## PROCEEDINGS OF THE 136<sup>th</sup> MEETING OF THE GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 20.09.2018

The 136<sup>th</sup>meeting of the Genetic Engineering Appraisal Committee (GEAC) was held on September 20, 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 14.09.2018, 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 and thereafter, the agenda items were taken up as under:

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

Two Members communicated their inability to attend the 136<sup>th</sup>meeting of GEAC, namely Dr. Lalitha Gowda and Dr. Sushil Gupta. In addition, Shri. Sunil Kumar Bakshi, Dr. Ashok Bhatnagar, Dr. Madhu Dixit and Dr. Geeta Jotwani also could not attend the meeting.

#### 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 135th GEAC meeting

The draft proceedings of the 135<sup>th</sup> meeting of GEAC held on July 25, 2018 at New Delhi were circulated to the Members vide email on 08.08.2018 seeking their comments. No comments were received from any of the Members.

#### Decision:

• Members confirmed the proceedings of the 135<sup>th</sup> GEAC meeting.

#### Action:GEAC Secretariat

#### Agenda Item No. 3: Action taken report on the decisions taken in the 135th GEAC meeting

The Member Secretary, GEAC briefed about the action taken on the decisions of the 135<sup>th</sup> meeting of GEAC, informing action has been completed on all the items as per decisions taken in the previous meeting. The Committee appreciated the mention of specific action taken in the action taken report by the GEAC Secretariat.

#### Decision:

• The Committee noted the compliance of actions taken by the 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 clarifications provided by the applicant and the revised protocols for demonstration studies prepared in consultation with ICAR-All India Crop Research Project (AICRP) on Honeybees were deliberated at length. After detailed deliberations, the Committee approved the protocols for conduct of field demonstration studies on honey bees and other pollinators at two locations namely, Punjab Agriculture University (PAU), Ludhiana and Indian Agricultural Research Institute (IARI), New Delhi. Further, the members also noted that the total area for conduct of these demonstration studies in each location including GM and non GM plantation could be up to an area of 5 acres only. It was agreed that any pesticide that adversely impact honey bees should not be used.

The Committee also deliberated on the issue of requirement of No Objection Certificate (NOC) from the State Governments for conduct of these field demonstration studies. Considering that these field demonstrations studies are in continuation of Biosafety Research Level (BRL)-I & BRL-II trials for which the two State Governments concerned had already given NOC earlier to the applicant, the members agreed that the State Governments of Delhi and Punjab may be suitably informed by the applicant.

The members also 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. The Committee further agreed to the request of the applicant to undertake two field demonstration studies in 0.4 acres at University of Delhi to assess hybrid seed efficiency and also for maintenance of male sterile *barnase* line *bn* 3.6.

#### Decision:

- The application and the protocols for conduct of field demonstration studies on honey bees and other pollinators prepared jointly by University of Delhi and ICAR-AICRP on honey bees at two locations up to 5 acres in each location namely PAU, Ludhiana and IARI, New Delhi have been approved.
- The request seeking exemption for conduct of soil microflora studies was approved by the Committee as these studies were already done during BRL-I and BRL-II trials.
- The request for conduct of two field studies to assess hybrid seed efficiency and for maintenance of male sterile *barnase* line *bn* 3.6 was approved.
- It was agreed that any pesticide that adversely impact honey bees should not be used.

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

# 5.1 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 and the comments received from Department of Animal Husbandry, Dairying and Fisheries (DADF) regarding this application has been examined by the Committee in its 136<sup>th</sup> meeting.

Further, recalling the decision of 135<sup>th</sup> GEAC meeting and the subsequent constitution of a Sub-Committee under the Chair of Dr. Lalitha Gowda, a decision regarding this application for import of horse feed was deferred by the Committee till such a time a uniform procedure and guidelines for dealing with applications related to import of animal feed including Distillers Dried Grain Solubles (DDGS) has been framed by GEAC.

The GEAC also agreed that the newly constituted Sub-Committee may take into consideration and benefit from the reports of the previously constituted Sub-Committee for dealing with applications related to DDGS, while framing new guidelines for import of animal feed in India.

#### Decision:

• The application for import of horse feed containing GM soybean was deferred by the Committee till a procedure and guidelines for dealing with applications related to import of animal feed (including DDGS) are framed by the newly constituted Sub-Committee.

### Action: GEAC Secretariat

#### 5.2 Application related to import of Distillers Dried Grain Solubles

The applications submitted by eleven companies seeking permission for import of DDGS and the comments received from Department of Animal Husbandry, Dairying and Fisheries have been discussed by the Committee in its 136<sup>th</sup> meeting. Reiterating the decision taken at Agenda Item No. 5.1, the Committee deferred the decision regarding these applications till such a time a uniform procedure and guidelines for dealing with applications related to import of animal feed including DDGS has been framed by GEAC.

#### Decision:

• The Committee deferred all the eleven applications seeking permission for import of DDGS, till a procedure and guidelines for dealing with import of animal feeds are framed by the newly constituted Sub-Committee.

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

# 6.1 Request to consider large scale environmental release/ demonstration of *Bt* Brinjal by Ms. Mahyco Pvt. Ltd

The Committee deliberated on the request made by M/s. Mahyco Pvt. Ltd seeking permission for large scale environmental release/ demonstration of *Bt* Brinjal. While deliberating, the Committee referred to the decision of 97<sup>th</sup> meeting of GEAC held on 14.10.2009 and decision of the Government imposing a moratorium on 9.2.2010 on the large scale release of *Bt* Brinjal, taking into consideration a cautious, precautionary principle-based approach, till such time as independent scientific studies are established to the satisfaction of public and professionals.

The Committee also noted that Bangladesh has commercialized the same Mahyco's *Bt* Brinjal technology in 2013 and *Bt* Brinjal is presently being grown approximately by 50,000 farmers this year.

After detailed discussion, keeping in view the decision of the Government dated 09.02.2010 on *Bt* Brinjal, the Committee directed the GEAC Secretariat to write to Secretary, Department of Agricultural Research (DARE) to request ICAR-Indian Institute of Horticultural Research (IIHR), Bangalore to obtain relevant information and data on the post commercial release effects of *Bt* Brinjal in Bangladesh from Bangladesh Agricultural Research Institute (BARI).

Further, the Committee also agreed that the company may be asked to provide reports of any independent studies with regard to post commercial release of *Bt* Brinjal in Bangladesh.

#### Decision:

- GEAC Secretariat to write to Secretary, DARE to request ICAR-IIHR to seek information from BARI on the post commercial release effect/ impact of *Bt* Brinjal in Bangladesh and also to direct ICAR-IIHR to undertake independent scientific study on post release effect of *Bt* Brinjal.
- GEAC Secretariat to seek reports of independent scientific studies on post commercial release of *B*t Brinjal from M/s. Mahyco.

Action: GEAC Secretariat

6.2 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 M/s PHI Seeds Pvt Ltd (Dupont / Pioneer).

The Committee reviewed the response received from M/s. PHI Seeds Pvt. Ltd vide its letter dated 12.09.2018regarding their decision to defer the conduct of 2<sup>nd</sup> year Biosafety Research Level (BRL)-I confined field trial with transgenic Maize hybrids containing *cry1F and cry1Ab* genes in a stack product DAS-01507-1 x MON- 00810-6 (referred as TC 1507 x Mon 810) along with MON 00810-6 (referred as Mon 810) single event in the States of Karnataka and Punjab during the season of Kharif 2018.

The Committee noted that the key reasons for deferment of their decision to conduct BRL-I trial of Maize was due to the uncertainties in timeframe for approval of GM food/ feed crops and the IPR landscape in India.

The Committee directed the GEAC Secretariat to communicate to the company that the liability on account of accidental release/ leakage/ theft/ spillage/ encroachment by unauthorized

persons/utilization of GE material will be on the applicant i.e., M/s. PHI Seeds Pvt Ltd, Hyderabad. The GEAC also agreed for storage of the GE material by the company for one year only, and renewal of this approval to be obtained by the applicant on an annual basis.

### Decision:

- The Committee noted the reasons submitted by the applicant and directed the GEAC Secretariat to communicate to the company that the liability on account of accidental release/ leakage/ theft/ spillage/ encroachment by unauthorized persons/utilization of GE material will be on the applicant.
- The GEAC also agreed for storage of the GE material by the company for one year only, and renewal of this approval to be obtained by the applicant on an annual basis. Action: GEAC Secretariat

6.3 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 M/s. Dow Agro Sciences Pvt. Ltd.

The Committee reviewed the response received from M/s. Dow Agro Sciences vide its letter dated 12.09.2018regarding their decision to defer the conduct of 2<sup>nd</sup> year BRL-I confined field trial with transgenic Maize hybrids i.e. TC1 and TC3 containing event TC 1507 in the State of Punjab during the season of Kharif 2018.

The Committee noted that the key reasons for deferment of their decision to conduct BRL-I trial of Maize was due to the uncertainties in timeframe for approval of GM food/ feed crops and the IPR landscape in India.

The Committee directed the GEAC Secretariat to communicate to the company that the liability on account of accidental release/ leakage/ theft/ spillage/ encroachment by unauthorized persons/utilization of GE material will be on the applicant i.e., M/s. Dow Agro Sciences Pvt Ltd. The GEAC also agreed for storage of the GE material by the company for one year only, and renewable of this approval to be obtained by the applicant on an annual basis.

#### Decision:

- The Committee noted the reasons submitted by the applicant and directed the GEAC Secretariat to communicate to the company that the liability on account of accidental release/ leakage/ theft/ spillage/ encroachment by unauthorized persons/utilization of GE material will be on the applicant.
- The GEAC also agreed for storage of the GE material by the company for one year only, and renewal of this approval to be obtained by the applicant on an annual basis.

# 7. Any other item with the permission of the Chairman

7.1 Next meeting of the GEAC may be tentatively scheduled for last week of December 2018.

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

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# Annexure-1

# List of Participants

	Official Mer	ibers who	o participated
1.	Shri Arun Kumar Mehta, Chairman, GEAC & Additional Secretary, Ministry of Environment, Forest & Climate Change, Jor Bagh, Aliganj, New Delhi.	3.	Dr. Sujata Arora, Advisor & Vice-Chairperson, GEAC Ministry of Environment, Forest & Climate Change, Jor Bagh, Aliganj, New Delhi.
2.	<b>Dr K. Veluthambi,</b> Co-Chairman and Professor (retd.), School of Biotechnology, Madurai Kamraj University, Madurai.	4.	<b>Dr. Murali Krishna Chimata</b> Scientist-D, and Member Secretary (GEAC),Ministry of Environment, Forests Climate Change, Jor Bagh, Aliganj , New Delhi.
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1.	<b>Dr. S.R. Rao</b> Senior Advisor & Member Secretary, RCGM, Department of Biotechnology, New Delhi	8.	<b>Dr B. Venkateswarlu</b> Former Vice-Chancellor Vasantrao Naik Marathwada Krishi Vidyapeeth, Parbani (Maharashtra).
2.	<b>Dr. Sanjeev Agarwal</b> Addl. Director, Biological Lab Central Pollution Control Board New Delhi	9.	Dr. S. J. Rahman, Principal Scientist & Univ. Head of Entomology, AICRP on Biological Control Agricultural Research Institute (ARI), Pro Jayashankar Telangana State Agri. University, Rajendranagar, Hyderabad.
3.	Dr. Dinesh K Agarwal, Principal Scientist In charge, Plant Breeding & Genetics,ICAR-Indian Institute of Seed Science, Mau, U.P	10.	<b>Dr. N. Sathyanarayana</b> Joint Director Plant Protection Quarantine & storage ,NH-IV, Faridabad, Haryana.
4.	<b>Dr. S De</b> Principal Scientist Animal Biotechnology Centre, National Dairy Research Institute, Karnal.	11.	<b>Dr. S. K. Barik</b> Director CSIR- National Botanical Research Institute, Lucknow
5.	<b>Dr. P. Suprasanna</b> Scientific Officer H (level 14) Biosciences Group, BARC, Mumbai.	12.	Dr. Usha Rao Assistant Controller of Patents & Designs Patent Office, New Delhi, India
6.	<b>Dr. A.K. Singh,</b> Head, Division of Genetics, IARI, New Delhi.	13.	Shri. Jayant Gangakhedkar Joint Drugs Controller, Central Drugs Standard Control Organizations, New Delhi.
7.	<b>Dr. S De</b> Principal Scientist Animal Biotechnology Centre, National Dairy Research Institute, Karnal.	14.	<b>Prof. P. Balasubramanian,</b> Former Director, Centre for Plant Molecular Biology, TNAU Coimbatore.

	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	4.	<b>Dr. Ashok Bhatnagar,</b> Former Professor, Department of Botany, University of Delhi, New Delhi			
2.	<b>Dr. Sushil Gupta,</b> Former Chairman, Central Ground Water Board, New Delhi	5.	<b>Dr. Madhu Dikshit</b> Former Director CSIR-Central Drug Research Institute, Lucknow.			
3	<b>Dr. Lalitha Gowda,</b> Former Chief Scientist, CSIR-CFTRI Mysore, Karnataka-570 020,India	6.	<b>Dr. Geeta Jotwani</b> Scientist F Indian Council of Medical Research, New Delhi.			