

**Ministry of Environment & Forests**  
**HSM DIVISION**

**Subject: Minutes of 11th Meeting of the Genetic Engineering Approval Committee**  
**held on 11.08.1995 at 11.00 a.m.**

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The 11th Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 11.08.1995 at 11.00 a.m. to consider three proposals as per agenda of the meeting. A list of members who attended the meeting is given at Annex-I.

2. Minutes of the 10th Meeting of GEAC were confirmed since there were no comments/ observations from the members.

**Agenda Item No. I: Import and marketing of Bacterial formulations for Bioaugmentation of Waste Water Treatment System submitted by Biotech Consortium India Ltd. and Premier Ziba India Pvt. Ltd.**

3. The proposal for import and marketing of bacterial formulation for the treatment of waste water from breweries, paper mills, tanneries and fish ponds in Uttar Pradesh submitted by M/s Biotech Consortium India Ltd. and Premier Ziba India Pvt. Ltd. was discussed in the meeting. The four test sites identified by the firm where the bacterial formulations will be used are Mohan Meakins Ltd., Lucknow, Rawal paper Ltd., Rae Bareilly, Zam Zam Tanneries, Unnao and Vidya Fish Farm, Samesi, Lucknow.

4. The proposal was initially referred to Dr. K.R. Ranganathan, Director, Centre for Environmental Studies, College of Engineering, Anna University, Madras. Dr. Vasantha, ICMR. Dr. Muthuswamy was doubtful as to how the firms going to take necessary precautions to avoid exposure to immune compromised individuals. Dr. S.K. Mahajan, BARC underlined the need for protecting the workers as the organisms are not totally harmless. Necessary precautions like utilization of such need for protecting the workers as the organisms are not totally harmless. Necessary precautions like utilization of such microbes in a contained manner should be undertaken. Dr. R.C Trivedi, Scientist, CPCB pointed out that standards for only coliform bacteria have been prescribed in treated effluents. Dr. S.C. Bansal pointed out that some of the bacterial strains listed by the firm are pathogenic. Dr. Ghosh, DBT explained that the bacterial formulations are occurring naturally. There may be a residual pathogenocity which is common to all effluent treatment plants in big industries. Dr. Sengupta, MoEF expressed his doubt about utility of such organisms for direct application to fish ponds. He however suggested that instead of giving blanket permission, permission for import of bacteria in phases be considered. Dr. Ghosh explained that due to low dissolved oxygen in the pond, the survival of fish

becomes difficult. The bacterial formulations will raise the dissolved oxygen content of water to enable small fish to survive. Dr. Mahajan, BARC was of the opinion that the bacterial formulations to be used in fish farms should be free from fish pathogens.

5. It was pointed out that treatment plants, where these bacteria are to be tried should meet the pollution standards related to bacteria counts. Shri Trivedi, CPCB informed that there are no standards available for these. Dr. Bansal also suggested a condition that input bacteria should be pathogen free especially of salmonella.

6. Dr. Sandip Basu, Co- Chairman, GEAC, emphasized the need for taking adequate safety precautions in handling such microorganisms. He suggested that the National Institute of Occupational Health, Ahmedabad be involved by the firms to monitor the occupational safety. Dr. S. Kulshreshtha, DPPGS suggested that local primary health centers may look into the safety of such microbes. Chairman, GEAC expressed reservations about the capability of PHCs in undertaking such monitoring. He suggested the ITRC and KG Medical College could be involved with the monitoring. Chairman, GEAC also pointed out that strict monitoring would be necessary since the test sites were located in areas that lack basic infrastructure for monitoring. It was agreed that the firms may be told to provide detailed action plans for ensuring the safety of the workers. They may also provide firm details regarding undertaking of comprehensive occupational health monitoring of workers at their own cost. Such monitoring will be required to be done by NIOH, ITRC, KGMC and the U.P. Department of Medical, Health and Family Welfare.

**Agenda Item No. II: Import and marketing of Interferon Alfa 2b Injection submitted by M/s J.B. Chemicals and Pharmaceuticals Ltd.**

7. The proposal submitted by M/s J. B. Chemicals and Pharmaceuticals Ltd., Bombay for import and marketing of Interferon Alfa 2b Injection from Argentina was discussed. Member secretary, GEAC explained that as per the claim made by the firm, Interferon Alfa 2b injections are available in India for the last two years. However such a proposal from M/s J.B. Chemicals and Pharmaceutical Ltd. has come up before GEAC for the first time. Earlier, permission was accorded for the clinical trials of Recombinant Human Gamma Interferon to Banaras Hindu University, Varanasi. Another proposal for clinical trials of Human Recombinant Interferon Alpha 2b eye-drops, cream and nasal spray submitted by M/s SIMMCO Ltd., New Delhi was also accorded approval earlier. The present proposal is regarding import and marketing of injection based on Recombinant Interferon Alfa 2b. As per the claim made by the firm, clinical trials have been done abroad and outside Argentina, but no details have been given. The firm has enclosed a copy of the product sale certificate issued by Ministry of Health and Social Welfare of Argentina. It was decided that the firm may submit detailed information on clinical trials done in Argentina and other countries before the proposal is considered further.

**Agenda Item III: Import and marketing of Recombinant Human Erythropoietin from Mazai Corporation, Moscow submitted by M/s Malledi Drugs and Pharmaceutical Ltd., Madras.**

8. The proposal for import and marketing of Recombinant Human Erythropoietin manufactured by M/s Mazai Corporation, Moscow submitted by M/s Malledi Drugs and Pharmaceutical Ltd., Madras was discussed. Dr. Bansal pointed out that certificate given by the firm from M/s Mazai Corporation is not a free-sale certificate but only permission for clinical trials. It was decided that the firm may be restricted to provide free sale certificate in the country of origin along with permission from the health/ environment authorities for use of the drugs in its country of origin.

9. In respect of proposal already approved by GEAC, Chairman expressed the view that regular monitoring mechanism be devised and a feed back be provided to the members of GEAC regarding all the proposals so far cleared. A summary should also be prepared of the decisions taken so far and circulated to GEAC members to keep them updated while considering similar proposals in future.

**List of Participants**

1. Shri K.K. Bansal, Additional Secretary, Ministry of Environment and Forests, New Delhi.- Chairman
2. Dr. Sandip.K. Basu, Director, National Institute of Immunology, Delhi.-Co-Chairman
3. Dr. S.K. Mahajan, Head, Molecular Biology and Agri. Division, BARC, Bombay.
4. Shri S.C. Bansal, D-131, Panchsheel Enclave, New Delhi.
5. Dr. R.P. Sharma, Head, Biotechnology Centre, Indian Agricultural Research Institute (IARI), Pusa, New Delhi-110012.
6. Dr. P.K.Gosh, Director, Department, Department of Biotechnology, New Delhi.
7. Dr. Vasantha Muthuswamy, Assistant Director General, Division of Basic Medical Science, Indian Council of Medical Research (ICMR) Ansari Nagar, Post Box No. 4508., New Delhi.
8. Dr. (Mrs) Sulbha Gupta, Director, Department of Science and Technology, New Delhi.
9. Dr. (Ms.) S. Kulshrestha, Medical Toxicologist, Directorate of Plant Protection, Quarantines and Storage, Faridabad.
10. Dr. B. C. Gupta, Assistant Director, Directorate of Plant Protection, Quarantines and Storage, Faridabad.
11. Shri Ashwini Kumar, Dy. Director C, Dte. General of Health Services (DGHS), Ministry of Health and Family Welfare, New Delhi.
12. Shri. A.B. Ramteke, Biochemist, Dte. General of Health Services (DGHS), Ministry of Health and Family Welfare, New Delhi.
13. Dr. M. Sengupta, Director, H.S.M. Division, Ministry of Environment and Forests, New Delhi.
14. Shri R.C. Trivedi, Scientist, Central Pollution Control Board, Delhi.
15. Dr. R.R Khan, Add. Director, H.S.M. division, Ministry of Environment and Forests, New Delhi.
16. Mrs. Sanchita Jindal, Deputy Director, H.S.M. division, Ministry of Environment and Forests, New Delhi.