

Decisions taken in the 106th meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 12.01.2011.

The 106th meeting of the GEAC was held on 12.01.2011 in the Ministry of Environment & Forests under the chairmanship of Shri M. F. Farooqui, Additional Secretary, MoEF and Chairman, GEAC.

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

Agenda item No.4 : Policy issues

4.1 The Committee considered the suggestions received from two industry associations namely Association of Biotechnology Lead Enterprises (ABLE) and National Seed Association of India (NSAI) pertaining to (i) Duration of BRL-1 and BRL-II trials; (ii) Data Generation during BRL-1 and BRL-II trials; (iii) Implementation of Event Based Approval Mechanism (EBAM); (iv) Use of imported germplasm for field trials in India; (v) Acceptance of laboratory biosafety data from overseas ; (vi) Deregulation of stacked events and subsequent regulatory status of single event parental lines in the approved stacked events for seed production; (vii) Zone classification for different crops; (viii) State Agricultural Universities (SAU) trials; (ix) Minimize the time for application processing & time limits for issuing the permit letter; (x) Pollen flow studies; (xi) Joint application and registration process; (xii) Protecting the field trials from vandals; (xiii) Web based mechanism for submission of applications; (xiv) Opportunity to meet and discuss applications with the Member Secretary of RCGM/GEAC; (xv) Refuge/IRM strategy for insect resistance crops; (xvi) Approval for transgenic parent lines of GEAC approved Bt Cotton hybrids.

4.2 The Committee gave an opportunity to the representatives of ABLE and NSAI to make a presentation on the above issues. The following points were noted:

A. Regulatory approval process

- a. Implementation of event based approval mechanism (EBAM) for approved events
 - Ensures availability of best hybrid choices to farmers relevant to their agro-climate.
 - Onus on technology provider to certify the event presence and protein expression prior to hybrid commercialization
 - The Standing Committee may approve hybrids based on the criteria stipulated by the GEAC in its EBAM policy
 - The Standing Committee meeting(s) may be held well in advance of the crop season
 - Since the Standing Committee approves new hybrids under EPA based on certain criteria and without considering the agronomic data, it is in no position to approve a hybrid for a particular zone. Hence, it may not mention any agro-climatic zone in its approval letter.
- b. Deregulation of stacked events covers individual/ combination components of stacked events
 - Commercial stack approval should cover seed production using parental lines containing individual/intermediate events

- For refuge, seed containing the event which is approved in other countries, globally generated bio-safety data should suffice as this event (non-Bt refuge) is part of the stack that is evaluated in all BRL trials in India

B. Bio-safety data requirements

- a. Pollen Flow Studies not required
 - Internationally accepted publications, viz. International/ Indian Seed certification standards, OECD crop specific consensus documents, should be accepted
 - Scientific rationale need to be established for trait specific studies, if required
 - Only agronomic performance and environmental impact assessment at local country level
- b. Clarity on specific data requirements at BRL-I/II trial stages
- c. Acceptance of laboratory Bio-safety data generated under GLP as data has been generate under scientifically rigorous controlled conditions following standardized protocols

C. Streamlining Regulatory Procedures

- a. Managing approval process flow to enhance efficiency by providing:
 - Web based mechanism for submission of applications
 - Opportunity to discuss applications with member Secretaries RCGM/GEAC prior to meetings
 - Opportunity to file simultaneous applications to RCGM and GEAC to accomplish approvals in the same month cycle
- b. Joint application and registration / approval process
 - Important in the era of collaborations and partnerships
 - Doesn't compromise on any safety assessments and data requirements
 - Individual onus on joint applicants to comply with permit conditions in the event of approval
 - Accepted norm globally

D. Strategies for Non Bt-Refuge in Cotton Crop

- a. Method of planting of refuge
 - GEAC to permit planting of non Bt refuge as a single patch adjoining Bt Cotton field instead of the current requirement to plant non-Bt cotton refuge all around Bt cotton field as farmers with small land holdings find it extremely difficult to comply with this requirement
- b. Type of genotype/species to be used as refuge

- GEAC to permit use of a non Bt cotton variety with similar fiber properties to be used as refuge in those areas where pigeon pea does not fit in the local cropping system as seed companies are finding it extremely difficult to produce adequate quantity of non-Bt hybrid seed

c. Area under non-Bt refuge

- Since two gene technologies have now been approved, GEAC may review the requirement of planting 20% of the total farm area as non-Bt refuge as added efficacy of two *Bt* genes can be translated to a requirement of a smaller refuge size
- In most countries such as US, South Africa, Brazil, Australia etc, either there is no requirement of structured refuge in the case of two Bt genes or the requirement is much less (5%)

E. Status of approval for transgenic parents of GEAC approved Bt. Cotton hybrids:

- As the GEAC approves Bt Cotton Hybrids which involve at least one transgenic parent, it is implicit that the parent has also been approved for environmental release for the purpose of undertaking large scale production.
- PPV & FR Authority does not accept this logical argument. All applications of transgenic parental lines have been kept in abeyance by PPV & FR Authority on the grounds that the GEAC has approved only the hybrid, and therefore the parent cannot be considered as approved by the GEAC.
- GEAC to issue appropriate orders to clarify that Bt parents of GEAC approved Bt Cotton hybrids may also be considered as approved under EPA

F. Stewardship

- Every technology developer to develop a stewardship plan in consultation with public sector experts that focuses on self regulation.
- It should cover areas like Trait integrity / purity, Insect Resistance Management (IRM) etc which is scientifically robust, practical and implementable.
- Science based consideration for individual technologies.

4.3 After a brief discussion on the above issues, the Committee was of the view that it may be clarified that the duration of BRL-I trials would be for a minimum period of two years and BRL-II trials would be for a minimum period of one year. As regards the request of DBT to transfer the responsibility under the EBAM mechanism for cotton from DBT to the State Governments, the Committee opined that the tenure of the 'Standing Committee' is for a period of three years of which only two years have been completed. Further, it was also noted that, with the approval of the new Seed Bill 2004, all transgenic crops will have to be registered. Therefore, putting in place a new mechanism for a short period may not be advisable. The Chairman, GEAC requested Member Secretary, RCGM to continue with the current mechanism until the tenure of the Standing Committee is complete, subsequent to which the matter may be reviewed again. In respect of all other issues raised by ABLE and NSAI, it was decided to consider the matter in the next GEAC meeting.

Agenda item No. 5: Consideration of applications for confined field trials of transgenic crops (Event selection, BRL-I) as recommended by the RCGM.

5.1 Permission to change the locations for conduct of BRL-1 trials of transgenic corn hybrids expressing stacked event of TC1507+NK603 by M/s. Pioneer Overseas Corporation, Hyderabad.

5.1.1 The Committee noted that the GEAC in its meetings held on 9.12.2009 had permitted M/s. Pioneer Overseas Corporation, Hyderabad to conduct BRL-I trials with two transgenic corn hybrids namely 30V92HR and 30B11HR with indigenously produced seeds containing *cry1F* & *PAT* and *CP4EPSPS* genes (TC1507 X NK603 (DAS-01507-1 x MON-00603-6) during Rabi 2009-2010 at four SAUs namely

1. Rajendra Agricultural University (RAU), Bihar.
2. Birsa Agricultural University (BAU), Jharkhand,
3. Tamil Nadu Agricultural University (TNAU), Coimbatore and
4. Acharya N.G. Ranga Agricultural University (ANGRAU), Hyderabad during Rabi 2010-11.

5.1.2 The GEAC subsequently extended validity of the approval for conduct of BRL-I trials with two transgenic corn hybrids namely 30V92HR and 30B11HR with indigenously produced seeds containing *cry1F* & *PAT* and *CP4EPSPS* genes (TC1507 X NK603) during Rabi 2010-2011 in the above mentioned four SAUs.

5.1.3 The Committee noted that the present request of the applicant is to change the locations from Birsa Agricultural University (BAU), Jharkhand and Rajendra Agricultural University (RAU), Bihar to University of Agricultural Sciences (UAS), Dharwad, Karnataka and Banaras Hindu University (BHU), Varanasi, U.P. respectively as BAU, Ranchi and RAU, Bihar are taking considerable time in finalizing the modalities and allotting the trial site for undertaking the trials.

5.1.4 The Committee further noted that IBSC in its meeting held on 6th November 2010 and the RCGM in its meeting held on 23.11.2010 have also recommended the alternate locations for conduct of BRL-I trials.

5.1.5 In view of the above stated facts, the Committee approved the change of locations to University of Agricultural Sciences (UAS), Dharwad, Karnataka and Banaras Hindu University (BHU), Varanasi, U.P. for conduct of BRL-1 trials of transgenic corn hybrids expressing stacked event of TC1507+NK603.

5.2 Permission to conduct seed production of non-Bt with Roundup Ready Flex (RRF) cotton hybrids containing *cp4epsps* gene (event MON 88913) by M/s Maharashtra Hybrid Seeds Company Limited (MAHYCO), Mumbai.

5.2.1 The Committee noted that the present request of M/s Mahyco is for seed production of non Bt Roundup Ready Flex (RRF) hybrids containing *cp4epsps* gene (event MON 88913), for use as refugia while planting transgenic cotton hybrids containing Bollgard II X Roundup Flex (BGIIIRRF). It was noted that the request was rejected by the GEAC in its meeting held on 29.9.2010 on the grounds that the Roundup Ready flex (RRF) in cotton hybrids (Event MON 88913) has not been approved for environmental release and therefore planting of refuge with unapproved events cannot be allowed.

5.2.2 The Committee also considered the following views received from, Director, CICR, Nagpur:

- (i) If the Refugia in BG-II-RR-Flex comprise only of non-Bt cotton without RR-Flex, there is every likely possibility of the refugia patch getting destroyed due to spray drift or inadvertent application of 'Round-up' on the 'non-RR-Flex-non-Bt-cotton'.
- (ii) Technically, it would be a mistake if only 'non-RR-Flex-non-Bt-cotton' is recommended as 'Refugia'. Therefore provision of 5% refugia seed of 'RR-Flex-non-Bt-cotton' hybrid or variety of corresponding maturity and fibre traits must be made mandatory for commercial cultivation along with RR-Flex-Bollgard-II.

5.2.3 After a brief discussion on the matter, the Committee reiterated that there is no need to have RRF trait in the seeds to be used in refuge as non transgenic (non Bt and non RRF) hybrids could be used as refuge.

5.2.4 During the deliberations, one of the expert members informed that the BRL-II trials are being conducted using non-Bt RR-Flex-Cotton as refugia. The Committee further noted that as per the directions issued by the GEAC, BRL-II trials with BG-II RRF cotton are being conducted under the supervision of Director CICR as per the protocol approved by him.

5.2.5 The Committee opined that RRF cotton hybrids (Event MON 88913) have not been approved for environmental release and therefore planting of refuge with unapproved events cannot be allowed. It is the responsibility of the applicant to ensure that all approvals have been obtained prior to initiating the trials.

5.2.6 After a brief discussion on the matter, the Committee decided to issue a 'Show Cause' notice to M/s Mayhco seeking explanation on why penal action under E(P)A should not be initiated for violations of 'Rules 1989' as well as the status of the ongoing field trials with BGII RRF cotton.

5.3 Permission to change the location from, KVK. Hadonohalli Bangalore to company leased land at Medak, Andhra Pradesh for conduct of event selection on transgenic rice events (Hybrid Rice SPT maintainer events) by M/s. E.I. Dupont India Pvt. Ltd., Dupont Knowledge Center, Hyderabad.

5.3.1 The Committee noted that the GEAC in its meeting held on 29.9.2010 had approved the event selection trials with transgenic rice (Hybrid rice SPT maintainer event) which was conducted at KVK. Hadonohalli, Bangalore within the SAU farm belonging to UAS, Dharwad.

5.3.2 The Committee further noted that the present request of the Company is to change the location of the event selection trials from KVK. Hadonohalli to company leased land at Medak District, Andhra Pradesh as the earlier trial was damaged by some local groups on November 17, 2010.

5.3.3 It was also noted that the RCGM in its meeting held on 23.11.2010 has recommended the change in location.

5.3.4 In view of the above stated facts, the Committee approved the change of location to company leased land at Medak, Andhra Pradesh for conduct of event selection on transgenic rice events (Hybrid Rice SPT maintainer events).

5.4 Permission to conduct event selection on seven transgenic rice events (Hybrid Rice SPT maintainer events to maintain male sterile female parental lines)

generated using the SPT1 construct for use in hybrid seed production by M/s. E.I. Dupont India Pvt. Ltd., Hyderabad.

5.4.1 The Committee considered the request of M/s. E.I. Dupont India Pvt. Ltd., Hyderabad to conduct event selection trials on seven transgenic rice events (Hybrid Rice SPT maintainer events to maintain male sterile female parental lines) generated using the SPT1 construct for use in hybrid seed production namely; DKC118, DKC45, JH02, JH04, JH11, JH22, and JH25a of BC4 generation containing DsRed2-Os-Msca1-ZM-AA1 gene during Kharif 2011 at Medak District, Andhra Pradesh. The events were developed by transforming M2O2 x T65 lines and then backcrossed into an elite indica line VIR54G9. All the events are single copy events.

5.4.2 The Committee noted that the purpose of this trial is to assess/evaluate: (i) the frequency of transgene transmission through pollen in different events; (ii) the seed producibility of the events; (iii) the expression levels of DsRed2 and ZM-AA1 in tissues of Hybrid Rice SPT maintainer events.

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

- A spatial isolation of 200 m from the last row of transgenic plant on all four sides will be maintained.
- Male sterile lines will be planted as the pollen recipient. Seeds set on these male sterile plants will be used to assess any transgenic transmission through pollen.
- The excess seedlings will be burnt after transplanting at the trial site.

5.4.4 The Committee also considered information on the gene construct and transformation method.

5.4.5 5.4.5 It was further noted that the IBSC in its meeting held on 07.12.2010 and the RCGM in its meeting held on 27.12.2010. have recommended the proposal.

5.4.6 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials on seven transgenic rice events (Hybrid Rice SPT maintainer events to maintain male sterile female parental lines) generated using the SPT1 construct for use in hybrid seed production by M/s. E.I. Dupont India Pvt. Ltd., Hyderabad

5.5 Permission to conduct event selection trial on transgenic rice events (Hybrid Rice SPT maintainer events to maintain male sterile female parental lines) generated using the SPT6 construct for use in hybrid seed production by M/s. E.I. Dupont India Pvt. Ltd., Hyderabad.

5.5.1 M/s. E.I. Dupont India Pvt. Ltd., Hyderabad has requested permission to conduct event selection trial on 15 transgenic rice events (Hybrid Rice SPT maintainer events to maintain male sterile female parental lines) generated using the SPT6 construct for use in hybrid seed production, namely; J6-1-139c, J6-1-129d, J6-3-36a, J6-3-31-4c, J6-2-16c, J6-4-M-1a of BC2 and J6-1-130, J6-1-76-3a, J6-1-142d, J6-1-105h, J6-3-33-3c, J6-350b, J6-3-6'a, J6-2-10b and J6-1-126c of BC1 generation containing Os-Msca1-ZM-AA1-DsRed2 gene during Kharif 2011 in one location at Raipur, Chattisgarh. The events were developed by transforming M2O2 x T65 lines and then backcrossed into an elite *indica* line VIR54G9.

5.5.2 The Committee noted that the purpose of the trials is to assess: (i) the frequency of transgene transmission through pollen in different events; (ii) the seed producibility of the events; (iii) the expression levels of DsRed2 and ZM-AA1 in tissues of Hybrid Rice SPT maintainer events.

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

- A spatial isolation of 200 m from the last row of transgenic plant on all four sides will be maintained.
- Male sterile lines will be planted as the pollen recipient (layout is provided). Seeds set on these male sterile plants will be used to assess any transgenic transmission through pollen.
- The excess seedlings will be burnt after transplanting at the trial site.

5.5.4 The Committee also considered information on the gene construct and transformation method.

5.5.5 It was further noted that the IBSC in its meeting held on 07.12.2010 and the RCGM in its meeting held on 27.12.2010 have recommended the proposal

5.5.6 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trial on 15 transgenic rice events (Hybrid Rice SPT maintainer events to maintain male sterile female parental lines) generated using the SPT6 construct for use in hybrid seed production.

5.6 Permission to conduct event selection on 23 transgenic rice events against yellow stem borer and rice leaf folder pests submitted by M/s. E.I. Dupont India Pvt. Ltd., Hyderabad.

5.6.1 The Committee considered the request of M/s. E.I. Dupont India Pvt. Ltd., Hyderabad to conduct event selection trials on 23 transgenic rice events against yellow stem borer and rice leaf folder pests. The one event generated using Bt38 (Cry1Ab + Cry2ad) construct, namely MP-38H-95-8-12 of T3 generation will be tested in the Event Selection Trial. The event was developed by transforming the elite Indica rice. The trials will be conducted at one location at Medak District, Andhra Pradesh.

5.6.2 Bt rice events were generated using *Agrobacterium* mediated transformation of Elite Indica rice. Co-transformation was done with 'two binary in one Agro' system, one binary containing two Cry genes and another containing Hygromycin. Hygromycin was used as the selectable marker but was segregated out in the subsequent generation to generate marker free Bt events.

5.6.3 The Committee noted that the purpose of the trials is to evaluate: (i) the efficacy of dual molecular stacked Cry genes in Bt rice events against Yellow stem borer and Rice leaf folder pests in the confined field trial; (ii) the expression levels of molecular stacked Cry proteins in tissues of Bt rice events.

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

- A spatial isolation of 200 m from the last row of transgenic plant on all four sides will be maintained.
- Male sterile lines will be planted as the pollen recipient (layout is provided). Seeds set on these male sterile plants will be used to assess any transgenic transmission through pollen.
- The excess seedlings will be burnt after transplanting at the trial site.

5.6.5 The Committee also considered information on the gene construct and transformation.

5.6.6 It was further noted that the IBSC in its meeting held on 07.12.2010 and the RCGM in its meeting held on 27.12.2010 have recommended the proposal subject to submission of information on the known allergens of transgenic rice (*Oryza sativa* L.).

5.6.7 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trial on transgenic rice events (Hybrid Rice SPT maintainer events to maintain male sterile female parental lines) generated using the SPT6 construct for use in hybrid seed production.

5.7 Permission to conduct event selection on 20 transgenic rice (*Oryza sativa* L.) events containing *cry1Ac* gene for the evaluation of the Bt events for resistance against lepidopteron insects and to identify events which are true-to-type agronomically by M/s. JK Agri Genetics Ltd., Hyderabad

5.7.1 The Committee considered the request of M/s. JK Agri Genetics Ltd., Hyderabad has requested permission to conduct event selection trials on 20 transgenic rice (*Oryza sativa* L.) events namely: AcE001 to AcE020 containing *cry1Ac* gene against yellow stem borer and rice leaf folder pests for the evaluation of the Bt events for resistance against lepidopteron insects and to identify events which are true-to-type agronomically at company farm/leased land during Rabi 2011 (Jan-June 2011) .

5.7.2 Decision on the proposal was deferred as the applicant had not submitted information pertaining to: (i) location of the event selection trials; and (ii) the marker used for selection of events.

5.8 Permission to conduct event selection trials on 20 transgenic rice (*Oryza sativa* L.) events namely Cry2AxE 001-to Cry 2AxE 020 containing *cry2Ax1* gene containing for the evaluation of the Bt events for resistance against lepidopteran insects and to identify events which are true-to-type agronomically by JK Agri Genetics Ltd., Hyderabad

5.8.1 The Committee considered the request of M/s. JK Agri Genetics Ltd., Hyderabad has requested permission to conduct event selection trials on 20 transgenic rice (*Oryza sativa* L.) events namely: Cry2AxE 001-to Cry 2AxE 020 containing *cry2Ax1* gene against lepidopteron insects and to identify events which are true-to-type agronomically during Rabi-2011 at company farm/leased land during Rabi 2011.

5.8.2 Decision on the proposal was deferred as the applicant had not submitted information pertaining to: (i) location of the event selection trials; and (ii) the marker used for selection of events.

Agenda Item No 6: Any other matter with the permission of the Chair.

6.1 Review of the isolation distance to conduct event selection trials on seven transgenic rice (*Oryza sativa L*) events by Department of Botany, University of Calcutta, Kolkata

6.1.1 The Committee noted that the GEAC in its meeting held on 15.11.2010 had approved the request to conduct event selection trials on seven transgenic rice (*Oryza sativa L*) events at Rice Research Station, Chinsurah, West Bengal for two seasons subject to the condition that the prescribed 200 m isolation distance would be maintained at the trial site.

6.1.2 Member Secretary GEAC informed that this issue has been brought before the GEAC in view of the query raised by DDG-ICAR wherein he has clarified that the prescribed isolation distance as per IMSCS, 1988, for inbred lines is 3 meter and for hybrids it is 200 m. As the trials conducted by university of Kolkata is with inbred lines, 10 m isolation distance as indicated in their application would be adequate. It was further clarified that the inbred variety is a stable and released variety. In view of the above stated facts, the GEAC conveyed its 'no objection' to maintain 10 m isolation distance during the event selection trials with transgenic rice developed by University of Kolkata.

Date of next GEAC: 9th February 2011.
