Minutes of the 130th meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 11.08.2016

The 130th meeting of the GEAC was held on August 11, 2016 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 anenxed at **Annexure-1**

Agenda item No.1 : Leave of absence

The Committee granted leave of absence to Dr. Gautam Chhaterjee and Dr. Vijendra Mishra

Agenda item No.2 : Confirmation of minutes of 129th meeting of the GEAC held on June 20, 2016

The Committee confirmed and accepted the Minutes of the 129th GEAC meeting circulated to the members on 08.07.2016

Agenda item No.3 : Action taken report on the decision taken in the 129th GEAC meeting

The Committee noted that all the actions points as suggested in 129th GEAC meeting were undertaken by the Secretariat.

Agenda Item No. 4: Information about the additional location or extension of validity period, applications approved by the Chairperson, GEAC

The Committee noted that subsequent to the decisions taken in 125th GEAC 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.

4.1. Request for extension of validity to conduct Biosafety Research level (BRL-1) trials on insect-tolerant chickpea namely; *Bt* chickpea 1, *Bt* chickpea 2, *Bt* chickpea 3, and *Bt* chickpea4 *(*event SSL-6) containing *Cry2Aa* gene by M/s. Sungro Seeds Limited, New Delhi

4.2. Application for including JAU, Junagadh Gujarat also as a trial location for Central zone transgenic cotton field trials by M/s Bayer Bioscience Pvt Ltd

4.3. Request for additional location for conduct Biosafety Research trials level (BRL-II) with two transgenic Bt Brinjal hybrids namely Janak and BSS-793 Bt, containing *Cry1Fa1* (Event 142) *gene by* M/s. Bejo Sheetal Seeds Pvt. Ltd., Jalna

4.4. Request for extension of validity to conduct Biosafety Research Level-1 (BRL-1) trial of Para Rubber Tree [*Hevea brasiliensis* [Wild. Ex Adr. De Juss.) Muell. Arg.] on Hb. SOD-L1 & L2 (Two transgenic events lines)] by Rubber Research Institute of India, Kottayam

4.5. Request for extension of validity to conduct Biosafety Research Level-II (BRL-II) trials on WideStrike™ cotton hybrids namely WS103 & WS106 containing cry*1F* (Event281-24-236+ *cry1Ac* (Event3006-210-23) in Central zone at eight locations by M/s. Dow Agro sciences India Pvt. Ltd., Mumbai

4.6. Request for additional location for conducting field trials of GlyTol® cotton to assess bio efficacy and residual analysis of the Glyphosate 41% SL herbicide containing *2mEPSPS* gene (event *GHB614*) at South Zone by M/s Bayer BioScience Pvt.Ltd., Gurgaon

Agenda Item No.5 : Application related to Environmental Release

5.1 Permission 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. CGMCP, University of Delhi.

5.1.1 The Sub-committee constituted under the Chairmanship of Prof. K Veluthambi to review the Dossier submitted by Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi 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. A report prepared incorporating the evaluation of biosafety data generated by the applicant by sub-committee along with inputs of Risk assessment unit of RCGM, peer reviewed scientific literature on the subject was submitted "Assessment of food and environmental safety "to GEAC. GEAC reviewed this and suggested that the report may be placed in MoEF&CC website for a period of 30 days from the date of placing in the website for inviting comments from stakeholders.

5.1.3 The Committee suggested that a special E-mail Id be created for receiving comments from all stakeholders. The comments received from stakeholders would be examined by the Sub-Committee and the same would be placed before the GEAC in next meeting.

Agenda Item 6: Applications related to Confined Field Trials of GE crops (Event selection/ BRL-I / BRL-II Trials)

6.1 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

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6.2 Request for changing the transgenic hybrids in the application for Conducting 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 application submitted by M/s. Pioneer Hi-Bred Private Limited has been deferred and the Committee suggested the applicant to generate/submit the following additional data and submit a fresh application to RCGM for its review and comments.

- Details on molecular characterization of each parental line/ events and hybrids along with the hybrid development strategies
- In the trial, all parental lines (containing individual event) that was used for generation of this hybrid should also be included in addition to GE maize stacked hybrid (P3401YH and P3396YH), its non transgenic counterparts appropriate national and zonal checks. For inclusion of the parental lines, the trial protocol should also be revised accordingly.
- Evaluation of hybrid should also be tested by spraying glufosinate and data on phytotoxixcity, weed control efficacy, residue analysis in soil should be generated
- Complete food and environmental safety data should be generated for the parental lines also where information on comparitive assessment between GE and non GE lines should be generated.

6.3 Request to make correction in the GEAC approval letter issued by GEAC titled, "Request for additional locations in the state of Delhi and company long leased land to conduct various BRL trials" by M/s Pioneer Hi-Bred Pvt.Ltd

The Committee reviewed the request of M/s Pioneer Hi-Bred Pvt.Ltd and approved the request made by the applicant. The Committee suggested the secretariat to issue a revised permit letter for first year BRL- I trials for maize hybrids containing the events TC1507xMON810

6.4 Application for hybrid seed production of wide Strike cotton hybrids during 2016-2017 by M/s Dow AgroScience, which will be used for conducting BRL-II trials.

The Committee reviewed the information provided by the applicant regarding the objective of the hybrid seed production and approved the request for hybrid seed production of wide Strike cotton hybrids during appropriate seasons in 2016-2017 and 2017-18.

6.5 Permission to conduct confined field trial BRL-II of transgenic Maize (Zea Mays L) containing Event NK 603 at North, Central and South Zones by Ms. Monsanto India Pvt. Ltd

The Committee reviewed the information provided by the applicant regarding number of herbicides sprays that would be applied per year and approved the request for conduct of confined field trial BRL –II of transgenic Maize (*Zea Mays L*) containing Event NK603 at North, Central and South zones for a period of 2 years.

6.6 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) M/s Pioneer Hi-Bred Pvt.Ltd, Hyderabad

The Committee reviewed the application submitted by M/s Pioneer Hi-Bred Pvt.Ltd for conduct of confined field trial BRL–I of transgenic Maize (*Zea Mays L*) 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)

The application submitted by M/s. Pioneer Hi-Bred Private Limited has been deferred and the Committee suggested the applicant to generate/submit the following additional data and submit a fresh application to RCGM for its review and comments.

- Details on molecular characterization of each parental line / events and hybrids along with the hybrid development strategies
- In the trial, all parental lines (containing individual event) that was used for generation of this hybrid should also be included in addition to GE maize stacked hybrid (P3401YH and P3396YH), its non transgenic counterparts (P3401YH and P3396YH), appropriate national and zonal checks. For inclusion of the parental lines, the trial protocol should also be revised accordingly.
- Evaluation of hybrid should also be tested by spraying glufosinate and data on phytotoxixcity, weed control efficacy, residue analysis in soil should be generated
- Complete food and environmental safety data should be generated for the parental lines also where information on comparitive assessment between GE and non GE lines should be generated.

Agenda Item No. 7: Application related to Pharmaceuticals

7.1 Clearance for phase III Clinical Trial Application of VPM 1002 (rBCG), Vaccine for Tuberculosis by Serum institute of India Pvt Ltd (SIIPL).

The Committee reviewed the application submitted by Ms. Serum Institute of India Pvt. Ltd and also heard the presentation made by the applicant seeking clearance for Phase-III Clinical Trial of VPM 1002 (rBCG), vaccine for Tuberculosis and opined that the data cannot be accepted in its present form as it may not be aptly applicable to Indian population and conditions.

The Committee suggested the applicant to supply relevant and additional information on safety assessment and pre clinical studies data generated in India and abroad for further examination by the Committee.

7.2 Permission for Import of vector Mune Fowl Pox –*Mycopasma gallissepticum* (MG) Poultry vaccine from USA and Marketing in India by M/s Ceva India Pvt Ltd.

The Committee reviewed the application submitted by Ms. Ceva India Pvt Ltd and also heard the presentation made by the applicant. The applicant informed the Committee that this application has been approved in USA since 2003.

The committee approved the application of M/s Ceva India Pvt Ltd, Delhi. The Committee also advised the applicant to generate laboratory / in vivo efficacy data under Indian conditions. The applicant should also approach Department of Animal Husbandry Dairy and Fisheries, Ministry of Agriculture and Drug Controller General of India (DCGI) etc. for seeking further approvals as per prevailing Indian laws.

7.3 Permission for Import and Market of Bursal Disease-Marek's Disease Vaccine Serotype 3, Marek's Disease Vector (Vaxxitek HVT+ IBD) M/s Sanofi Synthelabo (India) Pvt Ltd.

The Committee reviewed the application submitted by M/s Sanofi Synthelabo (India) Pvt Ltd and also heard the presentation made by the applicant.

The committee approved the application of M/s Sanofi Synthelabo (India) Pvt Ltd. The Committee also advised the applicant to generate laboratory / in vivo efficacy data under Indian conditions. The applicant should also approach Department of Animal Husbandry Dairy and Fisheries, Ministry of Agriculture and Drug Controller General of India (DCGI) etc. for seeking further approvals as per prevailing Indian laws.

7.4 Permission for import and market of the Canine Distemper – Adenovirus type 2-corona virus-para influenza Vaccine Modified Live Virus (Recombitek®C6/CV) by M/s Sanofi Synthelabo (India) Pvt Ltd.

The Committee reviewed the application submitted by M/s Sanofi Synthelabo (India) Pvt Ltd and also heard the presentation made by the applicant.

The committee approved the application of M/s Sanofi Synthelabo (India) Pvt Ltd. The Committee also advised the applicant to generate laboratory / in vivo efficacy data under Indian conditions. The applicant should also approach Department of Animal Husbandry Dairy and Fisheries, Ministry of Agriculture and Drug Controller General of India (DCGI) etc. for seeking further approvals as per prevailing Indian laws.

7.5 Permission for import and market of the Canine Distemper – Adenovirus type 2-coronavirus-para influenza Vaccine Modified Live Virus (Recombitek®C6) by M/s Sanofi Synthelabo (India) Pvt Ltd.

The Committee reviewed the application submitted by M/s Sanofi Synthelabo (India) Pvt Ltd and also heard the presentation made by the applicant.

The committee approved the application of M/s Sanofi Synthelabo (India) Pvt Ltd. The Committee also advised the applicant to generate laboratory / in vivo efficacy data under Indian conditions. The applicant should also approach Department of Animal Husbandry Dairy and Fisheries, Ministry of Agriculture and Drug Controller General of India (DCGI) etc. for seeking further approvals as per prevailing Indian laws.

7.6 Permission for import and market of the Canine Distemper – Adenovirus type 2-corona virus-para influenza Vaccine Modified Live Virus (Recombitek®C4) by M/s Sanofi Synthelabo (India) Pvt Ltd.

The Committee reviewed the application submitted by M/s Sanofi Synthelabo (India) Pvt Ltd and also heard the presentation made by the applicant.

The committee approved the application of M/s Sanofi Synthelabo (India) Pvt Ltd. The Committee also advised the applicant to generate laboratory / in vivo efficacy data under Indian conditions. The applicant should also approach Department of Animal Husbandry Dairy and Fisheries, Ministry of Agriculture and Drug Controller General of India (DCGI) etc. for seeking further approvals as per prevailing Indian laws.

7.7 Permission for import and market of the Canine Distemper – Adenovirus type 2-conona virus-para influenza Vaccine Modified Live Virus (Recombitek®C3) byM/s Sanofi Synthelabo (India) Pvt Ltd.

The Committee reviewed the application submitted by M/s Sanofi Synthelabo (India) Pvt Ltd and also heard the presentation made by the applicant.

The committee approved the application of M/s Sanofi Synthelabo (India) Pvt Ltd. The Committee also advised the applicant to generate laboratory / in vivo efficacy data under Indian conditions. The applicant should also approach Department of Animal Husbandry Dairy and Fisheries, Ministry of Agriculture and Drug Controller General of India (DCGI) etc. for seeking further approvals as per prevailing Indian laws.

7.8 Permission for import and marketing of Combined Newcastle Disease and Marek's Disease:

(i) VECTORMUNE HVT NDV & SB -1 Marek's Disease-Newcastle Disease and Vaccine, serotypes 3, Live Virus, Live Marek's Disease factor and

(ii) Newcastle Disease and Marek's Disease: VECTORMUNE HVT NDV & SB -1 Marek's Disease-Newcastle Disease and Vaccine, Serotypes 2 & 3, Live Virus, Live Marek's Disease factor M/s Ceva India Pvt Ltd

The Committee reviewed the application submitted by Ms. Ceva India Pvt Ltd and also heard the presentation made by the applicant. The applicant informed the Committee that this application has been approved in USA since 2007.

The committee approved the application of M/s Ceva India Pvt Ltd, Delhi. The Committee also advised the applicant to generate laboratory / in vivo efficacy data under Indian conditions. The applicant should also approach Department of Animal Husbandry Dairy and Fisheries, Ministry of Agriculture and Drug Controller General of India (DCGI) etc. for seeking further approvals as per prevailing Indian laws.

Agenda Item No. 8 : Any other item with the permission of Chair.

8.1 Adoption of Environmental Risk Assessment (ERA) Guidelines for Genetically Engineered (GE) Plants, Risk Analysis Framework and Users Guide

The Committee formally adopted the following three guidelines prepared as part of Phase-II Capacity Building Project on Biosafety through an Expert Committee under the Chairmanship of Prof. C.R.Babu and Prof. K.Veluthambi as Co-Chair.

1) Environmental Risk Assessment (ERA) Guidelines for GE Plants
2) Risk Analysis Framework
3) Users Guide

The Committee appreciated the efforts of the Expert Committee Members and all other concerned officials and staff engaged in formulation of these guidelines.

8.2 Discussion on No Objection Certificate (NOC) from State Governments for conduct of confined field trials

- The Committee discussed in detail about the issue of NOC from State Government prior to conduct of confined field trials and discussed the following points:
    - The conduct of confined field trials of genetically engineered (GE) crops is regulated under Rules for the manufacture, use, import, export & storage of hazardous micro- organisms, genetically engineered organisms or cells, 1989 notified under the Environment (Protection) Act, 1986 notified by the Ministry of Environment, Forest and Climate Change (MoEF&CC), Government of India.
    - GEAC in its 110th meeting held on 06.07.2011 has introduced the requirement to seek the NOC from the State Government, in which any organization / applicant proposes to conduct field trials
    - Various State Governments have introduced their own mechanisms to issue NOC for conduct of confined field trials

- Several State Governments have refused to issue NOC for conduct of confined field trials despite of approval of Genetic Engineering Appraisal Committee (GEAC), Apex Committee notified under Rules 1989. State Governments of Kerala, Uttarakhand and Tamil Nadu has completely refused to allow the conduct of confined field trials in their States

- Subsequent to the meeting of Secretaries held in Prime Minister's Office (PMO) on November 24, 2015, Department of Biotechnology (DBT), Ministry of Science and Technology has constituted a Working Group to examine and finalize modalities for establishment of Notified Field Trial Sites (NFTS) under the Chairmanship of Dr.B.S.Dhillon, Vice-Chancellor, Punjab Agricultural University (PAU)

- The first meeting of the Working Group was held on 17.06.2016 to deliberate on modalities for implementation of the same. Some of the key points discussed in the meeting are as follows:

  A. Required notification on NFTS under the provisions of Rules 1989
  B. In principle approval of 10 years per site by the State Governments with a review after 5 years with further scope for renewal
  C. Approval of NFTS through an Expert Committee consisting of Inter-Ministerial representatives
  D. Site selection criteria to be drafted and it was opined that a Minimum of 5 Hectares (12.35 Acres) should be assigned for NFTS in State Agricultural Universities (SAUs)
  E. In first Phase, 30-40 sites to be notified in various SAUs covering all the agro-climatic zones for crops which are under various stages of product development in India
  F. To provide grant-in-aid seed money by Government of India for developing infrastructure pertaining to NFTS. Further for regular maintenance of the site and day to day operations, an optimal fee could be charged from the applicant by the agency hosting the site for applicants.

After detailed deliberations, the Committee made the following recommendations:

- Whenever, an approval letter is being issued by RCGM/GEAC for BRL-I and BRL-II Trials a copy of the letter along with summary of the application should also be sent to State Department of Agriculture informing them about the approval given by RCGM/GEAC.

- Even though there is no such provisions as per Rules 1989 to inform the State Governments, the Committee opined that since the trials would be conducted in those respective states and officials from that state would be engaged as members in Central Compliance Committee (CCC) and also as per applicable statutory provisions through State Biotechnology Coordination Committees

(SBCCs) and District Level Coordination Committees (DLCCs) as per Rules 1989, it would facilitate the States as well as the applicant to seek NOC in time from State Government, so that cropping season is not missed by the applicant.

- Further, in continuation to the decisions taken in 129th GEAC meeting on 20.06.2016, the Committee reiterated that a maximum period of 90 days should be given to State Governments to give their consent for conduct of confined field trials failing which it should be deemed to be considered as agreed.

- Since, Event Selection Trials (ESTs) are conducted strictly within the institutional premises, the clause of NOC to be removed for approvals given to applicants for conduct of event selection trials.

- Further, more stringent monitoring mechanisms should be put in place for monitoring of ESTs and for the same a Sub-Committee under the Chairmanship of Prof. Veluthambi be convened to frame the relevant Standard Operation Procedures (SOPs) and guidelines. The committee may also deliberate on merging BRL I and BRL II for generation of data as per international practice.

- It has also been decided to prescribe a standard format for issuing NOCs by the State Government/ UTs. The GEAC Secretariat may devise it and with the approval of Chairperson, GEAC may forward to all State Governments/ UTs

- The strategy for taking further the proposal of Notified Field Trials (NFTS) and put forward may be discussed in the next GEAC meeting.

8.3 Discussion on issues related to dispensing of NOC from Technology provider for approving new *Bt* cotton hybrids by GEAC and its sub-committee

The Committee deliberated and discussed regarding the issue of NOC between technology provider and Sub-Licensee and suggested the matter of hybrid approval of Bt cotton through a standing committee be in future be referred to Ministry of Agriculture /ICAR for further implementation.

8.4 To prepare a panel of new experts (8-15 Members) from various disciplines like Veterinary, Animal Husbandry, Food Safety, Molecular Biology, Biotechnology, Environmental Sciences etc.

The Committee deliberated and disussed regarding the increasing number of applications being received by GEAC requesting for various types of approvals like veterinary vaccines, food / feed and processed foods etc., it was recommended that a panel of experts to be constituted and whenever required, those experts to be consulted for review of applications.

The Committee also suggested preparing a panel of important government laboratories for testing.

8.5 Application for permission to conduct confined field trial for event selection trial 6 of events *Cry1Fa1* (BtB2-3, BtB2-8, BtB2-23, BtB2-34, BtB2-41 and Event-142), three events (BtB3-18, BtB3-36 and BtB3-37) for *Cry2Aa* and fifteen stacked events of *Cry1Fa1* and *Cry2Aa* (BtBS1 to BtBS15) generated by intercrossing (excluding Event-142) for Fruit and Shoot Borer resistant Bt Brinjal by M/s Global Transgenes Ltd. Aurangabad

The committee reviewed the document of RCGM covering information on the application including details of the trial; information about the crop; details of the transgenes used; and proposed biosafety measures for the conduct of the trial and approved the event selection trials

8.6 Public Awareness/ Outreach materials developed by MoEF&CC

The Committee appreciated and noted that MoEF&CC has prepared several public awareness and outreach materials as part of its UNEP-GEF supported Phase-II Capacity Building Project on Biosafety implemented by MoEF&CC. The Committee appreciated the initiatives taken by MoEF&CC especially in translation of these outreach and public awareness materials in eight regional languages also for wider distribution and dissemination among stakeholders.

The following public awareness materials were circulated to all the Members

- Biosafety Resource Kit developed by BCIL consisting of 5 Booklets viz:
  - Cartagena Protocol on Biosafety
  - Indian Regulatory Framework
  - Confined Field Trials
  - Frequently Asked Questions (FAQs)
  - Accessing Information Sources

- Resource Catalogue developed by CABI consisting of
  - Overview of GM Crops
  - Animated CD on GM crops
  - GM Crops—Adoption and Impact
  - Procedure for import and export of GM Plant and Planting Material
  - Role of Customs in Transboundary Movement of plant materials and GMOs
  - Biotechnology and Biosafety Glossary of Terms
  - Detection tools for GMOs

The meeting ended with a Vote of Thanks to the Chair.

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ANNEXURE-1

S.No.	Name and Designation
1.	Dr. Amita Prasad, Chairperson, GEAC and Additional Secretary, Ministry of Environment, Forests & Climate Change, Jor Bagh, Aliganj , New Delhi.
2.	Dr K. Veluthambi, Co-chairman, GEAC and Professor (Retd), School of Biotechnology, Madurai Kamraj University, Madurai
3.	Shri. Gyanesh Bharti, Vice Chiarman,GEAC and Joint Secretary, Ministry of Environment, Forests & Climate Change, Jor Bagh, Aliganj , New Delhi.
4.	Prof. C.R. Babu,Emeritus Professor, Centre for Environmental Management of Degraded Ecosystems, School of Environmental Studies, University of Delhi, Delhi
5.	Dr. Luther Rangreji, Director ,Ministry of External Affair,Legal and Treaties Division , Jawaharlal Nehru Bhawan ,Janpath New Delhi.
6.	Dr. S. R. Rao,Advisor, Department of Biotechnology, C. G. O, Complex, Lodhi Road, New Delhi.
7.	Dr. Vijay Kumar,Scientist G & Head,Division of Basic Medical Sciences,Indian Council of Medical Research (ICMR) Ministry of Health and Family Welfare Ramalingaswami Bhavan, Ansari Nagar, New Delhi
8.	Dr. Ramesh Sonti, Chief Scientist, CSIR, Centre for cellular &Molutar Biology (CSIR-CCMB) Uppal Road, Hyderabad.
9.	Prof. O. P. Govila, Former Prof. of Genetics, Indian Agricultural Research Institute. "MANAS", House No. BU- 58, Pitampura, Delhi.
10	Dr. J.S.Sandhu,DDG(Crop Science) Indian Council of Agricultural Research, Krishi Bhawan, New Delhi
11	Dr. Renee M Borges,Professor, Centre for Ecological Sciences, Indian Institute of Science, Bangalore
12	Dr.P.M.Bhargava. Former Director , CCMB , Hyderabad (Special Invitee)
13	Dr. V.V Ramamurthy,Former Professor , Entomology Division, IARI, New Delhi,Centre for Ecological Sciences, Indian Institute of Science, Bangalore
14	Dr. S. K. Apte, Former Director, Bio-Medical Group, BARC, Mumbai.
15	Dr. Madhumita Biswas, Member Secretary (GEAC) and Director Ministry of Environment, Forests & Climate Change, Jor Bagh, Aliganj , New Delhi.
16	Ms. P. Saranya, Scientist C, Ministry of Environment, Forests & Climate Change, Jor Bagh, Aliganj , New Delhi