

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

**Subject: Minutes of 7th Meeting of the Genetic Engineering Approval  
Committee held on 28.01.1993 at 11.00 a.m.**

\*\*\*\*\*

The 7th Meeting of the Genetic Engineering Approval Committee (GEAC) was held under the Chairmanship of Shri A. Bhattacharjya, Additional Secretary, Ministry of Environment and Forests and Chairman, GEAC on 28.01.1993 at 11.00 a.m. to consider various proposals as per agenda of the meeting. A list of members who attended the meeting is given at Annex-I. The following proposals came up for discussion:-

**Agenda Item No. I: Import and Marketing of Recombinant Hepatitis-B Vaccine form Cuba by M/s. CIMMCO, New Delhi.**

2. This proposal was discussed in the Sixth meeting of GEAC and it was decided that the firm should provide complete information on (i) immunogenicity and (ii) efficacy with side effect Information submitted by the Firm was discussed by experts. It was observed that the data submitted by the Firm pertain to certain trials conducted in Cuba which is the country of origin of vaccine. It was emphasized that both safety of the vaccine to the users as well as its long term effects on the environment should be considered by GEAC before giving permission for import for marketing purposes. Dr. P. Das Gupta, representing the Drug Controller of India (DCI) could not attend the meeting. He, however, conveyed that the permission for clinical trials for safety and efficacy has been granted to the firm by DCI. These trials will be conducted at G. B. Pant Hospital, Delhi, SSK Medical College, Calcutta and KEM Hospital, Bombay. Members wanted to know as to how the permission for clinical trials has been granted by DCI before first referring the case to GEAC. It was decided that the import of recombinant Hepatitis-B Vaccine need not to be allowed at this stage for marketing purpose. The proposal may be submitted to GEAC after the results of clinical trials are examined by the Drug Controller of India.

**Agenda Item No. II: Import of NBL Bio-control products from New Biolabs Inc. USA-Proposal submitted by Kidwai, Consultants, New Delhi.**

3. Dr. Sandip Basu, Co-Chairman pointed out that the proposal as contained in Agenda Noted is unsigned. He wondered whether such unsigned proposal be considered by GEAC. It was clarified by the Member-Secretary, GEAC that signed copies of the proposal have also been received by the Ministry including the one forwarded by the Department of Biotechnology. Dr. Mahajan, BARC mentioned that various statements made in the enclosures submitted by the firm cannot be accepted. Moreover, the data

supplied by the firm are inadequate. It was decided that it is not advisable to import such micro-organisms for pollution control as a number of such organisms are already identified by various research laboratories which can be used for pollution control. The proposal is therefore, not cleared by the GEAC.

**Agenda Item No. III: Import, Storage and Use of specialist Bacterial Products for pollution control activities – submitted by M/s. Wockhard Ltd., Bombay.**

4. Experts noted that the data supplied by the firm are incomplete. It was decided that it is not advisable to import such micro-organisms for pollution control as a number of such chemicals are already identified by various research laboratories which can be used for pollution control. The proposal is, therefore, not cleared by the GEAC.

**Agenda Item No. IV: Import of Double Recombinant Vaccine Rinderpest Vaccine – submitted by Indian Immunologicals, Hyderabad**

5. The proposal for the import of rinderpest vaccine submitted by Indian Immunologicals, Hyderabad for import of 500 doses of rinderpest vaccine for confined trials be sent to Dr. B.B. Malik, Joint Director, Research, IVRI for his expert comments in the first instance.

**Agenda Item No. V: Application for import, storage and use of Bacterial products for pollution control submitted by M/s. Seaking Marine Industry Ltd., Bombay.**

**Agenda Item No. V-A:- Application for import of liquid live microorganisms for pollution control – submitted by M/s. Madhusudan Shah, Surat, Gujarat**

**Agenda Item No. V-B:- 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.**

6. Experts noted that in spite of repeated reminders there is no response from respective firms. The case may, therefore, be closed in view of non- response from the firms since long.

**Agenda Item No. VI: - Import of 6 lakhs doses of Bovine Somatotropin (BST) by Indian Immunologicals, Hyderabad.**

7. The proposal from Indian Immunologicals, Hyderabad was put up to GEAC in various past meetings for consideration. After long follow-Up, the protocols for mass-scale field trials have been submitted by the firm. It was, however, observed that the protocols submitted are not adequate. It was mentioned that the proposal has not yet been approved by the US Food and Drugs Administration and therefore the clearance by GEAC for large-scale field trials at this stage is not desirable. Experts mentioned several harmful effects to cows as well as consumers as a result of consumption of this milk

particularly for the cattle population which is under- nourished due to lack of adequate fodder.

8. Dr. Mahajan, BARC mentioned that excessive lactation facilitated by treatment of under-nourished cows with BST can lead to mobilization of the adipose tissue where pesticides are concentrated. This is not a serious problem in USA as there is abundant supply of fodder which is not the case in India. Dr. Bansal mentioned that considering the cost of the vaccine and associated harmful effects on the consumers like hyperthyroidism and other associated dangers to animals like hypoglycaemia and possible resistance to insulin, it is advisable not to permit such large scale field trials of BST at this stage.

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

## Annex- I

### List of Participants

1. Shri A. Bhattacharjya, Additional Secretary, Ministry of Environment and Forests, Paryavarn Bhavan, CGO Complex, Lodi Road, New Delhi.- Chairman
2. Dr. Sandip.K. Basu, Director, National Institute of Immunology, New Delhi.-Co-Chairman
3. Shri Ashok Kapoor, Joint Secretary, Department of Biotechnology, CGO Complex, Lodi Road, New Delhi-110003.
4. Dr. P.K.Gosh, Director, Department of Biotechnology, CGO Complex, Lodi Road, New Delhi-110003.
5. Dr. S.K. Mahajan, Head, Molecular Biology and Agri. Division, BARC, Bombay.
6. Dr. Sushil Kumar, Head, HRDG, Council of Scientific and Industrial Research, Anusandhan Bhavan, Rafi Marg, New Delhi-110001.
7. Dr. K.R. Ranganathan, Member Secretary, Central Pollution Control Board, Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, Delhi-110032.
8. Shri R.C. Trivedi, Central Pollution Control Board, Parivesh Bhavan, CBD-Cum-Officer complex, East Arjun Nagar, Delhi-110032.
9. Dr. Lalit Kant, Deputy Director General, Indian Council of Medical Research, Ansari Nagar, Post Box 4508, New Delhi-110029.
10. Dr. (Mrs) Sulbha Gupta, Principal Scientific officer, Department of Science and Technology Bhavan, New Mehrauli Road, New Delhi-110016.
11. Dr. S.C. Bansal, D-131, Panchsheel Enclave, New Delhi-110017.
12. Dr. R.P. Sharma, Biotechnology Centre, IARI, New Delhi-110012.
13. Shri M.G. Hussain, Central Pollution control Board, Parivesh Bhavan, CBD-Cum-Officer Complex, East Arjun Nagar, Delhi-110032.
14. Shri N.C. Tiwari, Directorate General of Technical Development, Udyog Bhavan, New Delhi-110011.
15. Dr. R.R Khan, Additional Director, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, Lodi Road, New Delhi-110003.

\*\*\*\*\*