

**PROCEEDINGS OF THE 137th MEETING OF THE GENETIC ENGINEERING APPRAISAL
COMMITTEE HELD ON 20.03.2019**

The 137th meeting of the Genetic Engineering Appraisal Committee (GEAC) was held on March 20, 2019 in Narmada Conference Hall, Ministry of Environment, Forest and Climate Change (MoEFCC), New Delhi under the Chairmanship of Shri Anil Kumar Jain, Additional Secretary, MoEFCC and Chairman, GEAC, to consider the agenda items circulated to Members by email on 12.03.2019, and by hard copy. The list of participants is placed at **Annex-1**.

At the outset, Shri. A.K. Jain, Chairman, GEAC 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

Five Members communicated their inability to attend the 137th meeting of GEAC, namely Dr. B. Venkateswarulu, Dr. P. Balasubramanian, Dr. Madhu Dixit, Dr. Suprasanna and Dr. S.J. Rahman.

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 136th GEAC meeting

The draft proceedings of the 136th meeting of GEAC held on 20.09.2018 at New Delhi were circulated to the Members seeking their comments. In response, comments were received from four members, which were appropriately incorporated and revised minutes circulated to Members again on 11.10.2019. No comments were received from any of the Members on the revised minutes.

Decision:

Members confirmed the proceedings of the 136th GEAC meeting.

Action: GEAC Secretariat

Agenda Item No. 3: Action taken report on the decisions taken in the 136th GEAC meeting

The Member Secretary, GEAC briefed about the action taken on the decisions of the 136th meeting of GEAC, informing action has been completed on all the items as per decisions taken in the previous meeting.

Decision:

The Committee noted the compliance of 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 Application submitted by University of Delhi, South Campus New Delhi for permission to conduct Event Selection Trials on Transgenic Mustard (*Brassica juncea*)

The applications related to conduct of confined field trial for event selection by University of Delhi on Transgenic Mustard (*Brassica juncea*) were reviewed by the Committee. It was noted that these applications as listed below were reviewed and examined by Review Committee on Genetic Manipulation (RCGM) in its 169th meeting held on 20.11.2018 and thereafter were recommended to GEAC for its approval.

- I. Application to conduct confined field trial for event selection on low glucosinolate *Brassica juncea* transgenic lines at own farm station in Bawana, Delhi.
- II. Application to conduct confined field trial for event selection on transgenic mustard (*Brassica juncea*) obtained using CBF1 and CBF3 genes developed with the objective of generating frost tolerant lines of mustard own farm station in Bawana, Delhi.
- III. Application to conduct confined field trial for event selection by checking for the oil content and oil composition of the transgenic plants of *Brassica juncea* var. Varuna (oilseed mustard) developed using *Wrinkled 1 (WRI1)* and *Diacylglycerol Acyltransferase 1 (DGAT1)* genes at own farm station in Bawana, Delhi.
- IV. Application to conduct confined field trial for event selection for testing seed oil composition of the field grown plants of high oleic and low linoleic transgenic line (event HO 3.18) in *Brassica juncea* developed by antisense suppression of *fad2* gene at own farm station in Bawana, Delhi.
- V. Application to conduct confined field trial for event selection on transgenic plants of *B. juncea* obtained using *CP4 EPSP synthase (5-enolpyruvylshikimate 3-phosphate)* and *ALS (acetolactate synthase)* genes developed of controlling root parasite *Orobanche* in mustard at own farm station in Bawana, Delhi.

After detailed deliberations, the Committee recommended the above five applications for conduct of event selection trials for: studies on low glucosinolate *Brassica juncea*; generating frost tolerant lines of mustard obtained from CBF1 and CBF3 genes; checking of oil content and oil composition in mustard variety Varuna developed using *Wrinkled 1 (WRI1)* and *Diacylglycerol Acyltransferase 1 (DGAT1)* genes; testing seed oil composition of field grown plants of high oleic and low linoleic transgenic line (event HO 3.18) in *Brassica juncea* developed by antisense suppression of *fad2* gene; testing of herbicide tolerant transgenic plants obtained using *CP4 EPSP synthase (5-enolpyruvylshikimate 3-phosphate)*; and *ALS (acetolactate synthase)* genes developed of controlling root parasite *Orobanche* in mustard.

Further, the Committee agreed that during the conduct of these trials, an isolation distance of 50 meters needs to be maintained as per Indian minimum seed certification standards.

Decision:

The Committee recommended the five applications for conduct of event selection trials of Transgenic Mustard (*Brassica juncea*) at its own farms in Bawana, New Delhi.

Action: GEAC Secretariat

4.2 Application submitted by M/s. Metahelix Life Sciences Ltd., Bangalore seeking permission for conduct of event selection trials of transgenic cotton and maize

The applications related to conduct of ESTs on transgenic Cotton and Maize by M/s. Metahelix Life Sciences Ltd, Bangalore were reviewed by the Committee. It was noted that these applications were initially reviewed and examined by RCGM in its 159th and 161st meetings and were also recommended by GEAC in its 135th meeting held on 25.07.2018. However, based on the request of the applicant, who sought revised permit letters with revised titles and events (number of events to be tested to be reduced from 10-12 events to 6-7 events and that too only in inbred background and not in hybrid background), clarification was sought from RCGM.

The Committee noted that the revised applications were examined by RCGM and were recommended to GEAC for consideration. After detailed deliberations, the Committee approved the applications submitted by M/s. Metahelix Life Sciences Ltd, Bangalore.

The Committee also deliberated on the issue relating to obtaining NOC from State Governments for conduct of ESTs in its own premises at different locations. The Committee agreed that NOC for conduct of ESTs are exempted only in cases where these trials are conducted strictly within the company's institutional premises.

Decision

The Committee recommended the five applications for conduct of event selection trials of Transgenic Cotton and Maize with revised titles/ events.

Action: GEAC Secretariat

4.3 Application submitted by M/s. Bioseed Research India for extension of validity of the permission to conduct confined field trials for event selection of cotton lines expressing synthetic Cry2Ai gene for pink bollworm resistance.

The application related to conduct confined field trials for event selection of cotton lines expressing synthetic Cry2Ai gene for pink bollworm resistance by M/S. Bioseed Research India was examined by the Committee. It was noted that the applicant could not undertake these trials due to climatic conditions and other associated factors. The Committee approved the request for extension of validity of the permission for conduct of these trials till the end of 2019.

Decision

The Committee recommended the extension of validity of the trial till the end of 2019.

Action: GEAC Secretariat

4.4 Application submitted by M/s. Bioseed Research India for extension of validity of the permission to conduct confined field trials for event selection of cotton lines expressing *asal* gene from *Allium sativum* exhibiting insecticidal property against sap-sucking pest.

The application related to confined field trials for event selection of cotton lines expressing *asal* gene from *Allium sativum* exhibiting insecticidal property against sap-sucking pest by M/s. Bioseed Research India was examined by the Committee. It was noted that the applicant could not undertake these trials due to climatic conditions and other associated factors. The Committee approved the request for extension of validity of the permission for conduct of these trials till the end of 2019.

Decision

The Committee recommended the extension of validity of the trial till the end of 2019.

Action: GEAC Secretariat

4.5 Application submitted by University of Agricultural Services, Dharwad to conduct BRL-I trial of UASD Bt Cotton Event No. 78 containing *Cry1Ac* gene for evaluation of expression of *Cry1Ac* Protein in different tissues and the efficacy in controlling target pest and agronomic performance at University's own farm at Walmi, Dharwad.

The applications related to conduct of Biosafety Research Level (BRL)-1 trial on transgenic *Bt* Cotton event no. 78 with *Cry1Ac* gene in its own farm at University of Agricultural Sciences (UAS), Dharwad was examined and reviewed by the Committee. After detailed deliberations, noting that these applications were reviewed and approved by RCGM in its 166th and 171st meetings, the Committee recommended the application for conduct of BRL-1 trial.

Decision

The Committee recommended the application for conduct of BRL-1 trial on transgenic *Bt* Cotton event No. 78 with *Cry1Ac* gene.

Action: GEAC Secretariat

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

5.1 Application submitted by M/s. Kaypeeyes Biotech Pvt. Ltd., Mysuru seeking permission for production of Xylanase enzyme from recombinant *Pichia pastoris*.

The application submitted by M/s. Kaypeeyes Biotech Pvt. Ltd., Mysuru seeking permission for production of Xylanase enzyme from recombinant *Pichia pastoris* in large scale fermenters (5000 L /day) was deliberated at length by the Committee. After thorough examination of the application, the Committee noted that there are several deficiencies in the application and accordingly 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)'s Biosafety Support Unit (BSU) 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's, BSU for preparation of a RARM Plan.

Action: GEAC Secretariat

5.2 Application submitted by M/s. Anthem Life Sciences, Bangalore seeking permission for production of Phytase enzyme for use as animal feed by using recombinant *Pichia pastoris*.

The application submitted by M/s. Anthem Life Sciences, Bangalore seeking permission for production of Phytase enzyme from recombinant *Pichia pastoris* was deliberated upon by the Committee. After thorough examination of the application, the Committee noted that there are several deficiencies in the application and accordingly 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)'s Biosafety Support Unit (BSU) 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's, BSU for preparation of a RARM Plan.

Action: GEAC Secretariat

5.3 Application submitted by M/s. Anthem Life Sciences, Bangalore seeking permission for production of Lipase enzyme for use as animal feed by using recombinant *Pichia pastoris*.

The application submitted by M/s. Anthem Life Sciences, Bangalore seeking permission for production of Lipase enzyme from recombinant *Pichia pastoris* was deliberated upon by the Committee. After thorough examination of the application, the Committee noted the gaps in information provided in the application and accordingly 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)'s Biosafety Support Unit (BSU) 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's, BSU for preparation of a RARM Plan.

Action: GEAC Secretariat

5.4 Application submitted by M/s. Kuantum Papers Ltd., Sailakhurd, Punjab for conducting experiments at pilot plant in fermenters of 25000 L capacity using genetically modified yeast imported from Denmark for production of bioethanol from rice straw (lignocellulosic biomass).

The application submitted by M/s. Kuantum Papers. Ltd. seeking permission for conducting experiments at pilot plant in fermenters of 25000 L (25000 x 6 No's) capacity using genetically modified yeast (*Saccharomyces cerevisiae*) imported from Denmark for production of bioethanol from rice straw was deliberated upon by the Committee. After thorough examination

of the application, the Committee noted the gaps in information provided in the application and accordingly 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)'s Biosafety Support Unit (BSU) 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's, BSU for preparation of a RARM Plan.

Action: GEAC Secretariat

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

6.1 Application for import of processed foods derived from soybean by Instituto de Agrobiotecnologia Rosario (INDEAR)

The application submitted by Instituto de Agrobiotecnologia Rosario (INDEAR) for import of processed foods derived from soybean was examined by the Committee, which directed the Secretariat to forward this application to Food Safety and Standards Authority of India (FSSAI) for necessary action as it falls under their mandate.

Decision

The Committee directed the Secretariat to forward the same to FSSAI for necessary action at their end, as it falls under their mandate.

Action: GEAC Secretariat

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

7.1 Deferment of field demonstration studies on honey bees and other Pollinators by University of Delhi

The Committee noted the response from the applicant regarding the reasons for deferment of field demonstration studies on transgenic Mustard during the season 2018-19.

Action: GEAC Secretariat

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

The Committee examined the communication received from RCGM regarding the request of M/s. Navbharat Seeds Pvt. Ltd. for renewal of its Institutional Biosafety Committee (IBSC). Noting that, there is an ongoing case in High Court of Ahmedabad, between MoEFCC and M/s Navbharat Seeds Pvt. Ltd, the Committee deferred the request of applicant for renewal of its IBSC. The Committee also directed the Secretariat to seek legal position on the matter.

Decision

- I. The Committee deferred the request of the applicant for renewal of its IBSC.
- II. The Committee directed the Secretariat to seek legal position on the matter.

Action: GEAC Secretariat

7.3 Clarification regarding NOC for Commercial Production of Recombinant Therapeutic Applications

The Committee examined the communication received from RCGM regarding the request of M/s. Richcore Life sciences Pvt. Ltd, Bangalore seeking clarification regarding issuance of NOC for commercial production of recombinant Human Transferrin (rTRF) for non-therapeutic applications using *Pichia pastoris* expression system.

After detailed deliberations, the Committee deferred the request of the applicant as Committee in the absence of relevant details. Accordingly, the Committee also directed the Secretariat to ask the applicant to submit complete application with all relevant details to GEAC Secretariat for examination.

Decision

The Committee deferred the request of the applicant and directed the Secretariat to ask the applicant to submit a complete application with all relevant details for examination by GEAC.

Action: GEAC Secretariat

7.4 Application for environmental approval for manufacture of large scale batches [40-50 litres] of conduct of various phases of clinical trials for Dengue tetravalent vaccine by M/s Serum Institute of India Pvt. Ltd

The Committee noted that the application submitted by M/s Serum Institute of India Pvt. Ltd seeking permission for environmental approval for various phases of clinical trials of Dengue tetravalent vaccine 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.

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

7.5 Application for revalidation of GEAC approval to store *Brucella abortus* (strain 19) bacteria required for *Brucella abortus* (strain 19) vaccine, live, IP by M/s. Intervet India Pvt. Ltd.

The Committee examined the application of M/s. Intervet India Pvt. Ltd, Pune seeking permission for extension of two years (2019-2021) for storage of *Brucella abortus* (strain 19), which is a Gram Negative coccus bacilli intended to be used for active vaccination of female cattle and buffalo calves against brucellosis.

After detailed deliberations, the Committee approved the request of the applicant for storage of *Brucella abortus* (strain 19) for another two years under BSL-III facilities and conditions. Further, the Committee also directed the applicant to strictly comply with the “*Regulations and Guidelines on Biosafety of Recombinant DNA Research & Biocontainment, 2017*” for storage of the Strain.

Decision

The Committee approved the request of the applicant and directed the applicant to store the strain *Brucella abortus* in BSL-III facilities and also to comply with “*Regulations and Guidelines on Biosafety of Recombinant DNA Research & Biocontainment, 2017*”.

Action: GEAC Secretariat

7.6 Update on progress in formulation of guidelines for import of GM animal feed including DDGS

The Committee while deliberating on the issue of Distillers Dried Grain Solubles (DDGS), was informed that the Sub-Committee constituted under the Chairpersonship of Dr. Lalitha R. Gowda met on two occasions during the interim period with representatives of Department of Dairying, Fisheries and Animal Husbandry, National Dairy Research Institute, Food Safety and Standards Authority of India, Department of Biotechnology, Compound Feed Manufacturers Association, US Department of Agriculture and other relevant stakeholders and also referred to several documents and inputs received from stakeholders.

Dr. Lalitha R. Gowda made a detailed presentation to the Committee and shared the progress made so far. Noting that this is work in progress, the Committee approved the request of the Sub-Committee for extension of the tenure of the Sub-Committee for another three months for finalization of the “Guidelines for Import of Genetically Modified (GM) animal feed including DDGS”.

Decision

The Committee approved the extension of the tenure of the Sub-Committee for another three months for finalization of Guidelines on import of GM animal feed including DDGS.

Action: GEAC Secretariat

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

List of Participants

Official Members who participated			
1.	Shri.A. K. Jain, Chairman, GEAC & Additional Secretary, Ministry of Environment, Forest & Climate Change, JorBagh, Aliganj , New Delhi.	3	Dr. Sujata Arora, Advisor & Vice-Chairperson, GEAC Ministry of Environment, Forest & Climate Change, JorBagh, Aliganj, New Delhi.
2.	Dr. K. Veluthambi, Co-Chairman and Professor (retd.), School of Biotechnology, Madurai Kamraj University, Madurai.	4	Dr. Murali Krishna Chimata Scientist-D, and Member Secretary (GEAC), Ministry of Environment, Forests & Climate Change, JorBagh, Aliganj , New Delhi.
Expert members			
1.	Dr. S.R. Rao Senior Advisor & Member Secretary, RCGM, Department of Biotechnology, New Delhi	9.	Dr. Ashok Bhatnagar, Former Professor, Department of Botany, University of Delhi, New Delhi
2.	Dr. Sanjeev Agarwal Addl. Director, Biological Lab Central Pollution Control Board New Delhi	10.	Dr. Sushil Gupta, Former Chairman, 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.	Dr. V. G. Somani Joint Drugs Controller – India Central Drugs Standard Control Organization, FDA Bhawan, Kotla Road, New Delhi - 110002	13.	Dr. Usha Rao Assistant Controller of Patents & Designs, Patent Office, New Delhi, India
6.	Dr. A.K. Singh, Head, Division of Genetics, IARI, New Delhi.	14.	Shri. Jayant Gangakhedkar Joint Drugs Controller, Central Drugs Standard Control Organizations, New Delhi.
7.	Shri. Tarun Kathula Director CS-III Ministry of Environment. Forest and Climate Change, New Delhi- 110003	15.	Dr. Lalitha Gowda, Former Chief Scientist, CSIR-CFTRI Mysore, Karnataka-570 020, India
8.	Shri. Yogesh Shelar Assistant Drugs Controller – India Central Drugs Standard Control Organization, FDA Bhawan, Kotla Road, New Delhi - 110002		

Member who did not participate			
1.	Shri. Sunil Kumar Bakshi Advisor (Codex/ regulations) Food Safety and Standards Authority of India (FSSAI), FDA Bhawan, New Delhi	5	Dr. Madhu Dikshit Former Director CSIR-Central Drug Research Institute, Lucknow.
2.	Dr. P. Suprasanna Scientific Officer H (level 14) Biosciences Group, BARC, Mumbai.	6	Dr. GeetaJ otwani Scientist F Indian Council of Medical Research, New Delhi.
3	Dr. B. Venkateswarlu Former Vice-Chancellor Vasantao Naik Marathwada Krishi Vidyapeeth, Parbani (Maharashtra).	7	Prof. P. Balasubramanian, Former Director, Centre for Plant Molecular Biology, TNAU, Coimbatore.
4.	Dr. S. J. Rahman, Principal Scientist & Univ. Head of Entomology, AICRP on Biological Control Agricultural Research Institute (ARI), Prof. Jayashankar Telangana State Agri. University, Rajendranagar, Hyderabad.		