### MINUTES OF THE 132<sup>NO</sup> MEETING OF THE GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 12.04.2017

The 132<sup>nd</sup> meeting of the Genetic Engineering Appraisal Committee (GEAC) was held on April 12, 2017 in the Ministry of Environment, Forest and Climate Change (MoEF&CC) under the Chairpersonship of Dr. Amita Prasad, Additional Secretary and Chairperson, GEAC.

List of participants is enclosed at Annexure-1

#### Agenda Item No.1 Leave of absence

The Committee granted leave of absence to the following members:

- 1) Dr. S.K. Apte
- 2) Dr. P.M. Bhargava
- 3) Dr. Renee Borges
- 4) Dr. O.P. Govila
- 5) Dr. V.V. Ramamurthy
- 6) Dr. C.R. Babu

#### Agenda Item No.2 Confirmation of minutes of 131st meeting of the GEAC held on 13.01.2017

The Committee confirmed and accepted the minutes of the 131st meeting circulated to Members on 17 02 2017

#### Agenda Item No. 3 Action taken report on the decisions taken in the 131st GEAC meeting

The Committee noted that all the action points as suggested in the 131st GEAC meeting were undertaken by the GEAC Secretariat

#### Agenda Item No. 4 Applications related to Environmental/ Commercial Release

Item No. 4.1 Application for Environmental Approval of Process change in manufacture of a Chiral Intermediate R-Phenyl Acetyl Carbinol (R-PAC) by a greener, efficient biotransformation process, using a category 1 GMO Yeast (IP-DSIR lab) on a commercial scale.

The Committee reviewed the application submitted by Ms. Embio Limited, Mumbai and heard the presentation made by the company representatives and **approved** the above application with following conditions as detailed below:

- To establish an Environmental Risk Management & Safety Plan (ERMP)
- To undertake an Environmental Audit of the existing plant
- To provide an Effluent Treatment Plan and Waste Disposal Strategy (Solid and Liquid Discharge)

The Committee suggested the applicant to furnish the above sought information within a period of next 3 months to GEAC Secretariat.

The Committee suggested constituting a monitoring team with experts from GEAC & RCGM for periodic review of the plant for ensuring the compliance and implementation of above listed recommendations.

### Agenda Item No. 5 Applications related to conduct of Confined Field Trials (CFTs) of GE Crops (Event Selection Trials/ BRL-1 and BRL-2 Trials

Item No. 5.1 Application for conduct of BRL-2 trials on Glytol @ Cotton containing GHB 614 Event in Central and Northern Zone based on the biosafety data generated during BRL-1 Trials by Ms. Bayer Biosciences Pvt. Ltd

The Committee reviewed the application submitted by Ms. Bayer Biosciences Pvt. Ltd and also heard the presentation made by the applicant for the conduct of BRL-2 trials on Glytol @ Cotton and approved the application subject to submission of following clarification

 To provide details of the States where the applicant proposes to carry out BRL-2 trials in Northern and Central Zone

The Committee noted that, as of now in India, *Bt* Cotton is the only crop approved for commercial cultivation with Insect Resistance Trait and this is the first time an application has come for BRL-II Trials for Cotton with Herbicide Resistance. Members had a very detailed discussion and debate regarding Herbicide Resistance crops for India and after detailed deliberations agreed to continue research on Herbicide Resistance Crops and accordingly suggested the applicant to generate the following additional data during the conduct of BRL-2 trials

- Base line data on development of resistance in natural weeds
- Data on retention/ leaching of pesticides into soil and water in fields where herbicides are used

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

## Item No. 6.1 Application for import of Partially Processed Soybean Oil derived from Herbicide Tolerant Soybean (Event SYHTOH2) by Ms. Syngenta Biosciences Pvt. Ltd

The Committee reviewed the application submitted by Ms. Syngenta Biosciences Pvt. Ltd and also heard the presentation made by the applicant seeking permission for import of partially processed Soybean Oil for food and feed purposes.

The Committee deferred the application due to lack of following information:

- Lack of clarity on reasons for import of partially processed oil to India for food/ feed purpose
- Non availability of substantial data to prove the absence of herbicide/ pesticide residue in processed/ partially processed oil samples
- No information on proposed safety measures to ensure contamination/ adventitious mixture of traces of seed/ grain in the partially processed oil
- Lack of detailed processing steps and country of origin from which the oil is proposed to be imported
- Lack of clear disposal mechanism of waste generated during refining process

### Item No. 6.2 Permission for import of Soybean Grain & Oil derived from Herbicide Tolerant Soybean (Event DAS-68416-4) for food & feed purpose by M/s Dow Agro Sciences India Pvt. Ltd

The Committee deferred the application on the request of applicant to consider the application in subsequent GEAC meeting

### Item No. 6.3 Permission for import of Soybean Grain & Oil derived from Herbicide Tolerant DAS-444Ø6-6 Soybean for food & feed purpose by M/s Dow Agro Sciences India Pvt. Ltd

The Committee deferred the application on the request of applicant to consider the application in subsequent GEAC meeting

### Item No. 6.4 Application for commercial import of oil derived from Insect protected Soybean (Event MON87751) by M/s Monsanto Holdings Pvt. Ltd.

The Committee rejected the application as it was in premature stage seeking permission from GEAC for import of oil from countries where even the Events were not approved.

#### Agenda Item No. 7 Other items

# Item No. 7.1 Notification of laboratories strengthened under Phase II Capacity Building project on Biosafety as National Referral Laboratories for detection of Living Modified Organisms (LMOs)

The Committee deliberated on the issue of Accreditation and Notification of 4 laboratories namely ICAR-National Bureau of Plant Genetic Resources (ICAR-NBPGR), New Delhi; Punjab Biotechnology Incubator (PBTI), Mohali; Export Inspection Agency (EIA), Kochi and DNA Fingerprinting and Transgenic Crop Monitoring Lab (DFTCML), Guntur as Referral Facilities for detection of living modified organisms (LMOs).

The Committee noted that the above 4 laboratories were strengthened both in terms of infrastructure and human resource capacities through financial support from MoEF&CC under the UNEP-GEF Phase-II Capacity Building Project on Biosafety.

Pursuant to detailed deliberations, the Committee suggested the four laboratories to get in touch with concerned agencies to get their labs notified as "Referral Facilities for Detection of LMOs" under the Seed Act, 1966 and Food Safety and Standards Act, 2006.

The Committee also requested Ministry of Agriculture and Food Safety and Standards Authority of India (FSSAI) to provide requisite guidance and support to the labs in getting their labs Notified under relevant provisions and sections of their respective Acts.

### Item No. 7.2 Authorizing Indian Council of Agricultural Research (ICAR) for approval of Bt Cotton Hybrids currently serviced through Standing Committee in Department of Biotechnology

The Committee deliberated on the issue of approval of Bt Cotton Hybrids which is currently being serviced through a Standing Committee in Department of Biotechnology following an Event Based Approval Mechanism (EBAM) as per MoEF&CC OM No. 13/39/2007-CS-II dated 17.04.2009.

The Committee after detailed deliberations recommended transferring the entire responsibility of evaluation, approval, management and monitoring of *Bt* Cotton Hybrids to Indian Council of Agricultural Research

(ICAR) in view of limited role of MoEF&CC and DBT and also recommended that hence forth the entire responsibility of confirmation of the presence or absence of the approved gene / event, level of protein expression etc. in *Bt* Cotton Hybrids would also be the sole responsibility of ICAR.

The Committee suggested MoEF&CC to issue an Office Memorandum (OM) regarding transferring the entire responsibility of approval of *Bt* Cotton Hybrids to ICAR in supersession of the earlier issued OM dated 17.04.2007.

#### Item No. 7.3 Date of next GEAC meeting

The Committee suggested convening the 133<sup>rd</sup> meeting of the GEAC on May 11, 2017.

### Agenda Item No. 8 Any additional Item with the permission of the Chair

### Item No. 8.1 Withdrawal of the Gazette Notification Number SO 1519 (E) dated 25.08.2007

The Committee deliberated on the issue of withdrawal of Rule 11 under the Rules 1989 regarding the Genetically Modified (GM) processed foods. The Committee noted that in 2007 the ministry has taken a decision to amend Rule 11 for excluding processed food from the purview of GEAC through a Gazette Notification No. SO 1519(E) dated 23 08 2007. The Ministry of Health and Family Welfare (MoH&FW) vide their communication dated 26 12 2007 requested MoEF&CC to continue regulation of GM processed foods till FSSAI is able to look into the matter in a scientific manner and come out with a Notification. Accordingly, MoEF&CC started keeping in abeyance the earlier issued notification at regular intervals and the last Gazette Notification got expired on March 31, 2016

The Committee suggested convening a meeting with FSSAI at the earliest to understand and resolve this issue of GM processed foods as currently there is a vacuum with respect to GM processed foods in the country. It was also agreed that GEAC should look into applications related to import of GM processed food till FSSAI comes with detailed guidelines / regulations.

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

### **ANNEXURE-I**

S. No.	NAME & DESIGNATION
1	Dr. Amita Prasad, Chairperson, GEAC and Additional Secretary, Ministry of Environment, Forest
	and Climate Change, Jorbagh, Aliganj, New Delhi
2	Dr K. Veluthambi, Co-chairman, GEAC and Professor (retd) & Head, School of Biotechnology,
	Madurai Kamraj University, Madurai
3	Shri. Gyanesh Bharti, Vice Chiarman, GEAC and Joint Secretary , Ministry of Environment,
	Forest & Climate Change, Jor Bagh, Aliganj, New Delhi.
Membe	rs
4	Dr. B. Sesikeran, Former Director, National Institute of Nutrition, Hyderabad & Chairman, RCGM
5	Dr. S.S. Banga, Plant Breeder, Punjab Agriculture University, Ludhiana
6	Dr. S. R. Rao, Advisor, Department of Biotechnology, C.G.O. Complex, Lodhi Road, New Delhi
7	Dr. R. P. Singh, ADG (Crop Science), Indian Council of Agricultural Research, Krishi Bhawan,
	New Delhi
8	Shri R.K Singh, Joint Secretary(Seeds), Department of Agriculture & Cooperation, Ministry of
	Agriculture, Krishi Bhawan, New Delhi
9	Dr. Sushil Gupta, Former Chairman, Central Ground Water Authority
10	Dr. Ranjini Warrier, Former Advisor, Ministry of Environment, Forests & Climate Change,
	Jor Bagh, Aliganj , New Delhi
11	Shri Umesh Chandra, Deputy Director, National Plant Quarantine Station, Ministry of Agriculture
	& Cooperation, New Delhi
12	Ms. Madhumita Biswas, Member Secretary (GEAC) and Director, Ministry of Environment,
	Forests & Climate Change, Jor Bagh, Aliganj , New Delhi.
Others	
13	Dr. Murali Krishna Chimata, Scientist D, Ministry of Environment, Forests & Climate Change, Jo
	Bagh, Aliganj , New Delhi
14	Dr. P. Saranya, Scientist C, Ministry of Environment, Forests & Climate Change, Jor Bagh
	Aliganj , New Delhi