Ministry of Environment & Forests
HSM DIVISION

Subject: Minutes of 10th Meeting of the Genetic Engineering Approval Committee held on 10.11.1994 at 11.00 a.m.

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The 10th Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 10.11.1994 at 11.00 a.m. to consider three proposals as per the agenda of the meeting. A list of members who attended the meeting is given at Annexure I.

2. Minutes of the 9th Meeting of GEAC were confirmed since there were no comments/observations from the members.

Agenda Item No I: Import, Storage and Use of Specialty Bacterial Product for Pollution Control Activities.

3. The proposal for the Import, Storage and Use of Specialty Bacterial Products for Pollution Control Activities has been submitted by M/s Wockhardt Ltd., Bombay. The observations made by members in the previous GEAC meeting and the clarification given by the firm were discussed. It was pointed out that the list of antibiotics to which the product shows resistance (as sent by the applicant firm) does not include important antibiotics like erythromycin and chloramphenicol. Members pointed out that the manner as to how sludge will be handled had been explained by the firm. It was observed that since the representatives of the firm were available for giving further clarification, they could be called in for further discussions in the matter.

4. The representatives of the firm (Shri Vinod Pabi and Dr. Maharaj Krishan Sahib) explained the utility of immobilized bacterial product for the control of pollution and removal of various organic and inorganic toxic substances present in effluents. They indicated that by addition of different matrices, toxic metals can be concentrated and removed and opined that existing technology developed in India was not so effective. Moreover the biofixed product offers certain advantages by which it can be very effectively used for cleaning of lakes, rivers and for treatment of solid wastes. At this stage, a query was made as to what happens after the sludge is mineralized in rivers and lakes. The representatives of the firm explained that all the organics and toxic metals present in the sludge are concentrated and can be recovered, and only the inert material remains. Enquires were also made as to where the firm propose to undertake the field trials. It was indicated that the product will be tested in Bombay, Ankleshwar, and Aurangabad. If allowed, the product would also be tried in Bhopal lake and for composting of solid wastes.

5. Co-Chairman cautioned that the firm should ensure that the project to use biofixed product is financially viable and the firm shuld be able to sustain it economically.

6. Dr. Mahajan of Basic enquired as to whether the antibiotics mentioned in the letter are the only ones which have been tried out, or are there other antibiotics like erythromycin and chloramphenicol which have also been tried for resistance. The firm was advised that it will be a good idea to see resistance phenomenon with these antibiotics as well. Shri V. Garg enquired if this product could be successful in removing heavy metal pollution in the grass fields. The representative of the firm mentioned that this can be done by changing the matrices of the product. The representatives of the firm assured GEAC that all necessary precautions will be taken while conducting the field trials and the proper monitoring of the field trials will be done. Resistance to various antibiotics and other pathogenic microorganisms will also be looked into.

7. Subsequently, after discussion among the members, it was decided that 15 tonnes of Specialty Bacterial Product as per the details given in the applications may be allowed to be imported by M/s Wochkardt Ltd., during one year period. It was also decided that monitoring of the field trials may be undertaken by Central Pollution Control Board, the Indian Institute of Technology, Bombay and any other organization or institution having the necessary testing capabilities (for which the representative of the firm will have to inform the GEAC through the MOEF). The imported product should only be used for treatment of industrial wastes for the present.

Agenda Item No II: Proposal for Import of Recombinant Human Erythropoietin in finished form from Bio Sidus SA Argentina.

8. The proposal for the import of Recombinant Human Erythropoietin from Bio Sidus, Argentina submitted by M/s Zieta pharmaceuticals, Ahmedabad was earlier discussed in the 9th Meeting of GEAC. The firm was requested to provide the certificate of approval of FDA in the country of origin. In response, the firm has submitted a certificate which has been given by the National Ministry of Health and Social Welfare, Argentina stating that the product to be imported is certified for good manufacturing practices. Since the firm is not manufacturing the product in India such a certificate is of no significance. The firm has to provide a certificate from concerned authority for handling and use since it is importing the product for direct use. It was decided that we may write, in confidence, to our mission in Argentina, as to whether the product in question has been cleared for human treatment in the country of origin.

Agenda Item No III: Import of Recombinant Anti Hemophilic Factor from Miles Inc. USA

9. The proposal for the import of one million IU (4000 vials) of Recombinant Anti Hemophilic Factor (KOGENATE) from Miles Inc. USA has been submitted by given by Hemophilia Federation (India). The product is to be given by M/s Miles Inc. of USA free-of-charge. No commercial angle is involved and Hemophilia Federation (India) wants to distribute the drugs to the hemophilia patient's free-of-charge. The expiry date

of the medicine is December 1994. It was pointed out that Dr. S.C. Bansal has sent in a note raising doubts about the stability of the drug vials. Dr. S. Basu, Co-Chairman mentioned and it was agreed that various reservations expressed by Dr. Bansal are essentially the concern of the Drug Controller of India, and not of GEAC. Dr. P.K. Ghosh of DBT asked whether the drug should only be allowed after clinical trials have been completed. Dr. Mahajan of BARC stated that a request has been made to clear a particular consignment for free distribution in India, and while there is no commercial angle at present, it has to be kept in mind that the foreign firm concerned may possibly be looking for a market in India.

10. Chairman at this stage invited the representative of Hemophilia Federation (India) to present their case. The Federation was represented by Shri Ashok Verma and he was accompanied by Dr. Lalit Dar, Asstt. Prof., Deptt. Of Microbiology, AIIMS, New Delhi. The applicant mentioned that the Federation had got the offer of the medicine about six months ago. The shelf life of the product is about two years. He said that the Federation expected that all the material to be imported would be used on patients in India and would be of immense help to hemophilia patients awaiting surgery for which tentative arrangement had already been made, and only approval for import and use were awaited.

11. Co-Chairman pointed out that FDA has already cleared the product and it would be ensured that the product will be used in India under the supervision of competent medical practitioner/ surgeon.

12. Dr. (Ms) S. Kulshrestha attending the meeting as the representative of Plant Protection Advisor mentioned that since the expiry data of the imported consignment is December end, 1994 and the conditions in which it is stored is not known, it should be made sure that the drug is effective and will give the desired results to avoid any unwanted incident during the operations.

13. Dr. Mahajan, of BARC recommended that this particular consignment may be granted clearance and members agreed that the risk, if any, is worth taking in the circumstances explained. Dr. Ghosh of DBT also mentioned that since the product is required for non-commercial activity, it was possible to clear the particular consignment. Chairman also agreed with these views. After details discussion it was agreed that the request may be approved subject to the following conditions:

(1) Hemophilia Federation (India) shall ensure that all care is taken for disposal of used and unused vials and syringes through hospital system where the vials shall be used.

(2) The Hemophilia Federation (India) shall also ensure that the data expired vials shall not be used by the patient/hospital concerned. Informed consent of patient shall be taken before the medicine is tried on him.

(3) The Hemophilia Federation (India) shall keep full record of usage of all the vials and the records may be available for verification whenever required.

(4) The vials import by the Hemophilia Federation (India) for free distribution should not be sold or diverted for any other commercial purposes.

The meeting ended with a vote of thanks to the Chairman and Co- Chairman.

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