

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

**Subject: Minutes of 6th Meeting of the Genetic Engineering Approval  
Committee held on 11.03.1992 at 10.30 a.m.**

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The 6th Meeting of the reconstituted Genetic Engineering Approval Committee (GEAC) was held on 11.03.1992 –at 10.30 am under the chairmanship of Shri A. Bhattacharjya, Additional Secretary (B). The List of participant is given as per Annexure I.

2. Welcoming the members, AS (B) gave background of the work done so far by the GEAC and desired that a copy of the rules and the check-lists finalized under the direction of the Co-Chairman, GEAC, Dr. Sandip Basu, may be made available to all the members. Thereafter, various proposals were discussed as per agenda notes.

**Agenda Item No. I: Marketing of Human r- Interferon by M/s. CIMMCO, Delhi.**

3. The committee noted that various documents required by the GEAC have been submitted by the firm. Clarifications regarding validity of test results and the evidence that they conform to WHO standards have also been given. Dr. S.C.Bansal mentioned that the information provided is scanty and it is not possible for him to evaluate the application. The Chairman explained that the proposal has been discussed in the last several meetings and desired that a full set of the papers received from the firm and the decisions of the GEAC on the issues raised may be communicated to Dr. Bansal.

4. It was decided that the GEAC has no objection from environment point of view to the Drug namely Interferon alpha 2 B (Eye drops, cream and nasal sprays) being subjected to clinical trials in the country in a phased manner before the question of marketing is decided by the Drug Controller of India under the relevant rules.

**Agenda Item No. II: Import and marketing Recombinant hepatitis Vaccine by CIMMCO, New Delhi.**

5. It was noted that the proforma checklist filled up by the firm has only mentioned reactogenicity under the heading clinical/field trials. Similarly on immunogenicity full information is not furnished. The firm was asked to provide complete information on (i) immunogenicity and (ii) efficacy with side effects for further discussion in the GEAC.

**Agenda Item No. III: Application for import, storage and use of bacterial product for pollution control submitted by M/s. Sea King Marine Industry Ltd., Bombay.**

6. The experts desired that the applicant should provide following information:
- (i) The method should indicate the biofixation process and the chemicals involved so as to know that they do not pose any hazard to the environment.
  - (ii) Whether the organism being used is safe.
  - (iii) That they do not pose any risk to the flora and fauna.
  - (iv) Whether the material is material for fixed reservoir of water.

7. The Committee recommended the import of the material for limited experimental trials and also required that the data to be generated at a Government recognized institutions like NEERI, Nagpur CPCB and IRTC Lucknow. The Committee also desired to have data indigenously developed on the use of material with the Madras Refineries. The firm should enter into collaboration work with firms abroad to indigenously develop bacterial products for pollution control.

**Agenda Item No. IV & V: Permission for import of Bio-lyte /Ecolyte and Bio-seeds from International Bio-chemicals Ltd. U.K. submitted by M/s. Ucal Biotech Pvt. Ltd. Madras**

**Import of liquid live microorganisms for pollution control by M/s. Madhusudan Shah, Surat, Gujarat.**

8. The information provided on both the proposals was found to be insufficient for taking a decision. The applicants were asked to fill up performa and submit to GEAC for consideration.

9. The next meeting of GEAC was tentatively fixed for 22<sup>nd</sup> / 23<sup>rd</sup> April, 1992. The meeting ended with a vote of thanks of Chair.

**Annex- I**

**List of Participants**

1. Shri A. Bhattacharjya, 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. K.M. Chadha, Joint Secretary, Ministry of Environment & Forests, New Delhi.-Member
4. Dr. R.B.L. Bhaskar, Plant Pathologist, Ministry of Agriculture and cooperation, Directorate of Plant Protection, Quarantine and Storage, Faridabad.-Member
5. Shri S.C. Bansal, D-131, Panchsheel Enclave,New Delhi.-Member
6. Dr. K.D. Sharma,I.A., DGTD.-Member
7. Dr. P. Das Gupta, Dy. Drug Controller of India (New Drugs),New Delhi.-Member
8. Dr. K. Narayanaswami, Director, Department of Biotechnology,New Delhi.- Member
9. Dr. K.R. Ranganathan, Member Secretary,Central Pollution Control Board,Delhi.- Member
10. Shri. Y.P. Kakkar, Director, Ministry of Environment and Forests, New Delhi.-Secretariat
11. Dr. Indrani Chandrasekharan, Scientist 'SE', Ministry of Environment and Forests, New Delhi.- Secretariat
12. Dr. R.R Khan, Additional Director, Ministry of Environment and Forests, New Delhi.- Secretariat

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