

Decisions taken in the 87th meeting of the Genetic Engineering Approval Committee (GEAC) held on 9.7.2008.

The 87th meeting of the Genetically Engineering Approval Committee (GEAC) was held on 9.7.2008 in the Ministry of Environment and Forests under the Chairmanship of Shri B. S. Parsheera, Additional Secretary, MoEF and Chairman, GEAC.

The deliberations of the GEAC in respect of Agenda Item 3 to 7 are as follows:

Agenda item No. 3: Action taken report.

1.0 The Member Secretary, GEAC informed the Committee that decisions taken in the GEAC meeting held on 28.5.2008 have been communicated to the applicants, State Government agencies and others, as applicable.

2.0 The follow-up action pertaining to the complaint received from M/s Greenpeace regarding the import of Dorito's Cool Ranch Corn chips containing GM ingredients was also discussed. Member Secretary, GEAC informed that M/s Greenpeace during the meeting with Chairman, GEAC on 25.6.2008, were advised to submit samples collected by them for further verification. The samples from M/s Greenpeace are still awaited.

3.0 The GEAC noted that response was still awaited from Ministry of Health and Family Welfare, Food Safety and Standards Authority and Ministry of Food Processing Industries on the complaint and decision taken in the GEAC meeting held on 25.6.2008. It was further informed that prior to drawing of samples, the sampling protocols need to be finalized in consultation with the Ministry of Health & Family Welfare, Food Safety and Standards Authority and the Ministry of Food Processing Industries. The Member Secretary, GEAC was advised to facilitate the inter-ministerial meeting expeditiously. The Committee also opined, as the Chairman of the Food Safety and Standards Authority has already been appointed, the feasibility of this matter being handled by Food Safety and Standards Authority may be explored by the GEAC.

4.0 To a query on the newspaper report which states that the GEAC has agreed to test samples of all food products in the market, it was clarified that no such decision was taken by the GEAC. The samples to be drawn for verification of GM ingredients would be limited to the complaint received from M/s Greenpeace in respect of Dorito's Cool Ranch Corn chip. The Member Secretary, GEAC informed the Committee that M/s PepsiCo International have sent the following clarifications:

"While Doritos is a PepsiCo brand, we do not manufacture it in India. Neither we nor our Parent Company PepsiCo, USA import this brand into India and we do not authorize this import by third party importers. For our entire range of snack products manufactured in India we use locally sourced ingredients and we ensure that they do not have any GMO. We are fully in compliance with all Government of India rules and regulations on GMO. I am enclosing a fact sheet on GMO, our products and issues raised by M/s Greenpeace in the media."

5.0 It was agreed that the Chairman, GEAC may give an opportunity for personal hearing as requested by the Company.

Agenda Item No 4: Consideration of Proposals related to Pharmaceuticals

4.1 Permission for import of recombinant HIV Vaccine TBC –M4 and ADVAX for conduct of phase I clinical trials of preventive AIDS vaccine from M/s Therion Biologics Corporation, Cambridge, MA, USA by National AIDS Research Institute (ICMR), Pune

1.0 The Committee noted that comments of the concerned experts /departments are awaited. Since the expert members were not present, it was decided to defer decision on the proposal. The Committee requested the experts to forward their comments, expeditiously.

Agenda Item No 5: Consideration of applications for commercial release of Bt Cotton hybrids expressing approved events for Central Zone during Kharif, 2008 as recommended by the MEC/RCGM.

- 5.1 Permission for commercialization of ACH-1019 Bt expressing (*cry 1Ab -cry 1Ac*) "GFM Cry 1A" in the Central Zone by M/s Navkar Hybrid Seeds Pvt. Ltd.
&
- 5.2 Permission for commercialization of GK 205 BG-II of expressing *cry 1Ac & cry 2Ab* genes (MON 15985 event) in the Central Zone by M/s Ganga Kaveri Seeds Pvt. Ltd.
&
- 5.3 Permission for commercialization of GBCH-01 Bt expressing (*cry 1Ab -cry 1Ac*) "GFM Cry 1A" in the Central Zone by M/s Green Gold Pvt. Ltd.
&
- 5.4 Permission for commercialization of MLCH-317 BGII expressing *cry 1Ac & cry 2Ab* genes (MON 15985 event) in the Central Zone by M/s Monsanto Genetics India Pvt. Ltd.
&
- 5.5 Permission for commercialization of MLCH-318 BGII expressing *cry 1Ac & cry 2Ab* genes (MON 15985 event) in the South Zone by M/s Monsanto Genetics India Pvt. Ltd.

1.0 The recommendations of SAU/MEC/ICAR in respect of 5 Bt cotton hybrids as contained in the proposal at agenda 5.1 to 5.5 namely ACH-1019 Bt and GBCH-01 Bt expressing (*cry 1Ab -cry 1Ac*) "GFM Cry 1A" and GK 205 BG-II, MLCH-317 BGII and MLCH-318 BGII expressing *cry 1Ac & cry 2Ab* genes (MON 15985 event) in the Central /South Zones were considered by the GEAC.

2.0 The Committee noted that the above hybrids have been approved for commercial release by the MEC Sub Committee in its meetings held on 28.4.2008 and 31.5.2008. It was explained by Member Secretary RCGM that MEC in its meeting held on 15.4.2008 was not able to take decision in respect of hybrids under ICAR trials. Accordingly MEC had constituted a Sub-Committee to consider the performance of the hybrids based on ICAR reports. Subsequently, two meetings of the Sub-Committee were held on 28.4.2008 and 31.5.2008 to consider the reports of the ICAR for the Central and South Zones, respectively. As advised by the GEAC, the MEC Sub-Committee had also considered the representations received from some of the seed industries regarding non-inclusion of their proposal in the GEAC meeting. It was also noted by the Committee that the proposals under consideration could not be considered in the earlier GEAC meetings mainly because either some of the applications were inadvertently missed out by the MEC for consideration or the applications seeking approval of the GEAC were not received in the Ministry in time. After discussions, the Committee was of the view, that the MEC while submitting its recommendations in respect of cases to be reconsidered should provide detailed justification for the same in future and try to ensure that all cases are considered at one go. Member Secretary, MEC and RCGM informed that such omissions have happened since the volume of applications was too high. In future such omissions would be avoided by appropriate tracking mechanism of applications through soft copies.

3.0 In light of the recommendations made by the MEC and the RCGM and taking into consideration the policy decision to adopt an event based approval mechanism for Bt cotton hybrids expressing approved events, the Committee approved the following hybrids for commercial release in the Central / South Zone:

1. ACH-1019 Bt expressing (*cry 1Ab -cry 1Ac*) "GFM Cry 1A" in the Central Zone by M/s Navkar Hybrid Seeds Pvt. Ltd
2. GK 205 BG-II of expressing *cry 1Ac & cry 2Ab* genes (MON 15985 event) in the Central Zone by M/s Ganga Kaveri Seeds Pvt. Ltd.

3. GBCH-01 Bt expressing (*cry 1Ab -cry 1Ac*) "GFM Cry 1A" in the Central Zone by M/s Green Gold Pvt. Ltd.
4. MLCH-317 BGII expressing *cry 1Ac & cry 2Ab* genes (MON 15985 event) in the Central Zone by M/s Monsanto Genetics India Pvt. Ltd.
5. MLCH-318 BGII expressing *cry 1Ac & cry 2Ab* genes (MON 15985 event) the South Zone by M/s Monsanto Genetics India Pvt. Ltd.

5.6 Permission for commercialization of Tulasi 9 Bt, Tulasi 45 Bt and Tulasi 118 Bt expressing Cry 1 Ac (MON 531 event) in the South Zone by M/s Tulasi Seeds Pvt. Ltd.

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5.7 Permission for commercialization Tulasi 7 BG II, Tulasi 9 BG II and Tulasi 118 BG II expressing Cry 1AC & Cry 2Ab genes (Mon 15985) in the South Zone by M/s Tulasi Seeds Pvt. Ltd.

1.0 M/s Tulasi Seeds Pvt. Ltd. has submitted their application for commercial release of Bt cotton hybrids namely Tulasi 9 Bt, Tulasi 45 Bt and Tulasi 118 Bt expressing Cry 1 Ac gene (MON 531 event) and Tulasi 7 BG II, Tulasi 9 BG II and Tulasi 118 BG II expressing Cry 1AC & Cry 2Ab genes (Mon 15985) in the South zone. The hybrids have completed MLRT and SAU trials in Kharif 2007. BG II hybrids have also undergone one year LST and one year ICAR trials during Kharif, 2007.

2.0 The MLRT/ SAU trials in respect of Tulasi BG I hybrids have been evaluated by the MEC in its meeting held on 15.4.2008. Subsequently, based on the ICAR report, the MEC Sub committee has evaluated the performance of Tulasi BG II hybrids in its meeting held on 31.5.2008. Tulasi 9 Bt, Tulasi 45 Bt and Tulasi 118 Bt cotton hybrid Tulasi 7 BG II, Tulasi 9 BG II and Tulasi 118 BG II have been approved by MEC for commercial release in the South Zone. RCGM has also recommended the trials of these hybrids in its meeting held on 22.4.2008 and 24.6.2008.

3.0 The Committee noted that in view of the complaint received from M/s Mahyco regarding the sale of BG II hybrid expressing stacked gene (MON 15985 event) in the name of Tulasi 4 Bt without the approval of the GEAC, decision on the above request was deferred in the GEAC meeting held on 28.5.2008. Subsequently, a show cause notice was issued to M/s Tulasi Seeds Pvt. Ltd. The explanation received from M/s Tulasi Seeds Pvt. Ltd was also considered by the GEAC in its meeting held on 25.6.2008 wherein it was recommended that the Ministry may condone the lapse after verifying the legalities involved, if any and confirmation of the NOC earlier issued by the technology provider as NOC is a pre-requisite for commercial release.

4.0 Regarding the issue of Tulasi 9 Bt, Tulasi 45 Bt and Tulasi 118 Bt for the South Zone which was earlier deferred by the GEAC in its meeting held on 28.5.2008, the Committee opined that the hybrids may be approved for commercial release subject to fulfilling the requirements of the regulatory procedure. On the issue of Tulasi BG II hybrids it was decided to consider the request after the applicant has resolved the issue with the technology provider. As of date the technology provider has not cancelled the license agreement with the applicant. Members were of the view that the issue of license agreement with the technology provider is a trade related issue and has no bearing on the applicability of Rules, 1989 under the EPA, 1986.

5.0 In light of the above stated facts and taking into consideration that the proposals at agenda item 5.4 and 5.5 have been approved by the MEC and the RCGM, the Committee approved the following hybrids for commercial release in the South Zone:

1. Tulasi 9 Bt *expressing cry 1 Ac* (MON 531 event) by M/s Tulasi Seeds Pvt. Ltd.
2. Tulasi 45 Bt *expressing cry 1 Ac* (MON 531 event) by M/s Tulasi Seeds Pvt. Ltd.

3. Tulasi 118 Bt *expressing cry 1 Ac* (MON 531 event) by M/s Tulasi Seeds Pvt. Ltd.
4. Tulasi 7 BG II *expressing cry 1Ac & cry 2Ab* genes (Mon 15985 event) by M/s Tulasi Seeds Pvt. Ltd.
5. Tulasi 9 BG II *expressing cry 1Ac & cry 2Ab* genes (Mon 15985 event) by M/s Tulasi Seeds Pvt. Ltd.
6. Tulasi 118 BG II *expressing cry 1Ac & cry 2Ab* genes (Mon 15985 event) by M/s Tulasi Seeds Pvt.

Agenda Item No 6: Consideration of applications for MLRT/Strip Trials and Experimental Seed Production of transgenic crops expressing new genes/events during Kharif, 2008 as recommended by the MEC/RCGM.

6.1 Application submitted by M/s. JK Agri Genetics Ltd., Hyderabad for permission to conduct Multi-location Research Trial (MLRT) and limited seed production with new (HXH) transgenic cotton hybrids containing *cry1Ac* (Event-1) and *cry1EC* (Event-24) namely JKCH-1050 Bt EGII, JKCH-1947Bt EGII & JKCH-226Bt EGII at five locations in North zone, five hybrids namely JKCH-99Bt EGII, JKCH-666BT EGII, JK-Indra Bt EGII, JK-Varun Bt EGII, JK-Durga Bt EGII at five locations in Central zone and four hybrids namely JKCH-99Bt EGII, JK-Indra EGII, JK-Durga Bt EGII, JKCH-2245Bt EGII at five locations in South zone.

1.0 The request of M/s. J. K Agri Genetics Ltd., Hyderabad for permission to conduct Multi location Research Trial (MLRT) with new (HXH) transgenic cotton hybrids containing *cry1Ac* (Event-1) and *cry1EC* (Event-24) in the North, Central and South zones, respectively was considered by the GEAC. M/s. J. K Agrigenetics Ltd has developed cotton hybrids by stacking the two genes i.e. *cry1Ac* (Event-1) and *cry1EC* (Event-24) genes. The *cry1Ac* (Event-1) is an approved event and *cry1EC* (Event-24) has been transferred to M/s J. K. Agri Genetics Ltd. from National Botanical Research Institute (NBRI), Lucknow. The company has sought permission to conduct MLRT with the new (HXH) transgenic cotton hybrids in the North, Central and South Zones. M/s. J. K. Agri Genetics Ltd., Hyderabad has developed hybrids by stacking the genes through crossing over the two events.

2.0 RCGM in its meeting held on 27.5.2008 had opined that the company needs to provide proof of concept of integration of both the events and submit data before approval was issued. Subsequent to the RCGM meeting, the applicant submitted the following information:

1. Level of protein (ug/g fresh tissue) expression from leaf tissues at different age of the crop.
2. Level of protein (ug/g fresh tissue) expression from different plant parts.
3. *In vitro* leaf bioassay at different age of the crop of JKAL-Bt EGII Cotton hybrids specific to *Helicoverpa*, *Earias* & *Spodoptera*
4. Integration of genes in the hybrids by conventional PCR method.

3.0 The Committee noted that the information submitted by the applicant has not been examined by the RCGM and therefore, the Committee requested RCGM to examine the additional information and send their report to the GEAC. It was decided to consider the request for MLRT in the next GEAC meeting based on the report received from RCGM.

4.0 The request of the company for limited experimental seed production for generating biosafety data was also discussed. The Committee noted that the applicant was unable to generate the requisite biosafety data in the absence of adequate seed material. After detailed deliberations, the Committee decided to approve limited seed production of the two hybrids within the applicants' research farm only.

6.2 Application submitted by M/s. Maharashtra Hybrid Seeds Co. Ltd., Maharashtra for permission to conduct Multi Location Research Trial (MLRT) on 4 transgenic stacked cotton hybrids namely MRC-8347 BG-II RRF Roundup, MRC-8351 BG-II RRF Roundup, MRC-8201 BG-II RRF Roundup, MRC-8160 BG-II RRF Roundup containing *cry1Ac*, *cry2Ab* and *CP4EPSPS* genes (MON 15985 X MON 88913) at five locations in Central zone during Kharif 2008.

1.0 The Committee noted that the present request is for conduct of MLRT of four transgenic BG II RRF cotton hybrids namely, MRC-8347 BG-II RRF Roundup, MRC-8351 BG-II RRF Roundup, MRC-8201 BG-II RRF Roundup, MRC-8160 BG-II RRF Roundup containing staked *cry1Ac* & *cry2Ab* genes (MON 15985) & *CP4 EPSPS* Event (MON 88913) at five locations i.e. Maharashtra (Jalna, Jalgaon), M.P. (Khargone), Gujarat (Rajkot, Vadodara) in Central zone.

2.0 The Committee further noted that the RCGM in its meeting held on 1.6.2007 has recommended MLRT with the above mentioned Bt cotton hybrids in the Central zone. Subsequently, the GEAC had accorded permission for conducting MLRT in the Central zone in its meeting held on 22.6.2007. The applicant has now informed that due to late permission, they were unable to conduct trials in the Central zone during Kharif 2007. The Company is now requesting to renew the earlier permission dated 23.7.2007 issued by DBT.

3.0 The request for renewal was considered by the RCGM in its meeting held on 27.5.2008. The RCGM recommended that the applicant may conduct the trials at two locations in their own research farms with two hybrids only. The company has also been advised to generate biosafety data with purified protein of both the genes as well as conduct other biosafety studies as per the new protocols approved by the GEAC.

4.0 After detailed deliberations and taking into consideration the recommendations of RCGM, the Committee agreed to renew the request of the Company to conduct MLRT at two locations in their own research farms with two hybrids only.

6.3 Application submitted by M/s. ICRISAT, Patancheru for permission to carry out contained field experiments for event selection with proper isolation distances for the evaluation of transgenic groundnut plants carrying coat protein gene (*cp*) of Tobacco Streak Virus (TSV) against Peanut Stem Necrosis Disease (PSND) at their own R&D Centre during Kharif 2008.”.

1.0 The request of M/s. ICRISAT, Patancheru for permission to carry out contained field experiments for event selection with proper isolation distances for the evaluation of above lines at their own R&D Centre during Kharif 2008 was considered by the GEAC. The Company has developed transgenic groundnut plants carrying coat protein gene (*cp*) of Tobacco Streak Virus (TSV) against Peanut Stem Necrosis Disease (PSND) by Agrobacterium-mediated transformation protocols developed at ICRISAT using Agrobacterium tumefaciens strain C58 containing the binary plasmid Pcambia-2300;TSVcp. These plants have been advanced to T2 generation in the containment glasshouse and have been characterized at the molecular level. 12 transgenic line carrying TSVcp have been selected for field evaluation.

2.0 The Committee noted that the RCGM in its meeting held on 24.6.2008 recommended conduct of confined field experiments for event selection with proper isolation distances for the evaluation of transgenic groundnut plants at their own R&D Centre during Kharif 2008. Simultaneously, the company should generate SOPs for conducting field trials as well as level of detection (LOD) of the selected event at 0.01% level as per the directions of the Hon'ble Supreme Court.

3.0 After detailed deliberations and taking into consideration the recommendations of the RCGM and noting that the request was only for event selection, the GEAC approved the conduct of

strip trials with transgenic groundnut plants carrying coat protein gene (*cp*) of *Tobacco Streak Virus* (TSV) against *Peanut Stem Necrosis Disease* (PSND) at their own R&D Centre during Kharif 2008.”

Agenda Item No 7: Other items

7.1 Discussions on the Newspaper reports regarding the functioning of the GEAC and testing of GM crops.

1.0 The Committee noted with concern the press statements made by Dr. P. M. Bhargava an invitee to the GEAC meetings. The Committee also noted that the Ministry has received several objections against the reports and distorted Bt brinjal pictures published by 'The HINDU' against the Bt crops based on Dr. Bhargava's comments. The Committee opined that the views of Dr. Bhargava have been appropriately recorded in the minutes of the GEAC meetings wherein he has been a party to several decisions. Dr. Bhargava has accepted and appreciated the records of the meetings. The Committee also expressed surprise at the varying stands taken by Dr. Bhargava within and outside the GEAC meetings and considered the same as highly unethical. The Committee noted that Dr. Bhargava has commended on the efficient functioning of the GEAC and the scientific competence of its members on several occasions during the GEAC meeting. He has also time and again informed the Committee that he was not familiar with the regulatory procedures and therefore, confused on the role of the different agencies notified within the Rules, 1989 under the EPA, 1986. It is therefore surprising that he has resorted to giving a distorted picture of the regulatory system which has been evolved during the last two decades as a dynamic process keeping in view the developments taking place worldwide in the regulatory process and products in pipeline.

2.0 The Committee also noted that Dr. Bhargava had actively supported the release of Bt cotton variety developed by CICR, Nagpur even though he claims to be not in favour of GM technology. He has also expressed his support to the approval for large scale field trials of Bt cotton developed by an Indian company. It is therefore not clear to the Committee whether Dr. Bhargava was against the multi national companies or his concern is based on his personal perceptions rather than scientific rationale. While reports on sheep mortality have been examined by the GEAC in consultation with the concerned departments wherein it has been concluded that there was no scientific evidence to prove that sheep deaths in Andhra Pradesh were due to grazing on Bt cotton. However, Dr. Bhargava has been insistent on the report of the civic society on sheep deaths rather than on the scientific evidence and reports submitted by the scientific institutions on the issue. It is unfortunate that he chose to provide only selective information to the media.

3.0 Dr. Bhargava's allegation that Bt cotton has been approved without any supervision or monitoring of field trials is factually incorrect. His remarks on Bt brinjal trials being 'slipshod' are unwarranted as the trials are being conducted under the supervision of Director, Indian Institute of Vegetable Research, Varanasi. He has called for a moratorium on GM crop field trials on the grounds that (i) there is no independent laboratory for testing and verification and (ii) the data submitted by the applicant is unreliable. While he is not willing to accept the food safety studies conducted by institutions such as Indian Veterinary Research Institute, Izatnagar, National Dairy Research Institute, Karnal, Indian Toxicological Research Institute, Lucknow, Avian Research Institute, Rae Bareilly, Central Fish Institute and Education, Mumbai, Rallies India Ltd, Bangalore, he has accepted the sampling process and test reports submitted by M/s Greenpeace from a private laboratory in Germany which concludes that Dorito chips contain GM ingredients.

4.0 Dr. Bhargava had also expressed his constraints in reviewing the information electronically and suggested that he would take some time to review the data in the Ministry during his visits to Delhi. The Ministry had agreed to provide support in accessing any document which he required. However, till date Dr Bhargava has not been able to take time off to review the documents/reports on biosafety submitted by various applicants.

5.0 The Committee was also of the view that Dr. Bhargava should understand the gravity of the situation and should avoid giving distorted views on the regulatory process. There is a certain degree

of confidentiality in the functioning / deliberations of the Statutory Committees of the Government. Views and counter views are bound to be expressed by the learned members. However, what the public is entitled to know is the combined wisdom and decisions of the Committee and not the individual views expressed in the meetings.

7.2 Complaint received from M/s Monsanto Mahyco Biotech Limited (MMBL) regarding sale/marketing of Bollgard technology in the name of Fusion Bt technology.

1.0 The Committee considered the complaint received from M/s Mahyco Monsanto Biotech Limited (MMBL) wherein it has been informed that Navkar 5 Bt being co-marketed by M/s Tulsi Seeds Pvt. Ltd., M/s Narmada Sagar Seeds Limited and M/s Dinakar Seeds Pvt. Ltd as fusion gene contains Bollgard technology. M/s Navkar 5 Bt expressing (*cry 1Ab -cry 1Ac*) "GFM Cry 1A" gene was approved by the GEAC in May, 2007.

2.0 It was also noted that the GEAC/RCGM has not approved any hybrids developed by M/s Narmada Sagar Seeds Limited, M/s Dinakar Seeds Pvt. Ltd and M/s Tulsi Seeds Pvt Ltd. It was clarified that M/s Tulsi Seeds Pvt Ltd under reference is not affiliated in any way with M/s Tulasi Seeds Pvt Ltd.

3.0 The Member Secretary GEAC informed the Committee that the complainant has provided three packets of seeds for verification and taking penal action under the EPA, 1986. The Committee opined that the complainant may be advised to submit analytical report from any NABL accredited laboratory. It was also agreed that the GEAC would be concerned only with matters related to biosafety issues. The Committee further advised, on trade related issues, the complainant may take necessary action under the appropriate laws. However, if the 'license agreement' from the technology provider is withdrawn or cancelled at any time, appropriate action would be taken by the GEAC.

Date of Next GEAC Meeting: The next GEAC meeting will be held on 13.8.2008.
