Ministry of Environment & Forests
HSM DIVISION

Subject: Minutes of 3rd Meeting of the Genetic Engineering Approval Committee held on 24.09.1991 at 10.30 a.m.

The third meeting of the Genetic Engineering Approval Committee (GEAC) was held under the chairmanship of Shri A. Bhattacharjya, Additional Secretary on 24.9.91 at 10.30 a.m. to consider five proposals under the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989. The list of members who attended the meeting is given as per Annex I.

2. Welcoming the members, Shri A. Bhattacharjya, Additional Secretary mentioned that five proposals have been received from the Department of Biotechnology to seek the view of GEAC about marketing/import of various genetically engineered products. He pointed out that there is as yet no well defined procedure to screen the applications to be put before GEAC for environmental clearance. There is a need for having a checklist for screening of applications by the Secretariat in the first instance, to collect basic information pertaining to the product and to evolve a procedure for getting the views of GEAC experts or any other expert available in the country or abroad. It was decided to constitute a sub-committee under the chairmanship of Dr. Kalyan Banerjee, Director, National is produced by fermentation using the transformed E.Coli strain K-12: LE 392 strain with the production of plasmid11-3. The quality control of the purified product is done by the Centro de Ingenieria Genetica Y Biotechnologia (CIGB). As per the information supplied by the DBT, the product has been tested for toxicity in mice. No behavioral, neurological or pathological damages or alterations in blood chemistry have been noticed. The product also does not show embryo toxicity or feto toxicity. The members made the following observations:

(i) The fact that clinical trials for human recombinant interferon alfa 2B nasal spray were conducted only on six children is not sufficient to determine the safety of the product. No information has been supplied with regard to clinical trials of other products like eye-drops and cream.

(ii) Full information on purification and manufacturing details be supplied. Even though there is sufficient literature on the subject, it is not possible to come to a coherent decision with regard to the safety of the product. It is necessary to have detailed information with regard to the purity of the product and its shelf- life in our country. There are doubts about the efficacy of injectables preparations Institute of virology, Pune with Dr. Sandip K. Basu Director, Institute of Microbiology Technology, Chandigarh, Dr. K. Narayanaswami, Director, Department of Biotechnology, Dr. B. B. Mallick, Director, Central Institute for Research on Goat, Mathura and Dr. R.R. Khan, Scientist 'SF',

Ministry of Environment and Forests, New Delhi as members. It was also decided that the members of this sub- committee will send their suggestions about the proposed checklist and a procedure for screening of applications to Dr. Kalyan Banerjee of National Institute of Virology, Pune with a copy to Dr. R.R. Khan, Scientist 'SF' Ministry of Environment and Forests. The views of various members could be consolidated by Dr. Kalyan Banerjee and Guidelines be finalized in consultation with the Ministry of environment and Forests by 31.10.91. A meeting of this sub- committee could also be arranged at the convenience of the chairman and other members of this sub- committee. The following proposals came for discussion:

(I) Marketing of Human Recombinant Interferon Alfa-2B- Eye Drops, Cream and Nasal Spray

3. The proposal for marketing human recombinant Interferon Alfa-2B in the form of eye-drop, cream and nasal spray submitted by CIMMCO, Delhi was sent by the Drug Controller of India to seek the views of the Department of Biotechnology who have in turn sent this proposal for the consideration of the GEAC. It is an anti-viral product and of interferon alfa 2B which is already in market for the last three years. Sufficient data should be supplied for the product by the country of origin including clearance certificate by the concerned drug control authority.

4. It was decided that full information be obtained from the firm before the proposal is reconsidered by the GEAC.

(II) Import of Maxiren- Genetically Engineered Chymosin Rennnet by M/s Essdee Chemocrats, Bombay

5. The application made by M/s Essdee Chemocrats, Bombay is regarding import of maxiren rennet produced by M/s Royal Gist- Brocades-nv, the Netherlands. The organism Kluyvercomyces lactis used for the production of chymosin is considered as GRAS (Generally Recongnised As Safe) by US FDA. It does not excrete toxins and is not pathogenic to mice. Toxicological data have established the safety of the product. It is also not mutagenic. US FDA has already approved recombinant chymosin derived from E-coli K12.

6. The following observations were made by members:

(i) Import of the product could be allowed in case there is a genuine need to do so. However, this was objected to by some of the members.

(ii) The product is widely used abroad and nearly 2200 varieties of cheese are produced from rennet from yeast. It is useful and can be imported. Attempts should also be made to produce it indigenously.

(iii) Since biotech products may pose danger to the environment, we have to follow step-by step treatment that is to say from small laboratory experiments to the large- scale field trials. We also have to see the shelf life of the product under different temperatures, the preservation methods and container-contents compatibility.

7. It was decided that the import of maxiren to the extent of 100 kg for one year be agreed to on an experimental basis with the following stipulations:

(i) The parent company should certify that the product sent to India is identical and not of inferior quality as compared to the product being used in the country of origin (the Netherlands).

(ii) The product should periodically be analysed by importing agency and a report submitted at GEAC at quarterly intervals. A d. o. letter is to be addressed to DG, ICAR by this Ministry to provide necessary analytical facilities for the product at NDRI, Karnal.

(iii) Specifications of the product imported like method of analysis, shelf life of the product and container- content compatibility should be submitted by the firm for every consignment.

(iv) The industry should carry out sponsored research to develop the product within 5 years and report to the committee.

(III) Import of recombinant FPV-NDV Vaccine by M/s Indian Immunologicals, Hyderabad

8. Indian Immunologicals, a subsidiary of National Dairy Development Board has made an application for import of 1000 doses of recombinant FPV-NDV vaccine- a product for in-house experimental trials on poultry. Department of Biotechnology has enclosed comments of experts on the use of recombinant FPV-NDV vaccine. Experts from Madras Veterinary College and Indian Institute of Science stated that poultry products are sale for human consumption. However, IVR has suggested not to allow import of this vaccine for safety reasons. No information is given whether the vaccine has been licensed in other western countries.

9. The following observations were made by members:

(i) The product is meant for in-house experiments trials in poultry to be done under P-3 laboratory. IVRI has only objected to field testing and not laboratory experiments as desired by the applicant.

(ii) Since the country of origin i.e. Australia has not licensed the product and it is still at an experimental stage, we must obtain the data from Australia as soon as they are available.

10. It was decided that:

(i) P-3 facilities available at Indian Immunologicals as claimed by them should be inspected by GEAC.

(ii) Indian Immunologicals should submit a summary of the research data about the safety of the product. The application should be reconsidered after obtaining the requisite information from the Company.

(iii) Clinical Trials of Recombinant Erythropoietin by M/s Hindustan Antibiotics Limited

11. Recombinant Erythropoietin is produced by genetic engineering of mammalian cell lines. The hormone from cell is extracted and purified by electrophoresis. The product is already launched in Latin American countries and was scheduled to be launched in European countries in May 1991. No toxicological data have been supplied by DBT.

12. The data supplied by the applicant are incomplete. It was decided that necessary literature be obtained from the applicant along with details of number of subjects to which clinical tests will be conducted. More information could be collected as per the Guidelines developed by the sub-committee. Only after this, the proposal could be reconsidered by GEAC.

(IV) Import of Recombinant Human Gamma Interferon by BHU, Varanasi

13. The product is to be used only for research purposes by the Department of Medicine, Institute of Medical Sciences, BHU, in small quantities of 1500 vials of 0.2 mg each.

14. Department of Medicine, BHU, Varanasi should give necessary protocols for the consideration of GEAC.

(V) Bovine Somatotropin (BST)

A request was made by Dr. M.P.G Kurup, Executive Director, National Dairy Development Board, Anand and Dr. K. Narayanaswami, Director, Department of Biotechnology for the early clearance of import of six lakhs doses of BST. The position in this regard was explained to the members that the Ministry of Agriculture has been repeatedly requested by the Secretariat to send the protocols as advised in the last GEAC meeting. In spite of repeated reminders, detailed protocols have not been received by this Ministry. In the absence of these protocols, it is not possible to take further action in this matter. Dr. Kurup was requested to expedite the submission of these protocols so that the matter could be taken up by the GEAC at the earliest.

Annex- I

List of Participants

1. Shri A. Bhattacharjya, Additional Secretary, Ministry of Environment and Forests, New Delhi.
2. Dr. S.K. Basu, Directory, Institute of Microbial Technology, Chandigarh.
3. Dr. K. Banerjee, Director, National Institute of Virology, Pune.
4. Dr. B.B. Mallick, Director, Central Institute for Research on Goat, Mathura.
5. Dr. K. Narayanaswami, Director, Department of Biotechnology, New Delhi.
6. Dr. S.A.H Abidi, Director, Department of Ocean Development, New Delhi.
7. Dr. M.P.G Kurup, Executive Director, National Dairy Development Board, Anand.
8. Dr. Y.P. Kakar, Scientist 'SG', Ministry of Environment and Forests, New Delhi.
9. Dr. S.K. Ghosh, Senior scientist, Central Pollution Control Board, Delhi.
10. Dr. Sulbha Gupta, Principal Scientific officer, Department of Science and Technology, New Delhi.
11. Dr. D. Kanungo, Medical Toxicologist, Directorate of Plant protection, Quarantine and Storage, Faridabad.
12. Shri N.C. Tiwari, Development officer, Directorate General of Technical Development, New Delhi-
13. Dr. Suman Sahai. TCS, Tilhar, U.P.
14. Dr. R.R Khan, Scientist 'SF', Ministry of Environment and Forests, New Delhi.

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