Decisions taken in the 95th meeting of the Genetic Engineering Approval Committee (GEAC) held on 8.7.2009.

The 95th meeting of the GEAC was held on 8.7.2009 in the Ministry of Environment and Forests (MoEF) under the Chairmanship of Shri B S Parsheera, Special Secretary, MoEF and Chairman, GEAC.

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

Agenda item No. 4: Consideration of application for confined field trials of BRL-1/event selection of transgenic crops expressing new genes/events as recommended by the RCGM.

4.1 Permission for confined field trials on Bollgard-II RRF hybrids namely MRC-8041 BG-II RRF, MRC-8045 BG-II RRF and MRC-8365 RRF in the north zone and MRC-8301 BG-II RRF, MRC-8326 BGII RRF & MRC-8373 BG II RRF in the central zone and MRC-8201 BGII RRF, MRC-8160 BGII RRF and MRC-8383 BGII RRF in the south zone expressing stacked *cry1Ac & cry2Ab* and *CP4EPSPS* Genes ((Mon-15985 + Mon-88913 events) by M/s Maharashtra Hybrid Seeds Co. Ltd., Mumbai.

4.1.1 The Committee noted that the present request of the applicant is to conduct confined field trials with the following new Bt cotton hybrids expressing *cry1Ac & cry2Ab and CP4EPSPS* genes (MON 15985 X MON 88913) in north, central and south zones.

S.No.	North	Central	South
1.	MRC-8041 BG-II RRF	MRC-8301 BG –II RRF	MRC-8201 BG II RRF
2.	MRC-8045 BG-II RRF	MRC-8326 BG II RRF	MRC-8160 BG II RRF
3.	MRC -8365 BG II RRF	MRC 8373 BG II RRF	MRC-8383 BG II RRF
Locations	At Hisar and Bhatinda	Jalna and Vadodara	Ranga Reddy and Coimbatore

The objective of the trials is to assess the weed control efficacy with roundup formulation, insect protection and agronomic evaluation.

4.1.2 The Committee further noted that the GEAC in its meeting held on 10.6.2009, has approved the request of the applicant to repeat BRL – I trials during the second year with the same transgenic cotton hybrids mentioned below at the same locations where the trials were conducted in Kharif, 2008.

S.No.	North zone	Central Zone	South Zone
1.	MRC-8017 RRF BG II	MRC-8347 RRF BG II	MRC-8347 RRF BG II
2.	MRC-8031 RRF BG II	MRC-8351 RRF BG II	MRC-8351 RRF BG II
Locations in Kharif, 2007	-	-	Farmers field in village-Takkalupadu (Guntur), Bhulkapur (Ranga Reddy), Kamalapur, (Dharwad), Alandurai, Coimbatore, Gandipuram (Salem) and Mahyco's Research Farm at Haveri.
Locations in Kharif, 2008	• Farmers field in Village- Mehma Sarja in Bhatinda, • Farmers field in Village-Majra in Hisar.	• Mahyco Research Farm at Jalna, • Farmers field in Village – Kuwadva,	• Mahyco Research Farm at Haveri, • Mahyco Research Farm at Ranga

		Rajkot.	Reddy.

4.1.3 The applicant has also been granted the following approvals:

a) for generation of plant material to conduct toxicity, allergenicity and food safety studies at Jalna, Maharashtra within the Company's own R&D farm in the 79th GEAC meeting held on 8.8.2007; and

b) to conduct evaluation of bio-efficacy, residue, phytotoxicity and carryover of potassium salt of glyphosate formulation of herbicide on transgenic stack cotton hybrids *(MON 15985XMON 88913*) at PAU, Ludhiana instead of MPKV, Rahuri by M/s Maharashtra Hybrid Seeds Company Ltd., Mumbai.

4.1.4 After detailed deliberations, the Committee did not approve the above request on the grounds that the proposal is not in line with the policy decisions earlier adopted by the Committee.

Agenda item No: 5: Consideration of applications for GM processed food.

5.1 Permission to import transgenic Liberty Link Soybean Oil from USA by M/s. Bayer BioSciences Pvt. Ltd, Gurgaon

5.1.1 The Committee considered the request from M/s Bayer Bioscience Pvt. Ltd. to import soybean oil derived from transgenic soybean (Liberty link Soybean), tolerant to Glufosinate ammonium herbicide for food and feed. The Committee noted that transgenic Liberty Link Soybean is being cultivated in the USA and Canada. The transgenic Liberty Link Soybean oil has been approved for food/ feed in countries such as EU, South Africa, Argentina, Japan, Korea, Australia, New Zealand, China, Philippines, Mexico, Russia and Taiwan. The Committee also considered the comments received from Director, NIN. The Committee noted that comments from the Food Safety and Standards Authority and Ministry of Health and Family Welfare are awaited.

5.1.2 During the deliberations, the representative of Food Safety and Standards Authority informed that they have certain concerns regarding the above product and comments would be submitted for consideration of the GEAC. One of the members further pointed out that clarification on whether the safety approval obtained from other countries is for glyphosate tolerant trait or for glufosinate tolerant trait also needs to be obtained. Accordingly, decision on the proposal was deferred.

5.2 Permission to import Japanese Food (Pickles) containing GM ingredients from M/s ASADA Co. Ltd., Nagoya, Japan by M/s. Mitsui & Co. India Pvt. Ltd., New Delhi

5.2.1 The Committee considered the request of M/s. Mitsui & Co. India Pvt. Ltd New Delhi to import of Japanese Food (Pickles) containing GM ingredients to India for sale in Japanese Restaurant in Delhi. The following points were noted:

a. Details of the product are as follows:

Name of the product (Japanese pickle)	**GM ingredient in the product**
1. Okaidoku Shouyu Sutamia	Corn and Soybean
2. Okaidoku Pirikara Kyuri	Corn and Soybean
3. Okaidoku Fukujin Zuke	Corn and Soybean
4. Ama Rakkyou	Corn
5. Wariboshi Kimuchi	Corn and Soybean
6. Suraisu Takuwan	-

b. The quantity of the 6 product to be imported will be maximum 64 kg.

c. All products mentioned above are allowed to be marketed and consumed in Japan with the approval of the Japanese Government. The products do not require GMO labeling in Japan.

5.2.2 The Committee also considered comments received from the Director, NIN and further noted that comments from the Food Safety and Standards Authority and Ministry of Health and Family Welfare are awaited. Accordingly, decision on the proposal was deferred.

Agenda Item No 6: Other Items

6.1 Review of the requirement for submission of a validated event specific test protocol at an LoD of 0.01% to detect before bringing out the GM material from the green house

6.1.1 The Committee noted that the GEAC in its 76th GEAC meeting, held on 11.5.2007, had constituted a Sub-Committee under the Chairmanship of Dr. B. M. Khadi, Member, GEAC to examine the implications of the Hon'ble Supreme Court Order dated 8.5.2007 with respect to submission of a validated event specific test protocol at an LOD of at least 0.01% to detect and confirm that there has been no contamination. Based on the following recommendations of the Sub-committee, the UoI has filed an application on 31.7.2007 for vacating / modifying the Hon'ble SC order dated 8.5.2007.

i. In view of the stringent guidelines of maintaining scientifically prescribed isolation distance in seed production standards (which, for several crops, is more than the 200 m isolation distance as prescribed by the Hon'ble Supreme Court) and additional biosafety measures prescribed during field testing of GM crops, the possibility of contamination is rare. Therefore, the requirement for a validated protocol of 0.01% LOD may be dispensed with.

ii That the LOD requirement is not relevant at the stage of trials and is relevant for the commercialization stage. Further, the same is a trade issue and therefore, it would be desirable to review the LOD requirements in importing countries at the stage of commercialization. Therefore, the LOD requirement will vary from country to country and should be applied on a case to case basis at the stage of commercialization.

iii. Prior to the commercial release/ export requirements, the LOD may be decided at levels that are practical to use, compatible with the acceptable thresholds that may be defined for labeling purposes and are based on the technical aspects of the analytical methods available in the international laboratories and the genome size of the crop. Thus the arbitrary requirement for provision of a detection method with an LOD of 0.01% at the time of field trial is scientifically not justified and may be dispensed with.

iv. The Sub-committee also opined that the lowest LOD made mandatory at the time of commercialization, by any country in the world is 0.9% in EU. Therefore a LOD requirement which is less than 0.9% may not be stipulated in any case by the GEAC prior to commercialization.

6.1.2 The Hon'ble Supreme Court in its hearing held on 8.4.2008 had directed the GEAC to examine and give a finding as to what should be the LOD, whether it should continue to be 0.01% or be less than 0.01% or more than 0.01% or whether it should be dispensed with altogether with an alternative protocol, and if so, what should be the alternative protocol. Subsequently, the UoI has submitted its response to the Hon'ble Court wherein it has been prayed that the Hon'ble SC order dated 8.5.2007 may be modified directing that the level of detection (LoD) be decided by the GEAC on a case by case basis prior to commercial release of GM crops/plants.

6.1.3 With the above submission, some members were of the view that the GEAC has complied with the Hon'ble SC directions dated 8.5.2007 and 8.4.2008 and therefore the need for continued submission of a validated event specific test protocol at a LoD of 0.01% needs to be re-examined.

After detailed deliberations, the Committee requested Prof. Govindraj Hegde, Legal expert to examine the above issue and advise the GEAC. Decision on the above matter was therefore deferred.

6.2 Representation from Ms Aruna Rodrigues regarding illegal HT cotton seeds being sold in Gujarat

6.2.1 The Committee considered the representation received from M/s Aruna Rodrigues regarding the sale of Bt cotton hybrids branded as WEEDGARD alleged to contain stacked genes with HT genes in Gujarat. The Member Secretary, GEAC informed that the Ministry had earlier received a complaint from M/s Monsanto regarding the presence of HT cotton in Gujarat, Maharashtra, Madhya Pradesh, Andhra Pradesh and Punjab. The matter was discussed in the GEAC meeting held on 11.1.2008 wherein the GEAC had constituted a monitoring team to verify the presence of HT cotton. However, the complaint could not be verified as the harvesting of cotton was over. The monitoring team in disguise also tried to procure seeds of WEEDGARD / HT cotton seeds from dealers in Bharuch, Amod, Palej and Karjan Talukas but was informed that the seeds are not available. The complaint was also forwarded to the respective State Department of Agriculture and State Department of Environment. The Ministry of Environment and Forests has also issued a Gazette Notification in September, 2006 empowering the Seed Inspectors, Seed Analysts and Laboratories under the Seed Act, 1966 and Seed Control Order, 1983 also under the EPA, 1986.

6.2.2 Subsequently, M/s Monsanto was advised to submit their complaint to Chief Secretary (Chairman of SBCC) to facilitate timely verification of the complaint. The Ministry has not received any response from the State Government. However, vide e-mail dated 7.7.2009, M/s Monsanto has informed that the company had filed its complaint to Chairman, SBCC, Gujarat in September, 2008. Based on the complaint, Directorate of Agriculture, Gujarat collected the samples and sent the samples to CICR, Nagpur. CICR, Nagpur returned the samples on the ground it was not notified to test samples to herbicide tolerant traits. Another raid was conducted at a ginning mill at Mansa in December, 2008. However, due to lack of clarity regarding testing of material the material was released by the Director of Agriculture, Gujarat in April, 2009.

6.2.3 Based on the complaint submitted by M/s Monsanto, the Chairman, SBCC, MP constituted a team for verification and collection of the samples. The samples collected by the team in January, 2007 were sent to DNA Fingerprinting laboratory in Hyderabad wherein it has been confirmed that all the four samples have been tested for RR presence. A similar exercise was also conducted by the State Vigilance Team in Andhra Pradesh. The samples collected were analyzed by the DNA Fingerprinting laboratory in Hyderabad who has confirmed the presence of RR. A case has been filed against the farmer and awaiting Court order.

6.2.4 The Committee expressed deep concern regarding the illegal sale and cultivation of HT cotton seeds in Gujarat, Madhya Pradesh and Andhra Pradesh and opined that matters of such serious nature needs to be investigated at the highest level and criminal proceedings should be initiated against the culprits. The Committee requested the Chairman, GEAC to take up the matter with the Chief Secretaries of the respective State Governments.

6.2.5 The Committee further decided that Ministry of Agriculture may be advised to immediately notify the CICR, Nagpur as the referral laboratory for testing of all GM cotton. As HT cotton has not been approved for field testing, it was also decided that the DGFT and the Customs who are responsible to monitor the entry of illegal GM seeds, may be advised to enhance their vigilance mechanisms.

6.2.6 During the deliberations, members were also of the view that crop specific referral laboratories need to be notified to avoid such situations in future. It was suggested that CDFD, Hyderabad and four other regional laboratories may be notified to facilitate the verification mechanism. It was agreed that the matter would be further examined in consultation with CDFD and other regional laboratories before a final view is taken on the matter.

6.3 Representation from Ms Kavitha Kuruganti, Kheti Virasat Mission, Punjab and others regarding regulation of GM crop and animal varieties including a paddy variety that has been created by micro-injection method by CRRI, Cuttack and auto transgenic fish by CCMB, Hyderabad

6.3.1 The Committee noted that the above representation is based on newspaper reports. One of the members clarified that the two rice varieties 'Swarna Sub-1' and 'IR.64 Sub-1' varieties developed by CRRI, Cuttack was done through traditional breeding and not through the genetic engineering.

6.3.2 As regards, the development of transgenic fish by CCMB, it was noted that this is a DBT sponsored research project and was not intended for commercialization by CCMB. However, CCMB would be required to comply with the regulatory process at all stages of research and development.

6.3.3 After detailed deliberations, it was decided that a factual report on the above matter would be obtained from both the institutions.

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