PROCEEDINGS OF THE 140th MEETING OF THE GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 28.07.2020

The 140th meeting of the Genetic Engineering Appraisal Committee (GEAC) was held on July 28, 2020 via video conferencing. The meeting was chaired by Smt. B.V. Umadevi, Additional Secretary, MoEFCC and Chairman, GEAC.The list of participants is placed at **Annexure.**

At the outset, Mrs. B.V. Umadevi, Chairperson, GEAC welcomed all the members. Ms. Richa Sharma, Vice Chair mentioned that GEAC meetings have moved to the virtual mode during the pandemic situation, and this is the second virtual meeting being organized within two months.

Agenda Item No. 1: Leave of absence

Four Members communicated their inability to attend the 140th meeting of GEAC, namely Prof. P. Balasubramanian, Dr. V.G. Somani, Dr. N. Sathyanarayana and Dr. Dinesh K. Agarwal.

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 139th GEAC meeting

Minutes of the 139th GEAC meeting were circulated to all the members for comments. Minutes were suitably amended to incorporate the comments received from the members .

Decision:
Members confirmed the minutes of the 139th GEAC meeting.

Action: GEAC Secretariat

Agenda Item No. 3: Action taken report on the decision taken in the 139th GEAC meeting

Member Secretary, GEAC briefed about the action taken on the decisions at the 139th meeting of GEAC. He informed that letters communicating GEAC decisions were issued to applicants. GEAC Secretariat sent communications to Ministries/ Agencies such as Ministry of Agriculture and Farmers, Welfare, Director (IVRI) etc, as per GEAC decisions. GEAC Secretariat was able to resolve matters pending with Director IVRI.

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 Genetically modified Rubber Plant developed by Rubber Board - permission for confined field trials.

Executive Director, Rubber Board, Kerala made a presentation on the proposal and informed that they have obtained no objection certificate from Government of Assam for conducting confined field trials. Representative from RCGM informed that RCGM has approved BRL-1 trials on GE Rubber (Event L1 and L2) modified with manganese superoxide dismutase (MnSOD) gene to confer tolerance to abiotic stress and tapping panel dryness syndrome in 159th meeting of RCGM. RCGM has advised the applicant to ensure due diligence during the trials as per Letter No. BT/BS/16/156/2015-PID dated 25th August 2017.

Members of GEAC examined and discussed the proposal from the perspective of environmental safety, impact on biodiversity and measures for ensuring biosafety during trials.

Decision:

The application of Rubber Board for BRL-1 trials was recommended with the following conditions stipulating that Rubber Board will:

i. adhere with the conditions mentioned in RCGM Letter No. BT/BS/16/156/2015-PID dated 25th August 2017, and conduct additional studies on micro-organisms as per existing protocols.
ii. share the NOC obtained from the State Government where the trials would be conducted, with GEAC Secretariat.
iii. share details of the trial site as required under part G of the Guidelines and SOPs for Confined Field Trials of regulated GE plants, including ownership of trial site.
iv. share information regarding confirmed availability of isolation distance, land use and its ownership.
v. share information regarding name of the lead scientist responsible for each trial, as well as expected date of sowing.
vi. the results of the field trials may also be shared with State Biodiversity Board and local panchayat Biodiversity Management Committees.

Action: Rubber Board , GEAC Secretariat

Agenda Item No. 5: Applications related to Commercial/ Environmental release

5.1 Application for Environmental approval for clinical trial of pharmaceutical drug derived from LMO {Live Attenuated Recombinant Tetravalent Dengue Vaccine} , for prophylaxis against Dengue infections, by M/s. Indian Immunologicals Limited, Hyderabad.

The applicant made a presentation on the environment safety measures being taken in the plant where the trials are proposed. and informed that they have obtained the clearance of RCGM for pre-clinical toxicology study and the formulation was found safe.

The committee deliberated the matter and recommended the proposal as the product is of live attenuated Recombinant Tetravalent Dengue Vaccine which has low virulence.

Decision:
The committee observed that the production is not more than 100 liters and therefore GEAC approval is not required. Further, the Committee has recommended environmental approval, if the production goes beyond 100 litres in future, for conducting Clinical Trial of Pharmaceutical Drug derived from LMO(Live Attenuated Recombinant Tetravalent Dengue Vaccine by M/s. Indian Immunologicals Limited, Hyderabad). This recommendation is subject to the following conditions:

a. Submission of Environmental Risk Management and Safety Plan within 3 months to MOEFCC.
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, as applicable.
d. Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises.
e. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.
f. The Ministry reserves the right to stipulate additional conditions if found necessary, in light of monitoring reports.
g. 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.

Action: GEAC Secretariat

5.2 Application for approval to commence commercial production of recombinant Human Transferin (rTRF) for non-therapeutic use - by Richcore Life Sciences Pvt. Ltd., Bangalore.

The applicant made a presentation on the environmental safety standards being maintained in their plant. RCGM had sent the Risk Assessment and Risk Management Plan submitted by the applicant , to GEAC Secretariat, on 27.07.2020.

The proposal was evaluated by GEAC members.

Decision:
The Committee recommended environmental approval for commercial production of recombinant Human Transferin (rTRF) for non-therapeutic use by M/s. Richcore Life Sciences Pvt. Ltd., Bangalore.

The recommendation is subject to submission of lab reports from an NABL(National Accreditation Board for Testing and Calibration Laboratories) accredited laboratory with its Unique Identification Number and NABL logo, to the GEAC Secretariat, and also subject to the following conditions:

a. Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises.
b. Other statutory clearances may also be taken, as applicable.
c. Submission of compliance report on ERMP plan every 6 months to the Regional Office of the Ministry of Environment, Forest and Climate Change, for

monitoring. The project authorities should extend full cooperation to the officer (s) of the Regional Office by furnishing the requisite data/ information/monitoring reports.

d. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is unsatisfactory.
e. The Ministry reserves the right to stipulate additional conditions if found necessary, in light of monitoring reports.

Action: GEAC Secretariat

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

6.1 Application for import of *Bacillus amyloliquefaciens, Bacillus licheniformis, Bacillus megaterium, Bacillus pumilus, Bacillus subtilis* for the purpose of waste-water treatment by M/s. Altima Technologies Pvt Ltd, Kerala.

The application submitted by M/s. Altima Technologies Pvt Ltd, Kerala pertains to import of *Bacillus amyloliquefaciens, Bacillus licheniformis, Bacillus megaterium, Bacillus pumilus, Bacillus subtilis* which is in Risk group I, for using in the treatment of residential waste water, from M/s Roebic Laboratories Inc. USA.

The application mentions that there is no inserted gene in the *Bacillius spp* and hence it is non LMO.

The applicant has informed that because of the unique and proven quality of the product and good will of the brand (ROEBIC), they may not be able to replace or use any other stain available in India.

The committee deliberated the matter and recommended the import subject to compliance with the provisions of Biological Diversity Act, 2002 and clearance from Plant Quarantine Department.

Decision:

The Committee recommended the import of Bacillus *amyloliquefaciens, Bacillus licheniformis, Bacillus megaterium, Bacillus pumilus, Bacillus subtilis* subject to compliance with the provisions of Biological Diversity Act, 2002 and clearance from Plant Quarantine Department.

Action: GEAC Secretariat

6.2 Application for permission of import of cell Associated Live Recombinant Herpes Virus of Turkey Strain HPV360 (Innovax ND IBD) by M/s. Intervet India Pvt. Ltd., Pune.

The applicant has sought change in the text of the letter issued by GEAC vide No. 12013/04/2018 CS-III dated 9th May 2018 for import of Associated Live Recombinant Herpes Virus of Turkey Strain HPV360 (Innovax ND IBD) from "generation of laboratory /in vivo efficacy data under Indian conditions" to "initial 3 batches of the subject vaccine to be certified in IVRI before it is marketed in the country".

A decision was taken by the committee in its 139th meeting that the view of Director, Indian Veterinary Research Institute (IVRI) may be sought, regarding the proposed change.

In response to the communication from GEAC Secretariat, IVRI has conveyed its agreement to the proposed change, vide letter No. STD/QC/VT/2020-21 dated 24th July 2020.

The committee deliberated the matter and recommended the change in the condition as suggested by IVRI.

Decision:
The committee recommended changing the condition from "generation of laboratory /in vivo efficacy data under Indian conditions" to "initial 3 batches of the subject vaccine to be certified in IVRI before it is marketed in the country" for import of cell Associated Live Recombinant Herpes Virus of Turkey Strain HPV360 (Innovax ND IBD).

Action: GEAC Secretariat

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

The applicant sought change in the text of the letter issued by GEAC vide letter No. 12013/37/2019-CS-III dated 11th February 2020 for import of Bursal Disease-Marek's vaccine and vaccines for Canine Distemper from "generation of laboratory /in vivo efficacy data under Indian conditions" to "initial 3 batches of the subject vaccine to be certified in IVRI before it is marketed in the country".

A decision was taken by the committee in its 139th meeting that the view of Director, Indian Veterinary Research Institute (IVRI) may be sought in the matter.

In response to a communication from GEAC Secretariat, IVRI has conveyed its agreement to the proposed change, vide its letter No. STD/QC/VT/2020-21 dated 24th July 2020.

The committee deliberated the matter and recommended the change in the condition as suggested by IVRI.

Decision:
The committee recommended changing the condition from "generation of laboratory /in vivo efficacy data under Indian conditions" to "initial 3 batches of the subject vaccine to be certified in IVRI before it is marketed in the country" for import of the Bursal Disease-Marek's vaccine and vaccines for Canine Distemper.

Action: GEAC Secretariat

Agenda Item No. 7: Additional Items for consideration/ information

7.1 Regulatory Reforms to improve Drug Development in India and Draft Document on Genome Edited Organisms: Regulatory Framework and Guidelines for Risk Assessment, 2019.

Dr. K.V. Prabhu, Chairman PPV&FRA and Chairman of the drafting committee for the "Draft Guidelines for Safety Assessment of Genome Edited Plants" made a presentation before the committee.

He informed that SDN1 and SDN2 categories of genome editing technologies do not involve or carry exogenous DNA and are comparable naturally occurring variance. Hence these technologies for genome editing should be exempted from Rules 7-11 of

Rules (1989) of EP Act(1986). MOEFCC may exercise its powers under Rule 20 of Rules (1989) to grant such exemption.

He also informed that the said guidelines were approved in the 1st meeting of the Recombinant DNA Advisory Committee (RDAC) held on 14th May 2020, and Chaired by Secretary, DBT.

The committee along with special invitees deliberated whether a process or technology can be exempted from Rules 1989 when GEAC's mandate is to evaluate environmental safety of the products at research and development stage and before its release into environment. Deliberations also addressed the issue of resultant traits from application of SDN 1 and SDN 2 technologies; how they are different from similar traits resulting from transgenic technologies and if the two sets of traits are different in terms of their environmental impacts.

While some members participated in the deliberations and conveyed their comments, others could not do so.

Since the matter is of significant importance, it was decided that all members may be requested to convey their written comments to GEAC Secretariat.

Decision:

a. GEAC members were requested to share written comments on "Draft Guidelines for Safety Assessment of Genome Edited Plants" at the earliest.
b. The said agenda would be discussed in the next meeting.

Action: GEAC Secretariat

7.2 Proposal for Establishment of Notified Field Trial Sites (NFTS) to conduct Confined Field Trials of GE Crops.

The Department of Biotechnology had constituted a Working Group under the Chairmanship of Prof. Baldev Singh Dhillon, Vice Chancellor, Punjab Agricultural University, Ludhiana with members from ICAR and Ministry of Agriculture in 2016. Department of Biotechnology has forwarded the 'Proposal for Establishment of Notified Field Trial Sites (NFTS) to conduct Confined Field Trials of GE Crops' to GEAC for consideration.

The matter was discussed in the 139th meeting of GEAC on 19th May 2020 and comments were sought from the members.

The proposal was once again evaluated in the 140th meeting of GEAC.

Decision:

i. The committee noted the proposal shared by Department of Biotechnology on the Notified Field Trial Sites and suggested that a one-time approval for 5 years may be sought from the respective State Governments.
ii. ICAR is the premier National Institute for agricultural research, including research involving genetic engineering technologies. The purpose of GE technologies in agricultural research is to ensure food security by developing plants with desirable traits such as tolerance to

drought/flood/salinity/pests/weeds; higher yield etc. Hence, a scheme for setting up NFTS may be formulated and SFC/EFC approval may be sought by the Department of Biotechnology and/or Ministry of Agriculture and Farmers' welfare.

iii. The committee suggested the Department of Biotechnology to include ground water quality assessment component in the proposal of establishing NFTS.

Action: GEAC Secretariat

7.3 Application for environmental approval for clinical trials of 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.

Member Secretary, RCGM informed that the matter was discussed in the 185th meeting of the RCGM held on 02.07.2020 and the applicant was asked to provide additional information for consideration.

Decision:

The Committee deferred consideration of the application, in view of information provided by RCGM.

Action: GEAC Secretariat

The meeting ended with a vote of thanks to the Chair, Co-Chair and all the members.

Annexure

List of Participants

Official Members who pa rticipated			
1.	**Mrs. B. V. Umadevi** Chairman, GEAC & Additional S ecretary, Ministry of Environmen t, Forest & Climate Change, Jor Bagh, Aliganj, New Delhi.	**3.**	**Mrs. Richa Sharma,** Joint Secretary & Vice-Chairp erson, GEAC Ministry of Envi ronment, Forest & Climate C hange, JorBagh, Aliganj, New Delhi.
2.	**Dr. K. Veluthambi** Co-Chairman, GEAC and Professor (retd) & Head, School of Biotechnology, Madurai Kamaraj University, Ma durai	**4.**	**Sh. Tarun Kathula** Scientist-F, and Member Secret ary (GEAC), Ministry of Enviro nment, Forests & Climate Cha nge, JorBagh, Aliganj, New Delhi.
Officials/ Expert members			
1.	**Dr. Nitin K.Jain** Scientist –F and Member Secretary , RCGM Department of Biotechnology, C. G. O, Complex, Lodhi Road, New Delhi-110003.	**9.**	**Dr. P. Suprasanna** Scientific Officer H (level 14) Bio sciences Group, BARC, Mumbai .
2.	**Dr. Ashok Bhatnagar,** Former Professor, Dep artment of Botany, University of Delhi, New Delhi	**10.**	**Dr. Usha Rao** Assistant Controller of Patents & Designs, Patent Office, New D elhi, India
3.	**Dr. B. Venkateswarlu** Former Vice-Chancellor Vasantrao Naik Marathwada Krish i Vidyapeeth, Parbani (Maharashtr a).	**11.**	**Dr. A.K. Singh,** Head, Division of Genetics, IA RI, New Delhi.
4.	**Dr. S. J. Rahman,** Principal Scientist & Univ. Head of Entomology, AICRP on Biological C ontrol Agricultural Research Instit ute (ARI), Prof. Jayashankar Telan gana State Agri. University, Rajendranagar, Hydera bad.	**12.**	**Dr. Geeta Jotwani** Scientist F Indian Council of Medical Research, New Delhi.
5.	**Dr. Sushil Gupta,** Former Chairman, Central Ground Water Board, New Delhi	**13.**	**Dr. S. K. Barik** Director CSIR- National Botanica l Research Institute, Luc know
6.	**Dr. Madhu Dikshit** Former Director CSIR-Central Drug Research In stitute, Lucknow.	**14.**	**Dr. Dilip Markandey** Central Pollution Control Board

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7.	**Dr. Lalitha Gowda,** Former Chief Scientist, CSIR -CFTRI Mysore, Karnataka-5 70 020, India	**15.**	**Dr. S De** Principal Scientist Animal Biotechnology Centre, National Dairy Research Ins titute, Karnal.
8.	**Dr. S. C. Khurana** Food Safety and Standards Author ity of India (FSSAI), FDA Bhawan, Kotla Road, New Delhi		
Special Invitees			
1.	**Dr. Baldev Singh Dhillon** Vice Chancellor, Punjab Agricultural University, Ludhiana - 141004, India	**3.**	**Dr. K.V. Prabhu** Chairman PPV&FRA Ministry of Agriculture Cooperat ion and Farmers' Welfare, New Delhi
2.	**Shri. C. Achalender Reddy** PCCF Arunachal Pradesh Itanagar	**4.**	**Dr. Tarun kant** Scientist-F Arid Forest Research Institute, J odhpur
Member who did not pa rticipate			
1.	**Prof. P. Balasubramanian** Former Director, Centre for Plant Molecular Bi ology, TNAU, Coimbatore	**3.**	**Dr. N. Sathyanarayana** Joint Director Plant Protection Quarantine & s torage, NH-IV, Faridabad, Harya na.
2.	**Dr. V.G. Somani** Joint Drugs Controller – India Central Drugs Standard Control Or ganizations, FDA Bhawan Kotla Road, New Delhi-110002.	**4.**	**Dr. Dinesh K Agarwal,** Principal Scientist, In ch arge, Plant Breeding & G enetics, ICAR-Indian Institute of Seed Science M au, U.P