**Decisions taken in the 116th meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 11.04.2012**

The 116th meeting of the GEAC was held on 11.4.2012 in the Ministry of Environment & Forests under the chairmanship of Shri M.F. Farooqui, Special Secretary, MoEF and Chairman, GEAC.

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

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

**4.1 Permission to conduct event selection trials on stacked transgenic Cotton [TwinLink® (events namely GHB119 (*cry2Ae & pat*) and T304-40 (*cry1Ab & pat*)) x GlyTol® (GHB 614 (*2mEPSPS*)) event] in the North, Central and South zones by M/s. Bayer BioScience Pvt. Ltd., Gurgaon**.

4.1.1 The Committee considered the application of M/s. Bayer BioScience Pvt. Ltd., to conduct event selection trials on stacked transgenic Cotton [TwinLink® (events namely GHB119 (*cry2Ae & pat*) and T304-40 (*cry1Ab & pat*)) x GlyTol® (GHB 614 (*2mEPSPS*)) event] in the North, Central and South zones at company's long leased land. The trials will be conducted at one location in each zone namely Bhatinda / Sirsa in North Zone; Rajkot / Aurangabad in Central Zone and Medak / Rangareddy in South Zone at company's long leased land. The size of the trial will be 4000 sq m./ trial location.

**NZ –** SP7007 GLT, SP7010 GLT, SP1169 GLT, SP7114 GLT, SP139 GLT, National check and Zonal check.
**CZ -** SP1171 GLT, SP7149 GLT, SP7157 GLT, SP7230 GLT, SP7152 GLT, SP7139 GLT, SP7195 GLT, SP7156 GLT, SP503 GLT, National check and Zonal check
**SZ -** SP1171 GLT, SP7149 GLT, SP7157 GLT, SP7230 GLT, SP7152 GLT, SP7139 GLT, SP7195 GLT, SP7156 GLT, SP503 GLT, National check and Zonal check.

4.1.2 The Committee recorded the following objectives of the trials:

- Evaluate the efficacy against *Lepidopteran* pests, herbicide Glyphosate & Glufosinate tolerance and agronomic performance of TL+GT cotton Hybrids)
- Evaluate the insect resistant & herbicide tolerant cotton hybrids containing cry 1Ab, cry 2Ae, bar and *2mEPSPS* gene event under confined field trial at two locations each in NZ,CZ and SZ.
- Generate data on phytotoxicity, insect bio-efficiacy, herbicide tolerance, weed control, effect on plant growth and yield, protein expression of different plants stage etc.

4.1.3 The Committee also noted the following details of the field experiment and proposed isolation measures:

- Replicated Randomized Complete Block Design will be used.
- The trials is surrounded by a conventional cotton hybrid (pollen trap) 5 m and a spatial isolation of 50 m.
- A fence will be put in place outside the pollen trap in order to prevent non authorized entry.
- Herbicide treatment will be foliar, over-the-top application of glufosinate.
- Need based spray of registered pesticides will be done.

4.1.4 The Committee also noted that the proposal has been recommended by the IBSC and RCGM in the meeting held on 27.12.2011.

4.1.5 The Committee considered the following information/ clarifications submitted by the applicant. :

(i) The trial is for efficacy against both glyphosate and glufosinate. This is a part of the strategy to pyramid herbicide tolerance genes for enhanced weed control as well as for more effective weed resistance management by rotation of herbicides.

(ii) The experimental protocol has a typo error on pg.3, Table 2 where glyphosate has been mentioned in both columns for herbicide application. Here one of the columns should be read as 'application of glufosinate' as in Table 1 on pg. 2. Further the detailed timing and dose of herbicide application for both glufosinate and glyphosate is mentioned on pg.4 (Table 3 and 4).

(iii) Glufosinate is registered in India for use as a herbicide on Tea and recently its use on Cotton as a weed control agent has also been approved. The application of glufosinate on non-transgenic cotton plants. The registration detail for glufosinate as a herbicide in Tea and the minutes of Central Insecticide Board and Registration Committee (CIB & RC) meeting to register it as a herbicide on cotton would be submitted.

(iv) Genes conferring tolerance to glufosinate ammonium occur naturally in several genera of common soil micro-organisms (bacteria). Many of these organisms also naturally produce L-phosphinothricin, the L-isomer (active form) of phosphinothricin (aka glufosinate ammonium). Therefore, soil micro-organisms would be exposed to phosphinothricin in their natural environment. Recently, the effect of glufosinate on soil micro-environment was assessed for registration of glufosinate on cotton. The study was conducted by International Institute of Bio-Technology & Toxicology (IIBAT) and it highlights that application of glufosinate does not cause any detrimental impact on soil microbes. The detailed study would be submitted.

4.1.6 During the deliberations, the Committee also gave an opportunity to the representative of M/s Bayer Bioscience Pvt Ltd to provide clarification on the following :

1) As the events are already established, does this trial qualify as event selection trial?
2) What is the purpose of this trial?
3) How are the hybrids being evaluated in this trial and what is the BC progeny of parents that have been crossed?
4) Details of the hybrids being tested.

4.1.7 The following clarifications were provided:

i. The trial is not for event selection. It is a Research Strip Trial (RST) for the purpose of hybrid evaluation. The covering letter for application from us clearly mentions that this is a RST however; the RCGM online application format does not have an option for mentioning RST. It only has an option to mention event selection.

ii. The purpose of this trial is to select best performing hybrids for taking up BRL trials in the three zones.

iii. The hybrids were developed by introgression of transgenic traits in parent lines by back cross breeding. The backcrossing program, conducted in greenhouse, was approved by the IBSC and RCGM. BC3 or more advanced progenies of parents were stabilized for the traits and the phenotypes for two generations and then used for developing hybrids.

iv. The details of the hybrids being tested is provided in the RCGM application at pg.42.

4.1.8 After a brief discussion on the matter, it was decided that the applicant may be advised to resubmit the application for hybrid evaluation trials instead of event selection trial. Accordingly, decision on the proposal was deferred.

**4.2 Permission to conduct Biosafety Research Level-1 (BRL-1) trials and experimental seed production of transgenic TwinLink® Cotton hybrids containing stacked events namely GHB119 (*cry2Ae/PAT*) & T304-40 (*cry1Ab/PAT*) containing *cry1Ab*, *cry2Ae* and *bar* genes in the North, Central and South zones by M/s. Bayer BioScience Pvt. Ltd., Gurgaon.**

4.2.1 The Committee considered the application of M/s. Bayer BioScience Pvt. Ltd., to conduct BRL-1 trials and seed production trials of transgenic TwinLink® Cotton hybrids containing stacked events namely GHB119 (*cry2Ae/PAT*) & T304-40 (*cry1Ab/PAT*) containing *cry1Ab*, *cry2Ae* and *bar*

genes in the North, Central and South zones at company's long leased land. Trials will be conducted at two locations in each zone at Ludhiana/ Bhatinda / Hisar/Sirsa in North Zone; Surat/Navsari/Rajkot / Aurangabad in Central Zone and Hyderabad/ West Godavari / Rangareddy/ Medak in South Zone at company's long leased land. The size of the location will be 4000 sq m / trial location.

4.2.2 The Committee noted that the applicant has also requested for experimental seed production in an area of 0.5 acres per hybrid per zone at Chitoor and Ananthapur. GEAC in its meeting held on 6.7.2011 had approved these hybrids for conduct of event selection trials to M/s Bayer BioScience Pvt. Ltd. (vide DBT letter no dated BT/BS/17/06/95-PID dated 06.09.2011).

- South Zone- SP7157TL and SP7149 TL.
- Central Zone- SP1171TL and SP7230TL.
- North Zone- SP7007TL and SP7010TL.

4.2.3 The Committee also noted that the seed production of the above hybrids is necessary for conduct of second year BRL-1 trials as well as initiate feeding studies with appropriate seed material.

4.2.4 The Committee noted the following objectives of the trial:

1. Evaluate the insect resistant & herbicide tolerant cotton hybrids containing *cry1Ab, cry2Ae* and *bar gene* event.
2. Generate data on phytotoxicity, insect bio-efficacy, herbicide tolerance (Glufosinate ammonium) and weed control, effect on plant growth & yield, protein expression of different plant parts of TwinLink® cotton plant at different stages of crop growth.
3. Evaluate efficacy of TwinLink® insecticidal proteins against Lepidopteron pests, agronomic performance and protein expression studies in Twinklink cotton hybrids.

4.2.5 The Committee took note of the proposed field designs and isolation measures:

- Replicated Randomized Complete Block Design will be used.
- The trials is surrounded by a conventional cotton hybrid (pollen trap) 5 m and a spatial isolation of 50 m.
- A fence will be put in place outside the pollen trap in order to prevent non authorized entry.

4.2.6 The Committee also observed that the proposal has been recommended by the IBSC and RCGM on 27.12.2012 and 22.2.2012 respectively.

4.2.7 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to (i) conduct BRL-1 trials of transgenic TwinLink® Cotton hybrids containing stacked events namely GHB119 (*cry2Ae/PAT*) & T304-40 (*cry1Ab/PAT*) containing *cry1Ab*, *cry2Ae* and *bar* genes in the North, Central and South zones; (ii) experimental seed production in an area of 0.5 acres per hybrid per zone at Chittoor and Ananthapur during appropriate seasons in 2012- 2013 subject to submission of NOC from the State Government where the trials will be conducted.

**4.3 Request for extension of the validity of the GEAC approval for the conduct of pollen flow study on GlyTol® cotton (*Gossypium hirsutum*) hybrids namely SP499 G by M/s. Bayer Bio-Science Pvt. Ltd., Gurgaon**

4.3.1 The Committee considered the request for extension of the validity of the GEAC approval for the conduct of pollen flow study on GlyTol® cotton (*Gossypium hirsutum*) hybrids namely SP499 G

4.3.2 The Committee also noted that the GEAC in its meeting held on 6.7.2011 had accorded approval of conduct pollen flow study of GlyTol® cotton hybrid namely SP499G containing 2mEPSPS gene (Event GHB614) at Yavatmal, Maharashtra *d*uring the appropriate season in 2011-2012 subject to submission of NOC from the respective State Department of Agriculture where the pollen flow study would be conducted.

4.3.3 The Committee observed that the applicant has informed that they could not undertake the trials because NOC from Government of Maharashtra was not issued. Therefore, they are requesting to extend the validity period of the pollen flow study during Kharif 2012. They have also indicated two more alternate sites in different states i.e. in Andhra Pradesh and Gujarat for keeping the flexibility of obtaining NOC.

4.3.4 The Committee noted that the approval earlier granted for pollen flow study was with GlyTol® cotton hybrids namely SP499 G. However the present proposal is to conduct the pollen flow study with homozygous parent of the GlyTol® cotton.

4.3.5 During the deliberation, the Committee gave an opportunity to the representative of M/s Bayer to provide clarification on the above. The following points were noted:

"The hemizygous F1 plants will have gametic segregation and as a result of this, the gametic frequency for F1 population will be: 50% null and 50% transgenic gametes/ pollen. Therefore, the exact extent of out crossing by the transgenic plants cannot be assessed using the hybrid for pollen flow study. An accurate account of out crossing can only be done using the homozygous parent which will produce 100% transgenic gamets/ pollen. In our earlier application, the hybrid was erroneously mentioned instead of the homozygous parent.

4.3.6 After a brief discussion on the matter it was decided that the applicant may be advised to submit a fresh application to conduct pollen flow study with homozygous parent of the GlyTol® cotton. Accordingly, decision on the proposal was deferred.

**4.4 Permission to conduct pollen flow study of insect resistant and herbicide tolerant (TwinLink®) stacked cotton events namely GHB119 (*cry2Ae/PAT*) & T304-40 *cry1Ab/PAT*) containing *cry1Ab*, *cry2Ae* and *bar* genes by M/s. Bayer BioScience Pvt. Ltd., Gurgaon.**

4.4.1 The Committee considered the request of M/s. Bayer Bio Science Pvt. Ltd. to conduct pollen flow study of insect resistant and herbicide tolerant (TwinLink®) stacked cotton events namely GHB119 (*cry2Ae/PAT*) & T304-40 (*cry1Ab/PAT*) containing *cry1Ab*, *cry2Ae* and *bar* genes at companies long leased land in an area of maximum 1.5 ha. The trials will be conducted at any one location at Rajkot/Yavatmal/Ranga Reddy during Kharif 2012.The objective of the trial is to evaluate the pollen flow study of TwinLink® cotton in homozygous parental lines carrying event T 304-40+ GHB 119.

4.4.2 The Committee noted that the purpose of the study is to:

- monitor the distance of pollen from a test plot of transgenic cotton on all the sides of the plot.
- measure the distance of pollen flow of insect resistant and herbicide tolerant containing *cry1Ab*, *cry2Ae* and *bar* gene event under the confined field trials.

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

- A spatial isolation distance of 50 m from transgenic border rows to any nearest cotton plants as per the regulatory requirements.
- The trial site will be provided with a fence.
- The field trial will be monitored by field supervisors.
- After completion of trial, biomass will be destroyed by burning.
- Need based spray of registered pesticide will be done.

4.4.4 The Committee noted that the proposal was recommended by the IBSC and RCGM on 27.12.2011and 22.2.2012 respectively.

4.4.5 During the deliberations, one of the members sought clarification on whether the application submitted by the Company is for conducting pollen flow study using a homozygous parent of TwinLink® cotton or hybrid. It was clarified that the application is for conducting pollen flow study

using a homozygous parent of TwinLink® cotton. No previous approval has been given for conducting pollen flow with hybrids.

4.4.6 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct pollen flow study using a homozygous parent of TwinLink® cotton during appropriate seasons in 2012 at any one location at Rajkot/Yavatmal/Ranga Reddy subject to submission of NOC from the State Government where the pollen flow study will be conducted

**4.5 Permission to conduct event selection trials on 45 transgenic rice (*Oryza sativa*) four events containing dual Bt ( *cry1Ab & cry1Ca*) and bar gene; 17 events with dual Bt and LLRice 62 with bar and 23 events containing *cry1Ab, cry1C* and *cry2Ad* gene at North Zone, Central Zone and South Zone by M/s. Bayer Bioscience Pvt. Ltd., Gurgaon.**

4.5.1 The Committee considered the request of M/s. Bayer BioScience Pvt. Ltd., to conduct event selection trials on 45 transgenic rice (*Oryza sativa*) four events containing dual Bt ( *cry1Ab & cry1Ca*) and bar gene; 17 events with dual Bt and LLRice62 with bar and 23 events containing *cry1Ab, cry1C* and *cry2Ad* gene at **North Zone** (Rajasthan / U.P. (non-basmati zone), **Central Zone** (Anand/ Surat/ Vadodara/ Panchmahal,/Nagpur,/Chandrapur/ other rice growing districts of Gujarat/ Maharashtra/M.P.) and **South Zone** respectively (Crop Development Centre, Medak (Andhra Pradesh) / Eluru/ Coimbatore/Trichy/Madurai (Tamil Nadu) / other rice growing districts of Orissa/ Kerala) in an area of one acre in each location at company's long leased land.

4.5.2 The Committee noted details of the events as given below:

(i) **4 events containing dual Bt *cry1Ab, cry1Ca* and *bar* gene –** RICE 1551, RICE 1552, RICE 1557, RICE 1558,

**(ii) 17 events containing dual Bt and LLRice 62 with *bar* gene-**

RICE 1576, RICE 4001, RICE 4002, RICE 4003, RICE 4004, RICE 4016, RICE 4019, RICE 4024, RICE 4026, RICE 4101, RICE 4102, RICE 4103, RICE 4104, RICE 4116, RICE 4118, RICE 4201, RICE 4205, LLRICE62

(iii) **23 events containing *cry1Ab, cry1C* and *cry2Ad gene** –** MP-38H-95-8-12, SK-40H-95-5-419, SK-40H-95-7-691, SK-40H-95-7-692, SK-40H-95-7-849, SK-40H-95-5-602, N-H39-95-7-94C, H39-5-76B, N-39-95-11-18, H39-12-72, H43-4-91A, 16BT43+HSGE-14, P43-H-10-32,P-43H-9-15, SK-43H-95-11-1777, SK-43H-95-12-1761, SK-43H-95-13-1828, SK-43H-95-7-964, SK-H43-95-12-1755, SK-H43-95-13-1817, SK-H43-95-5-284, SK-H43-95-5-359, SK-H43-95-6-724. (*23 events containing cry1Ab, cry1C and cry2Ad gene have been transferred from Dupont India Pvt. Ltd. to Bayer BioScience Pvt. Ltd. through MTA approved from RCGM vide letter dated BT/BS/17/06/95-PID dated 26.04.2011.

4.5.3 The Committee also noted that the purpose of the trial is to:

- Evaluate and select superior Bt events in comparison to non-transformed genotype for agronomic parameters, seed producibility, restoration capacity, herbicide tolerance and insect efficacy).
- Generate data on days of flowering, No. of tillers and panicles, plant height, seed set 100%, insect efficiency, seed producibility herbicide efficacy, seed producibility, herbicide efficacy and restorability.

4.5.4 The Committee further noted that the following isolation measures are proposed:

- Randomized Complete Block Design with three replications.
- A spatial isolation distance of more than of 200 m from any nearest cultivated crop of the same species.
- The trial site will be provided with a fence.
- After completion of trial, biomass will be destroyed by burning.

- Each trial will be marked with board till post harvest monitoring period and corner poles with flag.
- All the pesticide to be used is registered in India for use in rice crop (or to be used for experimental purpose only).

4.5.5 The Committee also observed that the proposal was recommended by IBSC and RCGM on 27.12.2011 and 22.2.2012 respectively.

4.5.6 During the deliberations, one of the experts pointed out that under the plasmid description the applicant has indicated that "two genes are inserted by the T-DNA being transferred to the plant genome by the *Agrobacterium"* whereas in the application, the event selection trials are with the six genes. The Committee was of the view that the applicant may be advised to submit clarification on the above discrepancy. Accordingly decision on the proposal was deferred.

**4.6 Permission to conduct field trials of Glytol® cotton hybrid for herbicide registration of glyphosate 41% SL on glytol cotton namely SP 7017G (North zone) and SP 7230G (South and Central zone) containing *2mEPSPS* (event GHB614) by M/s. Bayer BioScience Pvt. Ltd., Gurgaon.**

4.6.1 The Committee considered the request of M/s. Bayer BioScience Pvt. Ltd., for permission to conduct field trials of Glytol® cotton hybrid for herbicide registration of glyphosate 41% SL on glytol cotton namely SP 7017G (North zone) and SP 7230G (South and Central zone) containing *2mEPSPS* (event GHB614) in an area of one acre at each location at company's long leased land during two successive seasons.

- **SP 7017G** (North zone) proposed to conduct at CCS, HAU, Hisar/PAU, Ludhiana/MPUAT, Udaipur.
- **SP 7230G** (South and Central zone) proposed to conduct at AAU, Anand, MPKV, Rahuri, TNAU, Coimbatore, UAS Dharwad/ ANGRAU, Hyderabad.

4.6.2 The Committee also noted that the purpose of undertaking the trials is to study bio-efficacy, phytotoxicity and effect on succeeding crops of Glyphosate 41% SL against mixed weeds in herbicide tolerant GlyTol $^{R}$ cotton containing ***2mEPSPSgene*** at different state Agricultural Universities (SAUs).

4.6.3 The Committee also recorded that objective of the trials is to:

- Evaluate bio-efficacy of Glyphosate 41% SL in transgenic Glytol® Cotton. This would include studies on:
- bioefficacy of Glyphosate 41%SL against weeds in Glyphosate tolerant transgenic Cotton (GlyTol®).
- effect on yield i.e total yield at harvest in Kg/ha
- phyto-toxic effect of on the top application of Glyphosate 41%SL on transgenic Glytol® cotton.

4.6.4 The Committee observed that to evaluate the recommended dose (X) and double of the recommended dose (2X) of Glyphosate 41% SL would include the following studies to assess:

- phytotoxicity to Glyphosate tolerant transgenic Cotton
- harvest time residues in cotton seed/ tissue, lint, oil at NRCG, Pune, Maharashtra and soil at IIBAT, Chennai, Tamilnadu
- effect of left over residues of Glyphosate 41% SL on 3 commonly grown succeeding/follow-up crops (1 crop /location) (Wheat, Oilseed crop/ vegetable, pulse crop). (Any Malvaceace family e.g. okra or other sexually compatible crops will not be grown as succeeding crop)
- effect on Physico-chemical & biological properties of soil.

4.6.5 The Committee also noted the following isolation measures as proposed:

- A spatial isolation distance of 50 m from transgenic border rows to any nearest cotton plants will be maintained as per the regulatory requirements.
- The trial site will be provided with a fence.
- The field trial will be monitored by field supervisors.

4.6.6 The Committee also noted that in response to a query on why data required for herbicide registration of glyphosate 41% SL cannot be conducted during BRL –I trials which has been earlier approved by the GEAC' the applicant has clarified that the purpose of herbicide registration trial of glyphosate 41% SL on Glytol cotton is to generate data for submission to Central Insecticide Board & Registration Committee for obtaining label claim for glyphosate 41% SL for its use on Glytol cotton. They have also clarified that although the objectives of the BRL-I trials may look similar, the purpose of the two trials are different. Further, as per guidelines of CIB & RC, registration trial for glyphosate 41% SL on Glytol cotton needs to be conducted at multi-location for 2 years by SAUs. Accordingly, BRL-1 trials for Glytol will be conducted at company's own leased land and the registration trial for glyphosate 41% SL on Glytol cotton has to be conducted by SAUs.

4.6.7 During the deliberation, the Committee gave an opportunity to the representative of M/s Bayer to provide clarification on the following:

1) This trial is for herbicide registration so how does it fall in the purview of GEAC?
2) Wouldn't it be more appropriate to call this bio-efficacy evaluation of glyphosate on GlyTol® cotton?

4.6.8 The following points were noted:

1) In order to use glyphosate on herbicide tolerant GM cotton (GlyTol®), the label claim for glyphosate 41% SL needs to be extended to GlyTol® cotton. In order to get approval for this from Central Insecticide Board (CIB), glyphosate needs to be registered for use on GlyTol® cotton. This registration process has mandatory State Agriculture University testing for bio-efficacy and residual analysis of glyphosate to be performed on GlyTol ® cotton. This trial involves the cultivation of a regulated GM event, therefore, we believe that GEAC's approval for using GlyTol® hybrids for this trial is mandatory. Clarification in this regard had also been sent earlier to GEAC vide our letter dated 28.03.2012.

2) The objective of this trial indeed is to test for bio-efficacy and residual analysis of glyphosate on GlyTol cotton. However, the purpose of this trial is to get approval for over-the-top application of glyphosate on GlyTol® cotton and the data coming from these trials would be submitted to CIB for the respective registration. Hence in order to differentiate this trial from other regulatory field trials, we have specifically named it according to the purpose.

4.6.9 The Committee observed that the purpose of the trial as indicated in the application is to generate data for submission to Central Insecticide Board & Registration Committee for herbicide registration of glyphosate 41% on Glytol cotton. Since this objective does not fall under the purview of GEAC, the application in the present form cannot be considered by the GEAC. In view of the above stated facts, the Committee recommended that the applicant may be advised to submit revised application for conducting trials to assess bio efficacy and residual analysis of the glyphosate 41% SL on Glytol cotton for consideration by the GEAC.

**4.7 Permission to conduct Biosafety Research Level-1 (BRL-1) trials of transgenic corn (*Zea Mays*) hybrids namely NK6240 Bt (Bt11), NK6240 (GA21) and NK6240 Stack (Bt11 X GA21) containing Bt11, GA21 and stack event of Bt11 X GA21 by M/s. Syngenta Bioscience Pvt. Ltd., Pune.**

**&**

**Permission to conduct F1 seed production of transgenic corn (*Zea Mays*) lines containing Bt11, GA21 and Bt11 X GA21 events and seed increase of transgenic corn (*Zea Mays*) lines containing Bt11 and GA21 events during Kharif and Rabi 2012 by M/s. Syngenta Bioscience Pvt. Ltd., Pune**

4.7.1 The Committee considered the request of M/s. Syngenta Bioscience Pvt. Ltd., to conduct BRL-I trials on transgenic corn (*Zea Mays*) hybrids namely NK6240 Bt (Bt11), NK6240 (GA21) and NK6240 Stack (Bt11 X GA21) containing Bt11, GA21 and stack event of Bt11 X GA21 at **12** locations namely; Anand Agriculture University, Gujarat; Haryana Agriculture University, Hissar; Punjab Agriculture University, Ludhiana; MPKV, Rahuri; MPUAT, Udaipur; TNAU, Coimbatore; ANGRAU, Rajendra Nagar; BHU, Varanasi; UAS, Bangalore/Dharwad; RAU, Bihar; DMR Bihar; Junagadh Agriculture University, Gujarat.

4.7.2 It was noted that the corn hybrids containing stacked events Bt11xGA21 express novel proteins such as the incisecticidal protein *Cry 1Ab* which confers resistance to lepidopteron insect pests and the *Mepsps* gene which confers tolerance to broad spectrum non selective glyphosate herbicide from GA21 event.

4.7.3 The Committee recorded the following objectives of the proposed trial :

- Study efficacy of cry1Ab (Event Bt11) in terms of level of infestation of the target lepidopteron insect pests i.e. Chilo partellus & Sesamia inferens as well as secondary pests on transgenic corn hybrid.
- Study the impact of transgenic corn hybrid containing stacked event of Bt11xGA21 against target lepidopteron pests, secondary pests and no non-target insect species.
- Evaluate weed management efficiency with Glyphosate 41% SL(IPA Salt) formulation under field conditions and carryover on succeeding crops.
- Comparative assessment of soil ecosystem & weediness, morphology & phenotypic characters of transgenic corn and its non-transgenic counterpart hybrids.
- Undertake gene expression of transgenic event GA21 and Bt11 at different crop growth stages.
- Produce sufficient plant material to undertake research on food and deed safety studies.

4.7.4 The Committee also observed the following details of field design and proposed isolation measures:

- Replicated randomized complete block design will be used.
- Isolation distance of 300 m or 25 days temporal isolation will be provided. The distance to nearest cultivated crop of the same species will be at least 300M.
- One transgenic corn hybrid with event Bt11 (NK6240 Bt) will be evaluated along with their non-transgenic counterpart, national and local check hybrids in three replications.
- One transgenic corn hybrid with event GA21 (NK6240 Gt ) will be evaluated along with their non-transgenic counterpart, national and local check hybrids in three replications.
- One transgenic corn hybrid with event Bt11 x GA21 (NK6240 Stack) will be evaluated along with their non-transgenic counterpart, national and local check hybrids in three replications.
- Non transgenic hybrids as control entries for comparison, against the transgenic hybrid and guard rows of African tall maize will be planted.

4.7.5 The Committee also observed that the proposal was recommended by the IBSC and RCGM on 25.01.2012. and 22.2.2012 respectively and advised that while selecting the final sites in the respective locations, the hot spot areas of particular insects should be selected.

4.7.6 It was also noted by the Committee that the applicant has also requested approval for F1 seed production of transgenic corn (*Zea Mays*) lines containing Bt11, GA21 and Bt11 X GA21 events and seed increase of transgenic corn (*Zea Mays*) lines containing Bt11 and GA21 events one at each location, at company leased land in Haryana/Maharashtra/Gujarat during Kharif and Rabi 2012 in an area of maximum 4399 sq. m.

4.7.7 The Committee also noted that the GEAC in its 111$^{th}$ meeting held on 6.7.2011 had accorded approval to M/s. Syngenta Biosciences Pvt. Ltd., to conduct second year BRL-I trials on two transgenic corn (*Zea mays*) hybrids namely NK6240, NK6607 containing *mepsps* gene (GA 21 event) and one transgenic corn (*Zea mays*) hybrid NK 6240 containing *cry1Ab & m epsps* genes (Bt11xGA21 stack event) at three locations.

4.7.8 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request (i) to conduct BRL-1 trials of transgenic corn (*Zea Mays*) hybrids namely NK6240 Bt (Bt11), NK6240 (GA21) and NK6240 Stack (Bt11 X GA21) containing Bt11, GA21 and stack event of Bt11 X GA21 at two to three location in Anand Agriculture University, Gujarat; Haryana Agriculture University, Hissar; Punjab Agriculture University, Ludhiana; MPKV, Rahuri; MPUAT, Udaipur; TNAU, Coimbatore; ANGRAU, Rajendra Nagar; BHU, Varanasi; UAS, Bangalore/Dharwad; RAU, Bihar; DMR Bihar; Junagadh Agriculture University, Gujarat. and (ii) to conduct F1 seed production of transgenic corn (*Zea Mays*) lines containing Bt11, GA21 and Bt11 X GA21 events and seed increase of transgenic corn (*Zea Mays*) lines containing Bt11 and GA21 events during appropriate seasons in 2012 -2013 to submission of NOC from the State Government where the trials will be conducted.

**4.8 Request for revised layout for conduct of BRL-1 trials of individual events MON 89034 and NK603 during 2012-13. M/s. Monsanto India Ltd., New Delhi.**

4.8.1 The Committee considered the request of M/s Monsanto India Ltd to revise the layout for conduct of BRL-1 trials of individual events MON 89034 and NK603 during 2012-13.

4.8.2 The Committee noted that the GEAC in its meetings held on 6.7.2011 and 8.2.2012 had approved BRL-I trials of transgenic corn individual events NK603 (six locations) and MON 89034 (three locations) during 2012-13.

4.8.3 The Committee noted that due to difficulty in getting isolation distance of 300 m at State Agriculture Universities, they have proposed a revised layout for the trials of two events at the same location adjacent to each other. The Committee observed that the border of thirteen rows of African tall maize would encompass the joint trial site. There would be no change in recording of data and observations from the previously submitted protocol. They do not intend to use the produce from these trials for livestock feeding studies.

4.8.4 The Committee also noted that the RCGM has recommended the revised layout on 22.2.2012.

4.8.5 After detailed deliberations, it was decided to obtain an undertaking from the applicant that all the produce from the trials will be destroyed before a final view is taken. Accordingly decision on the proposal was deferred.

**4.9 Information submitted by M/s. Mahyco to use non-transgenic check Suruchi MRP5401 in place of Sahyadri-5 to conduct event selection trial of salt tolerant rice (*Oryza sativa L.)* events containing *the nhx1 gene*.**

4.9.1 The Committee noted that the information submitted by M/s. Mahyco to use non-transgenic check Suruchi MRP5401 in place of Sahyadri-5 to conduct event selection trial of salt tolerant rice (*Oryza sativa L.)* events containing *the nhx1 gene.*

4.9.2 The Committee also noted that the GEAC in its meeting held on 14.12.2011 had accorded permission to conduct event selection trial of salt tolerant rice (*Oryza sativa L.)* events containing *the nhx1* gene on receipt of confirmation from the applicant that the transgenic rice incorporating *OsNHX1* are free of GUS marker gene. It was also clarified that *OsNHX1* gene does not encode a transcription factor and plays no role in direct regulation or triggering of other downstream genes.

4.9.3 It was also noted by the Committee that the applicant has informed that because of the non-availability of the non-transgenic Check “Sahyadri-5”, they have proposed to use “Suruchi MRP5401” as an alternate non–transgenic Check.

4.9.4 After a brief discussion on the matter, it was decided to obtain clarification from the applicant on whether both “Sahyadri-5” and “Suruchi MRP5401” non checks are local checks having similar features.

**4.10 Permission to conduct event selection trials on *Artemisia annua L.* (Sweet worm) transgenic lines (Event-hmgr-ads) developed by them in an Institute-Industry Collaborative research Project Sponsored by DST-DPRP, Govt. of India and M/s. IPCA Pvt. Ltd., Mumbai .**

4.10.1 The Committee considered the request of M/s. IPCA Pvt. Ltd., Mumbai to conduct event selection trials on *Artemisia annua L.* (Sweet worm) transgenic lines (Event-hmgr-ads) developed by them in an Institute-Industry Collaborative research Project Sponsored by DST-DPRP, Govt. of India.

4.10.2 The Committee also noted that the application of M/s. IPCA Pvt. Ltd., Mumbai was deferred as they have not complied with the requirement of constituting the Institutional Biosafety Committee (IBSC) which is mandatory under clause 4 (3) of the Rules 1989 for any developer before initiating research activities involving recombinant technology. The Committee had earlier directed the applicant to constitute IBSC and resubmit the application along with IBSC minutes.

4.10.3 The Committee noted that M/s. IPCA has informed vide letter dated 24.2.2012 that they have constituted IBSC and also organized a meeting on 24$^{th}$ Feb, 2012, wherein the proposal of M/s IPCA was discussed. The IBSC has verified the facilities required for handling transgenic plants and field trials under controlled conditions and recommended that the confined field trials of transgenic *Artemisia annua.L* in nethouse and open field trial at M/s. IPCA Laboratories Ltd, Ratlam (M.P.) and at Baroda (Ranu) field of IPCA to select best transgenic events may be allowed.

4.10.4 The Committee also noted that the RCGM has recommended the proposal on 20.3.2012.

4.10.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request of M/s IPCA to conduct event selection trials on *Artemisia annua L.* (Sweet worm) transgenic lines (Event-hmgr-ads) within the IPCA research farm at Baroda (Ranu) to select best transgenic events during appropriate seasons in 2012-2013 subject to submission of NOC from the State Government where the trials will be conducted.

**4.11 Permission for extension of the validity period from 2011-2012 to 2012-2013 for conduct of BRL-I trials with Bt rice events expressing *Cry 1Ac and Cry 1Ab* by M/s Metahelix Life Sciences.**

4.11.1 The Committee considered the request of M/s Metahelix Life Sciences for extension of the validity period from 2011-2012 to 2012-2013 for conduct of BRL-I trials with Bt rice events expressing *Cry 1Ac and Cry 1Ab*

4.11.2 The Committee noted that the GEAC in its 112$^{th}$ meeting held on 21.9.2012 had approved the request for conduct of BRL-1 on rice (*Oryza sativa*) events namely MHR03, MHR05, MHR32, MHR174, MHR256, MHR83, MHR90, MHR95, MHR489 and MHR509 containing *cry1Ac* and *cry1Ab* gene in long leased land at Ranga Reddy District in Andhra Pradesh during appropriate season in 2011-2012.

4.11.3 The Committee noted that NOC from Government of Andhra Pradesh is awaited and therefore the applicant has requested GEAC to extend the validity period from 2011-2012 to 2012-2013.

4.11.4 In view of the above, the Committee approved the request for extension of the validity period from 2011-2012 to 2012-2013 to conduct BRL-I trials with Bt rice events expressing *Cry 1Ac and Cry 1Ab* during appropriate seasons in 2012-2013 subject to submission of NOC from the State Government where the trials will be conducted.

**4.12 Permission for extension of the validity period from 2011-2012 to 2012-2013 and request for additional locations for conduct of event selection trials using SPT1 and ST6 constructs at Gujarat/Maharashtra in addition to Andhra Pradesh by M/s. E.I. Dupont India Pvt. Ltd., Hyderabad.**

4.12.1 The Committee considered the request of M/s E.I. Dupont India Pvt Ltd for extension of the validity period from 2011-2012 to 2012-2013 and request for additional locations for conduct of event selection trials using SPT1 and ST6 constructs at Gujarat/Maharashtra in addition to Andhra Pradesh

4.12.2 The Committee noted that the GEAC in its meeting held on 8.2.2012 had extended the validity period and also approved the change in location to conduct event selection trials with transgenic rice generated using SPT1 and SPT6 construct from Koppalapally (AP) during 2011 to Gujarat or Maharashtra during 2012.

4.12.3 The Committee also noted that the request to conduct trials in Gujarat / Maharashtra in addition to the approval for Andhra Pradesh was to maintain flexibility in the trial locations due to difficulty in getting NOC from the State Governments. However, trials will be conducted only at one location. The Committee opined that this aspect may be specified in the minutes as well as the approval letter.

4.12.4 The Committee further noted that the RCGM has recommended the request on 20.3.2012.

4.12.5 In view of the above stated facts and taking into consideration the RCGM recommendations, the Committee approved extension of the validity period from 2011-2012 to 2012-2013 and request for conduct of event selection trials using SPT1 and ST6 constructs at any one location in Andhra Pradesh/Gujarat/Maharashtra during appropriate seasons in 2012-2013 subject to submission of NOC from the State Government where the trials will be conducted.

**Agenda Item No 5 : Other items**

**5.1 Status of NOC from State Government for GM Crop Field trials:**

5.1.1 The Committee took note of the following information on the status of NOC issued by the State Government for conduct of GM crop field trials :

| Name of the company | Approval | State Govt approval | Date of issue |
|---|---|---|---|
| Directorate of Sorghum Research, Hyderabad | BRL-I trials for Sorghum | Andhra Pradesh | 5.7.2011 |
| Central Research Institute for Dryland Agriculture | Sorghum with Mtld gene | Andhra Pradesh | 11.7.2011 |
| M/s. Mahyco | BRL-I trials with RR Flex Cotton | Gujarat/ Andhra Pradesh | 8.8.2011 and 17.10.2011 |
| M/s Mayhco | BRL-II trials with BG-II RRF | Gujarat/ Andhra Pradesh | 8.8.2011 and 17.10.2011 |
| M/s Bayer Biosciences Pvt Ltd | BRL-I trials with Glytol Cotton Hybrids | Andhra Pradesh | 19.8.2011 |
| M/s Bayer Biosciences Pvt Ltd | Event selection trials with Glytol Cotton Hybrids | Andhra Pradesh | 19.8.2011 |
| M/s. Dow Agro Sciences India Pvt Ltd, Mumbai | BRL-II trials with WideStrike Cotton | Gujarat | 8.8.2011 |
| M/s.Syngenta Biosciences Pvt Ltd, Pune | BRL-I trials with Transgenic Corn | Gujarat | 8.8.2011 |
| M/s Metahelix Life Sciences Ltd | Event selection trials with Bt Cotton | Andhra Pradesh | 14.7.2011 |
| M/s Monsanto | BRL –II trials with transgenic corn | Gujarat/Punjab | 5.8.2011/ 28.11.2011 |
| M/s EI Dupont India Pvt Ltd | Event selection trials for Rice | Andhra Pradesh | 19.8.2011 |
| M/s. Pioneer Overseas Corporation | BRL-I trials with transgenic corn | Gujarat | 8.8.2011 |

| | | | |
|---|---|---|---|
| M/s Directorate of oilseeds Research, | Event selection trials of transgenic castor | Andhra Pradesh | 17.10.2011 |
| M/s. Mahyco | Event selection trials of rice (Salinity Tolerance OsNHX1 | Andhra Pradesh | 17.10.2011 |
| M/s Bayer Biosciences Pvt Ltd | BRL-I trials with Glytol Cotton Hybrids | Gujarat | 9.11.2011 |
| CGMCP, University of Delhi ***** | BRL-I second year of transgenic mustard | Rajasthan | 19.9.2011 |
| NRCPB, IARI | Field trials to analyze the effect of Azotobactor mutant strains on wheat | Delhi | 20.3.2012 |

****** *NOC has recently been withdrawn by the Government of Rajasthan for BRL-I trials of transgenic mustard.*

**5.2 Alleged Violation of Rules 1989 in GM Crop Field Trials in Gujarat.**

5.2.1 The Ministry has received a representation from a NGO "Coalition for a GM-Free India" wherein it has been alleged that the ongoing GM crop field trials in Gujarat is in violation of Rules 1989 notified under EPA 1986 on the following grounds:

(i) The State Biotechnology Coordination Committee, the State level implementation of the GEAC is not operational. This clearly violates the provisions of the 1989 Rules

(ii) Adequate biosafety oversight is absent during GM crop field trials;

(iii) The state has the unfortunate distinction of being the origin of illegal GM cotton planting incidents.

5.2.2 The Committee decided to obtain views of the State Government before taking a view on the matter.

**Agenda Item No 6 : Any Other item with the permission of the Chair.**

**6.1 Withdrawal of NOC by Department of Agriculture, Govt of Rajasthan for conducting BRL-I second year trial on transgenic mustard at three locations namely; Agricultural Research Station Experimental Farm, Navgaon (RAU), Bikaner); Agricultural Research Station, Sri Ganganagar (RAU, Bikaner) and KVK, Kumher (Bharatpur) during Rabi-2011-2012.**

6.1.1 Member Secretary, GEAC presented the facts of the case. The following points were noted:

1. The Genetic Engineering Appraisal Committee (GEAC) in its meeting held on 21.09.2011 had approved the second year BRL-I trials with transgenic mustard developed by UDSC subject to NOC from the State Government.

2. Rajasthan State Government has issued NOC for conduct of the BRL-1 trials at three locations on 19.9.2011. Subsequently, RCGM has issued the approval letter on 17.10.2011.

3. BRL-I second year trial on transgenic mustard was initiated at three locations namely; Agricultural Research Station Experimental Farm, Navgaon (RAU), Bikaner); Agricultural Research Station, Sri Ganganagar (RAU, Bikaner) and KVK, Kumher (Bharatpur) during Rabi-2011-2012.

4. The second season BRL-I trials of transgenic mustard at Agriculture Research Station, Navgoan (Alwar) of Rajasthan Agriculture University, Bikaner was visited by the Chairman and Member Secretary GEAC on 31.1.2012 wherein it was noted that the compliance is in order.

5. The Ministry received a communication from DBT and PMO forwarding a copy of the letter dated 9.3.2012 received from Dr Deepak Pental, University of Delhi informing that the State Government of Rajasthan has decided to withdraw the NOC granted for GM Mustard trials and directions have been issued for terminating the trials by burning immediately.

6. Dr Deepak Pental also telephonically informed Chairman, GEAC that the trial is going to be over in about a week's time and now he has suddenly received a letter from Rajasthan Government where they have asked them to uproot all the plants within a week's time. This, according to him, would completely destroy all the R&D efforts put in so far.

7. Views of the Committee on the above are as given under:

   i. In the letter of the Government of Rajasthan, no new facts on non-compliance or evidence of harm were brought to their notice after the commencement of the field trials which have compelled them to withdraw their NOC. The letter, on the contrary, says –

      *"The matter for permitting trials of transgenic crops has indeed being fraught with concerns as no unanimity has arrived at, either in their favour or against them. ICAR too seems to be grappling with the disquiet. The government has taken a view to wait until a national consensus is evolved. It has also been decided that discussions should be held with all stake holders and to reach to a general agreement on the controversy."*

      This does not appear to be a good enough reason to withdraw NOC at this late stage.

   ii. Any regulatory system has to be transparent, consistent and predictable. That is the best way to ensure compliance with the regulatory requirements. Once after the due process of permission to carry out experiments has been granted, then we should not withdraw it arbitrarily.

   iii. Decision to withdraw permission on precautionary principles should be based on new facts indicating that biosafety measures are not being observed. However, that does not seem to be the case here.

   iv. If the Government of Rajasthan does not want to give NOC in future, we will naturally honour such decisions of the Government of Rajasthan.

   v. As far as the instant case is concerned, the field trials which were coming to a closure may be allowed to be completed.

8. The Committee also took note of the following information submitted by Prof Deepak Pental for consideration of the GEAC:

*"1. The trials were being conducted at all the three places as per the guidelines laid down by the RCGM and the GEAC.*

*2. On March 9, 2012, the state agriculture department, Government of Rajasthan sent a communication to me indicating that the government has decided to withdraw the NOC given earlier and directing for destruction of the trial within seven days. The reason for withdrawing the NOC was cited as lack of consensus among the stakeholders and not any compliance issue by the applicant.*

*3. On March 12, 2012, the request was sent from me to the PMO seeking intervention for continuation of the trials. Copies of the letter were marked to the Union Ministers of Agriculture, Environment and Forests, Science and Technology, Chief Minister and concerned ministers in the government of Rajasthan, Concerned Secretaries in the union and state government, DG, ICAR, VC and Director Research of Rajasthan Agriculture University. Subsequently, a letter was also sent to CM, Rajasthan requesting for allowing the completion of the trials by March 31, 2012 providing the pending list of studies/data to be recorded.*

*4. Although the Director Research of RAU had earlier directed the Trial-in-charges for immediate destruction of the trials, later they were informally told to continue and complete the trials as early as*

*possible. Accordingly the trials at Bharatpur and Alwar were harvested as the crop was mature on March 16, 2012, while the trial at Sriganganagar was continuing as the crop was not mature for harvest.*

*5. All the material including the standing crop (green and not yet mature) at Sri Ganganagar was destroyed by burning on March 26,2012 in the presence of officials from State agriculture department of Rajasthan and RAU, Bikaner. The data has been recorded from Alwar and Bharatpur but the data on maturity could not be taken at Sri Ganganagar as the crop was still not mature.*

*6. It may be stated without any ambiguity that all the biosafety rules were being followed fully and regular monitoring was taking place, yet the NOC was withdrawn and the trials were destroyed.*

*Please take this matter up in the GEAC as it is important to streamline the process, otherwise it is going to be difficult to undertake any trials in future."*

6.1.2 The Committee opined that decision of the State Government of Rajasthan is rather arbitrary as the direction for withdrawal does not state any evidence of harm or non compliance. It was also felt that once a NOC has been issued; it should not be withdrawn in the interim period without any scientific reasons. However, notwithstanding the above, the Committee also reiterated that agriculture is a State subject and decision of the State Government on whether to allow GM crop field trials or not should be honored. Accordingly, the Committee took note of the decision of the Government of Rajasthan not to allow GM crop field trials in the State.

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