Decisions taken in the 119th meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 25.04.2014

The 119th meeting of the GEAC was held on 25.4.2014 in the Ministry of Environment and Forests (MoEF) under the chairmanship of Shri Hem Pande, Additional Secretary, MoEF and Chairman, GEAC

The deliberations and decisions taken in the GEAC meeting in respect of Agenda items 4

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

4.1 Permission to conduct Biosafety Research Level-1 (BRL-1) trials on seven transgenic HT rice (Oryza sativa L.) hybrids containing *cp4epsps gene* (event OS_A17314) by M/s. Maharashtra Hybrid Seeds Company (MAHYCO), Mumbai

4.1.1 The Committee considered the application of M/s MAHYCO to conduct BRL-1 trials on seven transgenic HT rice (Oryza sativa L.) hybrids namely; Suruchi MRP 5401 RR, Suruchi MRP 5402 RR, Suruchi MRP 5403 RR, Suruchi MRP 5629 RR, Suruchi MRP 5632 RR, Suruchi MRP 5633 RR and Suruchi MRP 5634 RR containing *cp4epsps gene* (event OS_A17314). The trial is proposed to be conducted at company's research farms or long-leased farms at 10 locations viz. Uttar Pradesh: Allahabad; Jharkhand: Ranchi; Chhattisgarh: Raipur; Andhra Pradesh: Guntur/Nizamabad; Karnataka: Davangere; Tamil Nadu: Coimbatore; Maharashtra: Thani/ Bhandara; Gujarat: Anand; WB: 24PGS (N)/ Burdwan; Orissa: Sambalpur in an area of 15 sq m / hybrid / trial.

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

- study the weed control efficacy in herbicide tolerant (HT) rice hybrids expressing the CP4EPSPS protein with application of Glyphosate herbicide (Roundup).
- estimate the level of expression of CP4EPSPS protein in various plant parts at different crop growth stages of HT rice hybrids. The protein expression data of CP4EPSPS in various plant parts will be recorded at the time of each Roundup application and also at 30, 60, 90 and 120 (or at maturity) days after transplanting (DAT) at all trial locations.
- observe growth habit, life cycle, plant height, impact on pollinator species and indicators of changes in weediness potential of HT rice hybrids, non-transgenic counterparts and checks.
- monitor the occurrence of beneficial insects and insects pests on HT rice hybrids, non-transgenic counterparts and checks.
- assess the effect of CP4 EPSPS protein on soil micro flora, earthworms and soil insect (Collembola) related to rhizosphere in the soil collected from HT rice and other non-transgenic rice plots. Data should be recorded during pre and post spray of Roundup herbicide and pre planting and post harvesting stage.
- estimate grain yield of HT rice hybrids, non-transgenic counterparts and checks.
- collect plant parts of HT rice hybrids, non-transgenic counterparts and checks for generation of plant material for biosafety studies.

4.1.3 The Committee also noted that the applicant has informed that for the purpose of compositional analysis about 1 kg of rice each of transgenic entry, non-transgenic counterpart, and non-transgenic reference will be harvested and retained.

4.1.4 The Committee also observed that the proposal has been recommended by the IBSC and RCGM in its meetings held on 31.01.2012 and 22.5.2012 respectively.

4.1.5 The Committee was of the view that in respect of HT crops, there is a need to verify if the herbicide has been approved by the Central Insecticide Board & Registration Committee (CIBRB). After detailed deliberations, it was decided to obtain following information from the applicant;

(i) Dosage of Herbicide Glyphosate spray
(ii) Approval of Central Insecticide Board & Registration Committee (CIBRB).
(iii) Nature and extent of biodegradation
(iv) Residual estimate of the herbicide in the soil
(v) Impact on Mollusca and Crustacean should also be studied during field trials.
(vi) Rational of using two promoters ;

4.1.6 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved for conduct of Biosafety Research Level-1 (BRL-1) trials on seven transgenic HT rice (Oryza sativa L.) hybrids containing *cp4epsps gene* (event OS_A17314) at company's research farms or long-leased farms at 10 locations viz. Uttar Pradesh: Allahabad; Jharkhand: Ranchi; Chhattisgarh: Raipur; Andhra Pradesh: Guntur/Nizamabad; Karnataka: Davangere; Tamil Nadu: Coimbatore; Maharashtra: Thani/ Bhandara; Gujarat during any appropriate season subject to:

i. Submission of NOC from the State Government where the trials will be conducted.
ii. Information sought in para 4.1.7.
iii. The field trials should include study on non-target organisms such as n Mollusca and Crustacean in the soil.

4.2 Permission to conduct Bio-safety Research Level-1 (BRL-1) trials on transgenic rice (Oryza sativa) containing two independent events namely; JKOsE081 (containing cry2Ax1 gene) & JKOsE016 (containing *cry1Ac gene*) and one stacked event JKOsE081xE016 with (*cry2Ax1 and cry1Ac gene*) by M/s. JK Agri Genetics Ltd., Hyderabad

4.2.1 The Committee considered the application of M/s. JK Agri Genetics Ltd., Hyderabad, to conduct BRL-1 trials on transgenic rice (Oryza sativa) containing two independent events JKOsE081 and JKOsE016 containing cry2Ax1 and cry1Ac genes respectively and one stacked event containing cry2Ax1 and cry1Ac gene**.** The trials (3) proposed to be conducted at main rice growing areas in the agro climatic zones at company's Farm/leased land at an area of 9x33 (sqm).

4.2.2 The Committee noted that the application submitted by the applicant is not in the correct formation and does not include relevant information such as (i) details of proposed locations, (ii) proposed isolation distance, (iii) details of the marker used etc; and advised re-submission of the application in the prescribed format. .

4.2.3 The Committee therefore decided to defer decision on the proposal.

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

Discussions on the above agenda item was deferred as experts were of the view that more time is needed to deliberate on the application for BRL-II trials. It was also decided to forward the biosafety dossier submitted by the applicant on completion of BRL-I trials to all members of the GEAC pursuant to which the proposal can be considered in the GEAC meeting.

4.4 Permission to conduct event selection trials on 10 Bt brinjal (*Solanum melongena L)* events expressing *cry IFa I gene* by M/s Rasi Seeds (P) Ltd., Coimbatore.

4.4.1 The Committee considered the application of M/s. Rasi Seeds (P) Ltd Coimbatore to conduct event selection trial on 10 Bt brinjal (Solanum melongena L) events namely**;** RB 42-IRE 112, RB 42-IRE 114, RB 42-IRE 116, RB 42-IRE 121, RB 42-IRE 123, RB 42-IRE 129, RB 42-IRE 131, RB 42-IRE 133, RB 42-IRE 135 and RB 42-IRE 140 expressing *cry IFa1 gene* for development of Fruit & Shoot Borer (FSBR) resistant Brinjal expressing *Cry 1Fa 1gene* obtained from Dr P. Ananda kumar, Project Director, NRCPB. The trial will be conducted at M/s Rasi Seeds R&D Centre, Attur in an area of 0.30 ha.

4.4.2 The Committee noted that the objective of the trial is to select the best performing event based on the comparison of the level of resistance to the insect pest-Fruit and Shoot borer (Leucinodes orbanalis), fruit yield, fruit quality and other economic agronomic parameters of Bt brinjal events corresponding to their non –Bt counterpart. The trials will include 10 events and 1 control.

4.4.3 The Committee also observed that the proposal has been recommended by the IBSC and RCGM in its meetings held on 30.01.2012 and 26.06.2012 respectively.

4.4.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for conduct of event selection trials on 10 Bt brinjal (*Solanum melongena L)* events expressing *cry IFa I gene* at company's R&D Centre, Attur during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted.

4.5 Permission to conduct Biosafety Research Level-I (BRL-I) trials on two transgenic rice (oryza sativa) events namely; B6 and C15 expressing *gly I and gly* II genes by M/s Bioseed Research India Pvt. Ltd, Hyderabad.

4.5.1 The Committee considered the request of M/s Bioseed Research India Pvt. Ltd, Hyderabad to conduct Biosafety Research Level-I (BRL-I) trials on two transgenic rice (oryza sativa) events namely; B6 and C 15 expressing *gly I and gly II genes*. The trial will be conducted at Company's Research farm at Rangareddy, AP, to generate information on drought and salinity tolerance rice as compared to non-transgenic counterparts in an area of 72 m^2 (excluding isolation distance).

4.5.2 The Committee noted the objective of the trial is to generate information on drought and salinity tolerance of transgenic rice as compared to non-transgenic counterparts, and also to demonstrate their agronomic performance.

4.5.3 The Committee observed that the proposal has recommended by the IBSC and RCGM in its meetings held on 20.04.2012 and 26.06.2012 respectively.

4.5.4 The Committee also noted that surplus planting material will be rendered non-viable via burning at the trial site.

4.5.5 After detailed deliberation, the Committee was of the view that the applicant may be advised to clarify the rationale for using two antibiotic resistance markers; (i) kanamycin as the bacterial selection marker and (ii) hygromycin as the plant selection marker as well as additional gfp+gus fusion as the reporter gene, as they may not be necessary for transformation.

4.5.6 The proposal was therefore deferred.

4.6 Permission to conduct Biosafety Research Level-I (BRL-I) trials on two transgenic rice (oryza sativa) events namely; T I-3 and T I-5 expressing DREB genes and three transgenic rice events namely; LEA-11, LEA-20 and LEA-21 expressing *lea* gene by M/s Bioseed Research India Pvt. Ltd, Hyderabad.

4.6.1 The Committee considered the application of M/s Bioseed Research India Pvt. Ltd, Hyderabad to conduct Biosafety Research Level-I (BRL-I) trials on two transgenic rice (oryza sativa) events namely; T I-3 and T I-5 expressing DREB genes. The trial will be conducted at Company's Research farm at Rangareddy, AP, in an area of 25 m^2 (excluding isolation distance).

4.6.2 The Committee noted the objective of the trial is to generate information on drought tolerance of transgenic rice as compared to non-transgenic counterparts, and also to demonstrate their agronomic performance.

4.6.3 The Committee noted that full details of the plasmid vector used for transformation has not been provided and decided to obtain the following details:

- The antibiotic resistance marker used in transformation (inclusive of promoter and terminator). Are additional antibiotic resistance markers present in the transgenic plant?
- Is any reporter gene such as GUS or GFP present in the transgenic plant?
- Is the plant a marker free transgenic?
- What is the promoter and the terminator used for expressing the gene of interest/s.

4.6.4 After detailed deliberations, the Committee decided to consider the proposal on receipt of information pertaining to gene construct as outlined in para 4.6.5. Accordingly decision on the proposal was deferred.

4.7 Permission to conduct event selection trials on 2 transgenic cotton (Gossypium hirsutum) events namely: CICR- Suraj –FBt-3 and CICR-Suraj -FBt-4 carrying *cry1F gene* for bollworm resistance by Central Institute for Cotton Research (CICR), Nagpur.

4.7.1 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) varieties CICR- Suraj –FBt-3 and CICR- Suraj -FBt-4 containing *cry1F gene*. The trial will be conducted at one location in an area of 90 m^2 at CICR, Panjari Farm, Wardha Road, Nagpur.

4.7.2 The Committee noted that the objectives of the trials are to**:**

- ❖ test the performance of new *Bt cry1F* events, and protection against the bollworm especially *S.litura* and some extent of *H.armigera* across the season. As per the guidelines laid down by the regulatory authorities (RCGM/GEAC) on biosafety confined trial would be carried out in the field condition to select the best event in terms of crop protection against Lepidopteron insect larvae and other parameters;
- ❖ record the experimental data on Cry1F protein expression, seed cotton yield, other economical characters, maturity (duration), resistance to pest and disease and fiber trait properties;
- ❖ no herbicide will be used; however for sucking pest, pesticide will be used as and when required.

4.7.3 The Committee observed that the proposal has been recommended by IBSC and RCGM in its meetings held on 27.02.2012 and 26.6.2012 respectively.

4.7.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for conduct of event selection trials on 2 transgenic cotton (Gossypium hirsutum) events namely: CICR- Suraj –FBt-3 and CICR-Suraj -FBt-4 carrying *cry1F gene* for bollworm resistance at Panjari Farm, Nagpur during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted.

4.8 Permission to conduct event selection trial on seven transgenic Cotton (Gossypium arboretum L. cv. DLSa-17) events namely; D1Ac to D7Ac events expressing *cry1Ac gene* by University of Agricultural Sciences (UAS), Dharwad

4.8.1 The Committee considered the request of UAS, Dharwad to conduct event selection trial on seven transgenic Cotton (*Gossypium arboretum* L. cv. DLSa-17) events namely; D1Ac to D7Ac events expressing cry1Ac gene, exhibiting tolerance to insects (*Helicoverpa armigera*). The trial will be conducted at Agriculture Research Station Dharwad Farm (University's own research farm); RARS Lam Guntur, ANGRAU, Andhra Pradesh; CICR, Nagpur; MCRS, RARS, Surat, NAU, Navsari, Gujarat in an area of 90 cm x 20 cm .

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

- ❖ to select best event among 7 events resistant to *Helicoverpa armigera* in field conditions.
- ❖ laboratory insect bioassay study will also carried out to select the best event besides selection based on field infestation.

4.8.3 The Committee observed that the proposal has been recommended by IBSC and RCGM in its meetings held on 04.06.2012 and 26.06.2012 respectively.

4.8.4 The Committee also noted that the seed cotton will be harvested. About 5 kg seed from each event will be retained after separating seeds and lint. Lint and other plant parts will be destroyed. Seeds will be used for BRL trials and to multiple in large scale to supply for animal feeding studies.

4.8.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for conduct of event selection trials of seven transgenic Cotton (Gossypium arboretum L. cv. DLSa-17) events namely; D1Ac to D7Ac events expressing *cry1Ac gene* at Agriculture Research Station Dharwad Farm (University's own research farm); RARS Lam Guntur, ANGRAU, Andhra Pradesh; CICR, Nagpur; MCRS, RARS, Surat, NAU, Navsari, Gujarat during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted.

4.9 Permission to conduct event selection trials on 12 transgenic Cotton (*Gossypium barbadense* L.cv. SBYF-425) events namely; SB1 Ac to SB12 Ac events expressing cry1Ac gene by University of Agricultural Sciences (UAS), Dharwad

4.9.1 The Committee considered the request of UAS, Dharwad to conduct event selection trial on twelve transgenic Cotton *Gossypium barbadense* L.cv. SBYF-425) events namely; SB1 Ac to SB12 Ac expressing cry1Ac gene for insect resistance (*Helicoverpa armigera*). The trial will be conducted at Agriculture Research Station Dharwad Farm (University's own research farm); RARS Lam Guntur, ANGRAU, Andhra Pradesh; CICR, Nagpur; MCRS, RARS, Surat, NAU, Navsari, Gujarat in an area of 90 cm x 20 cm .

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

- to select best event among 12 events resistant to *Helicoverpa armigera* in field conditions.
- laboratory insect bioassay study will also carried out to select the best event besides selection based on field infestation.

4.9.3 The Committee observed that the proposal is recommended by the IBSC and RCGM in its meetings held on 04.06.2012 and 26.06.2012 respectively.

4.9.4 The Committee noted that the seed cotton will be harvested. About 5 kg seed from each event will be retained after separating seeds and lint. Lint and other plant parts will be destroyed. Seeds will be used for BRL trials and to multiple in large scale to supply for animal feeding studies.

4.9.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for conduct of event selection trials on 12 transgenic Cotton (*Gossypium barbadense* L.cv. SBYF-425) events namely; SB1 Ac to SB12 Ac events expressing cry1Ac gene at Agriculture Research Station Dharwad Farm (University's own research farm); RARS Lam Guntur, ANGRAU, Andhra Pradesh; CICR, Nagpur; MCRS, RARS, Surat, NAU, Navsari, Gujarat during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted.

4.10 Permission to conduct event selection trial on 24 transgenic Cotton (Gossypium herbaceum cv. Jayadhar) events namely; J1 Ac to J24 Ac expressing cry1Ac gene by University of Agricultural Sciences (UAS), Dharwad

4.10.1 The Committee considered the request of UAS, Dharwad to conduct event selection trial on twenty four (24) transgenic Cotton (Gossypium herbaceum cv. Jayadhar) events namely; J1 Ac to J24 Ac expressing cry1Ac gene,for insect resistance (Helicoverpa armigera). The trial will be conducted at Agriculture Research Station Dharwad Farm (University's own research farm); RARS Lam Guntur, ANGRAU, Andhra Pradesh; CICR, Nagpur; MCRS, RARS, Surat, NAU, Navsari, Gujarat in an area of 90 cm x 20 cm .

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

- ❖ to select best event among 24 events resistant to Helicoverpa armigera in field condition
- ❖ laboratory insect bioassay study will also carried out to select the best event besides selection based on field infestation.

4.10.3 The Committee observed that the proposal has been recommended by IBSC and RCGM in its meetings held on 04.06.2012 and 26.06.2012 respectively.

4.10.4 The Committee also noted that the seed cotton will be harvested. About 5 kg seed from each event will be retained after separating seeds and lint. Lint and other plant parts will be destroyed. Seeds will be used for BRL trials and to multiple in large scale to supply for animal feeding studies.

4.10.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for conduct of event selection trials event selection trial on 24 transgenic Cotton (Gossypium herbaceum cv. Jayadhar) events namely; J1 Ac to J24 Ac expressing cry1Ac gene Agriculture Research Station Dharwad Farm (University's own research farm); RARS Lam Guntur, ANGRAU, Andhra Pradesh; CICR, Nagpur; MCRS, RARS, Surat, NAU, Navsari, Gujarat during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted.

4.11 Permission to conduct event selection trial on transgenic Cotton (Gossypium hirsutum L.) event BNAcF expressing cry1Ac and cry1F genes by University of Agricultural Sciences (UAS), Dharwad

4.11.1 The Committee considered the request of UAS, Dharwad to conduct event selection trial on transgenic Cotton (Gossypium hirsutum L.) event BNAcF expressing cry1Ac and cry1F genes,for insect resistance (Helicoverpa armigera). The event developed by crossing between cry1Ac and cry1F genes in Bikaneri Nerma transgenic cotton events named as BNAcF. The trial will be conducted at (i) Agriculture Research Station Dharwad Farm (University's own research farm); (ii) RARS Lam Guntur, ANGRAU, Andhra Pradesh; (iii) NBPGR, New Delhi; and (iv) MCRS, RARS, Surat, NAU, Navsari, Gujarat in an area of 90 cm x 20 cm .

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

- ❖ to evaluate event BNAcF for its resistance to both Helicoverpa armigera and Spodopter litura insects in field conditions in comparison with BNAc and BNF Bt cotton independent events.
- ❖ laboratory insect bioassay study will also be carried out to evaluate performance of BNAcF in comparison with BNAc and BNF.

4.11.3 The Committee observed that the proposal has been recommended by IBSC and RCGM in its meetings held on 04.06.2012 and 26.06.2012 respectively.

4.11.4 The Committee also noted the information provided by the company that the Seed cotton will be harvested. 5 kg seed from each event will be retained after separating seeds and lint. Lint and other plant parts will be destroyed. Seeds will be used for BRL trials and to multiple in large scale to supply for animal feeding studies.

4.11.5 As the event developed by crossing between cry1Ac and cry1F genes in Bikaneri Nerma transgenic cotton events named as BNAcF members requested to check the source of the gene is similar to Bikaneri nirma**.** It is to inform that it is a new event, crossing between cry1Ac and cry1F genes while the CICR gene was single gene developed by *cry 1 Ac gene.*

4.11.6 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved for conduct of event selection trials event selection

trial on on transgenic Cotton (Gossypium hirsutum L.) event BNAcF expressing cry1Ac and cry1F genes at Agriculture Research Station Dharwad Farm (University's own research farm); RARS Lam Guntur, ANGRAU, Andhra Pradesh; CICR, Nagpur; MCRS, RARS, Surat, NAU, Navsari, Gujarat during any appropriate season subject to (i) confirmation that the source of gene is not the same as that used for Bt Bikaneri Nirma and (ii) submission of NOC from the State Government where the trials will be conducted.

4.12 Permission to conduct the event selection trials on 25 transgenic rice events rice expressing *ipt gene* protein Water Use Efficient (WUE) rice by M/s. Maharashtra Hybrid Seeds Co. Ltd

4.12.1 The Committee considered the request of M/s. Maharashtra Hybrid Seeds Co. Ltd, to conduct event selection trials on 25 transgenic rice expressing *ipt gene* protein Water Use Efficient (WUE) rice events. The trials will be conducted at one location at company's own research farm at Anand Nagar, Nizamabad District (Andhra Pradesh) in a total area of 2913.84 sq.m.

4.12.2 The Committee noted the purpose of the trials is to evaluate the efficacy of transgenic rice events expressing *ipt* protein compared to their non transgenic counterparts and checks for drought tolerance.

4.12.3 The Committee also noted to the clarifications provided by the Company that the Selectable marker genes are included in transformation systems to aid selection of plants, but they are usually not required once transgenic plants are produced. It is desirable to remove the marker genes in established transgenic plants as they do not contribute to the desired trait being introduced.

4.12.4 The Committee observed that the proposal is recommended by IBSC and RCGM in its meetings held on 13.8.2012 and 28.8.2012 respectively.

4.12.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for conduct of event selection trials on 25 transgenic rice events rice expressing *ipt gene* protein Water Use Efficient (WUE) rice at company's own research farm at Anand Nagar, Nizamabad, Andhra Pradesh during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted.

4.13 Permission to conduct confined field trials with transgenic maize (Event MON 89034 x NK603) to evolve a refuge strategy for transgenic maize hybrids. The field studies are aimed to evolve a method for delivering IRM benefits through planting non-*Bt* maize plants interspersed within the main *Bt* maize crop by M/s. Monsanto India Ltd., New Delhi

4.13.1 The Committee noted that the GEAC in its meeting held on 15.11.2010 had considered the application submitted by the M/s. Monsanto India Ltd., New Delhi for conduct of IRM trials for transgenic maize (Event MON 89034 x NK603). The application was deferred as the protocol included use of single event NK603. Transgenic maize (Event NK603) is undergoing BRL-1 trials.

4.13.2 The Committee considered the fresh request for conduct of confined field trials with transgenic maize (Event MON 89034 x NK603) to evolve a refuge strategy for transgenic maize hybrids. In the present application the protocol is revised and does not include single event NK603. The trials will be conducted at six locations during dry season of 2012 namely

Andhra Pradesh, Karnataka, Tamil Nadu, Gujarat, Maharashtra and Bihar and eight locations during wet season of 2013 namely Gujarat, Rajasthan, Haryana, Madhya Pradesh, Tamil Nadu, Andhra Pradesh, Karnataka and Uttar Pradesh.

4.13.3 The Committee noted the information provided by the applicant that they are conducting BRL-II trials on transgenic maize (Event MON 89034 x NK603) and collected data on efficacy of the insecticidal proteins Cry1A.105 and Cry2Ab2 towards target pests and its safety towards non-target pests. They have also conducted studies to monitor the baseline susceptibility levels and insect behavioral studies across the country. This data will be helpful in ascertaining refuge requirements for the sustenance of the technology.

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

a) study abundance/productivity of the Pink stem borer (*Sesamia inferens*), maize stalk borer (*Chilo partellus*) and cob borer, *Helicoverpa armigera*, from non-*Bt* plants (serving as refuge) interspersed (termed as built-in-refuge, BIR) within the *Bt* maize crop at levels of 0% (no BIR), 5% and 10% in a main crop of *Bt* maize (event MON 89034 x NK603). For comparison, block refuges (in which non-*Bt* plants would be grown at one end of the plot) at 5 and 10% levels would be grown.
b) study movement of larvae of *C. partellus, S. inferens* and *H. armigera* from Non-*Bt* BIR refuge plants to t*he* surrounding *Bt* maize plants.
c) evaluate the concept of BIR for long term sustainability of *Bt* maize(event MON 89034 x NK603).
d) evaluate abundance of beneficial arthropods including Coccinelids and spiders on the *Bt* maize and non-*Bt* plants

4.13.5 The Committee also observed that the proposal was approved by IBSC and RCGM in its meetings held on 28.6.2012 and 20.11.2012 respectively. RCGM recommendation was subject to submission of clarification as sought by the Members during the meeting.

4.13.6 After detailed deliberations, it was decided to obtain the following information from the applicant;

(i) Dosage of Herbicide Glyphosate spray
(ii) Approval of Central Insecticide Board & Registration Committee (CIBRB).
(iii) Nature and extent of biodegradation
(iv) Residual estimate of the herbicide in the soil
(v) Impact on Mollusca and Crustacean should also be studied during field trials.
(vi) Whether requisite clarification sought by RCGM has been furnished.

4.13.7 The Committee requested that chronology of approvals granted by the RCGM/GEAC and present status of field trials for both events namely stacked events (MON 89034 x NK603) and single event NK-603 may be provided in the first instance.

4.13.8 The Committee therefore decide to decision on the proposal.

4.14 Permission for production of forage under confined conditions of transgenic corn hybrid 900M Gold (MON 89034XNK603) at NDRI, Karnal for the purpose of cow feeding study by M/s. Monsanto India Ltd., New Delhi.

&

Permission for approval of protocol for conducting feeding study in lactating cows for assessment of food and feed safety of transgenic corn (MON 89034XNK603) by M/s. Monsanto India Ltd., New Delhi

4.14.1 The Committee considered the request of M/s. Monsanto India Ltd., New Delhi for production of forage of transgenic corn hybrid 900M Gold (MON 89034XNK603) and its non-transgenic counterpart at National Dairy Research Institute (NDRI), Karnal for conducting eight week dairy cow feeding study. The company has also sought approval of protocol for conducting these studies in lactating cows for assessment of food and feed safety of transgenic corn (MON 89034XNK603)

4.14.2 The Committee took note of the field experiment design and proposed isolation measures as given below:

- The forage production will be conducted as per stipulated guidelines and SOPs of RCGM and GEAC for confined field trials of transgenic plants (2008)
- Maintaining an isolation distance of 300 mts from other nearest maize crop.
- The planting of transgenic maize hybrid (900M Gold) containing Events MON 89034 x NK603 is only for the purpose of producing green chop.
- Sufficient quantities of the test substance for feeding as green chop will be grown on-site such that a sufficient amount of whole plant corn can be produced to feed 10 cows for 28 days taking into account wastage and spoilage

4.14.3 The Committee observed that the proposal was recommended by the IBSC in its meeting held on 23.06.2011 and recommended by RCGM in the meeting held on 28.8.2012.

4.14.4 After detailed deliberations, the adequacy of feeding studies in lactating cows just for 8 weeks and justification of the proposed Protocol was discussed. After detailed discussion the Committee decided to allow production of forage at NDRI subject to NOC from the State Government. In respect of approval for the protocol for conducting feeding studies at NDRI, it was decided that the applicant may be requested to make a detailed presentation on the same for further consideration of the matter.

4.15 Permission for Forage Production for Cattle Feeding Study of Transgenic and Non-Transgenic Maize Hybrids by M/s. E. I. DuPont India Pvt. Ltd, Hyderabad to be conducted at National Dairy Research Institute, Karnal

4.15.1 The Committee considered the request of National Dairy Research Institute (NDRI), Karnal for forage production of maize hybrid containing the combined trait product TC1507 x NK603, and its non-transgenic counterpart for conducting eight week dairy cow feeding study. The forage production will be conducted at NDRI in Karnal. Seeds for transgenic (30B11HR), non-transgenic (30B11) and two other reference groups of maize hybrids, generated in India, will be provided by M/s. E.I. DuPont India Pvt. Ltd, Hyderabad, to NDRI, Karnal, which will be used to cultivate the maize crop for obtaining forage.

4.15.2 The Committee noted the transgenic maize hybrid 30B11HR containing the stacked events TC1507 x NK603 (containing *cry1F*, *pat* and *cp4 epsps* genes) will be produced along with the non-transgenic counterpart 30B11 and two commercially available reference hybrids.

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

(i) eight week dairy cow feeding study with forage derived from transgenic Maize hybrid containing the combined trait product TC1507xNK603.

(ii) green fodder production for cattle feeding study of transgenic and non-transgenic maize hybrids

4.15.4 The Committee noted that RCGM in its meeting held on 26.12.2012, opined that the approval of IBSC and of IAEC of National Dairy Research Institute (NDRI), Karnal, Haryana are required for the conduct of feeding study on cattle. RCGM advised that a separate application for approval of RCGM/GEAC for conduct of confined field trials for forage production is required to be submitted. RCGM also sought information on the selection criteria of animals for the feeding study. The matter was reconsidered by the RCGM in the meeting held on 24.12.2013 wherein the proposal for generation of fodder at NDRI was recommended to the GEAC. However, the protocol for feeding studies was not recommended.

4.15.5 From the information furnished, it is not clear whether the details sought by RCGM on proposed protocol have been provided. Accordingly RCGM was requested to clarify the same. The Committee further advised that a detailed presentation on the protocol for feeding studies may also be made before the GEAC.

4.15.6 In view of the above stated facts, the Committee decided to approval the request for generation of fodder at NDRI subject to (i) confirmation from RCGM that the IBSC at NDRI has approved the same and (ii) submission of NOC from the State Government. Decision on the protocol for feeding study was deferred.

4.16 Permission to conduct Biosafety Research Level-1 (BRL-1) trials and experimental seed production of breeding stack of GlyTol® X TwinLink® cotton (*Gossypium hirsutum*) hybrids that express *2m EPSPS, cry1Ab, cry2Ae* and *bar* genes; [GlyTol® event GHB614 (*2mEPSPS*) X TwinLink® [event GHB119 (*cry2Ae/bar*) X event T304-40 (*cry1Ab/bar*)] in North, Central and South zone) by M/s. Bayer Bioscience Pvt. Ltd, Gurgaon.

4.16.1 The Committee considered the proposal of M/s. Bayer Bioscience Pvt. Ltd, Gurgaon to conduct BRL-1 trial and experimental seed production of breeding stack of GlyTol® X TwinLink® cotton (*Gossypium hirsutum*) hybrids that express *2m EPSPS, cry1Ab, cry2Ae* and *bar* genes; [GlyTol® event GHB614 (*2mEPSPS*) X TwinLink® [event GHB119 (*cry2Ae/bar*) X event T304-40 (*cry1Ab/bar*)] during 2013 and 2014 (1st week of May in North zone to 2nd week of June in Central and South) at SAUs/company's long leased land an area of 4000 sq m./ trial. The proposed area for experimental seed production is 0.5 acre.

4.16.2 Details of the entries of the trials would be:

Zone	Entries	Locations
NZ	SP7007 GLT, SP7007 GLT, SP7007 GLT, SP7007, SP7010 GLT, SP7010 GLT, SP7010 GLT, SP7010, Zonal check (CSHH198), National check (LHH144)	PAU, Ludhiana/HAU Hisar/Bayer BioScience Bhathinda/Mansa/Sirsa
CZ	SP7149GLT, SP7149GLT, SP7149GLT, SP7149, SP7230GLT, SP7230GLT, SP7230GLT SP7230, Zonal check (H8),	JAU, Junagadh/NAU, Navsari/MBKV, Rahuri/MAU, Parbhani/DPDKV, Akola/ Bayer BioScience, Rajkot/ Bhavnagar/Yavatmal

	National check NHH44	
SZ	SP7149GLT, SP7149GLT, SP7149GLT, SP7149, SP7343 GLT, SP7343 GLT, SP7343 GLT, SP7343, Zonal check Bunny, National check NHH44	ANGRAU, Hyderabad/ Bayer BioScience Patancheru in SZ

4.16.3 The Committee noted that the objectives of the trials are to evaluate

1. efficacy of the breeding stack (GlyTol® × TwinLink -GLT) cotton against *Lepidopteran* pests.
2. herbicide tolerance of GLT cotton to glufosinate ammonium and glyphosate.
3. agronomic performance of GLT cotton hybrids

4.16.4 The Committee observed that the proposal was approved by IBSC and RCGM in its meetings held on 22.11.2012 and 30.1.2013 respectively.

4.16.5 The Committee also considered the information provided by the applicant that total quantity of seed cotton (raw cotton with seed) required for each replication = 1 kg. Analyses to be performed with these retained seeds are:

i. Ginning per cent: 1 kg raw cotton is ginned to know the percent lint recovered.
ii. Seed index: 100 random seeds from ginned cotton are weighed to calculate seed index
iii. Compositional analysis: 300 g see is taken, crushed to devitalize and to use for compositional analysis.
iv. Fiber analysis: Lint received from ginning is sent to fiber testing lab.
v. The balance seed and fiber will be destroyed by incineration.

4.16.6 After detailed deliberations, the Committee was of the view that the applicant may be requested to make a detailed presentation on (i) rationale of using two herbicide resistance genes, (ii) how resistance development would be managed and global scenario in this regard and , (iii) the need for 30 entries in BRL-I trials.

4.16.7 Decision on the proposal was therefore deferred.

Agenda Item 4.17 to 4.30

Discussions on the agenda items 4.17 to 4.30 were deferred due to paucity of time. It was decided to consider these agenda items during the next GEAC meeting tentatively scheduled for 12th May 2014.

****