### Minutes of the 120<sup>th</sup> meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 12.5.2014

The 120<sup>th</sup> meeting of the GEAC was held on 12.05.2014 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

### Agenda Item No 1 Leave of Absence

1.1 The Committee granted leave of absence to Dr B. Sesikeran and Dr P.M. Bhargava (special invitee) as requested by them.

1.2. Member Secretary, GEAC requested all Members of the GEAC who have not submitted the 'Statement of Declaration of Independence' and 'Statement of Confidentiality' in accordance with the decision taken in the GEAC in its meeting held on 8.12.2010 to do so at the earliest.

1.3 Member Secretary, GEAC also briefed the Committee regarding the status of the Supreme Court hearing held on 9.5.2014. The Committee noted that the Supreme Court has not imposed any ban on GM crop field trials. The final hearing is now scheduled for July 15, 2014.

### Agenda Item No 2: Confirmation of Minutes of the 119<sup>th</sup> meeting

Minutes were confirmed subject to amendments in the following paras as highlighted in 'bold italics'.

1. In agenda item 3 para 3.2.2, 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 multidisciplinary expertise from State Agricultural University, ICAR. IARI and representatives from RCGM/ GEAC/ State Department of Agriculture. The monitoring teams visit the trial fields at defined stages of crop growth and that the observations are recorded in standard reporting formate. He further indicated that all procedures are strictly followed in the conduct of monitoring of the field trials. In respect of BRL-II trials monitoring is undertaken by MoEF.

2. In agenda item 3 para 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 *that a wider consultation is necessary before GEAC makes its recommendation in this matter.* 

3. Agenda item no 4.5 para 4.5.5, with respect of Bioseed application, the Committee noted that the product contains two addition marker genes gfp+gus and reiterated its opinion expressed in the 101<sup>st</sup> meeting held on 9.6.2010 wherein it was stated that the presence of gratuitous *marker genes* such as gus and *gfp* in the food crops, may not be considered for environmental *release as their presence is not essential for either generation of transgenic crop or its performance.* These issues need to be further discussed and guidelines for biosafety testing need to be developed.

4. Agenda item no 4.5 para 4.5.8, with respect of Bioseed application, After detailed deliberation, the Committee was of the view that the applicant may be advised to clarify the rationale for using *gfp and +gus as reporter genes, as they are not necessary for transformation*.

5. Agenda item no 4.11 para 4.11.7, with respect of UAS application, As the **BNAcF** was developed by crossing between cry1Ac and cry1F genes in Bikaneri Nerma transgenic cotton the members requested to check whether the source of the gene is similar to BT Bikaneri Nirma, it is to confirm that it is a new event which is different from the one that was present in Bt Bikaneri nirma.

6. Agenda item no 4.13 para 4.13.10, with respect of Monsanto application, the Committee therefore decide to *defer* decision on the proposal.

### Agenda item No. 3 Action taken report on the decision taken in the 119<sup>th</sup>GEAC Meeting held on 12.5.2014.

3.1 The Committee noted that decisions taken in the GEAC meeting held on 25.4.2014 have been communicated to the project proponents, concerned government departments and other agencies.

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 event selection trial with 44 transgenic *Bt*rice events (*Oryzae sativa* containing dual *Bt* (*Cry1Ab* & *Cry1Ca*) and bar genes, 18 events from *dual Bt*, and one event of LL Rice 62 with bar as control and 21 events containing *Cry1Ab* & *Cry1Ca* and *Cry 2 Ad* gene at Central and South zones by M/s. Bayer Biosciences Pvt. Ltd., Gurgaon

4.1.1 The Committee considered the application of M/s. Bayer Biosciences Pvt. Ltd., Gurgaon to conduct event selection trial of *Bt* rice containing *cry1Ab*, *cry1Ca*, *bar* and *cry2Ad* genes four events containing dual *Bt* (*cry1Ab* & *cry1Ca*) and *bar* gene; 18 events with dual *Bt* (*cry1Ab* & *cry1Ca*) one event of LL Rice 62 with *bar* as control and 21 events containing *cry1Ab*, *cry1C* and *cry2Ad* gene in Anand/ Surat/ Vadodara/ Panchmahal/ Nagpur/ Chandpur in Central zone and Patancheru and Eluru / Coimbatore/Trichy/ Madurai in South Zones respectively at company's long leased land in an area of 1 acre of each location by M/s. Bayer Bioscience Pvt. Ltd., Gurgaon. Proposed events for conduct of trials are:

- 4 events of dual *Bt (Cry1Ab & Cry1Ca*) and bar genes namely; OSB952, OSB957, OSB958, RICE1576;
- 18 events with *Cry1Ab* & *Cry1CaBt* and one event of LL Rice 62namely; RICE4001-RICE4004, RICE4016, RICE4019, RICE4101- RICE4104, RICE4116, RICE4118, RICE4201- RICE4205, RICE4207 and
- 21 events containing *Cry1Ab, Cry1C and Cry 2Ad* gene (namely; MP-38H-95-8-12-29, N39-95-1-18, N-H39-95-7-94c, H39-5-76b, 152780725, SK-40H-95-7-692, SK-40H-95-7-849, 16BT43+HSGE-3.1-14, H43-4-91A, P43-H-9-15, SK-43H-95-13-1817, SK-H43-95-5-284, SK-H43-95-5-359A, Sk-H43-95-6-724,SK-H43-95-7-964, OE6-T5-95-43H-49, OE14-T1-95-43H-3CIA, OE14-T4-95-43H-3CIB to be transferred from DuPont India Pvt. Ltd).
- 4.1.2 The Committee noted that the objectives of the trials are:

- to evaluate and select the superior Bt events in comparison to non-transformed genotype for agronomic parameters, seed producibility, restoration capacity, herbicide tolerance and Insect Efficacy.
- randomized Complete Block Design with 3 replications.
- the seed producibility study will be non-replicated.

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

- Isolation distance will be maintained as per the regulatory requirements.
- The non -transformed genotype will be planted in between the events to compare the agronomic parameters. Also the border rows of non-transformed plants will be planted. The surplus seeds will be buried in muddy rice field.
- Harvested FI seeds producibility experiments would be kept for testing in next generation.

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

#### I) Plasmid description

Three plasmid vectors (pTIBE 67, 68 and 70) dual T-DNA technique has been used so that bar selectable marker gene can be segregated out. 3' g7 in PTIBE 70 vector does not code any protein. It is a genetic element that ends transcription of DNA into RNA and its presence decreases the probability un-intended RNA transcripts. The genetic elements other than the transgenes coding for proteins in the vector plasmids are: Promoters: P35S3 from cauliflower mosaic virus 35 S transcript, PubiZm-ubiquitin-1 prmoter from Zeamays: transcript peptide: TPotpC transit peptide sequences from Zeamays and Helianthus annuus.; others-3' nos and 3' ocsuntranslated regions of nopaline and octopine synthase gene of A. *tumifaciens.* 

II) Transformation method : Agrobacterium mediated transformation

4.1.5 The Committee observed that the proposal has been recommended by the IBSC and RCGM in its 40<sup>th</sup> meeting and 23.10. 2012 respectively.

4.1.6 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

4.1.9 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 trial with 44 transgenic *Bt*rice events (*Oryzae sativa* containing dual *Bt* (*Cry1Ab* & *Cry1Ca*) and bar genes, 18 events from *dual Bt and* one event of LL Rice 62 with bar as control and 21 events containing *Cry1Ab* & *Cry1Ca* and *Cry 2 Ad* gene at company's long leased land in an area of *1 acre* at one location each in the Central and South zones during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted. In addition, the Committee stipulated the following conditions:

- (i) Trials to be conducted with Alpha design and not Randomized Complete Block Design
- (ii) Surplus seeds to be burned and not be buried in muddy rice field as indicated in the application.

- (iii) If a gene shows weediness it should be reported immediately.
- (iv) Information sought in para 4.1.8

4.2 Permission to conduct Biosafety Research Level-1 (BRL-1) on trials of transgenic cotton (*Gossypiumhirsutum*) hybrids containing breeding stack events MON 15985 x COT102 (BGIII); transgenic cotton of breeding stack events MON 15985 x COT102 x MON 88913 (BGIII RRF) and transgenic cotton containing event COT102 during the years 2013-14 and 2014-15 in North, Central and South zone in India by M/s. Monsanto Holdings Private Ltd.

4.2.1 The Committee considered the request of M/s. Monsanto Holdings Private Ltd. to conduct BRL-1 trial on transgenic stacked cotton hybrids containing insect resistance genes *Cry1Ac*, *Cry2Ab2* and *Vip3A* i.e. Events MON 15985 X COT 102 (BGIII) ; stacked cotton hybrids containing insect resistance genes *Cry1Ac*, *Cry2Ab2* and *Vip3A* and herbicide tolerant gene *Cp4 epsps* i.e. Events MON 15985 X COT 102 X MON 88913 (Roundup Ready Flex; BGIII RRF) and transgenic cotton containing insect resistant gene *Vip3A* event COT102 in the North, Central and South Zones in Kharif 2013-14 and Kharif 2014-15.

- The hybrids proposed to be tested in North zone are MaxxCot BGIII; MaxxCot BGIIIRRF; DPC 3083 BGIII and DPC 3083 BGIIIRRF; MaxxCot COT 102 their DPC 3083 COT 102; BGII and conventional counterparts hybrids along with Zonal Non Bt. check hybrid.
- Hybrids proposed to be tested in central and South zone are Brahma BGIII; Brahma BGIIIRRF; Sudarshan BGIII and Sudarshan BGIIIRRF; Brahma COT102; Sudarshan COT102 and their BGII and conventional counterparts hybrids along with Zonal Non Bt. check hybrid.

4.2.2 The Committee noted that the trials will be conducted at one location in each zone either in an SAU or in company's owned facility or Company leased land at Punjab, Haryana and Rajasthan, Maharashtra, Gujarat, Madhya Pradesh, Andhra Pradesh, Karnataka and Tamil Nadu in an area of less than 1 acre.

4.2.3 The Committee observed that Bollgard II Event MON 15985 is an approved event in India since 2006 and expresses Cry1Ac and Cry2Ab2 proteins providing resistance to target lepidopteron insects in cotton. COT 102 is a proprietary technology of Syngenta Company which expresses for vegetative insecticidal protein called Vip3A. MHPL through its parent company Monsanto USA has the license to use COT102 technology to develop superior breeding stacks with its own proprietary Events- MON 15985 and MON 88913. The NOC has been provided by the company for the trait introgression of Event COT102 into MHPL's proprietary cotton germplasm under the License Agreement made between Syngenta (Switzerland) and Monsanto (USA).

4.2.4 The Company took note on the documents provided by the applicant:

- Experiment protocol- BRL-1
- No Objection Certificate from Syngenta
- Biology of *GossypiumSpp* (Cotton).
- Evaluation of insect efficacy and quantification of different proteins in tissues of BGIII (Events MON 15985 X COT 102) and BIIIRRF (Events MON 15985 X COT 102 X MON 88913) hybrids under greenhouse conditions.
- RCGM and NBPGR clearance letter for import of transgenic cotton lines.
- Limit of Detection (0.01%) study (Event COT 102)
- Overall safety assessment of event MON 15985 and event MON 88913 for molecular characterization, Stability of events; Heat stability, Bioinformatics analysis against TOXIN and Allergen, Acute oral tox, In-vitro Digestive fate is submitted

• The desired studies pertaining to event COT102 have been submitted by Syngenta with a letter of access allowing MHPL to refer the data in support of this application.

4.2.5 The Committee also observed that the BGIII will provide broad spectrum of control over target lepidopteron insects such as *Helicoverpa* spp.; Pink Bollworm; Spodoptera spp. (armyworm) etc. with alternative modes of action therefore offering an effective IRM tool for long term sustenance of insect protection technology in Cotton. Similarly, BGIII RRF, in addition to offering above benefits will also provide an option to the farmers for over the top spray of approved Glyphosate based herbicide formulation helping to manage weeds that impact the productivity.

4.2.6 The Committee noted the objectives of the trials are:

- 1. to evaluate the efficacy of the BGIII cotton containing *Cry1Ac, Cry2Ab2* and *Vip3A*genes against target lepidopteron insect pests in transgenic cotton corresponding to their conventional counterpart and checks.
- 2. to study the weed control efficacy in BGIIIRRF cotton with glyphosate tolerant trait (Event MON 88913) with post emergent application of Roundup formulation.
- 3. to estimate of level of expression of Cry1Ac, Cry2Ab2, Vip3A and CP4 EPSPS proteins in various plant parts (terminal leaf, square, boll) at different crop growth stages.
- 4. to monitoring the occurrence of beneficial and non-target insects on transgenic and non-transgenic counterparts and checks.
- 5. to comparatively assess oil ecosystem, effect on germination, aggressiveness, weediness, morphology and phenotypic characters of transgenic cotton and its conventional counterpart.
- 6. to generate baseline susceptibility data on detectable protein Vip3A proteins on target insect pest populations collected from the sites of trials.
- 7. to produce sufficient produce material to undertake required composition; feed and food safety studies.

4.2.7 The Committee also noted the response provided by the company that in order to fulfill the requirement of food and feed safety studies mandated by RCGM and GEAC, we intend to retain cotton seed produced from BRL-1 trials of BG III and BG III RRF cotton. Approximate production of cotton seed per treatment per location will be 12 kg. This material is planned to be used for compositional analysis study and any other mandatory feeding study as recommended by RCGM/GEAC. According to our previous experience, approx 500 gm seeds of all treatments and all replications are required for compositional studies; and depending on the dosage incorporation in the test diets at least 25 kg of test material is required for rat feeding study. We maintain all records of production and utilization as per the SOPs.

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

- Isolation distance of 50 m will be maintained.
- 5 rows of non-transgenic cotton crop surrounding the trial plot area.
- Trial site will be surrounded by fencing to prevent entry of local fauna.
- Distance to the nearest cultivated Gossypium spp. (cotton) crop 50m.
- Surplus planting material will be shifted back to company storage facility at Hyderabad.

#### Experimental Design:

Experimental design for conducting trials is RBD (Randomized Block Design) with 3 replications.

#### 4.2.9 **Observations**

- Morphological and phenotype comparisons
- Weed control observations

- Crop phytotoxicity
- Disease incidence
- Soil ecosystem study
- Aggressiveness and weediness
- Quantification of protein

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

(i) **Plasmid description**: Event COT102 cotton was produced by Agrobacterium-mediated transformation of the cotton variety 'Coker 312.' Transformation was achieved using the vector pCOT1, which contained sequences corresponding to a synthetic vip3A(a) gene from Bacillus thuringiensis strain AB88 coding for the vegetative insecticidal protein VIP3A, and the aph4 gene from E. coli, coding for hygromycin-B phosphotransferase (APH4), an enzyme which confers resistance to the antibiotic hygromycin. Southern blot analysis of the genomic DNA from COT102 revealed the incorporation of single intact copies of the vip3A(a) and aph4 genes.

### (i) Transformation method: Agrobacterium mediated transformation and Biolistic /particle gun transformation

4.2.11 The Committee observed that the proposal has been recommended by IBSC and RCGM in its meetings held on 18.12.2012 and 26.02.2013 respectively.

4.2.12 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.

4.2.13 The Committee also requested the GEAC Secretariat to verify the reasons for withdrawl of an earlier application containing *Vip3A*genes submitted to the GEAC.

4.2.14 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for conduct of BRL-1 on trials of transgenic cotton (*Gossypiumhirsutum*) hybrids containing breeding stack events MON 15985 x COT102 (BGIII); transgenic cotton of breeding stack events MON 15985 x COT102 x MON 88913 (BGIII RRF) and transgenic cotton containing event COT102 in one location in the North, Central and South zones either in an SAU or in company's owned facility or Company's leased land at Punjab, Haryana and Rajasthan, Maharashtra, Gujarat, Madhya Pradesh, Andhra Pradesh, Karnataka and Tamil Nadu in an area of less than 1 acre during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted and submission of details sought at para 4.2.12.

# 4.3 Permission to conduct second year Biosafety Research Level-I (BRL-I) trial with 2 transgenic maize (*Zea mays* L.) hybrids containing *cry1F*, *cry1Ab* and *CP4EPSPS* genes (stacked events of TC1507 x MON 810 x NK 603 (DAS-01570-1 x MON-00810-6 x MON-00603-6) by M/s. Pioneer Overseas Corporation (POC), Hyderabad.

4.3.1 The Committee considered the request of M/s. Pioneer Overseas Corporation (POC), Hyderabad to conduct second year BRL-I trial with 2 transgenic maize (*Zeamays* L.) hybrids namely; P3501YHR and 30B07YHR containing*cry1F*, *cry1Ab* and *CP4EPSPS*genes (stacked events of

TC1507 x MON 810 x NK 603 (DAS-01570-1 x MON-00810-6 x MON-00603-6). The GEAC in its meetings held on 06.07.2011 and 08.02.2012 had approved the conduct of first year of BRL-I trials of above mentioned two hybrids at three different locations during appropriate seasons.

4.3.2 The Committee observed that the second year trials will be conducted at 3 to 4 locations among the eleven locations: Anand Agricultural University, Gujarat; Navasari Agricultural University, Gujarat; Punjab Agricultural University, Punjab; CCS Haryana Agricultural University, Haryana; Maharana Pratap University of Agriculture and Technology, Rajasthan; Marathwada Agricultural University, Maharashtra; Acharya N.G. Ranga Agricultural University, Andhra Pradesh; Tamil Nadu Agricultural University, Tamil Nadu; University of Agricultural Sciences-Dharwad, Karnataka; Jawaharlal Nehru KrishiVishwa Vidyalaya, Madhya Pradesh and Directorate of Weed Science Research, Madhya Pradesh and Jawaharlal Nehru Krishi visvidhalaya, Jabalpur in an area of 2502.4 sq m (73.6 m x 34m).

4.3.3 The Committee also noted that the Maize hybrids containing stacked events TC1507 x MON810 x NK603 express novel proteins: the insecticidal protein Cry1F which confers resistance to lepidopteron stem borers (from TC1507), Cry1Ab which confers resistance to lepidopteran cob borers (from MON810) and the CP4 EPSPS protein which confers tolerance to the herbicide glyphosate (from NK603).

4.3.4 The Committee noted the objectives of the trials are:

- to study the efficacy of *cry*1*F* and *cry*1*Ab* genes (stacked event of TC1507 x MON810 x NK603) in terms of level of infestation of target lepidopteron insect pests and other secondary pests on transgenic maize hybrids corresponding to their conventional (nontransgenic) counterparts and checks.
- 2. to conduct comparative assessment of soil ecosystem & weediness, morphology & phenotypic characters of transgenic maize and its non-transgenic counterpart hybrids.
- 3. to evaluate weed management efficiency with K salt of glyphosate formulation under field conditions and carryover effect of glyphosate on succeeding crops.
- 4. to monitor the occurrence of beneficial insects, non-target insect pests and soil fauna on transgenic and non-transgenic maize hybrids.
- 5. to produce sufficient plant material to undertake biosafety research and to generate data on feed and food safety.
- 6. to study the level of expression of candidate proteins expressed by stacked event of TC1507 x MON810 x NK603 in different plant parts at regular intervals during crop growth stages.

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

- A spatial isolation of 300 meters will be maintained.
- Treatment will consist of 6 transgenic maize hybrids and 10 non-transgenic counterparts during the trials.
- All regulatory conditions of RCGM including SOP for conduct of confined field trials will be followed.
- Design: Randomized Complete Block Design (RCBD).
- Treatment: 16(6 transgenic+10 non transgenic)
- Replication : 3
- Row length: 5b m
- No of rows of African tall maize : 10 rows.

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

### (i) Plasmid description:

- TC1507 event Plasmid PHP8999 is used in the construction of insert PHI8999A.
- NK603 event Plasmid PV-ZMGT32 is used in the construction of insert PV-ZMGT32L.
- MON810 event Plasmid PV-ZMBK07 is used in the construction of the insert.
- (ii) **Transformation method:** Each of the maize events was transformed using biolistic/particle gun method.

4.3.7 The Committee also observed that the proposal has been recommended by the IBSC. RCGM has also recommended the proposal on 28.5.2013.

4.3.8 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). One of the members informed that the K salt of glyphosate is not approved. After detailed deliberations, it was decided in the first instance 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.
- 4.3.9 The decision on the proposal was therefore deferred.

# 4.4 Permission to conduct Biosafety Research Level-I (BRL-I) trials with 2 transgenic maize P3501YH and 30B07YH (*Zea mays* L.) hybrids containing cry1F and *cry1Ab* genes (stacked events of TC1507 X MON 810) the events TC1507 x MON810 by M/s. Pioneer Overseas Corporation (POC), Hyderabad.

4.4.1 The Committee considered the request of M/s. Pioneer Overseas Corporation (POC), Hyderabad, to conduct BRL-I trials with 2 transgenic maize (*Zea mays* L.) hybrids namely; P3501YH and 30B07YH containing the containing *cry1F* and *cry1Ab* genes (stacked events of TC1507 X MON 810). The trials will be conducted in 3 to 4 locations among the ten locations:, Gujarat; Punjab; Haryana; Rajasthan; Maharashtra; Tamil Nadu; -Dharwad, Karnataka; Madhya Pradesh and Directorate of Weed Science Research, Madhya Pradesh Jawaharlal Nehru Krishi visvidhalaya, Jabalpur in an area of 2106 Sq m.

4.4.2 The Committee observed that the Maize hybrids containing stacked events TC1507 x MON810 express novel proteins: the insecticidal protein Cry1F which confers resistance to lepidopteron stem borers (from TC1507) and Cry1Ab protein which confers resistance to lepidopteron cob borers (from MON810).

4.4.3 The Committee noted the objective of the field trials are:

- to study the efficacy of the cry1F and cry1Ab genes (stacked event of TC1507 x MON810) in terms of level of infestation on the target lepidopteran insect pests and other secondary pests on transgenic maize hybrids corresponding to their conventional (non-transgenic) counterparts and checks.
- 2. to conduct comparative assessment of soil ecosystem, morphology & phenotypic characters of transgenic maize and its non-transgenic counterpart hybrids.
- 3. to monitor the occurrence of beneficial insects, non-target insect pests and soil fauna on transgenic and non-transgenic maize hybrids plots.

- 4. to produce sufficient plant material to undertake biosafety research and to generate data on feed and food safety.
- 5. to study the level of expression of candidate proteins expressed by stacked event of TC1507 x MON810 in different plant parts at regular intervals during crop growth stages.

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

- An isolation distance of 300 meters will be maintained.
- Treatment will consist of 2 transgenic maize hybrids and 8 non-transgenic counterparts during the trials.
- Proposed trial plot layout model will have 9 rows.
- Design:Randomized Complete Block Design (RCBD).
- Treatment (10 (2 transgenic+8 non transgenic)
- Replications 4
- No of rows of African tall maize : 10
- All regulatory conditions of RCGM including SOP for conduct of confined field trials will be followed.

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

#### (i) Plasmid description:

- TC1507 event Plasmid PHP8999 is used in the construction of insert PHI8999A.
- MON810 event Plasmid PV-ZMBK07 is used in the construction of the insert.

### (ii) **Transformation method**: Each of the maize events was transformed using biolistic/particle gun method.

4.4.6 The Committee also observed that the proposal is recommended by the IBSC. RCGM has also recommended the proposal on 28.5.2013.

4.4.7 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 therefore 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.
- 4.4.7 The decision on the proposal was therefore deferred.

## 4.5 Permission for conduct of event selection trial (EST17) on 16 SPT1 and 16 SPT6 Rice (*Oryzasativa L.*) containing *DsRed2, Zm-AA1, OsMSCA1* genes by M/s. Pioneer Overseas Corporation, Hyderabad.

4.5.1 The Committee considered the request of M/s. Pioneer Overseas Corporation, Hyderabad to conduct event selection trials on 32 transgenic Rice (*Oryzasativa L*.) events from SPT1 and SPT6

constructs. These are DKC118, SPT1-3006, SPT1-4015, JH15b, JH36, SPT1-3011, SPT1-4011, DKC1049a, DKC376, SPT1-4007, SPT1-4010, SPT1-4006, JH26a, SPT1-3002, JH17 and DKC45 derived from SPT1 and SPT6-2008, J6-1-129d, SPT6-1007, SPT6-1008, SPT6-1016, J6-1-4d, SPT6-1004, SPT6-1005, J6-1-7d, J6-1-8, SPT6-1003, SPT6-2014, SPT6-2009, SPT6-1018, SPT6-1009 and SPT6-2005 derived from SPT6 construct. The trial will be conducted at 4 locations, in Medak Distt and Nizamabad distt Andhra Pradesh, and Navsari and Anand Agricultural University in Gujarat in both Kharif 2014 and Rabi 2014-15 seasons. The size of the each trial will be 1 hectare.

4.5.2 The Committee noted that the SPT rice events were generated in Japonica Rice line M202 using *Agrobacterium* mediated transformation containing SPT1 and SPT6 vector. After molecular characterization, single copy events were backcrossed into Pioneer inbred line VIR54G9.

4.5.3 The Committee also noted that the Rice Seed Production Technology (SPT) is a process that facilitates large-scale production of male sterile rice lines. These male sterile lines can be used as female inbred parents for subsequent hybrid seed production. Rice SPT is a transgene based process for production of maintainer lines, rather than a trait or product. Rice SPT maintainer was generated by *Agrobacterium* mediated transformation of a male sterile *(Os-msca1/Os-msca1)* mutant rice line with the Rice SPT1 and SPT6 plasmids containing three genes namely, *Os-Msca1* (Mod1), *Zm-AA1* and *DsRed2* (Alt1). These genes are essential for the functioning of Rice SPT process.

4.5.4 The Committee noted the objectives of the trial are:

- 1. to assess the frequency of transgene transmission through pollen in SPT events.
- 2. to assess the outcross seed producibility of SPT events.
- 3. to evaluate DsRed2 and Zm-AA1 expression in leaf, anther and seeds of SPT events.
- 4. to study transgene segregation in SPT maintainer events.

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

- Spatial Isolation distance in the proposed trial 10 meters
- Distance to the nearest cultivated crop of the same species >10 m
- Distance to the nearest commercial crop of any kind- 10 m
- Trial will be marked for clear identification
- Surplus planting material will be either burnt or buried deep in the soil
- Non-transgenic line VIR54G9 will be planted as control

#### 4.5.6 Trial Protocol:

- Experimental design for conducting trials is RCBD (Randomized Complete Block Design) with 3 replicates.
- Thirty two transgenic events (16 SPT1 and 16 SPT6) will be used as a pollinator parent to produce seeds on non-transgenic male sterile line
- Trial area will be 1 hectare
- Field layout: events will be protected by barriers to avoid contamination.
  - Agronomy Practices:
  - a Nursery or seed bed preparation and sowing
  - b. Nursery/seed bed management
  - c. Main land preparation and transplanting
  - d. Fertilizer management
  - e. Weed management

f. Pest and disease managementg. seed production practices to increase the seed yieldh.Harvesting and post-harvest management

- Observations:
- a. Pollen transmission
- b. Seed producibility and agronomic traits
- c. Biochemical observations
- d. Transgene segregation in maintainer events

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

- I. Plasmid description: Both SPT1 and SPT6 plasmid have same genetic elements. These are Zm-AA1- Alpha amylase gene from corn, Os-Msca1-Native fertility restoration gene from Rice and DsRed2- Florescence colour marker gene from *Discosoma sp.* The different between SPT1 and SPT6 is the relative position of Zm-AA1 and Os-Msca gene in the plasmid.
- **II. Transformation method**: SPT rice events were generated using *Agrobacterium* mediated transformation of M202 Japonica line containing *Os-msca* allele.

4.5.8 The Committee also observed that the proposal has been recommended by IBSC and RCGM on 22.08.2012and 25.09.2013 respectively.

4.5.9 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 trial (EST17) on 16 SPT1 and 16 SPT6 Rice (*Oryzasativa L.*) containing *DsRed2, Zm-AA1, OsMSCA1* genes in any one locations each in Andhra Pradesh (Medak/ Nizamabad District) and Gujarat (Navsari / Anand Agricultural University) during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted. The Committee also advised that the applicant may be requested to make a presentation on SPT technology before the Committee.

#### 4.6 Permission to conduct event selection on transgenic rice (*Oryzasativa*) marker free Bt events namely MHRM01 to MHRM20 containing *cry1Ab* gene for resistance to Rice Yellow Stem Borer (*Scirpophagaincertulas*) by M/s. Metahelix Life Sciences Ltd., Bangalore.

4.6.1 The Committee considered the request of M/s. Metahelix Life Sciences Ltd., Bangalore to conduct event selection on transgenic rice (*Oryzasativa*) marker free Bt events namely MHRM01 to MHRM20 containing *cry1Ab* gene for resistance to Rice Yellow Stem Borer (*Scirpophagaincertulas*) at Vattinagulapalli Village, RR Dist. Andhra Pradesh in an area of 612m<sup>2</sup>

4.6.2 The Committee noted the objective of the trial is to validate the agronomically superior and the most efficacious event (s) against rice stem borer and leaf folder.

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

- Spatial isolation distance and Guard rows
- 200M Isolation from any other rice crop.
- Border buffer zone with a non-transgenic rice variety with similar flowering time all around the trial area

• 2M high Physical barricade with polythen sheet around the trial area, if required

4.6.4 Trial Protocol:

- No. Of events for screeding-20+2 checks (non-transgenic lines IR58025B and Jaya)
- No. Of application -3
- Design Randomized Complete Block Design
- No herbicide or pesticide will be used.
- Border buffer area- 4 M buffer Zone with rice all around trial area

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

- I. Plasmid description: pMH1172 and pMH1199
- **II. Transformation method**: agrobacterium mediated transformation

4.6.6 The Committee observed that the proposal has been recommended by the IBSC. RCGM has also recommended the proposal on.25.06.2013.

4.6.7 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 on transgenic rice (*Oryzasativa*) marker free Bt events namely MHRM01 to MHRM20 containing *cry1Ab* gene for resistance to Rice Yellow Stem Borer (*Scirpophagaincertulas*) at Vattinagulapalli Village, RR Dist. Andhra Pradesh during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted.

# 4.7 Permission to conduct event selection trials (EST -8) on 23 transgenic rice (Oryzasativa) events generated using constructs namely Bt38 (Cry1Ab + Cry2Ad), Bt40 (Cry1Ab+Cry2Ad), Bt46 (Cry1Ab + Cry2Ad), pTVE544 (Cry1Ca + bar) and pTSVH0207 (Cry1Ab + bar) constructs by M/s Pioneer Overseas Corporation, Hyderabad

4.7.1 The Committee considered the request of M/s Pioneer Overseas Corporation Limited, Hyderabad to conduct event selection trials with 21 transgenic rice (*Oryzasativa* L.) comprising events with Cry1Ab and Cry2Ad genes in Bt and null inbred and Bt hybrid backgrounds for 1 event from Bt38, 16 event from Bt40 and 4 events from Bt46 constructs. In addition to 21 events, two events namely, OSB952 and OSB958 containing *Cry1C and Cry1Ab* genes from construct (pTVE544 + pTSVH0207) would be tested in Bt inbred background.

- The one (1) Bt rice event generated using Bt38 (Cry1Ab + Cry2Ad) construct will be tested in Bt Inbred (BT-121), null inbred (BT-121 (N)) and Bt hybrid ((BT-121 (H) backgrounds.
- The Sixteen (16) Bt rice events generated using Bt40 (Cry1Ab + Cry2Ad) construct will be tested in Bt inbred (BT-122 to BT-137), null inbred ((BT-122 (N) to BT-137(N)) and Bt hybrids ((BT-122 (H) to BT-137 (H)) backgrounds.
- The Four (4) Bt rice events generated using Bt46 (Cry1Ab + Cry2Ad) construct will be tested in Bt inbred (BT-138 to BT-141), null inbred ((BT-138 (N) to BT-141(N)) and Bt hybrids ((BT-138 (H) to BT-141 (H)) backgrounds.
- The Two (2) Bt rice events, namely OSB952 and OSB958 generated using pTVE544 and pTSVH0207 (Cry1Ab + Cry1Ca + bar) construct will be tested in Bt inbred background.

4.7.2 The Committee observed that the Bt rice events were generated using *Agrobacterium* mediated transformation of indica inbred rice. The constructs Bt40 and Bt46 were generated through co-transformation as 'two binary in one Agro' system, one binary containing two Cry genes and another containing Hygromycin. Hygromycin was used as a selectable marker but was segregated out in the subsequent generation to generate marker free Bt events. All the bt rice events determined to be single Bt copy insertion in the genome and efficacious against Yellow Stem Borer a rice leaf folder in green house and laboratory experiments. The trial will be conducted at any two of the locations at Gujarat/Maharashtra/Tamil Nadu/Andhra Pradesh during any appropriate seasons of 2014. The trials will be conducted in an area of 4000 m<sup>2</sup>.

4.7.3 The Committee noted the objective of the trial is to evaluate dual mode of action Bt rice events for the phenotypic performance and trait efficacy against Yellow stem borer under field conditions.

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

- 1. Spatial isolation of 200 m from the row of transgenic plant on all four sides will be maintained as per guidelines
- 2. No cultivation of rice in the same plot during the post-harvestmonitoring period
- 3. All the trials will be marked for clear identification
- 4. The surplus planting material will be seedlings and these excess seedlings will be burnt at the trial site
- 5. Non transgenic IRV95 and 6G4317 will be planted as the Controls
- 4.7.5 Experimental design:
- The trial design is Randomized Complete Block Design (RCBD).

Treatments:

- Experiment A Transgenic inbreds and nulls + nontransgenic control
- Experiment B Transgenic Hybrids + nontransgenic control
- Experiment C Transgenic inbreds + nontransgenic control
- Experiment D Transgenic inbreds + nontransgenic control

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

### (i) Plasmid description:

- Bt38, Bt40and Bt46(Cry1Ab + Cry2Ad) has the molecular stack of Cry1Ab and Cry2Ad under the control of Corn Ubiquitin promoter and Banana Streak Virus (BSV) promoter respectively
- pTVE544 has the Bt gene, Cry1Ca under the control of Corn Ubiquitin promoter and the bar gene under 35S promoter
- pTSVH0207 has the Bt gene, Cry1Ab under the control of Corn Ubiquitin promoter and the bar gene under 35S promoter
- (ii) **Transformation:** All the marker free events from the constructs Bt38, Bt40 and Bt46 were generated by Agrobacterium mediated co-transformation of the elite Indica rice line IRV95. OSB952 and OSB958 events were generated Agrobacterium mediated transformation of the rice line 6G4317 with pTVE544 & PTSVH0207.

4.7.7 The Committee observed that the GEAC in its meetings held 12<sup>th</sup> January 2011, 21<sup>st</sup> September 2011, 12<sup>th</sup> October 2011 and 8<sup>th</sup> February 2012 had accorded approvals to M/s. E.I. Dupont India Pvt. Ltd., Dupont Knowledge Center, Hyderabad to conduct events selection trials on Inbreds and Inbred and Hybrids on transgenic rice events against Yellow stem borer and rice leaf folder using Bt39, Bt40 & Bt43 constructs and pTVE544 and pTSVH0207 constructs.

4.7.8 The Committee also observed that the proposal has been recommended by IBSC and RCGM on 07.05.2013and 25.05.2013 respectively.

4.7.9 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 (EST -8) on 23 transgenic rice (Oryzasativa) events generated using constructs namely Bt38 (Cry1Ab + Cry2Ad), Bt40 (Cry1Ab+Cry2Ad), Bt46 (Cry1Ab + Cry2Ad), pTVE544 (Cry1Ca + bar) and pTSVH0207 (Cry1Ab + bar) constructs at any two of the locations in Gujarat/Maharashtra/Tamil Nadu/Andhra Pradesh 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 trials on 32 transgenic rice (Oryzasativa) events generated using constructs namely Bt38 (Cry1Ab + Cry2Ad), Bt40 (Cry1Ab+Cry2Ad), Bt46 (Cry1Ab + Cry2Ad) and pTVE544 (Cry1Ca + bar) and pTSVH0207 (Cry1Ab + bar) constructs by M/s Pioneer Overseas Corporation, Hyderabad.

4.8.1 The Committee considered the request of M/s Pioneer Overseas Corporation Limited, Hyderabad has requested for permission to conduct event selection trials with 30 transgenic rice (*Oryzasativa* L.) comprising events with Cry1Ab and Cry2Ad genes in Bt and null inbred and Bt hybrid backgrounds for 1 event from Bt38, 16 event from Bt40 and 13 events from Bt46 constructs. In addition to 30 events, two events namely, OSB952 and OSB958 containing Cry1C and Cry1Ab genes from construct (pTVE544 + pTSVH0207) would be tested in Bt inbred background.

- The one (1) Bt rice event generated using Bt38 (Cry1Ab + Cry2Ad) construct will be tested in Bt Inbred (BT-121), null inbred (BT-121 (N)) and Bt hybrid (BT-121 (H)) backgrounds.
- The Sixteen (16) Bt rice events generated using Bt40 (Cry1Ab + Cry2Ad) construct will be tested in Bt inbred (BT-122 to BT-137), null inbred ((BT-122 (N) to BT-137(N)) and Bt hybrids ((BT-122 (H) to BT-137 (H)) backgrounds.
- The Thirteen (13)Bt rice events generated using Bt46 (Cry1Ab + Cry2Ad) construct will be tested in Bt inbred (BT-138 to BT-150), null inbred ((BT-138 (N) to BT-150(N)) and Bt hybrids ((BT-138 (H) to BT-150 (H)) backgrounds.
- The Two (2) Bt rice events, namely OSB952 and OSB958 generated using pTVE544 and pTSVH0207 (Cry1Ab + Cry1Ca + bar) construct will be tested in Bt inbred background.

4.8.2 The Committee observed that the Bt rice events were generated using *Agrobacterium* mediated transformation of indica inbred rice. The constructs Bt40 and Bt46 were generated through cotransformation as 'two binary in one Agro' system, one binary containing two Cry genes and another containing Hygromycin. Hygromycin was used as a selectable marker but was segregated out in the subsequent generation to generate marker free Bt events. All the bt rice events determined to be single Bt copy insertion in the genome and efficacious against Yellow Stem Borer a rice leaf folder in green house and laboratory experiments. The trial will be conducted at any two of the locations at Gujarat/Maharashtra/Tamil Nadu/Andhra Pradesh during appropriate seasons of 2014. The trials will be conducted in an area of 4000 m<sup>2</sup>.

4.8.3 The Committee noted the objective of the trial is to evaluate dual mode of action Bt rice events for the phenotypic performance and trait efficacy against Yellow stem borer under field conditions.

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

- 1. Spatial isolation of 200 m from the row of transgenic plant on all four sides will be maintained as per guidelines
- 2. No cultivation of rice in the same plot during the post-harvest monitoring period
- 3. All the trials will be marked for clear identification
- 4. The surplus planting material will be seedlings and these excess seedlings will be burnt at the trial site
- 5. Non transgenic IRV95 and 6G4317 will be planted as the Controls
- 4.8.5 Experimental design: RCBD (Randomized Complete Block Design)

Treatments:

- Experiment A Transgenic inbreds and nulls + nontransgenic control
- Experiment B Transgenic Hybrids + nontransgenic control
- Experiment C Transgenic inbreds + nontransgenic control
- Experiment D Transgenic inbreds + nontransgenic control

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

#### (i) Plasmid description:

- Bt38, Bt40 and Bt46 (Cry1Ab + Cry2Ad) has the molecular stack of Cry1Ab and Cry2Ad under the control of Corn Ubiquitin promoter and Banana Streak Virus (BSV) promoter respectively
- pTVE544 has the Bt gene, Cry1Ca under the control of Corn Ubiquitin promoter and the bar gene under 35S promoter
- pTSVH0207 has the Bt gene, Cry1Ab under the control of Corn Ubiquitin promoter and the bar gene under 35S promoter
- (ii) **Transformation:** All the marker free events from the constructs Bt38, Bt40 and Bt46 were generated by Agrobacterium mediated co-transformation of the elite Indica rice line IRV95. OSB952 and OSB958 events were generated Agrobacterium mediated transformation of the rice line 6G4317 with pTVE544 & PTSVH0207.

4.8.7 The Committee noted that the GEAC in its meetings held 12<sup>th</sup> January 2011, 21<sup>st</sup>September 2011, 12<sup>th</sup> October 2011 and 8<sup>th</sup> February 2012 had accorded approvals to M/s. E.I. Dupont India Pvt. Ltd., Dupont Knowledge Center, Hyderabad to conduct events selection trials on Inbreds and Hybrids on transgenic rice events against Yellow stem borer and rice leaf folder using Bt39, Bt40 & Bt43 constructs and pTVE544 and pTSVH0207constructs.

4.8.8 The Committee observed that the proposal has been recommended by the IBSC and RCGM on 07.05.2013and 25.05.2013 respectively.

4.8.9 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 32 transgenic rice (Oryzasativa) events generated using constructs namely Bt38 (Cry1Ab + Cry2Ad), Bt40 (Cry1Ab+Cry2Ad), Bt46 (Cry1Ab + Cry2Ad) and pTVE544 (Cry1Ca + bar) and pTSVH0207

(Cry1Ab + bar) constructs at any two of the locations at Gujarat/Maharashtra/Tamil Nadu/Andhra Pradesh 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 (Trial-4) on 48 transgenic rice (Oryzasativa) events generated using DKHT3, DKHT4, DKHT5, DKHT6, DKHT17 and DKHT18 constructs at Andhra Pradesh/Gujarat/Maharashtra/Tamil Nadu by M/s. Pioneer Overseas Corporation, Hyderabad

4.9.1 The Committee considered the request of M/s. Pioneer Overseas Corporation (POC), Hyderabad has requested for permission for event selection (Trial-4) on 48 transgenic rice (Oryzasativa) events generated using DKHT3, DKHT4, DKHT5, DKHT6, DKHT17 and DKHT18 constructs All events are single copy events. The trials will be conducted at Andhra Pradesh/Gujarat/Maharashtra/Tamil Nadu. The events were developed by transforming inbred Indica line and in an area of 4000m<sup>2</sup>

Details of constructs are as follows.

- **Construct DKHT3** 8-10 events from DKHT3.1 to DKHT3.16
- **Construct DKHT4** 8-10 events from DKHT4.1 to DKHT4.15
- Construct DKHT5 8-10 events from DKHT5.1 to DKHT5.16
- **Construct DKHT6** 8-10 events from DKHT6.1 to DKHT6.13
- **Construct DKHT17** 8-10 events from DKHT17.1 to DKHT17.13
- Construct DKHT18 Events are DKHT18.1, DKHT18.2, DKHT18.3, DKHT18.4, DKHT18.5, DKHT18.6, DKHT18.7, DKHT18.8

4.9.2 The Committee noted that the Herbicide tolerant (HT) rice events were generated using Agrobacterium-mediated transformation of Indica inbred line with the six GAT constructs and callus was selected using glyphosate. Plants were regenerated and taken for generation advancement seed production was done in the green house. Molecular characterization (qPCR and Southern) was used to advance only single copy insert plants. They were tested for trait efficacy in green House in T1 generation and homozygous plants are advanced for seed production for testing in this selection trials (EST) As a non transgenic control, VIR54G9 (inbred line) will be used.

4.9.3 The Committee also noted that the objectives of the field trial are:

- 1. to evaluate the trait efficacy
- 2. to assess agronomic parameters of GAT events

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

- A spatial isolation of 10 meters from the last row of transgenic plant on all four sides will be maintained.
- All regulatory conditions of RCGM including SOP for conduct of confined field trials will be followed.

4.9.5 Experimental design:

Trial design is Split Plot Design (SPD) Number of treatments : A. Unsprayed B.Glyphosate spray (3600 g a.i./ha) 4.9.6 The Committee noted the following information on the gene construct and transformation method:

### (i) Plasmid description:

- **DKHT3** construct has GAT4621 under the control of Corn Ubiquitin promoter and Pin II terminator from Potato.
- **DKHT4** construct has GAT4621 under the control of 3 copies of 35S enhancer and Corn Ubiquitin promoter and Pin II terminator from Potato
- **DKHT5** construct has GAT901B9 under the control of Corn Ubiquitin promoter and Pin II terminator from Potato
- **DKHT6** construct has GAT901B9 under the control of 3 copies of 35S enhancer and Corn Ubiquitin promoter and Pin II terminator from Potato
- **DKHT17** construct has GAT891G3 under the control of Corn Ubiquitin promoter and Pin II terminator from Potato
- **DKHT18** construct has GAT891G3 under the control of 3 copies of 35S enhancer and Corn Ubiquitin promoter and Pin II terminator from Potato
- (iii) **Transformation method**: All these constructs were transformed in rice using *Agrobacterium* mediated transformation.

4.9.7 The Committee observed that the proposal has been recommended by the IBSC. The proposal is also recommended by RCGM on 25.6.2013.

4.9.8 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

4.9.9 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 (Trial-4) on 48 transgenic rice (Oryzasativa) events generated using DKHT3, DKHT4, DKHT5, DKHT6, DKHT17 and DKHT18 constructs at Andhra Pradesh/Gujarat/Maharashtra/Tamil Nadu any two locations during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted. The Committee also advised applicant to submit details of the GAT gene.

### 4.10 Permission to conduct event selection (Trial-5) on 48 transgenic rice (Oryzasativa) events generated using DKHT3, DKHT5, DKHT9, DKHT10, DKHT15 and DKHT16 constructs by M/s. Pioneer Overseas Corporation, Hyderabad.

4.10.1 The Committee considered the request of M/s. Pioneer Overseas Corporation (POC), Hyderabad to conduct event selection (Trial-5) on 48 transgenic rice (Oryzasativa) events generated using DKHT3, DKHT5, DKHT9, DKHT10, DKHT15 and DKHT16 constructs The events were developed by transforming inbred Indica line. All events are single copy events. The

trial will be conducted at Andhra Pradesh or Gujarat or Maharashtra or Tamil Nadu at an area of 4000 m2. The details of constructs are as follows:

- **Construct DKHT3** 8-10 events from DKHT3.1 to DKHT3.16
- **Construct DKHT5** 8-10 events from DKHT5.1 to DKHT5.16
- **Construct DKHT9** 8-10 events from DKHT9.1 to DKHT9.13
- **Construct DKHT10** 8-10 events from DKHT10.1 to DKHT10.13
- **Construct DKHT15** Events are DKHT15.1, DKHT15.2, DKHT15.3, DKHT15.4, DKHT15.5, DKHT15.6, DKHT15.7, DKHT15.8
- **Construct DKHT16** Events are DKHT16.1, DKHT16.2, DKHT16.3, DKHT16.4, DKHT16.5, DKHT16.6, DKHT16.7, DKHT16.8

4.10.2 The Committee observed that the Herbicide tolerant (HT) rice events were generated using Agrobacterium-mediated transformation of Indica inbred line with the six GAT constructs and callus was selected using glyphosate. Plants were regenerated and taken for generation advancement seed production was done in the green house. Molecular characterization (qPCR and Southern) was used to advance only single copy insert plants. They were tested for trait efficacy in green House in T1 generation and homozygous plants are advanced for seed production for testing in this selection trials (EST)

4.10.3 The Committee also noted that the objectives of the field trial are:

- 1. to test the trait efficacy and agronomics of glyphosate tolerant rice events.
- 2. to assess agronomic parameters of GAT events

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

- A spatial isolation of 10 meters from the last row of transgenic plant on all four sides will be maintained.
- All regulatory conditions of RCGM including SOP for conduct of confined field trials will be followed.
- 4.10.5 Experimental design:

Trial design is Split Plot Design (SPD) Trial design is Split Plot Design (SPD) Number of treatments : A. Unsprayed B.Glyphosate spray (3600 g a.i./ha) on events C.Glyphosate spray (3600 g a.i./ha) on events at development stage.

4.10.6 The Committee noted the following Information on the gene construct and transformation method:

### (i) Plasmid description:

- **DKHT3** construct has GAT4621 under the control of Corn Ubiquitin promoter and Pin II terminator from Potato.
- **DKHT5** construct has GAT901B9 under the control of Corn Ubiquitin promoter and Pin II terminator from Potato
- **DKHT9** construct has GAT901B9 under the control of BSV (Banana streak virus) promoter and Pin II terminator from Potato
- **DKHT10** construct has GAT901B9 under the control of BSV (Banana streak virus) promoter with Adh1 intron and Pin II terminator from Potato

- **DKHT15** construct has GAT4621 under the control of BSV (Banana streak virus) promoter and Pin II terminator from Potato
- **DKHT16** construct has GAT4621 under the control of BSV (Banana streak virus) promoter with Adh1 intron and Pin II terminator from Potato

(ii)**Transformation method**: All these constructs were transformed in rice using *Agrobacterium* mediated transformation.

4.10.7 The Committee observed that the proposal is recommended by the IBSC. RCGM has also recommended on 25.6.2013

4.10.8 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

4.8.8 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 (Trial-5) on 48 transgenic rice (Oryzasativa) events generated using DKHT3, DKHT5, DKHT9, DKHT10, DKHT15 and DKHT16 constructs locations at anv two at Andhra Pradesh/Gujarat/Maharashtra/Tamil Nadu during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted. The Committee also advised applicant to submit details of the GAT gene.

## 4.11 Permission to conduct confined field trial for event selection (Trial-6) on 48 transgenic rice (Oryzasativa) events generated using DKHT3, DKHT5, DKHT16, DKHT10, DKHT17 and DKHT19 constructs at Andhra Pradesh/Gujarat/Maharashtra/Tamil Nadu by M/s. Pioneer Overseas Corporation, Hyderabad.

4.11.1 The Committee considered the request of M/s. Pioneer Overseas Corporation (POC), Hyderabad for event selection (Trial-6) on 48 transgenic rice (Oryzasativa) events generated using DKHT3, DKHT5, DKHT16, DKHT10, DKHT17 and DKHT19 constructs at Andhra Pradesh/Gujarat/Maharashtra/Tamil Nadu. The events were developed by transforming inbred Indica line. All events are single copy events. The trial will be conducted at Andhra Pradesh or Gujarat or Maharashtra or Tamil Nadu. Details will be provided when the trial will be initiated during the appropriate season of 2014.

The details of constructs are as follows:

- **Construct DKHT3** 8-10 events from DKHT3.1 to DKHT3.24
- **Construct DKHT5** 8-10 events from DKHT5.1 to DKHT5.24
- **Construct DKHT16** 8-10 events from DKHT16.1 to DKHT16.16
- Construct DKHT10 8-10 events from DKHT10.1 to DKHT10.21
- Construct DKHT17 8-10 events from DKHT17.1 to DKHT17.21
- **Construct DKHT19** Events are DKHT19.1, DKHT19.2, DKHT19.3, DKHT19.4, DKHT19.5, DKHT19.6, DKHT19.7, DKHT19.8

4.11.2 The Committee noted that the Herbicide tolerant (HT) rice events were generated using Agrobacterium-mediated transformation of Indica inbred line with the six GAT constructs and callus was selected using glyphosate. Plants were regenerated and taken for generation advancement seed production was done in the green house. Molecular characterization (qPCR and Southern) was used to advance only single copy insert plants. They were tested for trait efficacy in green House in T1 generation and homozygous plants are advanced for seed production for testing in this selection trials (EST) As a non transgenic control, VIR54G9 (inbred line) will be used. The trials will be conducted at an area of 4000m2.

4.11.3 The Committee noted that the objectives of the field trial are:

- 1. to test the trait efficacy and agronomics of glyphosate tolerant rice events.
- 2. to assess agronomic parameters of GAT events

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

- A spatial isolation of 10 meters from the last row of transgenic plant on all four sides will be maintained.
- All regulatory conditions of RCGM including SOP for conduct of confined field trials will be followed.
- 4.11.5 Experimental design:

Trial design is Split Plot Design (SPD)

- A. Unsprayed
- B. Glyphosate spray (3600 g a.i./ha) on events
- C. Glyphosate spray (3600 g a.i./ha) on events at development

stage

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

### (i) Plasmid description:

- DKHT3 construct has GAT4621 under the control of Corn Ubiquitin promoter and Pin II terminator from Potato.
- DKHT5 construct has GAT901B9 under the control of Corn Ubiquitin promoter and Pin II terminator from Potato
- DKHT16 construct has GAT4621under the control of BSV (Banana streak virus) promoter with Adh1 intron and Pin II terminator from Potato
- DKHT10 construct has GAT901B9 under the control of BSV (Banana streak virus) promoter with Adh1 intron and Pin II terminator from Potato
- DKHT17construct has GAT891G3 under the control of Corn Ubiquitin promoter and Pin Il terminator from Potato
- DKHT19 construct has GAT891G3mod1under the control of Corn Ubiquitin promoter and Pin II terminator from Potato
- (iii) **Transformation method:** All these constructs were transformed in rice using *Agrobacterium* mediated transformation.

4.11.7 The Committee observed that the proposal has been recommended by the IBSCand RCGM on 07.05.2013 and 25.6.2013 respectively.

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

In view of the above stated facts and taking into consideration the recommendations 4.11.8 of the RCGM, the Committee approved the request for conduct of event selection (Trial-6) on 48 transgenic rice (Oryzasativa) events generated using DKHT3, DKHT5, DKHT16, DKHT10, DKHT17 DKHT19 constructs one and at any two locations at Andhra Pradesh/Gujarat/Maharashtra/Tamil Nadu at Andhra Pradesh/Gujarat/Maharashtra/Tamil Nadu during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted. The Committee also advised applicant to submit details of the GAT gene.

### 4.12 Permission to conduct event selection (Trial-7) on 48 transgenic rice (Oryzasativa) events (Hybrids) generated using DKHT3, DKHT5, DKHT16, DKHT10, DKHT17 and DKHT19 constructs by M/s. Pioneer Overseas Corporation, Hyderabad.

4.12.1 The Committee considered the request of M/s. Pioneer Overseas Corporation (POC), Hyderabad for event selection (Trial-7) on 48 transgenic rice (Oryzasativa) events (Hybrids) generated using DKHT3, DKHT5, DKHT16, DKHT10, DKHT17 and DKHT19 constructs at Andhra Pradesh/ Gujarat/ Maharashtra/ Tamil Nadu The events were developed by transforming inbred Indica line. All events are single copy events. The trial will be conducted at Andhra Pradesh or Gujarat or Maharashtra or Tamil Nadu. The trials will be conducted at an area of 4000m<sup>2</sup>.

The details of constructs are as follows:

- **Construct DKHT3** –8 events from DKHT3.1 to DKHT3.24
- Construct DKHT5 8 events from DKHT5.1 to DKHT5.24
- **Construct DKHT16** 8 events from DKHT16.1 to DKHT16.16
- **Construct DKHT10** 8 events from DKHT10.1 to DKHT10.21
- Construct DKHT17 8 events from DKHT17.1 to DKHT17.21
- **Construct DKHT19** Events are DKHT19.1, DKHT19.2, DKHT19.3, DKHT19.4, DKHT19.5, DKHT19.6, DKHT19.7, DKHT19.8

4.12.2 The Committee noted that the Herbicide tolerant (HT) rice events were generated using Agrobacterium-mediated transformation of Indica inbred line with the six GAT constructs and callus was selected using glyphosate. Plants were regenerated and taken for generation advancement seed production was done in the green house. Molecular characterization (qPCR and Southern) was used to advance only single copy insert plants. They were tested for trait efficacy in green House in T1 generation and homozygous plants are advanced for seed production for testing in this selection trials (EST) As a non transgenic control, VIR54G9 (inbred line) will be used.

4.12.3 The Committee also noted that the objectives of the field trial are:

1. to evaluate the trait efficacy and agronomics of glyphosate tolerant rice events. to assess agronomic parameters of GAT events

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

- A spatial isolation of 200 meters from the last row of transgenic plant on all four sides will be maintained.
- All regulatory conditions of RCGM including SOP for conduct of confined field trials will be followed.
- 4.12.5 The experimental design:

Trial design is Split Plot Design (SPD) Number of treatments: A. Unsprayed B. Glyphosate spray (3600 g a.i./ha) on events

4.12.6 The Committee noted the following information on the gene construct and transformation method is as follows:

### (i) **Plasmid description**:

- DKHT3 construct has GAT4621 under the control of Corn Ubiquitin promoter and Pin II terminator from Potato.
- DKHT5 construct has GAT901B9 under the control of Corn Ubiquitin promoter and Pin II terminator from Potato
- DKHT16 construct has GAT4621under the control of BSV (Banana streak virus) promoter with Adh1 intron and Pin II terminator from Potato
- DKHT10 construct has GAT901B9 under the control of BSV (Banana streak virus) promoter with Adh1 intron and Pin II terminator from Potato
- DKHT17 construct has GAT891G3 under the control of Corn Ubiquitin promoter and Pin II terminator from Potato
- DKHT19 construct has GAT891G3mod1 under the control of Corn Ubiquitin promoter and Pin II terminator from Potato

(ii)**Transformation method:** All these constructs were transformed in rice using *Agrobacterium* mediated transformation.

4.11.7 The Committee observed that the proposal has been recommended by the IBSC and RCGM on 07.05.2013 25.6.2013 respectively.

4.11.8 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;

- (vi) Dosage of Herbicide Glyphosate spray
- (vii) Approval of Central Insecticide Board & Registration Committee (CIBRB).
- (viii) Nature and extent of biodegradation
- (ix) Residual estimate of the herbicide in the soil
- (x) Impact on Mollusca and Crustacean should also be studied during field trials

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 (Trial-7) on 48 transgenic rice (Oryzasativa) events (Hybrids) generated using DKHT3, DKHT5, DKHT16, DKHT10, DKHT17 and DKHT19 constructs at Andhra Pradesh/Gujarat/Maharashtra/Tamil Nadu at any two locations at Andhra Pradesh/Gujarat/Maharashtra/Tamil Nadu during any appropriate

season subject to submission of NOC from the State Government where the trials will be conducted. The Committee also advised applicant to submit details of the GAT gene.

## 4.13 Permission for conduct of event selection trial (EST15) on 10 SPT1 and 10 SPT6 Rice (*Oryzasativa L.*) containing *DsRed2, Zm-AA1, OsMSCA1* genes by M/s. Pioneer Overseas Corporation, Hyderabad.

4.13.1 The Committee considered the request of M/s. Pioneer Overseas Corporation, Hyderabad has requested for permission to conduct event selection trials on 20 transgenic Rice (*Oryzasativa L.*) events from SPT1 and SPT6 constructs. These are JH02, JH17, JH22, JH37, DKC118, DKC320, SPT1-3002, SPT1-3006, SPT1-3011 and SPT1-3012 derived from SPT1 and J6-1-4d, J6-1-7d, SPT6-1006, SPT6-1007, SPT6-1008, SPT6-1011, SPT6-1012, SPT6-1015, SPT6-1016 and SPT6-1020 derived from SPT6 construct. The trial will be conducted at 4 locations, Andhra Pradesh (Masaipet Village, Medak Distt, and in Gujarat (Anand Agricultural University, Navasari Agricultural University in Kharif and Rabi season. The size of the each trial will be 4000 m<sup>2</sup>.

4.13.2 The Committee noted that the SPT rice events were generated in Japonica Rice line M202 using *Agrobacterium* mediated transformation using SPT1 and SPT6 vector. After molecular characterization, single copy events were backcrossed into Pioneer inbred line VIR54G9.

4.13.3 The Committee observed that Rice Seed Production Technology (SPT) is a process that facilitates large-scale production of male sterile rice lines. These male sterile lines can be used as female inbred parents for subsequent hybrid seed production. Rice SPT is a transgene based process for production of maintainer lines, rather than a trait or product. Rice SPT maintainer was generated by *Agrobacterium* mediated transformation of a male sterile *(Os-msca1/Os-msca1)* mutant rice line with the Rice SPT1 and SPT6 plasmids containing three genes namely, *Os-Msca1* (Mod1), *Zm-AA1* and *DsRed2* (Alt1). These genes are essential for the functioning of Rice SPT process.

4.13.4 The Committee noted that the objectives of the trial are:

- 1. to assess the frequency of transgene transmission through pollen in SPT events.
- 2. to assess the outcross seed producibility of SPT events.
- 3. to evaluate DsRed2 and Zm-AA1 expression in leaf, anther and seeds of SPT events.
- 4. to study transgene segregation in SPT maintainer events.

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

- Spatial Isolation distance in the proposed trial 10 meters
- Distance to the nearest cultivated crop of the same species >10 m
- Distance to the nearest commercial crop of any kind- 10 m
- Trial will be marked for clear identification
- Surplus planting material will be either burnt or buried deep in the soil
- Non-transgenic line VIR54G9 will be planted as control

4.13.6 Trial Protocol :

- Experimental design for conducting trials is RCBD (Randomized Complete Block Design) with 2 replicates.
- Twenty transgenic events (10 SPT1 and 10 SPT6) will be used as a pollinator parent to produce seeds on non-transgenic male sterile line
- Field layout: events will be protected by barriers to avoid contamination.

Agronomy Practices:

a Nursery or seed bed preparation and sowing

- b. Nursery/seed bed management
- c. Main land preparation and transplanting
- d. Fertilizer management
- e. Weed management
- f. Pest and disease management
- g. seed production practices to increase the seed yield
- h. Harvesting and post-harvest management
- Observations:
- a. Pollen transmission
- b. Seed producibility and agronomic traits
- c. Biochemical observations
- d. Transgene segregation in maintainer events

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

- I. Plasmid description: Both SPT1 and SPT6 plasmid has same genetic elements. These are Zm-AA1- Alpha amylase gene from corn, Os-Msca1-Native fertility restoration gene from Rice and DsRed2- Florescence color marker gene from *Discosoma* s. The different between SPT1 and SPT6 is the relative position of Zm-AA1 and Os-Msca gene in the plasmid.
- **II. Transformation method**: SPT rice events were generated using *Agrobacterium* mediated transformation on M202 Japonica line containing *Os-msca* allele.

4.13.8 The Committee observed that the proposal has been recommended by the IBSC and RCGM on 03.12.2012and 26.2.2013 respectively

4.13.9 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 (EST15) on 10 SPT1 and 10 SPT6 Rice (*Oryzasativa L.*) containing *DsRed2, Zm-AA1, OsMSCA1* genes at any two locations in Andhra Pradesh (Masaipet Village, Medak Distt, and in Gujarat (Anand Agricultural University, Navasari Agricultural University during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted. The applicant is also advised to make a presentation before GEAC as indicated in the Agenda item No. 4.5.

## 4.14 Permission for conduct of event selection trial (EST16) on 10 SPT1 and 10 SPT6 Rice (*Oryzasativa L.*) containing *DsRed2, Zm-AA1, OsMSCA1* genes by M/s. Pioneer Overseas Corporation, Hyderabad.

4.14.1 The Committee considered the request of M/s. Pioneer Overseas Corporation, Hyderabad to conduct event selection trials on 20 transgenic Rice (*Oryzasativa L.*) events from SPT1 and SPT6 constructs. These are JH04, JH16b, JH25b, JH26a, JH35, JH36, DKC45, DKC376, DKC1049a and SPT1-3016 derived from SPT1 and J6-1-8, SPT6-1001, SPT6-1002, SPT6-1003, SPT6-1004, SPT6-1005, SPT6-1009, SPT6-1017, SPT6-1018 and SPT6-1019 derived from SPT6 construct. The trial will be conducted at 4 locations, in Andhra Pradesh (Masaipet Village, Medak Distt , and in Gujarat (Anand Agricultural University, Navasari Agricultural University)in Kharif and Rabi season. The size of the each trial will be 4000 m<sup>2</sup>.

4.14.2 The Committee observed that the SPT rice events were generated in Japonica Rice line M202 using *Agrobacterium* mediated transformation using SPT1 and SPT6 vector. After molecular characterization, single copy events were backcrossed into Pioneer inbred line VIR54G9.

4.14.3 The Committee also observed that the Rice Seed Production Technology (SPT) is a process that facilitates large-scale production of male sterile rice lines. These male sterile lines can be used as female inbred parents for subsequent hybrid seed production. Rice SPT is a transgene based process for production of maintainer lines, rather than a trait or product. Rice SPT maintainer was generated by *Agrobacterium* mediated transformation of a male sterile *(Os-msca1/Os-msca1)* mutant rice line with the Rice SPT1 and SPT6 plasmids containing three genes namely, *Os-Msca1* (Mod1), *Zm-AA1* and *DsRed2* (Alt1). These genes are essential for the functioning of Rice SPT process.

4.14.4 The Committee noted that the objectives of the trial are:

- 1. To assess the frequency of transgene transmission through pollen in SPT events.
- 2. To assess the outcross seed producibility of SPT events.
- 3. To evaluate DsRed2 and Zm-AA1 expression in leaf, anther and seeds of SPT events.
- 4. To study transgene segregation in SPT maintainer events.

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

- Spatial Isolation distance in the proposed trial 10 meters
- Distance to the nearest cultivated crop of the same species >10 m
- Distance to the nearest commercial crop of any kind- 10 m
- Trial will be marked for clear identification
- Surplus planting material will be either burnt or buried deep in the soil
- Non-transgenic line VIR54G9 will be planted as control

4.14.6 Trial Protocol :

- Experimental design for conducting trials is RCBD (Randomized Complete Block Design) with 2 replicates.
- Twenty transgenic events (10 SPT1 and 10 SPT6) will be used as a pollinator parent to produce seeds on non-transgenic male sterile line
- Field layout: events will be protected by barriers to avoid contamination.
  - Agronomy Practices:

a Nursery or seed bed preparation and sowing

- b. Nursery/seed bed management
- c. Main land preparation and transplanting
- d. Fertilizer management
- e. Weed management
- f. Pest and disease management
- g. seed production practices to increase the seed yield
- h. Harvesting and post-harvest management
- Observations:
- a. Pollen transmission
- b. Seed producibility and agronomic traits

- c. Biochemical observations
- d. Transgene segregation in maintainer events

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

- I. Plasmid description: Both SPT1 and SPT6 plasmid have same genetic elements. These are Zm-AA1- Alpha amylase gene from corn, Os-Msca1-Native fertility restoration gene from Rice and DsRed2- Florescence color marker gene from *Discosoma s.* The different between SPT1 and SPT6 is the relative position of Zm-AA1 and Os-Msca gene in the plasmid.
- **II.** Transformation method: SPT rice events were generated using *Agrobacterium* mediated transformation on M202 Japonica line containing *Os-msca* allele.

4.14.8 The Committee observed that the proposal has been recommended by the IBSC and RCGM on 03.12.2012 and 26.2.2013 respectively

4.14.9 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 (EST16) on 10 SPT1 and 10 SPT6 Rice (*Oryzasativa L.*) containing *DsRed2, Zm-AA1, OsMSCA1* genes at any two locations in Andhra Pradesh (Masaipet Village, Medak Distt) and in Gujarat (Anand Agricultural University /Navasari Agricultural University) during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted. The applicant is also advised to make a presentation before GEAC as indicated in the agenda item No. 4.5.

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

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Annexure –1

### List of the Members who attended the 120<sup>th</sup> GEAC meeting held on 12.05.2014

S.No.	Name and address
1.	Shri Hem Pande, Additional Secretary, MoEFand Chairman, GEAC.
2.	Dr K Veluthambi, Professor (retd) & Head, School of Biotechnology, Madurai Kamraj University, Madurai and Co-chairman ,GEAC.
3.	Shri Bishwajnath Sinha, Joint Secretary, MoEF and Vice-Chairman, GEAC
4.	Prof. C.R. Babu, Centre for Environmental Management of Degraded Ecosystems, School of Environmental Studies, DU, Delhi
5.	Dr. S.S. Banga, Plant Breeder, Punjab Agriculture University, Ludhiana.
6.	Dr. S. R. Rao, Advisor, DBT, and Member Secretary, RCGM.
7.	Dr. S. K. Apte, Director, Bio-Medical Group and Head, Molecular Biology Division, BARC, Mumbai
8.	Shri R.K. Mishra, ADC(Seeds) Department of Agriculture & Cooperation Ministry of Agriculture, Krishi Bhawan, New Delhi
9.	Dr. Ramesh Sonti, (Representative of DG-CSIR) Chief Scientist, CCMB, Hyderabad
10.	Dr Vijendra Mishra, Associate Professor, National Institute of Food Technology Entrepreneurship of Management (NIFTEM), Sonepat, Haryana.
11.	Prof. O.P. Govila, Former Prof. of Genetics, IARI, Delhi
12.	Prof. Akshay Kumar Pradhan, Department of Genetics, University of Delhi, South Campus, New Delhi
13.	Dr. V V Ramamurthy, Principal Scientist, Entomology Division, IARI, New Delhi.
14.	Dr. Renee M Borges, Professor, Centre for Ecological Sciences, Indian Institute of Science, Bangalore.
15.	Dr. Luther Rangreji, Associate Professor, Faculty of Legal Studies, South Asian University, Chankyapuri, New Delhi.
16.	Dr. Ranjini Warrier, Director, Ministry of Environment & Forests and Member Secretary ,GEAC.
17.	Smt. Madhu Gupta, Research Officer, MoEF