Ministry of Environment & Forests
HSM DIVISION

Subject: Minutes of 12th Meeting of the Genetic Engineering Approval Committee held on 17.05.1996 at 10.30 a.m.

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The 12th Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 17.05.1996 at 10.30 a.m. to consider eight proposals as per agenda of the meeting. The meeting was chaired by Dr. Sandip Basu, Co-Chairman, GEAC. A list of members who attended the meeting is given at Annexure-I.

2. Welcoming the members, Co-Chairman observed that since Chairman, GEAC is on long leave, he has been requested by the Ministry to chair the meeting. He however, observed that since the Ministry of Environment and Forests is the administrative Ministry for implementing Rules on Hazardous Micro-organisms, an officer of the Minsitry should chair GEAC meetings. Member Secretary, GEAC explained that approval of the competent authority has been taken before requesting Co-Chairman, GEAC to chair the meeting. Chairman also observed that in view of paucity of time, it may not be possible to consider all the proposals. The remaining proposals could be taken – up in the next GEAC meeting. Member Secretary. GEAC explained that since time is short, we may skip-over Agenda Items 2 and 3 regarding "Overview of the proceedings of the GEAC meetings held till date" and "Revision of policies for expert comments on project proposals". These may be taken-up in the next meeting.

3. The following proposals were, then, taken- up for discussions:

Proposal 1: Import and Marketing of Injection Lispro (rDNA) – A Human Insulin Analogue by Eli Lilly Ranbaxy Ltd., New Delhi from Eli Lilly and Co., USA.

Proposal 2: Import and Marketing of Injection c7E3 Fab- Abciximab (Reopro) and antiplatelet antibody for high risk coronary angioplasty by Eli Lilly Ranbaxy Ltd., New Delhi from Centocor B.V., The Netherlands.

Proposal 3: Import and Marketing of injection Somatropin (Humatrope)- Human growth hormone by Eli Lilly Ranbaxy Ltd., New Delhi from Eli Lilly and company, France.

Proposal 4: Import and Marketing of 'Granocyte' (Lenograstim-r HuG-CSF) by Rhone Poulene Rorer (Indi) Ltd., Bombay from Rhone Poulene Rorer, France.

Proposal 6: Import and Use of "CHY-MAX" (100% Chymosin Enzyme) by Four Vees Sales and Export) Corporation, Bombay from Pfizer Inc., USA.

Proposal 7: Import of Chymogen (100% Chymosin enzyme), a milk coagulating enzyme by Ess Dee Chemocrfates, Bombay from CHR, Hansen, Denmark.

4. Based on the observations made by the Department of Biotechnology, it was decided that respective firms will have to submit information on the following before the proposal is reconsidered in the next GEAC meeting:

(1) Details of the expression hosts.
(2) Characterization of the target genes and vectors.
(3) Approaches adopted for expression of genes.
(4) Quality control and quality assurance methods deployed for identifying the bulk and formulated materials.
(5) Presence of contaminating DNA, RNA, Lipids, Proteins and processing chemicals into finished products.

5. In respect of Proposal No. 5, namely, "Import and Use of Alpha Bio Sea Microorganisms for Microbially Enhanced Oil Recovery Technique for increasing crude oil product by Assam Tea Co., Dibrugarh, Assam, it was pointed out that in the IXth GEAC meeting, a similar proposal was approved by the Committee. Accordingly, the proposal was recommended for import and use of alpha biosea Microorganisms only for microbially enhanced oil recovery. No approval is given for paraffin management and bioremediation of hydrocarbon pollution. Chairman, however, pointed out that proper monitoring of various conditions given with the clearance letter be undertaken by the Secretariat, IIP, Dehradun and NEERI, Nagpur may be approached for monitoring the performance of microbial treatment.

6. In respect of Proposal- 8 entitled "Import of BOOSTIN –S BST) for conducting clinical trials in India" by M/s. Alembic Chemical Works Company Ltd., Baroda, it was decided that the results of trials conducted earlier on rBST by M/s. Monsanto Chemicals be considered before discussing the similar proposals meeting. Representatives of IVRI, Izzatnagar and Department of Animal Husbandry and Dairying, Government of India may also attend the meeting as special invitees.

7. Dr. P.K. Ghosh, Advisor, DBT pointed that an extended a Performa for inviting applications for genetically engineered drug and pharmaceuticals products has been revised by his Department, which may be used in future. This was agreed by the Committee.

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

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Annexure-I

List of Participants

1. Dr. Sandip.K. Basu, Director, National Institute of Immunology, Delhi.
2. Dr. S.K. Mahajan, Head, Molecular Biology and Agri. Division, BARC, Bombay.
3. Dr. P.K.Ghosh, Director, Department of Biotechnology, New Delhi.
4. Dr. (Mrs) Sulbha Gupta, Director, Department of Science and Technology, New Delhi.
5. Dr. (Ms.) S. Kulshrestha, Medical Toxicologist, Directorate of Plant Protection, Quarantine and Storage, Faridabad.
6. Shri A.B. Ramteke, Biochemist, Dte. General of Health Services, Ministry of Health and Family Welfare, Nirman Bhavan, New Delhi.
7. Shri R.C. Trivedi, Scientist, CPCB, Delhi.
8. Dr. R.R. Khan, Director, H.S.M. Division, Ministry of Environment and Forests, New Delhi.
9. Ms. Madhu Gupta, Research Assistant, Ministry of Environment and Forests, New Delhi.