Ministry of Environment & Forests
HSM DIVISION

Subject: Minutes of 9th Meeting of the Genetic Engineering Approval Committee held on 29.07.1994 at 11.00 a.m.

****

The 9th Meeting of the Genetic Engineering Approval Committee (GEAC) was held under the chairmanship of Shri K.K Baksi, Additional Secretary, Ministry of Environment and Forests and Chairman, GEAC on 29.07.1994 at 11.00 a.m. to consider various proposals as per agenda of the meeting. A list of members who attended the meeting is given at Annexure-I.

2. Welcoming the members, Chairman recalled the suggestion made at the previous meeting of GEAC to streamline the procedure of processing the proposals received in the Ministry for consideration of the GEAC. He informed the Members that, in consultation with DBT, it has not been decided to refer each proposal to an expert institution or individual and a comprehensive list had been drawn up for referring these proposals. The comments of the experts would be placed before GEAC for free discussion so as to arrive at a decision. This procedure had been followed in respect of all the seven proposals being considered in present (9th) meeting of GEAC. The comments received from each of the experts had been appended with the proposals.

3. Minutes of the 8th meeting of GEAC were confirmed since there were no comments/observations from the members.

Agenda Item No. 1: Import Storage and Use of Specialty Bacterial Products for Pollution control Activities

4. The proposals submitted by M/s Wockhardt Ltd., Bombay, for the import, storage and use of specialty bacterial products for pollution control activities was considered by the 7th and 8th meeting of GEAC during which certain clarifications were sought by experts. Exports were concerned about the manner in which the firm would handle and dispose of the waste sludge, rich in toxic metals trapped in matrix. Director, HSMD, explain that the sludge containing toxic metals will have to be regulated under Hazardous waste (Management and Handling) Rules, 1989. He suggested that the firm may be asked to handle these wastes in an environmentally sound manner. Chairman, GEAC pointed out that there appeared to be lack of clarity in the explanations given by the firm as to how it will handle the sludge and leachates. He also solicited opinion about the safety of such treatment system for human health.

5. Director, DBT pointed out that a majority of the organisms like Bacillus subtitles, Enterobactor and Pseudomonas putida which will be involved in the treatment are reported to be non-pathogenic. In order to confirm this, he suggested that a few samples could be tested at National Institute of Communicable Diseases., Delhi. He suggested that conditional clearance for limited field trials involving the imported bacterial culture maybe permitted. He further suggested that sensitivity of this microbe pool to the common antibiotics may be ascertained so that in case of any unwanted exposure, the necessary measures to control the microbes could be taken.

6. Co- Chairman and Director, NII, New Delhi expressed his reservation whether NICD could test the biofixed material and cautioned that such a treatment system is likely to generate waste. He was also doubtful whether the process will prove to be a success commercially. According to him, the Govt. should pointedly ask the firm as to how the sludge and other hazardous wastes present will be treated. Chairman, GEAC, suggested that the firm maybe asked to give documentary proof of the approval of the use of such bio-fixed material in the country origin. He further added that there was a need to evolve a monitoring mechanism, once the limited field trials are allowed to be conducted at NEERI/IPCL. The proposal was deferred till complete information was supplied by the firm.

Agenda Item Nos. 2 & 3: Import of Recombinant Biovine Somatotropin (r-BST), submitted by M/s Indian Immunologicals and Monsanto Chemicals of India Ltd., for large scale trial

7. The proposal for the import of r-BST, developed by M/s Eli Lilly of USA has been submitted by Indian Immunologicals, a subsidiary of National Dairy Development Board for large-scale field trials. This proposal was discussed in the 1st, 2nd, 3rd and 7th meetings of GEAC. Since several harmful effects of r-BST to the animals as well as consumers had been mentioned by experts, it was decided in the 7th meeting of GEAC that the product should not be cleared form environmental angle. Chairman, GEAC, referred to the appeal made by NDDB to grant environmental approval on the basis of various studies which have indicated that r-BST does not pose any hazard to the environment. Chairman, GEAC, also referred to the report received from DBT which has also referred to the report received from DBT which has also favored field evaluations. Animal Husbandry Commissioner, Govt. of India, has certified that the product is already cleared by US FDA. He also agreed with members that in course of correspondence NDDB should have opined that the GEAC had not judicially applied its mind in its earlier deliberations on the subject and regretted that such an arbitrary and erroneous opinion, not based on facts, should have been expressed.

8. Another proposal for the import of r-BST developed by Monsanto, USA under the trade name Posilac(R) has been submitted by M/s Monsanto Chemicals India Ltd., for field trials. The clinical trials for the product were earlier conducted in USA, U.K., France, Germany and the Netherlands. The US Food Drug Administration of the United States has recently authorised the product for commercialization in USA. U.K., France, Germany and the Netherlands. The US Food Drug Administration of the United States

has recently authorised the product for commercialization in USA. The protocol for conducting field trials submitted by the applicant was circulated to the National Dairy Research Institute, Karnal, for their expert opinion. They have suggested that the cross-bred cows should be sued instead of Sahiwal cows.

9. Considering the above facts, it was felt that both the product develop by M/s Eli Lilly and Monsanto may be allowed to be imported for limited field trials under the supervision on Animal Husbandry Commissioner of Government of India, as may be directed by the Commissioner. The results of field trials would be assessed by the Animal Husbandry Commissioner and the findings would be communicated to MOEF.

10. Dr. Bansal expressed his reservations about the availability of such large number of animals at NDRI, Karnal as proposed by NDDB in their protocols. In light of this, the following schedule was approved:

(i) No. of animals to be tested on limited trials for 2 years.
Cows 2500 per year by each firm
Buffaloes 2500 per year by each firm

(ii) No. r-BST vials that may be permitted to be imported for the trial for two years = 1, 12,500 nos. by each firm.

(iii) Both the companies shall keep full record of the usage of all the vials and the records may be available for verification whenever required.

Agenda Item No. 4 Environmental clearance for the application of MEOR Technology for Oil Fields of OIL and ONGC

11. The Proposal has been submitted by M/s Dalmia (Bros) Pvt. Ltd., New Delhi for environment clearance for the application of Microbial Enhanced Oil Recovery (MEOR) technology for oil field of OIL and ONGC. The applicant has sought the approval for the importation and use of Alpha Biosea for the microbes, Alpha Biocatalyst and AMT Petroprime for the nutrient to be used in an around oil fields and at storage and distribution facilities of OIL and ONGC for the purpose of microbially enhanced oil recovery and for bioremediation of hydrocarbon pollution. The material will not be offered to general public and will be used under the direct supervision of their collaborators M/s Rus petrol Ltd.

12. The proposal was considered by the GEAC in its 8th meeting held on 22-07-1993. On the advice of the GEAC, the matter was referred to Indian Petrochemicals Corporation Ltd. (IPCL), Vadodara who have favored extensive trials and use of these products under Indian conditions.

13. Chairman, GEAC, pointed out that since India has to spend valuable foreign exchange on the import of petroleum oil, a technology which can enhance oil recovery needs to be encouraged. Co-Chairman, GEAC greed that since the microbes will be used under deep petroleum well, there is a no possibility of any adverse impact on the ground. The firm has proposed a quantity of 3000-5000 pounds (approximately 1.5 – 2.5 tonnes)

of alpha biosea products, 125-175 pounds of bio-catalyst and 3000-5000 pounds of nutrients for the enhanced oil recovery. Co-Chairman, GEAC advised that the Ministry may consult Petroleum Biotechnology Task Force set up by the Department of Biotechnology for suggesting the quantities required to be imported. It was also recommended that a group of experts from CPCB/State Pollution Control Board, Ministry of Petroleum and NEERI, Nagpur should monitor the results of the trials at the oil fields of OIL and ONGC.

Agenda Item No. 5. Environmental Approval for Recombinant Human Erythropoietin for Import, Manufacture and Marketing

14. The proposal was submitted by Hindustan Antibiotics Ltd., Pimpri, Pune for environmental clearance of manufacturing of finished vials of Recombinant Human Erythropoietin from pure rHu Erythropoietin supplied by M/s Elanex Pharmaceuticals Inc., USA and for marketing the product. Quantity of the product (rHu EPO Omega bulk) to be imported will be 400 million International units per annum. The finished vials of 2000 IU and 4000 IU will be manufactured from the above product and marketed under the brand name HEMAX (recombinant human erythropoietin omega).

15. It was explained that the comprehensive proposal for the manufacture of the recombinant human erythropoietin has also been submitted by the HAL separately to the Impact Assessment Division of this Ministry. The proposal submitted to GEAC is only to look into specific aspects of any possible danger involved in the use of recombinant product. The Ministry had earlier given the approval of recombinant human erythropoietin for clinical trials in India.

16. Clinical trials of the product were conducted at PGI, Chandigarh, AIIMS, New Delhi, KEM Hospital, Bombay and Belle Vue Clinic, Calcutta. The Representative of the Drug Controller of India mentioned that the clinical trials were found to be successful, based on which the product is approved for marketing by DCI. As the papers placed before the Members indicated, proposal had also been referred to Dr. G.P. Talwar, Professor of Eminence, National Institute of Immunology for his expert opinion and Dr. Talwar had indicated that the product does not present any environmental hazard. Since the representative of Drug Controller of India had indicated in the meeting that they have satisfied themselves with the clinical trials that have been carried out on recombinant human erythropoietin, it was decided that GEAC have no objection to clear the product from environmental angle while leaving it to DCI such further action as is deemed necessary on the question of manufacturing of finished vials.

Agenda Item No. 6. Proposal for Import of Recombinant Human Erythropoietin in finished form from Bio Sidus S.A. Argentina

17. The above proposal has been submitted by M/s Sieta Pharmaceuticals, Ahmedabad for import of recombinant human Erythropoietin (rHu EPO) in finished form from Bio Sidus S.A. Argentina and marketing it under the brand name of ZYROP.

18. It was pointed out by the Department of Biotechnology that as this was a recombinant product, it was essential that clinical trials be conducted in India before the product was allowed to be marketed. Co-chairman, GEAC mentioned that no data have been submitted of the results of clinical trials in the country of origin. This should be followed by clinical trials to be done in India too. The representative of DCI pointed out that even if the product is not approved in the country of origin, DCI may still allow the clinical trials to be undertaken in India. It was decided that GEAC may request the firm to first provide details, if any, of approval of FDA in the country of origin.

Agenda Item No. 7. Permission to manufacture Human Insulin Injections for Domestic Market

19. The proposal was submitted by M/s M. J. Pharmaceuticals Ltd., Bombay. The firm has averred that they are manufacturing the above products for export during the past 3-4 years. Similar products are imported in the finished form by various companies in India. The quantity of the product proposed to be manufactured for local market will be 10 lakh vials.

20. The Drug Controller of India has mentioned that people have been using similar products for quite some time. Clearance had also been granted by DCI to M/s Torrent Pharmaceuticals and M/s Boots India Pvt. Ltd. for marketing the imported finished formulations of similar products from the Netherlands. Dr. Bansal pointed out that M/s Eli Lilly was the first to market recombinant insulin in 1982 in USA after rigorous trials. It was agreed that GEAC may clear the product from environmental angle subject to the clearance of the Drug Controller of India who would satisfy himself about the safety and efficacy of the product. The DCI may also look into the need of directing limited field trials of the product in India as the product is a recombinant one and is not fully identical to other recombinant products already in the market. The quantity to be imported may also be decided by DCI depending upon the requirement.

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

Annexure I

LIST OF PARTICIPANTS

S. No. Name, Designation & Organization

1. Shri K.K. Bakshi — Chairman
   Additional Secretary
   Ministry of Environment & Forests
   New Delhi.

2. Dr. Sandip K. Basu — Co-chairman
   Director
   National Institute of Immunology
   New Mehrauli Road, New Delhi – 16

3. Shri J.C. Kala
   Joint Secretary
   Ministry of Environment & Forests
   New Delhi.

4. Dr. P.K. Ghosh, Director
   Department of Biotechnology
   CGO Complex Lodi Road,
   New Delhi.

5. Dr. Mrs. Sulbha Gupta
   Director
   Department of Science & Technology,
   Technology Bhawan,
   New Mehrauli Road,
   New Delhi – 110 016

6. Shri T. Ramasubramanian
   Industrial Advisor
   Department of Industrial Development
   Udyog Bhavan, New Delhi.

7. Shri A.B. Ramteke
   Biochemist
   Directorate General of Health Services
   Ministry of Health & Family Welfare
   Nirman Bhavan, New Delhi.

8. Shri S.M. Sharma
Technical Officer
Directorate General of Health Services,
Ministry of Health,
Nirman Bhavan, New Delhi.

9. Dr. Vasantha Muthuswamy
Assistant Director General
Indian Council of Medical Research
New Delhi.

10. Dr. S.P. Kulshrestha
Deputy Director
Directorate of PPQ&S, NH-IV
Faridabad – 121 001.

11. Dr. Y.P. Kakkar,
Director,
Ministry of Environment & Forests,
New Delhi.

12. Shri R.C. Trivedi,
Central Pollution Control Board,
Parivesh Bhavan,
E. Arjun Nagar,
Delhi.

13. Dr S. C. Bansal,
D-131, Panchsheel Enclave,
New Delhi-110017

14. Dr. R. R. Khan,
Additional Director,
Ministry of Environment & Forests,
New Delhi.

15. Dr. Mrs. Kamini Shravah,
Research Officer,
Ministry of Environment & Forests,
New Delhi.