Brief record of the 27th meeting of the Genetic Engineering Approval Committee (GEAC) held on 8th August 2001.

The 27th meeting of the Genetic Engineering Approval Committee (GEAC) was held on 8th August 2001 at 11.15 a.m. under the Chairmanship of Shri A.M. Gokhale, Additional Secretary, Ministry of Environment & Forests. List of participants is annexed.

At the outset, the Chairman in his opening remarks referred to the expansion of the GEAC, which was carried out recently so that it is adequately geared up to consider proposals relating to transgenic crops and GM foods. The Chairman particularly welcomed the new members: Dr. O.P. Agarwal, Joint Secretary, Council for Scientific and Industrial Research; Shri Govindan Nair, Joint Secretary, Department of Agriculture & Cooperation; Dr. R. Gopalan, Joint Secretary, Ministry of Commerce and Industry; Shri A. Gopinathan, Joint Secretary, Ministry of External Affairs; Shri Deepak Gupta, Joint Secretary, Ministry of Health & Family Welfare; Ms. Vibha Puri Das, Joint Secretary, Department of Food Processing Industries.

The Chairman referred to the minutes of the 26th meeting of GEAC held on 19.6.2001, which were circulated to all members. As there were no comments received from members, the minutes were confirmed. Thereafter, the agenda items were taken up for discussion.

Agenda item no. 3.1: Large scale trials and seed production of transgenic mustard by Proagro-PGS India Ltd., Gurgaon.

Dr. P.K. Ghosh explained the protocols approved by the RCGM for conducting multicentric trials and for evaluating environmental and food safety. Dr. Ghosh informed that though the pollen flow was upto 35 metres, this did not add to any new property, including weediness and aggressiveness.

Dr. Sushil Kumar expressed concern regarding transfer of male sterility to the related local varieties of Brassica. This may lead to genetic contamination and erosion of native germplasm, which may have long term implications.

Dr. R.P. Sharma stated that though pollen flow induces male sterility, the resultant plant will produce seeds because of female fertility and cross pollination. There is therefore a need to generate data on impact of pollen transfer through large scale trials.

Dr. Paroda informed that in Brassica, 4-14% out-pollination takes places in nature. Since the pollen flow is upto 35 metres, maintaining appropriate isolation distance will take care of the concerns raised. He further suggested that there is a need to study the effect of pollinators under natural conditions, when no beehives are specifically provided.

After careful consideration, the following decisions were taken:

- The firm shall be permitted to undertake large scale field trials in 37.5 acres and seed production in 31 acres.
- The firm shall make available 10 kg of seed to ICAR for conducting trials under their All India Coordinated Project.
- The seeds produced should not be used for commercial purposes.

- Before conducting the trials, the firm shall submit protocols and checklist to RCGM/MEC for approval.
- Simultaneously, the firm shall obtain the consent of the State Government concerned before undertaking the trials.
- During the large scale field trials and seed production, the crop residue should be destroyed.
- The firm shall interalia undertake studies on the impact of pollen transfer on yield, and effect of pollinators, when no beehives are specifically provided. These studies will also be conducted independently by ICAR.

Agenda item no. 3.2: Hybrid seed production for Bt cotton on an area of 300 hectares by MAHYCO, Mumbai

The GEAC in its 23rd meeting held in June 2000, had accorded approval of MAHYCO for undertaking large scale field trials of Bt cotton in 85 hectares and hybrid seed production in 150 hectares. Thereafter, the GEAC in its 26th meeting agreed that large scale trials be repeated on 100 hectares under the supervision of ICAR.

MAHYCO has now requested for permission to produce hybrid seeds of Bt cotton on 300 hectares in the states of Tamil Nadu and Maharashtra, in the year 2001-2002.

The Committee approved hybrid seed production for Bt cotton in an area of 300 hectares by MAHYCO with the following terms and conditions:

(1) The firm shall provide the state-wise details of the locations (area, village, name of the farmer) where it intends to take seed production.
(2) Around the periphery of each plot upto 5 metres trapper rows of non Bt counterparts shall be planted.
(3) The lint should be baled and stored separately.
(4) Bt cotton plant residue after harvesting be destroyed by burning.
(5) The seeds produced should not be used for commercial purposes.

Agenda item no. 3.3: Import and marketing of r-Bovine Somatotropin 320 mg. By M/s L.G. Chemicals Pvt. Ltd., New Delhi from M/s L.G. Chemicals Ltd., Korea.

During the discussions, it came out that BST stimulates higher production of milk through increased metabolic rate which in turn require more consumption of fodder by the cattle. In the Indian conditions, where cattle are likely to be subjected to starvation stress, there is a possibility of break-down of adipose tissue because of high metabolism. This might lead to release of a pesticide residue deposited in the adipose into the milk. Hence, there is a need to generate data on presence of pesticide residue in the milk of BST treated cattle. Further, it was pointed out that in studies conducted in USA, the treated animals initially develop high temperature. Thus, there is a need to generate data on this parameter also. In addition, there is a need to gather information on the following parameters:

(1) Incidence of mastitis
(2) Incidence of delayed subsequent pregnancy
(3) Incidence of diabetes

The Committee decided to approve limited import of r-BST for undertaking trials through NDRI, Karnal for generating data on the above five parameters in 100 cows and buffaloes.

Agenda item no. 3.4: Import and marketing of REBIF 22 ug and 44 ug (r-Human Interferon beta 1a) by Serum Institute of India, Pune from M/s Senora, Italy.

M/s Serum Institute of India, Pune had submitted a proposal for import and marketing of REBIF 22 ug and 44 ug (r-Human Interferon on beta 1a) from M/s Senora, Italy.

Extensive multicentric clinical trials have been conducted by the firm in several countries, the Committee decided to approve import and marketing of REBIF 22 ug and 44 ug (r-Human Interferon on Beta 1a) from M/s Senora, Italy with the following conditions:

(1) A Post Market Surveillance will be conducted on 100-125 recipients of the drug with regard to the toxicity, side effects, allergenicity etc. for the use of drug.
(2) Data on serum neutralizing antibody in Indian population with reference to the efficacy and safety of the product will be generated by way of conducting suitable studies in consultation with the DCGI.
(3) The product will be accompanied by the certificate that it is free from opportunistic microbial fungal, mycoplasma and viral infections.
(4) The product will also be accompanied with the certificate that it conforms to the specifications submitted to Government of India.

Agenda item no. 3.5: Import and marketing of interferon alpha 2 b by M/s Cadilla Health Care Ltd., Ahmedabad from M/s Biosidus, Argentina.

Earlier GEAC in its 25th meeting had considered the proposal. It was deferred for want to comments from DCGI. The DCGI has communicated its no objection to the proposal.

The Committee approved the import and marketing of interferon alpha 2 b by M/s Cadilla Health Care Ltd., Ahmedabad from M/s Biosidus, Argentina, with the following conditions:

(1) Efficacy and safety data of the product in Indian population to be generated by way of conducting Phase IV trials.
(2) Each consignment/batch should accompany a certificate from the manufacturer, stating that the preparation is free from opportunistic viruses like HIV-1, HBV and HCV etc.

Agenda item no. 3.6: Import and marketing of interferon injection (3, 6, 9, MIU) by M/s L.G. Chemicals Pvt. Ltd., New Delhi, from M/s L.G. Chemicals Ltd., Korea.

Earlier GEAC in its 25th meeting had considered the proposal. It was deferred for want to DCGI's comments. The DCGI has now communicated its no objection to the proposal.

The Committee decided to give permission for Import and marketing of interferon injection (3,6,9 MIU) by M/s L.G. Chemicals Pvt. Ltd., New Delhi from M/s L.G. Chemicals Ltd., Korea, for conducting Phase IV trials to establish safety and efficacy of the drug in human subjects in India.

Agenda item no. 3.7: Import and marketing of Espogen (r-Human erythropoietin) by M/s L.G. Chemicals Pvt. Ltd., New Delhi from M/s L.G. Chemicals Ltd., Korea.

The proposal was considered in the 25th meeting of GEAC. The comments from DCGI were not received at that time. It was agreed that on receiving DCGI's comments, the Chairman may approve small scale import of the product for limited Phase III Clinical Trials as per the standards earlier laid down by the Committee for generating data as suggested by DBT. Accordingly, on receipt of no objection from DCGI, the proposal for small scale import of the product for Phase III clinical trials was approved by the Chairman and sanction issued to the applicant on 31.7.2001.

Thereafter, the applicant submitted an application for re-consideration of the approval, and requested the grant approval for import and marketing of the product with the condition that Phase IV clinical trial i.e. Post Market Surveillance will be conducted.

The Committee approved the proposal for import and marketing of Espogen (r-Human erythropoietin) by M/s L.G. Chemicals India Pvt. Ltd., New Delhi from M/s L.G. Chemicals Ltd., Korea with the condition that Post Market Surveillance data will be generated as per the norms of DCGI.

Agenda item no. 3.8: Import, manufacture and marketing of r-Human Erythropoietin Alpha by M/s Emcure Dragon Biotech Ltd., Dapodi, Pune from Nanjung Huaxin Pharmaceuticals and Bioengineering Co. Ltd., Nanjung Jiangsu, China

M/s Emcure Dragon Biotech Ltd., Dapodi, Pune had submitted a proposal for import, manufacture and marketing of r-Human Erythropoietin alpha from Nanjung Huaxin Pharmaceuticals and Bioengineernig Co. Ltd., Nanjung Jiangru, China.
The product is found safe in animals and in human clinical trials and is being marketed in many countries. The Committee decided to approve the import, manufacture and marketing of r-Human Erythropoietin alpha with the following conditions:

(1) Efficacy and safety data of the product in Indian population to be generated by way of conducting Phase IV trials.
(2) Each consignment should be accompanied by a certificate from concerned authorities indicating that the product is free from bacteria, fungus, mycoplasmas and adventitious viruses like HIV, HBV, HCV etc. tested by scientifically tested methods.
(3) For manufacturing the product in India, the applicant has to comply with the existing Rules and Regulations of the country for manufacturing r-DNA Pharmaceutical Products.

Agenda item no. 4.1: Any other item: Revalidation of approval for import and marketing of injection – Human Insulin Lispro (r-DNA) by Eli Lilly Ranbaxy Ltd., Delhi from M/s Eli Lilly & Co., U.S.A.

M/s Eli Lilly Ranbaxy Ltd., Delhi submitted application for revalidation of approval for import and marketing of injection – Human Insulin Lispro (r-DNA) from Eli Lilly & Co., U.S.A.
GEAC in its 13th meeting held on 15.1.1997 had given permission to this firm to import and market injection Human Insulin Lispro (r-DNA). As per rule 13(2) of 1989 rules, the

approvals of the Genetic Engineering Approval Committee are valid for four years at the first instance and renewable for two years at a time.

While approving the request, the Committee decided that the proponents be asked to provide information on:

(1) Quantity of insulin imported and marketed
(2) Future plans of the company.

Agenda item no. 4.2: Request for making public the results of field trials and other relevant data.

The Ministry has been receiving requests from various quarters, including from NGOs, to make public the results of field trials on transgenic crops. This would ensure more transparency to the decision making process of GEAC. This would also facilitate public awareness, education and participation concerning the handling and use of genetically engineered organisms.

The Committee felt that it would be useful to make the decision making process more transparent and participating. However, the members agreed that some more discussion was required on how to make the process more participatory. It was agreed that the matter would be discussed in subsequent meetings of GEAC.

Agenda item no. 4.3: Revalidation of approval for manufacture of Human Insulin by M/s M.J. Pharmaceuticals Ltd., Mumbai

The GEAC in its 9th meeting held on 29.7.94 had given permission to manufacture and marketing of human insulin injection. As per Rule 13(2) approvals of GEAC are valid for four years at the first instance and renewable for two years at a time. The firm manufactured the drug upto 1997. Thereafter it discontinued the manufacture. Now they wish to renew the manufacturing and have requested for revalidation of the permission for manufacturing the product with the same technology. The proposal for revalidation of the approval was considered by the GEAC in its 25th meeting. It was decided that information may be obtained from the applicant with respect to interalia:

- any adverse incident that might have occurred during manufacturing
- details of management problems for which the manufacturing process was discontinued.

Accordingly, the Ministry sought information from the applicant.

The applicant has communicated that no adverse incident occurred during the manufacture of the drug. The applicant has also enclosed certificates regarding the quality of the product. The applicant has confirmed that there has been no management problem at the location of manufacturing of Human Insulin. The manufacturing was discontinued solely on the reason that Eli Lilly Ranbaxy had decided to source the material from elsewhere.

The Committee approved revalidation of the approval for manufacture and marketing of Human Insulin Injection.

The next meeting of GEAC was fixed for 8th November, 2001.

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