

**PROCEEDINGS OF THE 135<sup>th</sup> MEETING OF THE GENETIC ENGINEERING APPRAISAL  
COMMITTEE HELD ON 25.07.2018**

The 135<sup>th</sup> meeting of the Genetic Engineering Appraisal Committee (GEAC) was held on July 25, 2018 in Narmada Conference Hall, Ministry of Environment, Forest and Climate Change (MoEFCC), New Delhi under the Chairmanship of Shri Arun Kumar Mehta, Additional Secretary, MoEFCC and Chairman, GEAC, to consider the agenda items circulated to Members by email on 05.07.2018, and by hard copy. The list of participants is placed at **Annex-1**.

At the outset, Shri. A.K. Mehta, Chairman, GEAC extended a warm welcome to all the members followed by a round of introduction. This being the first meeting of newly constituted GEAC, Vice-Chair, GEAC briefed the participants about the genesis and mandate of this Committee and all the members were presented with a plant and some resource material on biosafety. Thereafter, the agenda items were taken up as under:

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

The Committee granted leave of absence to one Member who communicated his inability to attend the 135<sup>th</sup> meeting of GEAC, namely Dr. P. Balasubramanian

**Decision:**

- Leave of absence was granted to Dr. P. Balasubramanian.

**Action: GEAC Secretariat**

**Agenda Item No. 2: Confirmation of minutes of the 134<sup>th</sup> GEAC meeting**

The draft proceedings of the 134<sup>th</sup> meeting of GEAC held on March 21, 2018 at New Delhi were circulated to the Members vide email on 02.05.2018 seeking their comments. No comments were received from any of the Members.

**Decision:**

- Members confirmed the proceedings of the 134<sup>th</sup> GEAC meeting.

**Action: GEAC Secretariat**

**Agenda Item No. 3: Action taken report on the decisions taken in the 134<sup>th</sup> GEAC meeting**

The Member Secretary, GEAC briefed about the action taken on the decisions of the 134<sup>th</sup> meeting of GEAC, informing that on most of the items action has been taken, and action on few items is in progress. Members suggested that from next time brief details on what action has been taken may also be mentioned in the action taken report.

**Decision:**

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

**Action: GEAC Secretariat**

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

**4.1 Application for Environmental release of Transgenic Mustard Hybrid DMH-11 and Parental lines containing events *bn 3.6* and *modbs 2.99* developed using *barnase*, *barstar* and *bar* genes by M/s. Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi.**

The application related to transgenic Mustard along with the protocols and response received from Delhi University was deliberated by the members in the 135<sup>th</sup> meeting. The members agreed to the request of applicant for exemption to conduct soil microflora studies, as these studies were already completed during the conduct of BRL-I & BRL-II trials.

Further, the members noted that the applicant proposes to undertake studies on Honeybees at two locations namely, Punjab Agriculture University, Ludhiana and Indian Agricultural Research Institute, New Delhi. Noting that the applicant proposes to undertake two field demonstration studies at Delhi to assess hybrid seed efficiency and also for maintenance of male sterile *barnase* line *bn 3.6*, the committee deliberated on the issue of requirement of No Objection Certificate (NOC) from the State Governments for conduct of these field demonstration studies. It was agreed that the State Governments of Delhi and Punjab may be requested to exempt the requirement of NOC for these field demonstration studies, as these are continuation of BRL-I & BRL-II trials for which the State Governments has already given NOC earlier to the applicant. Further, the members also noted that the total area for conduct of these demonstration studies including non GM plantation would be in an area of 5 acres.

As informed by the applicant, the protocols for these demonstrations were prepared in consultation with ICAR-All India Crop Research Project on Honeybees. However, the members felt that additional time would be required to examine these protocols submitted by the applicant as these were received only 3 days prior to the meeting. It was agreed that members would communicate their comment, if any on the protocols submitted by the applicant within a week. It was agreed that if no comments are received in this period, it would be presumed that the members agree to the protocols, and in case any comments are received expressing concerns about the protocols, the matter would have to be considered in next meeting of GEAC.

The GEAC Secretariat received comments from 2 members expressing concerns about the use of unapproved pesticides/ herbicides during the studies and lack of complete details of the protocols to be followed by the applicant. Hence, as agreed in the meeting, the proposal would need to be considered again by the Committee in its next meeting.

**Decision:**

- The application was deferred and would be considered in the next meeting of GEAC, as two members expressed concerns about the protocols submitted by the applicant regarding use of unapproved pesticides/ herbicides and lack of complete details of the protocols.

**Action: GEAC Secretariat**

**Agenda Item No. 5: Applications related to Confined Field Trials of GE crops (Event Selection/ BRL-I/ BRL-II Trials)**

**5.1 Application submitted by M/s. Metahelix Life Sciences Ltd. for conduct of event selection trial for lepidopteran insect resistant transgenic cotton events (total 14 events- 12 events to be screened in line background and 2 events to be screened in hybrid background) containing cry1Ac gene at company manned secured locations (long leased lands) at Bangalore, Aurangabad, Hyderabad and Dehgan.**

**5.2 Application submitted by M/s. Metahelix Life Sciences Ltd. for conduct of event selection trial for herbicide tolerant transgenic cotton events (total 12 events- 8 events to be screened in line background and 4 events to be screened in hybrid background) containing synthetic EPSPS gene at company manned secured locations (long leased lands) at Bangalore, Aurangabad, Hyderabad and Dehgan.**

**5.3 Application submitted by M/s. Metahelix Life Sciences Ltd. for conduct of event selection trial for lepidopteran insect resistant and herbicide tolerant transgenic maize events (total 13 events- 10 events to be screened in line background and 3 events to be screened in hybrid background) containing cry1Ab gene and synthetic EPSPS gene at company manned secured locations (long leased lands) at Bangalore, Aurangabad, Hyderabad and Dehgan.**

**5.4 Application submitted by M/s. Metahelix Life Sciences Ltd. for conduct of event selection trial for lepidopteran insect resistant and herbicide tolerant transgenic maize events (total 12 events- 11 events to be screened in line background and 1 events to be screened in hybrid background) containing cry1F gene and synthetic EPSPS gene at company manned secured locations (long leased lands) at Bangalore, Aurangabad, Hyderabad and Dehgan.**

**5.5 Application submitted by M/s. Metahelix Life Sciences Ltd. for conduct of event selection trial of six transgenic cotton events expressing cry1F gene for conferring resistance to Lepidopteran pest, *Spodoptera litura* in line background (MLS005) at Bangalore, Aurangabad, Hyderabad and Dehgam at either company's own land or on long leased land.**

The Committee examined the applications submitted by M/s. Metahelix Life Sciences Ltd, seeking permission for conduct of event selection trials in Cotton and Maize. The Committee also invited the applicant and heard the presentation on the proposals. The Committee also noted that these applications were recommended by RCGM in its 161<sup>st</sup> and 163<sup>rd</sup> meetings. After detailed deliberations, the Committee recommended the applications of M/s. Metahelix Life Sciences Ltd.

**Decision:**

- The applications of M/s. Metahelix Life Sciences Ltd. were recommended by GEAC.

**Action: GEAC Secretariat**

**5.6 Application submitted by M/s. Bioseed Research India, Hyderabad seeking permission to conduct event selection trial of transgenic cotton lines containing 20 transgenic events i.e., Cot 001-20 overexpressing the *asal* gene from *Alium sativum* exhibiting insecticidal property against sap sucking pests at Ranga Reddy District, Telangana and in Hissar, Haryana.**

**5.7 Application submitted by M/s Bioseed Research India, Hyderabad seeking permission to conduct event selection trial of transgenic cotton lines expressing synthetic *cry2Ai* gene for Pink Bollworm resistance at company's own location in Hyderabad, Telangana.**

The Committee examined the applications submitted by M/s. Bioseed Research India, Hyderabad seeking permission for conduct of event selection trials in Cotton. The Committee also invited the applicant and heard the presentation on the proposals. The Committee also noted that these applications were recommended by RCGM in its 163<sup>rd</sup> meeting. After detailed deliberations, the Committee recommended the applications of M/s. Bioseed Research India, Hyderabad.

**Decision:**

- The applications of M/s. Bioseed Research India, Hyderabad were recommended by GEAC.

**Action: GEAC Secretariat**

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

**6.1 Application submitted by M/s P.R. Seeds & Grains Pvt. Ltd for import of Horse Feed containing GM Soybean products.**

The application submitted by M/s P.R. Seeds & Grains Pvt. Ltd. seeking permission for import of horse feed containing GM Soybean was examined by the Committee. It was noted that comments from Department of Animal Husbandry, Dairying and Fisheries (DADF) were awaited.

Members deliberated at length on the issue of streamlining the procedure for import of animal feed (such as horse feed, DDGS etc.) in the country. With a view to establish a uniform procedure for dealing with applications related to import of animal feed (including DDGS), the Committee recommended to constitute a Sub-committee under the Chairpersonship of Dr. Lalitha Gowda with Dr. Sachinandan De (NDRI, Karnal), Shri S.K. Bakshi (Advisor, FSSAI) and one nominee each from RCGM, GEAC, ICAR and DADF as its members.

**Decisions:**

- The application was deferred till the time comments from DADF were received.
- A Sub-committee may be constituted with Dr. Lalitha Gowda as the Chair and Dr. S.De (NDRI), Shri. S.K. Bakshi (Advisor, FSSAI) and representatives from RCGM, GEAC, ICAR and DADF as members with a view to recommend a procedure for import of animal feed in India.

**Action: GEAC Secretariat**

**7. Any other item with the permission of the Chair**

**7.1 Representation by Coalition for GM Free India on the decision of GM Mustard**

The members noted the issues raised in the representation by Coalition for GM Free India on the decision of GM Mustard. The members opined that these issues were the same as received earlier and were already considered and discussed by GEAC and the Sub-committee on GM Mustard on several occasions in the past and addressed appropriately.

**Decision:**

- No further action is required on the representation received from the Coalition for GM Free India.

**Action: GEAC Secretariat**

**7.2 Comments of FSSAI regarding the import of GM Processed Food applications transferred by GEAC**

The members took note of the response of Food Safety and Standards Authority of India (FSSAI) that they are in the process of framing Guidelines for dealing with applications related to GM processed foods, and a time period of about nine months would be required to finalise these Guidelines. The members suggested FSSAI to finalise these guidelines expeditiously.

**Decision:**

- FSSAI may be requested to finalise the Guidelines for dealing with applications related to GM processed foods expeditiously.

**Action: GEAC Secretariat & FSSAI**

**7.3 Update on Regulations and Guidelines for Recombinant DNA Research and Biocontainment-2017 published by Department of Biotechnology (DBT)**

Members took note of the updated Guidelines on “Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017” published by Department of Biotechnology. Representative of DBT briefed about the key features of these Guidelines. The members requested a hard copy of these Guidelines from DBT.

**Decision:**

- DBT may provide a hard copy of updated Guidelines on “Regulations and Guidelines for recombinant DNA Research and Biocontainment, 2017” to all the members of GEAC.

**Action: RCGM Secretariat**

**7.4 Updation on Status/ Key findings of Field Inspection and Scientific Evaluation Committee by representative of DBT**

Representative of DBT made a detailed presentation on the key findings of the Field Inspection and Scientific Evaluation Committee (FISEC) that was constituted by DBT to ascertain the spread of unapproved Herbicide Tolerant Cotton in the country. The FISEC in its report based on the result of genotyping, indicated that it was evident that 4 hybrids of M/s. Mahyco which were tested under field trials were not found in the field cultivated unapproved HT cotton, and accordingly concluded that deliberate release and pollen flow is a remote possibility. FISEC further recommended State Government and concerned Ministries and Departments to take appropriate action to destroy all illegal HT Cotton cultivation and also to take suitable legal action against responsible companies/ persons. The Committee took note of the proposed recommendations for different Ministries/ Agencies and State Governments and actions to be taken by different agencies for curtailing the spread of unapproved cultivation of HT Cotton.

The Committee suggested that actions proposed to be undertaken by MoEFCC and GEAC as per recommendations of the FISEC, may be taken up by the Secretariat.

**Decision:**

- GEAC Secretariat may undertake actions as per recommendations of the FISEC.

**Action: GEAC Secretariat**

**7.5 Information on deferral of 2<sup>nd</sup> year BRL-1 confined field trial with transgenic Maize hybrids containing cry1F and cry1Ab in a stacked product as TC 1507x Mon 810 along with Mon 810 as single event in the States of Karnataka and Punjab by PHI Seeds Pvt Ltd (Dupont / Pioneer).**

The Committee deliberated on the Communication sent by Ms. DuPont/ Pioneer regarding deferral of their second year BRL-I trial on transgenic Maize in the States of Karnataka and Punjab during Kharif 2018. The representative of DBT informed that a similar communication was received by RCGM Secretariat, which had sought a clarification from the company regarding the specific reasons for deferment of their BRL-I trial along with other details like availability of seeds, storage conditions etc.

The members suggested that the Secretariat may seek a similar clarification along with other relevant details from the applicant as was done by the RCGM Secretariat.

**Decision:**

- GEAC Secretariat may obtain a clarification from the applicant regarding the reasons for deferment of their BRL-I trial on Maize, along with other relevant details.

**Action: GEAC Secretariat**

**7.6 Information on deferral of 2<sup>nd</sup> year BRL-1 confined field trial with transgenic Maize hybrids TC 1 and TC 3 containing event TC 1507 in the State of Punjab by Ms. Dow Agro Sciences Pvt. Ltd.**

The Committee deliberated on the Communication sent by Ms. Dow Agro Sciences Pvt. Ltd. regarding deferral of their second year BRL-I trial on transgenic Maize in the State of Punjab during Kharif 2018.

The members suggested that the Secretariat may seek a clarification from the applicant, on deferral and other relevant details.

**Decision:**

- GEAC Secretariat may obtain clarification from the applicant regarding the reasons for deferment of their BRL-I trial on Maize, along with other relevant details.

**Action: GEAC Secretariat**

**7.7 Demonstration of GEAC Website**

Secretariat gave a demonstration of the new GEAC website developed with improved features wherein e-monitoring and e-permitting systems were added to the existing online system. The members appreciated the efforts of the Ministry and Secretariat for putting up a dedicated website for GEAC with a view to enhance transparency as well as to facilitate ease of doing business initiative. The members opined that this new website is quite useful as all the decisions of GEAC and copies of relevant Acts/ Guidelines/ Manuals etc. are available online and easily accessible.

**Decision:**

- The Committee noting the new features in the GEAC website appreciated the efforts of the Ministry and the Secretariat, and suggested that this may be made operational including e-monitoring systems at the earliest. Information about this may also be disseminated widely.

**Action: GEAC Secretariat**

**7.8 Demonstration of E-Learning Module on ERA of GE Plants**

The members were introduced to an e-learning module on Environmental Risk Assessment (ERA) of GE plants prepared by the Ministry. The members were informed that this e-learning module was developed for wider dissemination among stakeholders based on the ERA Guidelines, 2016 that was adopted by GEAC in its 130<sup>th</sup> meeting held on 11.08.2016.

**Decision:**

- The Committee took note of the newly developed e-learning module ERA of GE plants, and suggested for its wider dissemination.

**Action: GEAC Secretariat**

**7.9 Discussion on Guidelines for Import of Dried Distillers Grains Soluble**

The Committee deliberated on the proposed form for import of applications related to DDGS that was considered in the 134<sup>th</sup> meeting of GEAC. After detailed deliberations the members felt that it would not be appropriate to have different forms for different products of animal feed. It was agreed to have a uniform proforma and procedure for dealing with applications related to import of animal feed including DDGS. Accordingly, the Committee reiterated their decision made under Agenda Item No. 6.1 to constitute a Sub-committee under the Chairpersonship of Dr. Lalitha Gowda.

**Decision:**

- A Sub-committee may be constituted with Dr. Lalitha Gowda as the Chair and Dr. S.De (NDRI) and Shri. S.K. Bakshi (Advisor, FSSAI) and representatives from RCGM, GEAC, ICAR and DADF as with a view to recommend a procedure for import of animal feed in India.

**Action: GEAC Secretariat**

### 7.10 Discussion on Guidelines for conduct of Confined Event Selection Trials

Members deliberated extensively on the issue of harmonization of procedures for ease of doing business with regard to approval of event selection trials (ESTs). The Members also discussed extensively about the proposed new guidelines for conduct of ESTs that were considered in the 134<sup>th</sup> meeting of GEAC. The Committee made several suggestions for strengthening the same. Members felt that, this is an important issue and to keep the momentum of research going on, it is essential that simplified procedures in conformity with existing regulations may be introduced by the regulators so that research and development activities are not hampered.

It was agreed that the Members would provide their comments/ suggestions on the guidelines so that a decision in this matter may be taken in the next meeting. Accordingly, the decision on guidelines and procedures for ESTs was deferred and it was agreed that the applicants may follow the existing procedure till the new procedures are adopted.

#### **Decision:**

- Members may communicate their comments/ suggestions on the guidelines and procedures for ESTs for their consideration in the next meeting. The decision on guidelines and procedures for ESTs was deferred till next GEAC meeting.

**Action: GEAC Secretariat & Members**

### 7.11 Discussion on new plant breeding technologies and tools such as Genome Editing etc. vis-à-vis Indian Biosafety regulatory framework.

Members took note on the new global developments occurring in the field of biotechnology and suggested that DBT/RCGM may keep a tab on such developments and if required to come up with new guidance documents for regulation of new and emerging gene technologies.

#### **Decision:**

- DBT/RCGM may keep a tab on new and emerging gene technologies and if required to come up with new guidance documents.

**Action: DBT/ RCGM**

### Agenda Item 8 (Additional Items with the permission of the Chair)

The members were appraised about the following items with the permission of the Chair.

- ❖ Writ Petition 4445 of 2018 filed by M/s. Seedsmen Association Vs GEAC, MoEFCC and Others in Hon'ble High Court of Hyderabad.
- ❖ Writ Petition 20230 of 2018 filed by M/s. Seedsmen Association Vs MoEFCC and Others in Hon'ble High Court of Hyderabad.
- ❖ Draft " Food Safety and Standards (Labelling and Display) Regulations, 2018" issued by FSSAI.
- ❖ Communication received from Government of Maharashtra with comments on requirement of NOC for conduct of event selection trials.



- ❖ Information and minutes of Institutional Biosafety Committee received from M/s. Mahyco regarding destruction of herbicide tolerant cotton seeds by officials of State Government of Maharashtra.
- ❖ Receipt of application for conduct of Phase-II trials on GE Silkworm on 23.07.2018.

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

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List of Participants

<b>Official Members who participated</b>			
<b>1</b>	<b>Shri Arun Kumar Mehta,</b> Chairman, GEAC & Additional Secretary, Ministry of Environment, Forest & Climate Change, Jor Bagh, Aliganj , New Delhi.	<b>4</b>	<b>Dr. Rajyalakshmi Muralidharan</b> Scientist 'F'/ Director Department of Biotechnology, C.G.O. Complex, New Delhi.110003
<b>2</b>	<b>Dr K. Veluthambi,</b> Co-Chairman and Professor (retd.), School of Biotechnology, Madurai Kamraj University, Madurai.	<b>5</b>	<b>Dr. Murali Krishna Chimata</b> Scientist-D, and Member Secretary (GEAC) Ministry of Environment, Forests & Climate Change, Jor Bagh, Aliganj , New Delhi.
<b>3</b>	<b>Dr. Sujata Arora,</b> Advisor & Vice-Chairperson, GEAC Ministry of Environment, Forest & Climate Change, Jor Bagh, Aliganj, New Delhi.		
<b>Expert members</b>			
<b>1.</b>	<b>Dr. Ashok Bhatnagar,</b> Former Professor, Department of Botany, University of Delhi, New Delhi	<b>9.</b>	<b>Dr B. Venkateswarlu</b> Former Vice-Chancellor Vasant Rao Naik Marathwada Krishi Vidyapeeth, Parbani (Maharashtra)
<b>2.</b>	<b>Shri. Sunil Kumar Bakshi</b> Advisor (Codex/ regulations) Food Safety and Standards Authority of India (FSSAI), FDA Bhawan, New Delhi	<b>10.</b>	<b>Dr. S. J. Rahman,</b> Principal Scientist & Univ. Head of Entomology, AICRP on Biological Control Agricultural Research Institute (ARI), PJTSAU, Hyderabad
<b>3.</b>	<b>Dr. Sushil Gupta,</b> Former Chairman, Central Ground Water Board, New Delhi.	<b>11.</b>	<b>Dr. N. Satyanarayan</b> Joint Director Plant Protection Quarantine & storage ,NH-IV, Faridabad, Haryana.
<b>4.</b>	<b>Dr. Madhu Dikshit</b> Former Director CSIR-Central Drug Research Institute, Lucknow.	<b>12.</b>	<b>Dr. Lalitha Gowda,</b> Former Chief Scientist, CSIR-CFTRI Mysore, Karnataka.
<b>5.</b>	<b>Dr. P. Suprasanna</b> Scientific Officer H (level 14) Biosciences Group BARC, Mumbai.	<b>13.</b>	<b>Dr. Usha Rao</b> Assistant Controller of Patents & Designs, Patent Office, New Delhi, India

6.	<b>Dr. A.K. Singh,</b> Head, Division of Genetics, IARI, New Delhi.	14.	<b>Dr. Geeta Jotwani</b> Scientist F Indian Council of Medical Research, New Delhi
7.	<b>Dr. S. K. Barik</b> Director CSIR- National Botanical Research Institute, Lucknow	15.	<b>Dr. V.G. Somani</b> Joint Drugs Controller, Central Drugs Standard Control Organizations, New Delhi.
8.	<b>Dr. S De</b> Principal Scientist Animal Biotechnology Centre, National Dairy Research Institute, Karnal	16.	<b>Dr.V.Siva Reddy</b> Chief Scientific Officer Biosafety Support, Unit of DBT, New Delhi
17	<b>Dr. Dinesh K Agarwal,</b> Principal Scientist In charge, Plant Breeding & Genetics, ICAR-Indian Institute of Seed Science, Mau, U.P	18.	<b>Dr. Sanjeev Agarwal</b> Addl. Director, Biological Lab Central Pollution Control Board' New Delhi
<b>Other Special Invitees</b>			
1.	<b>Dr. Dwarkesh S.Parihar</b> Bioseed Research India	4.	<b>Dr. R.M.Singh,</b> Bioseed Research india Hyderabad.
2.	<b>Ms. Sandhya Agarwal</b> Team Leader, Regulatory Sciences Metahelix Life Sciences Ltd.	5.	<b>Dr. Vibha Ahuja</b> Chief General Manager Biotech Consortium India Limited .
3.	<b>Mr.Pankaj Kakkar</b> Golddrop Digital	6.	<b>Shri Ramanathan Vairamani</b> CTO Metahelix Life Sciences Ltd. Bangalore
<b>Member who did not participate</b>			
1.	<b>Prof. P. Balasubramanian,</b> Former Director, Centre for Plant Molecular Biology, TNAU, Coimbatore		

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