

Decisions taken in the 66th Meeting of the Genetic Engineering Approval Committee held on 2.05.2006.

The 65th Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 2nd May 2006 in the Ministry of Environment and Forests under the Chairmanship of Shri B S Parsheera Additional Secretary, MoEF and Chairman GEAC.

A Presentations / Representation

1.0 Presentation by M/s Mahyco on the results of the biosafety studies conducted in respect of stacked Cry X (Cry I Ac and Cry 2 Ab) genes (event MON 15985) in cotton crop.

1.1 M/s Mahyco have developed Bt cotton hybrids (Bollgard –II) containing stacked Cry X (Cry I Ac and Cry 2 Ab) genes (event MON 15985) in cotton crop. Member Secretary GEAC informed the Committee that some of the Bollgard –II (BG-II) hybrids have completed two year of LST under GEAC and two years of ICAR trials under the AICCIP testing system. The Company has submitted their application to the GEAC for commercial release of two of their BG-II hybrids in the Central zone. As these hybrids contain a new gene, the Company was requested to make a detailed presentation on the biosafety data during the previous meeting. At the request of the Company, the presentation and consideration of BG-II proposals for commercial release was deferred to this meeting.

1.2 The Committee invited the representatives of the Company to present the biosafety data. It was informed that M/s Mahyco has developed a new genetically modified cotton Bollgard –II by using cotton event Bollgard II 15985 developed by M/s Monsanto by using particle acceleration plant transformation procedures to insert the cry 2 Ab insect control gene and the *uidA* scorable marker gene into the Bollgard cotton genome. Event 15985 provides season long control of key lepidopteron pests including *Spodoptera litura*. Combining the Cry 2Ab protein with the Cry 1 Ac protein is also expected to delay the development of lepidopteron resistance to the Cry 1 Ac protein.

1.3 The presentation also covered the studies carried out by the Company during 2002-2005. The biosafety studies include pollen escape, outcrossing, aggressiveness and weediness, effect on non-target organisms, presence of Cry 1AC protein in soil, effect of Cry1 AC protein on soil microflora, confirmation of the absence of Terminator Gene, and baseline susceptibility studies. The food safety studies conducted include compositional analysis, allergenicity studies, toxicological study, presence of Bt gene and protein in Bt cottonseed oil and feeding studies on fish, chicken, cows and buffaloes. The following points were noted:

1. The pollen flow study revealed that outcrossing occurred maximum only upto a distance of 15 m.
2. No significant difference in germination, aggressiveness as well as weediness as compared to non Bt. counterpart.
3. Bt cotton hybrids do not have any toxic effects on the non-target species, namely sucking pests (aphids, jassids, white fly and mites).
4. Bt protein was not detected in soil samples indicating that Bt protein is rapidly degraded in the soil on which Bt cotton is grown.
5. There was no significant difference in population of microbes and soil invertebrates like earthworm and Glembola between Bt and non-Bt soil samples.
6. There is no change in the composition of Bt and non Bt seeds, with respect to proteins, carbohydrates, oil, calories and ash content.
7. No significant differences in feed consumption, animal weight gain and general animal health were found between animals fed with Bt cotton seed and no cottonseed.
8. A goat feeding study was conducted for understanding the toxicological effects of Bt cottonseed. The animals were assessed for gross pathology and histopathology. No significant differences were found between animals fed with Bt and non Bt cottonseed.

9. Feeding experiments conducted with Bt cotton seed meal on fish chicken, cows and buffaloes indicated that Bt cotton seed meal is nutritionally equivalent, wholesome and safe as the non-Bt cottonseed meal.

1.4 The Committee further noted that the Company has completed the biosafety studies as authorized by RCGM. The biosafety studies have been presented before the RCGM in its meeting held on 27.10.2005. Recommendations of the RCGM on the efficacy and safety of the new genes has been received. It was also decided in the above meeting that the entire biosafety studies be forwarded to Dr B M Khadi for his comments. The recommendations of RCGM and Dr B M Khadi, Director CICR indicate that Bt cotton hybrids expressing Cry 1 Ac & Cry 2 Ab (event No 15985) are as safe non-transgenic cotton without any appreciable environmental risks.

2.0 Presentation by Central Organization for Oil Industry and Trade, Cargill India and the Solvent Extractors Association of India on the import of GM Soybean oil from USA and South America.

2.1 The Member Secretary briefed the Committee on the link between the new import policy on GMOs/LMOS notified by Ministry of Commerce in the Foreign Trade Policy (2004-2009) and the above request. As per the new import policy approval of the GEAC prior to import of any GM foods or declaration that it does not contain GM product is mandatory. The urgency in the matter is because India imports 2 million tones of de-gummed Soybean Oil (crude) from Argentina, Brazil & USA mostly produced from GM or mixed GM / Non GM Soybean seed for further processing (refining) and refined oil is sold for direct human consumption. Only a small quantity of refined soybean oil for which no further processing is required is being sold for direct human consumption.

2.2 She further informed that, Rules 1989 have been in force since 5th December 1989, but no request for import and commercial marketing of GM food have been received mainly because the declaration at the point of entry was that of a voluntary nature. The only application received by the GEAC is for import of Corn Soya Blend (CSB), Refined Vegetable Soybean oil (RVSO) and Crude de-gummed Soybean oil (CDSO) by CARE and CRS. The GEAC had approved refined vegetable soybean oil after verification from CDFD that oil does not contain protein or DNA. The GEAC had also approved the import of CDSO only for a period of one year subject to post market surveillance. The request of CARE & CRS for waiver of the post market surveillance was not granted by the GEAC.

2.3 The Committee then invited the oil trade industry to make a presentation on their proposal wherein the following points were noted:

- a) About 2 million MT of crude de-gummed Soybean oil is imported annually from USA, Brazil and Argentina. Soybean in crude form is not imported.
- b) The de-gumming process at origin virtually removes any GM DNA from the oil. As the oil is further refined any residual traces of DNA/protein are eliminated.
- c) The only GM Soybean approved for commercial cultivation in the world is the Roundup Ready Soybeans (herbicide tolerant), the main producers being USA, Argentina and Brazil.
- d) The Round-up ready Soybean has been permitted for use in 48 countries and approved by 40 regulatory authorities from the food safety angle, the main importers of Soybean oil being Japan, China, India, Philippines, Australia, New Zealand, Mexico and EU.
- e) Regulators in most countries have permitted free import of de-gummed Soybean oil from origin of Round –up ready Soybean under an event based approval system.
- f) Extensive food safety studies conducted establish that the compositional analysis of Round-up Ready soybean is substantially equivalent to the non-transgenic parental Soybean variety and other commercially grown non-GM soybean varieties and shows none of the properties of allergens.
- g) There is no environmental release of the by product from the refining process.

2.4 During the deliberations, it was pointed out by the Vice-Chair that Rules for import of GMO and products thereof under the EPA have been in force since 1989. In response to a query on why

approval of GEAC was not obtained earlier, especially when the product has been proved to be safe for consumption, the representative of Cargill stated that there was no one to stop the import at the point of entry. The GEAC expressed extreme displeasure in the attitude of the Company in not abiding by the domestic regulation.

2.5 The Committee also noted that the GMO test certificate submitted by the Company is from countries which are producers of GM Soybean and not consumers of the product. The Company agreed to submit certification from the importing countries. To a query on whether the exporters can certify that the crude-degummed soybean oil exported to India is derived from Round-up Ready Soybean, the company confirmed that the required certification can be submitted along with each shipment.

2.6 The Committee also discussed the policy decision of MoEF to regulate only LMOs. The Committee supported the policy decision but was of the view that until the rules 1989 are amended and an alternate mechanism is in place, the present regulatory mechanism should be followed.

2.7 The Committee deliberated at length on various policy issues involved in the regulation of GM food products and noted that comments of Ministry of Health, Ministry of Food Processing and Industry, ICMR/ NIN are essential before taking a final view. However, on an interim basis, to avoid dislocation in the supply of edible oil supply and taking into consideration that the GEAC had earlier approved the import of refined Soybean oil and also looks into the clearance certificates issued by laboratories/authorities of the country of origin, the Committee approved the import of refined soybean oil subject to certification from the country of export that it has been derived from Roundup Ready Soybeans. In case of crude degummed soybean oil, in addition to the certification, regarding it having been derived from Round up Ready Soybean, the importer is also required to submit the analytical report from either CFTRI/NIN/Shri Ram Laboratories on the composition of crude-degummed Soybean oil both pre and post processing stage. The test results should also include the pre and post refining levels of glyphosate in the oil as well as in the residue.

2.8 this may however not be construed as the final approval of round up ready Soybean by the GEAC for which formal proposal is pending before the GEAC. The industry may like to bring a formal proposal for clearance of this variety of Soybean at the earliest.

2.9 During the deliberations the issue of importing refined Soybean oil was also discussed. It was clarified that the shipment takes about 45 to 60 days to reach the port. During this duration there is a deterioration in the quality of oil and it has to be re-processed which makes it economically unviable. It was also noted that the quantity of refined oil imported is very small and is mainly from USA by Care and CRS under the ICDS program.

4.3 Discussion on the representations received from NGOs regarding irregularities in the field trials of transgenic crops.

3.1 The Member Secretary briefed the Committee on the representations received from several NGOs regarding the performance of Bt cotton and alleged irregularities during large scale trials of Bt cotton based on the Monitoring & Evaluation Committee comprising of civil society groups and the action taken by the Ministry in this regard. She further briefed the Committee on the discussions held in the meeting with the NGOs, Director CICR, State Govt and Company representatives under his Chairmanship of Shri B S Parsheera, Additional Secretary & Chairman GEAC on 27.2.06. While some of the issues raised by the NGOs were clarified by the Company representatives & State Govt representatives it was noted that the gaps identified in the monitoring mechanism and lack of transparency needs to be addressed on a priority basis. She proposed that the issues raised by the NGOs may be referred to the sub-Committee under Dr C D Mayee, Chairman ASRB and Co-Chair GEAC for their due consideration while making recommendations to streamline and strengthen the regulatory mechanism.

3.2 The Members were of the view that the issues raised and suggestions made by the NGOs merits consideration. The Committee endorsed the proposal of the Member Secretary to refer the matter to the sub-committee on Bt Cotton and related issues constituted by the MoEF under the chairmanship of Dr C D Mayee.

3.0 Permission for export of Eggplant transgenic seeds containing cry1 Ac gene to Institute Of Plant Breeding, College Of Agriculture, University of Philippines and Bangladesh Agriculture Research Institute, Bangladesh by M/s Mahyco.

3.1 The Committee invited the representatives of the Company to present their proposal. The following points were noted:

1. Under a public private partnership program, Agriculture Biotechnology Support Project II (ABSPII) in part supported by USAID, ICAR, DBT, partner institutions and Mahyco and coordinated by Cornell University, M/s Mahyco has developed a fruit and shoot borer resistant eggplant. This project includes East West Seeds limited, Bangladesh, Bangladesh Agricultural Research Institute and Institute of Plant Breeding, College of Agriculture, University of Philippines as one of the partners.
2. As part of the MOU, it has been agreed to provide the Bt brinjal technology for development of pro-poor varieties of brinjal to Bangladesh and Philippines.
3. Initially a small quantity of the seed of certain varieties were imported from Bangladesh and Philippines. These lines were crossed with the Mahyco's transgenic Bt eggplant event (EE-1) containing cry 1 Ac gene. The backcrossed material will be imported to Bangladesh and Philippines. T
4. Under the ABSP-II program, scientists from the partner institutes have been imparted training on Bt brinjal monitoring/ testing.

3.2 The issues related to IPR of Bt brinjal were also discussed by the Committee. It was clarified that M/s. Mahyco has rights to use the cry1Ac gene under an agreement with Monsanto. Mahyco has developed transformation protocol from brinjal and done all the transformations at Mahyco research center. The rights for the transformation and selection of event, characterization and establishment of an identity rests with Mahyco. Partner material received from Bangladesh and Philippines came under a Material Transfer Agreement through NBPGR. The rights of the genetic material imported rests with the partner institutes.

3.3 Mahyco an agreement with all the partner institutes which defines the rights which are granted under the Agriculture biotechnology Support Project II (ABSPII). ABSPII also has agreement with each of the institutes.

3.4 In view of the above stated facts and clarifications, and taking into consideration that the NBA recommendation, the GEAC approved the export of transgenic eggplant seeds to Bangladesh and Philippines provided these germplasm were initially brought from these countries only.

4.0 Permission for import and conduct of Phase II clinical trials of Chimerivaxtm –JE in children of descending age from USA by M/s. Quintiles.

4.1 Member Secretary briefed the Committee on the discussion held in the GEAC meeting held on 8.2.2006. The Committee also considered the response of CRI, Kasuali and the additional information submitted by the applicant to prove that the risk of introducing Yellow fever virus from the use of Chimerivax – JE is minimal.

4.2 The Committee noted that the vaccine is urgently required for India. The Expert Member also pointed out that the Protocol for conduct of phase-II clinical trials submitted by the applicant is in order and adequate to take care of the concerns expressed in the previous meeting. In view of the above and taking into consideration that the alternative available in India is not sufficient to meet the

present requirement, the Committee approved the conduct of Phase –II clinical trials in children of descending age in India subject to the conditions that patients would be recruited in a phased manner.

B. COMMERCIAL RELEASE IN CENTRAL ZONE

1.0 The GEAC considered the proposals for commercial release (Agenda Item 6.1 to 6.8) in the light of the GEAC decisions taken in the meeting held on 4.4.2006. It was noted that in the previous meeting, the GEAC had approved Bt cotton hybrids fulfilling the following criteria for commercial release in the Central and North zones.

- a. Hybrid has completed one year LST.
- b. Hybrid has been recommended by MEC for cultivation in the North/ Central zone
- c. Hybrid has completed two years of ICAR trials and in case of notified varieties one year of ICAR trials.
- d. Hybrid containing released gene event recording a yield upto 5 % less than the best Bt check under irrigated/rainfed conditions in protected conditions.
- e. Hybrid containing new gene event recording a yield upto 10 % less than the best Bt check under irrigated/rainfed conditions in protected conditions.

2.0 One of the Members sought clarification on whether the yield criteria at point (d) and (e) above was based on the protected condition or unprotected conditions. It was clarified that the yield data from ICAR trials in respect of protected conditions was the criteria considered while taking a decision for commercial release in the North Central Zones. The ICAR representative further clarified that the farmers practice an ETL based plant protection and the performance of a hybrid is based on the data generated from protected condition. Trials are also conducted in unprotected conditions mainly to generate data on pest action on a long term basis.

1.0 Permission for commercial release of transgenic cotton hybrids NCS 138 Bt containing Cry1 Ac gene (MON 531 event)— by M/s Nuziveedu Seeds Ltd.

1.1 The Committee considered the request for commercial release and marketing of **NCS-138 Bt** containing Cry 1 A(c) gene Mon 531 event, in the Central zone. It was noted that MEC had not recommended the hybrid for LST based on the multi-location trial data during Kharif 2005. The hybrid has not completed the requirement of LST. During the deliberation the representative from DBT clarified that the Company had represented the matter to MEC for reconsideration of its earlier decision. However, MEC directed the Company to approach GEAC since approval for ZSI is given by GEAC - The Committee was of the view that only hybrids approved by MEC are considered for LST and accordingly, MEC may give its clear cut recommendation in its meeting held on 1-2 April, 2006 to the GEAC.

1.2 In respect of the request for commercial release of NCS 138, the Committee was of the view that the request is pre-mature as the hybrid has not completed the requirement of LST. However, the GEAC may consider the hybrid for LST if a clear cut recommendation from MEC is received in this regard during the next GEAC meeting.

2.0 Permission for commercial release of transgenic cotton hybrids Tulasi-117 Bt containing Cry1 Ac gene (MON 531 event) — by M/s Tulasi Seeds Ltd.

2.1 The Committee considered the request for commercial release and marketing of Tulasi-117 Bt containing Cry 1 A(c) gene Mon 531 event, in the Central zone.

2.2 The Committee further noted that the Company has completed the first year 'Large Scale Field (LST)' during Kharif 2005 and both MEC and RCGM have recommended the suitability of Tulasi-

117 Bt for commercial cultivation in the central zone. It was also noted that the The hybrids have completed two year of ICAR trials. As per the two year ICAR report the hybrid exhibited a yield of 12.4 % less than the Bt check under irrigated conditions and 10.75 % less than the Bt check under rain-fed conditions

2.3 The GEAC did not approve Tulasi 117 Bt as the yield of the hybrid was lower than the norm fixed by the Committee.

3.0 Permission for commercial release of transgenic cotton hybrids MRC-7301 BG II and MRC – 7326 BG II containing stacked genes Cry1 Ac and Cry 2Ab (MON 15985 event)—BG-II by M/s Mahyco.

3.1 The Committee considered the request for commercial release and marketing of MRC-7301 BG II and MRC – 7326 BG II containing stacked genes Cry1 Ac and Cry 2Ab (MON 15985 event)—BG-II in the Central zone. The Committee further noted that the Company has completed two years of 'Large Scale Field (LST)' during Kharif 2004 and 2005 and both MEC and RCGM have recommended the suitability of MRC-7301 BG II and MRC – 7326 BG II for commercial cultivation in the central zone. It was also noted that the hybrids have completed two years of ICAR trials during 2003 and 2004. As per the two year ICAR report, MRC-7301 BG II exhibited a yield of 4.2 % less than the Bt check under protected conditions. In respect of MRC 7326 BG-II, the hybrid exhibited a yield of 0.7 % more than the Bt. check.

3.2 In view of the above and taking into consideration the discussion held in agenda item 4.1 and decisions taken in the previous GEAC meeting, the GEAC accorded approval for commercial cultivation of MRC-7301 BG II and MRC – 7326 BG II in the Central zone for a period of three years.

6.4 Permission for commercial release of transgenic cotton hybrids ACH-11-2 BGII containing stacked genes Cry1 Ac and Cry 2Ab (MON 15985 event)—BG-II by M/s Ajeet Seeds Ltd.

4.1 The Committee considered the request for commercial release and marketing of ACH-11-2 BGII containing stacked genes Cry1 Ac and Cry 2Ab (MON 15985 event)—BG-II in the Central zone. M/s. Ajeet Seeds Ltd is a sub- licensee of the Bt. Cotton technology (BG-II), which was acquired by Mahyco from Monsanto USA.

4.2 The Committee further noted that the Company has completed one year of 'Large Scale Field (LST)' during Kharif 2005 and both MEC and RCGM have recommended the suitability of ACH-11-2 BGII for commercial cultivation in the central zone. It was also noted that the hybrids have completed two year of ICAR trials during 2004 and 2005. As per the two year report, ACH 11-2 BG-II exhibited a yield of 7.1 % less than the Bt check (RCH 2 Bt) under irrigated conditions and 10.9 % less than the Bt Check under rain-fed conditions.

4.3 In view of the above the GEAC accorded approval for commercial cultivation of **ACH-11-2 BGII under irrigated conditions** in the Central zone for a period of three years

5.0 Permission for commercial release of transgenic cotton hybrids KDCHH-441 BGII, and KDCHH-621 BG II, containing stacked genes Cry1 Ac and Cry 2Ab (event MON 15985)—BG-II by M/s Krishidhan Seeds Ltd.

5.1 The Committee considered the request for commercial release and marketing of **KDCHH-441 BGII, and KDCHH-621 BG II**, containing stacked genes Cry1 Ac and Cry 2Ab (event MON 15985) in the Central zone. M/s. Krishidhan Seeds Ltd is a sub- licensee of the Bt. Cotton technology (BG-II), which was acquired by Mahyco from Monsanto USA.

5.2 The Committee further noted that the Company has completed the first year 'Large Scale Field (LST)' during Kharif 2005 and MEC and RCGM have recommended the suitability of **KDCHH-441 BGII and KDCHH-621 BG II**, for commercial cultivation in the central zone subject to completion of procedural requirements.

5.3 It was noted that the hybrid KDCHH 441 BG-II has completed two years of ICAR trials. **KDCHH 441 BG-II** exhibited a yield of 18 % less than the Bt check (RCH 2 Bt) under irrigated conditions and 2.4 % less than the Bt Check under rain-fed conditions.

5.4 In view of the above the GEAC accorded approval for commercial cultivation of KDCHH-441 BGII **under rain-fed conditions** in the Central zone for a period of three years.

5.5 However in respect of KDCHH -621 BG-II, it was noted that only one year of ICAR trials have been completed. As per the prevailing practice, two years ICAR trials are mandatory for non-notified hybrids. This has been reiterated in the ICAR letter dated 27.4.2006. The Committee therefore concluded that the request for commercial release is pre-mature as it has not completed the requirement of two years ICAR trials.

6.0 Permission for commercial release of transgenic cotton hybrid KDCHH-9810 Bt containing Cry 1Ac gene (MON-531 event) by M/s Krishidhan Seeds Ltd.

6.1 The Committee noted that the request for commercial release and marketing of KDCHH-9810 Bt containing Cry 1 A(c) gene Mon 531 event, in the Central zone was considered in the GEAC meeting held on 4.4.2006 wherein it was concluded that the request for commercial release is pre-mature as it has not completed the requirement of two years ICAR trials.

6.2 The Committee further noted that the Company has requested the GEAC to reconsider its decision on the following grounds:

- a. In addition to one year LST and one year ICAR trials during Kharif 2005, the company has conducted additional six trials through five State Agriculture Universities of central zone.
- b. The State Agriculture University (SAU) trials may be treated equivalent to ICAR trials.
- c. During the first year ICAR trials, KDCHH has exhibited a yield advantage of 11% over the Bt check.

6.3 The Committee reconsidered the above request in the light of the comments received from Dr C D Mayee, Dr Anand Kumar and ICAR. It was noted that ICAR has explicitly stated that two years of ICAR trials is mandatory before commercial release of all un-notified Bt cotton hybrid. The Expert Members were of the view of that the requirement of ICAR should be fulfilled in the first instance. The Committee also noted that the hybrid has not performed well in the first year ICAR trials wherein it has exhibited a yield of 14.6 % less than the Bt check under irrigated conditions and 12.6 % under rain-fed condition in a ETL based protected evaluation. In view of the above the committee reiterated its earlier stand.

6.7 Permission for commercial release of transgenic cotton hybrid NCS 913 containing Cry 1 Ac gene (MON 531 event) by M/s Nuziveedu.

6.7.1 The Committee noted that the request for commercial release and marketing of NCS 913 containing Cry 1 A(c) gene Mon 531 event, in the Central zone was considered in the GEAC meeting held on 4.4.2006 wherein it was concluded that the request for commercial release is pre-mature as it has not completed the requirement of two years ICAR trials.

6.7.2 The Committee further noted that the request for reconsideration is similar to the request made at Agenda Item 6.6 and concluded that the decision taken therein would be applicable in this case also. The GEAC therefore reiterated its earlier stand.

6.8 Permission for commercial release of transgenic cotton hybrid NPH 2171 Bt containing Cry 1Ac gene (MON-531 event) by M/s Prabhat Agri biotech Ltd.

6.8.1 The Committee noted that the request for commercial release and marketing of NPH 2171 Bt containing Cry 1 A(c) gene Mon 531 event, in the Central zone was considered in the GEAC meeting held on 4.4.2006 wherein the GEAC did not approve NPH 2171 Bt as the yield of the hybrid was 5% less than that of the Bt check.

6.8.2 The Committee reiterated its earlier stand on the ground that request does not merit reconsideration as the yield under ICAR trials is less than 5% of Bt Check under ETL based protected conditions.

C LARGE SCALE TRIALS IN CENTRAL ZONE

1.0 The GEAC considered the proposals for large scale trials (Agenda Item 6.9 to 6.23) in light of the GEAC decisions taken in the meeting held on 4.4.2006. It was noted that in the previous meeting, the GEAC had approved Bt cotton hybrids fulfilling the following criteria for LST in the Central and North zones.

- a. Completion of multi-locational trials under RCGM.
- b. Recommendation of MEC and RCGM on the suitability of the hybrid for a specific zone based on the MEC evaluation multi-locational trials.
- c. Since ICAR has informed that the maximum numbers of hybrids that can be included in the AICCIP trials are about 25 per zone including the checks, it was decided to advise the applicant to forward only one of their best Bt hybrid for testing under ICAR trials. The hybrid so selected by the Company would enter ICAR and LST during Kharif 2006.
- d. The LST would be conducted at 40 locations in the North zone and 60 locations in the Central Zone for a period of 2 years as per the protocol recommended by Dr S Nagarajan Committee.
- e. The GEAC also approved seed production in an area of 10 ha during first year LST and in an area of 100 ha during second year LST.

7.0 Permission for large scale trials and seed production of transgenic cotton hybrids Krishna BG, Chetna BG, Sudershan BG and MLCH – 318 BG containing Cry 1Ac gene (MON 531 event) by M/s Emergent Research India Ltd.

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8.0 Permission for large scale trials and seed production of transgenic cotton hybrids Paras, Laxmi (HXB) containing Cry 1Ac gene (MON 531 event) by M/s Emergent Research India Ltd.

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9.0 Permission for large scale trials and seed production of transgenic cotton hybrids- Rudra- Bt, PRCH-31 Bt, containing Cry 1Ac gene (MON-531 event) by M/s Pravardhan Seeds.

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10.0 Permission for large scale trials and seed production of transgenic cotton hybrids- KDCHH- 9821 Bt and KDCHH-9632 Bt, containing Cry 1Ac gene (MON-531 event) by M/s Krishidhan Seeds Ltd.

1.0 The Committee considered the request for large scale trials in the Central zone with Krishna BG, Chetna BG, Sudershan BG and MLCH – 318 BG by M/s Emergent Research India Ltd, Paras, Laxmi (HXB) by M/s Emergent Research India Ltd, Rudra- Bt, PRCH-31 Bt by M/s Pravardhan Seeds and KDCHH- 9821 Bt and KDCHH-9632 Bt by M/s Krishidhan Seeds Ltd.

2.0 The Committee noted that the above mentioned hybrids have completed the multi-locational field trials under RCGM. It was noted that MEC has recommended 20 Bt cotton hybrids namely **Sudershan BG, Rudra- Bt, PRCH-31 Bt, KDCHH- 9821 Bt and KDCHH-9632 Bt** for LST in the central zone. It was also noted by RCGM that the report of the MEC has been endorsed in the meeting held on 27.3.2006.

3.0 After detailed deliberations and taking into consideration the findings of the multi-location trials and recommendations made by RCGM and MEC and in accordance with decisions taken in the previous GEAC meeting the following decisions were taken:

- a. The GEAC found the following hybrids suitable for large scale trials in the Central zone.
 - Sudershan BG containing Cry 1Ac gene (MON-531 event) by M/s Emergent Research India Ltd,
 - Rudra- Bt and PRCH-31 Bt containing Cry 1Ac gene (MON-531 event) by M/s Pravardhan Seeds and
 - KDCHH- 9821 Bt and KDCHH-9632 Bt containing Cry 1Ac gene (MON-531 event) by M/s Krishidhan Seeds Ltd.
- b. Since ICAR has informed that the maximum numbers of hybrids that can be included in the AICCIP trials are about 25 per zone including the checks, it was decided to advise the applicant to forward only one of their best Bt hybrid for testing under ICAR trials. The hybrid so selected by the Company would enter ICAR and LST during Kharif 2006.
- c. The LST would be conducted at 60 locations in the Central Zone for a period of 2 years as per the protocol recommended by the Nagarajan Committee.
- d. The GEAC also approved seed production in an area of 10 ha during first year LST and in an area of 100 ha during second year LST.

11.0 Permission for 2nd Year large scale trials and seed production of transgenic cotton hybrids-ACH-155-2 containing stacked genes Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Ajeet Seeds.

11.1 The Committee considered the request for conduct of second year LST with ACH-155-2 containing stacked genes Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Ajeet Seeds. in the Central zone .

11.2 The Committee noted that the GEAC in its meeting held on 3.5.2006 had approved large scale trials of **ACH-155-2** at 80 locations in Central Zone during Kharif 2005 based on the recommendations of RCGM and MEC. The MEC and RCGM have recommended both the hybrids for commercial release. However, the Company has chosen not to promote these hybrids during Kharif 2006 and have requested permission to repeat the LST during Kharif 2006 as they are yet to complete the second year ICAR trials..

11.3 In view of the above stated facts, the GEAC approved the conduct of second year LST with ACH-155-2 in the Central zone at 60 locations during Kharif 2006.

12.0 Permission for large scale trials and seed production of transgenic cotton hybrids Paras, Laxmi (HXB) containing stacked genes Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Emergent Research India Ltd.

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13.0 Permission for large scale trials and seed production of transgenic cotton hybrids Chetna BG II, Atal BG II, MLCH – 315 BG II and Brahma BG II containing stacked genes Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Emergent Research India Ltd.

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14.0 Permission for large scale trials and seed production of transgenic cotton hybrids Dhruv Bt (ZCH – 50064), Polaris Bt (ZCH – 50081) and K – 5038 Bt (ZCH-50067)) encoding fusion genes (cry 1Ab+Cry Ac) ` GFM by M/s Zuari Seeds Ltd.

1.0 The Committee considered the request for large scale trials in the Central zone with Paras, Laxmi (HXB) by M/s Emergent Research India Ltd., Chetna BG II, Atal BG II, MLCH – 315 BG II and Brahma BG II by M/s Emergent Research India Ltd, Dhruv Bt (ZCH – 50064), Polaris Bt (ZCH – 50081) and K – 5038 Bt (ZCH-50067)) encoding fusion genes (cry 1Ab+Cry Ac) ` GFM by M/s Zuari Seeds Ltd.

2.0 The Committee noted that the above mentioned hybrids have completed the multi-locational field trials under RCGM. It was noted that MEC and RCGM have recommended **Paras Laxmi BG-II , Atal BG II and MLCH – 315 BG II, Dhruv Bt (ZCH – 50064) and Polaris Bt (ZCH – 50081)** for LST in the central zone.

3.0 After detailed deliberations and taking into consideration the findings of the multi-location trials and recommendations made by RCGM and MEC and in accordance with decisions taken in the previous GEAC meeting the following decisions were taken:

- a. The GEAC found the following hybrids suitable for large scale trials in the Central zone.
 - Paras Laxmi BG-II containing stacked genes Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Emergent Research India Ltd.,
 - Atal BG II and MLCH – 315 BG II containing stacked genes Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Emergent Research India Ltd,
 - Dhruv Bt (ZCH – 50064) and Polaris Bt (ZCH – 50081) encoding fusion genes (cry 1Ab+Cry Ac) ` GFM by M/s Zuari Seeds Ltd.
- b. Since ICAR has informed that the maximum numbers of hybrids that can be included in the AICCIP trials are about 25 per zone including the checks, it was decided to advise the applicant to forward only one of their best Bt hybrid for testing under ICAR trials. The hybrid so selected by the Company would enter ICAR and LST during Kharif 2006.
- c. The LST would be conducted at 60 locations in the Central Zone for a period of 2 years as per the protocol recommended by the Nagarajan Committee.
- d. The GEAC also approved seed production in an area of 10 ha during first year LST and in an area of 100 ha during second year LST.

15.0 Permission for large scale trials and seed production of transgenic cotton hybrids-Navkar-5 encoding) encoding fusion genes (cry 1Ab+Cry Ac) ` GFM by M/s Navkar Hybrid Seeds.

15.1 The Committee noted that the above request is for direct entry into large scale field trials on the grounds that the GEAC in its meeting held on 3rd May 2005 had approved the entry of certain hybrids fulfilling the following case verification criteria for direct entry into LST:

- A. The non-Bt. hybrid should be a Notified and released hybrid by the Central Government with reference to specific zones.
- B. Applications should be supported by documentary evidence of the following:
 - (a) Confirmation that the hybrid contains approved gene event.
 - (b) Protein expression level in different tissues at different intervals.
 - (c) DNA finger printing to prove its genotype equivalent to non-Bt hybrid.

15.2 It was noted that the Central Sub-Committee on Crop Standards, Notification and Release of Varieties for Agricultural Crops in its meeting held on 27th and 28th January, 2006 has recommended and approved the cotton variety VASANT (Navkar-5) for release and notification. This has been confirmed by the Ministry of Agriculture vide their letter no. 17-8/2005/SD IV dated 18.4.2006. The Member Secretary informed that the Company has furnished the DNA fingerprinting and protein expression level.

15.3 After detailed deliberations the Committee concluded that the request for direct entry into LST may be considered after the hybrid has been formally notified. The Committee also decided to set up a two Member sub-committee comprising of Dr Akhilesh Tyagi and Dr P Anand Kumar to evaluate the case verification documents submitted by the Company. Decision on the proposal was therefore deferred.

16.0 Permission for large scale trials and seed production of transgenic cotton hybrids G-Cot Hybrid -8 encoding fusion genes (cry 1Ab+Cry Ac) ` GFM by M/s Nath Seeds Ltd.

16.1 The Committee considered the request for large scale field trials of **G-Cot Bt** containing encoding fusion genes (cry 1Ab+Cry Ac) ` GFM at 60 locations in the central zone and noted that both MEC and RCGM have recommended the suitability of the hybrid for Central zone.

16.2 During the deliberation, the representative of DBT informed that a representation has been made by Navsari Agriculture University, Surat to RCGM that the G-Cot germplasm was released by them and M/s Nath Seeds have no propriety right to convert it to a Bt hybrid. Accordingly RCGM has sought clarification on whether the Company has obtained NOC/permission from Navsari Agriculture University to convert the non-Bt G-Cots hybrid to a Bt hybrid. Since the above matter is an IPR issue it was decided to await clarification from the Company. Decision on the proposal was therefore deferred.

17.0 Permission for large scale trials and seed production of transgenic cotton hybrids NHH- 44, Kashinath Bt encoding fusion genes (cry 1Ab+Cry Ac) ` GFM by M/s Nath Seeds Ltd.

17.1 The committee considered the request for conducting large scale field trials of **NHH- 44 Bt and Kashinath Bt** containing encoding fusion genes (cry 1Ab+Cry Ac) ` GFM at 60 locations in the central zone and noted that both MEC and RCGM have recommended the suitability of the hybrids for Central zone.

17.2 During the deliberation, the representative of ICAR informed that NHH- 44 has been released by Parbhani Agriculture University, Nanded and has been identified as national check. As per the decision taken in the agenda item 6.18, the Committee concluded, to protect the IPR of the Public funded institutions, NOC/permission from the Agriculture University need to be obtained in the first instance. Decision on the request was therefore deferred.

17.3 In respect of Kashinath Bt the GEAC approved the conduct of LST for a period of two years at 60 locations as per the Protocol prescribed by GEAC in other cases. The GEAC also approved seed production in an area of 10 ha during first year LST and in an area of 100 ha during second year LST.

18.0 Permission for large scale trials and seed production of transgenic cotton hybrids JKCH –666 Bt, JKCH – 226 Bt, JKCH – 2301 Bt and JK - Gowri containing Cry 1Ac gene (Event 1) by M/s JK Agri Genetocs.

18.1 The Committee considered the request for large scale trials of the above mentioned hybrids in the Central zone and noted both RCGM and MEC have recommended the suitability of **JKCH –666 Bt and JKCH – 226 Bt** for Central zone.

18.2 Accordingly, the GEAC approved the conduct of LST for a period of two years at 60 locations as per the Protocol prescribed by GEAC in other cases. The GEAC also approved seed production in an area of 10 ha during first year LST and in an area of 100 ha during second year LST.

V. LARGE SCALE TRIALS IN NORTH ZONE

19.0 Permission for large scale trials and seed production of transgenic cotton hybrids JKCH – 226 Bt containing Cry 1Ac gene (MON 531 event) by M/s JK Agri Genetics Ltd.

19.1 The Committee considered the request for large scale trials of **JKCH – 226 Bt** containing Cry 1 A(c) gene (Event 1) in the North zone and noted that the hybrid has not been tested in the multi-locational trials under RCGM which is a pre-requisite for consideration for LST.

19.2 The Committee also noted that the hybrid has undergone two years of ICAR trials even before the hybrid has been approved for multi-locational trials by RCGM/ Large scale trials by GEAC trials and even before the gene event has been approved from biosafety angle. The Committee requested ICAR to examine the above issue and clarify the basis on which the hybrid JKCH 226 BT has entered the ICAR trials.

19.3 The Committee concluded that the request for LST is pre-mature as it has not completed the requirement of multi-location trials.

**VI. LARGE SCALE TRIALS IN NORTH ZONE
Hybrids Containing New gene**

20.0 Permission for large scale trials and seed production of transgenic cotton hybrids-Navkar-5 encoding fusion genes (cry 1Ab+Cry Ac) ` GFM by M/s Navkar Hybrid Seeds.

20.1 The Committee noted that the above request for direct entry large scale field trials is similar to the request made in Agenda Item 6.17 and therefore decision taken therein would apply.

VII. REQUEST FOR SECOND YEAR LST IN THE CENTRAL ZONE

21.0 Permission for 2nd year large scale trials of transgenic cotton hybrids KDCHH-621 BGII containing stacked genes Cry Ac gene (MON-15985 event) by M/s Krishidhan Seeds Pvt. Ltd.

21.1 The Committee considered the request for conduct of second year LST with KDCHH-621 BGII containing stacked genes Cry Ac gene (MON-15985 event) by M/s Krishidhan Seeds Pvt. Ltd in the central zone .

21.2 The Committee noted that the Company has completed the first year 'Large Scale field (LST)' during Kharif 2005. The MEC has recommended the suitability of KDCHH-621 BG II, for commercial release in the Central zone subject to completion of procedural requirement.

21.3 The Company's request for commercial release was not considered by the GEAC (under agenda item 6.5) on the grounds that it has not completed two years of ICAR trials. Since commercial release has not been permitted, the Company has requested for 2nd year LST.

21.4 In view of the above stated facts, the GEAC approved the conduct of second year LST with KDCHH-621 BG II in the Central zone at 60 locations during Kharif 2006 and seed production in an area of 100 ha during second year LST.

Other Items

22.0 Revalidation of GEAC permission for import and marketing of Humlog (Human Insulin Lispro –r-DNA) by Eli Lilly Company (India) Pvt. Ltd, Gurgaon.

22.1 The Committee noted that the GEAC in its 15th Meeting held on 4.11.97 had approved import and marketing of r-human insulin injection for a period of four years. As per Rule 13(2) of the 1989 Rules approvals of GEAC are valid a period of four years at the first juncture and renewable for two years at a time. It was also noted that in accordance with the above provisions, the approval was revalidated for a period of two years by the GEAC in the 27th Meeting of GEAC held on 8th August 2001 and 7th April 2004.

22.2 The GEAC Conveyed its 'No Objection' for revalidation of GEAC permission for two more years.

23.0 Revalidation of GEAC permission for import and marketing of r-human Insulin (Huminsulin) by M/s Sun Pharmaceuticals Industries Ltd, Mumbai.

23.1 The Committee noted that the GEAC in its meeting held on 15.1.97 had approved import and marketing of r-human insulin injection for a period of four years. In accordance with the above provisions, the approval was revalidated for a period of two years by the GEAC in its meeting held on 8th August 2001 and 3rd February 2004.

23.2 The GEAC conveyed its 'No Objection' for revalidation of GEAC permission for two more years.

The next date of the GEAC meeting is scheduled for 22.5.2006
