Brief record of the 33rd Meeting of GEAC held on 05.07.2002

The 33rd meeting of the GEAC was held on 05.07.2002 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 meeting. The Chairman referred to the minutes of the 32nd meeting of GEAC held on 26.03.2002, 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.

Agenda Item No. 3.1: Permission for production of hybrid seeds of MECH – 915 BT cotton in an area of 300 hectares during 2002-2003 by MAHYCO, Mumbai.

The GEAC in its 25th meeting held on 27.3.01 has accorded approval to MAHYCO for conducting large scale field trials of MECH -915 Bt cotton in Northern India. MAHYCO has requested the GEAC for permission for production of hybrid seeds of MECH-915 Bt cotton in an area of 300 hectares.

The Committee decided to approve the proposal with the same terms and conditions as were communicated to MAHYCO with the earlier approval for seed production of 3 Bt Cotton varieties, namely MECH 12, MECH 162 and 184.

Agenda Item 3.2: (a): Permission for import of Corn Soya Blend (CSB), refined vegetable soybean oil, and crude de gummed Soybean oil by CARE and CRS from US A.

The Committee discussed various aspects of this matter at length. Out of the three products, the refined Soya oil does not contain proteins or DNA, whereas the other 2 products certainly contain GM proteins or DNA. The Committee also considered the comments from ICMR regarding effects on human health. Some other attendant issues include labeling, threshold limit, traceability, effect on trade and commerce, etc. The policy in the Govt. with respect to GM foods is still evolving. In view of the above, the Committee decided to accord clearance for import of only Soya oil and not to allow the import of Corn Soya Blend and Crud degummed Soya oil, till a policy decision is taken on the matter relating to GM foods.

The Committee further agreed that clarifications may be sought from ICMR with respect to safety aspects of human health, specifically on issues raised in paragraph 2 of their comments, in consultation with Ministry of Health and Family Welfare. Specific comments may also be sought from Ministry of Commerce, Department of Women and Child Development, and Ministry of Social Justice and Empowerment.

Agenda Item No. 3.2 (b): Request from CRS and CARE for interim permission for clearing their next consignments of 510 MT (CRS) and 1200 MT (CARE) of refined Soybean Oil due to arrive in Kolkata in May / June 2002.

Considering that CRS and CARE have enclosed a certificate from USDA that the consignment of refined Soya oil due to arrive at Kolkata port of the same specification as the Soya oil imported earlier, the GEAC accorded clearance for the 510 MT of refined Soya oil (for CRS) and 1200 MT of refined Soya oil (for CARE) due to arrive at Kolkata Port in May – June 2002.

The Committee however resented that these organizations continued to import Soya oil when there application was still pending with the GEAC.

Agenda Item No. 3.3: Import of genetically modified *Pichia pastoris* cell line (104 vials X 1.5ml) from Cuba for manufacture and marketing r-Hepatitis B vaccine indigenously by M/s Panheber Biotech Pvt. Ltd., New Delhi.

M/s Panheber Biotech Pvt. Ltd., New Delhi had submitted a proposal for import of genetically modified *Pichia pastoris* cell line (104 vials X 1.5ml) from Cuba for manufacture and marketing r-Hepatitis B vaccine indigenously.

The Committee approved the proposal for import of genetically modified *Pichia pastoris* cell line (104 vials X 1.5ml) from Cuba for manufacture and marketing r-Hepatitis B vaccine indigenous from environmental angle, subject to other required approvals.

Agenda Item No. 3.4: Import and marketing of Mylotarg Injection (Gemtuzumab Ozogamicin) from M/s. Wyeth – Ayerest Research, New York – 10965 by M/s. Wyeth Lederle Ltd., Mumbai.

M/s. Wyeth Lederle Ltd., Mumbai had submitted a proposal for import and marketing of Mylotarg injection (Gemtuzumab Ozogamicin) from M/s. Wyeth – Ayerest Research, New York. The Committee approved the proposal from environmental angle subject to the other required approvals.

Agenda Item No. 3.5: Import and Marketing of Erythropoietin Injection from M/s North China Pharmaceuticals, China by M/s Claris Life Sciences Ltd., Ahmedabad.

M/s Claris Life Sciences Ltd., Ahmedabad submitted a proposal for import and marketing of Erythropoietin Injection from M/s North China Pharmaceuticals, China. The Committee approved the proposal from environmental angle, subject **a** to other required approvals.

Agenda item no. 3.6: lmport and marketing of r-human growth hormone (Europin) by M/s L.G. Chemicals Pvt. Ltd., New Delhi from M/s L.G. Chemicals, Korea.

M/s L.G. Chemicals 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 approved the proposal for import and marketing of r-human growth hormone (Eutropin) from environmental angle, subject to other required approvals.

Agenda item no. 3.7: lmport and marketing of Human Insulin (r-DNA) and its formulations from M/s Novo Nordisk A/S, Denmark by M/s Novo Nordisk lndia Pvt. Ltd. Bangalore

M/s Novo Nordisk lndia Ltd., Bangalore had submitted a proposal for import and marketing of Human Insulin (r-DNA) and its formulations from M/s Novo Nordisk A/s, Denmark. The Committee approved the proposal from environmental angle subject to other required approvals.

Agenda item no. 3.8: Manufacture and marketing of Ecovac – 4 (Quadruple Vaccine - Diptheria, Tetanus, W. Pertussis and r-Hepatitis -B) in two strengths (1 ug and 5 ug) by M/s Panacea Biotech Ltd., New Delhi

M/s Panacea Biotech Ltd., New Delhi had submitted the proposal for manufacture and market Ecovac - 4 (Quadruple Vaccine - Diptheria, Tetanus, W. Pertussis and r-Hepatitis B) in two strengths (1-ug and 5 ug**).** The committee approved the proposal from environmental angle, subject to other required approvals.

Agenda item no. 3.9: lmport and marketing of Drotrecogin Alpha (activated) - Xigris in two strengths - 5 mg and 20 mg vials by M/s Eli Lilly and Co (India) Pvt. Ltd., New Delhi from M/s DSM Pharmaceuticals, Inc., Greenville, U.S.A.

M/s Eli Lilly and Company (India) Pvt. Ltd., New Delhi had submitted a proposal for import and marketing of Drotrecogin Alpha (activated) - Xigris in two strengths - 5 mg and 20 mg vials from M/s DSM Pharmaceuticals, Inc, Greenville, U.S.A. The Committee approved the proposal from environmental angle, subject to other required approvals.

Agenda item no. 3.10 : lmport of already approved r-Hepatitis B surface antigen from CIGB, Cuba for manufacture and marketing of a pentavalent vaccine (Diptheria - Tetanus - Pertussis - Hepatitis B Haemophilus lnfluenzae b) by M/s Panacea Biotech, New Delhi

M/s Pancea Biotech, New Delhi had submitted a proposal for import of already r-Hepatitis B surface antigen from CIGB, Cuba for manufacture and marketing of a pentavalent vaccine (Diptheria - Tetanus - Pertussis - Hepatitis B – Haemophilus Influnzae b). The Committee approved the proposal from environmental angle, subject to the other required approvals.

Agenda item no. 3.11: lmport and marketing of Eptacog alfa (activated) r- Coagulation factor Vlla (r-F Vlla) Novo Seven from M/s Novo Nordisk A/S, Denmark by M/S Novo Nordisk India Pvt. Ltd., Bangalore.

M/s Novo Nordisk India Pvt. Ltd., Bangalore had submitted a proposal for import and marketing of Eptacog alfa (activated) r-Coagulation factor Vlla (r-F Vlla) Novo Seven from M/s Novo Nordisk A/S**,** Denmark. The Committee approved the proposal from environmental angle subject to other required approvals.

Agenda item no. 3.12 : lmport and marketing of recombinant Human alpha 2b interferon (3 miu), (5miu), (10 miu) from M/s Laboratorio Pablo Aires, Argentina by M/s lntas Pharmaceuticals Ltd., Ahmedabad.

M/s lntas Pharmaceuticals Ltd., Ahmedabad had submitted a proposal for import and marketing of r-Human alpha 2b interferon (3 miu), (5miu), (10 miu) from M/s Laboratorio Pablo Aires, Argentina. The Committee approved the proposal from environmental angle, subject to other required approvals.

Agenda item no. 3.13: lmport and marketing of r-Human GM-CSF 150, 300, 400 ug malgramostin from M/s Laboratorio Pablo, Aires, Argentina by M/s lntas Pharmaceuticals Ltd., Ahmedabad.

M/s lntas Pharmaceuticals Ltd., Ahmedabad had submitted a proposal for import and marketing of r-Human GM-CSF 150, 300, 400 ug malgramostin from M/s Laboratorio Pablo, Aires, Argentina. The Committee approved the proposal from environmental angle, subject to other required approvals.

Agenda item no. 3.14 : Manufacture and marketing of r-DNA Hepatitis B Vaccine by M/s Dr. Reddy's Laboratories Ltd., Hyderabad.

M/s Dr. Reddy's Laboratories Ltd., Hyderabad had submitted a proposal for manufacture and marketing of r-DNA Hepatitis B vaccine. The Committee approved the proposal from environmental angle, subject to other required approvals.

Agenda item no. 4.1: Revalidation of permission for import and marketing of somatropin injection (r-DNA) from M/s Eli-Lilly Co. USA by M/s Eli Lilly company (India) Pvt. Ltd., New Delhi.

M/s Eli Lilly company (India) Pvt. Ltd., New Delhi had submitted a proposal for revalidation of permission for import and marketing of Somatropin injection (r-DNA) from M/s Eli-Lilly Co. USA. The Committee approved revalidation of the approval for import and marketing of Somatropin injection (r- DNA) for two years with the same terms and conditions as were stipulated in the earlier section of GEAC.

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