

Decisions taken in the 111th meeting of the Genetic Engineering Appraisal Committee (GEAC) to be held on 06.07.2011

The 111th meeting of the GEAC was held on 06.07.2011 in the Ministry of Environment & Forests under the chairmanship of Shri M. F. Farooqui, Additional Secretary, MoEF and Chairman, GEAC.

Inadvertently the Special meeting of the GEAC with Experts held on 27.4.2011 has not been numbered. The following amendments may be noted:

GEAC meeting on 27.4.2011:	109 th GEAC meeting
GEAC meeting on 11.5.2011:	110 th GEAC meeting
GEAC meeting on 06.7.2011:	111 th GEAC meeting

The deliberations and decisions taken in the GEAC meeting in respect of Agenda items 4 to 8 are as follows:

Agenda item No.4 : Policy issues

4.1 Clarifications sought by the Standing Committee on the Event Based Approval Mechanisms for Bt Cotton hybrids expressing approved events.

4.1.1 The Committee considered the recommendations of the Standing Committee to incorporate the requirement of (i) one year field testing; (ii) morphological characteristics using DUS descriptors as per PPVF&RA guidelines; & (iii) data on CLCuV for the North Zone as a mandatory requirement under the Event Based Approval Mechanism.

4.1.2 The Committee noted that the Cotton sowing season for Kharif 2011 is over. Further, the Standing Committee has also completed its three year tenure and as agreed in the 107th GEAC meeting held on 9.2.2011, there is a need to review the same holistically taking into consideration the recommendations of the Standing Committee and DBT who has been servicing the Committee for three years.

4.1.3 The Committee further noted that the GEAC in its meeting held on 9.2.2011 had constituted a Sub-Committee to review measures to streamline the regulatory process. The TOR of the Committee includes the review for 'Event Based Approval of Bt Cotton'. The Member Secretary GEAC informed that the first meeting of the Sub-Committee is scheduled for July 19, 2011. It was therefore decided to await the recommendations of the Sub-Committee before taking a view on the matter.

4.1.4 Decision on the matter was therefore deferred.

4.2 Approval from State Governments to conduct GM crop field trials.

4.2.1 The Committee noted that in the 108th GEAC meeting held on 9.3.2011, the permission granted to M/s Monsanto India Ltd. for conduct of BRL-II trials for transgenic Maize in Bihar was withdrawn by the GEAC on the basis of the request received from the Chief Minister, Bihar. In the said meeting, it was also decided, in future, GEAC may give one

month's time to the State Governments to convey their no objection prior to issue of the approval letter for field trials with a view to avoid disruption of the on-going field trials even though it is not a statutory requirement under Rules 1989.

4.2.2 The Member Secretary further informed that in view of several applications pending before the GEAC and taking into consideration the seasonality involved, applicants for field trials have been requested to obtain NOC from the respective State Governments (Principal Secretary, State Department of Agriculture) so as to initiate early action on the process in the current GEAC meeting. Cases where GM crop field trials have been approved by the GEAC but field trials have not been initiated; applicants have been directed not to initiate the trials without obtaining NOC from the State Government.

4.2.3 The Committee further considered the communication received from M/s Monsanto and ABLE (Industry Association) informing that on approaching the State Government, some of them have informed that they have not received any communication from GEAC/MoEF on the subject without which they will not be able to consider issuance of NOC as there is no provision in the law under which they can give NOC.

4.2.4 The Committee extensively deliberated on the following three options for obtaining State Government approval for conducting GM crop field trials:

- (i) The GEAC may write to the State Government on a case-by-case basis which have been approved for field trials and issue the approval letter only on receipt of consent from the State Government. In case no communication is received in one month, the applicants may be allowed to initiate the trials.
- (ii) The GEAC may accord approval to the applicant for field trials subject to the condition that sowing will be initiated only on receipt of consent from the State Government. Copy of the consent from the State Government and details of sowing should be submitted to the GEAC within 7 days of receipt of consent from the State Government.
- (iii) The applicant may be advised to submit consent from the State Government along with the application for which the GEAC may communicate to the State Governments the new requirement.

4.2.5 After detailed deliberation, it was agreed that agriculture being a State subject, it is important to take the views of the State Government on board and to promote their involvement in activities pertaining to GM crop field trials especially its effective monitoring. It was decided that in respect of all GM crop field trials, the GEAC/RCGM would issue the approval letter only on receipt of NOC from the respective State Department of Agriculture. A communication in this regard would be sent to all applicants whose proposal has been approved by the GEAC along with a copy to the State Government to enable them to obtain the NOC from the State Government.

4.2.6 During the deliberation, Member Secretary, RCGM pointed out that the present requirement of approval at several levels (RCGM/GEAC/State Government) for the same application makes it difficult for the applicants to conduct the trial during the normal sowing season. He therefore suggested that MoEF may consider issuing a Gazette Notification authorizing RCGM to accord approval for event selection and BRL-I trials which are basically

for the purpose of research. The Committee noted that this was the earlier practice as the GEAC had earlier authorized RCGM to accord approval for research trials. However, subsequent to the Supreme Court order dated 1.5.2006 these proposals are being referred to the GEAC.

4.2.7 The Chairman requested the Member Secretary to examine the above matter and also obtain legal opinion on the implication of the Supreme Court Order.

Agenda item No.5 : Consideration of applications for confined field trials of transgenic crops (Event selection/ BRL-I/BRL-II) as recommended by the RCGM.

5.1 Permission to conduct event selection trials of 45 events of transgenic rice (*Oryza sativa*) (22 containing *cry1Ab*, *cry1Ca* and *bar* genes +23 containing *cry1Ab*, *cry1C* and *cry2Ad*) by M/s. Bayer Biosciences Pvt. Ltd., Gurgaon .

5.1.1 The Committee considered the request of M/s. Bayer Bio Science Pvt. Ltd., Gurgaon to conduct event selection trials on 45 transgenic rice (22 events (*Oryza sativa*) containing *cry1Ab*, *cry1Ca* and *bar* gene from Bayer Bioscience Ltd, and 23 events containing *cry1Ab*, *cry1C* and *cry2Ad* from *Du Pont India Ltd*). The trials will be conducted at two locations within the institutional research farm at Crop Development Centre, Patancheru in an area of 3000 sq. meter and in long leased land/company owned facility at Davangere, Karnataka in an area of 1500 sq m.

5.1.2 The Committee noted that the objective of the trials is to evaluate the Bt events in comparison to non-transformed genotype for agronomic parameters and Insect Efficacy. Bt events would also be tested for effect, if any, on restoration capacity and seed producibility of the transformant & herbicide efficacy caused due to presence of *bar* gene.

5.1.3 The experimental design for confined field trials would be Randomized Complete Block design with 3 replications. The seed producibility study will be non-replicated. Data would be for agronomic parameters (days to flowering, No. of tillers & panicles, plant height, paddy yield) Insect efficacy, (Dead hart/white heads), Seed producibility (weight of F1 seed produced), herbicide efficacy, restorability (paddy yield per unit area). All the pesticide to be used are registered in India for use in rice crop.

5.1.4 It was further noted that the IBSC has recommended the proposal in its 36th meeting held on 4.02.2011, RCGM recommended the proposal in its 99th meeting held on 22.3.2011.

5.1.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials of 45 events of transgenic rice (*Oryza sativa*) (22 containing *cry1Ab*, *cry1Ca* and *bar* genes +23 containing *cry1Ab*, *cry1C* and *cry2Ad*) during the appropriate season in 2011-2012 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.2 Permission to conduct event selection trials of transgenic cotton events (*Gossypium hirsutum*) namely stacked events - GHB119 (*cry2Ae/PAT*) & T304-40 (*cry1Ab/PAT*) containing *cry1Ab*, *cry2Ae* and *bar* gene by M/s. Bayer Biosciences Pvt. Ltd., Gurgaon.

5.2.1 The Committee considered the request of M/s. Bayer Bio Science Pvt. Ltd., Gurgaon to conduct event selection trials on twinlink transgenic cotton hybrids namely; SP7007TL, SP7010 TL and SP1169 TL in North zone (Bhatinda, Punjab) and SP499 TL, SP503 TL, SP 504 TL, SP 1037 TL, SP 1136 TL, SP 1171 TL, SP 7230TL, SP 7157 TL and SP 7149 TL in Central zone (Aurangabad, Maharashtra) and South zone (Patancheru, A.P.). The trials will be conducted in long leased land/company owned facility at one location per zone.

5.2.2 The objective of the trials is (i) to evaluate the insect resistant & herbicide tolerant cotton hybrids containing *cry1Ab*, *cry2Ae* & *bar* gene event under confined field trial and (ii) to generate data on phytotoxicity, insect bio efficacy, herbicide tolerance, weed control, effect on plant growth, and yield, protein expression of different plants parts at different plant stage etc.

5.2.3 The Committee also noted that the IBSC has recommended the proposal in its 36th meeting held on 4.02.2011, RCGM recommended the proposal in its 99th meeting held on 22.3.2011 and also recommended that the approved commercial checks should be used during the trials.

5.2.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials of transgenic cotton events (*Gossypium hirsutum*) namely stacked events - GHB119 (*cry2Ae/PAT*) & T304-40 (*cry1Ab/PAT*) containing *cry1Ab*, *cry2Ae* and *bar* gene during the appropriate season in 2011-2012 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.3 Permission to conduct Biosafety Research Level-1 (BRL-1) trials and seed production with herbicide tolerant Glytol cotton hybrids containing *2mEPSPS* gene (Event GHB614) by M/s. Bayer Biosciences Pvt. Ltd., Gurgaon.

5.3.1 The Committee considered the request of M/s. Bayer Bio Science Pvt. Ltd., Gurgaon to conduct BRL-1 trials on five herbicide tolerant Glytol cotton hybrids containing *2mEPSPS* gene (Event GHB614) namely; SP 499G, SP 7017G, SP 7230 G SP 7139G and SP 7152 G in North, Central and South Zone respectively. The trials will be conducted at two locations each zones in the company's owned facility.

5.3.2 The Committee also noted that the company has requested for seed production of Glytol cotton hybrids namely; SP 499 G, SP 7017G (North) and SP 7230 G SP 7139 G in the (Central & South) in an area of 0.5 acre per zone for further testing in BRL-1 (2nd year) trials and to initiate feeding studies.

5.3.3 The objective of the trials is : (i) to evaluate the herbicide tolerant cotton hybrids containing *2mEPSPS* gene event by spraying Glyphosate herbicide under BRL-1 trial at two

locations each in NZ, CZ & SZ and (ii) to generate data of phytotoxicity, herbicide tolerance, weed control, effect on plant growth and yield, protein expression of different plant parts at different plant stage etc. Need based spray of registered pesticides will be done.

5.3.4 The Committee also noted that the GEAC in its 103rd meeting held on 29.9.2010 had approved the following hybrids for event selection:

- SP 499 G, SP 7017 G in the North,
- SP 499 G, SP 503 G, SP 7017 G, SP 7140 G, SP 7139 G, SP 7152 G and SP 7230 G in the Central and South Zone.

5.3.5 It was further noted that the proposal was recommended by the RCGM in its 99th meeting held on 22.3.2011.

5.3.6 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct BRL-1 trials for two years and seed production in an area of 0.5 acres with herbicide tolerant Glytol cotton hybrids containing *2mEPSPS gene* (Event GHB614) during the appropriate season in 2011-2013 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.4 Permission to conduct pollen flow study of Glytol cotton hybrid namely SP499G containing 2mEPSPS gene (Event GHB614) at Yavatmal, Maharashtra by M/s. Bayer Biosciences Pvt. Ltd., Gurgaon.

5.4.1 The Committee considered the request of M/s. Bayer Bio Science Pvt. Ltd., Gurgaon to conduct pollen flow study of Glytol cotton hybrid namely SP499G containing 2mEPSPS gene (Event GHB614) at companies trial site about 12544 sq meter at Yavatmal, Maharashtra during Kharif 2011. The objective of the trial is to evaluate the pollen flow study of Herbicide Tolerant Cotton hybrid SP 499 G having gene event GHB 614.

5.4.2 The Committee noted that the purpose of the study is to (i) measure the distance of pollen flow of herbicide tolerant cotton hybrid containing 2mEPSPS gene event under confined field trial at one location and (ii) evaluate whether the transgenic pollen flows out and cross pollinate with compatible crops cultivated in the adjacent area.

5.4.3 It was also noted that the IBSC in its 36th meeting has recommended the proposal on 4.2.2011. RCGM also recommended the proposal in its 99th meeting held on 22.3.2011 wherein the applicant was directed to generate data on pollen morphology, pollen production, pollen viability and pollination behavior also.

5.4.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct pollen flow study of Glytol cotton hybrid namely SP499G containing 2mEPSPS gene (Event GHB614) at Yavatmal, Maharashtra during the appropriate season in 2011-2012 subject to submission of NOC from the respective State Department of Agriculture where the pollen flow study would be conducted.

5.5 Permission to conduct event selection trials of transgenic castor (*Ricinus communis L.*) events namely AMT-1, NBRI-1, AK1304 PB-1, 804-1, Control (DCS-9) containing *cry1Ec* and *cry1Aa* genes at DSR- ICAR organization by Directorate of Oilseeds Research, Hyderabad

5.5.1 The Committee considered the request of Directorate of Oilseeds Research, Hyderabad to conduct event selection trials on four transgenic castor (*Ricinus communis L.*) events namely AMT-1, NBRI-1, AK1304 PB-1, 804-1, Control (DCS-9) containing *cry1Ec* and *cry1Aa* genes at DSR- ICAR organization. The objective of field trial is to assess the performance of the transgenic castor harboring *Cry 1EC* and *Cry 1Aa* genes under artificial bioassays.

5.5.2 The Committee noted that the purpose of the study is (i) artificial bioassays of the field raised material against castor semilooper and *spodopetra litura* will be repeated once again for selection of the events with high expression of the proteins. (tolerance to lepidopteran insects semilooper and *spodopetra litura*) and (ii) promising material will be multiplied and advanced further.

5.5.3 The Committee further noted that the IBSC in its 8th meeting has recommended the proposal on 11.2.2011. RCGM also recommended the proposal in its 99th meeting held on 22.3.2011.

5.5.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials of transgenic castor (*Ricinus communis L.*) events namely AMT-1, NBRI-1, AK1304 PB-1, 804-1, Control (DCS-9) containing *cry1Ec* and *cry1Aa* genes within the institutional research farm during the appropriate season in 2011-2012 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.6 Permission to conduct second year Biosafety Research Level-1 (BRL-1) trials on two transgenic corn (*Zea mays*) hybrids namely NK6240, NK6607 containing *mepsps* gene (GA 21 event) and one transgenic corn (*Zea mays*) hybrid NK 6240 containing *cry1Ab* & *m epsps* genes (Bt11xGA21 stack event) by M/s. Syngenta Biosciences Pvt. Ltd., Pune.

5.6.1 The Committee considered the request of M/s. Syngenta Biosciences Pvt. Ltd., Pune to conduct second year Biosafety Research Level-1 (BRL-1) trials on two transgenic corn (*Zea mays*) hybrids namely NK6240, NK6607 containing *mepsps* gene (GA 21 event) and one transgenic corn (*Zea mays*) hybrid NK 6240 containing *cry1Ab* & *mepsps* genes (Bt11xGA21 stack event) under confined conditions. The first year BRL-I trials of these events have been approved for planting in Rabi 2010 and are ongoing within three SAUs namely; Maharana Pratap University of Agriculture & Technology (MPUAT), Udaipur and Banaras Hindu University, Varanasi; for generating the following data:

1. Evaluate efficacy of the stacked event against specific lepidopteron insect pest of corn viz. stem borers (*Chilo partellus* and *Sesamia inferens*) and cob borer (*Helicoverpa armigera*) and other secondary pests on transgenic corn hybrids corresponding on their conventional (non-transgenic) counterparts and checks and application of Glyphosate herbicide.
2. Evaluate the efficacy of GA21 event on corn against application of Glyphosate herbicide.
3. Comparative assessment of soil ecosystem/rhizosphere indicators, effect on germination, aggeassiveness, weediness, morphology and phenotypic charactersof transgenic corn and its conventional counterpart hybrids.
4. Monitoring the occurrence of beneficial and non target insects on transgenic as well as non-transgenic corn hybrid and study the impact of the event on NTOs and soil ecosystem.
5. To produce sufficient plant material to under take biosafety research and to generate data on feed and food safety.
6. To study the level of expression of candidate protein expressed by the inserted gene i.e. mepsps and cry 1Ab Xmepsps in different plant parts at a regular intervals as per schedule given .
7. Generation of base line susceptibility data of candidate protein on representative insect pest population of key target lepidopteron pests i.e. *Chilo partellus* and *Sesamia inferens* and *Helicoverpa armigera* insect pests collected from various locations including the field trial sites during the growing season /trial period by rearing them in the bioassay laboratory and also the efficacy testing of Glyphosate herbicide application.
8. In case of non occurrence of the target insect pests during the crop growth period, efficacy study of the gene /event at the field level may be conducted by artificial; infestation of key target pests on all trial plant at 10-15 days after germination.
9. Generation of DNA fingerprinting data each genotype /hybrid.

5.6.2 The Committee further noted that the present request of the applicant is to conduct BRL-I trials during the second year with the same transgenic corn hybrids at seven more locations:

1. DMR, Bihar;
2. Rajendra Agricultural University, Bihar;
3. NRCWS, Jabalpur;
4. UAS, Dharwad/Bangalore;
5. APAU (ANGRAU);
6. Haryana Agriculture University, Hissar;
7. MPKV, Rahuri

5.6.3 The Committee further noted that the RCGM in its 99th meeting held on 22.3.2011 has recommended BRL-I trials on two transgenic corn (*Zea mays*) hybrids namely NK6240, NK6607 containing *mepsps* gene (GA 21 event) and one transgenic corn (*Zea mays*) hybrid NK 6240 containing *cry1Ab* & *mepsps* genes (Bt11xGA21 stack event. within the University/research institute farm) during June/July, 2011 for Kharif, 2011 and during October/November for Rabi, 2011 subject to submission of consent letters from these SAUs.

RCGM advised the applicant to specify the target insects and also include Bt national check in the trials.

5.6.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct second year Biosafety BRL-1 trials on two transgenic corn (*Zea mays*) hybrids namely NK6240, NK6607 containing *mepsps* gene (GA 21 event) and one transgenic corn (*Zea mays*) hybrid NK 6240 containing *cry1Ab* & *m epsps* genes (Bt11xGA21 stack event) at three locations during the appropriate seasons in 2011-2012. The approval is subject to (i) submission of NOC from the respective State Department of Agriculture where the trials would be conducted and (ii) maintaining a H4 reproductive isolation distance (300 m including 6 to 7.8 meters all around the experimental field and planting of 10-13 rows. of African Tall Maize plants covering a distance of 6 to 7.8 meters all around the experimental plot area).

5.7 Permission to conduct Biosafety Research Level-1 (BRL-1) trials on transgenic maize (*Zea mays L.*) hybrids namely P3501YHR and 30B07YHR with stacked event of TC1507xMon810xNK603 (DAS-01507-1xMON-00810-6xMON-00603-6) containing *cry1F* and *cry1Ab* genes by M/s. Pioneer Overseas Corporation, Hyderabad .

5.7.1 The Committee considered the request of M/s. Pioneer Overseas Corporation, Hyderabad to conduct Biosafety Research Level-1 (BRL-1) trials on transgenic maize (*Zea mays L.*) hybrids namely P3501YHR and 30B07YHR with stacked event of TC1507xMon810xNK603 (DAS-01507-1xMON-00810-6xMON-00603-6) containing *cry1F* and *cry1Ab* genes. The maize hybrids with stacked event TC1507xMON810xNK603 express the insecticidal proteins *Cry1F* (TC1507 event) and *Cry1Ab* (MON810 event) which confer resistance to lepidopteron insect pest viz., *Chilo partellus*, *Sesamia inferens* and *Helicoverpa armigera* and the CP4EPSPS protein (NK603 event).

5.7.2 The Committee also noted that the single events, namely TC1507, NK603 and MON810, and the combined stacked events have been approved in various countries including US for cultivation, import for food & feed purposes. The trials will be conducted during Oct/Nov 2011 at one of each within the University/research institute farm following locations:

1. Regional Agricultural Station, CCS Haryana Agricultural University, Karnal, Haryana
2. University of Agricultural Sciences, Dharwad, Karnataka
3. Acharya N. G. Ranga Agricultural University, Hyderabad, Andhra Pradesh
4. Maharana Pratap University of Agriculture and Technology, Udaipur, Rajasthan
5. Punjab Agricultural University, Ludhiana, Punjab
6. Tamil Nadu Agricultural University, Coimbatore, Tamil Nadu

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

1. Study the efficacy of the *cry1F* and *cry1Ab* genes in the transgenic hybrids expressing the stacked events TC1507xMON810xNK603 against target lepidopteran insects viz., *Chilo partellus*, *Sesamia inferens* and *Helicoverpa*

armigera compared to their conventional (non transgenic) counterparts and checks.

2. Evaluate weed tolerance of transgenic maize and weed management efficacy of CP4 EPSPS gene (event NK603) with K salt of Glyphosate formulation under field conditions and the effect of carryover on succeeding crops.
3. Conduct comparative assessment of soil ecosystem & weediness, morphology and phenotypic characters of transgenic corn and its non-transgenic counterpart hybrids.
4. Monitor occurrence of beneficial and non-target insect species on transgenic and non transgenic corn hybrids and the impact on soil micro-flora.
5. Produce sufficient plant material to undertake biosafety research on feed and food safety and compositional analysis.
6. Undertake analysis of expression levels of candidate proteins Cry1F; Cry1Ab and CP4EPSPS expressed in different plant parts at regular intervals during crop growth stages.

5.7.4 The Committee noted that the Company has provided “No Objection Certificate’ to refer to Regulatory Data concerning insect-protected corn NK603 and MON810 proprietary of Monsanto Company”. They have also submitted the report on efficacy testing of transgenic maize hybrids 32B34HYR and 32N89HYR with stacked event MON810xTC1507xNK603 in greenhouse conditions.

5.7.5 The Committee further noted that the applicant has also submitted a validated event specific LOD protocol of 0.01% from SGS India Pvt. Ltd, Ahmedabad. RCGM recommended the proposal in its 99th meeting held on 22.3.2011 *subject to submission of consent letters from these SAUs.*

5.7.6 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct Biosafety Research Level-1 (BRL-1) trials on transgenic maize (*Zea mays L.*) hybrids namely P3501YHR and 30B07YHR with stacked event of TC1507xMon810xNK603 (DAS-01507-1xMON-00810-6xMON-00603-6) containing *cry1F* and *cry1Ab* genes at three locations during the appropriate season in 2011-2012. The approval is subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted. and (ii) maintaining a H4 reproductive isolation distance (300 m including 6 to 7.8 meters all around the experimental field and planting of 10-13 rows. of African Tall Maize plants covering a distance of 6 to 7.8 meters all around the experimental plot area).

5.8 Permission to conduct event selection of six transgenic Sorghum (*Sorghum bicolor L. Moench*) (Events with p^{CAMBIA} 1300: *mtID* CRIDA 1-6-1-8-4, *mtID* CRIDA 2-9-3-3-5, *mtID* CRIDA 4-7-1-7-4, *mtID* CRIDA 26-1-11-6-1, *mtID* CRIDA 75-2-21-2-1 and Events with p^{CAMBIA} 1305.1: *mtID* CRIDA 3-3-18-7-2 and untransformed control: SPV-

462 containing *mtlD* genes) by Central Research Institute for Dryland Agriculture (CRIDA), Hyderabad .

5.8.1 The Committee considered the request of CRIDA, Hyderabad to conduct event selection of six transgenic Sorghum (*Sorghum bicolor* L. Moench) (Events with p^{CAMBIA} 1300: *mtlD* CRIDA 1-6-1-8-4, *mtlD* CRIDA 2-9-3-3-5, *mtlD* CRIDA 4-7-1-7-4, *mtlD* CRIDA 26-1-11-6-1, *mtlD* CRIDA 75-2-21-2-1 and Events with p^{CAMBIA} 1305.1: *mtlD* CRIDA 3-3-18-7-2 and untransformed control: SPV-462 containing *mtlD* genes). The trials will be conducted at one location at CRIDA Complex, Santoshnagar, Hyderabad.

5.8.2 The Committee noted the objective of the trials is to evaluate:

- Seven genotype of Sorghum (six transgenic events of *mtlD* and one untransformed control (SPV-462) would be assessed under well watered and dryland conditions in triplicate .
- Molecular characterization of selected transgenic lines using PCR,RT-PCR etc.
- Physiological testing of selected transgenic plants for Excised Leaf Water Retention Capacity, Relative water Content and Photosynthesis rate.
- Overall growth and biomass in the selected transgenic lines will be assessed.

5.8.3 The Committee noted that the IBSC in its 8th meeting has recommended the proposal on 11.2.2011. RCGM also recommended the proposal in its 99th meeting held on 22.3.2011 and informed that the applicant has submitted report on the confined field trial conducted earlier for event election of transgenic sorghum lines with *mtlD* gene for salinity and drought tolerance.

5.8.4 The Committee also noted that GEAC in its 100th meeting held on 12.5.2010 had approved to conduct event selection trials on transgenic Sorghum (*Sorghum bicolor* L. Moench) containing *mtlD* gene for drought and salinity tolerance namely; p^{CAMBIA} 1300: *mtlD* CRIDA 1-6-1-8-4, *mtlD* CRIDA 2-9-3-3-5, *mtlD* CRIDA 4-7-1-7-4, *mtlD* CRIDA 26-1-11-6-1, *mtlD* CRIDA 75-2-21-2-1 and Events with p^{CAMBIA} 1305.1: *mtlD* CRIDA 3-3-18-7-2 and untransformed control: SPV-462 containing *mtlD* gene to Central Research Institute for Dryland Agriculture (CRIDA)

5.8.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection of six transgenic Sorghum (*Sorghum bicolor* L. Moench) (Events with p^{CAMBIA} 1300: *mtlD* CRIDA 1-6-1-8-4, *mtlD* CRIDA 2-9-3-3-5, *mtlD* CRIDA 4-7-1-7-4, *mtlD* CRIDA 26-1-11-6-1, *mtlD* CRIDA 75-2-21-2-1 and Events with p^{CAMBIA} 1305.1: *mtlD* CRIDA 3-3-18-7-2 and untransformed control: SPV-462 containing *mtlD* genes) during the appropriate seasons in 2011-2012 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.9 Permission to conduct event selection trials on seven transgenic potato (*Solanum tuberosum* subsp. *Tuberosum*) events namely SP 951, SP 904,

KB/SP951, KB/SP904, KJ/SP951, KBRB, KJRB containing RB gene at Central Potato Research Institute Campus (CPRI), Shimla .

5.9.1 The Committee considered the request of CPRI, Shimla to conduct event selection trials on seven transgenic potato (*Solanum tuberosum subsp. Tuberosum*) events namely SP 951, SP 904, KB/SP951, KB/SP904, KJ/SP951, KBRB, KJRB containing RB gene for resistance to late blight pathogen *phytophthora infestans*. The trials will be conducted at one location at CPRI, Shimla

5.9.2 The Committee noted that the IBSC has recommended the proposal on 12.8.2010. RCGM also recommended the proposal in its 99th meeting held on 22.3.2011 *subject to the condition that the number of replications should be increased to satisfy statistical analysis.*

5.9.3 In view of the above stated facts and taking in to consideration the recommendations of the RCGM, the Committee approved the request conduct event selection trials on seven transgenic potato (*Solanum tuberosum subsp. Tuberosum*) events namely SP 951, SP 904, KB/SP951, KB/SP904, KJ/SP951, KBRB, KJRB containing RB gene. during the appropriate seasons in 2011-2012 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.10 Permission to conduct event selection trials on 20 transgenic rice (*Oryza sativa L.*) events containing *cry1Ac* gene by M/s. JK Agri Genetics Ltd., Hyderabad.

5.10.1 The Committee noted that the above request was earlier considered by the GEAC in its 107 meeting held on 9.2.2011 to conduct event selection on 20 transgenic rice (*Oryza sativa L.*) events containing *cry1Ac* gene for the evaluation of the Bt events for resistance against lepidopteron insects and to identify events which are true-to-type agronomically and the following information /clarifications provided by the applicant was considered by the Committee:

1. The trial of transgenic rice with 20 events with *cry1Ac* gene will be carried out at company's R&D Centre, Ranga Reddy, Andhra Pradesh.
2. Marker genes E-GFP, CodA-NptII and NptIII were used in the plasmid vector
3. Marker genes E-GFP, CodA-NptII are present within the T-DNA sequence and will be inserted into plant genome.
4. NptIII is present outside the T-DNA sequence is useful for bacterial selection

5.10.2 The Committee considered the additional information subsequently provided by the applicant pertaining to (i) Structure of MAP; (ii) Construct and (iii) Insert Map.

5.10.3 In view of the above stated facts and taking in to consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials on 20 transgenic rice (*Oryza sativa L.*) events containing *cry1Ac* gene during the appropriate seasons in 2011-2012 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.11 Permission to conduct event selection trials on 20 transgenic rice (*Oryza sativa* L.) events namely Cry2AxE 001-to Cry 2AxE 020 containing *cry2Ax1* gene by JK Agri Genetics Ltd., Hyderabad.

5.11.1. The Committee noted that the GEAC in its 107 meeting held on 9.2.2011 had reconsidered the request of M/s. JK Agri Genetics Ltd., Hyderabad to conduct event selection on 20 transgenic rice (*Oryza sativa* L.) events containing *cry2Ax1* gene for the evaluation of the Bt events for resistance against lepidopteron insects and to identify events which are true-to-type agronomically. The following information /clarifications provided by the applicant was considered by the Committee:

1. The trial of transgenic rice with 20 events with *cry2Ax1* gene will be carried out at company's R&D Centre, Ranga Reddy, Andhra Pradesh.
2. Marker genes E-GFP, CodA-NptII and NptIII were used in the plasmid vector
3. Marker genes E-GFP, CodA-NptII are present within the T-DNA sequence and will be inserted into plant genome.
4. NptIII is present outside the T-DNA sequence is useful for bacterial selection

5.11.2 The Committee considered the additional information subsequently provided by the applicant pertaining to (i) Complete Structure of MAP; (ii) Complete Construct and (iii) Insert Map.

5.11.3 In view of the above stated facts and taking in to consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials on 20 transgenic rice (*Oryza sativa* L.) events namely Cry2AxE 001-to Cry 2AxE 020 containing *cry2Ax1* gene during the appropriate seasons in 2011-2012 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.12 Permission to conduct event selection trials on transgenic banana cv Rasthali (AAB) (Natural hybrid *Musa accuminata* X *M. balbisiana*) events namely ECSRS1-17 and SUCRS 1-3 containing Anti Microbial Peptide (AMP) gene by Indian Institute of Horticultural Research (IIHR), Bangalore.

5.12.1 The Committee considered the request of IIHR, Bangalore to conduct event selection trials on transgenic banana cv Rasthali (AAB) (Natural hybrid *Musa accuminata* X *M. balbisiana*) events namely ECSRS1-17 and SUCRS 1-3 containing Anti Microbial Peptide (AMP) gene at their own farm (IIHR, Block-II-ESTB) to screen transgenic plants for fusarium wilt.

5.12.2 The Committee noted that the transgenic banana cv Rasthali (AAB) are derivatives of complex hybridization of *Musa accuminata* and *M. balbisiana*. The basic chromosome in the edible banana is n=11. Edible banana have 22, 23, 44 chromosomes depending on which they are classified as diploid, triploid and tetraploid. AAB is classified as a triploid. Rasthali is threatened by the deader disease *Fusarium wilt* which has limited its cultivation.

5.12.3 The Committee noted that the objective of the trials is to (i) screen transgenic plant for *Fusarium wilt* and (ii) to study yellowing of the leaves, stem splitting corm discoloration, overall phenotypic characteristics like, vegetative growth, flowering and fruiting details.

5.12.4 The Committee also noted that the IBSC has recommended the proposal. RCGM recommended the proposal in its 100th meeting held on 18.4.2011.

5.12.5 In view of the above stated facts and taking in to consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials on transgenic banana cv Rasthali (AAB) (Natural hybrid *Musa accuminata* X *M. bulbisiana*) events namely ECSRS1-17 and SUCRS 1-3 containing Anti Microbial Peptide (AMP) gene during the appropriate seasons in 2011-2012 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted..

5.13 Permission to conduct Biosafety Research Level (BRL-I) trials on Roundup Ready Flex cotton (*Gossypium hirsutum* L). hybrids namely MRC 8017 RRFTM and MRC 8031 RRFTM in the North Zone, MRC 8347 RRFTM and MRC 8351 RRFTM in Central and South Zones containing *cp4epsps* gene (Event MON 88913) by M/s. Mahyco.

5.13.1 The Committee considered the request of M/s. Mahyco to conduct BRL-I trials on two Roundup Ready Flex cotton (*Gossypium hirsutum* L). hybrids namely MRC 8017 RRFTM and MRC 8031 RRFTM containing *cp4epsps* gene (Event MON 88913) during Kharif 2011 at three locations in Punjab; Haryana and Rajasthan in the North Zone and MRC 8347 RRFTM and MRC 8351 RRFTM in Gujarat; Maharashtra and Madhya Pradesh in Central zones and in Karnataka; Andhra Pradesh and Tamil Nadu in South Zone respectively within the applicant's farm/ long leased farms.

5.13.2 The Committee noted that the trials will be conducted with transgenic cotton hybrids mentioned above with following objectives:

1. To study the weed control efficacy in RRFTM hybrids with Glyphosate tolerant trait (MON 88913) with application of Roundup (MON 76366) on RRFTM cotton hybrids.
2. To estimate of level of expression of CP4 EPSPS protein in various plant parts at different crop growth stages of RRFTM cotton hybrids.
3. The protein expression data of CP4 EPSPS in various plant parts will be recorded at the time of the each Roundup application and also at 60, 80, 100, 120, 140 and 160 days after sowing at all trial locations.
4. Observe with respect to growth habit, life cycle, plant height, impact on pollinator species and indicators of changes in weediness potential of RRFTM hybrids, non-transgenic counterparts and checks.
5. Monitor the occurrence of beneficial insects and insect pests on RRFTM hybrids, non-transgenic counterparts and checks.
6. To assess the effect of CP4 EPSPS protein on soil microflora, earthworms and soil insect (Collembola) related to rhizosphere on the soil of RRFTM and non-RRF plots.

Data should be recorded during pre and post spray of Roundup herbicide (MON 76366) and pre planting and post harvesting stage.

7. To estimate seed cotton yield of RRF™ hybrids, non-transgenic counterparts and checks.
8. To collect plant parts of RRF™ hybrids, non-transgenic counterparts and checks for generation of material for biosafety studies.

5.13.3 The Committee noted that the Sources of Genes and Cloning Strategy: MON 88913 was developed through *Agrobacterium*-mediated transformation of cotton hypocotyl tissue using the double-border, binary vector PV-GHGT35.

5.13.4 It was also noted that the IBSC has recommended the proposal in its 90th meeting held on 7.4.2011. RCGM recommended the proposal in its 100th meeting held on 18.4.2011.

5.13.5 In view of the above stated facts and taking in to consideration the recommendations of the RCGM, the Committee approved the request to conduct two year BRL-I trials on Roundup Ready Flex cotton (*Gossypium hirsutum L.*) hybrids namely MRC 8017 RRF™ and MRC 8031 RRF™ in the North Zone, MRC 8347 RRF™ and MRC 8351 RRF™ in Central and South Zones containing *cp4epsps* gene (Event MON 88913) at three locations during the appropriate seasons in 2011-2013 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.14 Permission to conduct BRL-I trials on Maize hybrids namely Hishell & 900M Gold containing Event MON NK603 at six locations by M/s. Monsanto India Ltd.

5.14.1 The Committee considered the request of M/s. Monsanto India Ltd to conduct BRL-I trials on Maize hybrids namely Hishell & 900M Gold containing Event MON NK603 at **six locations** during **kharif 2011**, Coimbatore (Tamil Nadu); Jabalpur (Madhya Pradesh); Ludhiana (Punjab); Sonapat (Haryana); Aurangabad (Maharashtra) and; Dharwad (Karnataka) and **5 locations** during **Rabi 2011**, Coimbatore(Tamil Nadu); Dharwad, (Karnataka); Jabalpur (Madhya Pradesh); Varanasi (Uttar Pradesh) and Aurangabad, Maharashtra.

5.14.2 The Committee noted that the Transgenic hybrid corn NK 603 was developed for preventing yield losses of corn crop to weeds and thereby improve productivity. Herbicide tolerant trait (NK603) with post emergence application of Roundup Ready Cropshield Herbicide (MON 76366) provides effective weed management system to farmer. The plant becomes tolerant to the herbicide while all other weed flora suppressed after implication of herbicides. Roundup Ready corn (Event NK603) containing *Agrobacterium* gene CP4 *EPSPS* is one of the earliest events which was granted approval for environmental release in USA (2000) and subsequently is approved for planting in 8 more countries including Canada, South Africa etc. Besides Roundup Ready corn (Event NK603) has also cleared safety assessment to gain food and feed approval in eighteen countries including the European Union. Global status of NK603 is given below.

5.14.3 The Committee also noted that the objective of the trials is to do (i) comparative assessment of soil ecosystem, weediness, morphology & phenotypic characters of transgenic corn and its conventional counterpart hybrids, (ii) to study the weed control efficacy of herbicide tolerant corn hybrids (Event NK603) with application of Roundup formulation (MON 76366) and (iii) to produce sufficient plant material to undertake food and feed safety studies.

5.14.4 It was also noted that the IBSC has recommended the proposal in its 36th meeting held on 4.02.2011, RCGM recommended the proposal in its 100th meeting held on 18.4.2011.

5.14.5 In view of the above stated facts and taking in to consideration the recommendations of the RCGM, the Committee approved the request to conduct BRL-I trials on Maize hybrids namely Hishell & 900M Gold containing Event MON NK603 at three locations during the appropriate seasons in 2011-2013 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted..

5.15 Permission to conduct Biosafety Research Level-1 (BRL-1) second year trials on two transgenic corn hybrids namely 30V92HR and 30B11HR containing *cry1F* & *cp4epsps* genes [stacked events TC1507XNK603 (DAS-01507-1XMON-00603-6)] at eight locations by M/s. Pioneer Overseas Corporation, Hyderabad.

5.15.1 The Committee noted that the GEAC in its meetings held on 10.6.2009 and 12.5.2010 had approved the request for conduct of BRL-I trials on two transgenic corn hybrids namely 30V92HR and 30B11HR containing *cry1F* & *cp4epsps* genes [stacked events TC1507XNK603 (DAS-01507-1XMON-00603-6)] at three State Agricultural Universities (SAUs) namely; University of Agricultural Science (UAS), Dharwad; Maharana Pratap University of Agriculture and Technology, Udaipur and Tamil Nadu Agricultural University (TNAU), Coimbatore.

5.15.2 The Committee also noted that during Kharif, 2009, BRL-1 field trials were conducted with the imported seeds at four locations. The GEAC adopted a policy of not allowing field trials with directly imported seeds. RCGM have not constituted the monitoring teams for these field trials and hence no visit was made. Hence results of these field trials were not submitted. During **Kharif, 2010**, BRL- 1 field trials were conducted at three locations with indigenously developed seeds. The monitoring team visited the field trials and results were presented to RCGM. During **Rabi, 2010-2011**, BRL-1 field trials were conducted at two locations with indigenously developed seeds. The trials were concluded by June. Monitoring reports are being prepared.

5.15.3 The Committee also noted that the applicant has submitted No Objection Certificate from M/s. Monsanto Company to refer to the regulatory data concerning herbicide tolerant corn NK603, property of Monsanto Company.

5.15.4 It was also noted by the Committee that the event TC1507 consists of *cry1F* & *PAT* genes. *PAT* gene is an integral part of the transformation cassette and is used as a selectable marker in the process of generating & selecting events.

5.15.5 The Committee considered the present request of the Company to conduct BRL-1 second year trials on two transgenic corn hybrids namely 30V92HR and 30B11HR containing *cry1F* & *cp4epsps* genes [stacked events TC1507XNK603 (DAS-01507-1XMON-00603-6)] during Kharif 2011 at eight locations i.e. Banaras Hindu University (BHU), Varanasi; University of Agricultural Sciences (UAS), Dharwad; Acharya N.G. Ranga Agricultural University (ANGRAU), Hyderabad; Maharana Pratap University of Agriculture & Technology (MPUAT), Udaipur; Punjab Agricultural University (PAU), Ludhiana; CCS Haryana Agricultural University (CCSHAU), Hissar; Tamil Nadu Agricultural University (TNAU), Coimbatore and Anand Agricultural University (AAU), Anand.

5.15.6 The Committee noted the following objectives of the trial:

- i) To study the efficacy of transgenic corn hybrids expressing TC1507xNK603 events (stacked events) against target *lepidopteran* insect pest (*Chilo partellus* and *Sesamia inferens*) and other secondary pest infestation in comparison to non transgenic hybrids (conventional counterparts and checks).
- ii) To study the weed control efficacy and crop tolerance with Glyphosate tolerant trait (NK603) following post emergence application of K salt of Glyphosate.
- iii) To monitor occurrence of beneficial and non-target insects on transgenic corn hybrids and their non-transgenic counterparts and checks.
- iv) To study the level of expression of candidate proteins expressed by the inserted genes in plant tissues at regular intervals during the growing season/trial period at selected locations.
- v) To generate baseline susceptibility data on *Chilo partellus* and *Sesamia inferens* collected from various trial locations to Cry1F protein.
- vi) To record data on agronomic parameters of transgenic corn, their non-transgenic counterparts and checks.
- vii) To produce sufficient plant material to undertake biosafety research and to generate data on feed and food safety.

5.15.7 The Committee further noted that the IBSC in its 21st meeting held on 1.4.2011 had approved the conduct of third season BRL-1 trials on the transgenic corn hybrids. The proposal was recommended by the RCGM in its 10^{1st} meeting held on 15.5.2011.

5.15.8 In view of the above stated facts and taking in to consideration the recommendations of the RCGM, the Committee approved the request to conduct Biosafety Research Level-1 (BRL-1) second year trials on two transgenic corn hybrids namely 30V92HR and 30B11HR containing *cry1F* & *cp4epsps* genes [stacked events TC1507XNK603 (DAS-01507-1XMON-00603-6)] at three locations during the appropriate seasons in 2011-2013 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.16 Permission to conduct event selection trials on two transgenic rice lines (*Oryza sativa* cv. *Taipae* 309) namely Godawari 8 & Salween-2 over expressing chloroplast targeted manganese superoxide dismutase (MnSOD) by M/s Atash Seeds Pvt. Ltd, Hyderabad .

5.16.1 The Committee considered the request of M/s. Atash Seeds Pvt. Ltd, Hyderabad to conduct event selection trials on two transgenic rice lines (*Oryza sativa* cv. *Taipae* 309) namely Godawari 8 & Salween-2 over expressing chloroplast targeted manganese superoxide dismutase (MnSOD) for their tolerance to drought and other agronomic characters in a small scale contained (strip trials). Evaluated lines displaying drought tolerance phenotypes will be further used purely as parents in breeding programs. The location code of the trial is AGT-AXD (Avesthagen-Alexandria) at SP Park, Alexandria, Hyderabad. Land is owned by Avesthagen Ltd.

5.16.2 The Committee noted that M/s. Avesthagen has out sourced the work of conducting strip trials of MnSOD transgenic rice to M/s Atash Seeds Pvt. Ltd, Bangalore. Project Transfer letter from Avesthagen is provided by the applicant. It may also be noted that the GEAC in its 88th meeting held on 13.08.2008 had accorded approval to M/s Avesthagen Ltd, Bangalore for conducting strip trials on transgenic rice (*Oryza sativa* cv. *Taipae* 309) plants tolerant to oxidative stress by over expressing superoxide dismutase.

5.16.3 The Committee noted that the objective of the trials is (i) to test two transgenic rice lines (Salween 2 and Godawari 8) overexpressing chloroplast targeted Manganese Superoxide Dismutase (*MnSOD*) for their tolerance to drought and other agronomic characters in a small scale contained (strip) trial, (ii) to check the metabolic fate of the recombinant protein in humans by carrying out pepsin digestibility assay in *vitro* and (iii) to assess the potential toxicity of foods derived from recombinant DNA plants for the protein expression product (s) of the inserted gene (s).

5.16.4 After detailed deliberation, it was decided to obtain information pertaining to (i) the background genotype in which the transgene was developed, (ii) origin and source of the gene.

5.16.5 Decision on the proposal was therefore deferred.

5.17 Permission to conduct event selection trials on transgenic tomato (*Lycopersicon esculentum* L.) resistant to Tomato leaf Curl Virus (TLCV) namely; Arka Meghali: AM-184-1, AM184-4, AM-184-6, AM188-26, AM184-31, AM171-2, AM171-9, AM171-11, AM171-12, AM171-16, AM171-17, AM190-11, AM-190-12, AM-190-14; Arka Saurabh: AS194-5, AS194-10, AS194-11, AS194-13, AS194-16; Pusa Ruby: PR148-37, PR148-49, PR149-23, PR149-31, PR200-9, PR208-27 by Indian Institute of Horticultural Research (IIHR), Bangalore

5.17.1 The Committee noted that the GEAC in its meeting held on 12.5.2010 had approved the request of IIHR, Bangalore to conduct event selection on transgenic tomato (*Lycopersicon esculentum* L.) resistant to Tomato leaf Curl Virus (TLCV).

5.17.2 The Committee also considered the information submitted by the Institute, that the trials of transgenic tomato for resistance to TLCV could not be conducted last year as the permission was received after the season was over and the leaf curl disease occurs in the month of May, June and July in Bangalore.

5.17.3 The Committee also noted that the Transgenic tomato (in T2 to T4) which have been earlier evaluated for resistance to TLCV and PBNV under artificial inoculation and in transgenic poly-house) is proposed to be evaluated for disease resistance, yield and quality under natural conditions. The trials are to be conducted at Hessaraghatta, within the Research Farm of IIHR. Bangalore

5.17.4 The Committee considered the present request of the Institute to conduct event selection trials on transgenic tomato (*Lycopersicon esculentum L.*) resistant to Tomato leaf Curl Virus (TLCV) namely;

Arka Meghali: AM-184-1, **AM184-4**, AM-184-6, AM188-26, AM184-31, AM171-2, AM171-9, AM171-11, AM171-12, AM171-16, AM171-17, AM190-11, AM-190-12, AM-190-14;

Arka Saurabh: AS194-5, **AS194-10**, AS194-11, AS194-13, AS194-16;

Pusa Ruby: PR148-37, PR148-49, PR149-23, PR149-31, PR200-9, PR208-27

Transgenic tomato (in T3 to T5) which has been earlier evaluated for resistance to TLCV and PBNV under artificial inoculation and in transgenic poly-house is proposed to be evaluated for disease resistance, yield and quality under natural conditions. The trials are to be conducted at Hessaraghatta, within the Research Farm of IIHR. Bangalore.

5.17.5 The Committee also noted that the RCGM recommended the proposal in its 101st meeting held on 15.5.2011.

5.17.6 In view of the above stated facts and taking in to consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials on transgenic tomato (*Lycopersicon esculentum L.*) resistant to Tomato leaf Curl Virus (TLCV) namely; Arka Meghali: Arka Saurabh: Pusa Ruby during the appropriate seasons in 2011-2012 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.18 Permission to conduct event selection trials on transgenic watermelon (*Citrullus lanatus (Thunb.) Matsum. & Nakai*) resistant to Watermelon Bud Necrosis Virus (WBNV) namely; AMa112a-1, AMa412-20, AMa432-6, AMa173-5, AMa545-1, AMa546-216, AMa547-230 and AMa548-10 by Indian Institute of Horticultural Research (IIHR), Bangalore.

5.18.1 The Committee noted that the GEAC in its meeting held on 12.5.2010 had approved the request of IIHR Bangalore to conduct event selection trials on transgenic watermelon (*Citrullus lanatus (Thunb.) Matsum. & Nakai*) resistant to Watermelon Bud Necrosis Virus (WBNV). The events proposed to be evaluated are AMa112a-1, AMa412-20, AMa432-6,

AMa173-5, AMa545-1, AMa546-216, AMa547-230 and AMa548-10 . Transgenic watermelon in T2 to T4 is proposed to be evaluated for disease resistance, yield and quality under natural conditions.

5.18.2 The Committee also considered the information submitted by the applicant that trials with respect to transgenic watermelon for resistance to WBNV could not be conducted last year since the permit letter mentioned an isolation distance of 1 km and the institute seed production block was close to the trial site. This year the seed production has been moved to a site beyond 1Km and therefore the trial can be conducted in the designated site. The present request is for permission to conduct event selection trials on transgenic watermelon this year at Hessaraghatta, within the Research Farm of IIHR, Bangalore

5.18.3 The Committee noted that the RCGM recommended the proposal in its 101st meeting held on 15.5.2011. RCGM also advised to submit a copy of duly signed copy of IBSC meeting before issuing the permit letter

5.18.4 In view of the above stated facts and taking in to consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials on transgenic watermelon (*Citrullus lanatus* (Thunb.) Matsum. & Nakai) resistant to Watermelon Bud Necrosis Virus (WBNV) during the appropriate seasons in 2011-2012 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.19 Permission to conduct event selection trials of transgenic tomato (*Lycopersicon esculentum* L.) combined resistant to Tomato leaf Curl Virus (TLCV) and Tospo (Peanut Bud Necrosis Virus: PBNV :PBNV) namely; Arka meghali: ANMi, ANM2, ANM3; Arka Vikas: Av 225-7, ANV-9, ANV-1; Pusa Ruby: PR130-13, PR 130-12; Arka Saurabh: AS231-7 by Indian Institute of Horticultural Research (IIHR), Bangalore.

5.19.1 The Committee noted that the GEAC in its meeting held on 12.5.2010 had approved to conduct event selection on transgenic tomato (*Lycopersicon esculentum* L.) combined resistant to Tomato leaf Curl Virus (TLCV) and Tospo (Peanut Bud Necrosis Virus: PBNV :PBNV). The events proposed to be evaluated are ANMi, ANM2, ANM3, Av 225-7, ANV-9, ANV-1, PR130-13, PR 130-12, and AS231-7. Transgenic tomato in T2 to T4 which have been earlier evaluated for resistance to TLCV and PBNV under artificial inoculation and in transgenic poly-house is proposed to be evaluated for disease resistance, yield and quality under natural conditions.

5.19.2 The Committee considered the information submitted by the applicant that the trials with respect to transgenic tomato for combined resistance to PBNV and TLCV were conducted; however there was no natural incidence of the disease in the field due to continuous rains during the trial period and due to the natural vector population of thrips not occurring till late in the season. Though inoculation was done artificially, it does not give a true picture and therefore the trial needs to be repeated this year.

5.19.3 The Committee also considered the fresh request to conduct event selection trials on transgenic tomato (*Lycopersicon esculentum* L.) combined resistant to Tomato leaf Curl

Virus (TLCV) and Tospo (Peanut Bud Necrosis Virus: PBNV :PBNV) namely; Arka meghali: ANMi, ANM2, ANM3; Arka Vikas: Av 225-7, ANV-9, ANV-1; Pusa Ruby: PR130-13, PR 130-12; Arka Saurabh: AS231-7 at IIHR, Bangalore.

5.19.4 In view of the above stated facts and taking in to consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials of transgenic tomato (*Lycopersicon esculentum L.*) combined resistant to Tomato leaf Curl Virus (TLCV) and Tospo (Peanut Bud Necrosis Virus: PBNV :PBNV) namely; Arka meghali: Pusa Ruby;; Arka Saurabh: during the appropriate seasons in 2011-2012 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.20 Permission to conduct event selection trials on transgenic Papaya (*Carica papaya*) resistant to PRSV namely; TSolo4R, TSolo4Y, TSolo7-1and TSolo7-3 containing *PRSV cp*-gene by Indian Institute of Horticultural Research (IIHR), Bangalore.

5.20.1 The committee noted that the GEAC in its meeting held on 12.5.2010 had approved conduct event selection trials of transgenic Papaya (*Carica papaya*) resistant to PRSV. The events proposed to be evaluated are namely, TSolo4R, TSolo4Y, TSolo7-1and TSolo7-3 containing *PRSV cp*-gene at IIHR. Bangalore. Transgenic papaya in T1 will be evaluated for disease resistance and yield.

5.20.2 The Committee also considered the information submitted by the applicant that the trial on transgenic papaya for resistance to PRSV could not be conducted last year due to following three reasons:

1. due to the requirement of 1 km isolation distance as laid down in the permit letter was difficult to adhere to because of a papaya crop cultivation close by ;
2. the area identified for conducting confined trials was inadequate for growing 5 rows of non-transgenic papaya all around the different events, and finally;
3. the duration of papaya crop from seed to seed is at least 18 months and therefore permit for only one year at a time makes it difficult to comply with. RCGM has been requested to give a permit for 2 years for papaya crop.

5.20.3 The committee considered the request of the applicant to revalidate the GEAC approval to conduct event selection trials at Hessaraghatta, within the Research Farm of IIHR. Bangalore

5.20.4 The Committee also noted that the RCGM recommended the proposal in its meeting held on 15.5.2011 to evaluate transgenic papaya in T1 for disease resistance and yield.

5.20.5 In view of the above stated facts and taking in to consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials on transgenic Papaya (*Carica papaya*) resistant to PRSV namely; TSolo4R, TSolo4Y, TSolo7-1and TSolo7-3 containing *PRSV cp*-gene during the appropriate seasons in 2011-2013

subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.21 Permission to repeat event selection trials of transgenic tomato (*Lycopersicon esculentum L.*) resistant to Tospo virus (Peanut Bud Necrosis Virus: PBNV). namely; PR 38-7, PR42-1, PR55-5; Arka Saurabh:AS78-7, AS194-11; Arka Vikas: AV60-2, AV1-5, AVNv4A, AVNv4B; Arka Meghali: AM97-9, AM95-16, AM93-5, AM190-8 and AM190 by Indian Institute of Horticultural Research (IIHR), Bangalore.

5.21.1 The Committee noted that the GEAC in its meeting held on 12.5.2010 had approved to conduct event selection trials on transgenic tomato (*Lycopersicon esculentum L.*) resistant to Tospo virus (Peanut Bud Necrosis Virus: PBNV). Transgenic tomato in T2 to T4 which have been earlier evaluated for resistance to PBNV under artificial inoculation in transgenic polyhouse will be evaluated for disease resistance, yield and quality under natural conditions.

5.21.2 The Committee also considered the information submitted by the applicant that the trial of transgenic tomato for resistance to PBNV was conducted; however there was no natural incidence of the disease in the field due to continuous rains during the trial period and due to the natural vector population of thrips not occurring till late in the season. Though inoculation was done artificially, it does not give a true picture and therefore the trial needs to be repeated this year.

5.21.3 The Committee considered the request of the Institute to repeat the event selection trials on transgenic tomato (*Lycopersicon esculentum L.*) resistant to Tospo virus (Peanut Bud Necrosis Virus: PBNV). namely; PR 38-7, PR42-1, PR55-5; Arka Saurabh:AS78-7, AS194-11; Arka Vikas: AV60-2, AV1-5, AVNv4A, AVNv4B; Arka Meghali: AM97-9, AM95-16, AM93-5, AM190-8 and AM190-11 at IIHR, Bangalore.

5.21.4 The Committee further noted that the RCGM recommended the proposal in its meeting held on 15.5.2011.

5.21.5 In view of the above stated facts and taking in to consideration the recommendations of the RCGM, the Committee approved the request to repeat event selection trials of transgenic tomato (*Lycopersicon esculentum L.*) resistant to Tospo virus (Peanut Bud Necrosis Virus: PBNV) during the appropriate seasons in 2011-2012 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.22. Permission to conduct Biosafety Research Level-II (BRL-II) trials on WideStrike™ cotton hybrids namely WS103 & WS106 containing *cry1F* (Event 281-24-236+ *cry1Ac* (Event 3006-210-23) in Central zone at eight locations by M/s. Dow Agrosciences India Pvt. Ltd., Mumbai

5.22.1 The Committee considered the request of M/s. Dow Agrosciences India Pvt. Ltd., to conduct BRL-II with WideStrike™ cotton hybrids namely WS103 & WS106 containing *cry1F* (Event 281-24-236) + *cry1Ac* (Event 3006-210-23) in the Central zone. The trials will be conducted at the following locations:

1. Aurangabad (Maharashtra),
2. Phulambri (Aurangabad, Maharashtra),
3. Jalna-1 (Maharashtra),
4. Jalna-2 (Maharashtra),
5. Pachora (Jalgaon, Maharashtra),
6. Budgaon (Jalgaon, Maharashtra),
7. Padra (Vadodara, Gujarat),
8. Baroda (Vadodara, Gujarat).

5.22.2 The main objectives of BRL-II trials is to:

- study the bio-efficacy of WideStrike trait on target lepidopteron pests and their impact on productivity in comparisons to non-transgenic hybrids and checks.
- establish biosafety of WideStrike trait for non-target organisms like beneficial insects, soil micro-flora etc.
- generate data on protein expression levels in different plants parts at different crop stage from 60-160 days after sowing.
- assess the yield performance of WideStrike hybrids in comparison to non-transgenic counterparts and checks
- estimate the economic benefits associated with cultivation of WS hybrids in comparison to non-transgenic counterparts and checks.

5.22.3 The Member Secretary informed that the GEAC in its meetings held on 10.6.2009 and 9.6.2010 had approved the conduct of BRL-I with two Bt cotton hybrids expressing *cry1F* (Event 281-24-236) + *cry1Ac* (Event 3006-210-23) at two locations i.e. Aurangabad (Maharashtra), Vadodara (Gujarat) in the central zone for generating bio safety data.

5.22.4 The Committee also noted the following documents have been submitted by the company:

a) Food, Feed Biosafety studies:

- Acute oral toxicity study in CD-1 mice.
- Protein Thermal Stability of Cry1F (synpro) and Cry1Ac (synpro).
- Pepsin Digestibility study of microbially- derived Cry1Ac (synpro) and Cry1F (synpro).
- Allergenicity Assessment of WideStrike proteins by sequence homology search.
- Compositional Equivalence of WideStrike in USA.
- Compositional Equivalence of WideStrike with *indigenously* grown cotton seeds in 2008 & 2009.
- Evaluation of the safety and nutritional equivalence of a genetically modified cotton seed meal in a 90-day dietary toxicity study in rats. (*published paper*)
- Nutritional Equivalence Study of Cry1F/Cry1Ac cotton seed meal: Poultry feeding study

- Safety of WideStrike transgenic cotton seeds in goats in India (2009-10).

b) Environmental Biosafety:

- Studies on micro-flora, earthworm and estimation of Cry1F and Cry1Ac protein concentration in soil from BRL-1 trials of Widestrike hybrids during Kharif 2009 and 2010. Conducted in (i) Institute of Microbial Technology, Chandigarh.(ii) SGS India Pvt Ltd, Ahmedabad.
- Study of pollen flow from WideStrike cotton in kharif .
- Studies on germination, aggressiveness and weediness of WS hybrid conducted during Kharif 2009 and 2010.

c) Biosafety Research Trials and Associated studies :

- Biosafety Research Level-1 (BRL-1) trials in Central Zone conducted during Kharif 2009 and 2010.
- Generation of baseline susceptibility data with detectable proteins on target pests.
- Bio-efficacy experiments with WideStrike hybrids.
- Quantification of Cry1F and Cry1Ac protein expression by WS hybrids in 2009 and 2010 by Enzene BioSciences, Pvt. Ltd., Bangalore.
- DNA fingerprinting of WS cotton hybrids conducted at NBPGR, Pusa Campus, N. Delhi.

5.22.5 The Member Secretary informed that the two seasons BRL-I trials conducted by the applicant in 2009 and 2010 were monitored by the monitoring teams constituted by RCGM.

5.22.6 The Committee noted that M/s. Dow Agrosiences India Pvt. Ltd., Mumbai made a detailed presentation to the RCGM in its 101st meeting held on 15.5.2011 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.

5.22.7 The Member Secretary informed that in the 108th meeting of GEAC it was decided that BRL-II trials will be conducted for a minimum of one year during major crop growing seasons at a minimum of eight locations. Additional trials will be called for depending on the agro-climatic zones to an area of 2.5.acres per trial site.

5.22.8 After detailed deliberations, the Committee approved the request to conduct Biosafety Research Level-II (BRL-II) trials on WideStrikeTM cotton hybrids namely WS103 & WS106 containing *cry1F* (Event 281-24-236+ *cry1Ac* (Event 3006-210-23) in Central zone at eight locations during the appropriate seasons in 2011-2012 subject to submission of NOC from the respective State Department of Agriculture.

5.23 Permission to conduct Biosafety Research Level I (BRL-I) second year trials and seed production with transgenic maize hybrids (TC1 and TC3) containing event

TC1507 (DAS-01507-1) at 11 locations to test hybrids containing TC1507 expressing Cry1F for biosafety, bioefficacy and agronomy evaluation by M/s. Dow AgroSciences India Pvt. Ltd., Mumbai.

5.23.1 The Committee noted that the GEAC in its meeting held on 10.6.2009 had approved to conduct BRL-I trials with transgenic maize (*Zea mays*) hybrids namely TC-1 and TC-2 containing *cry1F* gene (Event TC1507 (DAS-01507-1)). Further in its meeting held on 9.6.2010, the GEAC also approved BRL-I trials with transgenic maize (*Zea mays*) hybrids namely TC-1 and TC-3 containing *cry1F* gene (Event TC1507 (DAS-01507-1)) at Coimbatore and Bhavani Sagar in TNAU; and Balajigapade and Kathalgere in UAS, Bangalore during Kharif 2010 for biosafety, bio-efficacy and agronomy evaluation. The company also requested for seed production of TC1 maize hybrid in 0.25 acre at Bangalore during Kharif -2011-to generate the following data :

1. Efficacy of the *cry1F* gene (event TC 1507) in terms of the level of infestation of the target lepidopteran insect pests i.e. stem borers (*Chilo partellus* and *Sesamia inferens*) and cob borer (*Helicoverpa armigera*) and other secondary pests on transgenic corn hybrids corresponding to their conventional (non-transgenic) counterparts and checks.
2. Comparative assessment of soil ecosystem/rhizosphere indicators, effect on germination, aggressiveness, weediness, morphology and phenotypic characters of transgenic corn and its conventional counterpart hybrids.
3. Monitoring the occurrence of beneficial and non-target insects on transgenic as well as non-transgenic corn hybrids.
4. To produce sufficient plant material to undertake biosafety research and to generate data on feed and food safety.
5. To study the level of expression of candidate proteins expressed by the inserted genes i.e. *cry1F* in different plant parts at regular intervals during the growing season/trial period.
6. Generation of baseline susceptibility data of candidate protein on representative insect pest population of key target lepidopteron pests i.e. *Chilo partellus* and *Sesamia inferens* and *Helicoverpa armigera* insect pests collected from various locations including the field trial sites during the growing season/trial period by rearing them in the bioassay laboratory.
7. In case of non-occurrence of the target insect pests during the crop growth period, efficacy study of the gene/event at the field level to be conducted by artificial infestation of key target pests.
8. Generation of DNA fingerprinting data of each genotype/hybrid.

5.23.2 The Committee considered the information submitted by the applicant i that during Kharif, 2009, BRL-1 field trials were conducted with the imported seeds at three locations. The GEAC adopted a policy of not allowing field trials with directly imported seeds. Hence results of these field trials were not submitted. During **Kharif, 2010**, BRL- 1 (**first season**) field trials were conducted at two locations with indigenously developed seeds. The monitoring teams visited the field trials and results were presented to RCGM.

5.23.3 The Committee also considered the present request to conduct BRL-I trial second year trials during Kharif 2011 on two transgenic corn hybrids namely TC-1 and TC-3

containing TC1507 (DAS-01507-1] expressing Cry IF protein for biosafety, bio-efficacy and agronomy evaluation at 10 locations namely :

- **TNAU, Coimbatore**
- **ARS Bhavanisagar , T.N.**
- **UAS, Bangalore**
- **UAS, Dharwad ;**
- ANGRAU, Hyderabad ;
- MPUAT, Udaipur ,
- AAU, Anand ;
- GBPUAT, Pant Nagar ,
- PAU, Ludhiana and
- HAU, Hisar to test hybrids containing TC1507 expressing Cry1F for biosafety, bioefficacy and agronomy evaluation during Kharif 2011.

5.23.4 The Committee noted the objectives of trial are (i) to study the impact of TC1507 transgenic maize hybrids against target *lepidopteran* pests, secondary pests and non-target insect species, (ii) comparative assessment of soil ecosystem & weediness, morphology & phenotypic characters of transgenic corn and its non-transgenic counterpart hybrids and (iii) undertake gene expression studies of transgenic event TC1507 at different crop growth stages.

5.23.5 The Committee noted that the applicant has submitted No Objection Certificate from M/s. Monsanto Company to refer to the regulatory data concerning herbicide tolerant corn NK603, property of Monsanto Company.

5.23.6 The Committee further noted that the IBSC in its meeting held on 5.4.2011 had approved the conduct of second season BRL-1 trials on the transgenic corn hybrids. The proposal was recommended by the RCGM in its 101st meeting held on 15.5.2011.

5.23.7 It may be noted that the present request is for conducting BRL-I at ten locations during Kharif 2011. However, the GEAC/ RCGM has taken a policy decision to recommend only 2-3 hybrids at 2-3 locations during BRL-I trials.

5.23.8 In view of the above stated facts and taking in to consideration the recommendations of the RCGM, the Committee approved the request to conduct Biosafety Research Level I (BRL-I) second year trials and seed production with transgenic maize hybrids (TC1 and TC3) containing event TC1507 (DAS-01507-1) at **three** locations to test hybrids containing TC1507 expressing Cry1F for biosafety, bioefficacy and agronomy evaluation during the appropriate seasons in 2011-2012 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.24 Permission to conduct event selection trials on 12 Bt cotton hybrids of Cry1C Event MLS9124 and GFM Cry1A events at three locations by M/s. Metahelix Life Sciences Ltd., Bangalore.

5.24.1 The Committee considered the request of M/s. Metahelix Life Sciences Ltd., Bangalore to conduct event selection trials of 12 Bt cotton hybrids combinations containing both events Event MLS9124 and GFM Cry1A events during Kharif-2011, at three locations viz. Aurangabad, Hyderabad and Attur to compare the performance of selected up to 12 Bt cotton hybrids carrying a breeding stack of Cry1C Event MLS9124 and GFM Cry1A Event for the biosafety of the breeding stack against boll worm complex.

5.24.2 The Committee noted that the both the events have been tested in the country as per the prevailing regulatory process and have been independently approved for commercial cultivation.

5.24.3 The Committee noted the objectives of the trials: (i) to assess the field efficacy of the two genes stacked Bt cotton hybrids against all the lepidopteran pests of cotton and (ii) to assess the productivity attributes of the hybrids in order to chose the best hybrid combination.

5.24.4 The Committee noted that the IBSC in its meeting held on 18.3.2011 had approved the proposal. RCGM recommended the request for event selection trials in its 101st meeting held on 15.5.2011.

5.24.5 The Committee also noted that as both the events have been approved for commercial cultivation, the applicant has sought advice from RCGM/GEAC on the safety studies to be conducted and the proposed next steps for commercialization. The matter was considered by the RCGM in its meeting held on 15.5.2011 wherein *it was decided to review the approach being adopted by other countries for safety assessment in such cases before a final view is taken on the matter.*

5.24.6 In view of the above stated facts and taking in to consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials on 12 Bt cotton hybrids of Cry1C Event MLS9124 and GFM Cry1A events at three locations during the appropriate seasons in 2011-2012 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.25 Permission to conduct seed production of WideStrike cotton hybrids namely; WS 103 and WS 106 expressing cry 1F and cry 1Ac proteins (WideStrike TM=cry 1F event 281-24-236+cry1Ac event 3006-210-23) in South zone by M/s. Dow AgroSciences India Pvt. Ltd., Mumbai.

5.25.1 The Committee considered the request of the company for seed production of WideStrike hybrids WS103 and, WS-106, in total area of 60 acres (30 acres /hybrids acres) at one location in Attur, Tamil Nadu, during Kharif 2011.

5.25.2 The Committee opined that the request for seed production in an area of 60 acres is very large and therefore the applicant needs to justify the basis on which the request has been made, including the total seed production so far and its utilization.

5.25.3 Decision on the request was therefore deferred.

Agenda Item No 6 : Consideration of applications related to Pharmaceuticals

6.1 Permission to manufacture indigenously developed recombinant Hepatitis B Viral Antigen for Diagnostic Kit Development by M/s Sudershan Biotech Ltd, Hyderabad

6.1.1 The Committee considered the request of M/s Sudershan Biotech Ltd, Hyderabad to manufacture indigenously developed recombinant Hepatitis B Viral Antigen for Diagnostic Kit Development. Hepatitis B virus (HBV) caused both acute and chronic infection in humans. Those infected with HBV are prone to the development of liver cirrhosis and liver cancer. A protein on the surface of the virus, called surface antigen, is used as vaccine. It is also used as an antigen for the diagnosis of HBV. The Company has cloned this antigen in the *27ichia pastoris* vector, pHIL-D2 and purified. The Company is planning to use the diagnostic kit for detecting acute infection. Chronic infections can be detected by raising antibody to this protein and making a detection kit using this antibody. The Committee noted that the *Pichia Pastoris* cells are classified under Risk Group II.

6.1.2 In view of the above stated facts and taking in to consideration the recommendations of the RCGM/DBT, the Committee approved the request to manufacture indigenously developed recombinant Hepatitis B Viral Antigen for Diagnostic Kit Development by M/s Sudershan Biotech Ltd.

6.2 Permission to conduct research trials with Somatotropin (r-bST) in bovines in India by Elanco, Animal Health (Division of Eli Lilly Asia Inc.) Bangalore.

6.2.1 The Committee noted that Ministry of Agriculture (Department of Animal Husbandry Dairying) has requested the GEAC to provide comments on the proposal received from M/s Elanco Animal Health, Eli Lilly & Co., Bangalore to conduct research trials with recombinant Bovine Somatotropin (r-BST) in dairy animals in India at four National Research Institutes namely IVRI, Izatnagar, NDRI, Karnal, CIRB, Hissar, GADVASU, Ludhiana and one private dairy farm at Chitale Dairy Pvt Ltd, Bhilawadi

6.2.2 After detailed deliberation, it was decided to await comments of experts before a final decision is taken on the matter. Decision on the proposal was therefore deferred.

Agenda Item No 7 : Other items

7.1 Appeal from M/s Mahyco against GEAC decision dated 9.3.2011 regarding the use of non-Bt RRF Cotton Hybrids containing cp4epsps gene (event Mon 88913) as Refugia during BRL-II trials.

7.1.1 The Committee noted that a 'Show Cause' notice was issued to M/s Mahyco on February, 7, 2011 for conducting BRL-II trials with BG-II RRF cotton by using non-Bt RR-Flex-Cotton, containing *cp4epsps* gene (event MON 88913) as refugia without obtaining the prior statutory approval under the provisions of Rules 1989.

7.1.2 The Committee also noted that response to the show cause notice was considered and discussed at length by the GEAC in its meeting held on 9.3.2011. The GEAC was of the opinion that clarifications submitted by the applicant are highly unsatisfactory as they do not justify the planting of non Bt RRF cotton hybrids (Event MON 88913); an event that has not been approved for environmental release without the prior approval of the GEAC. The Committee also noted that the trials were conducted with the protocols approved by Director, CICR.

7.1.3 It was also noted that the GEAC had issued a warning letter to M/s. Mahyco on May 2, 2011 stating that (i) any non compliance in future would attract punitive actions under EPA 1986; (ii) to adopt a resolution through the Mahyco Board of Directors expressing regret and reaffirming that such lapses will not be repeated. The resolution so taken shall be put on the website. (iii) data generated during BRL-II trials using non-Bt RRF flex as refuge shall not be considered for regulatory purpose.

7.1.4 The Committee considered the appeal submitted by the applicant and clarifications submitted by Director, CICR and gave an opportunity to present their views before the GEAC.

7.1.5 The representatives of M/s Mahyco informed:

- i. There is no violation of the EP Act and rules framed thereunder as the BRL-II trials were conducted as per the protocol approved by Director, CICR as per GEAC direction.
- ii. The trials were conducted in full conformity with the prescribed guidelines and under the supervision of Director, CICR.
- iii. The planting of non-Bt RRF merits technical consideration as the essence of the planting of non-transgenic insect resistant crop is purely to delay resistance development in the target insect population and thereby making the technology sustainable. As Bollgard II RRF requires to be sprayed with herbicide, which in all probabilities may damage the refugia plants. Therefore to achieve a luxuriant growth of Non-Bt refugia for BGIIRRF cotton can only be achieved by planting non-Bt RRF as refugia.
- iv. M/s Mahyco has been conducting GM crop field trials since 1994 and till date they have not violated any norms.
- v. Mahyco is also willing to express regret and reaffirm that there shall be no lapses under the EPA/Rules framed thereunder.

In light of the above stated facts, M/s Mahyco requested GEAC to reconsider its earlier decision and accept the data generated during BRL-II trials in Kharif 2010.

7.1.6 Director, CICR in his clarification stated:

- i. The BRL-II trials were basically meant to evaluate RRFlex (Roundup Ready Flex), which is a GM cotton event with cp4 epsps gene that makes cotton plants resistant to the herbicide glyphosate. Mahyco has applied for the RRFlex trials in combination with BG-II hybrids referred as BG-II RRFlex (Bollgard-II Roundup Ready Flex). BG-II RRFlex can resist bollworms and glyphosate. BG-II contains Cry1Ac+Cry2Ab as two

separate Bt gene events that were approved by the GEAC as MON531 (Cry1Ac) in 2002 and as MON15985 (Cry2Ab) in 2005. Thus the BRL-II trails are meant to seek the final approval of the GEAC for commercial cultivation of RRFlex.

- ii. The non-Bt RRFlex (Mon 88913 containing the gene cp4epsps) was used as border rows for BG-IIRRFlex (Mon 15985 x Mon 88913) plots, as part of experimental protocols and not for commercial cultivation, as it appears from the letter. Isolation distance and all other bio-safety procedures including incineration were followed for the non-Bt RRFlex exactly in the same manner as was followed for BG-II RRFlex. The Mon 88913 is part of BG-II RRflex (Mon15985 x Mon 88913) and was used in the same experimental trials as part of GEAC approved BRL-II protocols. Statutory approval for BG-II RRFlex (Mon15985 x Mon 88913) has not yet been granted much the same way as was the case with Mon 88913 all of which were being tested under BRL-II trials in the same plot. Therefore it is not clear as to how this can be construed as violation of section 7(i) and section 9 of the EPA 1986.
- iii. Refugia is one of the essential components of 'Insect Resistance Management' for BG-II. BG-II-RR-Flex will also require a refugia patch of at least 5% to 10% non-Bt cotton area to harbor Bt-susceptible bollworms. If the Refugia in BG-II-RR-Flex comprises only non-Bt cotton without RR-Flex, there is every likely possibility of the refugia patch getting destroyed due to spray drift or inadvertent application of 'Round-up' on the 'non-RR-Flex-non-Bt-cotton'. Technically, it would be a mistake if only 'non-RR-Flex-non-Bt-cotton' is recommended as Refugia. Therefore I reaffirm that the provision of at least 5% to 10% refugia seed of 'RR-Flex-non-Bt-cotton' hybrid or variety of corresponding maturity and fibre traits must be made mandatory for commercial cultivation.

7.1.7 The Committee deliberated at length the submissions made by M/s Mahyco and Director, CICR. While some of the members were of the view that the procedural lapse may be condoned as it has occurred due to lack of clarity and prescribed guidelines. However, it was agreed that it is the responsibility of the applicant to obtain the statutory clearances. After detailed deliberation, the Committee rejected the appeal. The Committee further opined that the applicant will be required to conduct fresh trials with protocols approved by the GEAC. The requirement of obtaining NOC from the State Government before initiating the BRL-II trials will also be applicable in the instant case.

7.1.8 It was further agreed, in future, the protocols for field trials will be approved by the GEAC. The need to develop guidelines and protocols for stacked events was reiterated by the Committee so as to prevent any procedural lapse in future.

7.2 Request from Department of AYUSH, Ministry of Health and Family Welfare.

7.2.1 The Committee considered the request from Department of AYUSH to co-opt three members of the AYUSH Department to the GEAC. After detailed deliberations, it was agreed that one member nominated by the Department of AYUSH may participate in the GEAC meeting as an observer.

7.3 Resignation of Dr P Anandakumar, as an expert member from the GEAC.

7.3.1 The Committee placed on record the excellent contribution made by Dr P Ananda Kumar, Project Director, NRCPB in his capacity as an expert member of the GEAC and accepted his resignation.

Agenda Item No 8 : Any Other Matter with the Permission of the Chair

8.1 Discussion on issues Related to Conflict of Interest

8.1.1 The GEAC in its 105th GEAC meeting held on 8.12.2010, had adopted the following criteria to address issues related to conflict of interest based on the recommendations of the sub-committee constituted by the GEAC:

- I. A member of the GEAC is either a team leader or member of a team that has developed a transgenic plant which has come up for consideration before the GEAC shall not participate in the discussion regarding such an application.
- II. A member of the GEAC is a consultant for an industry/research foundation that has developed a transgenic plant which has come up for consideration before the GEAC shall not participate in the discussion regarding the said application.
- III. A Member of the GEAC is involved in the development of transgenic plant constituting the same crop/trait of interest that is being considered by the GEAC or is involved in the development of a recombinant vaccine/drug against the same disease. The GEAC member shall not participate in the discussion regarding such an application.
- IV. Further, in all the three situations mentioned above, the GEAC member should not be involved in the conduct or monitoring of field trials/clinical trials with regard to an application being considered by the GEAC.

8.1.2 The Committee noted that the criteria for 'Declaration and Statement of Independence' to be submitted to the GEAC were specific to the involvement of the Member with respect to an application under consideration of the GEAC.

8.1.3 The matter was reconsidered in the GEAC meeting in light of a recent report. The GEAC has now decided that the 'Conflict of Interest' clause would be triggered if the member or his/her spouse or children are involved in terms of the criteria mandated above. As a proactive step to streamline the conflict of interest issue, members were also requested to submit information pertaining to their involvement in GM crop research /consultancy/ advisory services along with the source of funding /sponsorship /voluntary during the last five years before the next GEAC meeting.

8.1.4 It was further decided to constitute a Sub-Committee to suggest further measures for avoiding such situations in future.

8.2 Discussion on issues raised by NGOs in the meeting held on 109th GEAC meeting held on 11.05.2011

8.2.1 The Committee considered the issues raised by five NGOs namely, Centre for Sustainable Agriculture, Greenpeace India, Thanal and Kheti Virasat Mission and Ms Aruna Rodrigues, petitioner in the SC PIL on GMOs who had made a detailed presentation to the GEAC regarding their concerns on GM regulations in the 110th GEAC meeting held on 11.05.2011 and noted that the issues raised are very complex and needs further deliberations and cannot be resolved in one meeting. The Committee also noted that the GEAC has taken several measures to streamline the regulatory process. The following mechanisms put in place will also give due consideration to issues raised by the NGOs:

- 1 Concerns over dilution of GM regulations by Ramanjaneyulu, Centre for Sustainable Agriculture: The representation of the NGO is in response to the suggestions from the Industry Association regarding streamlining of the regulatory process which includes the event based approval mechanism, acceptance of biosafety data from the country of origin, independent testing, pollen flow data etc. The Committee noted that the GEAC has constituted a Sub-Committee to examine the issues. The Sub-Committee meeting is scheduled for 19.7.2011. The Sub-committee while making its recommendations would take into consideration the concerns of the NGOs.
2. Review of Bt Cotton approval based on 10 years experience. The presentation covered violations, inadequacy in the biosafety assessment, absence of IRM strategy, availability of alternate technology, absence of periodic review as required under Rules 1989. While one of the Members pointed out that that there is an urgent need to review the approvals granted to Bt cotton, other Members were of the view that cultivation of Bt cotton has crossed 9.0 million ha and there has been no request from the State Governments to ban Bt cotton in the State. It was decided to consider this issue in one of the subsequent GEAC meeting,
3. Gaps in Risk Assessment identified based on the Bt Brinjal review process and reports received from international experts: This issue is being examined by the GEAC in consultation with experts and others as part of the post moratorium follow-up. Further, in accordance with the Supreme Court order, the Ministry as the lead respondent along with the petitioner in WP (Civil) 260 of 2005 has agreed to the constitution of an Expert Committee to review the adequacy of the GM regulation in India including issues related to risk assessment, GM crop field trials, independent testing etc.
4. Concerns about the current field trial procedures including absence of mechanism to verify and contain the contamination from GM crop field trials. The Committee agreed that this is an area which needs further strengthening and requested the Sub-Committee constituted to recommend measures to streamline the regulatory process to also look into this aspect. It was further opined that with the increased involvement of the State Government, issues related to non-compliance and effective monitoring can be further strengthened.

5. Mechanism for avoiding Conflict of interest. This issue has been addressed by the GEAC in the agenda item No 8.1. Decision taken therein may be referred
6. Absence of State Government involvement in the decision making process. This issue has been addressed by the GEAC in the agenda item No 4.2. Decision taken therein may be referred
7. Violations and Liability would be covered as per provision of E(P)A, 1986, Rules 1989 and NGT

8.2.2 The Chairman reiterated that decisions of the GEAC are based on inputs received from different stakeholders and available scientific facts. He assured that the concerns of the NGOs will be given due consideration while taking a decision along with other available facts as the GEAC has to take a balanced view.

8.3 Storage of Bt brinjal Seeds at NBPGR

8.3.1 The Committee noted that ICAR in accordance with the decision taken in the GEAC meeting has prepared three MOAs on “Non-Commercial Memorandum of Agreement for Storage of Transgenic Bt Brinjal seed Material” wherein ICAR is the first party, MoEF the second party and M/s Mahyco, UAS Dharwad and TNAU Coimbatore would be the third party respectively. Member Secretary GEAC informed that the matter has been placed before the GEAC to address certain unresolved issues in the MOA.

8.3.2 Decision on the matter was deferred due to paucity of time.

8.4 Violations of biosafety norms at GM corn experimental seed production site by Monsanto.

8.4.1 The Committee noted that the GEAC in its 104th meeting held on 15.11.2010 had approved the request for BRL-II trials and experimental seed production in an area of 25 acres per hybrid in confined conditions.

8.4.2 The GEAC considered the representation from some of the interested stakeholder pertaining to non compliance by M/s Monsanto during experimental seed production of GM corn at Bijapur District, Karnataka and decided to ask the State Government to have the site inspected and send a report urgently. It was also agreed that response of the applicant on the matter may be obtained. Further action will be taken on getting the report of the State Government.

8.5 Event selection trials on seven transgenic rice (oryza sativa L) by the Department of Botany, Kolkata University at Rice Research Station, Chinsurah

8.5.1 The above proposal was discussed in light of the recent report published in the TOI (Delhi/Hyderabad) dated 2.7.2011 wherein it has been alleged that the GEAC has relaxed

the isolation distance for GM rice trials by Calcutta University at the behest of a GEAC member. The Committee also took into consideration the following facts of the case:

1. The GEAC in its 104th meeting held on 15.11.2010 had allowed event selection trials on seven transgenic rice (*oryza sativa* L) by the Department of Botany, Calcutta University at Rice Research Station, Chinsurah. Dr Swapan Datta was not present in the GEAC meeting.
2. The proposal was recommended to the GEAC by the RCGM in its 94th meeting held on 26.10.2010 wherein the prescribed isolation distance was only 10 m. Dr. Swapan Datta is not a member of RCGM.
3. During the GEAC deliberation in its meeting held on 15.11.2010, the Committee noted that the proposed isolation measure is not in line with the Indian Minimum Seeds Standard Certification (IMSCS) which prescribes 200 m isolation distance. Accordingly the GEAC approved the proposal subject to compliance of 200 m isolation distance. RCGM was also informed to issue the permit letter accordingly.
4. Subsequently, Dr. Swapan Datta on receiving the minutes of the GEAC which he had not attended, pointed out that the isolation distance *for inbred lines as per guidelines of IMSCS 1988 is 3 m and for hybrid rice it is 200m.*
5. The matter was placed before the GEAC in the 106th GEAC meeting held on 12.1.2011. The Committee noted that as per IMSCS, 1988, for inbred lines the isolation distance is 3 meter and for hybrids it is 200 m. As the trials conducted by the University of Calcutta with inbred lines, it was observed that 10 m isolation distance is adequate. Accordingly, the GEAC conveyed its 'no objection' to maintain 10 m isolation distance during the event selection trials with transgenic rice developed by University of Calcutta.
6. Meanwhile DBT directed Calcutta University to submit 'no objection' from the State Government for the event selection trials. Directorate of Agriculture, Government of West Bengal vide communication No.210-PS dated 24.3.2011 has given their consent with the condition of plastic barrier to be placed around the GM rice field trial site in addition to the 10 m isolation distance. DBT has recently issued the approval letter for event selection trials. However, the trials have not been initiated.

8.5.2 In view of the newspaper report, the GEAC in its meeting held on 6.7.2011, decided to reconsider the issue of approval given to GM rice trials developed by Calcutta University. The above matter was discussed in the absence of the concerned member. The Committee reconsidered the case and reiterated its earlier decision to allow Calcutta University to conduct event selection trial maintaining an isolation distance of 10 m. In light of the fact that the isolation distance under Indian Minimum Seed Certification Standards (notified under Seed Act 1966) is 3 m for inbred rice lines, the Committee was of the view that the 10 m isolation distance stipulated by the GEAC is adequate.

8.5.3 As regards the GEAC flouting the SC direction for maintaining 200 m isolation distance it was noted that the SC order dated 8.5.2007 which stipulates that an isolation

distance of 200 m should be maintained for all GM crop field trials has been waived through an order dated 8.4.2008. As the isolation distance is crop specific, the GEAC had constituted a Sub-Committee to review the SC orders. Based on the recommendations of the Sub-Committee, the Ministry had filed an application for waiver of the condition. The SC in its order dated 8.4.2008 noted that:

“On 8th May, 2007 this Court had directed that when field trials are conducted, there must be 200 meters isolation distance between the trial fields and the neighbouring fields having cultivation of same crop, to avoid contamination. It is submitted on behalf of the applicants in I.A.s 22 and 23 that the distance to be maintained should depend upon the nature of the crop. It is submitted that some crops may require less than 200 meters and some may require more than 200 meters. GEAC will examine this issue and prescribe the isolation distance depending upon the nature of the crop”.

8.5.4 In light of the above, the GEAC has not flouted any of the Supreme Court direction.

Next GEAC Meeting: 10.08.2011
