PROCEEDINGS OF THE 138th MEETING OF THE GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 11.11.2019

The 138th meeting of the Genetic Engineering Appraisal Committee (GEAC) was held on November 11, 2019 in Brahmaputra Conference Hall, Ministry of Environment, Forest and Climate Change (MoEFCC), New Delhi under the Chairmanship of Shri. Ravi S. Prasad, Additional Secretary, MoEFCC and Chairman, GEAC, to consider the agenda items circulated to Members by email on 17.10.2019, and by hard copy. The list of participants is placed at **Annex-1.**

At the outset, Shri. Ravi S. Prasad, Chairman, GEAC ánd Ms. Richa Sharma, Co-Chair extended a warm welcome to all the members and thereafter, the agenda items were taken up as under:

Agenda Item No. 1: Leave of absence

Six Members communicated their inability to attend the 138th meeting of GEAC, namely Dr. K. Veluthambi, Dr. B. Venkateswarulu, Dr. P. Balasubramanian, Dr. P. Suprasanna, Dr. Geeta Jotwani and Dr. Usha Rao.

Decision:

Leave of absence was granted to the members who could not attend the meeting.

Action: GEAC Secretariat

Agenda Item No. 2: Confirmation of minutes of the 137thGEAC meeting

The 137th GEAC meeting minutes were circulated to all the members for comments and the comments received from members were duly incorporated.

Decision:

Members confirmed the proceedings of the 137thGEAC meeting.

Action: GEAC Secretariat

Agenda Item No. 3: Action taken report on the decisions taken in the 137th GEAC meeting

The Member Secretary, GEAC briefed about the action taken on the decisions taken in the 137th meeting of GEAC and stated that letters were issued to all the concerned communicating the decisions taken in 137th meeting.

Decision:

The Committee has noted the compliance of actions taken by the Secretariat.

Action: GEAC Secretariat

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

4.1 Response to the query letter F. No. C-12013/04/2019-CS-III dated 23.04.2019 received on the application submitted for permission for production of Xylanase Enzyme from recombinant *Pichia pastoris* by M/s. Kaypeeyes Biotech Private Limited, Mysuru.

As per the decisions taken in the 137th meeting of the GEAC held on 20.03.2019, the applicant submitted the Environment Risk Management and Safety Plan (ERMP) and also made a presentation before the Committee. Further, RCGM approved the Risk Assessment and Risk Management Plan (RARMP). RCGM also stated that the IBSC of the applicant has expired on 21.08.2019. Therefore, the RCGM has requested the firm to constituted the IBSC at the earliest.

Decision:

The Committee has granted the permission for production of Xylanase Enzyme from recombinant *Pichia pastoris* by M/s. Kaypeeyes Biotech Private Limited, Mysuru subject to the following conditions:

a. Reconstitution of the IBSC which expired on 21st September 2019
b. Submission of compliance report on ERMP plan every 6 months to the Regional Office of the Ministry of Environment, Forest and Climate Change
c. The approval is subject to other statutory clearances.

Action: GEAC Secretariat

4.2 Response to the query letter F. No. C-12013/02/2019-CS-III dated 06.05.2019 received on application bearing No: RA/AB/GEAC/18/002 dated 10.01.2019 to grant permission to manufacture Phytase from *Pichiapastoris*by r-DNA related activity by M/s. Anthem Biosciences Pvt. Ltd., Bengaluru.

The applicant has withdrawn the application, therefore this was not considered in the meeting.

Action: GEAC Secretariat

4.3 Response to the query letter F. No. C-12013/03/2019-CS-III dated 06.05.2019 received on application bearing No: RA/AB/GEAC/18/001 dated 10.01.2019 to grant permission to manufacture Lipase from *Pichiapastoris* by r-DNA related activity by M/s. Anthem Biosciences Pvt. Ltd., Bengaluru.

The applicant has withdrawn the application, therefore this was not considered in the meeting.

Action: GEAC Secretariat

4.4 Response to the query letter F. No. C-12013/05/2019-CS-III dated 06.05.2019 received on application dated 25.02.2019 for environmental approval of clinical trial / Pharmaceutical Drug Derivd from LMO (BakersYeast–*Saccharomyces cerevisiae*) for conducting experiments at pilot plant in fermenters of 25000 liters capacity using yeast, to assimilate xylose extracted from lingo cellulosic biomass by M/s Kuantum Paper Limited.

As per the decisions taken in the 137th meeting of the GEAC held on 20.03.2019, the applicant submitted the Environment Risk Management and Safety Plan (ERMP) and also made a presentation before the Committee. Further, RCGM approved the Risk Assessment and Risk Management Plan (RARMP) and observed that the IBSC is constituted in the firm.

Decision:

The Committee has granted the permission for environmental approval of clinical trial / Pharmaceutical Drug Derived from LMO (Bakers Yeast–*Saccharomyces cerevisiae*) for conducting experiments at pilot

plant in fermenters of 25000 liters capacity using yeast, to assimilate xylose extracted from ligno cellulosic biomass by M/s Kuantum Paper Limited, Saila Khurd, Punjab subject to the following conditions:

a. Submission of compliance report on ERMP plan every 6 months to the Regional Office of the Ministry of Environment, Forest and Climate Change
b. The approval is subject to other statutory clearances.

Action: GEAC Secretariat

4.5 Application for Environmental approval of Clinical Trial/Pharmaceutical Drug derived from LMO (Transferrin for non-therapeutic use) by Richcore Life Sciences Pvt. Ltd., Bangalore.

The application submitted by M/s. Richcore Life Sciences Pvt. Ltd., Bangalore is for commercial production of recombinant Human Transferrin (rTRF) for non-therapeutic applications using *Pichia pastoris* expression system was deliberated at length by the Committee. After thorough examination of the application, the Committee agreed to seek additional information from the applicant on the following:

a. Environmental standards being maintained in the plant
b. Undertaking an Environmental Audit
c. Life cycle analysis of the product and process detailing critical steps at which probability of solid and liquid discharge into the environment (soil and water) exist and the proposed precautionary measures being taken for tackling the same, in case of unintended release into the environment.
d. Details on Effluent Treatment Plant (ETP) and Standards being maintained in the plant along with waste disposal strategy
e. GEAC to appoint an expert for review and monitoring of the plant/ project

The Committee also agreed to refer this application to Review Committee on Genetic Manipulation (RCGM) to examine and submit a Risk Assessment and Risk Management Plan (RARMP) for further examination and consideration by GEAC.

Decision:

I. The Committee deferred the application submitted by the applicant and sought additional information.
II. The Committee directed the Secretariat to forward these applications to RCGM for preparation of a RARM Plan.

Action: GEAC Secretariat

Agenda Item No. 5: Applications related to Import/ Export

5.1 Request for NOC from GEAC for import and market of Distemper Vaccine, Live Canarypox Vector (PUREVAX® FERRET DISTEMPER) under Rule 122A of Drugs & Cosmetic Rules, 1945: ANIMAL HEALTH PRODUCTS by M/s. Boehringer Ingelheim India Private Limited, Mumbai.

The application submitted by M/s. Boehringer Ingelheim India Private Limited, Mumbai is for import and marketing of Distemper Vaccine, Live Canarypox Vector (PUREVAX® FERRET DISTEMPER) under Rule 122A of Drugs and Cosmetic Rules, 1945: ANIMAL HEALTH PRODUCTS was deliberated at length by the Committee. The committee was of the view that the vaccines are to be used as per the purchase orders received from various departments and agencies.

Decision:

The Committee has agreed for import of Distemper Vaccine by M/s. Boehringer Ingelheim India Private

Limited, Mumbai based on the earlier decisions taken in the 130th meeting of the GEAC for import of Distemper Vaccine, for supply to various departments and agencies.

Action: GEAC Secretariat

Agenda Item No. 6: Additional Items for consideration/ information

6.1 Application for environmental approval of clinical trials / pharmaceutical Drug derived from LMO {Urease enzyme by recombinant DNA technology in *E. coli* for being a part of sorbent cartridge by M/s. Unique Biotech Limited, Hyderabad.

The Committee noted that the application submitted by M/s. Unique Biotech Limited, Hyderabad seeking permission for environmental approval of clinical trials / pharmaceutical Drug derived from LMO {Urease enzyme by recombinant DNA technology in E. coli for being a part of sorbent cartridge has not been recommended by RCGM and the pre-clinical toxicity studies of the applicant are still under examination of RCGM. Accordingly, the Committee deferred the application and directed the applicant to re-submit its application upon obtaining requisite clearances for its pre-clinical toxicity studies from RCGM for assessing the purity profile.

Decision:

The Committee deferred the request of the applicant and directed the applicant to re-submit its application after obtaining requisite clearances for its pre-clinical toxicity studies from RCGM.

Action: GEAC Secretariat

6.2 Application for environmental approval to carryout scale up of genetically modified *E.coli* BL21 (DE3) expressing recombinant liraglutide for development of rDNA products for healthcare and industrial use by M/s Levim Biotech, Chennai.

M/s. Levim Biotech, Chennai made a presentation before the Committee on scale up of genetically modified *E.coli* BL21 (DE3) from 50 liters to 200 liters expressing recombinant liraglutide for development of rDNA products for healthcare and industrial use. The applicant has also presented the ERMP plan and informed that the M/s Levim Biotech is situated in the Tidel Park, Chennai which has all the facilities required for treatment of discharge. Further, RCGM informed that the firm M/s Levim Biotech has obtained approval for the pre-clinical toxicity studies.

Decision:

The Committee has granted the permission to carryout scale up of genetically modified *E.coli* BL21 (DE3) expressing recombinant liraglutide for development of rDNA products for healthcare and industrial usage by M/s. Levim Biotech, Chennai subject to the following conditions:

a. Submission of Environmental Risk Management and Safety Plan within 3 months to this Ministry
b. Submission of compliance report on ERMP plan every 6 months to the Regional Office of the Ministry of Environment, Forest and Climate Change
c. The approval is subject to other statutory clearances.

Action: GEAC Secretariat

6.3 Application for Environmental approval of Clinical Trial/Pharmaceutical Drug derived from LMO {VP2 antigen as part of Gumbin VP2/ Quadractin VP2/ ND+IB+VP2 inactivated oil emulsion vaccines (VP2 antigen Subunit antigen vaccine against Infectious Bursal Disease Virus (IBDV).)} (Produces uniform & high antibody titre against very virulent IBD virus in poultry birds) for (To provide protection in poultry birds against very virulent IBD virus) by (Zydus Animal Health, A division of Cadila Healthcare Ltd, Ahmedabad).

The Committee discussed that this application comes under the Protocol –V (Import and marketing of Pharma Products derived from LMOs in bulk and/or Finished Formulations where the end product is not

a LMO) as per the Mashelkar Committee.

Decision:

Since the end product is non-LMO, the committee felt that the committee has no role in this application.

Action: GEAC Secretariat

6.4 Withdrawal of application for import of Soybean grain and oil from herbicide tolerant soybean (Event DAS-68416-4) for food and feed purpose by Dow Agro Sciences India Pvt. Ltd., Mumbai.

M/s. Dow Agro Sciences India Pvt. Ltd., Mumbai would like to withdraw the application.

Decision:
Placed before the committee for information.

Action: GEAC Secretariat

6.5 Request of M/s. Navbharat Seeds Pvt. Ltd, Ahmedabad for registration of Institutional Biosafety Committee (IBSC)

The 137th GEAC Committee had deferred the request of the applicant and had directed the GEAC Secretariat to seek legal position for renewal the IBSC. Accordingly, the opinion of the Law and Policy Division was sought in the Ministry. The Policy and Law Division informed that as on date, there are ongoing matters in the Hon'ble High Court of Gujarat and Court of Metropolitan Magistrate, Ahmedabad between MoEF&CC and M/s Navbharat Seeds Pvt. Ltd. and no order/judgment has yet been passed in either court. Accordingly, the 138th GEAC Committee decided that it would not be appropriate to consider the application of the renewal of the IBSC in view of the ongoing Criminal Case No. 390/2014 filed by MoEF&CC against M/s Navbharat Seeds Pvt. Ltd. in the Court of Metropolitan Magistrate, Ahmedabad.

Decision:

Since the matter is sub-judice, the committee decided that no decision regarding the renewal of IBSC could be taken till the final decision/judgment of the court is passed.

Action: GEAC Secretariat

6.6 Change of ownership on approvals from Bayer Bio Science Pvt Ltd to BASF India Limited acting on behalf of BASF Agricultural Solutions Seed US LLC.

On acquisition of M/s Bayer BioScience Pvt by M/s BASF India Limited, New Delhi, an application was submitted by M/s. BASF India Limited, New Delhi requesting to transfer ownerships of oil import approvals granted by GEAC for M/s Bayer BioScience Pvt Limited to M/s BASF India Limited.

Decision:

a. The committee has noted the acquisition of M/s Bayer BioScience Pvt by M/s BASF India Limited, New Delhi and approved the request of transfer of approvals given by GEAC for M/s Bayer BioScience Pvt to M/s BASF India Limited, New Delhi
b. The approval is subject to other statutory clearances.

Action: GEAC Secretariat

6.7 Bt. Brinjal status / seed storage at NBPGR

The decisions were taken in 99th and 100th Decisions to deposit seeds for Cry1AC event of Bt Brinjal in the NPBGR. However, seeds have not been stored in NPBGR so far. As per records, a total of 685.517 Kg seeds of Bt Brinjal are with Mahyco (685 Kgs), TNAU (100 grams) and UAS (417 grams). The Committee decided that it doesn't make sense to store such a huge quantity of seeds which are 10 years

old in NPBGR. GEAC members suggested that an optimum quantity of seeds may be retained by these agencies, and the balance may be considered for disposal as per protocols.

Action: GEAC Secretariat

6.8 Update on preparation and formulation of guidelines for import of GM animal feed including DDGS

The third and final meeting of the Sub-Committee on "Framing Guidelines for import of Animal feed including DDGS" was held on 09.08.2019 in the Ministry of Environment, Forest and Climate Change (MoEFCC) under the Chairpersonship of Dr. Lalitha R. Gowda, Former Chief Scientist, CFTRI and Member, Genetic Engineering Appraisal Committee (GEAC).

Dr. Lalitha R. Gowda made a detailed presentation to the Committee and shared the following draft documents:

i. Procedures for handling applications on import of animal feed containing or derived from genetically modified organisms (GMOs)/ living modified organisms (LMOs)
ii. Application Form
iii. Production, processes, uses and safety of Dried Distillers Grains with Solubles (DDGS) for animal feed.

Decision:

The Committee has sought comments/inputs from all the members on the aforementioned documents over email for further consideration.

Action: GEAC Secretariat

6.9 Advisory to State/UTs Government for dealing with suspected illegal cultivation of Genetically Modified GM Crops

Considering that various complaints were received by GEAC on illegal GM crops cultivation in India, it is desired to have an advisory to the States and UTs for dealing such cases within the ambit of 1989 rules and EP Act and the same has been discussed in the GEAC meeting. The same may be sent by email to the GEAC Secretariat.

Decision:

The Committee sought comments/inputs on the draft advisory prepared by Ministry on suspected illegal cultivation of Genetically Modified Crops from all the members so that same may be incorporated in the final document.

Action: GEAC Secretariat

Supplementary Agenda Item No. 1: Applications related to Commercial/ Environmental release

1.1 Application for environmental approval for manufacture of large scale batches [40-50 liters] for conduct of various phases of clinical trials for dengue tetravalent vaccine by Serum India Pvt. Ltd.

An application was submitted by Serum India Pvt. Ltd. for environmental approval for manufacture of large scale batches [40-50 liters] for conduct of various phases of clinical trials for dengue tetravalent vaccine. After the presentation made by the applicant, it is observed that the discharge is of only of 40-50 liters per batch.

Decision:

Since the environmental discharge is less than 100 liters i.e., 40-50 liters and GEAC approval is required only for batches of more than 100 liters, the committee informed the applicant that GEAC approval is not required in the present case. However, other approvals may be taken as required.

Action: GEAC Secretariat

1.2 Development and scale up of technology for Microbial Extension of Xylose from Agro waste materials and subsequent conversion into Xylitol by Department of Biotechnology, Punjabi University, Patiala.

An application was submitted by Department of Biotechnology, Punjab University, Patiala for development and scale up of technology for Microbial Extension of Xylose from Agro waste materials and subsequent conversion into Xylitol. The applicant was not present before at the meeting, however submitted relevant documents like summary of the proposal and environmental feasibility report and also informed that the production will not be more than 100 liters.

Decision:

As it is observed that the production is not more than 100 liters, the committee observed that GEAC approval is not required.

Action: GEAC Secretariat

Supplementary Agenda Item No. 2: Additional Items for consideration/ information

2.1 NOC for the conduct of field demonstration studies on honey bees and other pollinators and filed studies to assess hybrid seed production efficiency of transgenic mustard hybrid DMH-11 developed by the Centre for Genetic Manipulation of Crop Plants (CGMCP), the University of Delhi in the growing season 2019-20.

The Centre for Genetic Manipulation of Crop Plants (CGMCP), the University of Delhi has submitted an application to this Ministry for conducting the Field demonstration study on honey bee in the year 2019-2020 instead of 2018-19 as approved earlier by GEAC. Therefore this Ministry has agreed to it. The same has been placed before the committee for information.

Decision:

The committee has noted the information.

Action: No action required.

2.2 Submission of a declaration on the purpose and storage of seeds of the transgenic maize hybrids containing TC1507 X MON810 stack and MON810 single event by M/s. Pioneer Hi-Bred Pvt. Ltd., Hyderabad.

An application was submitted by M/s. Pioneer Hi-Bred Pvt. Ltd., Hyderabad regarding storage of TC1507 X MON810 and MON810 transgenic maize seeds. RCGM in its 174th meeting held on 13.08.2019 has given permission for storage of seeds till August 2020.

Decision:

The committee has approved the extension of storage of seeds as approved by RCGM and stated that any leakage of seed is punishable under Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells 1989 (Rules, 1989) of Environmental (Protection) Act, 1986.

Action: GEAC Secretariat

2.3 Change of name in NOC from Sanofi Synthelabo India Pvt. Ltd. to Boehringer Ingelheim India Pvt. Ltd.

The firm Boehringer Ingelheim India Pvt. Ltd has acquired the firm Sanofi Synthelabo India Pvt Ltd,

therefore an application was submitted by Boehringer Ingelheim India Pvt. Ltd., Thane requesting for transfer of NOCs give to Sanofi Synthelabo India Pvt. Ltd. to Boehringer Ingelheim India Pvt. Ltd for import of vaccines to Boehringer Ingelheim India Pvt. Ltd. In this regard, the applicant also requested the GEAC that they are facing problems in generating data for Indian conditions as no institute is supporting such research, therefore, requested GEAC that such tests may be allowed to be conducted in Indian Veterinary Research Institute (IVRI).

Decision:

The committee has agreed for transfer of NOCs given by GEAC for import of animal vaccines by Sanofi Synthelabo India Pvt. Ltd to Boehringer Ingelheim India Pvt. Ltd. Further the committee has also suggested that the experiments for generating data for Indian conditions may be conducted with the support of IVRI and the cost for such activity has to be borne by the applicant.

Action: GEAC Secretariat

The meeting ended with a vote of thanks to the Chair.

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Annexure-1

List of Participants

Official Members who participated			
1.	**Shri Ravi S. Prasad,** Chairman, GEAC & Additional Secretary, Ministry of Environment, Forest & Climate Change, JorBagh, Aliganj, New Delhi.	**3.**	**Shri Tarun Kathula** Scientist-F, and Member Secretary (GEAC), Ministry of Environment, Forests & Climate Change, JorBagh, Aliganj ,New Delhi.
2.	**Ms. Richa Sharma,** Joint Secretary & Vice-Chairperson, GEAC Ministry of Environment, Forest & Climate Change, JorBagh, Aliganj, New Delhi.		
Expert members			
1.	**Dr. NitinK.Jain** Scientist –F and Member Secretary, RCGM Department of Biotechnology, C. G. O, Complex, Lodhi Road, New Delhi-110003.	**9.**	**Dr. S. C. Khurana** Food Safety and Standards Authority of India (FSSAI), FDA Bhawan, Kotla Road, New Delhi
2.	**Dr. Vanga Siva Reddy** CSO, BSU Department of Biotechnology, C. G. O, Complex, Lodhi Road, New Delhi-110003.	**10.**	**Dr. SushilGupta,** FormerChairman, Central Ground Water Board, New Delhi
3.	**Dr. Dinesh K Agarwal,** Principal Scientist, In charge, Plant Breeding &Genetics,ICAR-Indian Institute of Seed Science, Mau, U.P	**11.**	**Dr. N. Sathyanarayana** Joint Director Plant Protection Quarantine & storage, NH-IV, Faridabad, Haryana.
4.	**Dr. S De** Principal Scientist Animal Biotechnology Centre, National Dairy Research Institute, Karnal.	**12.**	**Dr. S. K. Barik** Director CSIR- National Botanical Research Institute, Lucknow
5.	**Shri. Chandra Shekar Ranga** Joint Drugs Controller, Central Drugs Standard Control Organizations, New Delhi.	**13.**	**Dr. MadhuDikshit** Former Director CSIR-Central Drug Research Institute, Lucknow.
6.	**Dr. A.K. Singh,** Head, Division of Genetics, IARI, New Delhi.	**14.**	**Dr. LalithaGowda,** Former Chief Scientist, CSIR-CFTRI Mysore, Karnataka-570 020, India
7.	**Dr.DilipMarkandey** Central Pollution Control Board ParvieshBhawan, CBD cum office complex, East Arjun Nagar, New Delhi- 110032	**15.**	**Dr. S. J. Rahman,** Principal Scientist & Univ. Head of Entomology, AICRP on Biological Control Agricultural Research Institute (ARI), Prof. JayashankarTelangana State Agri. University, Rajendranagar, Hyderabad.

8.	**Dr. Ashok Bhatnagar,** Former Professor, Department of Botany, University of Delhi, New Delhi	**16.**	
Member who did not participate			
1.	**Dr. K. Veluthambi** Co-Chairman, GEAC and Professor (retd) & Head, School of Biotechnology, Madurai Kamaraj University, Madurai	**4.**	**Dr. P. Suprasanna** Scientific Officer H (level 14) Biosciences Group, BARC, Mumbai.
2.	**Dr. B. Venkateswarlu** Former Vice-Chancellor VasantraoNaikMarathwadaKrishiVidyapeeth, Parbani (Maharashtra).	**5.**	**Dr. Usha Rao** Assistant Controller of Patents & Designs, Patent Office, New Delhi, India
3	**Prof. P. Balasubramanian,** Former Director, Centre for Plant Molecular Biology, TNAU, Coimbatore.	**6.**	**Dr. GeetaJotwani** Scientist F Indian Council of Medical Research, New Delhi.