Decision taken in the 104th meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 15.11.2010.

The 104th meeting of the GEAC was held on 15.11.2010 in the Ministry of Environment and Forests (MoEF) under the chairmanship of Shri M.F. Farooqui, Additional Secretary, MoEF and Chairman, GEAC.

The deliberations and decision taken in the GEAC meeting in respect of Agenda items 4 to 6 are as follows:

Agenda item No. 4 Policy issue

4.1 Discussion on the duration of BRL-I and BRL-II confined field trials and requirement for the generation of data for environmental safety assessment during trials

4.1.1 The Committee noted that in the 101st GEAC meeting held on 9.6.2010, it was decided that BRL-II trials would be conducted for two seasons irrespective of whether BRL-I trials have been done for 1 year or 2 years. Subsequently the GEAC has received request for reconsideration of this decision both from the experts and industry wherein it was decided to bring this issue as a separate agenda item for discussion. The Committee also took into consideration the recommendations of RCGM in the matter. The Chairman GEAC requested the Committee to examine the matter in detail as there will be no going back on the decision once taken.

4.1.2 The Committee discussed at length the basis for BRL-I and BRL-II trials. Members were in agreement that BRL-I trials for two years is necessary to provided sufficient time and material to the applicant for conducting both food safety and environmental safety data. Only after completion of these studies, .BRL-II trials should be permitted.

4.1.3 The Committee deliberated in detail on the scope and objectives of BRL-2 trials. The following points were noted:

i. Both BRL-1 and BRL-2 trials is an experimental activity carried out in confined conditions to collect data on potential impacts of genetically engineered plants on the receiving environment (*i.e.*, the agro-ecosystem). These trials are permitted subsequent to the green house studies in contained conditions.
ii. The objective of BRL-I/II trials is to generate ecological data required for environmental safety assessment, agronomic data to assess the efficacy of the introduced trait in comparison to its non-modified counterpart, protein expression data to assess the stability of the gene, and generation of plant material for generating food/feed safety data.
iii. The basic difference between BRL-1 and BRL-2 trials is in term of scale of operation. BRL-1 trials are conducted in a limited area (1 acre) in two-three locations whereas BRL-II trials are conducted in a larger area (2.5 acres) at multiple locations depending on the agro-climatic zones in which the crop is cultivated.
iv. BRL-1 trials are a pre-requisite to BRL-2 trials as it provides information on the likely potential impacts on the receiving environment, efficacy and stability of the product before it is allowed for release in a larger area. It also allows for mid-course correction in the design of the protocols and tests to be conducted, if required.
v. BRL-2 trials are necessary to confirm the replicability of the safety data generated during BRL-1 trials on a larger scale.
vi. The combined three season's data under normal sowing season is considered adequate to assess the safety, efficacy and stability of the genetically modified plant under regulatory consideration.

4.1.4 In view of the above stated facts, the following decisions were taken:

i. BRL-1 trials will be conducted for a minimum of two seasons in two to three locations.

ii. BRL-2 trials will be conducted for a minimum one season on the understanding that the data generated during BRL-1 trials will be generated during BRL-2 trials;

iii. Additional trials may be called for based on the quality of data generated and /or new scientific evidence.

iv. Applicants may, for the purpose of research or otherwise may conduct BRL-1 / BRL-2 trials for more than the prescribed seasons with the approval of the RCGM/GEAC.

4.2 Discussion on draft position paper on use of antibiotic resistance markers in GM plants.

4.2.1 Discussion on the matter was deferred due to paucity of time. It was agreed to consider the matter in the next GEAC meeting.

4.3 Requirement of GEAC permission to export GM cotton to other countries.

4.3.1 The Committee noted that the GEAC has been receiving a number of requests for export of approved Bt cotton events to Pakistan. The intended purpose of the export is for research / field testing. The need for obtaining such approvals was discussed wherein the Committee opined that approval from GEAC is not necessary as it is the responsibility of the importing country to take such decisions. Therefore export of Bt cotton seeds can be allowed subject to the exporter obtaining the following approvals:

- Approval of the Competent Authority of the importing country.

- Approval from the National Biodiversity Authority, Chennai as per the provisions of the Biological Diversity Act, 2002.

In view of the above stated facts, exporters are not required to obtain approval of GEAC prior to export of Bt cotton seeds expressing approved events. However information on the export may be submitted to the GEAC for records.

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 on 34 transgenic rice events by M/s. Bayer Bio Science Pvt. Ltd., Gurgaon.

5.1.1 The Committee considered the request M/s. Bayer Bio Science Pvt. Ltd., Gurgaon to conduct event selection trials on transgenic rice events RICE 1502, RICE 1503, RICE 1504, RICE 1507, RICE 1515, RICE 1526, RICE 1551, RICE 1552, RICE 1557, RICE 1558, RICE 1576, RICE 2112, RICE 3130, RICE 3315, RICE 3316, RICE 3403, RICE 3405, RICE 3406, RICE 3407, RICE 3411, RICE 3413, RICE 3432, RICE 3435, RICE 3436, RICE 3437, RICE 3438, RICE 3439, RICE 3441, RICE 3442, RICE 3447, RICE 3449, RICE 3451, RICE 3457 and LLRICE62 containing *cry1Ab, cry1Ca* and *bar* genes. The trials will be conducted at two locations namely within the institution farm at Crop Development Centre, Patancheru in an area of 3000 sq. meter and Bayer Bioscience Pvt. Ltd., Davangere, Karanataka in an area of 1500 sq m, during Rabi 2010-11.

5.1.2 The Committee noted the purpose of the trials is to evaluate (i) The Bt events in comparison to non-transformed genotype for phenotypic assessment; (ii) Insect Bio-efficacy – Insect resistance against Pink Stem Borer (Sesamia

inferens L.) under artificial infestation conditions ; (iii)Testing Bt rice events for flowering synchronization with the female rice line line; (iv) Herbicide tolerance of the plant against Glufosinate ammonium herbicide. Study the effect of Bt rice events on trait performance in hybrid background.

5.1.3 The Committee further noted the following reproductive isolation measures are proposed:

- Spatial Isolation of 200 m from border rows to any nearest rice plants as per the regulatory requirements;
- Trial site will be provided with a fence.
- The field trial will be monitored by field supervisors.
- After completion of trials, biomass will be destroyed by burning.

5.1.4 The member Secretary informed that the GEAC in its earlier meetings had permitted M/s. Bayer Bio-Science Pvt. Ltd; to conduct event selection trials on transgenic rice events containing cry1Ab, cry1Ca and bar genes:

- on 28 transgenic rice in its 88th meeting held on 13.8.2008
- on 41 transgenic rice in its 91st meeting held on 14.1.2009
- on 88 transgenic rice in its 94th meeting held on 10.6.2009
- on 49 transgenic rice in its 97th meeting held on 14.10.2009, and
- on 56 transgenic rice in its 100th meeting held on 12.5.2010

5.1.5 The Committee also noted that the IBSC in its 35th meeting has recommended the proposal on 30.3.2010. The proposal was recommended by the RCGM in its 93rd meeting held on 28.9.2010, subject to submission of the status report of the event selection trials on transgenic rice permitted by RCGM/GEAC earlier. The Committee took note of the clarifications submitted by the applicant.

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5.1.6 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 on 34 transgenic rice events containing *cry1Ab, cry1Ca* and *bar* genes at two locations within the institutional research farm.

5.2 Permission to conduct event selection trials on three events of transgenic cotton (*Gossypium hirsutum*) variety Anjali-AcBt namely; Anjali-AcBt-1, Anjali-AcBt-2 and Anjali-AcBt-3 containing *cry1Ac* gene at CICR, Nagpur by Central Institute for Cotton Research (CICR), Nagpur .

5.2.1 The Committee considered the request of Central Institute for Cotton Research (CICR), Nagpur to conduct event selection trials on three events of transgenic cotton variety Anjali-AcBt namely; Anjali-AcBt-1, Anjali-AcBt-2 and Anjali-AcBt-3 containing *cry1Ac* gene at CICR, Panjari Farm, Wardha Road, Nagpur.

5.2.2 The Committee noted the purpose of the trials is to evaluate (i) the performance of new transgenic cotton (G. hirsutum) events carrying Bt cry1Ac gene, and protection against the bollworm across the season. As per the biosafety guidelines laid down by the regulatory authorities (RCGM/GEAC) confined field trial would be carried out in the field condition to select the best events in terms of crop protection against lepidopteran insect larvae and other parameters ;(ii) the experimental data will be recorded on Cry1Ac protein expression, seed cotton yield, other economical characters, maturity (duration), resistance to pest and disease and fiber trait properties. (iii) no herbicide will be used; however for sucking pest, pesticide will be used as and when required.

5.2.3 The Committee also noted following reproductive isolation measures are proposed:

- Refugee crop (pigeon pea)
- 50 m isolation distance will act as reproductive isolation measures.

- All the open bolls will be handpicked and kept in special bag with proper closing mechanism to avoid spill over and it will be transported from field to godown created for transgenic materials.
- Cloth bags will be used for storing and the transgenic material will be in the form of seed so there is no chance of contamination and destroying the container.
- Around 100 gm of Bt transgenic seeds will be used. The excess seed will be used for gap filling and future use.

5.2.4 The Committee further noted that IBSC in its 5th meeting has recommended the proposal on 02.07.2010. The proposal was recommended by the RCGM in its 93rd meeting held on 28.9.2010 subject to submission of information on the source of gene. The applicant vide their letter dated 18.10.2010 informed that Bt cry 1Ac gene has been obtained from NRCPB.

5.2.5 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 on three events of transgenic cotton (*Gossypium hirsutum*) variety Anjali-AcBt namely; Anjali-AcBt-1, Anjali-AcBt-2 and Anjali-AcBt-3 containing *cry1Ac* gene at the CICR institutional farm.

5.3 Permission to conduct event selection trials on two events of transgenic cotton (*Gossypium hirsutum*) variety Anjali-FBt namely; Anjali-FBt-1 and Anjali-FBt-2 containing *cry1F* gene at CICR, Nagpur by Central Institute for Cotton Research (CICR), Nagpur.

5.3.1 The Committee considered the request of Central Institute for Cotton Research (CICR), Nagpur to conduct event selection trials on two events of transgenic cotton (*Gossypium hirsutum*) variety Anjali-FBt namely; Anjali-FBt-1 and Anjali-FBt-2 containing *cry1F* gene at CICR, Panjari Farm, Wardha Road, Nagpur.

5.3.2 The Committee noted the purpose of the trials is to evaluate **(i)** the performance of new transgenic cotton (G. hirsutum) events carrying Bt cry1F events, and protection against the bollworm especially *S.litura* and some extent of H.armigera across the season. As per the biosafety guidelines laid down by the regulatory authorities (RCGM/GEAC) confined field trial would be carried out in the field condition(as a strip trial) to select the best events in terms of crop protection against Lepidopteron insect larvae and other parameters;(ii)the experimental data will be recorded on Cry1F protein expression, seed cotton yield, other economical characters, maturity (duration), resistance to pest and disease and fiber trait properties;(iii) no herbicide will be used; however for sucking pest, pesticide will be used as and when required.

5.3.3 The Committee noted the following reproductive isolation measures are proposed:

- Refugee crop (pigeon pea)
- 50 m isolation distance will act as reproductive isolation measures.
- All the open bolls will be handpicked and kept in special bag with proper closing mechanism to avoid spill over and it will be transported from field to godown created for transgenic materials.
- Cloth bags will be used for storing and the transgenic material will be in the form of seed so there is no chance of contamination and destroying the container.

5.3.4 The Committee noted that the IBSC in its 5th meeting has recommended the proposal on 02.07.2010. The proposal was recommended by the RCGM in its 93rd meeting held on 28.9.2010 subject to submission of information on the source of gene. The applicant vide their letter dated 18.10.2010 informed that Bt cry 1F gene has been obtained from NRCPB.

5.3.5 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 on two events of transgenic cotton (*Gossypium hirsutum*) variety Anjali-FBt namely; Anjali-FBt-1 and Anjali-FBt-2 containing *cry1F* gene at the CICR institutional farm.

5.4 Permission to conduct event selection trials on ten events of transgenic cotton (*G. arboreum*) varieties viz. RG-822-Bt (4 events) and PA255-Bt (6 events) containing *cry1Ac* gene by Central Institute for Cotton Research (CICR), Nagpur.

5.4.1 The Committee considered the request of Central Institute for Cotton Research (CICR), Nagpur to conduct event selection trials on ten events of transgenic cotton (*Gossypium arboreum*) varieties viz. RG-822-Bt (4 events) and PA255-Bt (6 events) by Central Institute for Cotton Research (CICR), Nagpur. Name or designation of events are as:

i Four events of G-822 named as Desi Bt G-822(Desi Bt G822-1 to Desi Bt G822- 4); and
ii Six events of PA-255 named as CICR Bt Desi (CICR Bt Desi-1 to CICR Bt Desi-6)

5.4.2 The Committee noted that the purpose of the trials is to evaluate **(i)** testing and evaluation of Bt Cry 1Ac event and protection against the bollworm across the season. ;(ii) the experimental data will be recorded on Cry1Ac protein expression, seed cotton yield, other economical characters, maturity (duration), resistance to pest and disease and fiber trait properties.;(iii)no herbicide will be used; however for sucking pest, pesticide will be used as and when required.

5.4.3 The Committee also noted that the following reproductive isolation measures are proposed:

- Refugee crop (pigeon pea) / 50 m isolation distance will act as reproductive isolation distance.
- All the open bolls will be handpicked and kept in special bag with proper closing mechanism to avoid spill over and it will be transported from field to godown created for transgenic materials.
- Cloth bags will be used for storing and the transgenic material will be in the form of seed so there is no chance of contamination and destroying the container.

5.4.4 The Committee also noted that the IBSC in its 5th meeting has recommended the proposal on 02.07.2010. The proposal was recommended by the RCGM in its 93rd meeting held on 28.9.2010 subject to submission of information on the source of gene. The applicant vide their letter dated 18.10.2010 informed that *Bt cry 1Ac* gene has been obtained from NRCPB.

5.4.5 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 on ten events of transgenic cotton (*G. arboreum*) varieties viz. RG-822-Bt (4 events) and PA255-Bt (6 events) containing *cry1Ac* gene at the CICR institutional farm.

5.5 Permission to conduct BRL-II trials on two transgenic corn hybrids containing stacked cry2Ab2, cry1A.105 (Event MON 89034) & cp4epsps (Event NK603) genes at nine locations during Rabi 2010-2011 by M/s. Monsanto India Ltd., New Delhi.

5.5.1 The Committee considered the request of M/s. Monsanto India Ltd., New Delhi to conduct BRL-II trials with two transgenic corn hybrids namely 900M Gold and Hishell, containing stacked cry2Ab2, cry1A.105 (Event MON 89034) & cp4epsps (Event NK603) genes at nine locations namely BHU Varanasi, UP; Begusarai Bihar; Bhagalpur Bihra; TNAU Coimbatore; UAS Dharwad; ANGRAU Karimnagar; MPUAT Udaipur; AAU Vadodara and DWSR Jabalpur MP. The applicant has also sought approval for seed production in an area of 1.00 acre each at two locations in Karnataka viz. Kunigal (Taluk) Tumkur (Dist), Karnataka and Sindagi (Taluk), Bijapur (Dist), Karnataka during Rabi 2010-11.

5.5.2 The Member Secretary informed that the GEAC in its meetings held on 12.11.2008, 10.06.2009, 14.10.2009 and 12.05.2010 had approved the conduct of BRL-I of above mentioned two corn hybrids expressing stacked events MON89034 and NK603 at three SAU's. The objectives of the BRL-II trials are:

- to study the impact of transgenic stacked corn (MON89034 and NK603) hybrids against target lepidopteron pests and weed control efficacy with glyphosate tolerant trait (NK603) with post application of Roundup Ready Herbicide with Cropsheild (MON76366);
- to monitor occurrence of beneficial and non target insects on stacked corn hybrids and their non transgenic counterparts and checks;
- 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; and
- to generate baseline susceptibility data of candidate protein on representative insect pest population of key target lepidopeteran pests i.e *chila partellus* and *Sesamia inference and Helicoverpa armigera* insect pests collected from various locations.

5.5.3 The following documents have been submitted by the company:

A. Application form containing the following information:

- Introduction
- Biology of the Plant System
- Molecular Biology of Plant and Transformation method
- Field Trials Plan
- Phenotypic characteristics of transformed fruit/seed
- Consequences to the environment
- Food and Feed Safety Evaluation
- Supportive evidences to all the chapters
- Summary and Conclusion

B. Reports containing results of the following studies:

i. Field Trial Permits
ii. Distribution of wild species of corn- by National Botanical Research Institute, Lucknow
iii. Bridging Studies for MON 89034 XNK603 corn hybrids
iv. BRL-I Field Trial Report of trial during Rabi 2009
v. Phenotypic Evaluation and Insect Observations of the Combined Trait Corn MON 89034 X NK603 in Argentina Field Trials
vi. Compositional study of MON89034 x NK603 grain and forage from Argentina field trials.

C. Studies previously submitted to RCGM and posted on the IGMORIS website (http://igmoris.nic.in) include:

i. Molecular analysis of the corn Event MON 89034
ii. Molecular analysis of the corn Event NK603
iii. BRL-I Field Trial Reports of trials during Rabi 2008
iv. BRL-I Field Trial Reports of trials during Kharif 2009
v. Protein expression report
vi. Bio-efficacy reports
vii. Pollen flow study (India 2004-05)
viii. Soil Micro-flora Studies (IMTECH)
ix. Baseline susceptibility (PDBC)
x. Bioinformatics comparison with known allergens and toxins for CP4 EPSPS Protein
xi. Bioinformatics comparison with known allergens and toxins for Cry1A.105 and Cry2Ab2 Protein

5.5.4 Member Secretary informed that the two season BRL-I trials conducted by the applicant in 2008-2009 were evaluated by MEC.

5.5.5 The Committee also noted that M/s Monsanto made a detailed presentation to the RCGM in its 94th meeting held on 26.10.2010 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.

5.5.6 After detailed deliberations, the Committee approved the request to conduct BRL-II trials on two transgenic corn hybrids containing stacked cry2Ab2, cry1A.105 (Event MON 89034) & cp4epsps (Event NK603) genes at nine locations during Kharif 2011 at nine locations in confined conditions under the direct supervision of Director, Directorate of Maize Research, IARI, Pusa for two seasons. The Committee also approved the request for seed production in an area of 25 acres per hybrid in confined conditions.

5.6 Permission to conduct Insect Resistance Management (IRM) trials for ascertaining refuge strategy for transgenic corn hybrids containing stacked cry2Ab2, cry1A.105 (Event MON 89034) & cp4epsps (Event NK603) genes at six locations by M/s. Monsanto India Ltd., New Delhi.

5.6.1 The Committee considered the request of M/s. Monsanto India Ltd., New Delhi to conduct Insect Resistance Management (IRM) trials for ascertaining refuge strategy for transgenic corn hybrids containing stacked cry2Ab2, cry1A.105 (Event MON 89034) & cp4epsps (Event NK603) genes at six locations namely: (i) Begusarai Bihar, (ii) Bhagalpur Bihar, (iii) Aurangabad Monsanto Farm, (iv) Coimbatore Tamilnadu (v) Davangere Karnataka and (vi) Warangal AP.

5.6.2 The Committee noted the objectives of the IRM trials is to: (i) establish baseline information on the occurrence of arthropod species in Bt maize field plots--MON89034 x NK603 vis-à-vis MON89034 x NK603 with 5%, 10%, 15% and 20% NK603 seed mix; (ii) quantify yield loss in Bt maize field plots--MON89034 x NK603 vis-à-vis MON89034 x NK603 with 5%, 10%, 15% and 20% NK603 seed mix. The experiment layout is as follows:

i. Row to row spacing: 60 cm
ii. Plant to plant spacing: 25 cm
iii. Individual plot area: 720 sq m
iv. Total area under transgenic: 720 x 5 = 3600 sq meter
v. Gross Experimental Area including African Tall Maize: 6818.24 sq meter

5.6.3 The Committee noted that each of the identified Refugia in Bag (RIB) demonstration sites will be established in 2 acres farm with layout and treatments illustrated below. This can be carried out with one hybrid 900M Gold. Planting will commence in 2010-11 dry season. The sites will be established and managed in-house and in partnership with some Universities. Except for non target insect pest management (no insecticide application), all other standard farm practices (land preparation, planting method, fertilization, water management, and weed management) will be followed.

5.6.4 The Committee noted that the corn hybrids expressing NK603 has not been approved for environmental release and, therefore, rejected the request of the applicant to use transgenic corn hybrids expressing NK603 while conducting IRM trials for ascertaining refuge strategy.

5.7 Permission to conduct Biosafety Research Level-1 (BRL-1) trials on transgenic potato (Solanum tuberosum subsp. Tuberosum) of invertase RNAi transgenic event, KchipLnvRNAi-2214 at Central Potato research Station, Jalandhar by Central Potato Research Institute (CPRI), Shimla

5.7.1 The Committee considered the request of Central Potato Research Institute (CPRI), Shimla, to conduct Biosafety Research Level-I (BRL-I) trials on transgenic potato (Solanum tuberosum subsp. Tuberosum) of invertase RNAi transgenic event, KchipLnvRNAi-2214. The trials will be conducted at Central Potato research Station, Jalandhar for multiplication and evaluation of stability of introduced trait, improvement in processing attributes by reduction of cold-induced sweetening.

5.7.2 The Committee noted the objective of the trial is (i) large scale confined field trials of valNV RNAI-transgenic potato event, KchipLnvRNAi-2214, for multiplication and evaluation of stability of introduced trait, improvement in processing attributes by reduction of cold-induced sweetening;(ii) the experiment will be conducted by planting each event in blocks of five rows. Wild type non-transgenic Kufri Chipsona -1 will serve as control. Control and seven transgenic events/clones will be planted in randomized block design (plot design is given) ;(iii) data on tuber shape, size processing grade yield, marketable yield and total yield will be recorded.;(iv)harvested tubers will be kept in cold store. Tubers will be taken out from cold store at 45 days intervals and processing attributes like chip colour, and reducing sugars and sucrose content will be evaluated.

5.7.3 The Committee also noted that the following reproductive isolation measures are proposed:

- Potato usually does not flower in the plains where the trial is to be conducted. In case of any chance flowering they will be removed manually and destroyed by burning.

- In addition, an isolation distance of 5 m will be kept on all sides of the trial plot.

5.7.4 The Committee also noted that the IBSC has recommended the proposal. The RCGM has considered the request in its 93rd meeting held on 28.09.10 and recommended to conduct BRL-I trials on transgenic potato hybrids. Event selection trials were approved by the GEAC in its 96th meeting held on 9.9.2009.

5.7.5 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 potato (Solanum tuberosum subsp. Tuberosum) of invertase RNAi transgenic event, KchipLnvRNAi-2214 at Central Potato research Station, Jalandhar.

5.8 Permission to conduct event selection trials on two transgenic potato (Solanum tuberosum subsp. Tuberosum) events namely SP951 and SP904 containing RB (RGA2) gene at Central Potato Research Institute Campus (CPRI), Modipuram by Central Potato Research Institute (CPRI), Shimla

5.8.1 The Committee considered the request of Central Potato Research Institute (CPRI), Shimla has requested permission to conduct event selection trials on two transgenic potato (Solanum tuberosum subsp. Tuberosum) events namely SP951 and SP904 containing RB (RGA2) gene at Central Potato Research Institute Campus (CPRI), Modipuram.

5.8.2 The Committee noted that the purpose of the trials is to evaluate**(i)** strip trial with RB transgenic potato clones for evaluation of late blight resistance and to make further selection on the basis of tuber characters;(ii)the experiment will be conducted by planting each clone in 3 lines. Late blight susceptible cultivar Kufri Jyoti will be planted surrounding the plot as inector row; (iii) data will be collected on late blight incidents and per percent infection atleast thrice during the growing period and rate of disease progress will be calculated; and (iv) data on tuber shape, size , uniformity, eye depth, skin color and yield will be recorded for each line at harvest.

5.8.3 The Committee also noted the following reproductive isolation measures are proposed:

- Potato usually does not flower in the plains where the trial is to be conducted. Incase of any chance flowering they will be removed manually and destroyed by burning.
- In addition, an isolation distance of 5 m will be kept on all sides of the trial plot.

5.8.4 The Committee also noted that the IBSC has recommended the proposal. The proposal was recommended by the RCGM in its 93rd meeting held on 28.9.2010, subject to the submission of details of the transgenic potato event / lines and the site map and vetting the same by identified RCGM members.

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 trials on two transgenic potato (Solanum tuberosum subsp. Tuberosum) events namely SP951 and SP904 containing RB (RGA2) gene at Central Potato Research Institute Campus (CPRI), Modipuram.

5.9 Permission to conduct event selection trials on seven transgenic rice (*Oryza sativa L*) events. by Department of Botany, University of Calcutta, Kolkata.

5.9.1 The Commiitttee considered the request of University of Calcutta, Kolkata has requested permission to conduct event selection trials on seven events on transgenic rice (Oryza sativa L) events. The events proposed to be evaluated include RICE 1502, RICE 1503, RICE 1504, RICE 1507, RICE 1515, RICE 1526, RICE 1551, FR19-7-3-4, FR19-7-3-5, FR19-7-7-3, FR19-11-7-4, FR19-11-2 (progenies of FR19-7 & FR19-11) containing ferritin gene for high iron content. The trials will be conducted at two seasons at Rice Research Station, Chinsurah, West Bengal in an area of 11 m x 14 m.

5.9.2 The Committee noted that the purpose of the trials is to evaluate (i) Agronomic evaluation of transgenic IR68144 high iron rice plants in field condition; (ii) Comparative assessment of morphology and phenotypic characters of transgenic rice and non-transgenic wild type plants; (iii)To evaluate the iron level of rice endosperm from the plants growing in field condition.

5.9.3 The Committee also noted that the following reproductive isolation measures are proposed:

i) The isolation distance will be more than 10 m to the nearest cultivated crop of the same species.
ii) For reproductive isolation, non-transgenic boarder rows will be maintained around the transgenic rice lines
iii) In addition, biological barrier with legume plants will be used on all four sides surrounding the experimental area.

5.9.4 The Committee noted that the proposed isolation distance is not in line with the Minimum Seeds Standard Certification which prescribes 200 m isolation distance.

5.9.5 The Committee also noted that the IBSC has recommended the proposal. The proposal was recommended by the RCGM in its 94th meeting held on 26.10.2010. It may also be noted that the proposed isolation distance is only 10 m whereas the prescribed distance as per Indian Seed Standards and condition stipulated by the GEAC is 200 m.

5.9.6 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 on seven transgenic rice (*Oryza sativa L*) events at Rice Research Station, Chinsurah, West Bengal for two seasons subject to the condition that the prescribed 200 m isolation distance would be maintained at the trial site.

5.10 Permission to conduct event selection trials on 140 transgenic rice (*Oryza sativa*) events by M/s. BASF India Ltd., Mumbai.

5.10.1 The Committee considered the request of the M/s. BASF India Ltd., Mumbai to conduct event selection trials on 140 transgenic rice (Oryza sativa L) events with construct RPD5 containing OS ARGOS like, Leucine zipper gene; construct RPD8 containing AT-CDKB1;2, Cyclin Dependent Kinase gene; construct RPD10 containing OS ARGOS like, Leucine Zipper gene and construct RPD11 containing OS-hox5, Homeobox- Leucine Zipper gene at four locations at Tamil Nadu Agricultural University (TNAU), Coimbatore in an area of 1 ha.

5.10.2 The Committee noted that the purpose of the trials is to evaluate the selection of events of that show higher yield because of the given construct after they have been tested in the open field in

an Indian environment. As the introduced trait is expected to give a higher seed yield it is essential to test the events under natural conditions.

5.10.3 The Committee also noted following reproductive isolation measures are proposed:

(i) The yield trials will be surrounded by a maximum of 1 m border of non-GM rice.
(ii) The distance to the nearest non-BASF rice is at least 200 m.

5.10.4 The Committee also considered the following information on the gene construct and transformation method:

5.10.5 The Committee further noted that the IBSC in its 4th meeting held on 4.10.2010 has recommended the proposal. The proposal was recommended by the RCGM in its 94th meeting held on 26.10.2010,

5.10.6 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 on 140 transgenic rice (*Oryza sativa*) events at four locations at Tamil Nadu Agricultural University (TNAU), Coimbatore. The Committee was also of the view that the applicant may be directed to submit information on how they propose to remove/segregate the selectable and visual markers.

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

5.11.1 The Committee considered the request of Rubber Research Institute of India, Kottayam. has requested permission to conduct Biosafety Research Level-1 (BRL-1) trial of Para Rubber Tree [*Hevea brasiliensis* (Wild. Ex Adr. De Juss.) Muell. Arg.] on Hb. SOD-L1 & L2 (two transgenic events (lines) developed using the same gene construct in the same species and variety) containing manganese superoxide dismutase gene (cDNA) . Trials will be conducted at two locations, namely Dapchari, Thane and Chethackal, Thombikandom, Kerala belongs to Rubber Research institute in an area of 0.4 ha.

5.11.2 The Committee noted that the purpose of the trials is to evaluate:

i. The potential of Hevea brasiliensis transgenic plant integrated with MnSOD gene for enhanced tolerance to abiotic stress and tapping panel dryness syndrome as well as to assess the capability of the plants to grow better with higher yield under adverse conditions.

ii. The proposed design is RBD with four treatments, five replicates and a plot size of six. Boundaries and isolation belt will be planted with non-modified Hevea brasiliensis plants.

iii. The data to be collected include growth and latex yield data recording; physiological parameters determining abiotic stress tolerance such as leaf water potential, photosynthetic net assimilation rate ('A'), fluorescent parameters like Dark Fv/Fm & Phi. PSII; antioxidant enzyme assay of superoxide dismutase & peroxidase and estimation of H2O2 content.

iv. TPD (tapping panel dryness syndrome) incidence will also be recorded.

5.11.3 The Committee also noted the following reproductive isolation measures are proposed**:**

i. In the Trial site-I, towards the eastern and western side, for about 200 m no sexually compatible species are growing. Towards the northern and southern side, 75 m each will be kept as isolation belt by planting the same species.

ii. In the Trial site-II, 50 m on all sides will be kept as isolation belt by planting the same species.

iii. In both the trial sites, after flowering (by the 5th year after planting), all the seeds produced by the existing plants of the same species within 100 m from the boundary of the trial area will be collected and destroyed by burning.

5.11.4 The Committee further noted that the IBSC has recommended the proposal. The application was earlier considered by the RCGM in the 88th meeting held on 20.04.2010 wherein it was decided that the opinion of three scientists specializing in molecular biology viz. Dr. M. Udaya Kumar, UAS, Bangalore; Dr. V. Siva Reddy, ICGEB, New Delhi and Dr. Sanjay Kumar, IHBT, Palampur may be taken prior to forwarding the same for GEAC approval as this would be the first transgenic tree crop to be permitted for BRL-I trials. Based on comments of the three scientists and clarifications submitted by the applicant, the proposal was recommended by the RCGM in the 94th meeting held on 26.10.2010. The Committee considered the comments received from the experts and noted that the applicant has provided requisite clarification satisfactorily.

5.11.5 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 of Para Rubber Tree [*Hevea brasiliensis (*Wild. Ex Adr. De Juss.) Muell. Arg.] on Hb. SOD-L1 & L2 (Two transgenic events lines.

5.12 Permission to conduct Biosafety Research Trials I (BRL-1) on two Bt sorghum lines containing cry 1B gene NRCSCRY1B event 4 and NRCSCRY 1B event 19 along with non transgenic lines (M35-1) by Directorate of Sorghum (DSR), Hyderabad, formerly known as National Research Centre for Sorghum.

5.12.1 The Committee considered the request of The Directorate of Sorghum Research (DoSR), Hyderabad to conduct Biosafety Research Level-1 (BRL-1) trials on two Bt transgenic Sorghum (Sorghum bicolor (L) Moench) lines containing *cry1B gene NRCSCRY1B* event 4 and NRCSCRY1B event 19 during Rabi season, 2010 along with non transgenic lines (M35-1) and natural resistance germplasm line (IS 2205) resistant to stem borer The trials will be conducted within the institutional research farm at DOR.

5.12.2 The Committee noted the purpose of the trials is to evaluate **(i)** the expressions of synthetic *Cry 1B* gene in Sorghum transgenic plants to be assessed through insect (stem borer) bioassay studies and cry 1B protein through ELISA.;(ii) One event of Bt transgenics along with susceptible nontransnics line (M-35-1); (iii) Data on leaf damage, deadheart formation., larval morality, exit holes and stem tunneling will be collected. Data on agronomic performance of plants will also be collected.; and (iv) No herbicide/pesticide will be used.

5.12.3 The Committee also noted that the following reproductive isolation measures are proposed:

I. The plot will be isolated by at least 500 m distance from any sorghum crop and the trial plot will be covered by a net enclosure;
II. Pollen contamination will be prevented by bagging flower initiating head;
III. Plant residue will be destroyed by burning (incineration) at all stages of trial.
IV. The trial site will have a compound wall fencing, 24 hours security and net enclosures.

5.12.4 Committee noted that the applicant has not provided the gene construct map. The Committee opined that the applicant may be advised to submit relevant vector maps may be provided to ascertain the use of antibiotic marker resistance selector gene and reporter gene. Accordingly, decision on the proposal was deferred. It was agreed to consider the proposal in the next GEAC meeting on receipt of the relevant information.

5.13 Permission to conduct seed production research trials for transgenic corn hybrids (Events MON 89034 x NK 603) at two locations in Andhra Pradesh by M/s Monsanto India Ltd.

5.13.1 The Committee considered the request of the M/s Monsanto India Ltd. to conduct seed production research trials for transgenic corn lines, namely Hishell and 900M Gold (Events MON 89034 x NK 603) at Kurnool (Dist), and West Godavari (Dist) in Andhra Pradesh at company's leased land. The purpose of the study to understand the flowering time pattern of the transgenic corn lines with event MON 89034 and event NK 603 under confined field conditions. Total required area for each location will be 0.98 acres for two plantings.

5.13.2 The Committee noted that the purpose of the trials is to evaluate the seed production of transgenic corn lines event MON 89034 and event NK 603 under confined open field conditions involving taking note of pollen dehiscence and flowering behavior which would help in working out the staggering requirements for the stack hybrid development.

5.13.3 The Committee also noted that the RCGM has recommended the seed production for research purpose in its 94th meeting held on 26.10.2010.

5.13.4 The GEAC recommended the seed production research trials for transgenic corn hybrids (Events MON 89034 x NK 603) at two locations in Andhra Pradesh at company's leased land to observe pollen dehiscence and flowering behavior which would help in working out the staggering requirements for the stack hybrid development

Agenda item No. 6: Other items:

6.1 Import of crude degummed oil produced from GenuityTM Insect Protected Roundup Ready 2 yieldR (BtRR2Y) soybean (breeding stack of Events MON87701XMON89788) from Brazil by M/s Monsanto Holdings Pvt. Ltd.

6.1.1 The Committee considered the request of M/s Monsanto Holdings Pvt Ltd. to import crude degummed oil produced from Genuity^{TM} Insect Protected Roundup Ready 2 yield^{R} (BtRR2Y) soybean (breeding stack of Events MON87701XMON89788) from Brazil. The transgenic soybean has been developed by Monsanto by forming a breeding stack of the Events MON87701 and MON89788. MON87701 was formed by introducing *cry1Ac* gene for insect resistance and is the same gene present in Bollgard and Bollgard II cotton (Events MON 531 and MON 15985) which are already approved in India. MON 87701 was produced by *Agrobacterium*-mediated transformation of soybean and contains marker free, single copy of *cry1Ac* gene. MON 89788 contains CP4 EPSPS gene which is tolerant to glyphosate. The oil derived from MON89788 soybean has been approved by GEAC in its 100th meeting held on 12.05.2010.

6.1.2 The Committee noted that the Event MON87701 is approved for cultivation in Brazil and for food & feed use in USA and Event 89788 is approved in the following countries:

Country	Environment	Food/safety	Food	Feed
Australia		2008		
Canada	2007		2007	2007
China		2008		
European Union		2008		
Japan	2008		2007	2008
Korea			2009	2009
Mexico		2008		
Philippines		2007		
Taiwan			2007	
United States	2007	2007		

6.1.3 After detailed deliberations, the Committee was of the view that the following clarifications may be obtained from the applicant:

(i) The composition of de-gummed crude oil derived from Genuity Insect Protected Roundup Ready 2 Yield soybean.
(ii) The intended purpose of import of the product.
(iii) The composition of the refined oil
(iv) Certification from the applicant that the final product does not contain detectable DNA or protein.

6.2 Import of crude degummed oil derived from BPS-CV127-9 soybean(CV127) from Brazil by BASF India Ltd.

6.2.1 The Committee considered the request of M/s BASF India Ltd. to import crude degummed oil produced from BPS-CV127-9 soybean (CV127) from Brazil. The transgenic CV127 soybean has been developed by BASF by introduction of the imidazolinone-tolerant acetohydroxyacid synthase large subunit (ahasl) gene csr1-2 with its native promoter from Arabidopsis thaliana into the plant genome.

6.2.2 The Committee also noted that the Event CV127 is approved for cultivation in Brazil and is under process in the following importing countries.

Country	**Environment**	**Food/safety**	**Food**	**Feed**
Australia/New Zealand		Oct 2009		
Canada	Feb 2009		Feb 2009	Feb 2009
China		Feb 2010		
European Union		Jan 2009		
Japan	Oct 2007		Oct 2007	Oct 2007
Korea	Jan 2010	Dec2009	Dec2009	Jan2010
Philippines		Feb 2010		
United States	Jan 2009			

6.2.3 After detailed deliberations, the Committee was of the view that the following clarifications may be obtained from the applicant:

(v) Composition of de-gummed crude oil derived from Genuity Insect Protected Roundup Ready 2 Yield soybean.
(vi) Intended purpose of import of the product.
(vii) Composition of the refined oil.
(viii) Certification from the applicant that the final product does not contain detectable DNA or protein.

6.3 Permission for Export of Ten Bt cotton BG II hybrid seed to Pakistan by M/s Monsanto Holdings Pvt Ltd, New Delhi.

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6.4 Permission for Export of seven Bt cotton BG II hybrid seed to Pakistan by M/s Monsanto Holdings Pvt Ltd, New Delhi.

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6.5 Permission for Export of six Bt cotton BG II hybrid seed to Pakistan by M/s Rasi Seeds.

1.0 In accordance with the policy decision taken in agenda item 4.3 regarding the need for obtaining GEAC approval prior to export of Bt cotton seeds, the Committee conveyed its 'no objection' subject to (i) approval of the Competent Authority of the country of import and (ii) Approval from the National Biodiversity Authority, Chennai as applicable under the Biological Diversity Act, 2002.

Date of next GEAC: 8th December 2010.

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