Ministry of Environment & Forests
HSM DIVISION

Subject: Minutes of 20th Meeting of the Genetic Engineering Approval Committee held on 10.06.1999.

****

The 20th Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 10.06.1999 under the Chairmanship of Shri Vinod Vaish, Special Secretary, and MOEF. 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. R.P. Sharma, Project Director, Indian Agricultural Research Institute (IARI), New Delhi.

4. Dr. P. K. Gosh, Advisor, Department of Biotechnology, New Delhi.

5. Dr. Vasantha Muthuswamy, Deputy Director General, Indian Council o Medical Research, New Delhi.

6. Dr. (Ms) Sulbha Gupta, Director, Department of Science and Technology, New Delhi.

7. Prof. A.K. Bhatnagar, Department of Botany, University of Delhi, Delhi.

8. Prof. Subhash Chard, Department of Biochemical Engineering, IIT, New Delhi.

9. Shri. A.B. Ramteke, Deputy Drug's Controller, Ministry of Health, New Delhi.

10. Dr. (Mrs.) S. Kulshrestha, Medical Toxicologist, Directorate of Plant Protection, Quarantines and Storage, Faridabad.

11. Dr. T.V. Ramanaiah, PSO, Department of Biotechnology, New Delhi.

12. Shri Suraj Bhan, Environmental Engineer, CPCB, Delhi.

13. Dr. R.R Khan, Director, Ministry of Environment and Forests, New Delhi.

14. Ms. Madhu Gupta, Research Assistant, MOEF, New Delhi.

2. Welcoming the members, the Chairman referred to the minutes of the 19th meeting of GEAC held on 08.03.1999 which were prepared in consultation with the Secretary, DBT. Member Secretary informed about the action taken on various issues as decided in the 19th Meeting. The minutes were earlier circulated to the members. Since there were no comments from the members, the minutes were confirmed.

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 whole blood

3. The proposal for the manufacture and marketing of a diagnostic kit comprising of recombinant proteins for the detection of HIV-1 and HIV-2 antibodies submitted by M/s Cadilla Pharmaceuticals Ltd., Ahmedabad is based on the technology developed jointly by DBT and South Campus, Delhi University. Cadilla has shown its willingness to enter into an agreement with DBT for the purchase of new technology.

4. Adviser, DBT explained that there were eight recombinant proteins which go in for the making of the composite kit. The product was claimed to be working satisfactory in the form of composite kit as evidenced from the evaluation reports at five hospitals in a sample size of 320 positives showing 100% sensitivity and specificity of 98.8% in a sample size of 1092. Further from the protocols it was seen that the kit was easy to use cost effective and would require minimum refrigeration. On an enquiry from Co-Chairman, Adviser, DBT confirmed that full amino acid sequences of all the eight recombinant proteins had been authenticated.

5. Adviser, DBT, however, mentioned that there was a need to generate baseline safety data on allergenicity and toxicity of recombinant proteins. Alternatively from the evidence of protein sequencing data, the firm may attempt to provide evidence that these sequences are safe. Moreover, factory premises of the firm were also required to be inspected. DDG, ICMR was, however, of the opinion that the firm could not be allowed to undertake production unless safety data was examined. Prof. Bhatnagar of Delhi University also supported the view that there was the need to identify the hazards in respect of organisms used and to confirm by experiments that they did not pose any environmental hazards. Adviser, DBT explained that the organisms, namely, E.coli, BL-21 was already in the category of GRAS (Generally Recognized As Safe). On an enquiry from Chairman, Adviser, DBT mentioned that full generation of the safety data may take about six months. However, the firm could use internet to collect basic data of toxicity and allergenic on the basis of amino acid sequence which was known and provide evidence that these sequences were safe. Dr. Sharma, IARI, however, pointed out that three months period was sufficient to generate requisite data.

6. Prof. Subhash Chand of IIT, Delhi raised the question of technician's safety handling the product. Adviser, DBT pointed out that there were instructions that the technicians must protect themselves with protective clothes ad gloves. Representative of CPCB enquired about treatment of effluents to be generated by the units. It was explained that the firm was yet to obtain consent under respective Air Act and Water Act. It was also explained that the firm will also have to obtain approval under EIA notification.

7. Chairman mentioned that as the technology was being developed in Delhi University by the DBT and as the technology was being procured by Cadilla, the technology was not yet a proven one and therefore, Cadilla should have made an application through their Institutional Biosafety Committee (IBSC) to the RCGM to enable the latter to assess all

aspects of the technology including Biosafety. Thereafter, the GEAC should have been approached.

8. It was decided that necessary safety data on the toxicity and allergenicity be carried out by the firm in the first instance. Such data should be examined by the RCGM before the matter is again considered by GEAC. It was also decided that factory premises be inspected during this period by a team constituted by DCGI and report be given to GEAC.

Permission for clinical trials (Phase III) of r-Hepatitis B Vaccine imported from China, by M/s V. H. Bhagat & Co.

9. The proposal seeking permission for conducting phase III clinical trials of recombinant Hepatitis B Vaccine was submitted by M/s V.H. Bhagat and Co., Mumbai. The vaccine is based on Chinese Hamster Ovary (CHO) cell lines imported from Changchun Institute of Biological Products, China. DBT have recommended that applicant should generate toxicity, allergenicity and antigenicity data during Phase III clinical trials. Adviser, DBT also mentioned that CHO cell line based hepatitis-B vaccine is only used in China, Pakistan and Israel. DCGI was also of the opinion that hepatitis –B vaccine derived from CHO cell line was not yet approved by them in India. Therefore, it was essential that Phase - III clinical trials be carried out by the firm. Adviser, DBT also suggested that the firm may be directed to take at least 10% of the subjects above the age of 40 in addition to other age groups as a sample size of at least 100 so that comparative results from different age groups could be evaluated. It was agreed that the firm may be asked to undertake Phase III clinical trials for which limited import be allowed subject to the approval by DCGI. DCGI will also decide about the quantity of the product to be imported by the firm for undertaking clinical trials. It was also decided that DCGI would consult ICMR on the results of clinical trials for examination by the Toxicological Review Panel of ICMR.

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

****