Ministry of Environment & Forests
HSM DIVISION

Subject: Minutes of 21st Meeting of the Genetic Engineering Approval Committee held on 08.11.1999.

The 21st Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 8th November, 1999 under the chairmanship of Shri Vinod Vaish, Special Secretary, Ministry of Environment & Forests. The following is the list of participants:

1. Shri Vinod Vaish, Special Secretary, MOEF, New Delhi- **Chairman**
2. Dr. Sushil Kumar, Director, Central Institute of Medicinal and Aromatic Plants, Lucknow **– Co-chairman**
3. Dr. Prasanta K. Gosh, Advisor, Department of Biotechnology, New Delhi.
4. Prof. A.K. Bhatnagar, Department of Botany, University of Delhi, Delhi.
5. Shri S.P. Das, Deputy Drug Controller, Ministry of Health, New Delhi.
6. Shri. A.B. Ramteke, Deputy Drug's controller, Ministry of Health, New Delhi.
7. Dr. T.V. Ramanaiah, PSO, Department of Biotechnology, New Delhi.
8. Dr. R.C. Trivedi, Senior Scientist, CPCB, Delhi.
9. Dr. R.R. Khan, Director, Ministry of Environment & Forests, New Delhi
10. Smt. Madhu Gupta, Research Assistant, Ministry of Environment & Forests, New Delhi.

2. Welcoming the members, Chairman referred to the minutes of the 20th meeting of GEAC held on 10.06.1999, which were circulated to all the members. Since there were no comments from the members, the minutes were confirmed.

Manufacture and marketing r-protein for in vitro use for the detection of HIV-1and HIV-2 antibodies in whole blood by M/s Cadilla Pharmaceuticals Ltd., Ahmedabad.

3. It was noted that the proposal for the manufacture and marketing of recombinant protein for in-vitro use in a diagnostic kit for the detection of HIV-1 and HIV-2 antibodies in the whole blood of humans submitted by M/s Cadilla Pharmaceuticals, Ahmedabad was discussed in the 20th Meeting of GEAC on 10th June, 1999. Since there were no safety data on toxicity and allergenicity generated by the firm at that time, it was decided in the above meeting that safety data should be generated by the firm and submitted to RCGM for scrutiny before the matter is considered by GEAC. It was also decided that the premises of the firm where it intends to manufacture the above product

be inspected by a team to be constituted by the DCGI. The Committee took note that the product to be introduced by the firm is based on the technology developed jointly by DBT and South Campus of Delhi University.

4. The report on the safety data on toxicity and allergenicity had since been received, considered and approved in the meeting of RCGM on 10.8.1999. The data available through literature as well as through experiments in mouse, monkey and humans indicated that recombinant fusion proteins being used in vitro agglutination assay are non-toxic and non-allergenic. It was decided that the proposal may be cleared from environmental angle subject to the satisfactory completion of the inspection of the premises by DCGI. The team to be constituted by DCGI for this purpose would also include an expert to be nominated by DBT. The proposed team shall inspect the arrangements existing at the firm premises which would inter-alia include adoption of good manufacturing practices, decontamination of waste and proper containment facilities.

Manufacture of Veterinary Vaccines by Brilliant Industries Ltd., Hyderabad

5. M/s Brilliant Industries Ltd., Hyderabad have given a proposal to manufacture 10 million doses of six veterinary vaccines namely, (i) Cell Culture Rabies Vaccine, (ii) Hemorrhagic Septicemia Vaccine, (iii) Black quarter disease Vaccine, (iv) Sheep Pox Vaccine, (v) Enterotoxemia Vaccine, and (vi) Canine distemper Vaccine. These vaccines are intended for use in animals to produce immuno response in the recipients so as to protect them against diseases. The vaccines proposed to be manufactured are non-genetically engineered. However, two of them, namely, cell culture Rabies vaccine and Sheep Pox vaccine are based on hazardous micro-organisms and are listed in Schedule I of HMO/GMO Rules, 1989. Since these are veterinary products, the matter was referred to the Department of Animal Husbandry and Dairy Development. They are of the opinion that permission to manufacture the above vaccine should be subject to fulfillment of Bio-safety Guidelines issued by DBT. Adviser, DBT confirmed that Bio-safety Guidelines brought out by them do provide details of good manufacturing practices (GMP) and if the guidelines are adhered to, his Department would have no objection to the clearance of this proposal.

6. It was confirmed by DCGI that the veterinary drugs are also covered by the procedure followed by DCGI. Chairman enquired about the system of monitoring the conditions stipulated with the letter of approval for each product and suggested that such monitoring be undertaken by RCGM as per the provisions of the Rules. Adviser, DBT mentioned that at present, DBT is only monitoring research proposals approved by it. Chairman mentioned that there is a need for greater clarity in interpretation of Rules and DBT may consider monitoring all recombinant activities including manufacturing of recombinant products going on in the country. Dr. Mahajan, BARC mentioned that the monitoring is to be done sector-wise, that is to say if it is a drug related product, the monitoring agency would be the DCGI, while in case of transgenic plants, it should be done by ICAR agencies. CPCB should monitor projects related to bio-remediation and pollution control. Prof. Bhatnagar suggested that Regional Offices of MoEF should also

be involved in the monitoring work. Chairman mentioned that the monitoring is an important activity and should not be left unattended. The representative of DBT was requested to identify areas where the guidelines were needed for the monitoring agencies and fill the gap. There was also need to put in place a system of proper check and supervision. The representative of DBT agreed to prepare a paper on this subject for consideration in the next meeting of GEAC.

7. It was agreed that the proposal submitted by M/s Brilliant Industries for manufacture of above vaccines may be approved subject to the satisfactory completion of the inspection of the premises by DCGI. The team to be constituted by DCGI for this purpose would also include an expert to be nominated by DBT. The proposed team shall inspect the arrangements existing at the firm premises which would inter-alia include adoption of good manufacturing practices, decontamination of waste and proper containment facilities.

Import and marketing of Erythropoietin (r-HuEPO) Epocin by U.S.V. Ltd., Mumbai

8. M/s U.S.V. Ltd. intends to undertake import and marketing of recombinant erythropoietin. Although the product is already registered in Cuba, the firm may be asked to undertake Phase III clinical trials for which minimum quantity to be decided by DCGI may be allowed to be imported. After the results of Phase III clinical trials are obtained, the request for marketing of the product may be reconsidered in GEAC.

Import and marketing of Neumega Oprelvekin recombinant human Interlukin II (rHu IL-11) by M/s Wyeth Lederle Limited, Mumbai

9. M/s Wyeth Lederle Limited, Mumbai intend to undertake import and marketing of recombinant human Interlukin 11 (rHU IL-11). Although the product is already approved by US Food and Drug Administration, the firm may be asked to undertake Phase III clinical trials. For this purpose minimum quantity to be specified by DCGI may be allowed to be imported. After the results of clinical trials are obtained, the matter may be reconsidered in GEAC for allowing the marketing of the product.

Notifying Laboratories/Institutions under Environment (Protection) Act, 1986

10. A list of 93 laboratories/institutions which have already set up the Institutional Biosafety Committees (IBSC) has been provided by DBT to be notified under Rule 7, sub-rule (ii) of HMO/GMO Rules. This was noted by the GEAC.

Any Other Matter

11. Adviser, DBT pointed out that the proposal submitted by M/s Transgene Limited, Hyderabad was earlier considered in the 19th meeting of GEAC held on 8th March, 1999. RCGM had already examined and cleared the matter. The firm was asked to conduct the phase-III clinical trials. These trials have since been completed. Member-Secretary,

GEAC pointed out that the proposal copies have been received only last week are yet to be examined by the Secretariat. The representative of DCGI mentioned that they have not yet received the copies of the clinical trials data. It was decided that the copy of the report submitted by M/s Transgene Ltd., may be forwarded to DCGI who will examine the data and send their comments to the Ministry. Based on the satisfaction of DCGI, the Committee authorized the Chairman to clear the proposal.

12. The status of various pending proposals was presented before the members which indicated that 10 proposals are still pending for want of comments from respective Departments (Annex-1). DCGI and DBT were requested to expedite sending their comments on various pending proposals. The proposals complete in all respects with comments from concerned Ministries/experts may be brought before the next meeting of GEAC for final consideration.

13. The meeting ended with a vote of thanks to the Chair.