Decisions taken in the 121st meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 18.07.2014

The 121st meeting of the GEAC was held on 18.07.2014 in the Ministry of Environment, Forests and Climate Change (MoEF& CC) under the chairmanship of Shri Hem Pande, Additional Secretary, MoEF and Chairman, GEAC

The deliberations and decisions taken in the GEAC meeting in respect of Agenda items 4 to 7 are as follows:

Agenda item No 4: Consideration of applications for confined field trials of transgenic crops (Event selection/ BRL-I/ BRL-II) as recommended by the RCGM.

4.1 Permission to conduct event selection trials on five Sugarcane *(Saccharum spp.)* events namely; BtS1, BtS2, BtS3, BtS4 and BtS85 containing *cry1Ac* gene by Sugarcane Research Institute, U.P. Council of Sugarcane Research (UPCSUR), Shahjahanpur.

4.1.1 The Committee considered the request of UPCSUR, Shahjahanpur to conduct event selection trials on five Sugarcane (Saccharum spp. CoS 96268) events namely; BtS1, BtS2, BtS3, BtS4 and BtS85 containing *cry1Ac* gene at one location within the The trials will be conducted at one location within the Sugarcane Research Institute Farm at Shahjahanpur in an area of 571 sq m.

4.1.2 The Committee also noted that the objectives of the trials are to:

- Assess the expression of *cry1Ac gene* in sugarcane plants.
- Examine further propagation to conform the gene stability in next clonal generation.
- Record the incidence of shoot borer.

4.1.3 The Committee observed that the proposal has been recommended by the IBSC and the RCGM in its meeting held on 24.4.2012.

4.1.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for conduct of event selection trial on Sugarcane *(Saccharum spp.)* events namely; BtS1, BtS2, BtS3, and BtS4 containing *cry1Ac* gene by Sugarcane Research Institute, U.P. Council at UPCSR, Shahjahanpur at one location during any appropriate season subject to submission of NOC from the State Government. The Committee also advised the applicant to submit the following information:

i. Source of Cry 1Ac gene
ii. Material transfer Agreement
iii. Target species
iv. Details of agrobacterium medium
v. Details of gene construct

4.2 Permission to conduct Biosafety Research Level (BRL-1) trials on insect-tolerant chickpea namely; Bt chickpea 1, Bt chickpea 2, Bt chickpea 3, and Bt chickpea 4 *(* event SSL-6) containing *Cry2Aa* gene by M/s. Sungro Seeds Limited, New Delhi.

4.2.1 The Committee considered the application of M/s. Sungro Seeds Limited, New Delhi, to conduct BRL-1 trials on insect-tolerant chickpea namely; *Bt chickpea 1, Bt chickpea 2, Bt chickpea 3, and Bt chickpea 4 (*event SSL-6 chickpea) containing *Cry2Aa* gene**.** The trial will be conducted at SAU or ICAR Farm/ Company's own land/ long leased farm in an area of 588.65 sq m. as per details given below:

S.No	Zone	State	Location
1	*North West Plain Zone (NWPZ)*	*Rajasthan*	*Durgapura*
		Haryana	*Hisar*
2	*North East Plain Zone (NEPZ),*	*Uttar Pradesh*	*Allahabad*
3.	*Central Zone*	*Maharashtra*	*Rahuri*
		Madhya Pradesh	*Jabalpur*
		Gujarat	*Junagadh*
4.	*South Zone*	*Andhra Pradesh*	*Nandyal*
		Karnataka	*Dharwad*

4.2.2 The Committee noted that the objectives of the trials are to:

- Evaluate the field infestation levels of target insect pest, pod borer (Helicoverpaarmigera), on transgenic Bt chickpea entries, non-Bt counterparts and checks.
- Estimate the level of expression of Cry2Aa protein in various plant parts at various crop growth stages of the Bt chickpea entries. The protein expression data of Cry2Aa in various plant parts will be recorded at an interval of 30 days, starting from 30 days after sowing (DAS) at all trial locations.
- Observe with respect to growth habit, life cycle, plant height, impact on pollinator species of Bt chickpea entries, their non-transgenic counterparts and checks and any indicators of changes in weediness potential in the Bt chickpea entries.
- Monitor the occurrence of beneficial arthropods and insect pests on Bt chickpea entries, their non-transgenic counterparts and checks.
- Observe the effect of Cry2Aa protein on soil microflora, earthworms and soil insects (Collembola spp.) present in the soil rhizosphere collected from Bt chickpea and other non-transgenic chickpea plots.

- Estimate the grain yield of Bt chickpea entries, their non-transgenic counterparts and checks.
- Generate the plant material of Bt chickpea entries, their non-transgenic counterparts and checks for biosafety studies.

4.2.3 The Committee also observed that the proposal was recommended by IBSC and RCGM in its meetings held on 9.9.2012and 28.8.2012 respectively.

4.2.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for conduct of BRL-1 trials on insect-tolerant chickpea namely; Bt chickpea 1, Bt chickpea 2, Bt chickpea 3, and Bt chickpea 4 *(*event SSL-6) containing Cry2Aa gene at SAU or ICAR Farm/ Company's own land/ long leased farm during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted. The Committee also advised the applicant to submit details of the source of gene.

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

4.3.1 The Committee considered the request of M/s. Bejo Sheetal Seeds Pvt. Ltd., Jalna, to conduct BRL-II trial with two transgenic Bt Brinjal hybrids namely; Janak and BSS-793Bt, containing *Cry1Fa1*gene (Event 142) at seven locations namely Maharashtra, Gujarat, Punjab, Haryana, Uttar Pradesh, New Delhi and Andhra Pradesh.

4.3.2 The Committee noted that discussion on the application was deferred by the GEAC in its 119th meeting held on 25.4.2014 as experts were of the view that more time is needed to review the biosafety data.

4.3.3 The Committee noted that the applicant has completed 2 years of BRL-I trials at three locations within their own research farms namely; Jalna, Guntur and Varanasi during 2009-2010.

4.3.4 The Committee also noted that the objectives of the BRL-II trials are to generate:

- Efficacy data of the Bt brinjal against target pest shoot and fruit borer (*Leucinodesorbonalis*).
- Information on yield and demonstrate agronomic performance of Bt brinjal hybrids as compared to their non-Bt counterparts and commercial check hybrids.
- Information on incidence of beneficial and non-target insects among Bt brinjal and their non-Bt counterparts.
- Information on insect infestation on Bt brinjal, their non-bt counter parts and non-bt commercial check hybrids

4.3.5 The Committee also took note of the fact that M/s. Bejo Sheetal Seeds Pvt. Ltd., Jalna had made a detailed presentation to the RCGM in its 113th meeting held on

22.05.2012 on the safety and efficacy of the product. RCGM noted that the data submitted by the Company is in order and recommended to the GEAC for BRL-II trials.

4.3.6 The Committee considered the following documents which were circulated to all the expert members on 26.5.2014 to review the data.

A. Application form containing the following information:

- ❖ Introduction
- ❖ Brinjal Crop Biology
- ❖ Molecular Characterization
- ❖ Field Trials Plan
- ❖ Executive Summary. Field Trial Permits
- ❖ BRL-I Field Trial Report of trial during Kharif-2009 and 2010

B. Reports containing results of the following studies:

a. History of Safe use of Bacillus thuringiensis
b. Safe use of Cry 1 F Protein.
c. Mode of action of Cry1 Fa1.
d. Safety assessment of Bt Brinjal carrying *Cry1Fa1 gene*, event 142.
e. Test with Cry 1 Fa1 purified. Study Center: National Institute of Nutrition, Hyderabad.
    - ➢ Pepsin Digestive Assay.
    - ➢ Thermo stability.
    - ➢ Acute oral toxicity.
f. Sub-chronic Feeding Test with Bt and non Bt Brinjal leaves and fruits. Study Center: National Institute of Nutrition, Hyderabad.
g. Comparative studies on Soil Ecosystem of Bt and Non Bt Brinjal field. Study Center: Institute of Microbial Technology, Chandigarh.
h. Detection of CrylFa1 protein in the soils of Bt brinjal trial fields.
i. Comparative studies on compositional study of Bt and Non Bt brinjal study Center: Institute for Analysis of Dairy, Food and cultures, Bangalore.
j. Pollen flow study.

4.3.7 The Committee after a lengthy discussion, decided to constitute a sub-committee to review the toxicity data in the context of the above discussions.

4.3.8 The Committee also noted that IBSC has recommended the proposal in its 20th meeting held on 31.1.2012 and RCGM has recommended BRL-II trials in its 113th meeting held on 22.5.2012

4.3.9 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved BRL-II trials with two transgenic Bt Brinjal hybrids namely Janak and BSS-793 Bt, containing *Cry1Fa1* (Event 142) *gene* at seven locations namely Maharashtra, Gujarat, Punjab, Haryana, Uttar Pradesh, New Delhi and Andhra Pradesh during any appropriate season subject to the following conditions:

i. NOC from the State Government where the trials will be conducted.
ii. Repeat Southern analysis in a single plant copy insertion to demonstration inheritance.
iii. Toxicity studies to be examined by a sub-Committee.

4.4 Permission to conduct BRL-II trials for transgenic mustard hybrid (DMH-11) (*Brassica juncea*) Events bn 3.6 (Barnase Line), modbs 2.99 (Barstar Line) &bn 3.6xmodbs 2.99containing *bar, barnase* and *barstar* genes by Centre for Genetic Manipulation of Crop Plants, (CGMCP), University of Delhi South Campus, New Delhi.

4.4.1. The Committee considered the request of CGMCP, to conduct Biosafety Research Level-II (BRL-II) trials on transgenic mustard hybrid (DMH-11) (*Brassica juncea*) containing *bar, barnase* and *barstar* genes [Events bn 3.6 (Barnase Line), modbs 2.99 (Barstar Line) &bn 3.6xmodbs 2.99. The trials will be conducted by India Council of Agriculture Research (ICAR) in their respective university's land at tenlocations namely; Navgaon, Sriganganagar, Kumher, Delhi, Bawal, Ludhiana, Bhatinda, (Zone II), Bharatpur, Morena, Kanpur and Faizabad (Zone III). The size of each trial will be 2142 sq m. At the outset, Dr Akshay Pradhan, Member GEAC informed that as a Scientist from CGMCP, he would like to be excused from the deliberations to avoid any conflict of issue unless the committee desires to seek any clarifications.

4.4.2 The Committee noted that the GEAC in its meetings held on 29.9.2010 and 21.09.2011 had approved BRL-I (first year and 2nd year) trial of above mentioned two events bn 3.6 (Barnase Line), modbs 2.99 (Barstar Line) at Bharatpur, Alwar, Sriganganagar, Kanpur, Ludhiana and Morena.

4.4.3 The Committee also noted the objectives of the trials are to:

i. Collect data on reproductive and survival biology parameters such as growth, life cycle, plant height, biomass, impact on pollinators etc. of transgenic *Brassica juncea* lines and their non-transgenic counterparts.

ii. Observe the susceptibility to pests and diseases in transgenic entries as compared to their non-transgenic counterparts.

iii. Study the impact on beneficial organisms

iv. Collect data regarding agronomic performance of the hybrid DMH-11 in comparison to national and zonal checks.

4.4.4 The Committee also noted that the CGMCP has completed safety studies as per the prescribed guidelines and the relevant documents have been forwarded to GEAC Expert members. .Two of the Members informed that they have not received the biosafety dossier. Member Secretary GEAC informed that the same would be circulated. Committee considered the following documents:

i) Molecular characterization studies:

a) Description of plant system.
b) Introduced genes, regulatory sequences and spacer fragment.
c) Methods of genetic transformation.
d) Characterization of the transgenic lines.
e) Genetic stability of the introduced genes.
f) Target gene efficacy.
g) Selection of transgenic events and their use in the development of B. juncea hybrid DMH-11.
h) Expression of the introduced genes bar, barnase and barstar.

ii) Safety Assessment Studies-Food safety studies:

a) Cloning, purification and production of pure proteins.
b) Bioinformatics analysis of the Bar, barnase and Barster proteins.
c) Pepsin digestibility of Bar, Barnase and Barstar proteins.
d) Thermal stability of Bar, Barnase and Barstar proteins.
e) Acute oral toxicity of Bar, Barnase and Barstar proteins.
f) Sub-chronic toxicity studies.
g) Compositional analysis of key components.

iii) Environmental Safety Assessment Studies:

a) Studies on weediness potential and aggressiveness parameters: comparative assessment of seed germination and seedling vigour.
b) Impact on soil microflora.
c) Crossability and pollen flow studies on the transgenic B. juncea hybrid DMH-11: study for intra-specific and inter-specific gene flow.
d) Studies on pollination behaviors of transgenic B. juncea lines: comparative studies on pollen morphology and physiology.
e) Agronomic performance of hybrid DMH-11 compared to local and national checks.

iv). Detection Protocols:

a) Protocol for testing at a level of detection (LOD) of 0.01%.
b) Development of ELISA kits for Bar, Barnase and Barstar .

4.4.5. The Committee observed that the proposal has been recommended by IBSC and RCGM in its meetings on 18.06.2012 and 22.4.2014 respectively with the conditions (i) that during the BRL-2 trials an entomologist should be included; (ii) data should be recorded on beneficial insects; no. of pollinators per plant or per meter row; and (iii) no. of replications should be increased to *5.*

4.4.6 On the issue of the toxicology studies concerns were expressed that unlike in the west, GM Canola is used as oil where as in India mustered leaves and seeds are also consumed and therefore, toxicology data should be reviewed with great caution. The

Committee decided to refer the matter to the sub-committee proposed under agenda item no 4.3.

4.4.7 In addition, it was decided to obtain the following additional information:

- What are the other hybrids of Canola approved for commercial cultivation in the West and how much of the cultivated hybrids fall under barnase and barstar genes.

- Whether Barnase is expressed in other tissues

- Whether Barstar is expressed in other tissues.

4.4.8 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved BRL-II trials BRL-II trials for transgenic mustard hybrid (DMH-11) (*Brassica juncea*) Events bn 3.6 (Barnase Line), modbs 2.99 (Barstar Line) & bn 3.6 x modbs 2.99 containing *bar, barnase* and *barstar* genes at Navgaon, Sriganganagar, Kumher, Delhi, Bawal, Ludhiana, Bhatinda, Bharatpur, Morena, Kanpur and Faizabad during any appropriate season subject to submission of NOC from the State Government. The Committee further decided to obtain additional information as indicated in para 4.4.11 above and also decided to refer the matter to the sub-committee proposed for the purpose of review to the toxicology data under agenda item 4.3.13 and 4.4.10.

4.5 Permission for conduct of experimental seed production of transgenic *B. juncea* EH2 barstar and non-transgenic EH2 line for livestock feeding studies by Centre for Genetic Manipulation of Crop Plants, University of Delhi South Campus, New Delhi.

&

4.6 Permission for conduct of confined field trials for the experimental leaves production of transgenic *B. juncea*EH2 barstar and non-transgenic EH2 line for live stock feeding studies at NDRI, by Centre for Genetic Manipulation of Crop Plants, University of Delhi South Campus, New Delhi.

4.5.1 The Committee considered the above request of CGMCP, New Delhi to conduct experimental seed and leaf production of transgenic *B. juncea*EH2 barstar and non-transgenic EH2 lines for livestock feeding studies, at one location in the farm land owned by University of Delhi at Jaunti Village, in an area of 2 acres (8094 sq meter). The seed meal will be transferred to NDRI, Karnal by CGMCP for livestock feeding studies with cattle.

4.5.2 The Member Secretary, RCGM informed that the applicant had sought exemption from feeding studies with leaves and seeds as they are not toxicological studies but basically meant to evaluate nutritional imbalance. As compositional equivalence of edible plant parts (leaf and seeds) has been established, and no Allergenicity has been observed, additional feeding studies may not be required. Further, the same genetic system has been in use for more than 15 years in several countries around the World. The matter was considered by

the RCGM in its 133rd meeting held on 22.4.2014. While the RCGM agreed to the above, the Secretariat was advised to send a brief note to the GEAC with justification on why feeding studies are not required in the present case.

4.5.3 After a brief discussion on the matter, the Committee requested that the Note forwarded by RCGM may be circulated to all members of the GEAC for consideration of the case in the next meeting. Accordingly decision on the two proposals mentioned above were deferred.

4.7 Permission to conduct event selection trials of transgenic rice (Oryzasativa) events namely; OSLR-01 and OSLR-04 containing *cry1Ab (DG) gene* by M/s. Devgen Seeds & Crop Technology Pvt. Ltd., Secunderabad

4.7.1 The Committee considered the request of M/s. Devgen Seeds & Crop Technology Pvt. Ltd., Secunderabad to conduct event selection trials of transgenic rice (Oryza sativa) events namely; OSLR-01 and OSLR-04 containing *cry1Ab* (DG) gene for resistance to feeding damage incurred by Lepidopteron pests. The trials will be conducted at one trial per location in an area of 678 m^2 at State Agricultural Universities; Company owned sites or long term leased land. Details of location will be provided after obtaining NOC from State Governments.

4.7.2 The Committee noted the objective of the trials is to:

- Compare morphological traits of transgenic rice with non-transgenic counterpart including grain yield and quality.
- Compare other characteristics of transgenic and non-transgenic rice hybrids such as susceptibility towards other pests and disease, and impact on non-target organisms.

4.7.3 The Committee observed that the proposal has been recommended by IBSC RCGM in its meeting held on 24.10.2013 and 25.02.2014 respectively.

4.7.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved conduct of event selection trials of transgenic rice (Oryzasativa) events namely; OSLR-01 and OSLR-04 containing *cry1Ab (DG) gene* during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted. The applicant was also advised to submit information on (i) Source of gene, (ii) Locations where trials are to be conducted and (iii) the target pest

4.8 Request for inclusion of two additional locations viz., Abohar (Punjab) and Gandhi Nagar (Gujarat) for the conduct of event selection trial on transgenic rice (*Oryza sativa*) events MHRM01 to MHRM20 containing *cry1Ab & cry1C* genes by M/s. Metahelix Life Sciences Limited, Bangalore.

4.8.1 The Committee noted that the GEAC in its 120th meeting held on 12.5.2014 had accorded approval to conduct event selection on transgenic rice (*Oryza sativa*) marker free Bt events namely MHRM01 to MHRM20 containing *cry1Ab* gene for resistance to Rice Yellow Stem Borer (*Scirpophagaincertulas*) at Vattinagulapalli Village, RR Dist. Andhra Pradesh during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted.

4.8.2 The Committee considered the present request of the company to include two more locations i.e. Abohar (Punjab) and Gandhi Nagar (Gujarat) in addition to Vattinagulapalli village, Ranga Reddy District, Telangana. The applicant has further informed that the proposed trials at the two additional locations are exactly the same as the one for which application was made previously i.e. with the same events, genes, trial plans etc

4.8.3 The Committee noted that the RCGM has recommended the request in its 132nd meeting held on 25.03.2014.

4.8.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for inclusion of two additional locations viz., Abohar (Punjab) and Gandhi Nagar (Gujarat) for conducting event selection trial on transgenic rice (*Oryza sativa*) events MHRM01 to MHRM20 containing *cry1Ab & cry1C* genes during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted.

4.9 Permission to conduct Biosafety Research Level-1 (BRL-1) trial on brinjal (*Solanummelongena* Linn.) hybrids namely; Ajay Bt 1, Vijay Bt 1 and KirtiBt 1 containing C*ry1Fa1* gene (ANK-19 event) by M/s. Ankur Seeds Pvt. Ltd., Nagpur

4.9.1 The Committee considered the request of M/s. Ankur Seeds Pvt. Ltd., Nagpur for to conduct Biosafety Research Level-1 (BRL-1) trial on brinjal (*Solanummelongena* Linn.) hybrids namely Ajay Bt 1, Vijay Bt 1 and KirtiBt 1 containing C*ry1Fa1* gene (ANK-19 event) stably integrated into the brinjal genome and imparting resistance to lepidopteran pests, particularly to *Leucinodesorbonalis*Guen. and*Spodopteralitura* (F.)

4.9.2 The Committee noted that the trial site locations will be finalized after receiving consent from the concerned Institute/SAU for conducting the trial in an area of 2295.7 sqm/location. The final list of the trial site locations will be submitted along with the NOC from the respective State Government.

4.9.3 The Committee noted the objectives of the trials are to:

- Evaluate three transgenic brinjal (*S. melongena*) hybrids with ANK-19 event. Evaluation will be done based on the resistance/protection offered against the *Lepidoteran* pests particularly to *Leucinodesorbonalis* (Guen.) and *Spodopteralitura* (F).
- Confirm consistency of Cry1Fa1 protein expression across the growing season.
- Examine the morphological equivalence with the non-transgenic counterpart.

4.9.4 The Committee also observed that the proposal has been recommended by IBSC and RCGM in its meetings held on 18.10.2012 and 25.03.2014.

4.9.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for conduct of BRL-1 trial on brinjal (*Solanummelongena* Linn.) hybrids namely Ajay Bt 1, Vijay Bt 1 and Kirti Bt 1 containing C*ry1Fa1* gene (ANK-19 event) 16 locations at namely; Punjab, Haryana, Uttar Pradesh, Gujarat , Maharashtra, Odisha, Andhra Pradesh, Karnataka and Tamil Nadu during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted. The applicant is also advised to submit details of source of gene.

4.10 Request for inclusion of an additional location for conduct of event selection trial of Water Use Efficient (WUE) rice containing *ipt* gene in the State Agriculture University Farm in Maharashtra by M/s. Maharashtra Hybrid Seeds Company Limited (MAHYCO).

4.10.1 The Committee noted that the GEAC in its 119th meeting held on 25.4.2014 had accorded approval to conduct event selection on Water Use Efficient (WUE) rice containing *ipt* gene at *Anand Nagar, Nizamabad district (Andhra Pradesh)* during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted.

4.10.2 The Committee took note that the Company has not received NOC from Andhra Pradesh till today. The present request of the company is to include two more locations at State Agriculture University Farm at Mahatma Phule Krishi Vidyapeeth, Rahuri or Dr. Balasaheb Sawant Konkan Krishi Vidyapeeth, Dapoli in Maharashtra in addition to Telangana.

4.10.3 The Committee observed that the request has been recommended by RCGM in its meeting held on 26.05.2014.

4.10.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for inclusion of an additional locations for conduct of event selection trial of Water Use Efficient (WUE) rice containing *ipt* gene at State Agriculture University Farm at Mahatma Phule Krishi Vidyapeeth, Rahuri or Dr. Balasaheb Sawant Konkan Krishi Vidyapeeth (DBSKKV) Dapoli in Maharashtra in addition to Telangana during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted.

4.11 Request for change of location for conduct of event selection trial of Nitrogen Use Efficient (NUE) rice containing *AlaAt gene* by M/s. Maharashtra Hybrid Seeds Company Limited (MAHYCO).

4.11.1 The Committee noted that the GEAC in its 115th meeting held on 8.2.2012 had accorded approval to conduct event selection trials with transgenic rice (Oryza sativa L.)

events; namely MW-01 to MW-25 containing the *AlaAt gene* at company's own research farm at Anand Nagar, Nizamabad district (Andhra Pradesh/ Telangana) during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted.

4.11.2 The Committee also observed that GEAC in its 118th meeting held on 21.3.2014 has changed the location from AP to Maharashtra, extended validity period and protocol to conduct trials at SAU's research farm at DBSKKV, Panvel, during any appropriate season.

4.11.3 The Committee noted that the present request of the Company is to further change the location of the trial site from Panvel to DBSKKV, Dapoli, Maharashtra during appropriate season due to non-availability of land to conduct trials at Panvel,

4.11.4 The Committee observed that the request has been recommended by the RCGM in its meeting held on 26.5.2014

4.11.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for change of location for conducting event selection trial of Nitrogen Use Efficient (NUE) rice containing *AlaAt gene* at Dr. Balasaheb Sawant Konkan Krishi Vidyapeeth, (DBSKKV) Dapoli, during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted

4.12 Request for change of location for conduct of event selection on BtBrinjal C*ry1Fa1* gene from Attur, Tamil Nadu to Gurgaon, Haryana by M/s. Rasi Seeds(P) Ltd., Tamil Nadu

4.12.1 The Committee noted that the GEAC in its 120th meeting held on 12.5.2014 had accorded approval for conduct of event selection trials on Bt Brinjal **C*ry1Fa1* gene** at R &D Centre, Attur, Tamil Nadu during the appropriate season subject to submission of NOC from the State Department of Agriculture where the trials would be conducted.

4.12.2 The Committee noted that the present request of the applicant is to change the trial site from Attur, Tamil Nadu to Gurgaon, Haryana in their own R&D farm procured for vegetable breeding.

4.12.3 The Committee observed that the request has been recommended by RCGM in its meeting held on 26.5.2014

4.12.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for change of location for conduct of event selection trials on Bt Brinjal C*ry1Fa1* gene from Attur, Tamil Nadu to Gurgaon, Haryana, during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted.

4.13 Request for additional location for conducting event selection trials (EST15, EST16 and EST17) on SPT transgenic rice (*Oryza sativa L.*) *DsRed2, Zm-AA1, OsMSCA1* genes submitted by M/s. Pioneer Overseas corporation India Pvt. Ltd., Hyderabad.

4.13.1 The Committee noted that the GEAC in its 120th meeting held on 12.5.2014 had approved the following three applications for conduct of event selection trials on SPT transgenic rice (*Oryza sativa L.*) containing *DsRed2, Zm-AA1, OsMSCA1* genes during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted:

- Event selection trial (EST15) on 10 SPT1 and 10 SPT6 Rice (*Oryzasativa L.*)at any two location in Medak Distt and Nizamabad distt Telangana , and Navsari and Anand Agricultural. University in Gujarat.
- Event selection trial (EST16) on 10 SPT1 and 10 SPT6 Rice (*Oryzasativa L.*) at 2 locations, in Andhra Pradesh (Masaipet Village, Medak Distt , and in Gujarat (Anand Agricultural University, Navasari Agricultural University)
- Event selection trial (EST17) on 16 SPT1 and 16 SPT6 Rice (*Oryzasativa L.*) at one location each in Medak Distt and Nizamabad distt Telangana, and Navsari and Anand Agricultural University in Gujarat.

4.13.2 The Committee considered the present request of the Company for inclusion of following two additional testing locations in Rajasthan:

- ✓ Maharana Pratap University of Agriculture & Technology, Udaipur.
- ✓ Kota Agricultural University, Kota

4.13.3 The Committee observed that the request has been recommended by RCGM in its meeting held on 26.5.2014.

4.13.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for additional location for conducting event selection trials (EST15, EST16 and EST17) on SPT transgenic rice (*Oryza sativa L.) DsRed2, Zm-AA1, OsMSCA1* genes during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted.

4.14 Permission for F1 Hybrid seed production (Two cycles / year) from constructs RPD5-RPD17 two at locations each in North, Central, South and East Zones by M/s. BASF India Ltd, New Delhi.

4.14.1 The Committee noted that the GEAC in its 118th meeting held on 21.3.2014 had considered the request of the company for **F1** Hybrid seed production (Two cycles / year) from constructs RPD5-RPD17 at two locations each in North, Central, South and East Zones**.** The decision on the request was deferred as the Committee was of the view that only limited seed production for conducting additional field trials may be allowed. It was therefore

decided to advise the applicant to submit minimum seed production required for future trials with due justification on the quantity as well as area required.

4.14.2 The Committee considered the following information /justification submitted by the applicant vide their letter No BASF/GEAC/05/2014-(103) dated 5.5.2014:

"The F1 seed production is an essential step to produce test hybrid seed with 1-3 female non-transgenic cytoplasmic male sterile lines and a transgenic event. The produced test hybrids will be tested in Elite event Selection Field trials in different agro-climatic ecosystems and finally the appropriate Elite Event will be selected. Production takes place in the open field: The Transgenic male line (Event) is planted at different planting dates with the non-transgenic female lines in order to assure a synchronized flowering of male and females. Only the seed harvested on the female lines will be used for yield trials. The seed of the male lines will be destroyed. The average area required for this purpose is 1000m2 (0.01 ha). The quantity of seed produced in one location would be approximately 400 grams per event and female cross, resulting in a total with 168 events 3 females of 504 F1 hybrid crosses and approximately 400 grams seed per cross. The amount of seeds produced would be sufficient to run the needed event selection trials in different locations as approved by GEAC.*

Although the primary F1 hybrid seed production for the field trial will happen only at one location we request the committee to give permission in a minimum of one location in any of the two zones considered in the last GEAC communication. .Given the uncertainty that surrounds NOC's this would give us the option to apply for a NOC to different states. The F1 hybrid seed production would however take place in only any one of the approved locations.

For BASF to conduct Event Selection Trial it is imperative to produce the seed this season and hence we kindly request GEAC to approve F1 hybrid seed production with 168 events of transgenic rice constructs RPD5-RPD17, in an area of 1000m2 (0.10ha) in one location each in any two zones (Central and South)".

4.14.3 In view of the above stated facts, the Committee approved the request for F1 Hybrid seed production (Two cycles / year) from constructs RPD5-RPD17 at one location each in any two zones during any appropriate season subject to submission of NOC from the respective State Governments where the trials will be conducted. The Committee further directed the applicant not to conduct the event selection trial in proximity to Basmati growing area.

4.15 Permission to conduct event selection trials on transgenic potato with *RB gene* at Central Potato Research Institute (CPRI), campus, Shimla.

4.15.1 The Committee noted that the GEAC in its 111th meeting held on 6.7.2011 had accorded approval for conduct of event selection trails on transgenic potato events namely; SP 951, SP 904, KB/SP951, KB/SP904, KJ/SP951, KBRB, KJRB containing RB gene

4.15.2 The Committee considered the present request of Central Potato Research Institute **(**CPRI), Shimla to allow them to conduct event selection trials on transgenic potato namely; KJ 16, KJ 21, KJ65, KJ 66 and KJ 77 (Progeny of event KJ/SP951) containing RB gene. It was noted that CPRI has informed that from data already generated under controlled environment chamber, they have selected five RB transgenic hybrids of the popular potato cultivar KulfiJyoti, i.e. KJ16, KJ 21, KJ 65, KJ 66, and KJ 77 for BRL-I trial.

4.15.3 The Committee noted that NOC obtained from Himachal Pradesh Govt., covered all different potato genotypes in which RB gene is incorporated. It covered direct transformants as well as RB-hybrids of two cultivars.

4.15.4 The Committee also noted that the RCGM has requested GEAC vide their letters dated 14.5.2012, 22.4.2013 and 5.5.2014, to clarify whether justification provided by the CPRI, Shimla can be agreed and a permit letter can be issued to them for conducting event selection trials on five RB transgenic hybrids of the popular potato cultivar KufriJyoti namely; KJ 16, KJ 21, KJ65, KJ 66 and KJ 77 belonging to KJ/SP951 which contains RB gene.

4.15.5 In view of the above stated facts, the Committee approved the request for conduct of event selection trials on transgenic potato hybrids of the popular potato cultivar KufriJyoti namely; KJ 16, KJ 21, KJ65, KJ 66 and KJ 77 belonging to KJ/SP951 event with *RB gene* at Central Potato Research Institute (CPRI), campus**,** during any appropriate season subject to submission of NOC from the respective State Governments where the trials will be conducted

Agenda Item No 5: Policy issues

5.1 Request for guidance on safety assessment studies required for stacked event of transgenic corn of Bt11 and GA21 events (stack of Insect tolerant and herbicide tolerant events*)* submitted by M/s. Syngenta Biosciences Pvt. Ltd., New Delhi.

5.1.1 The Committee considered the request of M/s. Syngenta Biosciences Pvt. Ltd., New Delhi for guidance on safety assessment studies required for stacked event of transgenic corn which was produced by conventional crossing of two single events of Bt11 and GA21. The main issue in the instant case is whether biosafety data generated on both the single events are adequate or biosafety data is required to be generated for the stacked event.

5.1.2 The Committee took note of the following information:

i. Maize with stacked event of Bt11xGA21 only will be sold as commercial product.
ii. Single event of Bt11 and GA21 will be released into the environment for commercial F1 seed production of the stack event of maize.
iii. Both the single events and stack event is approved in a number of countries for food/feed/cultivation.
iv. Biosafety studies as required by RCGM on both single events of Bt11 and GA21 have been completed and submitted to RCGM. Both the events of stack are approved in many countries and extensive safety data is available.

v. RCGM in its meeting held on 26.3.2013 and allowed *for conducting the feeding studies on both single events of transgenic corn i.e. Bt11 and GA21 only.*

5.1.3 Members discussed the need for generation of biosafety data on stacked products if both products have been independently shown to be "as safe as" other commercial crop varieties and whether the combination of the two traits by conventional breeding techniques would raise any new safety concerns as this process is similar to combining conventional traits using traditional plant breeding techniques. Members were of the view that if both the events are in the same genetic background, then repeating the safety assessment may not be required.

5.1.4 The Committee after detailed deliberations decided to obtain information on (i) genetic background (ii) compositional analysis (iii) agronomic performance; (iii) substantial equivalence. Accordingly decision on the proposal was deferred.

5.2 Protocols (two) for conducting feeding studies on rat and broiler chicken using transgenic corn grains at International Institute for Biotechnology and Toxicology (IIBAT), Padappai, Chennai by M/s Syngenta Biosciences Pvt. Ltd., Pune.

5.2.1 The Committee considered the request of M/s Syngenta Biosciences Pvt. Ltd., Pune for approval of two protocols (i) Sub chronic 90 day feeding study in Wistar rats and (ii) Feeding study in broiler chicken at International Institute for Biotechnology and Toxicology (IIBAT), Padappai, Chennai.

5.2.2 As the above request is linked to the decision under agenda item 5.1, it was decided to consider the matter after taking a view on the previous agenda in the next GEAC meeting.

Agenda Item No 6: Application related to Pharmaceuticals:

6.1 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.

6.1.1 The Committee decided in the first instance to obtain comments from the experts prior to placing the proposal in GEAC agenda. Accordingly decision on proposal was deferred.

6.2 Request for revalidation of GEAC permission for manufacture and marketing of Foot and Mouth disease (FMD) Vaccine by M/s Intervet India Pvt. Ltd, Pune.

6.2.1 The Committee considered the request of M/s Intervet India Pvt. Ltd for revalidation of GEAC permission dated 1.6.2009. It was noted that the above request was considered by the GEAC in its meeting held on 21. 3.2014, wherein the Committee opined that in the first instance, the applicant may be advised to submit information on (i) Post Marketing Surveillance data, (ii) Marketing feedback and (iii) Incidence of disease.

6.2.2 The Committee noted that M/s Intervet India Pvt Ltd vide their letter No IIPL/RA/GEAC/FMDV/2014/36 dated 14.05.2014 has submitted the following clarifications:

i. For the last 10 years, FMD vaccine is being manufactured and supplied to Department of Animal Husbandry and Dairying under the Ministry of Agriculture as per tender conditions set on yearly basis.
ii. Number of FMD vaccines supplied to the Govt from 2009-2013 are 99.66 million doses.
iii. Number of FMD vaccines supplied to commercial dairy farms from 2009-2013 are 1.26 million doses.
iv. Post marketing surveillance data is maintained by Department of Animal Husbandry, Delhi. Post-vaccination sero-surveillance amongst few dairy farms do indicates that protective antibody titers are obtained in the farm conditions.
vi. Regarding marketing feedback it was noted that Department of Animal Husbandry, Delhi is the main customer for FMD vaccine and vaccine is used by them. Same dairy farmer is using the vaccine repeatedly on annual basis with satisfactory results. Technical advice is extended to all dairy farmers through specialized cell called" Veterinary Services Department" as and when required.
vii. Regarding the Incidence of disease it was noted that FMD is part of control program by Government of India and therefore the disease situation is monitored by the government directly. Sporadic outbreaks are reported whenever unrestricted animal movement is there in few commercial dairy farms. Overall disease situation is under control in dairy farms where strict bio-containment practices are followed which is mandatory for FMD control.

6.2.3 After detailed deliberations, and taking in to the consideration the information provided by the applicant, the Committee decided to revalidate the GEAC permission for manufacture and marketing of FMD Vaccine.

6.3 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 18 to 45 years in India (Protocol No. CYD 48) by M/s Sanofi Pasteur India Private Limited, Mumbai.

6.3.1 The Committee decided in the first instance to obtain comments from the experts prior to placing the proposal in GEAC agenda. Accordingly decision on proposal was deferred.

Agenda Item No 7: Applications related to import of Soybean Oil (reconsidered case)

7.1 Permission to import transgenic Soybean Oil by three company's viz. M/s. Bayer BioSciences Pvt. Ltd, Gurgaon, M/s by BASF India Ltd and M/s Monsanto Holdings Pvt. Ltd

7.1.1 The Committee noted that the requests of the M/s. Bayer BioSciences Pvt. Ltd, Gurgaon, M/s by BASF India Ltd and M/s Monsanto Holdings Pvt. Ltd, for import of Soybean oil was considered by the GEAC in its 118th meeting held on 23.3.2014 wherein the Committee observed certain discrepancies and decided to obtain clarification from CFTRI on (i) why +ve controls show –ve results and (ii) why – ve controls show + results. Further, the Committee was also of the view that +ve control should be same oil spiked with r-DNA or Protein.

7.1.2 The Committee considered the clarification received from CFTRI and noted that the Test Reports received from CFTRI indicate (a) DNA was absent in Refined Soybean oil and Crude Oil LL Soybean for all events (LL event AA547-127, LL event A2704-12, RR event (BtRR2Y) and event BPS-CV127-9); and (b) No protein was detected by amino acid analysis for all Soybean events mentioned above. The Committee also noted that the tests have been conducted at a detection level of 0.01 %. Further, the test samples have been spiked with nanogram levels of r-DNA for confirming the validity of the tests.

7.1.3 After detailed deliberations, the Committee was in a view that the clarifications provided by the CFTRI are in order and decided to approve the import of Refined Soybean Oil derived from transgenic Soybean by three company's viz. M/s. Bayer Bio-Sciences Pvt. Ltd, Gurgaon, M/s by BASF India Ltd and M/s Monsanto Holdings Pvt. Ltd.

****