

Minutes of 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

List of the participants is annexed as Annex 1

1.0 At the outset, the Chairman welcomed all the Members and explained the reasons for delay in sending the agenda and agenda notes for the meeting. He informed that the Supreme Court hearing in the matter of Writ Petition (Civil) 260/2005) filed by Ms Aruna Rodgries and others vs UoI had commenced on 22.04.2014 and was to continue on 23.04.2014 and 24.04.2014. As the subject matter of the hearing was specific to whether GM crop field trials should be allowed or not, any orders emanating from the hearing would have had implications on the GEAC decisions. It was therefore decided to defer issuing the agenda and agenda notes till 24.04.2014. In the absence of any order or ban on GM crop field trials, it was decided to hold the GEAC meeting as scheduled. Some of the members were of the view, in future, if issues like this comes before the GEAC meeting, then it is better to postpone the meeting and reschedule the same at short notice for proper evaluation of the applications. Chairman, informed that most members are very busy and unable to attend meetings at short notice which as per earlier experience had led to absence of quorum. Besides several members had already made their bookings. He requested the Members that having come so far, it would be better to go through the applications one by one and take up as many agenda items as considered appropriate / possible by the Committee. The remaining could be taken up in next meeting. All members agreed with the Chairman's suggestion. Chairman then invited Member Secretary, GEAC to take up the agenda items for discussion.

Agenda Item No 1 Leave of absence

The Committee granted leave of absence to Shri Bishwanath Sinha, Joint Secretary, and Vice Chair, GEAC, Dr O. P. Govilla, Dr B. Sesikeran and Dr V. V. Ramamurthy as requested by them.

Agenda Item No 2: Confirmation of minutes of the 118th GEAC held on 21.4.2014.

2.1 Minutes of the 118th GEAC meeting were confirmed without any amendments.

2.2 One of the Members raised the issue of placing the minutes of the meeting on the GEAC website and sought clarification for discontinuing with the earlier practice. Chairman informed that it has been decided to place information on the decisions taken in the GEAC meeting only after its ratification in the next meeting. It has been further decided to post only a brief note on the decisions of the previous meeting and agenda for the present meeting instead of the verbatim proceedings. If anyone desires to have the detailed records, they can obtain the same through Right to Information Act, 2005.

Agenda Item No 3: Action taken report on the decisions taken in the 118th GEAC meeting held on 21.3.2014.

3.1 The Committee noted that decisions taken in the 118th GEAC meeting held on 21.3.2014 have been communicated to the project proponent, concerned government departments and other agencies.

3.2 It was informed that all communications sent to the applicant for obtaining NOC from the State Government have been also marked to the respective State Department of Agriculture. In addition a communication will also be sent to the Chief Secretary of the State by Chairman GEAC informing the decision to conduct allow field trials with GM crops subject to NOC from the State.

3.2 At the request of one Member, Member Secretary, RCGM briefly explained the monitoring protocols and compliance monitoring currently being followed. He informed that as per Rules 1989, BRL-I trials falls under aegis of RCGM. Therefore monitoring is organized by DBT. The Monitoring Team consist of Members having multi-disciplinary expertise from State Agricultural University, ICAR, IARI and representatives from RCGM / GEAC / State Department of Agriculture. In respect of BRL II trials, the monitoring is undertaken by MoEF.

3.3 As some members are new to GMO regulations, it was also agreed that copies of the relevant Act, Rules and Guidelines along with the web-links will be made available to the Members. It was also decided Member secretary RCGM and GEAC will make a presentation on the biosafety framework pertaining to the mandate assigned to each committee and procedure followed under Rules 1989 for safety assessment including field trials and compliance monitoring.

3.4 Prof Veluthambi, Co-Chair referring to a concept note prepared by Dr Renee Borges regarding additional mechanism for evaluation of bio-safety in the context of eco-system management, suggested that Dr Borges may be requested to make a presentation in this regard to the GEAC. Member Secretary GEAC informed that MoEF has recently constituted an Environmental Risk Assessment Committee under the Chairmanship of Prof C. R. Babu and suggested that to begin with, it would be the appropriate forum to discuss this issue. It was agreed that the concept note prepared by the Dr Borges may be presented and considered by the ERA Committee.

3.5 One of the Members pointed out that a policy decision on the use of antibiotic resistance marker gene in food crops is pending consideration of the GEAC. It was noted that Dr. Ramesh Sonti had prepared a base paper with various options which could be taken up for discussion in the GEAC meeting. One of the Members pointed out that policy decisions on such matters is undertaken through an inter-ministerial consultations and does not fall under the mandate of GEAC.

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.

4.1.3 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.

4.1.4 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.

4.1.5 The Committee also took note of the field experiment design and proposed isolation measures as given under:

- Randomized Complete Block Design with three replications will be used.
- An isolation distance of 200 meters from the periphery of the outermost row of HT rice would be maintained.
- A fence will be put in place outside the trial site.

Treatments: The trials will be conducted with a total of 18 treatments as follows:

Seven HT rice hybrids incorporating *cp4epsps* genes (event OS-A17314) sprayed with Roundup herbicide:

- Suruchi MRP 5401 RR, Suruchi MRP 5402 RR, Suruchi MRP 5403 RR, MRP 5629 RR, Suruchi MRP 5632 RR, Suruchi MRP 5633 RR and Suruchi MRP 5634 RR
- Seven non-transgenic counterparts of HT rice hybrids : (manually weeded)
- Two national checks (Non –transgenic rice hybrids) viz PA 6129 and KRH-2 Manually weeded
- Two local checks (Non –transgenic rice varieties/hybrids): Manually weeded.

Observations to be recorded:

- Number of weeds per unit (1sq m) and species wise initial weed count from the unit area will be noted before each Roundup spray. Observations will be recorded by placing quadrant randomly at 3 different places in each treatment.
- Visual observations on herbicide treated plots for yellowing, scorching and wilting will be recorded at 4,7,14 and 21 days after each treatment.
- Agronomic parameters
- Entomological observations
- Plant diseases
- Indicators of changes in weediness potential:
- Number of panicles produced perplant

4.1.6 The Committee considered the following Information on the gene construct and transformation method:

(i) Plasmid description: PV-TXGT10 binary vector carrying two copies of *cp4 epsps* gene. (i) One copy of the *cp4 epsps gene* is between *ract1* promoter and NOS termination sequence and (ii) Second copy of the *cp4 epsps gene* is between CaMV e-35S promoter and NOS termination sequence.

(ii) Transformation: Agrobacterium-mediated transformation

4.1.7 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.

4.1.8 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 ;

4.1.9 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 IFa I* gene for development of Fruit & Shoot Borer (FSBR) resistant Brinjal expressing *Cry 1Fa 1* gene 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 took note of the field experiment design and proposed isolation measures as given below:

- the trials will be conducted at three replications with Randomized Block Design (RBD) at company's own land.
- the trials will be surrounded by a guard row of non-transgenic brinjal. The proposed trials will be separated from other experimental trials.
- distance to the nearest cultivated crop of the same species 1k.m.
- distance to the nearest commercial crop of any kind- 1 km.
- the Trial site is protected with either compound wall or by fencing so as to prevent gazing animals.
- no herbicide will be sprayed.
- for control of sucking pest2 sprays of imidocloprid 17.8 SL @0.8 ml/1;2 sprays of Thiamethoxam @ 25% WPO.6ml/1; Acetamiprid 20% SP would be sprayed.

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

- (i) Plasmid description: The gene cassette containing the *cry 1Fa 1* gene with 35 S promoter and OCS terminator was cloned in the MCS region exactly at EcoR/Hind III restriction site.
- (ii) Transformation method: Agrobacterium mediated transformation

4.4.5 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.

4.4.6 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 m² (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 took note of the field experiment design and proposed isolation measures as given below:

- ❖ Spatial reproductive Isolation distance of 200 m and Guard rows will be maintained.
- ❖ Isolation distance will be maintained either by planting guard rows of non-regulated plants of similar variety to act as a pollen trap or by planting other sexually incompatible crop.
- ❖ The trials boundaries will be marked according to the trial protocol. The four corners of the trial sites will be maintained with physical landmarks suitable to permit identification and facilitate subsequent inspection and harvesting. (e.g. fence post, PVC piping)
- ❖ Distance to the nearest cultivated crop of the same species 200 mts.
- ❖ Distance to the nearest natural ecosystem – 200 mts.
- ❖ The Trial site will be monitored at least once every two weeks from time of planting until the time of harvest of trial site.
- ❖ The record of spatial isolation will be used to document all monitoring and field activities needed to demonstrate reproductive isolation of the trial site. The growth stage of any prohibited plants found on the trial site will be recorded during monitoring.

➤ Description of the field Trial:

- ◆ Total entries -19
- ◆ No of rows/entry -2
- ◆ Replication-2
- ◆ Row-row spacing -20 cm
- ◆ Spacing between plants within row-15 cm
- ◆ Total plot size-72m²
- ◆ Salinity level- 5000-6000 Us/cm.

➤ Data to be collected:

- Trial Record Data.
- Salinity Profile during the season and

➤ Data will be used to Observe:

- Salinity tolerance of transgenic rice
- Comparative tolerance to Salinity by non-transgenic counterpart
- Other characteristics such as growth habit, life cycle, biomass, yield and other biotic and abiotic stresses will be evaluated in the study of reproductive and survival biology.

4.5.4 The Committee considered the following Information on the gene construct and transformation method:

(i) Plasmid description:

The gly I gene is from Brassica Juncea and gly II gene is from Pennisetum glaucum. Both the genes are driven by 35SCaMV promoter.

Details of the Vector Map: glyI+glyII –pCAMBIA1304-Gly

The plasmid contains glyoxalase 1 (557bp long) and glyoxalase II (1.0Kb long) c DNAs cloned together in the pCAMBIA1304background with kanamycin as the bacterial selection marker, hygromycin as the plant selection marker and gfp+gus fusion as the reporter gene.

(ii) Transformation method: Agrobacterium mediated transformation

4.5.5 The Committee noted that the product contains two addition marker genes *gfp+gus* and reiterated its opinion expressed in the 101st meeting held on 9.6.2010 wherein it was stated that the presence of gratuitous gene such as *gus* in the food crops, may not be considered for environmental release as the biosafety issues that are to be addressed in respect of such transgenic crops are more complex as the transcriptional factors are known to trigger production of a large number of proteins downstream. These issues need to be further discussed and guidelines for biosafety testing need to be developed.

4.5.6 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.

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

4.5.8 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.

4.5.9 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 m² (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 took note of the field experiment design and proposed isolation measures as given below:

- Spatial reproductive Isolation distance of 200 m and Guard rows will be maintained.
- Isolation distance will be maintained either by planting guard rows of non regulated plants of similar variety to act as a pollen trap or by planting other sexually incompatible crop.
- The trials boundaries will be marked according to the trial protocol. The four corners of the trial sites will be maintained with physical landmarks suitable to permit identification and facilitate subsequent inspection and harvesting. (e.g. fence post, PVC piping)
- Distance to the nearest cultivated crop of the same species 200 mts.
- Distance to the nearest natural ecosystem – 200 mts.
- The Trial site will be monitored at least once every two weeks from time of planting until the time of harvest of trial site.

- The record of Spatial isolation will be used to document all monitoring and field activities needed to demonstrate reproductive isolation of the trial site. The growth stage of any prohibited plants found on the trial site will be recorded during monitoring.
- Description of the field Trial:
 - ◆ Total entries -8
 - ◆ No of rows/entry -2
 - ◆ Replication-2
 - ◆ Row-row spacing -20 cm
 - ◆ Spacing between plants within row-15 cm
 - ◆ Total plot size-25m²
- Data to be collected: At each time point randomly 5 plants will be selected to take observation. Data will be used to observe:
 - Drought tolerance of transgenic rice
 - Comparative tolerance to drought by non-transgenic counterpart, resistant and susceptibility checks.
 - Other characteristics such as growth habit, life cycle, biomass, yield and other biotic and abiotic stresses will be evaluated in the study of reproductive and survival biology.

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

(i) Plasmid description: The *dreB* gene is cloned from *oryza sativa* and it is driven by *rd29a* promoter from *oryza sativa*.

Details of the Vector Map: pGreen0179-Osdreb

pGreen0179-RD 29A-OsDREB2-Poly A

(ii) Transformation method: Agrobacterium mediated transformation

4.6.5 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.

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

4.6.7 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 m² 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 took note of the field experiment design and proposed isolation measures as given below::

- ❖ 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.
- ❖ Distance to the nearest crop of the same species will be 50m
- ❖ Distance to the nearest commercial crop of any will be 50m

4.7.4 The Committee noted the following information on the gene construct and transformation method:

1. Plasmid description: Synthetic gene *Bt cry1F* (1.851kb) was cloned into pBinAR binary vector. BinAR, Bin19 derivative (binary vector: M. Bevan (84) NAR12,8711) containing expression cassette for constitutive expression of chimeric transgene in plants. Expression cassette cloned into Hind-III/Eco RI sites of Bin19.
2. Transformation: Agrobacterium-mediated transformation was used as the method of insertion of the gene of interest into the plant genome.

4.7.5 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.

4.7.6 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 arboreum* 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 arboreum* 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 took note of the field experiment design and proposed isolation measures as given below:

- ❖ Spatial reproductive Isolation distance of 50 m will be maintained.
- ❖ Unreplicated design will be followed.
- ❖ Five rows of non-transgenic cotton will be planted around the plot. Apart from the top rows, isolation distance as prescribed for cotton crop will be maintained.
- ❖ Non transgenic cotton hybrids would be planted as check and as top rows.
- ❖ Distance to the nearest cultivated crop of the same species 50 mts.
- ❖ Distance to the nearest natural ecosystem – 100 mts.
- ❖ No insecticide sprays will be given to control *Helicoverpa armigera*.

• Description of the field Trial:

- ❖ Total entries - 8
- ❖ No of treatments -8 (7 transgenic events + 1 non- transgenic counterpart)
- ❖ No of rows – Each 5 rows of 6 m length
- ❖ Spacing - 90 cm x 20 cm

• Scoring/grading based on field incidence will be done to identify best event. Insect bioassay will also be carried out in vitro to identify the best event

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

- (i) Plasmid description : pBIN Bt 3.
- (ii) Transformation method: Agrobacterium mediated transformation

4.8.5 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.

4.8.6 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.

4.8.7 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 arboreum* 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 .

4.9.3 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.

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

- Spatial reproductive Isolation distance of 50 m will be maintained.
- Unreplicated design will be followed.
- Five rows of non-transgenic cotton will be planted around the plot. Apart from the top rows, isolation distance as prescribed for cotton crop will be maintained.
- Non transgenic cotton hybrids would be planted as check and as top rows.
- Distance to the nearest cultivated crop of the same species 50 mts.
- Distance to the nearest natural ecosystem – 100 mts.
- No insecticide sprays will be given to control *Helicoverpa armigera*.

Description of the field Trial:

- Total entries -13
- No of treatments -13 (12 transgenic events + 1 non- transgenic counterpart)
- No of rows – Each 5 rows of 6 m length
- Spacing - 90 cm x 20 cm

Scoring/grading based on field incidence will be done to identify best event. Insect bioassay will also be carried out in in vitro to identify the best event

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

- (i) Plasmid description : pBIN Bt 3.
- (ii) Transformation method: Agrobacterium mediated transformation

4.9.6 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.

4.9.7 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.

4.9.8 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 .

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.

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

- ❖ Spatial reproductive Isolation distance of 50 m will be maintained.
- ❖ Unreplicated design will be followed.
- ❖ Five rows of non-transgenic cotton will be planted around the plot. Apart from the top rows, isolation distance as prescribed for cotton crop will be maintained.
- ❖ Non transgenic cotton hybrids would be planted as check and as top rows.
- ❖ Distance to the nearest cultivated crop of the same species 50 mts.
- ❖ Distance to the nearest natural ecosystem – 100 mts.
- ❖ No insecticide sprays will be given to control *Helicoverpa armigera*.
- ❖ Description of the field Trial:
 - ✓ Total entries -25
 - ✓ No of treatments -25 (24 transgenic events + 1 non- transgenic counterpart)
 - ✓ No of rows – Each 5 rows of 6 m length

✓ Spacing - 90 cm x 20 cm

Scoring/grading based on field incidence will be done to identify best event. Insect bioassay will also be carried out in vitro to identify the best event

4.10.5 The Committee observed the following information on the gene construct and transformation method:

- (i) Plasmid description : pBIN Bt 3.
- (ii) Transformation method: Agrobacterium mediated transformation

4.10.6 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.

4.10.7 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.

4.10.8 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 *Spodoptera 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 took note of the field experiment design and proposed isolation measures as given below:

- ❖ Spatial reproductive Isolation distance of 50 m will be maintained.
- ❖ RBD with 4 replications design will be followed.

- ❖ Five rows of non-transgenic cotton will be planted around the plot. Apart from the top rows, isolation distance as prescribed for cotton crop will be maintained.
 - ❖ Non transgenic cotton hybrids would be planted as check and as top rows.
 - ❖ Distance to the nearest cultivated crop of the same species 50 mts.
 - ❖ Distance to the nearest natural ecosystem – 100 mts.
 - ❖ No insecticide sprays will be given to control *Helicoverpa armigera* and *Spodopetra litura* .
- Description of the field Trial:

No of treatments -5
 - ✓ Treatment 1. BNAcF
 - ✓ Treatment 2. BNAc
 - ✓ Treatment 3. BNF
 - ✓ Treatment 4. BN(non Bt)
 - ✓ Treatment 5. Local check (non-Bt).
 - No of rows – Each 4 rows of 6 m length
 - Spacing - 90 cm x 20 cm

Scoring/grading based on field incidence will be done to evaluate effectiveness of BNAcF event in controlling both *Helicoverpa armigera* and *Spodopetra litura*. Insect bioassay will also be carried out in in vitro to validate the field results.

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

- (i) Plasmid description: pBIN Bt 3 for cry 1Ac and pGreen for cry 1F (pGreen cdn1+npt II, cryIF Cassettes
- (ii) Transformation method: Agrobacterium mediated transformation

4.11.5 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.

4.11.6 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.

4.11.7 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*.

4.11.8 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 as given below:

T01 MAH-21501, T02 MAH-21502, T03 MAH-21503, T04 MAH-21504, T05 MAH-21505, T06 MAH-21506, T07 MAH-21507, T08 MAH-21508, T09 MAH-21509, T10 MAH-21510, T11 MAH-21511, T12 MAH-21512, T13 MAH-21513, T14 MAH-21514, T15 MAH-21515, T16 MAH-21516, T17 MAH-21517, T18 MAH-21518, T19 MAH-21519, T20 MAH-21520, T21 MAH-21521, T22 MAH-21522, T23 MAH-21523, T24 MAH-21524, T25 MAH-21525, T26 Non-transgenic counterpart, T27 Moroberakan (tolerant check) and T27 Moroberakan (tolerant check) 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 took note of the field experiment design and proposed isolation measures as given below:

- ❖ Split plot design. Water stresses will be assigned into main plots and different entries in to subplots for higher precision.
- ❖ Top rows of non-transgenic rice will be planted in the perimeter of the trial area, up to a distance of 5 m. There will be a gap of 2 m between trial area and the trap rows.
- ❖ An isolation of 3 meters (since the background of the events is an inbred line) from the periphery of the outermost trap row will be maintained all around the trial site (as per Indian Minimum Seed Certification Standard) for rice varieties).
- ❖ Plants will be germinated in 98 well plastic germination trays and grown there till the three leaf stage. After 4 weeks, plants will be transplanted in to the fields.
- ❖ For growth and yield under stress in vegetative stage, watering will be withhold around pre –anthesis (maximum tillering stage and booting stage, 80-90 DAS), the stress will be continued till soil moisture level reaches 30% across the plot as well as water stress symptoms are prominently visible like leaf rolling and leaf tip burning.
- ❖ The yield penalty on the non-transgenic control liner in the water stressed basin should be in the range of 30- 40% of the control line in the normally irrigated basin. The acceptable limits of yield penalty are 10-60% of the total line in the irrigated basin.
- ❖ During the trial, standard rice growing practices will be followed in all treatments, and observations on stress-related symptoms such as leaf rolling and tip burning will be recorded along with plant height, tiller number, days to flowering, panicle number, seed setting rate, seed moisture, and total grain yield.
- ❖ Total grain yield per plant in water stressed versus control plots will be used as the measure for event performance. Plants will be harvested individually. Efficacy will be defined as events with significant grain yield increase ($p < 0.1$), as compared to the non transgenic counterpart (sibling null control).

- **Observations:**

- A. Yield and other agronomic parameters
- B. Entomological observations
- C. Observation on diseases

4.12.4 The Committee considered the information on the gene construct and transformation method is as follows:

- (a) Plasmid description:**
1. IPTpMLB41pSB1 carrying the IPT gene with SARK promoter & NOAS polyA terminator
 2. pC1301 carrying *GUS* and *hpt* (selectable marker)
- Both these plasmids are placed in the single *Agrobacterium* strain LBA 4404 (One *Agrobacterium* strain containing two plasmids).
- (b) Transformation:** *Agrobacterium* -mediated transformation

4.12.5 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.

4.12.7 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.

4.12.8 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.

4.13.4 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.

4.13.5 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 the 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 Coccinellids and spiders on the *Bt* maize and non-*Bt* plants

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

- Replicated complete block design with 6 treatments
- 12 rows/treatment with 40 plants/row
- Row – row distance: 60 cm; plant-plant distance: 20 cm
- 13 perimeter rows of African tall maize.

4.13.7 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.

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

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

4.13.9 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.

4.13.10 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.

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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. The Committee further noted that the RCGM considered both the above requests in its meetings held on 30.08.2011 and 26.6.2012 respectively and approved only the protocol for conducting feeding study in lactating cows with the suggestion to ensure that the presence of both the transgenic proteins is tested in the milk of the cows. The RCGM deferred the permission for production of forage under confined conditions of transgenic corn hybrid 900M Gold (MON 89034XNK603) at NDRI, Karnal on want of recommendations of IBSC of NDRI. Subsequently the proposal was reconsidered and recommended by RCGM in the meeting held on 28.8.2012.

4.14.4 The Committee also noted that transgenic maize hybrid (Events MON 89034 x NK603) and its conventional counterpart hybrid will be grown at NDRI, Karnal in a staggered manner so that fresh fodder (40-50 day plant) can be collected at regular intervals during the course of the feeding study. No transgenic material will be left at the end of the study. Projected requirement of fodder is approximately 10 kg/animal/day along with the feed concentrate (approx 150 kg transgenic corn grain for the 28 day feeding period). Therefore, 2800 kgs approximately of test material forage will be required to feed 10 animals for 28 days. The representative of NDRI was informed that adequate land for generating fodder material and infrastructure for conducting the feeding studies is available at NDRI.

4.14.5 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. Respective maize forage will be provided daily to each cow in weighed amount at a stipulated time. The performance of lactating dairy cattle consuming the transgenic maize forage will be compared with those observed in cows consuming the non-transgenic near-isogenic control forage. Performance of cows that are fed forage from non-transgenic commercially available reference maize hybrids will be used to interpret the biological significance of the statistical comparisons.

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 It was also noted that the transgenic maize hybrids containing the combined traits TC1507 (Dow Agro) x NK603(Monsanto) were produced by crossing individual maize (*Zea mays* L.) lines containing TC1507 and NK603 events using conventional breeding methods. The company has given agreement with Dow Agro (TC1507) and Monsanto (NK603).

4.15.4 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

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

- ❖ A spatial isolation distance of 300 mts will be maintained from other nearest maize crop
- ❖ All regulatory conditions of RCGM including SOP for conduct of confined field trials will be followed

4.15.6 The Committee noted that the fodder requirement is 35 kg/cow/day. With 10 cows/group, fodder required will be 350 kg/day and 19.6 tons for the duration of 8 weeks (56 days). Total requirement for 4 groups is 78.4 tons for the entire feeding duration of 8 weeks. To ensure enough supply, staggered cultivation in 8 + 2 = 10 weeks is planned.

4.15.7 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.

4.15.8 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.

4.15.9 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), National check NHH44	JAU, Junagadh/NAU, Navsari/MBKV, Rahuri/MAU, Parbhani/DPAKV, Akola/ Bayer BioScience, Rajkot/ Bhavnagar/Yavatmal
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 took note of the field experiment design and proposed isolation measures as given below:

- Distance of 50 m will be maintained from any sexually compatible/ cotton crop.
- Details of the trial design:

The Trial Design:	Complete randomized block
No. of entries:	10
Replications:	3

4.16.5 The Committee considered the information that the Experimental seed production will be done on the following hybrids for further testing the above in BRL-1 (2nd year) trials. Details of the hybrids are as follows: SP7149GLT, SP7230GLT, SP7343GLT, SP7230GTL, SP7007GLT and SP7010GTL in South Zone.

4.16.6 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.

4.16.7 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.

4.16.8 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.

4.16.9 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.

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

Annexure- I

List of the Members who attended the 119th GEAC meeting held on 25.04.2014

S. No.	Name and address
1.	Shri Hem Pande, Additional Secretary, Ministry of Environment and Forests and Chairman, GEAC.
2.	Dr K. Veluthambi, Professor (retd) & Head, School of Biotechnology, Madurai Kamraj University, Madurai and Co-Chairman , GEAC .
3.	Prof. C. R. Babu, Centre for Environmental Management of Degraded Ecosystems, School of Environmental Studies, Delhi University New Delhi.
4.	Dr. S.S. Banga, Plant Breeder, Punjab Agriculture University, Ludhiana
5.	Dr. S. R. Rao, Advisor, DBT and Member Secretary RCGM.
6.	Dr. S. K. Apte, , Member, Director, Bio-Medical Group and Head, Molecular Biology Division, BARC, Mumbai
7.	Dr. Swapan Kumar Datta, DDG (Crop Science), Indian Council of Agricultural Research, Krishi Bhawan, New Delhi.
8.	Dr Atanu Purkayastha, Joint Secretary, (Seeds) Department of Agriculture & Cooperation Ministry of Agriculture, Krishi Bhawan, New Delhi
9.	Shri R.K. Mishra, ADC (Seeds) Department of Agriculture & Cooperation Ministry of Agriculture, Krishi Bhawan, New Delhi
10.	Dr. Ramesh Sonti, (Representative of DG, CSIR) Chief Scientist, CCMB Hyderabad
11.	Dr Vijendra Mishra, Associate Professor, National Institute of Food Technology Enterprenuraship of Management (NIFTEM), Sonapat, Haryana
12.	Prof. Akshay Kumar Pradhan, Department of Genetics, University of Delhi, South Campus, Benito Juarez Road, New Delhi
13.	Dr. Renee M Borges, Professor, Centre for Ecological Sciences, Indian Institute of Science, Bangalore.
14.	Dr. Luther Rangreji, Associate Professor, Faculty of Legal Studies, South Asian University, 233, Akbar Bhavan, Chankyapuri, New Delhi.
15.	Dr. Ranjini Warriar, Director, Ministry of Environment & Forests and Member Secretary, GEAC.
16.	Smt. Madhu Gupta, Research Officer , MoEF
Special Invitee	
17.	Dr. P.M.Bhargava, Former Director ,CCMB, Hyderabad