

Decisions taken in the 90th meeting of the Genetic Engineering Approval Committee held on 12.11.2008.

The 90th meeting of the Genetically Engineering Approval Committee (GEAC) was held on 12.11.2008 in the Ministry of Environment and Forests under the Chairmanship of Shri B. S. Parsheera, Special Secretary and Chairman GEAC.

The deliberations of the GEAC in respect of Agenda Items 4 and 5 are as follows:

Agenda Item No 4: Policy Issues.

4.1 Recommendations of the Sub-committee constituted by the Ministry to operationalize the 'event based approval mechanism' adopted by the GEAC in its meeting held on 2.4.2008.

4.1.1 Since the release of Bt. Cotton in India, several measures have been initiated for streamlining the Bt cotton approval process in India. The first such initiative was the setting up of a 'Task Force on Agriculture Biotechnology' under the chairmanship of Prof. M.S. Swaminathan. The report of the Task Force recommended: (i) an event based approval system; (ii) once an event has been declared as 'bio-safe', its derivatives need not be subjected to extensive biosafety testing; and (iii) a fast track approval process for notified varieties expressing the approved events.

4.1.2 While the GEAC adopted the recommendations that Bt cotton hybrids expressing approved events need not repeat the biosafety studies and a fast track system for centrally notified varieties was introduced, decision on 'event based approval system' was deferred until experience is gained.

4.1.3 On the basis of six years of experience in commercial cultivation of Bt cotton, there has been a demand for consideration of an 'event based approval system' in Bt cotton. Accordingly, the GEAC in its meeting held on 8.8.2007 decided to set up a sub-committee under the Chairmanship of Dr. B.M. Khadi, Director, CICR, Nagpur with the following terms of reference:

- a) To review the need for continued case by case regulation of Bt cotton expressing *cry 1Ac* (MON 531 event) and implication of de regulation, if any;
- b) Rationalization of the zones based on the agro-climatic conditions; and
- c) recommendations regarding suitability for release of Bt cotton in other cotton growing states.

4.1.4 The sub-committee under Dr Khadi, based on extensive consultations with the state government, state agriculture universities and industries, recommended that in respect of Bt cotton hybrids expressing approved events, a decentralized system involving the SAU and state department of agriculture may be followed.

4.1.5 The recommendations of the sub-committee was considered by the GEAC in its meeting held on 2.4.2008 wherein it was decided to adopt the 'event based approval mechanism' for Bt cotton hybrids expressing approved events. The GEAC further decided to constitute a sub-committee under the chairmanship of Dr. P. L. Gautam, Deputy Director General (Crop Science), ICAR, New Delhi to suggest suitable guidelines and to prepare the draft notification to operationalize the event based approval mechanism adopted by the GEAC in its meeting held on 2.4.2008.

4.1.6 The recommendations of the sub-committee are as follows:

- i) The proposed guidelines would be applicable to Bt cotton hybrids expressing events approved by the GEAC namely; *cry 1Ac* (MON 531), *cry 1Ac and cry 2Ab* genes (MON) 15985 event), *cry 1Ab-cry 1A* "GFM", *cry 1A*, *cry 1Ac* (event 1) and truncated *cry1Ac* gene (Dharwad event).

- ii) The applicant (private/public sector organizations) shall file a written request to the concerned State Agricultural University clearly indicating the zone and area (irrigated/ rainfed) for which the trials on concerned Bt cotton hybrid/variety containing any of the approved event are to be evaluated. It shall be mandatory for the applicant to file an affidavit confirming/stating the following:
 - a) Confirmation of gene/ event through molecular characterization by the Licensor that the gene(s) which is being used is one of the approved events.
 - b) Level of protein expression in green house and field trials
 - c) Morphological characters using DUS descriptors
 - d) Bio-efficacy data generated in laboratory conditions
 - e) Authorization / No Objection Certificate from technology provider in case of sub-licensee.
- iii) The trials shall be conducted for two consecutive years by the State Agricultural Universities after due process of consultation with the Commissioner/Director of Agriculture / Horticulture as per the AICCIP rules/ protocols and data should be presented in prescribed format so as to have uniformity while presenting the results.
- iv) While evaluating the performance, SAUs should consider information generated on productivity, fibre quality, oil content, insect and disease reactions and the in-house data submitted by the applicant and any other information if found relevant. Based on zone wise evaluation of cotton genotypes, the most potential genotypes would be identified by the SAU for each zone and area (irrigated/rainfed). If the superior performance of genotype/hybrid is confirmed, it should be recommended by the SAU to the State Department of Agriculture for commercial cultivation for a specified period as deemed fit for that particular State/situation (rainfed/irrigated).
- v) The Secretary (Agriculture) or Director of Agriculture of respective States will submit the report of evaluation of the Bt cotton hybrids to the State Varietal Release Committee for permitting further commercialization in the respective State for a specified period.
- vi) In case the applicant likes to identify certain (hybrids/varieties), as centrally notified varieties, they should follow the prevailing All India Coordinated Cotton Improvement Project (AICCIP) procedure under the ICAR system.

4.1.7 While discussing the report of the sub-committee, some of the members were of the view that entrusting the regulation of Bt cotton expressing approved events to the state government needs re-consideration on the following grounds:

- i) The proposed decentralized mechanism would be extremely cumbersome as the seed industry would have to obtain approval from each state government (which in the instant case is about nine approvals).
- ii) The state agricultural universities / state governments do not have adequate expertise to verify the information related to gene confirmation, protein expression, etc., submitted by the applicant along with the affidavit (refer para 4.1.6 (ii) at page 2).
- iii) Instead of two year SAU trials, the mechanism of one year trial by the company and one year under the SAUs, presently followed while releasing 'truthfully labeled seeds', may be considered.
- iv) The standard statistical design followed by ICAR may not be made mandatory as each state agriculture university has its own design taking into consideration the agro-climatic conditions.

4.1.8 In light of the above, some members opined that the GEAC may consider constituting a 'Standing Committee' at the central level for evaluation of Bt cotton hybrids expressing approved events under the event based approval mechanism. In response, the following points were raised by some of the members:

- i) Agriculture is a state subject and therefore approval of the genotype suitable for a particular region would fall under the mandate of the state government. Even as per the existing mechanism i.e. after obtaining approval of the GEAC, the applicants are required to obtain consent of the State Department of Agriculture before its commercialization in the State.
- ii) The GEAC has adopted an event based approval mechanism on the grounds that there are no further biosafety issues involved with respect to Bt cotton hybrids expressing approved events. Therefore agronomic evaluation does not fall under the mandate of the GEAC or the RCGM.
- iii) The constitution of a 'Standing Committee' for evaluating the Bt cotton hybrids expressing approved events in place of the State Agriculture Department / State Varietal Committee would mean that the GEAC/RCGM would have to service the central committee which defeats the purpose of adopting an event based approval mechanism.
- iv) It may also not be advisable to set up a new Committee at the central level considering that a well established mechanism already exists under the ICAR system. Every year several cotton hybrids including transgenic cotton are evaluated for their agronomic superiority under the All India Co-ordination Cotton Improvement Project (AICCIP). The data generated from these trials are evaluated in the AICCIP meetings based on which superior genotypes are short listed. The meetings of the AICCIP trials are conducted every year on zonal basis. Therefore, it was suggested that the results of the SAU trials may be discussed / evaluated as part of the existing mechanism under AICCIP to be serviced by ICAR or any other agency recommended by the ICAR.

4.1.9 After detailed deliberations, it was decided that ICAR may be requested to take the responsibility of operationalizing the 'event based approval mechanism' in view of the vast experience and expertise available with ICAR under the existing AICCIP mechanisms. The GEAC further recommended that the new system should be made effective by 1st March 2009 in time for granting approvals during 2009.

4.1.10 The recommendations of the sub-committee and the views of the GEAC may be communicated to DG, ICAR for suitably incorporating while laying down procedure for evaluation and approval of Bt cotton hybrids expressing approved events.

4.2 List of studies to be conducted by the applicants under Biosafety Research Trial Level I (BRL-I) and Biosafety Research Trial Level II (BRL-II) of Genetically Engineered Plants.

4.2.1 Member Secretary, GEAC informed that as per 'Rules, 1989', the GEAC has been permitting the release of GM crops in the country on a hybrid by hybrid basis. The field trials of various Bt cotton hybrids released upto date as well as other GM crops in the pipeline have been conducted in three stages consisting of strip trials, Multi Location Research Trials (MLRT) in different agro climatic zones and Large Scale Trials (LST) along with field evaluation in ICAR's All India Coordinated Cotton Improvement Programme or other ICAR institutions. However, the focus of MLRT and LST was more on agronomic evaluation rather than on biosafety testing, although the desired tests were being undertaken by the product developers on a piecemeal basis.

4.2.2 The GEAC has now adopted an event based approval system, wherein the focus of the field testing would be on biosafety issues particularly the environmental and health safety. The responsibility of agronomic evaluation has been entrusted to the National Agricultural Research System (consisting of ICAR's institutions and state agricultural universities). Further, a new set of guidelines and standard operating procedures (SOPs) for the conduct of confined field trials of regulated, genetically engineered (GE) plants have been recently introduced by RCGM and GEAC. As per the new set of guidelines the field trials of GM crops have been redefined as Biosafety Research Level – I and Biosafety Research Level – II in place of MLRT and LST, respectively.

4.2.3 The present proposal to pre-define the objectives of the field trials and list out biosafety studies to be conducted under BRL-I and BRL-II has been initiated by MoEF and DBT with a view to streamline the regulatory mechanism and also to provide guidance to the project developer.

4.2.4 The Committee, after a brief discussion was of the view that the draft note circulated by the Member Secretary GEAC is quite comprehensive. However, before finalizing the document it would be useful if a small group of experts could review the document carefully. It was therefore decided to set up a Sub-committee comprising of Dr S. K. Apte, BARC, Mumbai, Dr. P. Anand Kumar, Project Director, NRCPB, Dr K. K. Tripathi, Adviser, DBT and Dr. R. Warriar, Director, MoEF under the Chairmanship of Dr K R Kranthi, Director CICR, Nagpur. The GEAC requested the Sub committee to take into consideration comments / views received from other members / experts while finalizing the report. The GEAC also requested the Sub-committee to convene the meeting at the earliest so that the proposal can be finalized in the next meeting of the GEAC.

Agenda Item No 5: Consideration of Applications for MLRT/strip trials/ experimental seed production of transgenic crops expressing new genes/events as recommended by the RCGM.

5.1 Permission to conduct strip trials for event selection with RB-transgenic potato clones at R&D Farm, located at CPRI Campus, Modipuram for evaluation of late blight resistance by M/s Central Potato Research Institute, Shimla.

5.1.1 The Committee considered the request of M/s Central Potato Research Institute, Shimla to conduct strip trials for event selection with RB-transgenic potato clones for evaluation of late blight resistance. It was noted that the trials will be conducted within the institutional research farm located at CPRI Campus, Modipuram.

5.1.2 It was further noted that experimental field trials on transgenic potato containing RB gene was conducted in June, 2006 with the approval of RCGM within the institutional research farm. Subsequent field trials were deferred in view of the Hon'ble Supreme Court direction regarding the requirement of an event specific protocol of 0.01%. The present request is for initiating the field trials which was abandoned for nearly two seasons. The IBSC has approved the proposal in its 8th meeting held on 4.8.2007.

5.1.3 RCGM in its meeting held on 30.9.2008 had recommended the conduct of strip trials with RB-transgenic potato clones for event selection within the institutional research farm located at CPRI for evaluation of late blight resistance subject to the conditions that the institute would generate the following information simultaneously with the trials:

- the protein expression data at green house/lab conditions;
- biosafety data using purified protein,
- SOPs for conducting field trials
- validated event specific protocol of 0.01% LOD of the selected event.

5.1.4 After detailed deliberations, the GEAC approved the conduct strip trials for event selection with RB-transgenic potato clones for evaluation of late blight resistance.

5.2 Permission to conduct bio-safety research level-1 field trials under confined condition on two transgenic corn hybrids namely Hishell and 900M Gold containing stacked events MON 89034 & NK603 at five SAUs by M/s Monsanto India Ltd., New Delhi.

5.2.1 The Committee considered the request of M/s. Monsanto India Ltd to conduct bio-safety research level-1 field trials under confined conditions on two transgenic corn hybrids namely Hishell

and 900M Gold containing stacked events MON 89034 (insect protection) & NK603 (herbicide tolerance) at five SAUs during Rabi – 2008. The stated objectives of the trials are as follows:

- To study the impact of transgenic corn (MON-89034XNK603) hybrids against target *lepidopteron* pests, secondary pests and non target insect pests species.
- Comparative assessment of soil ecosystem & weediness, morphology & phenotypic characters of transgenic corn and its conventional counterpart hybrids.
- Evaluate weed management efficiency with K salt of Glyphosate formulation under field conditions and carryover on succeeding crops.
- Undertake gene expression studies of transgenic corn event (MON 89034) and to produce sufficient plant material to undertake research on safety & residue studies as per the respective guidelines.

5.2.2 The RCGM in its 70th meeting held on 30.9.2008 had recommended the proposal of M/s Monsanto for conduct of biosafety research trial level – I (BRL-I) trials at three locations within the State Agriculture Universities.

5.2.3 The Committee also noted that in accordance with the Hon'ble Supreme Court directions, the applicant has complied with the LOD requirement of 0.01% for both events validated by M/s Avesthagen Quality Agriculture Service.

5.2.4 After detailed deliberations, the GEAC approved the request to conduct bio-safety research level-1 field trials under confined conditions on two transgenic corn hybrids namely Hishell and 900M Gold containing stacked events MON 89034 (insect protection) & NK603 (herbicide tolerance) at three locations within the SAUs during Rabi – 2008.

5.3 Request for waiver of pollen flow studies on JKL Transgenic cotton containing genes *cry1Ac* (Event-1) and *cry1EC* (Event-24) genes by M/s J. K. Agri Genetics Ltd., Hyderabad.

5.3.1 The Committee rejected the request for waiver of pollen flow studies on JKL Transgenic cotton containing genes *cry1Ac* (Event-1) and *cry1EC* (Event-24) genes by the applicant.

5.4 Permission to conduct evaluation of bio-efficacy, residue, phytotoxicity and carryover and effect of glyphosate herbicide (potassium salt of glyphosate formulation) on transgenic stack cotton hybrids (MON 15985 x MON 88913) at two locations in Central and South Zones by M/s Maharashtra Hybrid Seeds Co. Ltd., Maharashtra.

5.4.1 The Committee noted that the present request is to conduct evaluation of bio-efficacy, residue, phototoxicity and carry over and effect of glyphosate herbicide (Potassium salt of glyphosate formulation) at two locations at Mahatama Phule Krishi Vidyapeeth, Rahuri in Maharashtra) and Anand Agriculture University in Gujarat in Central zone and at Acharya NG Ranga Agricultural University, Hyderabad in Andhra Pradesh and Tamil Nadu Agricultural University, Coimbatore in South zone. The request has been examined by the RCGM in its 70th meeting held on 30.9.2008 and recommended for consideration of the GEAC.

5.4.2 It was also noted that the GEAC in its meeting held on 22.6.2008 had permitted the applicant to conduct BRL-1 field trials of transgenic stacked gene cotton hybrids (MON 15985 x MON 88913) at two locations namely Jalana (Maharashtra) and Rajkot (Gujarat) in Central zone and in Shamshabad of RR district in Andhra Pradesh and Ranebennur of Haveri Dist in Karnataka in South Zone.

5.4.3 During the deliberations, it was noted that, in future, the applicant should approach the regulatory authorities with a comprehensive work plan for conducting biosafety studies so that field trials are restricted to a minimum of two to three locations. It was noted that the guidance

documents on studies to be conducted under BRL-I and BRL-II which is under finalization would resolve the issue of the applicant approaching the regulatory agencies on a piecemeal basis.

5.4.4 After detailed deliberations, the GEAC approved the request to conduct evaluation of bio-efficacy, residue, phototoxicity and carry over and effect of glyphosate herbicide (Potassium salt of glyphosate formulation) at two locations each in the Central and South zone.

5.5 Permission for experimental seed production of one Bt cotton hybrid Wide Strike™ WS103 expressing Cry1Ac and Cry 1F genes (Widestrike=Event 3006-210-23 and Event 281-24-236) at one location in South zone by M/s Dow Agro Sciences India Pvt. Ltd, Mumbai.

5.5.1 The Committee noted that the applicant is seeking approval of the GEAC for seed multiplication of transgenic cotton hybrid Wide Strike™ WS103 expressing Cry1Ac and Cry 1F genes (Widestrike=Event 3006-210-23 and Event 281-24-236) at one location in the South zone. The applicant will use composite seed material derived from MLRT and seed multiplication for conducting toxicity allergenicity and feeding studies. The request has been examined by the RCGM in its 69th meeting held on 26.8.2008 and recommended for consideration of the GEAC.

5.5.2 It was further noted that the GEAC in its 85th meeting held on 28.5.2008 had approved the conduct of MLRT with two transgenic cotton hybrids namely WS 103 and WS 106 expressing *cry1Ac* and *cry1F* proteins (WideStrike = Event 3006-210-23 and Event 281-24-236) at two locations in the South zone for generating the biosafety data during Kharif 2008. Subsequently, in the 86th GEAC meeting held on 25.6.2008 the Committee had approved experimental seed production of WS-106 transgenic cotton expressing cry 1Ac and cry 1F genes (Widestrike = Event 3006-210-23 and Event 281-24-236) in 0.5 acres in South Zone.

5.5.3 In light of the above, the GEAC approved the request for experimental seed production in an area of 0.5 acres in the South zone.
