Minutes of the 123rd meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 27.2.2015

The 123rd meeting of the GEAC was held on 27.02.2014 in the Ministry of Environment, Forest and Climate Change (MoEF& CC) under the chairmanship of Shri Hem Pande, Additional Secretary, MoEF& CC and Chairman, GEAC.

List of the participants is annexed as Annex 1

Agenda Item No 1: Leave of Absence

The Committee granted leave of absence to Dr B.Sesikaran, Former Director, NIN, Dr. Luther Rangreji, Associate Professor, Dr. V V Ramamurthy, Principal Scientist, DrVijendra Mishra, Associate Professor, NIFTEM, and DrP.M.Bhargava, as requested by them.

Agenda Item No 2: Confirmation of Minutes of the 122nd meeting held on 28.8.2014

Minutes were confirmed without any amendments.

Agenda item No. 3: Action taken report on the decision taken in the 122nd GEAC Meeting held on 12.5.2014.

Member Secretary GEAC informed that as GEAC meetings could not be held, minutes could not be ratified and therefore follow-up action was deferred.

Agenda item No. 4: Policy issues

4.1 Discussion on Status of NOC from the State Governments for GM crop field trials and modalities for streamlining the same

4.1.1 The Committee noted that during the last five meetings of the GEAC held during March 2014 to July 2014 approximately 80 applications including 25 cases for revalidation / change in locations etc were approved by the GEAC subject to NOC from the State Govt. However due to delay in issuance of NOC, only nine trials have been initiated and two have been completed.

4.1.2 The Committee was of the view that there is an urgent need to develop a structured and uniform approach for streamlining the GM crop field trials which also ensures full involvement of the State Government. Until then the practice of obtaining NOC from the State Government should continue.

4.1.3 In this regard, Dr S R Rao, Advisor DBT and Member Secretary RCGM proposed notification of field sites in consultation with the State Govt by providing financial support to the SAUs for maintenance of field sites. A concept note in this regard was circulated to all

members. While Members agreed "in principal" with the proposed approach, the Committee opined that the modalities for implementation needs to be elaborated and requested RCGM to submit an elaborate proposal for consideration of the GEAC. Members were also requested to forward their views / suggestion on DBT proposal for streamlining the GM crop field trials.

4.2 Discussion on Compliance Monitoring of GM Crops field trials

4.2.1 Members briefly discussed the current mechanism for monitoring GM crop field trials and suggested that the proposal for streamlining GM crop field trials being developed by DBT / RCGM should also include the feasibility of developing a dedicated compliance monitoring and review mechanism.

4.2.2 Further, Member Secretary GEAC informed that as part of the UNEP-GEF Phase –II Capacity Building Project on Biosafety, a training manual for confined field trials has been circulated. A set of 150 questions have also been included for Members to familiarize themselves on the mandate and approach. Members were requested to forward their comments on the Manual which would be circulated online.

4.3 Discussion on the outcome of the Consultative Meeting held with Farmers Association by the Minister of Environment, Forests and Climate Change:

4.3.1 Chairman, GEAC informed the Committee that two consultative meetings were held under the Chairmanship of Minister for Environment Forest and Climate Change with the Farmers Association to address concerns on GM crop field trials and their introduction in the country. The Committee took note of the following action points that emerged from the above meetings.

1. Ministry of Agriculture (MOA) has been requested to issue a gazette notification for testing of Bt cotton events approved by GEAC other the cry 1 AC gene MON 531 event).and also notify referral laboratories for testing of the same. In this regards, Joint Secretary (Seeds) informed that gazette notification dated November 12, 2003, has been amended vide gazette notification dated May 8, 2008 to include all types of *Bacillus thuringiensis in place of* Cry 1 AC gene. It was also noted that additional laboratories would be notified by MOA shortly.
2. A communication is being sent to MOA to request NBPGR to verify whether the Bt cotton seeds sold in the market contain the events as claimed by the technology provider in the seed packet.
3. A report is being obtained from CICR Nagpur regarding the present status of development of insect resistance to *Cry 1 Ac* (MON 531 event).
4. An Inter-Ministerial Standing Committee would be constituted by the Ministry to ensure close coordination and monitoring.
5. As regards the suggestion that researchers from State Agriculture Universities should be involved in the monitoring of GM crop field trials, the Committee noted that this practices is being followed as of now also.

6. During the consultative meeting, one of the farmer's representative referred to the mismanagement of Bt Okra trials at Guntur and requested the Ministry to examine the same. Member Secretary GEAC informed that no such reports or representation has been received in this Ministry and requested Member Secretary RCGM and MOA to check if any such reports are available in their respective departments.
7. As regards the representations regarding cultivation of unapproved RRF cotton in Maharashtra, Andhra Pradesh and Telangana, it was noted that factual information from the respective State Governments are awaited.
8. As regards the need for a programme for sensitizing the Vidharba farmers regarding adoption of cotton cultivation in rain-fed regions and loamy soils, it was opined that MOA / ICAR through their extension mechanism should take up such programme.

Agenda item No 5: Consideration of applications related to recombinant Pharma

5.1 Permission for import of Vector Mune Fowl Pox –Mycoplasma gallissepticum (MG) Poultry Vaccine from USA and Marketing in India by M/s Ceva India Pvt Ltd., Delhi

5.1.1 The Committee noted that the proposal of M/s Ceva India Pvt Ltd for import of Vectormune FP MG Poultry Vaccine from USA and Marketing in India was discussed in its 121st meeting of the GEAC held on 18.7.2014 wherein the Committee decided, in the first instance, to obtain comments from the experts prior to placing the proposal in GEAC agenda.

5.1.2 Mycoplasma gallissepticum (MG) is a Live Fowl Pox vector. The recombinant virus of VECTORMUNE FP MG was developed by inserting the mgc3 and 40K genes of Mycoplasma gallissepticun in to the fowl pox virus genome. The efficiency of VECTORMUNE FP MG was approved in target animal by challenged with virulent strains of fowl pox virus (FPV) and MG. Quantity of the product to be manufactured/ imported per year is 5,000 vials per year.

5.1.3 The Committee considered the comments received from Dr B. Sesikaran, Asst Director General (Animal Health) Division of Animal Science, ICAR, Dr R. Sonti and Dr Vijendra Mishra in this regard.

5.1.4 The Committee decided to defer decision on the proposal as there is a difference of opinion amongst experts. The Committee was of the view that the applicant should clarify concerns raised by the experts and also submit revised document with commplet data before the proposal is considered by the GEAC. The Committee also opined that the applicant may be advised to make a detailed presentation in the next GEAC meeting. It was also decided that Dr M Subramanian, TANUVAS and ADG Division of Animal Science as special invitee to the meeting.

5.1.5 In view of the above, decision on the proposal was kept in abeyance.

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

5.2.1 The Committee noted that the request of M/s Sanofi- Synthelabo for import of above vaccine from M/s Merial Select Inc. USA and marketing in India was considered by the GEAC in its 118th meeting held on 21.3.2014 wherein the Committee decided, in the first instance, to obtain comments from the experts prior to placing the proposal in GEAC agenda.

5.2.2 The Vaxxitek HVT+IBD is a live vaccine against Bursal Disease-Marek's Disease prepared from a Marek's disease vectored Bursal Disease recombinant virus. The starting material is a Turkey Herpes virus (HVT), FC-126 strain isolated from turkey blood obtained through American Type Culture Collection. It is a veterinary medicine for use in healthy one day old chickens and healthy 18 to 19 days old chicken embryos as an aid in the prevention of Marek's disease and infectious bursal disease.

5.2.3 The Committee considered the comments of Dr Gaya Prasad, Department of Animal Health (ICAR); Dr Vijay Kumar, ICMR; Dr M. Subramanian, TANUVAS, Chennai; Prof M S Shaila IISC, Bangalore and Dr R.N. Chatterjee, Directorate of Poultry Research, Hyderabad; for comments. Comments received from (i) Directorate of Poultry Research; Dr Gaya Prasad, (iii) Dr M.S Shaila, and (iv) Dr M. Subramanian and (v) Dr Vijay Kumar in this regard.

5.2.4 The Committee decided to defer decision on the proposal as there is a difference of opinion amongst experts. The Committee was of the view that the applicant should clarify concerns raised by the experts and also submit revised document with complete data before the proposal is considered by the GEAC. The Committee also opined that the applicant may be advised to make a detailed presentation in the next GEAC meeting. It was also decided that Dr M Subramanian, TANUVAS and ADG Division of Animal Science as special invitee to the meeting.

5.2.5 In view of the above, decision on the proposal was kept in abeyance. ,

5.3 Permission for Import and market of the Canine Distemper -Adenovirus type 2-Coronavirus-Parainfluenza- Parvovirus Vaccine, Modified Live Virus, Live Canarypox Vector, Leptospira Canicola – Icterohaemorrhagiae Bacterin (Recombitek® C6/CV) by M/s Sanofi-Synthelabo (India) Ltd.

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5.4 Permission for Import and market of the Canine Distemper-Adenovirus type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Canarypox Vector, Leptospira Bacterin (Recombitek®C6) by M/s. Sanofi-Synthelabo (India) Ltd.

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5.5 Permission for Import and market of the Canine Distemper-Adenovirus type 2-Parainfluenza -Parvovirus Vaccine, Modified Live Virus, Canarypox Vector (Recombitek® C4) by M/s Sanofi-Synthelabo (India) Ltd.

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5.6 Permission for Import and market of the Canine Distemper-Adenovirus -Parvovirus Vaccine, Modified Live Virus, Canarypox Vector (Recombitek® C3) by M/s Sanofi-Synthelabo (India) Ltd.

1 The Committee noted that the above four requests of M/s Sanofi- Synthelabo for import of above vaccines from M/s Merial Select Inc. USA and marketing in India was considered by the GEAC in its 118th meeting held on 21.3.2014 wherein the Committee decided, in the first instance, to obtain comments from the experts prior to placing the proposal in GEAC agenda prior to placing the proposal in GEAC agenda.

2 These vaccines are for vaccinating dogs against common diseases in India such as canine parvovirus (CPV) enteritis, canine Distemper (CD), Canine infectious hepatitis (ICH), canine adenovirus 2 (CAV 2) and leptospirosis.

3 The Committee considered the comments received from (i) Dr Gaya Prasad, Department of Animal Health, (ii) Dr Vijay Kumar, ICMR, (iii) Dr M. Subramanian, TANUVAS, Chennai, (iv) Dr M S Shaila, IISc, Bangalore in this regard.

4 The Committee decided to defer decision on the proposal as there is a difference of opinion amongst experts. The Committee was of the view that the applicant should clarify concerns raised by the experts and also submit revised document with complete data before the proposal is considered by the GEAC. The Committee also opined that the applicant may be advised to make a detailed presentation in the next GEAC meeting. It was also decided that Dr M Subramanian, TANUVAS and ADG Division of Animal Science as special invitee to the meeting.

5 In view of the above, decision on the proposal was kept in abeyance.

5.7 Permission to conduct Phase III clinical trials on study titled "Immunogenicity and Safety of a Tetravalent Dengue Vaccine manufactured by Sanofi Pasteur, SA Lyon, France in healthy subjects aged 2 to 45 years in India (Protocol No. CYD 48) by M/s Sanofi Pasteur India Private Limited, Mumbai.

5.7.1 The Committee considered the request of M/s Sanofi Pasteur India Pvt. Ltd, Mumbai, for permission to conduct Phase III clinical trials to study "Immunogenicity and Safety of a Tetravalent Dengue Vaccine manufactured by Sanofi Pasteur, SA Lyon, France in healthy subjects aged 2 to 45 years in India (Protocol No. CYD48)". It is a human use vaccine. Quantity of the product to be imported 1470 CYD Dengue vaccine doses for phase III clinical trials. It is intended for prevention of dengue illness caused by dengue virus serotype 1, 2, 3 and 4.

5.7.2 The Committee also noted that the name of the Vaccine: Internal name of the vaccine is: CYD (Chimera Yellow Fever Dengue) Dengue Vaccine. International name (WHO): Tetravalent Dengue Vaccine (Live, attenuated).

5.7.3 The Committee observed the following objectives of the proposal:

I. Is to use the CYD dengue vaccine in a phase III trial in India (*study* CYD48: *Immunogenicity and Safety of a Tetravalent Dengue Vaccine in Healthy Subjects Aged 18 to 45 Years in India*, sponsor Sanofi Pasteur).

II. CYD48 is a Phase III randomized, observer-blind FOR THE FIRST AND 2ND VACCINATIONS And single blind for the 3rd vaccination, controlled, multi-center trial in 420 subjects in India with enrolled in 2 groups , 3 vaccinations (0, 6, and 12 months) followed by a 6-month safety follow-up.

III. The subjects will be randomized in a 3 to 1 ratio to receive CYD dengue vaccine or control.

IV. Inclusions in children, adolescent, and adult age cohorts (2-11 years, 12-17 years and 18–45 years of age) will be done and the randomization will be stratified according to site and age group.

V. Group 1: CYD dengue vaccine (n=315)

VI. Group 2: Control vaccine (n=105)

All subjects will receive 3 doses and will provide blood samples for baseline flavivirus (FV) status (before the first dose) and for vaccine immunogenicity assessment after each of the 3 doses.

5.7.4 **Vectors**: Infectious RNA transcripts used for transfection to obtain chimeric viruses are limited to YF17D and dengue viral sequences and do not possess any sequence from the molecular vectors used during the construction steps (pBR322- or pCL-derived plasmids).

5.7.5 The committee also took note on the Regulatory Status: CYD dengue vaccine is an investigational product, to date two phase III large efficacy studies (CYD 14 & CYD 15) have been completed the vaccination and long-term follow-ups are ongoing in Asia and Latin America. Up to Feb. 2014 more than 28,000 subjects have received at least one dose of CYD dengue vaccine. The vast majority of exposed subjects are children (14066), 2-11 years of age, and adolescent (120956), 12-17 years of age.

5.7.6 The Committee noted that the Company has conducted Phase II clinical trials to study titled "Immunogenicity and Safety of a Tetravalent Dengue Vaccine manufactured by Sanofi

Pasteur, SA Lyon, France in healthy subjects aged 18 to 45 years in India (Protocol No. CYD 47)

5.7.7 The Committee considered the recommendations of (i) Dr Amita Agarwal, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow (ii) Dr B. Sesikaran, Former Director, NIN (iii) Dr S.K. Rath, Principal Scientist, CSIR, (iv) Dr Vijay Kumar, ICMR; (v) Dr M. Subramanian, TANUVAS, Chennai; (vi) Dr M.S Shaila, IISc, Bangalore, (vii) Dr R. Sonti, and (viii) Dr Vijendra Mishra in this regard.

5.7.8 In view of the above and based on the recommendations of experts the Committee decided to approve Phase III Clinical trials on study titled "Immunogenicity and Safety of a Tetravalent Dengue Vaccine manufactured by Sanofi Pasteur, SA Lyon, France in healthy subjects aged 2 to 45 years in India (Protocol No. CYD 48).

Agenda item No 6 : Any other item:

6.1 Extending the tenure of the Standing Committee to review applications for commercial release of Bt cotton hybrids expressing approved events.

6.1.1 The GEAC had adopted the 'Event Based Approval Mechanism (EBAM)' for regulating Bt cotton hybrids expressing approved events and had constituted a Standing Committee to operationalize the new procedure on 16.4.2009 for a period of three years (16.4.2012) under the aegis of DBT. The tenure of the Standing Committee was extended for a period upto October 2012. The matter was reconsidered in the GEAC meeting held on 22.3.2013 wherein DBT informed that they are not in position to continue serving the Standing Committee as the mandate of DBT is specific to biosafety assessment and not agronomic performance. However, in the absence of an alternative mechanism and seasonality involved, the tenure of the Standing Committee was extended by the GEAC in the meeting held on 22.3.2013 for four months with the revised composition as follows:

S.No.	Name and Designation of Experts	Designation
1.	Dr. N Gopalkrishnan, ADG (commercial crops), ICAR, Krishi Bhavan New Delhi.	Chairman
2.	Dr. D. Monga, Head, Regional Station, Central Institute of Cotton Research, Sirsa, Haryana.	Member
3.	Dr. Punit Mohan, Principal Scientist, Plant Breeding, CICR, Nagpur	Member
4.	Project Coordinator, All India Cotton Crop Improvement Project (AICCIP) or his nominee.	Member
5.	Prof Ramesh Poombar, Punjab Agriculture University	Member
6.	Dr S.J. Rahman, Principal Scientist & Head, Agriculture Research Institute (ANGRAU), Hyderabad	Member
7.	Director (Seeds), Ministry of Agriculture	Member

8.	Dr. S R Rao, Adviser, DBT and Member Secretary, RCGM	Member
9.	Ms Rajalakshmi Muralidharan, Scientist D, DBT	Member Secretary

6.1.2 Subsequently on completion of the tenure of the Standing Committee, DBT again informed the GEAC that they are not in a position to continue servicing the Standing Committee as it does not fall under their mandate. The matter was discussed in the GEAC meeting held on 28.8.2014 wherein, the Committee opined that the position taken by DBT merits consideration as Rules 1989 is specific to biosafety assessment of an event in a specific crop whereas the review undertaken by the Standing Comm9ttee is specific to agronomic performance of Bt cotton hybrids expressing approved events and its suitability for commercial cultivation in a particular region. In this regard GEAC has been perusing with ICAR to set up an alternate mechanism under the AICCIP to evaluate the performance of approved Bt cotton events before release. No formal proposal has been received from ICAR.

6.1.3 In the absence of an alternate mechanism, the Committee requested DBT to service the Standing Committee with the same TOR and composition for one more season which would be the last request.

6.1.4 The Committee further requested DDG, ICAR to set up an alternate mechanism under the AICCIP to evaluate the performance of approved Bt cotton events to ensure Bt cotton hybrids suitable to various agro-climatic zones are released; at the earliest. After detailed deliberations, it was decided that a formal communication would be sent to DG, ICAR by Chairman, GEAC.

6.1.5 In light of the above discussions, the Committee decided to extend the tenure of the Standing Committee to review applications for commercial release of Bt cotton hybrids expressing approved events for one season. DBT agreed for reviewing the applications for one season only.

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

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List of the Members who attended the 123rd GEAC meeting held on 27.02.2015

S.No.	Name and address
1.	Shri Hem Pande, Additional Secretary, Ministry of Environment, Forests and Climate Change and Chairman, GEAC.
2.	Dr K. Veluthambi, Professor (retd) & Head, School of Biotechnology, Madurai Kamraj University, Madurai and Co-chairman, GEAC
3.	Shri. Anil Sant, Joint Secretary, Ministry of Environment, Forests and Climate Change and Co-Chairman ,GEAC
4.	Shri R.K. Singh, Joint Secretary. (Seeds), Department of Agriculture & Cooperation Ministry of Agriculture, Krishi Bhawan, New Delhi
5.	Dr. S. R. Rao, Advisor, Department of Biotechnology, CGO Complex, New Delhi
6.	Prof.C.R. Babu, Centre for Environmental Management of Degraded Ecosystems, School of Environmental Studies, DU, Delhi
7.	Dr. Ramesh Sonti, Chief Scientist, CSIR, Centre for cellular & Molecular Biology (CSI-CCMB) Uppal Road, Hyderabad
8.	Dr. S.S. Banga, Plant Breeder, Punjab Agriculture University, Ludhiana
9.	Dr. S. K. Apte, Director, Bio-Medical Group, BARC, Mumbai.
10.	P.K. Chakrabarty, ADG (PP&B), Indian Council of Agricultural Research, Krishi Bhawan, New Delhi
11.	Prof. O. P. Govila, Former Prof. of Genetics, Indian Agricultural Research Institute, "MANAS" House No. BU-58, Pitampura, Delhi
12.	Prof. Akshay Kumar Pradhan, Department of Genetics, University of Delhi, South Campus, Benito Juarez Road, New Delhi
13.	Dr. Renee M Borges, Professor, Centre for Ecological Sciences, Indian Institute of Science, Bangalore.
14.	Dr. Ranjini Warrier, Director, Ministry of Environment, Forests and Climate Change and Member Secretary, GEAC.
15.	Smt. Madhu Gupta, Research Officer , Ministry of Environment, Forests and Climate Change