

Ministry of Environment & Forests
HSM DIVISION

**Subject: Minutes of 18th Meeting of the Genetic Engineering Approval
Committee held on 13.10.1998.**

The 18th Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 13.10.1998 under the Chairmanship of Shri Vinod Vaish, Special Secretary in the Ministry. The following is the list of participants:

1. Shri Vinod Vaish, Special Secretary, MOEF- Chairman
2. Dr. Sushil Kumar, Director, Central Institute of Medicinal and Aromatic Plants, Lucknow- Co-Chairman
3. Shri V. Rajagopalan, Joint Secretary, Ministry of environment and Forest, New Delhi.
4. Dr. Vasantha Muthuswamy, Chief, Indian Council of Medical Research, New Delhi.
5. Dr. S.K. Mahajan, BARC, Bombay.
6. Dr. K.K Tripathi, Director, Department of Biotechnology, New Delhi.
7. Shri. A.B. Ramteke, Deputy Drug's Controller, Ministry of Health, New Delhi.
8. Dr. (Mrs.) S. Kulshrestha, Medical toxicologist, Directorate of Plant Protection, Quarantines and Storage, Faridabad.
9. Shri John Thomas, Assistant Director, National Productivity Council, New Delhi.
10. Dr. R.R Khan, Director, Ministry of Environment and Forests, New Delhi.
11. Ms. Madhu Gupta, Research Assistant, MOEF, New Delhi.

2. Welcoming the participants, Chairman referred to the minutes of the 17th meeting of GEAC held on 18th August, 1998 which were circulated to all the members. Since no comments have been received on the minutes of 17th meeting of GEAC, these were confirmed. Thereafter the proposals as mentioned in the agenda notes were taken up for discussion.

Large Scale Field Trials on Transgenic Cotton Hybrid Seeds(Commercial name - Bollgard) by M/s Maharashtra Hybrid Seed Company Limited (Mahyco), Mumbai.

3. Member Secretary, GEAC informed that the application put up by M/s Mahyco. Mumbai for large-scale field trials on transgenic cotton in 205 acres of land at Mahyco farms is the first proposal of its type submitted to GEAC for clearance. Therefore, it may be necessary to understand details of proposal for which the firms have been asked to make a presentation. Chairman invited the representative of Mahyco to make a brief presentation.

4. Giving details of the proposal, the representative of the firm mentioned that the transgenic cotton (Commercial name-Bollgard) is an insect tolerant variety of cotton plant able to resist attack by insect of lepidopteron group. This in-built protection in Bollgard cotton is provided by the presence of the B.t (Bacillus thuringiensis) gene in the seed. Bacillus thuringiensis var kurstaki is a soil bacterium that produces a crystal protein that controls a specific group of insects, called lepidopteron insect pests. Bt protein, when ingested by the insect larva that feeds on the plant, binds with the receptors present in the insect's gut. This leads to loss of activity in the insect leading to death. It is, however ineffective against any other cotton pest. The Bollgard gene is currently in an advanced stage of back-crossing into Indian cotton germplasm at the greenhouses of Mahyco. These back-crossed varieties and hybrids are currently being tested for insect tolerance restricted plots.

5. As per information presented by the firm, Bollgard cotton has been screened extensively in other countries to establish its safety to animals and human beings. Studies show that Bt is very safe for consumption as cotton-seed cake or oil and poses no threat whatsoever to organisms feeding on it except the specific target insect pests (bollworm). Studies done in various experimental animals could not manifest any harmful health effects. Risk from out crossing studies was negligible. In response to a query from Co-chairman, it was clarified that there is no possibility of any allergic reaction during the use of Bt cotton as there is no Bt protein left in the cotton boll. As far as insect resistance is concerned, the firm is prepared to give specific proposal for insect resistance management. Dr. Mahajan from BARC posed the question about the possible increase in the population of certain other insects if the pesticides are not used as claimed by the firm. The extra insect load obtained in this manner should be determined. It was clarified by the firm that in accordance with the permission given by DBT, field trials in small fields are being carried out. However no large scale seed production is being attempted.

6. The representative of Department of Plant Protection Quarantine and Storage mentioned that since Heliothes pest is the major problem in the cotton growing areas, the trials should be conducted in these areas. Moreover severe resistance problem in areas like Guntur, Sirsa, Shriganganagar, etc. due to chemical pesticides has been reported. It was explained by the firm that the trials conducted in six other countries namely USA, Australia, Mexico, China, Argentina and South Africa, the problem of resistance has not been noticed. On behalf of Mahyco it was explained that the firm will submit detailed resistance management plan as an overall strategy for integrated pest management in the areas where field trials will be conducted. Although, the pollen of cotton crop does not travel more than two meters distance as an abundant caution the firm agreed to maintain an isolation distance of 30 mts. Co-chairman wanted the firm to ensure that the level of expression of B.t toxin gene in various tissues of cotton is at the same level as transgenic cotton so that resistance to insects does not develop faster.

7. Chairman however expressed his anxiety as to how such large production of seeds in the 205 acres of land is going to be managed. It was clarified that multiplication of seeds is only to generate data on the efficacy and biosafety of the product. The firm will follow guidelines on proper storage of transgenic cotton seeds and specific conditions imposed by GEAC in this regard will be maintained. Proper security conditions will be maintained around the farm owned by the firm.

8. Chairman mentioned that there is serious concern about introducing the transgenic variety into the country. Following disadvantages have been described in scientific literature introducing the transgenic cotton:

- (a) Introduction of genetically modified crops will spell disaster for ecology agronomy, environment and health of the people.
- (b) There are social dimensions as farmers will be dependent on private source of supply of seed and will be forced to pay higher prices for seeds and pesticide packages.
- (c) There is a risk of transfer of new gene from transgenic crop to wild species of weeds and other normal crops making weeds more resistant to available herbicides.
- (d) There are chances of disease causing bacteria becoming resistant to antibiotics.
- (e) Monsanto subsidiary is developing “Terminator” seeds, which only germinate for one season. Farmers would then have to buy new seeds every season.

9. In view of above concerns, the Ministry has made wide consultations with the concerned agencies in the country responsible both for promotional and regulatory aspects of introduction of new plant varieties in the country. Experts are of the view that unless biosafety of such products is fully established in the Indian context such products will not be allowed to be commercialized in India. Following are the views of experts to whom the matter was referred:

Department of Biotechnology: The Company has made substantial progress in completing the generation of safety information and it is expected that the work will be over for a review by the beginning of 1999. The appropriate authorities namely the RCGM and GEAC would be able to look at the complete data at that time. The haste shown by the company to multiply seeds at this stage is preempting the full evaluation of the safety protocols.

The department is of the opinion that as the field trials as well as the safety studies in goats and other animals are in progress, it would not be proper to allow permission to produce large quantities of seeds for commercial use at this stage. Such production of seeds could be allowed only after the products have been found to be safe from all count under the EPA.

The request of the company for growing the seeds on 205 acres would not be consistent with the Rules of Procedure as they stand today. Commercial seed production has to taken up only after the bio-safety and economic superiority of the transgenic has been established.

Central Institute for cotton Research, Nagpur: Thorough testing in fields has to be undertaken before transgenic cotton goes into the farmer’s hands. The trails have to be conducted in various agro-climatic regions of the country. Permission on insect biology, population dynamics and resistance management strategies have to be generated.

Indian Council of Agricultural Research: The proposed seed multiplication is a pre-commercialization activity. Several safety precautions have been suggested for conducting large-scale field trials involving transgenic cotton. Safety data on aquatic animals should also be generated

Jawaharlal Nehru University (Prof. C. K. Varshney): The safety of the product is based on limited studies. Long-term studies under Indian eco-system are required. Such studies should cover domestic animals and humans. Several doubts have been expressed about large-scale trials taken at this stage.

10. Chairman observed that it appears that M/s Mahyco is already conducting limited experimental trials at 25 locations on transgenic cotton in accordance with the permission granted to them by DBT on 22nd July 1998. Other feeding studies on goat are also being conducted at ITRC, Lucknow for which only an Interim Report has been submitted. Member Secretary, GEAC also invited the attention of members to DBT "Revised Guidelines for Research in Transgenic Plants" issued in 1998. According to these Guidelines, Category III experiments involving genetically modified plants in open field conditions could be conducted only after clearance from DBT. The results of small-scale experimental trials allowed by DBT are still being conducted and the data are yet to be submitted by the firm. In view of the comments offered by DBT (Para: 9 above), members felt that it may be premature for the GEAC to allow large-scale field trials involving transgenic cotton in 205 acres. The firm should complete investigations as proposed by DBT and submit the report by the early 1999 to DBT for further decision making. Only after the recommendations of DBT are available, GEAC will decide about extending trials involving transgenic cotton to larger area as requested by the firm.

Import of EPREX prefilled syringes containing 500, 1000 and 3000 i.v. of rHuEPO submitted by M/s Johnson and Johanson Limited, Mumbai.

11. The proposal is to import recombinant human erythropoietin (rHuEPO) used in the treatment of serious anemic conditions in humans. The firm is already importing vials of 2000, 4000 and 10,000 units under permission from DCGI. In order to enlarge the range of the products, the firm intends to import prefilled syringes containing 500, 1000 and 3000 units for the benefit of patients. DBT have already recommended the import of this product. It is also used in countries like Switzerland, U.K, Belgium, France and Germany. It was recommended that the import of the above product may be approved subject to clearance by DCGI and other terms and conditions imposed for the import of drugs and pharmaceuticals.

The meeting ended with a vote of thanks to the chair.