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Ministry of Environment & Forests
(HSM Division)

Subject: Minutes of the 19th Meeting of the Genetic Engineering Approval Committee held on 8th March, 1999.

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The nineteenth meeting of the Genetic Engineering Approval Committee (GEAC) was held on 8th March, 1999 under the Chairmanship of Shri Vinod Vaish, Special Secretary, Ministry of Environment & Forests. The following is the list of participants:

1) Shri Vinod Vaish, Special Secretary, Ministry of Environment & Forests, New Delhi. **– Chairman**
2) Dr. (Mrs.) Manju Sharma, Secretary, Department of Biotechnology, New Delhi. **– Special Invitee**
3) Dr. Sushil Kumar, Director, Central Institute of Medicinal and Aromatic Plants, Lucknow (U.P.). **– Co-chairman**
4) Shri V. Rajagopalan, Joint Secretary, Ministry of environment and Forest, New Delhi.
5) Shri Prasanta K. Ghosh, Advisor, Department of Biotechnology, New Delhi.
6) Dr. Vasantha Muthuswamy, Deputy Director General, Indian Council of Medical Research, New Delhi.
7) Dr. S.K. Mahajan, Head, Agricultural Sciences Group, Bhabha Atomic Research Centre, Mumbai
8) Dr. (Ms) Sulbha Gupta, Director, Department of Science and Technology, New Delhi.
9) Prof. A.K. Bhatnagar, Department of Botany, University of Delhi, Delhi.
10) Prof. Subhash Chard, Department of Biochemical Engineering, Indian Institute of Technology, New Delhi.
11) Shri. A.B. Ramteke, Deputy Drugs Controller, Ministry of Health, New Delhi.
12) Dr. (Mrs.) S. Kulshrestha, Medical Toxicologist, Directorate of Plant Protection, Quarantines and Storage, Faridabad.
13) Shri Gajraj Singh, Department of Industrial Policy and Promotion, Ministry of Industry, New Delhi.

14) Dr. R.R Khan, Director, Ministry of Environment & Forests, New Delhi.

15) Ms. Madhu Gupta, Research Assistant, Ministry of Environment & Forests, New Delhi.

2. Welcoming the members, Chairman introduced Prof. A.K. Bhatnagar of the University of Delhi who has recently been made a member of GEAC. Chairman thanked Dr. Manju Sharma, Secretary, DBT for being able to spare some time to participate in the meeting as a special invitee.

3. On Agenda Item No. 2 regarding confirmation of Minutes of the 18th Meeting of GEAC, Dr. S.K. Mahajan, BARC pointed out that the minutes of the 18th meeting were found in free circulation with persons who not members of GEAC. Secretary, DBT suggested that the minutes may be marked as "for official use only". Dr. Mahajan, BARC raised another issue as outlined in para 6 of the Minutes of the Meeting and mentioned that

7. Dr. Mahajan, BARC desired to know the procedures followed by RCGM. It was decided that DBT shall prepare a detailed note on procedures being followed by RCGM for being circulated to the GEAC members before the next meeting. (Action: DBT)

8. Chairman referred to the Hazardous Micro-organisms Rules, 1989 which provide that approval of activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle shall be given by the GEAC. This Committee shall also be responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment including experimental field trials. The working arrangements so far have been that RCGM has, as part of its mandate laid down in Rule 4(2) of Hazardous Micro-organisms Rules 1989, been granting approvals for experiments being conducted in laboratories, green houses and small fields and has also been monitoring safety related aspects in respect of these research projects. Members felt that there was need for bringing in a degree of clarity in regard to "large scale use of recombinants in research" and "experimental field trials" in relation to the work of RCGM. In this context, the letter of Secretary, DBT dated 3.2.1999 to the Chairman, GEAC was taken note of by the Committee, the relevant portion of this letter being as under:

> "RCGM can approve applications for generating research information on transgenic plants. Such information may be generated in contained green house as well as in very small plots, as research needs to be conducted in such environment for seeking answers to specific environmental safety issues emanating from the use of transgenic plants. The small experimental field trials should be limited to a total area of 20 acres in multi-locations. In one location where the experiment is conducted with transgenic plants, the land used should not be more than one acre. Any experiment beyond 20 acres in total on a plot size bigger than 1 acre would require GEAC's approval."

Co-chairman pointed out that the suggested criteria of a maximum of 20 acres experimentation in multi locations, with one location not exceeding one acre, should be related to a single applicant. The Committee after discussion approved the demarcation of functions between RCGM and GEAC on the above basis.

Although this kind of division of work seemed to fall well within the framework of the Hazardous Micro-organisms Rules 1989 and was considered desirable for implementing the Rules in a pragmatic manner, the Committee felt that in case there was need to amend the existing rules, requisite action may be taken by MoEF. Also DBT was advised to revise the Guidelines for Research in Transgenic Plants 1998 in order to incorporate the above provisions. (Action: DBT/MoEF)

9. Chairman pointed out that as per existing provisions of Hazardous Microorganisms Rules 1989, under Rule 4(2), the RCGM has been given the mandate to lay down procedures restricting or prohibiting production, survey, importation and use of genetically engineered organisms or cells as are mentioned in the Schedule. On the other hand, Rule 7 stipulates that import, export, transport, manufacture, processing, use or sale of any hazardous micro-organisms or genetically engineered organisms or substances or manufacture of two million doses per year of both the bulk and formulated material. Prof. Subhash Chand, IIT, Delhi enquired about the disposal of liquid wastes to be generated during fermentation. It was explained that methanol which is used in fermentation is to be completely utilized. Moreover, the firm has to treat its wastes as per Hazardous Waste (Management & Handling) Rules, 1989.

13. Doubts were also raised as to whether the application is on behalf of Wockhardt Ltd. or Wockhardt Rhein Pvt. Ltd. The representative of the firm, who was called to provide details of the proposal, explained the hepatitis-B bulk is from Wockhardt Rhein Pvt. Ltd. while hepatitis-B formulated vaccine is from Wockhardt Ltd. He was asked to submit in writing as to which company should be considered for granting approval. It was agreed that based on the comments of ICMR and the clarification sought from the firm, the Chairman, GEAC could take a decision on giving approval for two million doses per year of both the bulk and formulated material. Meanwhile, an inspection team shall visit the manufacturing site of M/s. Wockhardt before considering their request for manufacture of 20 million doses of recombinant hepatitis-B bulk. (Action: MoEF)

Manufacture and Export of Purified Recombinant Hepatitis-B Antigen Protein by M/s Transgene Vaccine Pvt. Ltd., Hyderabad

14. It was pointed out that the proposal was incomplete since Phase-II and III clinical trials are yet to be completed by the firm. It was decided that the firm be asked to complete the clinical trials and submit them to DCGI. Only after DCGI gives its clearance, the matter may be brought before GEAC. (Action: DCGI)

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

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