23rd Meeting

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Ministry of Environment and Forests
(HSM Division)

Subject: Minutes of the 23rd Meeting of Genetic Engineering Approval Committee held on 30th June, 2000.

The twenty-third meeting of the Genetic Engineering (GEAC) was held on 30th June, 2000 under the Chairmanship of Dr. K.K. Kundra, Special Secretary, Ministry of Environment & Forests.

2. Dr. (Smt.) Manju Sharma, Secretary, Department of Biotechnology and Dr.R.S. Paroda, Director General, Indian Council of Agricultural Research attended the meeting as special invitees. The following is the list of other participants:

1) Dr. Sushil Kumar, Director, Central Institute of Medicinal and Aromatic Plants, Lucknow (U.P.). - Co-chairman

2) Shri B.S. Dhillon, Addl. Director General (Food Crops), Indian Council of Agricultural Research, New Delhi.

3) Dr. P.K. Ghosh, Advisor, Department of Biotechnology, New Delhi.

4) Dr. S.K. Mahajan, Head, Molecular Biology & Agricultural Division. Bhaba Atomic Research Centre, Mumbai

5) Prof. A.K. Bhatnagar, Department of Botany, University of Delhi, Delhi.

6) Shri A.B. Ramteke, Deputy Drugs Controller, Ministry of Health, New Delhi.

7) Dr. R.P. Sharma, Head of Biotechnology Centre, Indian Council of Agricultural Research, New Delhi

8) Prof. Subhash Chand, Centre for Biochemical Engineering, New Delhi.

9) Dr. (Mrs.) S. Kulshreshtha, Plant Protection Advisor, Directorate of Plant Protection, Quarantine & Storage, Faridabad.

10) Dr. R.R. Khan, Director, Ministry of Environment & Forests, New Delhi.-. Member Secretary

11) Smt. Madhu Gupta, Research Assistant, Ministry of Environment & Forests. New Delhi.

Agenda Item No. I : Welcome

3. Dr. Sushil Kumar, Co-chairman welcomed Dr. A.K. Kundra, Special Secretary, Ministry of Environment & Forests and congratulated him on his taking over as the Chairman of GEAC. Initiating the discussion, Special Secretary, MoEF briefly mentioned the proposa1s to be discussed during the meeting. These proposals were taken up for discussion as per agenda notes circulated earlier.

Agenda Item No.2 : Confirmation of the Minutes of the 22nd Meeting

4. The minutes of the last meeting were circulated to all the members. As, no comments have been received, the minutes were confirmed. Chairman referred to para 3 of the Minutes of the last meeting requesting Advisor, DBT to prepare a Base Paper on Monitoring Mechanism to be evolved for production and use of recombinant products in the country. DBT was requested to expedite preparation of such a paper.

Agenda Item 3 : Large-scale Field Trials on Transgenic Cotton (Bt Cotton) by M/s Mahyco, Mumbai

5. It was noted that M/s Mahyco, Mumbai had imported the Bt cotton seeds in 1996 after permission by the Review Committee on Genetic Management (RCGM) set up by the Department of Biotechnology (DBT). According to the statement made by the representatives of Mahyco, the firm had backcrossed these Bt Cotton plants with Indian cotton variety. The firm had conducted greenhouse and small scale field trials alongwith toxicity and allergenic studies during 1996-99 using the backcrossed Indian cotton variety. The Monitoring and Evaluation Committee (MEC) constituted by DBT and RCGM had monitored the small-scale field trials conducted by the firm. Based on the data obtained, RCGM/DBT had recommended to the Ministry of Environment & Forests that the firm may be allowed to conduct large-scale field trials in the country. As per DBT communication dated 5.5.2000. Mahyco had requested DBT vide their letter dated 01.05.2000 that they may be permitted to raise seeds of Bt cotton in 4000 hectares of land during the 2000-2001 season. They have further asked for permission to conduct large-scale demonstration in 1000 hectares of land using Bt cotton plants.

6. While the GEAC noted that Bt cotton has already been commercialised in countries like USA, China, Australia, South Africa and Argentina, it was clarified on behalf of MoEF that any new technology could only be allowed in the country after biosafety and health issues are fully addressed. It was, therefore, considered necessary that rigorous testing of the new technology should be undertaken in a step-by-step manner. In the present case, MoEF has also to satisfy itself about agronomic performance of Bt cotton alongwith the larger issue of farmers acceptance of the new technology and its socio-economic impact.

7. The Member-Secretary, GEAC clarified that the area to be used in the large-scale field trials as mentioned in the agenda notes is based on the DBT‘s communication dated 5th May, 2000. However, M/s Mahyco had subsequently clarified that the proposed area for large-scale field trials is only 150 hectares and 210 hectares for demonstration.

8. The consensus of opinion was that the demonstration of the technology to the farmers be allowed only after the bio-safety issues have been further examined. Presently, the firm should concentrate only on large-scale field trials and for seed

production. At the same time, it is desirable that the total time required for undertaking trials is minimized and number of steps reduced. This could be done by simultaneously undertaking small-scale field trials under the supervision of RCGM/DBT and ICAR coordinated trials in various agro-climatic regions of the country during the first year and large-scale field trials in the second year. This schedule should be adopted for trials of subsequent transgenic crops. After detailed discussion and consultation with the firm on the issue of availability of locations, following decisions were taken:

(i) The firm shall be permitted to undertake the trials as per the following details:
Large-scale field trials - 85 hectares
Seed production - 150 hectares

(ii) The firm shall also make available seeds to ADG (Food Crops), ICAR to enable them to undertake trials at their own farms. The total area to be covered by ICAR in such trials will be indicated so that the large-scale field trials undertaken by the firm and ICAR do not exceed the above limit of 85 hectares.

(iii) While sowing will now be possible in the southern part of the country in the northern areas, it could be done in next season. The firm shall provide MoEF the state-wise details of locations where it intends to, undertake sowing.

(iv) Only those hybrids which have shown better agronomic performance shall be used in testing. The firm has indicated that it proposes to test MECH-l 2, MECH-162 and MECH-184 hybrids. Molecular characteristics of these hybrids shall be made available to GEAC.

(v) During the large-scale field trials and seed production, lint can be baled and stored separately. This can either be destroyed or put to some use later once biosafety issues have been properly settled. Cotton plant residues after harvesting be converted to compost by using vermin-composting.

9. GEAC also decided that the firm will be required to undertake following studies during the trials and the results of these studies shall first be examined by RCGM:

i) To get authentic report from an Indian laboratory like South Campus of Delhi University or Centre for Cellular & Molecular Biology, Hyderabad that Bt seeds do not contain 'Terminator Gene' to reassure the public and NGOs that the introduction of new technology would not in any way affect our farming practices.

ii) To undertake nutritional studies in buffaloes and cows to determine as to whether Bt cotton seed as well as Bt cotton seed oil has any effect on animal health, milk production and quality of milk vis-a-vis, health of the people.

iii) To undertake insect-resistance studies on other plant pests.

iv) To undertake toxicity studies on other animal species like poultry, fish etc., under Indian conditions.

v) To generate data on the stability of Cry 1Ac gene.

vi) To undertake fresh studies on gene flow/pollen and the assessment of impact of such migration on non-transgenic cotton.

vii) To make available socio-economic data like cost of Bt cotton seed, projected demand and the area to be covered under Bt cotton cultivation.

10. It was also decided that before conducting the above studies, the firm shall submit protocols/check-lists to the Monitoring and Evaluation Committee and get them approved.

11 . It was realized that a strong monitoring strategy needs to be evolved to evaluate large-scale field trials and other data to be generated during the next one year. Since it is an agriculture based product, it was decided that ICAR system including agricultural universities be fully utilized for monitoring seed production. It was also decided that the Monitoring-cum-Evaluation Committee (MEC) set up earlier by DBT would continue to monitor large-scale-field trials and other studies suggested in para 8 and 9 above. Arrangements for field visits of MEC experts and meetings would be the responsibility of the firm. The State Biotechnology Coordination Committee (SBCC) and District Level Committee (DLC) as provided under HMO/GMO Rules shall also undertake field visits alongwith a representative of State Agricultural University/ICAR Institute.

Agenda Item 4 : Production of recombinant, insulin in 125 litre fermentor by M/s Wockhardt, Mumbai :

12. Since toxicity data have not been generated by the firm, it was decided that the firm may generate such data and submit it to RCGM to take a view in the matter. At this stage, the proposal was considered to be pre-mature by GEAC and was rejected.

Agenda Item 5: Manufacture and Marketing of recombinant human ervthropoietin by M/s Wockhardt, Mumbai:

13. It was noted that multi-centric clinical trials have been carried out at three centres without any side-effects in the patients suffering from anaemia due to chronic renal failure and the fact that the RCGM has already cleared the product; it was decided to accord environmental clearance to the product subject to clearance by the Drug Controller General of India.

Agenda Item 6 : Application for Human clinical trials on Interferon Alpha by M/s Shantha Biotechnics Ltd., Hvderabad :

14. Since toxicity tests have successfully been done in animals, it was agreed that the request for phase-Ill clinical trials may be agreed to.

Agenda Item 7: Import of recombinant Insulin by M/s Eli Lilly Ranbaxy Ltd

15. The product was earlier approved in the 13th Meeting of GEAC held on 14th November, 1996. The firm has given details of various formulations in which it intends to import the product. This was agreed to.

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