

Minutes of the 131st Meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 13.01.2017

The 131st meeting of the GEAC was held on January 13, 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 annexed at **Annexure-1**

Agenda item No.1 Leave of absence

The Committee granted leave of absence to following members:

1. *Dr. Sesikeran,*
2. *Dr. P.M. Bhargava,*
3. *Dr. C.R. Babu*
4. *Dr. Vijendra Mishra*

Agenda item No.2 Confirmation of minutes of 130th meeting of the GEAC held on 11.08.2016

The Committee confirmed and accepted the minutes of the 130th GEAC meeting circulated to members on 28.09.2016

Agenda item No.3 Action taken report on the decision taken in the 130th GEAC meeting

The Committee noted that all the actions points as suggested in 130th GEAC meeting were undertaken by the Secretariat

Agenda Item no. 4: Information about the applications related to Additional Location or Extension of Validity Period, approved by the Chairperson, GEAC

The Committee noted that subsequent to the decisions taken in 125thGEAC meeting dated 11.12.2015 approval for additional location or extension of validity period without change in technical details were accorded to the following applicants with the approval of Chairperson, GEAC for information.

- 4.1 Request by M/s Dow Agrosciences Pvt. Ltd., Mumbai seeking permission to conduct Biosafety Research Level (BRL-1) trials on transgenic Maize Event (TC1507) at additional locations - Haryana and Maharashtra.
- 4.2 Request by M/s Dow AgroSciences India Pvt. Ltd., Mumbai seeking permission for conducting F2 grain production of transgenic Maize hybrid TC1 (Event TC1507) at additional locations at Maharashtra, Andhra Pradesh and Telangana.

- 4.3 Request by M/s MSD Animal Health Pvt. Ltd. (IntervetPvt Ltd) seeking permission for revalidation of GEAC approval to store Foot and Mouth Disease (FMD) virus and manufacturing and marketing of FMD Virus vaccine, inactivated IP
- 4.4 Request by M/s MSD Animal Health Pvt Ltd (IntervetPvt Ltd) seeking permission for revalidation of GEAC approval to store *Brucellaabortus* (strain 19) virus and manufacturing and marketing of *Brucellaabortus* (strain 19) vaccine, live, IP

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

5.1 Permission to conduct Confined Field Trial for Event Selection of Genetically Engineered Chickpea lines harbouring *Cry1Ac/ Cry1Aabc* gene at ICAR-Indian Institute of Pulses Research (ICAR-IIPR) research farm, Kanpur, U.P by ICAR-IIPR Kanpur

The Committee reviewed the request of ICAR-Indian Institute of Pulses Research (IIPR), Kanpur and the information document prepared by Biosafety Support Unit (BSU) of Review Committee on Genetic Manipulation (RCGM) and **approved** the request made by the applicant for conduct of Event Selection Trial (EST) of GE Chickpea lines harbouring *Cry1Ac/ Cry1Aabc* gene. The Committee suggested the following:

- RCGM to provide requisite mentorship and stewardship trainings to concerned scientists of ICAR-IIPR for ensuring regulatory compliance as per prescribed Indian guidelines
- To instruct ICAR-IIPR to conduct experiments strictly within the premises of the Institute as per stipulated regulatory guidelines as requirement of No Objection Certificate (NOC) from State Governments has been exempted for EST's vide decision taken by GEAC in its 130th meeting (Agenda Item 8.2) held on 11.08.2016
- To forward a copy of the permit letter (when issued by GEAC/RCGM) along with information document to respective State Government to keep them apprised of the trial

5.2 Permission to conduct Confined Field Trial for Event Selection trial of transgenic Pigeonpea containing *cry1Ac/cry1Aabc* genes at ICAR-IIPR research farm, Kanpur, U.P by ICAR-IIPR Kanpur

The Committee reviewed the request of ICAR-IIPR, Kanpur and the information document prepared by BSU of RCGM and **approved** the request made by the applicant for conduct of EST of transgenic Pigeonpea lines harbouring *Cry1Ac/ Cry1Aabc* gene. The Committee suggested the following:

- RCGM to provide requisite mentorship and stewardship trainings to concerned scientists of ICAR-IIPR for ensuring regulatory compliance as per prescribed Indian guidelines
- To instruct ICAR-IIPR to conduct experiments strictly within the premises of the Institute as per stipulated regulatory guidelines as requirement of No Objection Certificate (NOC) from

State Governments has been exempted for EST's vide decision taken by GEAC in its 130th meeting (Agenda Item 8.2) held on 11.08.2016

To forward a copy of the permit letter (when issued by GEAC/RCGM) along with information document to respective State Government to keep them apprised of the trial.

Agenda Item No. 6: Applications related to Industrial processes

6.1 Application for approval of manufacture of Ethanol from Nonfood Biomass like Agricultural residues mainly Bagasse using genetically modified yeast strain *Saccharomyces cerevisiae* cV110 by M/s ShreenathMhaskobaSakharKarhkama Ltd, Pune

And

6.2 Application for approval of manufacture of Ethanol from Nonfood Biomass like Agricultural residues mainly Bagasse using genetically modified yeast strain *Saccharomyces cerevisiae* Cellux 4 by M/s ShreenathMhaskobaSakharKarhkama Ltd, Pune

The Committee reviewed the applications submitted by M/s. ShreenathMhaskobaSakharKarhkama Ltd, Pune seeking approval for manufacture of Ethanol from Non Food Biomass like Agricultural residues mainly bagasse using genetically modified yeast strains *Saccharomyces cerevisiae* cV110 and *Saccharomyces cerevisiae* Cellux 4

The Committee heard the detailed presentation made by the company representatives and **approved** the above applications. The Committee also sought the following information from the applicant and few suggestions as detailed below:

- Information on the Environmental Standards being maintained in the existing plant as well as in the new plant proposed to be established
- To undertake the Environmental Audit for the existing and new proposed ethanol plant
- Life Cycle analysis of the product and process detailing critical steps at which probability of solid or liquid discharge into the environment (soil/ water) exists and the proposed precautionary measures being taken for tackling the same, in case of unintended release into the environment
- Details on Effluent Treatment Plant (ETP) and standards being maintained for the existing plant
- The project should be implemented under the oversight of IBSC of the applicant with regular annual reports to RCGM.
- GEAC to appoint an expert for review and monitoring of the process of establishment of the facility and progress of the project at regular intervals as required.

Agenda Item No. 7: Applications related to Pharmaceuticals

7.1 Permission for import of INNOVAX-ND (Marek's Disease- Newcastle Disease Vaccine, Serotype 3, Live virus, Live Marek's Disease Vector) a recombinant live Poultry vaccine for preventive vaccination from USA and marketing in India by M/s MSD Animal Health Pvt Ltd (IntervetPvt Ltd), Pune

The Committee reviewed the application submitted by M/s MSD Animal Health Pvt Ltd (IntervetPvt Ltd), Pune and also heard the presentation made by the applicant. The committee **approved** the application of M/s MSD Animal Health Pvt Ltd (IntervetPvt Ltd), Pune and made the following suggestions/ recommendations to the applicant:

- To generate laboratory / in vivo efficacy data of the vaccine under Indian conditions in labs like ICAR-Indian Veterinary Research Institute (IVRI), Izatnagar
- To establish the need for import of a recombinant NDV vaccine as against the already existing NDV vaccines in the Indian market.
- To provide Environmental Safety Management Plan
- The project should be implemented under the oversight of IBSC of the applicant with regular annual reports to RCGM.

The applicant is also advised to approach Department of Animal Husbandry, Dairying and Fisheries (DADF), Ministry of Agriculture and Drug Controller General of India (DCGI) etc. for seeking further approvals as per prevailing Indian laws.

7.2 Permission for storage of Foot and Mouth Disease (FMD) virus strain O1 Manisa required for manufacturing of FMD vaccine, inactivated for export purpose by M/s MSD Animal Health Pvt Ltd (IntervetPvt Ltd), Pune

The applicant was called for a presentation but the company representative did not make the presentation. However, the committee **approved** the application considering routine nature of such application and the fact that the exporter should abide by the conditions of the importing country.

7.3 Clearance for Phase III Clinical Trial Application of VPM 1002 (rBCG), Vaccine for Tuberculosis by M/s Serum institute of India Pvt Ltd (SIPL).

The Committee re-considered the application submitted by M/s Serum institute of India Pvt Ltd (SIPL) seeking clearance for Phase III Clinical Trial Application of VPM 1002 (rBCG), Vaccine for Tuberculosis based on the inputs/ comments provided by RCGM.

The Committee approved the application for Phase III Clinical Trial Application of VPM 1002 (rBCG), Vaccine for Tuberculosis based on the revised guidelines/ amendments published by Ministry of Health and Family Welfare (Department of Health and Family Welfare) vide its Gazette Notification No171 dated-16 March 2016G.S.R. 11(E) which is an amendment to the Drugs and Cosmetics Rules, 1945. The Amended Clause may be read as follows In Schedule Y to the said rules, in Appendix I, in item 4, after sub-item 4.8, the following notes shall be inserted, namely: -

“Note.- Where the data on animal toxicity as per the specifications of Appendix III has been submitted and the same has been considered by the regulatory authority of the country which had earlier approved the drug, the animal toxicity studies shall not be required to be conducted in India except in cases where there are specific concerns recorded in writing.”

Agenda Item No. 8: Applications related to import

8.1 Permission for import of High Oleic Soy oil:- “Plenish” stack genes DP-305423-1xMON04032-6 from USA by M/s Pioneer Hi-Bred Private Limited

The Committee reviewed the applications submitted by M/s Pioneer Hi-Bred Private Limited seeking permission for import of High Oleic Soy oil-: "Plenish" stack genes DP-305423-1xMON04032-6 from USA. The Committee heard the detailed presentation made by the company representatives and reviewed the test analysis report submitted by CSIR-Central Food Technological Research Institute (CFTRI), Mysore.

The Committee after analysis of the report submitted by CSIR-CFTRI noted that no DNA or Proteins were present in the analyzed sample and found it safe for usage and accordingly, approved the application for import of High Oleic Soy oil-: "Plenish" stack genes DP-305423-1xMON04032-6 from USA.

The Committee further requested information from the applicant regarding the annual quantity of oil proposed to be imported for next three years to be submitted within a month of receipt of the permit letter.

Agenda Item No. 9: Any other issues

9.1 Decrease in production of pulses in our country in the year 2014 & 2015 due to insufficient rain

The Committee deliberated and discussed regarding the issue of decrease in production of pulses in India and opined that technological interventions from Ministry of Agriculture is required for addressing issue of enhanced production of pulses.

9.2 Inadvertent corrections in 130th GEAC Minutes

The Committee noted and **approved** the inadvertent corrections for Agenda items (7.4, 7.5, 7.6 & 7.7) related to M/s SanofiSynthelabo (India) Pvt Ltd which was discussed during the 130th meeting of the GEAC held on 11.08.2016 and the corrections may be read as below:

Recorded in 130th GEAC meeting	Revised Titles
Import and market of the Canine Distemper — Adenovirus type 2- corona virus-para influenza Vaccine Modified Live Virus (Recombitek [®] C6/CV)	Import and market of the Canine Distemper-Adenovirus type 2-Coronavirus-Parainfluenza-Parvovirus vaccine Modified live virus, Live Canarypox vector, LeptospiraCanicolaIcterohaemorrhagiaeBacterin (Recombitek [®] C6/CV)
Import and market of the Canine Distemper — Adenovirus type 2- corona virus-para influenza Vaccine Modified Live Virus (Recombitek [®] C6)	Import and market of the Canine Distemper-Adenovirus type 2-Parainfluenza-Parvovirus vaccine, Modified live virus, Canarypox vector, LeptospiraBacterin (Recombitek [®] C6)
Import and market of the Canine Distemper — Adenovirus type 2- corona virus-para influenza Vaccine Modified Live Virus (Recombitek [®] C4)	Import and market of the Canine Distemper-Adenovirus type 2-Parainfluenza- Parvovirus vaccine, Modified live virus, Canarypox vector (Recombitek [®] C4)
Import and market of the Canine Distemper — Adenovirus type 2-	Import and market of the Canine Distemper-Adenovirus type 2-Parvovirus vaccine, Modified

corona virus-para influenza Vaccine Modified Live Virus (Recombitek®C3)	Live Virus, Canarypox Vector (Recombitek® C3)
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9.3 Application to conduct two years of BRL-I trials of transgenic maize hybrids expressing stacked events TC1507 x MON810 during appropriate seasons during the years 2016 and 2017 by M/s Pioneer Hi-Bred Pvt.Ltd

The Committee re-considered the application submitted by M/s Pioneer Hi-Bred Pvt.Ltd seeking permission for conduct of two years of BRL-I trials of transgenic maize hybrids expressing stacked events TC1507 x MON810 during appropriate seasons based on information document and recommendations made by RCGM.

The application related to conduct of two years of BRL-I trials of transgenic maize hybrids expressing stacked events TC1507 x MON810 was **approved** and the applicant was suggested to generate all relevant additional data as detailed below prior to submitting an application to GEAC for conduct of BRL-II Trials.

The applicant is permitted for BRL-1 trial as per the locations identified with two-stack hybrid (TC1507 x MON810) and its comparator non GMO and other checks as proposed. This trial should also include the single event (MON810) and its comparator for biosafety data generation as per the field trial layout submitted on the recommendation of RCGM. As informed by the applicant, it was noted that the biosafety data for individual event TC1507 shall be generated by the collaborators as per the regulatory requirements in the ongoing applications and BRL-1 trials.

It is recommended that when the applicant submits BRL-2 field trials shall the biosafety data for all the two single events should be made available and the BRL-2 trial should include all the stacks and the events for comparative assessment.

9.4 Permission to conduct second year Biosafety Research Level-I (BRL-I) trial with 2 transgenic maize (Zea mays L.) hybrids containing cry1F, cry1Ab and cp4epsps genes (stacked events of TC1507 x MON 810 x NK 603 (DAS-01570-1 x MON-00810-6 x MON-00603-6) by M/s Pioneer Hi-Bred Pvt.Ltd

The application related to conduct second year Biosafety Research Level-I (BRL-I) trial with 2 transgenic maize (Zea mays L.) hybrids containing cry1F, cry1Ab and cp4epsps genes (stacked events of TC1507 x MON 810 x NK 603 (DAS-01570-1 x MON-00810-6 x MON-00603-6) was **approved** and the applicant was suggested to generate all relevant additional data as detailed below prior to submitting an application to GEAC for conduct of BRL-II Trials.

The applicant is permitted for BRL-1 trial as per the locations identified with three-stack hybrid (TC1507 x MON810 x NK603) and its comparator non GMO and other checks as proposed. As informed by the applicant, it was noted that the biosafety data for individual events TC1507 and NK603 shall be generated by the collaborators as per the regulatory requirements in the ongoing applications and BRL-1 trials. It is recommended that when the applicant submits BRL-2 field

trials all the biosafety data for all the three single events should be made available and the BRL-2 trial should include all the stacks and the events for comparative assessment.

9.5 Request for changing the transgenic hybrids in the application of Conduct 1st and 2nd year of BRL I trials of transgenic maize hybrids expressing stacked events TC1507 x MON 810 by M/s Pioneer Hi-Bred Pvt.Ltd

The Committee noted that the application related to request for change of transgenic hybrids for conduct of 1st and 2nd year of BRL I trials of transgenic maize hybrids expressing stacked events TC1507 x MON 810 by M/s Pioneer Hi-Bred Pvt.Ltd has been withdrawn by the applicant in view of their business priorities vide their formal communication dated January 10, 2017 and approved the request made by the applicant.

9.6 Increasing number of applications related to import of Distiller's Dried Grains with Solubles (DDGS) made from GM corn from USA

The Committee deliberated on the issue related to import of DDGS made from GM Corn from USA and noted that similar applications have been considered positively by several countries in Asia Pacific region also.

However, the Committee noted that there are no defined guidelines in India and recommended to constitute to Sub-Committee to prepare a draft guideline with a prescribed application format for seeking requisite information from the applicant. The Sub-Committee was suggested to submit its report before end of March 2017. The Members of this Sub-Committee would include the following:

- Prof. K. Veluthambi, Co-Chair, GEAC
- Member Secretary, RCGM
- Joint Secretary (seeds) or his nominee, Ministry of Agriculture
- Representative from Department of Animal Husbandry, Dairying & Fisheries
- Representative from MOEF&CC

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

ANNEXURE-1

S.No.	Name and Designation
1.	Dr.Amita Prasad, Chairperson, GEAC and Additional Secretary, Ministry of Environment, Forests & Climate Change, JorBagh, Aliganj , New Delhi.
2.	Dr K. Veluthambi, Co-chairman, GEAC and Professor (Retd), School of Biotechnology, Madurai Kamraj University, Madurai
3.	Dr. S. R. Rao,Advisor, Department of Biotechnology, C. G. O, Complex, Lodhi Road, New Delhi.
4.	Dr.J.S.Sandhu,DDG(Crop Science) Indian Council of Agricultural Research, KrishiBhawan, New Delhi
5.	Dr. R.K. Mishra, Additional Commissioner (seeds), Department of Agriculture, Co-operation and Farmer's Welfare, Ministry of Agriculture, New Delhi
6.	Dr. S.S. Banga, Plant Breeder, Punjab Agriculture University, Ludhiana
7.	Dr. Ramesh Sonti, Chief Scientist, CSIR, Centre for cellular &Molecular Biology (CSIR-CCMB) Uppal Road, Hyderabad.
8.	Prof. O. P. Govila, Former Prof. of Genetics, Indian Agricultural Research Institute. "MANAS", House No. BU- 58, Pitampura, Delhi.
9.	Dr. Renee M Borges,Professor, Centre for Ecological Sciences, Indian Institute of Science, Bangalore
10	Dr. V.V Ramamurthy,Former Professor, Entomology Division, IARI, New Delhi,Centre for Ecological Sciences, Indian Institute of Science, Bangalore
11	Dr. S. K. Apte,Emeritus Professor, HBNI, BARC, Mumbai.
12.	Ms. Madhumita Biswas, Member Secretary (GEAC) and Director Ministry of Environment, Forest& Climate Change, JorBagh, Aliganj, New Delhi.
13.	Dr.P. Saranya, Scientist C, Ministry of Environment, Forest& Climate Change, JorBagh, Aliganj , New Delhi