Brief record of the 35th Meeting of GEAC held on 6.3.2003.

The 35th meeting of the GEAC was held on 6.3.2003 at 3.00 PM in MoEF under the Chairmanship of Ms Sushma Choudhary, Additional Secretary, MoEF. List of participants is annexed.

1.0 Opening Remarks of the Chairman

The Chairman welcomed all the members. The Chairman briefly dwelt upon the agenda before the Committee with specific reference to the proposal of M/s CARE and CRS to import Corn Soy Blend as food aid through USAID.

She informed the Committee that consequent to the GEAC's decision taken in the 34th meeting on 7th November, 2002, CARE and CRS, USAID and US embassy have been pursuing with the Ministry for presenting their case before the GEAC. It is in this context the CARE and CRS will be making a presentation before the GEAC on their proposal. The Chairman requested the Committee to take a final decision after carefully reviewing the information submitted by CARE and CRS.

As a follow up to the decision taken in the 7th Nov GEAC meeting, the Chairman requested all members especially the MOA and ICMAR to get their views on the Proagro's for commercial release of transgenic mustard crop in two weeks time

2.0 Confirmation of the Minutes of the 34th meeting of the GEAC held on 07.11.2002.

The Chairman referred to the minutes of the 34th meeting of GEAC held on 7th Nov 2002, 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, beginning with the proposal on import of Corn Soy Blend by M/s CARE and CRS.

PART A

3.0 Consideration of New proposals

Agenda Item No 3.1: Permission for import of Corn Soy Blend (CSB) by CARE and CRS.

A power point presentation was made by CARE, CRS and US officials regard to the above subject. The proponents focused on the following points in their presentation:

- Procedure for approval of GM crops in the US.
- The varieties of GM corn/ Soy approved for human consumption in the US on a continuing basis and variety of GM corn/ Soya approved only for animal consumption in the US.
- Results of food safety evaluation conducted in the US for the varieties approved for direct human consumption.
- Names and addresses of all the beneficiary organizations and arrangement for monitoring the health of the beneficiaries.
- List of Countries to which CSB proposed under ICDS are being shipped.
- Health monitoring facilities set up to monitor the impact on health due to consumption of GM food both in the US and under ICDS program.

In light of the above presentation, the GEAC noted the following:

1. The proponents failed to submit an authenticated certificate that the consignment containing CSB as food aid under ICDS program does not contain the Starlink corn. Particularly, in light of the recent information from the news paper reports that starlink corn surfaced in the shipment to Japan from USA, serious apprehensions were expressed about the possibility of such incidence recurring in the shipment to India.

2. ICMR cautioned on the susceptibility of the vulnerable populations to long term exposure to CSB containing the genetically modified corn as well the absence of a mechanism for post aid disbursement surveillance.

After detailed deliberations, the GEAC felt that in the absence of a clear certificate regarding the absence of starlink corn in the proposed consignment as food-aid to India, there is no merit in reviewing the committee's earlier decision and reiterated the same.

Agenda item no. 3.2: Permission for import and marketing of r-human Granulocyte stimulating factor (rh-G-CSF) by M/s Kee Pharma Ltd., New Delhi from M/s Shandong Geneleuk Bio Pharamaceutical Co. Ltd., Jinan, Shandong, China.

M/s Kee Pharma Ltd., New Delhi had submitted a proposal for import and marketing of r-human Granulocyte stimulating factor (rh-G-CSF) from M/s Shandong Geneleuk Bio Pharamaceutical Co. Ltd., Jinan, Shandong, China. In line with the recommendations made by DBT, the proposal was approved by the Committee only for phase III human clinical trials to establish the safety of the product.

Agenda item no. 3.3: Permission for manufacture and marketing of FMD (Foot and Mouth Disease) vaccine by M/s Brilliant Industries Ltd., Hyderabad.

M/s Brilliant Industries Ltd., Hyderabad had submitted a proposal for manufacture and marketing of FMD vaccine. The committee didn't approve the proposal as the proposal was not found to be satisfactory on the basis of monitoring report received from the MOEF Regional office at Bangalore. The Committee decided to obtain a fresh review report from the regional office and reconsider the proposal in the next meeting.

Agenda item no. 3.4: Permission for import and marketing of r-human Insulin by M/s Shreya Life Sciences Pvt. Ltd., Mumbai from M/s Bioton Company Ltd., Warszawa.

M/s Shreya Life Sciences Pvt. Ltd., Mumbai had submitted a proposal for import and marketing of r-human Insulin from M/s Bioton Company Ltd., Warszawa. In line with the recommendations made by DBT, the proposal was approved only for phase III human clinical trials to establish the safety of the product.

Agenda item no. 3.5: Permission for Import and marketing of filgrastim 75 ug 150 ug and 300 ug by M/s Ranbaxy laboratories Ltd., New Delhi from Xiamen Amoytop Biotech Co. Ltd., Xiamen, China.

M/s Ranbaxy laboratories Ltd., New Delhi had submitted a proposal from Xiamen Amoytop Biotech Co. Ltd., Xiamen, China for import and marketing of filgrastim 75 ug, 150 ug and 300 ug. In line with the recommendations made by DBT, the proposal was approved only for phase III human clinical trials to establish the safety of the product.

Agenda item no. 3.6: Permission to carry out 500 lts batch formulation regarding M/s Cadilla Health Care Ltd., Hyderabad.

M/s Cadilla Health Care Ltd., Hyderabad had submitted a proposal to carry out 500 lts batch formulation for producing r-human albumin. The committee approved the proposal.

Agenda item no. 3.7: Permission to use 150 L fermentation volume for Lab Scale r-human Insulin process development by M/s Wockhardt Ltd., Mumbai.

M/s Wockhardt Ltd., Mumbai had submitted a proposal to use 150 L fermentation volume for Lab Scale r-human Insulin process development and for test marketing. The committee approved the proposal for lab scale of r-human Insulin process development. The Company's request for carrying out test marketing was not approved at this stage.

Agenda item no. 3.8: Permission for Import and marketing of recombinant Interferon alpha 2b by M/s Ranbaxy Laboratories Ltd., New Delhi from M/s Anhui Anke Biotech Co. Ltd., China.

M/s Ranbaxy Laboratories Ltd., New Delhi had submitted a proposal from M/s Anhui Anke Biotech Co. Ltd., China for import and marketing of recombinant Interferon alpha 2b. In line with the recommendations made by DBT, the proposal was approved only for phase III human clinical trials to establish the safety of the product.

Agenda item no. 3.9: Permission for Import and marketing of human Insulin Analogue Injection formulations (Bio. Synthetic, r-DNA Origin) M/s Novo Nordisk India Pvt. Ltd., Bangalore from M/s Novo Nordisk Denmark.

M/s Novo Nordisk India Pvt. Ltd., Bangalore had submitted a proposal for Import and marketing of human Insulin Analogue Injection formulations (Bio. Synthetic, r-DNA Origin). The committee approved the proposal subject to post marketing surveillance studies to generate data on safety and immunogenicity for a period of one year.

Agenda item no. 3.10: Permission for Import and Marketing of recombinant Erythropoeitin by M/s Intas Pharmaceuticals Ltd., Ahmedabad from M/s Laboratorio Pablo Cascara S.R.L. Argentina.

M/s Intas Pharmaceuticals Ltd., Ahmedabad had submitted a proposal from M/s Laboratorio Pablo Cascara S.R.L. Argentina, for import and marketing of recombinant Erythropoeitin. In line with the recommendations made by DBT, the proposal was approved only for phase III human clinical trials to establish the safety of the product.

Agenda item no. 3.11: Permission for Import and Marketing of recombinant rhu EPO by M/s Glenmark Laboratories Pvt. Ltd., Mumbai from M/s Beijing Four Rings Bio engineering Product Factory, China.

M/s Glenmark Laboratories Pvt. Ltd., Mumbai had submitted a proposal from M/s Beijing Four Rings Bio engineering Product Factory, China for import and marketing of recombinant rhu EPO. In line with the recommendations made by DBT, the proposal was approved only for phase III human clinical trials to establish the safety of the product.

Agenda item no. 3.12: Permission for Import of the bulk Insulin and manufacturing its formulations from M/s Novo Nordisk, Denmark by M/s Torrent Pharmaceuticals Ltd., Ahmedabad.

M/s Torrent Pharmaceuticals Ltd., Ahmedabad had submitted a proposal for import of the bulk Insulin and manufacturing its formulations. The committee approved the proposal.

Agenda item no. 3.13: Permission for Import and Marketing of r-human Granulocyte colony stimulating factor (hurG-CSF) by M/s Cadilla Pharmaceuticals Ltd., Ahmedabad in 3 strengths 75ug, 150 ug, 300 ug from M/s Hangzhou Jiuyuan Gene Engg. Co. Ltd., China.

Agenda item no. 3.14: Permission for large scale process optimization studies of r-human Insulin (for R&D purpose) by M/s Biocon India Ltd., Bangalore.

M/s Biocon India Ltd., Bangalore had submitted a proposal for large scale process optimization studies of r-human Insulin (for R&D purpose). The committee approved the proposal.

Agenda item no.3.15: Permission for Manufacturing and Marketing of Insulin Injection from M/s. Sherya Healthcare Ltd, Mumbai by M/s. Cipla Ltd., Mumbai.

M/s. Cipla Ltd, Mumbai had submitted a proposal for manufacturing and marketing of Insulin Injection. In line with the recommendations made by DBT, the proposal was approved for phase III human clinical trials to establish the safety of the product.

Agenda item no.3.16: Permission for marketing of Pegasys (Peginterferon alfa 2a) (INF) from F.hoffmann La Roche Switzerland by M/s. Roche Scientific Company (India) Pvt. Ltd., Mumbai.

M/s. Roche Scientific Company (India) pvt. Ltd., Mumbai had submitted a proposal for marketing of Pegasys (Peginterferon alfa 2a) (INF). The committee approved the proposal subject to post marketing surveillance studies to generate data on safety and immunogencity for a period of one year.

Agenda item no.3.17: Permission for Import and Marketing of r-human Granulocyte colony stimulating factor (r-hu-G-CSF) in three strength 75 ug, 150 ug, 300 ug by M/s Glenmark Lab Pvt. Ltd., New Delhi from Beijng Rings Bioengineering Products Factory, China.

M/s Glenmark Lab Pvt. Ltd., New Delhi had submitted a proposal for import and marketing of r-human Granulocyte colony stimulating factor (r-hu-G-CSF) in three strength 75 ug, 150 ug, 300 ug. In line with the recommendations made by DBT,

the proposal was approved only for phase III human clinical trials to establish the safety of the product.

PART B

4.0 Considerations of Revalidation Cases:

Agenda Item No. 4.1: Revalidation permission for import and marketing of Gonal-F (r-Human follicale stimulating Hormone (follitropin alpha) by M/s Serum Instt. of India. Ltd., pune.

M/s. Serum Instt. of India. Ltd., Pune had requested for revalidation of the approval granted by the GEAC in 1997 for import and marketing of Gonal-F (r-Human follicle stimulating Hormone (follitropin alpha). The committee approved revalidation of the proposal for import and marketing of Gonal-F (r-Human follicle stimulating Hormone (follitropin alpha) for a period of one year.

Agenda Item No. 4.2: Revalidation permission for Import and Marketing of SAIZEN (r DNA Human Growth hormone) by M/s Serum Instt. of India Ltd., Pune.

M/s. Serum Instt. of India.Ltd. Pune had requested for revalidation of the approval granted by GEAC in 1997 for import and marketing of SAIZEN (r DNA Human Growth hormone). The committee approved revalidation of the proposal for import and marketing SAIZEN (r DNA Human Growth Hormone) for a period of one year.

Agenda Item No. 4.3: Request from M/s Zydus Cadila, Healthcare Ahemdabad, seeking permission to use Filgrastim word in their approved product FIGRASTIM (r-human Granulocyte).

M/s Zydus Cadila, Healthcare Ahemdabad had requested GEAC to reconsider its earlier decision and permit them to use the term “Filgrastim” for their product. The Committee was of the view that it is not the GEAC’s mandate to decide on matters related to proprietary items and recommended that the earlier condition which stipulates that the company shall not use the word “Filgrastim” be withdrawn.

5.0 Policy Issues:

The following policy issues were discussed:

1. DBT is receiving many proposals from companies to permit use of higher fermentation vessels (more than 20 lit.) for standardization of process and also using the product for development of pre-clinical and clinical data. As per DBT guidelines any production above 20 lit requires the approval of GEAC. DBT has recommended that cases where higher fermentation capacities are required for research purpose standardization of process, and generation of pre-clinical and clinical data, permission may be granted by RCGM on a case to case basis after making the necessary amendments in the DBT guidelines.

2. The stepwise procedure for development of r-DNA pharmaceuticals approved by the RCGM was circulated to all members. It was decided that the matter will be discussed in the next GEAC meeting after obtaining comments of the members.

3. The minutes of the inter-ministerial meeting held on 26th February, 2003 will be circulated to all members for obtaining a feedback/suggestion on the specific issues flagged for discussion in the above meeting.

4. Some members were of the view that revalidation cases needs to be examined in terms of environmental and safety compliance before renewing the approvals. It was decided that the DBT proforma for revalidation cases would be circulated to all members for obtaining their comments and suggestions on the matter.

Annexure I

List of Participants

Genetic Engineering Approval Committee (GEAC)

1. Ms. Sushma Choudhary,	Chairman
2. Dr. Sushil Kumar	Co-Chairman
3. Dr. D. D. Verma	Member
4. Dr. S. K. Mahajan	Member
5. Dr. D. R. Chawla	Rep. of M/o Industry
6. Sh. R. K. Trivedi	Rep. of Deptt. Of Agriculture
7. Sh. Subhash Chand	Member
8. Sh. M. Sundaravadivel	Rep. of CPCB, Delhi
9. Sh. A. K. Bhatnagar	Member
10. Dr. V. Muthuswamy	Member
11. Dr. Rakesh Mittal	Rep. of ICMR
12. Dr. P. S. Raju	Rep. of CSIR
13. Dr. Gautam Kalloo	Member
14. Dr. T. V. Ramnaiah	Member
15. Dr. J. S. Choudhary Dy. Secy.	Rep. of M/o Health
16. Ms. Sripriya Ranganathan.	Rep. of M/o Commerce & U. Sect. Industry
17. Dr. Ranjini Warrier	Member Secretary

MoEF Officials

1. Dr. G. V. Sarat Babu, Additional Director
2. Sh. A. A. Rao, Information Officer
3. Ms. Madhu Gupta, RA

Project Authorities

Representatives of CARE, CRS and U. S. Govt.