioethanol. Whereas, traditional yeast cannot efficiently utilize xylose.

In Cellerity S 1.0, the genes inserted are Xylose isomerase gene (mgXI), Pentose transporter (GXF) Xylulokinase gene (XKS), Ribulose 5 phosphate epimerase (RPE1), Ribulose 5 phosphate isomerase gene (RKI1), Transketolase gene (TKL1), Transaldolase gene (TAL1). The product Cellerity S 1.0 was granted an approval by US Environmental Protection Agency (US EPA), bearing reference No. J-14-0021 Chemicals Determined Not Likely to Present an Unreasonable Risk Following Pre-Manufacture Notification Review.

### **Decision:**

The proposal of M/s Novozymes South Asia Pvt. Ltd., Bangalore for import of 2000 Kgs of Active dried yeast, Cellerity S 1.0, per annum, from USA and its marketing for the production of 2G bioethanol was recommended by the Committee subject to the condition that applicant shall ensure strict compliance of zero discharge of viable Cellerity S 1.0 yeast strain into the environment at any stage including import, transport, storage, handling, management etc.

The Committee also recommended that the firms, whomsoever using the imported genetically modified Cellerity S 1.0 (Active Dried Yeast) strains, has to obtain separate approval from GEAC for large scale manufacturing from in accordance with Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017.

# 6.3 M/s Biopestiphage Hindustan Pvt. Ltd., New Delhi for import of samples of bacteriophage based microbial biopesticide regulatory field trials and other scientific research/testing for registration at CIBRC.

The applicant made a presentation before the Committee and informed that microbial biopesticide product, XooPhage, that is intended for import contains bacteriophages that work against the rice pathogen *Xanthomonas oryzae*. The bacteriophages used in this microbial biopesticide product belong to the Order Caudovirales, family Myoviridae, group OP2-like bacteriophages and their scientific names are as below:

- a. Xanthomonas bacteriophage XOO1
- b. Xanthomonas bacteriophage XOO2
- c. Xanthomonas bacteriophage XOO3
- d. Xanthomonas bacteriophage XOO4
- e. Xanthomonas bacteriophage XOO5
- f. Xanthomonas bacteriophage XOO6

These bacteriophages are host specific, obligately lytic (lytic and non-temperate, unable for lysogenic life cycle, unable to integrate into the genome of the target bacterium), non-transducing (unable for specialized and generalized transduction, horizontal gene transfer) bacteriophages.

The product is intended to import for research testing and trials in Indian labs and bioefficacy field trials at the State Agriculture Universities in India. Some samples are also required to be submitted for DNA figure printing and accession number at the NBAIM, MAU as per CIB&RC requirement.

### **Decision:**

After deliberations, the Committee recommended that the proposal of M/s Biopestiphage Hindustan Pvt. Ltd., New Delhi for import of samples of bacteriophage based microbial biopesticide for registration at CIB&RC is forwarded to RCGM for further necessary action since RCGM is the Competent Authority approving import of GMOs/ hazardous microorganisms for the purpose of Research & Development in India.

**Action: GEAC Secretariat** 

# 6.4 M/s Centaur Pharmaceuticals Pvt. Ltd., Pune for import of Zein F4000C-Pharmaceutical Grade for use in pharmaceuticals dosage formulation.

The applicant made a presentation before the Committee and informed that M/s Centaur Pharmaceuticals Pvt. Ltd., Pune is a Contract Manufacturing Organisation for manufacturing and supply of pharmaceutical finished product to regulated market like US, Europe, Australia, Canada etc.

The product, Zein F 4000C Pharmaceutical Grade, is derived from genetically modified *Zea mays* (Maize/Corn) and will be imported from FloZein Products, USA. This product is intended for exclusive use as excipient/ ingredient in manufacturing of pharmaceuticals dosage

formulation, namely "Pyridostigmine Bromide 180mg Tablets", the product is owned by Rising Pharma Holdings Inc., USA. The pharmaceuticals dosage formulation, "Pyridostigmine Bromide 180mg Tablets" is an approved product by US Food and Drug Administration (bearing application number A205464) and is registered for marketing in USA only.

The applicant informed the Committee that they have obtained the License of Manufacturing from Food and Drugs Administration, Maharashtra vide License No. 25-PD/182 dated 23.08.2022. The pharmaceuticals formulation, "Pyridostigmine Bromide 180mg Tablets" manufactured by M/s Centaur Pharmaceuticals Pvt. Ltd., Pune will be exported completely to USA. Accordingly, no part of pharmaceuticals dosage formulation, "Pyridostigmine Bromide 180mg Tablets" will be diverted for sale in domestic/ India market.

### **Decision:**

After deliberations, the proposal of /s Centaur Pharmaceuticals Pvt. Ltd., Pune for import of 150 Kgs of Zein F4000C-Pharmaceutical Grade, per annum for use in pharmaceuticals dosage formulation "Pyridostigmine Bromide 180mg Tablets" was recommended by the Committee subject to the following conditions:

- i. The manufacturing of pharmaceuticals formulation, "Pyridostigmine Bromide 180mg Tablets" shall be as per the prescribed rules/guidelines/ procedures in place.
- ii. All aspects of manufacturing including management of residue and effluents should be implemented under the oversight of Licensing Authority, Food and Drugs Administration, Maharashtra.
- iii. The overall project should be implemented under the oversight of IBSC of the applicant with regular annual reports to RCGM.
- iv. The applicant will submit Environmental Risk Management and Safety Plan (ERMP) within 3 months, after approval to this Ministry;
- v. The applicant will submit compliance report on ERMP plan every 6 months to the concerned Regional Office of this Ministry;
- vi. It is obligated to ensure environmentally sound and safe management of any residue/discharge of the production process as per existing laws, rules, regulations applicable.
- vii. The records of generation, treatment, recycle/reuse and disposal of related to production process shall be maintained and submitted to concerned SPCB at regular intervals of twice in a year, on 15<sup>th</sup> October (for April-September) and 15<sup>th</sup> April for October to March).
- viii. The Regional Office of this Ministry shall monitor compliance of the stipulated conditions. The project authorities should extend full cooperation to the officer (s) of the Regional Office by furnishing the requisite data / information/monitoring reports.
- ix. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.
- x. The Ministry reserves the right to stipulate additional conditions if found necessary. The Company in a time bound manner shall implement these conditions.
- xi. The clearance granted to the project/activity is strictly under the provisions of the EIA Notification 2006 and its subsequent amendments. It does not tantamount/construe to

approvals/consent/permissions etc. required to be obtained or standards/conditions to be followed under any other Acts/ Rules/ Subordinate legislations, etc., as may be applicable to the project. The applicant shall obtain necessary permission as mandated under the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981, as applicable from time to time, from the State Pollution Control Board, prior to construction & operation of the project.

xii. The approval is subject to other statutory clearances.

The RCGM to examine and submit a Risk Assessment and Risk Management Plan to GEAC, which would be shared with applicant for compliance.

**Action: RCGM & GEAC Secretariat** 

## 6.5 M/s Zoetis India Limited, Mumbai submitting IVRI test reports for import and marketing of Bedinvetmab solution (Brand Name: Librela) for veterinary use only.

The Committee was informed that application for import of Bedinvetmab Solution for Injection 5mg/ml, 10mg/ml, 20mg/ml and 30mg/ml (Brand Name: Librela) for veterinary use was recommended in the 145th meeting of GEAC held on 27.07.2022 subject to the conditions "i. Applicant needs to inform the quantity of import per annum 30 days before import to the GEAC; ii. Initial 3 batches of the subject vaccine to be certified in ICAR-Indian Veterinary Research Institute (ICAR-IVRI), iii. 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. iv. 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 dated 27.01.2022 for import and marketing of Bedinvetmab Solution for Injection 5mg/ml, 10mg/ml, 20mg/ml and 30mg/ml (Brand Name: Librela). ICAR-IVRI vide Letter No. STD/QC/VT/Zoetis/2022-23 dated 28.07.2022 informed M/s Zoetis India Limited, Mumbai that testing/analysis of Lokivetmeb, Frunevetmab, Bedinvetmab cannot be done at ICAR-IVRI since they are not vaccine/diagnostic.

### **Decision:**

After deliberations, the Committee was of the view that the applicant shall be directed to obtain permission from the Drug Controller General of India (DCGI) as per the recommendations of the Task Force on Recombinant Pharma, 2005 (Mashelkar Recommendations) with respect to Import and marketing of recombinant pharma products in bulk/finished form where the end product is not a LMO (Protocol V).

### Agenda Item No. 7: Any other Item with the permission of the Chairman

## 7.1 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 the proposal was recommended in 146<sup>th</sup> GEAC Meeting held on 25.08.2022 for conduct of BRL-I trials during 2022 at two sites, namely ICAR-CPRI Headquarters, Shimla and ICAR-CPRI regional station, Kufri after applicant obtained NOC from Government of Himachal Pradesh. Further, the proposal was recommended in 147th GEAC Meeting held on 18.10.2022 for conduct of BRL-I trials during 2022 at ICAR-CPRI regional station, Shillong after applicant obtained NOC from Government of Meghalaya.

For both aforementioned recommendations, permit letter was to be issued by RCGM. However, the permit letter has not been issued yet by RCGM. Accordingly, RCGM vide email dated 13.01.2023 has requested to consider the request of M/s ICAR-CPRI for a change with respect to growing season 2022 in the 146<sup>th</sup> and 147<sup>th</sup> GEAC Decision, by permitting to conduct trials in 2023-24.

### **Decision:**

The Committee was of the view that the permit letter be issued by RCGM for the growing seasons 2023-24 while all other conditions as stipulated in 146<sup>th</sup> and 147<sup>th</sup> GEAC Decisions remains the same.

**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, Jor Bagh road, Aliganj, New Delhi- 110003	9.	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	10.	Scientist F, Central Pollution Control Board Parivesh Bhawan, East Arjun Nagar, Delhi- 110032	
3.	Ms. Rita Khanna Advisor, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jor Bagh road, Aliganj, New Delhi- 110003	11.	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)	
4.	Dr. Satyendra Kumar Director, CS-III Division Ministry of Environment, Forest and Climate Change, Jorbagh, New Delhi- 110003	12.	Dr. P.K. Dass Department of Anatomy LHMC & Associated Hospitals, New Delhi- 110 001	
5.	Dr. Nitin K. Jain Scientist–F and Member Secretary RCGM, Department of Biotechnology, C. G. O, Complex, Lodhi Road, New Delhi-110003	13.	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	14.	Dr. Sanjeev Khosla Director, CSIR-Institute of Microbial Technology, Chandigarh- 160 036	
7.	Dr. U. S. N. Murthy Director, National Institute of Pharmaceutical Education and Research, Guwahati- 781101	15.	Dr. Chaitanya Joshi Director, Gujarat Biotechnology Research Centre, Gandhinagar, Gujarat- 382 011	

8.	Dr. H. K. Sharma	16.	Dr. Triveni Dutt		
	Director,		Director,		
	National Institute of Technology,		ICAR-Indian Veterinary Research Institute		
	Agartala, Tripura- 799 046		(IVRI), Bareilly, Uttar Pradesh- 243122		
	Members who did not participate				
1.	Dr. P. Suprasanna	6.	Dr. Dinkar M. Salunkhe		
	Scientific Officer H (Retd.)		Director,		
	Biosciences group		International Centre for Genetic		
	BARC, Mumbai-400085		Engineering and Biotechnology		
			New Delhi-110 067		
2.	Dr. Vinay K. Nandicoori	7.	Shri Sunil Kumar Bakshi		
	Director,		Head, Regulation,		
	CSIR-Centre for Cellular & Molecular		Food Safety and Standards Authority of		
	Biology,		India, FDA Bhawan, Kotla, New Delhi -		
	Hyderabad - 500 007		110002		
3.	Dr. J. P. Shukla	8.	Dr. Rekha S. Singhal		
	Scientist,		Professor,		
	CSIR-Advanced Materials and Process		Food Technology,		
	Research Institute,		Institute of Chemical Technology,		
	Bhopal- 462 026		Mumbai- 400 019		
4.	Dr. Geeta Jotwani	9.	Dr. Alka Rao		
	Scientist G		Principal Scientist, Protein Science and		
	Indian Council of Medical Research		Engineering & Adjunct Associate		
	(ICMR),		Professor, GNR Protein Centre, CSIR-		
	Ministry of Health and Family Welfare		Institute of Microbial Technology (CSIR-		
	Ramalingaswami Bhavan, Ansari Nagar,		IMTECH), Sector 39-A, Chandigarh-		
	New Delhi—110029		160036		
5.	Dr. J.P. Singh	10.	8		
	Plant Protection Adviser(PPA),		Joint Secretary, IPR, Department for		
	Directorate of Plant Protection, Quarantine		Promotion of Industry and Internal Trade,		
	& Storage, NH IV, Faridabad-121001. New		Udyog Bhawan, New Delhi 110011		
	Delhi	Invit	too		
1.	Special Invitee    Swi Hannmant V Zandaga IAS				
1.	Sri Hanumant K Zendage IAS Special commissioner of Agriculture,				
	Government of Telangana				
	Officer from the Ministry				
1.	Dr. Abhilasha Singh Mathuriya				
1.	Scientist D, CS-III Division, Ministry of				
	Environment, Forest and Climate Change,				
	Jorbagh, New Delhi-110003				
	Jordagn, New Denn-110003	1			