Ministry of Environment & Forests
HSM DIVISION

Subject: Minutes of 13th Meeting of the Genetic Engineering Approval Committee held on 14.11.1996.

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The 13th Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 14.11.1996 in MOEF. The following participated in the meeting:

1.	Shri Vishwanath Anand	Chairman
2.	Dr. Sushil Kumar	Co- Chairman
3.	Shri Vijay Sharma	Member
4.	Dr. P.K Ghosh.	Member
5.	Prof. Subash Chandra	Member
6.	Dr. V. Muthuswamy	Member
7.	Dr. B. Ramtake	Member
8.	Dr. S.K. Mahajan	Member
9.	Dr. (Mrs.) S. Kulshreshtha	Member
10.	Dr. S.C. Bansal	Member
11.	Dr. R.R Khan	Member Secretary

2. The meeting was also attended by Dr. T.V. Ramanaiah, Principal Scientific Officer, DBT and Dr. Rashid Hasan, Joint Director and Ms. Madhu Gupta, Research Assistant of MOEF. Dr. K.R. Vishwanathan, Department of Animal Husbandry and Dairying attend the meeting as Special Invitee. Dr. (Mrs) Sulbha Gupta, Director, Department of Science and Technology, Shri T.R Subramanian, Industrial Advisor, Department of Industrial Policy and Promotion, Shri D.K Biswas, Chairman of Central Pollution Control Board, Dr. S.C. Saxena, Director, National Productivity Council could not attend the meeting.

Agenda Item No. 1: Field trials of Posilac recombinant Bovine Somatotropin by Monsanto Chemicals, Bombay.

3. The proposal on the import of r-BST received from Monsanto Chemicals, Bombay was approved in the 11th meeting GEAC for large-scale field trials in the country. The field trials have since been completed. The firm has now requested commercial use of the product in the country. The reports of field trials submitted by the firm have been circulated to DBT and Department of Animal Husbandry and Dairying.

4. Dr. P.K. Gosh, Adviser, DBT, proposed that the product should be allowed to be commercially used for a period of years in both cows and buffaloes to increase milk production to level of over 20% without any deleterious effects. Dr. Ghosh mentioned that the product has been tried in over 600 buffalos and 200 cows under Indian conditions

and therefore the release of the product for commercial application for two years would be order.

5. Dr. K.R. Vishwanathan, Deputy Commissioner, Department of Animal Husbandry and Dairying, offered the comments based on the results of cows trials carried out by Dr. R. S. Ludai at NBRI and the sponsored trials at Bombay Veterinary College, Department of AH&D is of the view that the product should not be allowed for commercial use in cows right now, as the number of cows on which the product has been tried under Indian conditions are relatively less and that consistent results are yet to be obtained on large scale in cows. The fact that the product is approved for commercial use by FDA in USA, the report of the EEC veterinary Medical Committee, etc should the GEAC decide to allow the product for commercial use in buffaloes, then the product should be allowed to be used on a limited scale only that too subject to the other built in safeguards which were elaborated at the meeting.

6. Various experts discussed the results obtained form the field trials conducted in the country and those obtained from controlled experiments, especially on the aspects relating to the safety of the product, advantages in terms of increase in milk production and possible effect of the product on increased use of the antibiotics due to increase in incidence of udder inflammation (mastitis), possible increase in body heat due to increased metabolic activity and possible effect of pesticide residues in the milk after consumption of excessive quantity of green fodder. The Committee also discussed at length the probable use of the products by various sections of farming community, including small holders, members of the cooperative societies and progressive livestock holders.

7. The representation received from Animal Welfare Society of India dated 5.5.91 raising certain doubts about the harmful nature of r- BST to the cows was also discussed and taken note of.

8. Summing up the discussions, Dr. Sushil Kumar Co-chairman observed that the results of extensive field trials conducted abroad and in India has proved that the product is safe and is effective in increase in milk production and productivity. No adverse effect has been observed which could be attributed to the use of the product. However, keeping in view the suggestions of the Department of Animal Husbandry and Dairying, it may not be advisable to allow commercial use of the product in buffaloes subject to the approval of Drug Controller of India and observance of the following conditions which are to be strictly followed:

a. The product should be used only in a limited number of buffaloes on a commercial scale. The Department of Animal Husbandry and Dairying had proposed to restrict the use of the product in States viz. Andhra Pradesh, Karnataka, Maharashtra and Haryana /Punjab on the basis of the fact that the field experiments were conducted in these States and that the awareness of the farmer's relating to the management and husbandry practices is relatively more. The Committee endorsed this view and at the same time opined that practical

difficulties in enforcing such restricted use in some States may have to be taken care of by the Drugs Controller of India.

b. The authorization for commercial use in limited number of buffaloes will be valid initially for one year only, during which post authorization surveillance will be undertaken by the firm in close coordination with the GEAC, Deptt. of Biotechnology and the Department of AH&D, after which a review will be undertaken by the GEAC on the impact of the product at the field level. The Drug Controller should have the power to withdraw or suspend the product at any point of time if some ADR (Adverse Drug Reaction) is noticed.

c. The firm will continue to undertake the field trials in a total of 2500 buffaloes and 2500 crossbred cows, in accordance with the approved protocol, which will also give us an idea on the long term negative effects, if any, of the product under Indian conditions of use. The firm will submit results of the above trials on a six monthly basis to the GEAC for consideration.

d. The product will be sold only under strict veterinary prescription and will be used under expert care relating to choice of animals and subsequent care, as the successful use of the product would require relatively high nutritional regime for the treated animals and hygienic precautions. The product will not be used in animals where satisfactory levels of nutrition cannot be assured and towards this end, the product should be accompanied by a package of recommendations for farmers.

e. The product will be allowed to be used from second lactation only.

Agenda Item No. 2: Import of Boostin-s (rBST) for conducting clinical trials in India by M/s Alembic Chemical Works Ltd., Baroda

9. M/s Allembic Chemical Works, Baroda, have proposed to undertake field trials using r-BST patented by LG group of companies of South Korea. The Committee observed that the product proposed for field trials is not the same as that of M/s Monsanto, as the methods involved in recombinant technology including gene construction, expression of the gene in the microorganism, production, purification, evaluation and standardization in respect of both the products are different as different patents are involved.

10. The Committee, after examination of the proposal, made the following major observations:

a. The product ‘Boostin’ does not seem to have been approved for use either by the FDA of the USA, the EEC or any other country, although it has been indicated that the product is approved for use in Korea.

b. Further, the product of M/s Allembic appears to have been field tested in less than 200 cows, that too only in Korea. This may be contrasted with the case of M/s Monsanto, where the field trials were allowed to be conducted only after a careful analysis of the results of field trials carried out in several thousands animals spread all over the world was done and after satisfying that the product was permitted for commercial use by the FDA of the USA and several other countries.

c. The trial reports and other world literature on the product of LG Group are not exhaustive.

d. In the documents submitted by Allembic, in many places the results obtained in different parts of the world using the product of M/s Monsanto have been quoted to substantiate the advantages of r-BST as a generic product, which is misleading.

e. While proposing the trials, detailed formats for the trials indicating the number of animals to be put to the trials, various experimental animal groups to be put to trials, season for undertaking the trials, methods of feeding and management, frequency at which the blood and milk samples to be tested, the tests involved and methodology, parameters to be used for judging the well being and reproductive health of the animals to be tested etc. have not been given in detail by the firm.

11. Under the above circumstances, the Committee decided not to agree to the request of M/s Allembic to undertake field trials of their product until the deficiencies pointed out above are rectified.

Agenda Item No. 3: Request for import and use of chymogen (100% chymogen enzyme) – A milk coagulating enzyme by Essdee Chemocrates, Bombay.

Agenda Item No. 4: Import and use of CHY-MAX by M/s Four Vees Sales and Export Corporation, Bombay.

12. It was decided to forward the copy of both the above proposals alongwith the comments received from Dr. Madan, Dy. Director General, Indian Council of Agricultural Research to Dr. K.R. Vishwanathan, Dy. Commissioner, Deptt. Of AH&D for obtaining the views of Department of Animal Husbandry and Dairying before taking a decision in the matter.

Agenda Item No. 5: Import and Marketing of GRANOCYTE by Rhone-Poulenc Rorer (India) Ltd., Bombay.

Agenda Item No. 6: Permission to import and market injection Somatropin, DNA by Eli Lilly, Ranbaxy Ltd., New Delhi.

13. It was decided to send both the above proposals to more experts and forward the same to the Department of Biotechnology for their advice.

Agenda Item No. 7: Import and Marketing of injection abciximab 2 mg/ml for high risk coronary angioplasties by Eli Lilly Ranbaxy Ltd., New Delhi.

14. The product is related to monoclonal antibodies which do not fall under the GEAC purview. The applicant may be informed accordingly.

Agenda Item No. 8: Import and Marketing of injection Lispro (rDNA) and Human insulin by Eli Lilly Ranbaxy Ltd., New Delhi.

15. Committee has approved the product subject to DCI clearance with the condition that limits of impurities be within the limits prescribed by World Health Organization.

Agenda Item No. 9: Environmental approval for marketing Interferon Alpha 2B by M/s Lupin Laboratories Ltd., Bombay.

Agenda Item No. 10: Hepavac Gene Injection (Hepatitis B Vaccine Recombinant) by M/s Cadila Health Care Pvt. Ltd., Ahmedabad.

16. The Committee decided to refer both the above proposals to DBT for their comments.

Agenda Item No. 11: Import and marketing of Hepatitis B Vaccine by M/s Panacea Drugs Pvt. Ltd., New Delhi.

17. GEAC decided to obtain more safety data from the firm and then it will be sent to DBT for the comments before a view is taken on the proposal.

Agenda Item No. 12: Permission to market Erythropoietin by M/s Boehringer Mannhein India Ltd, New Delhi.

18. It was decided to enquire about the antecedent of the firm from DCI in view of certain press reports about adverse effects of other products introduced by the firm.

Agenda Item No. 13: Application for environmental approval for manufacture, marketing of Hepatitis B Vaccine by M/s Shantha Biotechnics Pvt. Ltd., Medical Rangareddy, Hyderabad.

19. Adviser, DBT informed that the above proposal is still under consideration of RCGM and as such it is premature to take up the above proposal in GEAC at this stage.

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

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