

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

**Subject: Minutes of 4th Meeting of the Genetic Engineering Approval  
Committee held on 11.11.1991 at 3.00 pm.**

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The Fourth Meeting of the Genetic Engineering Approval Committee (GEAC) was held under the chairmanship of Shri A. Bhattacharjya, Additional Secretary (G) on 11.11.91. at 3.00 p.m. Dr. Sandip K. Basu, Co-Chairman was also present. The meeting considered the proposals on (i) Import/Clinical Trials of Erythropoietin by M/s Hindustan Antibiotics Limited, Pune; (ii) Import of Human Gamma Interferon by Department of Medicine, BHU, Varanasi; and (iii) Marketing of Human Gamma Interferon Alpha 2B Eye Drops, Cream and Nasal Spray by M/s CIMMCO, Delhi. The list of members who attended the meeting is given as per Annex I.

2. Welcoming the members, the Chairman emphasized the need to have the checklist ready to facilitate early clearance of the proposals by GEAC. He pointed out that on the request of GEAC, Dr. Kalyan Banerjee, Director, National Institute of Virology, Pune and Member, GEAC, has sent a draft checklist for the proposals coming for approval by GEAC. Since Dr. Banerjee is not available for further consultation on the matter, he requested Dr. Sandip K. Basu, Co-Chairman, GEAC to prepare the checklist on the basis of the draft given by DBT, Ministry of Environment and Forests and Dr. Kalyan Banerjee. In view of the urgency, the chairman desired that this work may be completed by 14.11.91.

3. The representatives of the firms/ organizations concerned with the proposals were present and the Committee took the opportunity to hear them. They have been asked to send the required but missing information quickly on the products from the point of view of environmental safety for reaching a decision on the applications in the next meeting on 23.12.91. The information required being as follows:

**(i) Erythropoietin:**

- (a) The suppliers should substantiate with evidence that the product is completely free from detectable viruses, nucleic acid or non-target antigenic material which may lead to transformation of mammalian cells.
- (b) Documentary proof that the product is approved by the appropriate authority in the country of origin. Additional information about its use in other countries, if any, should also be provided.

- (c) The quality assurance of the product would be established on testing in a recognized institution in India.

**(ii) Interferon: Y**

- (a) A certificate to show that the product quality is as per recommended WHO specifications.
- (b) The level of adventitious nucleic acid in the product even though the bacterium cells are used in the preparation.

**(iii) Interferon Alpha 2B**

- (a) The limit of foreign DNA in the product.
- (b) The certificate provided with the literature is to be authenticated by the Head of the business concern.

4. The Co-Chairman requested the Chairman to give reasonable time for calling of GEAC meeting so as to ensure full participation by the members. The Chairman decided that the next meeting of GEAC may be called on 23.12.91 and desired that members should be informed immediately so that they may make arrangements for attending the GEAC meeting.

**Annex- I**

**List of Participants**

1. Shri A. Bhattacharjya, Additional Secretary, Ministry of Environment and Forests, New Delhi.
2. Dr. Sandip K. Basu, Director, National Institute of Immunology, Delhi.
3. Dr. K. Narayanaswami, Director, Department of Biotechnology, New Delhi.
4. Dr. M.P.G Kurup, Executive Director, National Dairy Development Board, Anand.
5. Dr. Y.P. Kakar, Director, Ministry of Environment and Forests, New Delhi.
6. Dr. P. Dasgupta, Dy. Drug Controller of India (New Drugs), representative of DGHS, New Delhi.
7. Dr. S.K. Ghosh, Senior scientist, Central Pollution Control Board, Delhi.
8. Dr. (Mrs.) S. Kulshrestha, Sr. Pharmacologist (Medical) Directorate of plant protection, quarantines and storage, faridabad.
9. Dr. T.V. Ramanaiah, Sr. Scientific officer, Department of Biotechnology, New Delhi.
10. Dr. R. R. Khan, Additional Director, Ministry of Environment and Forests, New Delhi.
11. Dr. Indrani Chandrasekharan, Scientist 'SE', Ministry of Environment and Forests, New Delhi.

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