Brief record of the 32nd Meeting of GEAC held on 26.03.2002

The 32nd meeting of the GEAC was held on **26.03.2002** at 11.00 a.m. under the chairmanship of Shri A.M. Gokhale, Additional Secretary, MoEF. List of participants is annexed.

At the outset, the Chairman welcomed all the members to this important meeting. The Chairman referred to the minutes of the 31st meeting of GEAC held on 31.12.01, 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 Bt cotton.

Part A of the minutes below deal with the agenda item on Bt cotton. Part B on the minutes pertains to the remaining agenda items.

Part – A

Agenda item no. 3.1: Permission for commercial release of Bt cotton hybrid by MAHYCO

The Chairman recalled that MAHYCO's proposal for release of Bt cotton was considered in the 26th meeting of GEAC held on 19th June 2001 and the committee had decided that the trials on Bt cotton hybrids be repeated by MAHYCO as well by ICAR. The results of these trials are contained in the reports which were sent to all the members, along with a background note prepared by this Ministry.

The Chairman invited the comments of the members on the proposal. Based on the reports of the MEC and the ICAR on the trials conducted, and the biosafety evaluation, the members unanimously opined that the Bt cotton hybrid varieties tested, namely Bt MECH 12, Bt MECH 162, and Bt MECH 184 can be accorded approval for commercial release, subject to some conditions.

As regards the Bt cotton variety Bt MECH 915, this variety has not yet been tested by the ICAR, though the trials conducted by MAHYCO on this variety have been monitored by MEC. It was therefore agreed that ICAR may conduct trials on this variety within their coordinated trials and submit the report to GEAC for consideration. For this purpose, the company be directed to supply the required amount of seed to the ICAR well in time for conducting the trials in northern region.

Thereafter, an in-depth discussion took place regarding the conditions for approval for the Bt cotton varieties: Bt MECH 12, Bt MECH 162 and Bt MECH 184. The following points emerged in these discussions:

- There is a need for maintaining refuge around the periphery of the fields. This refuge belt would serve the dual purpose of (i) trapping the pollen; and (ii) addressing resistance development.

- Shri Mahesh Sachdeva, Joint Secretary, Ministry of External Affairs suggested that there may be some arrangement of funds from the company to meet any eventuality, in the event of anything going wrong. Thus, he suggested could be a one-time deposit, or could be a cess on the sale of seeds, for a limited period. Shri Sachdeva also raised the issue of non-tariff barriers, which could be used for restricting the trade by importing countries. There is also a need for coordination and exchange of data with other countries growing Bt cotton.

- There is a need for continuously monitoring the susceptibility of insects, not only by the company, but also by an independent agency identified by the Ministry of Environment and Forests, at the company's cost.

- There is need for involving State Governments, and local bodies for monitoring the implementation of the conditions.

- There is a need for maintaining seed samples and DNA fingerprints of approved varieties of Bt cotton in the NBPGR.

- Based on these discussions, the following decision was worked out which was signed by all the members present.

Approval is hereby granted for release into the environment of three transgenic Bt hybrid cotton varieties, developed by MAHYCO namely, Bt MECH 12, Bt MECH 162, and bt MECH 184, containing Cry 1 Ac gene and *nptll* and *aad* marker genes subject to the following conditions:

i. The period of validity of approval is three years from April 2002- March 2005.

ii. Every field where Bt cotton is planted shall be fully surrounded by a belt of land called 'refuge' in which the same non-Bt cotton variety shall be sown. The size of the refuge belt should be such as to take at least five rows of non-Bt cotton or shall be 20% of total sown area whichever is more.

iii. To facilitate this, each packet of seeds of the approved varieties should also contain a separate packet of the seeds of the same non-Bt cotton variety which is sufficient for planting in the refuge defined above.

iv. Each packet should be appropriately labeled indicating the contents and the description of the Bt hybrid including the name of the transgenes, the GEAC approval reference, physical and genetic purity of the seeds. The packet should also contain detailed direction for use including sowing pattern, pest management, suitability of agro- climatic conditions etc., in vernacular language.

v. MAHYCO will enter into agreements with their dealers/agents, that will specify the requirements from dealers/agents to provide details about the sale of seeds, acreage cultivated, and state/regions where Bt cotton is sown.

vi. MAHYCO will prepare annual reports by **31*** March each year on the use of Bt cotton hybrid varieties by dealers, acreage, locality (state and region) and submit the same in electronic form to GEAC, if asked for by the GEAC.

vii. MAHYCO will develop plans for Bt based Integrated Pest Management and include this information in the seed packet.

viii. MAHYCO will monitor annually the susceptibility of bollworms to Bt gene vis-a-vis baseline susceptibility data and submit data relating to resistance development, if any, to GEAC.

ix. Monitoring of susceptibility of bollworms to the Bt gene will also be undertaken by an agency identified by the Ministry of Environment and Forests at applicant's cost.

x. MAHYCO will undertake an awareness and education programme, interalia through development and distribution of educational material on Bt cotton, for farmers, dealers and others.

xi. MAHYCO will also continue to undertake studies on possible impacts on nontarget insects and crops, and report back to GEAC annually.

xii. The label on each packet of seeds, and the instruction manual inside the packet should contain all relevant information.

xiii. MAHYCO will deposit 100 g seed each of approved hybrids as well as their parental lines with the National Bureau of Plant Genetic Resources (NBPGR).

xiv. MAHYCO will develop and deposit with the NBPGR, the DNA fingerprints of the approved varieties.

xv. MAHYCO will also provide to the NBPGR, the testing procedures for identifying transgenic traits in the approved varieties by DNA and protein methods.

2. The Ministry of Environment and Forests may stipulate additional conditions from time to time

3. The Ministry of Environment and Forests may revoke the clearance, if implementation of above stipulations is not satisfactory.

PART – B

Agenda item no. 3.2 : Import and marketing of r-human Insulin (Insuman Comb and other formulations) by MIS Aventis Pharma Ltd. Mumbai from HMR Deutschland Gmbh. Germany.

M/s Aventis Pharma Ltd., Mumbai had submitted a proposal for import and marketing of r-human Insulin from HMR Deutschland Gmbh**,** Germany**.** The Committee approved the proposal for import and marketing of r-human Insulin from environmental angle, subject to other required approvals.

Agenda item no. 3.3: Manufacture and marketing of recombinant human interferon alpha by M/s Shantha Biotechnics Pvt. Ltd.. Hyderabad

M/s Shantha Biotechnics Pvt. Ltd., Hyderabad had submitted a proposal for manufacture and marketing of r-human interferon alpha. The Committee approved manufacture and marketing of r-human interferon alpha from environmental angle subject to other required approvals.

Agenda item no. 3.4 : Import of recombinant HIV proteins for production of HIV Diagnostic Test kits by M/s J. Mitra and Co. Ltd., New Delhi from USA

M/s J. Mitra & Co. Ltd., New Delhi had submitted a proposal for import of r-proteins for production of HIV Diagnostic Test Kits from U.S.A. The Committee approved the proposal from environmental angle, subject to other required approvals.

Agenda item no. 3.5 : Import and marketing of Filgrastim (recombinant 300 mcg, 480 mcg human granulocyte - colony stimulating factor) by M/s Zydus Cadila Healthcare Ltd., Ahmedabad from M/s Biosidus, Argentina

M/s Zydus Cadila Healthcare Ltd., Ahmedabad had submitted a proposal for import and marketing of Filgrastim (recombinant 300 mcg, 480 mcg human granulocyte - colony stimulating factor) from M/S Biosidus, Argentina. The Committee approved the proposal from environmental angle subject to other required approvals. The Committee also decided that the company be asked not to use the term Filgrastim for this product.

Agenda item no. 3.6 : Permission to manufacture and market Ecovac - 4™ (Quadruple vaccine – Diphtheria, Tetanus, W-Pertussis and recombinant Hepatitis B) in two strengths (1-ug and 5 ug) by M/s Panacea Biotech Ltd.. New Delhi

The proposal was considered in the 26th meeting of GEAC. The comments from DCGl were not received at that time, and applicant had not provided information on the source of procuring vaccine other than Hepatitis B, status of approvals of other vaccines was also not mentioned. Thereafter, the applicant submitted the required information. The Committee decided that the data now received from the company may be circulated to

Deptt. of Biotechnology and Drug Controller General of India for their comments. Thereafter, the proposal may be considered by the GEAC.

Agenda item no. 4 : Any other item

Agenda item no. 4.1: Request from M/s L. G. Chemicals Pvt. Ltd. New Delhi for consideration of some conditions specified in sanction letter dated 23.10.01 regarding import for limited trials of r-Bovine Somatotropin

The GEAC in its 27th meeting held on 8.8.01 considered the proposal for import and marketing of r- Bovine Somatotropin (r-BST) by M/s L.G. Chemicals Pvt. Ltd. New Delhi form L.G. Chemicals, Korea and accorded approval for limited import of r-Bovine Somototropin for undertaking experimental trials through NDRI, Karnal for generating data on the following five parameters in 100 cows and 100 buffaloes.

I. Presence of pesticide residue in the milk.
II. Data on body temperature of BST – treated cattle.
III. Incidence of mastitis in BST – treated cattle.
IV. Incidence of delayed subsequent pregnancy in BST – treated cattle.
V. Incidence of diabetes in BST – treated cattle.

The company approached the GEAC with request to reduce the number of animals from 100 to 20 cows and 20 buffaloes and also to delete the parameters at (IV) and (V) above from the list.

The company has also informed the NDRI did not agree for conducting Phase III clinical trials due to feasibility reasons and other practical problems. The company is proposing to conduct the trials from IVRI, Izzatnagar, who have agreed to conduct the studies.

The Committee considered the request and agreed to delete the two parameters at (IV) and (V) above during the experimental trials. The Committee further agreed that parameters at (I) should be tested in animals with nutritional levels as prevailing in the Indian conditions.

Agenda Item No. 4.2: Request for locational change for manufacture and marketing of Hepatitis B antigen/ vaccine from Hyderabad to Pune by M/s. Serum Institute of India, Pune.

GEAC in its 21st meeting held on 08.11.1999 accorded approval to M/s. Transgene Vaccine Ltd., Hyderabad for manufacture and export of purified r-HBS Ag protein. Thereafter M/s. Transgene Vaccine Lab, Hyderabad was amalgamated with M/s. Serum Institute Pune. M/s Serum Institute Pune requested the GEAC for necessary locational clearance.

The proposal was considered in the 25th meeting of GEAC held on 27th March 2001 wherein it was agreed that shifting entails some other implications which require compliance under 1989 rules like setting up of IBSC and necessary of approvals from concerned State Government etc. It was therefore decided that the applicant may be asked to resubmit the proposal indicating all necessary compliance under the Rules. The Committee had rejected the proposal at that juncture for want of information compliance of statutory requirements.

The company has now complied with the formalities and informed the Ministry. The Committee took note of the above information.

Agenda Item No. 4.3: Re-validation of permission of Import and Marketing of Saizen (recombinant DNA, human growth hormone) by M/s. Serum Institute of India Ltd., Pune from M/s. Lab Serono, Switzerland.

The product was considered in the 15th meeting of GEAC held on 4th Nov 1997 and firm was given permission of import and marketing of the drug Saizen (r-DNA Hormone growth) from Laboratories Serono, Switzerland. Now they wish to renew the import from the same source, and have therefore requested the GEAC for revalidation of the permission for import and marketing of the product with the same technology.

As per rule 13(2) of the 1989 Rules, approvals of GEAC are valid for 4 years at the first instance and renewable for 2 years at a time.

It was decided that the applicant may be asked to submit the information in the proforma devised by the DBT and thereafter place the same before the Committee for consideration.

Agenda Item No. 4.4: Revalidation of permission for import and marketing of Somototropin Injection (r-DNA) by M/s. Eli Lily Company (India) Pvt. Ltd., New Delhi (formally M/s. Eli Lily Ranbaxy), New Delhi from M/s. Eli Lily Co., U.S.A.

The GEAC in its 15th meeting held on 4th Nov 1997 had approved import and marketing of the drug Somototropin injection by Eli Lilly Ranbaxy Ltd. from M/s. Eli Lily Co., U.S.A.

The firm wants to renew the import and marketing and has requested for revalidation of permission for import and marketing the product from the same source

As per Rule 13(2) of the 1989 Rules approvals of GEAC are valid for 4 years at the first instance and renewable for 2 years at a time.

The company informed that Eli Lilly Ranbaxy, which was earlier a 50-50 joint venture between ‘Eli Lilly and Co.’ and ‘Ranbaxy Lab Ltd.’ has now become a 100% wholly owned subsidiary of Eli Lilly and Company, subsequent to Ranbaxy divesting its 50% equity stake in the ownership of Eli Lilly Ranbaxy Ltd.

It was decided that the applicant may be asked to submit information in the proforma devised by the DBT and thereafter place the same before the Committee for consideration.

Agenda Item No. 4.5: Request from CRS for revising the quantity of Soybean Oil clearance by GEAC (vide sanction letter dated 2.1.02)

The GEAC in its 31st meeting held on 31.12.2002 had accorded clearance for held up consignment of Soya Oil (approximately 1000 MT) imported by the organization

The CRS informed the GEAC that this clearance will help clear only 50% of the oil received at Kolkata Port by CRS. The total amount held up at Kolkata Port is 2024 MT with the following details of shipment:

Shipment	Weight of oil in MT	Arrival data
PL 3935	199	01.05.01
PL 3939	150	22.04.01
PL 3943	738	10.06.01
PL 3950	070	05.08.01
PL 3951	546	14.09.01
PL 3953	119	11.10.01
PL 3953	202	21.10.01

The CRS has therefore requested the quantity of Soybean oil clearance from 1000 MT to 2024 MT.

The Committee felt that CRS continued import Soya oil, even when its application was still under consideration of GEAC. It was decided to communicate the Committee's displeasure over this to the applicant. The Committed agreed to accord clearance to the consignment.

Agenda Item No. 5.1: Import and marketing of Lantus (Insulin Glargine) for Diabetes by M/s. Aventis Pharma, Mumbai from M/s. Aventis Pharma Frankfurt, Germany

M/s. Aventis Pharma, Mumbai had submitted a proposal for import and marketing of Lantus (Insulin Glargine) for Diabetes from M/s. Aventis Pharma Frankfurt, Germany. The Committee approved the proposal from environmental angle subject to other required approvals.

Agenda Item No 5.2: Import and marketing of r-human growth hormone (eutropin) by M/s. L.G. Chemicals Pvt. Ltd., New Delhi from L.G Chemicals Korea.

M/s. L.G. Chemicals Pvt. Ltd., New Delhi had submitted a proposal for import and marketing of r-human growth hormone (Eutropin) from M/s. L.G. Chemicals, Korea. The Committee deferred the proposal as the members requested for more time to evaluate the proposal.

List of participants who attended 32nd meeting of GEAC on 26.03.2002

1. Shri A.M. Gokhale — Chairman
   Additional Secretary
   Ministry of Environment & Forests
   New Delhi

2. Shri Sushil Kumar — Co-chairman
   4/11, Sarvapriya Vihar
   New Delhi – 110 016

3. Dr. Mangla Rai
   Deputy Director General
   Indian Council of Agricultural Research
   Krishi Bhawan, New Delhi – 110 001

4. Shri Ashish Bahuguna
   Joint Secretary
   Department of Agriculture & Cooperation
   Krishi Bhawan, New Delhi – 110 001

5. Shri Mahesh Sachdeva
   Joint Secretary (ITP)
   Investment & Technology Promotion (ITP) Division
   Ministry of External Affairs
   South Block, New Delhi – 110 011

6. Dr. C.D. Mayee
   Director
   Central Institute of Cotton Research
   Nagpur

7. Shri S.K. Mahajan
   Head, Molecular Biology & Agricultural Division
   Bhabha Atomic Research Centre
   Bombay – 400 085

8. Shri A.B. Ramteke
   Drugs Controller General of India,
   Directorate of Health Services,
   Nirman Bhawan, New Delhi – 110 011

9. Shri R.P. Sharma
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   Indian Agricultural Research Institute
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