**Decisions taken in the 70th Meeting of the Genetic Engineering Approval Committee held on 17.8.2006.**

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The 70th Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 17.8.2006 in the Ministry of Environment and Forests under the Chairmanship of Shri B S Parsheera Additional Secretary, MoEF and Chairman GEAC.

## 1.0 Consideration of Proposals

### 1.1 Permission for import of Indiage MAX L from M/s Genecor International, The Netherlands by M/s Lumis Pvt. Ltd.

1.1.1 The Committee noted that the present application is for import of Indiage MAX L –A cellulase enzyme produced by M/s Genecor International for use in denim washing. The present purpose of import is for value addition and subsequent export.

1.1.2 The Committee also considered the certificate from the supplier confirming that the enzyme is produced by different selected micro-organisms which have been genetically modified. However due to efficient separation process, no production strain is present in the final enzyme product. On this issue one of the Members opined that the presence or absence of production strain in the final product depends on the type of processing namely solid state fermentation process or submerged formation process. In the instant case the Committee noted that the product has been derived from the submerged fermentation process and therefore the presence of production strain is unlikely.

1.1.3 During the deliberations the Committee further noted that only importers availing import duty exemption under the Advance Licensing Scheme offered by DGFT are approaching the GEAC for clearance of such products. However there are several companies importing the recombinant enzymes for indigenous use. The Committee therefore desired that list of companies importing similar products be obtained from the applicant.

1.1.4 The Member Secretary informed the Committee that, the GEAC in its earlier meetings had approved the import of Denimax399S, Aquazyme and Denimax Acid XCL (cellulose enzymes) used by the textile industry for denim washing from M/s Novonenzyme Denmark by M/s Lumis Biotech Ltd after obtaining a declaration that the import is for value addition and subsequent export only subject to the following conditions:.

a) The DGFT would monitor the quantity of import and subsequent export after value addition.

b) The DGFT should direct the Company to follow 'Rules 1989' and obtain approval of GEAC prior to such imports in future.

1.1.5 Since the proposal under consideration is similar to the proposals earlier approved by the GEAC, the GEAC approved the import of Indiage MAX L from M/s Genecor International, by M/s Lumis Pvt. Ltd for value addition and subsequent export.

### 1.2 Permission for import and marketing of Phytase Enzyme (Poultry feed supplement) from Suson Industry Group Co. Ltd. Beijing, China by Elder Pharmaceuticals Ltd. Mumbai.

1.2.1 The Committee noted that the present request is for import and marketing of enzyme (Phytase) from China. The product is used for Poultry feed supplement.

1.2.2 The Member Secretary informed the Committee that the GEAC had earlier considered two applications namely import of the same product from the same source submitted by M/s Chembond Chemicals and the import of Finase PC enzyme (poultry feed supplement) from Germany by M/s Textan Chemicals Pvt. Both the proposals are pending consideration of the GEAC for want of comments from Department of Animal Husbandry.

1.2.3 After detailed deliberations it was decided that the three proposals may be referred to Food Technology Division, BARC and CFTRI for comments. The Committee also requested the Chairman GEAC to take up the matter with the Department of Animal Husbandry at the highest level. It was decided to reconsider the proposals in the next GEAC meeting.

**1.3 Permission for import of Lecithin (DNA –ve) and Standard Lecithin derived from Roundup Ready Soybean from ADM, USA by M/s Tina oils.**

1.3.1 The Committee noted that the present request from M/s Tinna Oil is for import of DNA –ve lecithin for use in confectionary industry and standard lecithin for use in the paint industry from ADM, USA. The Committee gave an opportunity to the applicant to present their case. During the deliberations the following points were noted:

1. M/s Tinna Oils and Chemicals Limited, JV partner of Archer Danniel Midland Company (ADM), headquartered at Decatur, USA, ADM is one of the largest agri-processors; processing com, wheat, soy and cocoa and are manufacturing value added ingredients from these basic crops.

2. Lecithin (DNA –ve) derived from Roundup Ready Soybean (a genetically modified soybean) is used by various food processing sectors like bakery, confectionery, dairy etc.

3. Even though the EC regulation and ANZFC –FSC standard A18 standards applicable for Australia and New Zealand exempts highly refined foods where modified DNA/ PROTEIN is not detectable, to assist the food manufactures , ADM has developed a documented program for the manufacture of GMO DNA Negative Specialty lecithin using mixed –source soybeans. The product has not been tested in any of the laboratories in India.

1.3.2 Standard Lecithin derived from roundup ready soybean is used in the paint industry. But since this material is meant for non edible application, no testing for presence of DNA have been carried out. The Committee sought clarification on the environmental implication of use of such product. The representative informed the Committee that the information will be obtained from the supplier and submitted to the GEAC.

1.3.3 After detailed deliberations, the Committee decided to obtain the following clarifications:

a. Details of the test results/ analytical report of Lecithin (DNA –ve) and Standard Lecithin from Sri Ram Laboratories / CFTRI / NIN. During the deliberations, one of the Expert Members advised that NIPER, Chandigarh which is a WHO accredited laboratory may also be considered. The Committee was of the view that for the present the three laboratories recommended in respect of Soybean oil may be considered. The Committee further requested the Member Secretary GEAC to seek the consent of NIPER in undertaking such assignments so that future proposal may be referred to them.
b. The list of countries importing Lecithin (DNA –ve) and Standard Lecithin.
c. The composition of the indigenously manufactured lecithin vs imported lecithin.
d. List of clients to whom the product is supplied.
e. Environmental implications and safeguards, if any for use of standard lecithin.

**1.4 Permission for export of transgenic groundnut seeds to South Africa for research purposes by International Crops Research Institute for Semi-Arid Tropics (ICRISAT), Patanacheru A.P.**

1.4.1 The Committee considered the request received from ICRISAT for export of 61 transgenic events in groundnut varieties JL 24 and ICGS 44 expressing the coat protein gene of the groundnut rosette assistor virus (GRAV) to South Africa for research purpose.

1.4.2 The Committee noted that JL 24 variety is an indigenous variety (ICAR variety) developed by National Research Centre for Groundnut , Junagarh Gujarat and ICGS 44 is a variety developed by ICRISAT. Both the varieties have been notified by the Central Seed Committee.

1.4.3 To a query on why the proposal has been referred to the GEAC, it was clarified:

a. Import of any Indian germplasm requires the approval of NBA under the Biodiversity Act
b. As per Rules 1989, approval of GEAC is mandatory prior to export of transgenic material.
c. In compliance with the requirement under the Cartagena Biosafety Protocol, approval of the National Competent Authority of the exporting country is necessary prior to import of the transgenic material.

1.4.4 It was further clarified that the proposal for export of Bt eggplant to Philippines and Bangladesh by M/s Mahyco was approved by the GEAC after seeking the recommendations of the Agro Biodiversity Task Force constituted by National Biodiversity Authority (NBA) and comments of Ministry of Agriculture and NBPGR. The export permission by GEAC was subject to the condition that the germplasm were initially bought from the country to where it is being exported.

1.4.5 In view of the above and taking into consideration that JL 24 is an Indian germplasm, it was decided that ICRISAT may be advised to obtain the approval of NBA. It was also decided to refer the proposal to Ministry of Agriculture and NBPGR.

**Reconsideration cases**

**1.5 Permission for manufacture of indigenous r-hepatitis C viral antigen core NS-3, NS-4 and NS-5 by Sundershan Biotech Ltd. Hyderabad.**

1.5.1 The present application is to commercialize the indigenously developed recombinant hepatitis C Viral antigens - Core NS3, NS4 and NS5 for use in diagnostic kits. The Committee noted that the proposal was considered by the GEAC in the meeting on 10.8.2005 wherein it was decided to obtain following information from the company:

- Details/results of the tests conducted at Centre for Liver Research & Diagnostics, Hyderabad. The results have been submitted.

- To obtain validation report from National Institute of Biological (NIB), which is the referral laboratory notified by Ministry of Health. The Company vide their letter dated 17th November, 2005 has informed that NIB is willing to take up the validation of complete diagnostic kit upon recommendation by Drug and Controller General of India (DCGI) but not the individual ingredients like antigens.

1.5.2 The proposal was reconsidered by the Committee in light of the recommendations of the Dr. Mashelkar Committee Report on R-Pharma adopted by the GEAC in its meeting held on 4.4.2006. As per the revised procedure, the present proposal falls under Protocol I as it involves use of LMOs during the manufacturing process. In such cases recommendation of RCGM on the containment

facility is mandatory prior to approval by GEAC. In the instant case since the same has not been received, decision on the proposal was deferred.

**1.6 Permission for import and marketing of purified Rabies Vaccine for human use (vero cell) manufactured by M/s Liaoning Cheng da Biotechnology Co. Ltd., China by May (India) Laboratories Pvt Ltd. Chennai.**

1.6.1 The Committee reconsidered the proposal in light of the recommendations of the Dr. Mashelkar Committee Report on R-Pharma adopted by the GEAC in its meeting held on 4.4.2006. It was noted that the Rabies Vaccine is an inactivated vaccine and has not been derived from a genetically modified organism. The Committee also considered the comments received from DBT vide their letter dated 20.2.2006.

1.6.2 In view of the above, the Committee decided to convey its no objection to the proposal subject to DCGI clearance. It was also decided to forward the views of DBT for consideration of DCGI.

**1.7 Permission for import of Finase PC enzyme for formulation from Germany and marketing in India by M/s. Textan Chemicals Pvt. Ltd.**

1.7.1 The proposal being similar to the proposal at agenda 4.2, decision taken therein would be applicable in this case also.

**1.8 Permission for import and marketing of enzyme Phytase (poultry feed supplement) from M/s Suson Industry Group Co. Ltd, Beijing, China by M/s. Chembond Chemicals Ltd. Mumbai.**

1.8.1 The proposal being similar to the proposal at agenda 4.2, decision taken therein would be applicable in this case also.

**1.9 Permission for import and conduct of Phase II clinical trials of Chimerivax tm – JE in children of descending age from USA by M/s Quintiles**

1.9.1 The Committee noted that the GEAC in its meeting held on 8.2.2006 had approved the conduct of Phase II clinical trials in children of descending age in India subject to the conditions that patients would be recruited in a phased manner. Subsequently in the GEAC meeting held on 2.5.2006, it was further clarified that in the first instance, the Company would complete the clinical trials in children of the higher age group (5 to 10 years) and submit the data for consideration of the GEAC before initiating the clinical trials in the lower age group.

1.9.2 The Committee considered the request of the Company to reconsider the decision taken in the GEAC meeting on 2.5.2006 on the grounds that this approach would cause delay (1 to 2 months) in completion of the clinical trials study and release of the product in India. Views were expressed that the clinical trials are conducted in healthy individuals and there is no recruitment of patients for the study. Besides, the total time for completion of the trials is not likely to be very long. Further it was noted that the vaccine has not been tested under phase-1 clinical trials.

1.9.3 In view of the above the Committee opined that the request of the Company does not merit consideration.

## 2.0 Other Items

### 2.1 Import of GM Soybean oil

2.1.1 The GEAC in its meeting held on 2.5.2006 had accorded approval as an interim measure for import of GM Soybean (RSVO and CDSO) subject to declaration that it has been derived from Round up Ready Soybean. For obtaining the final approval, the importers of GM Soybean oil have been advised to submit test result from either CFTRI /NIN/ Shri Ram Laboratories on the composition of the CDSO both pre and post processing as well as in the residue. The parameters to be monitored should include the herbicide level.

2.1.2 The Member Secretary briefed the Committee on the latest developments of the Soybean oil imports. It was noted that the test results are awaited since May 2006. Meanwhile DGFT with the approval of the Cabinet have extended the date for implementation of the DGFT notification for import of Soybean oil up to March, 2007.

2.1.3 The Committee was of the view that the Rules 1989 under EPA, 1986 is in force since, 1993. While the mandatory declaration under DGFT notification can be dispensed with until March, 2007, the statutory approval of the GEAC under Rules 1989 notified under EPA 1986 cannot be dispensed with until Rule 11 of the above mentioned Rules is suitably amended.

2.1.4 After detailed deliberations, the Committee opined that, the Soybean Oil Importers/ Association may be advised to submit the analytical report in respect of CDSO within a period of one month.

### 2.2 Representation received from Seed Industries

2.2.1 The GEAC in its meeting held on 30.6.2006 had taken a view that no specific approval for seed production is necessary for Bt Cotton expressing CRY 1 Ac gene (MON 531 Event). However, RCGM may obtain a declaration from the applicant along with the application that no seed production for commercial sale shall be undertaken till the hybrid is approved for commercial release.

2.2.2 The Committee considered the request received from seed industries to amendment the wordings of the declaration as that would imply no seed production on a commercial scale can be initiated until the hybrid is approved for commercial release. Therefore it would take two years before the hybrid is commercially released.

2.2.3 Views were expressed that the request of the seed industry merits consideration as the objective of deregulating the hybrids expressing cry1 Ac gene (Mon 531 event) gets defeated. After detailed deliberations it was decided to amend the wordings of the declaration as follows:

***"RCGM may obtain a declaration from the applicant along with the application for MLT that in case the hybrid ( name of hybrid to be indicated) is not approved for environmental release by the GEAC, the seeds if produced shall not be sold or used for any other purpose."***

2.2.4 The sub-committee had recommended at Page 17 para E (1) of the report that the yield comparison should be with a non Bt check. However in the GEAC meeting after extensive deliberation it was agreed that though the yield cannot be the primary parameter, for holistic assessment it should be compared with a recently released and related Bt check. The main objective of this amendment was to compare the efficacy of the technology and performance of the hybrid. This can be evaluated only when compared with the Bt check.

2.2.5 The request of the seed industry for amendment /deletion of the sentence that the "However the yield comparison should be with a recently released and related Bt check" was discussed and it was decided to amend the above sentence as ***"However, the performance of the test hybrid would be evaluated holistically with non Bt check, zonal check as well as Bt check as recommended by RCGM."***

**2.3 Representation received from Centre for Sustainable Agriculture regarding mortality in Sheep flocks after grazing on Bt Cotton field at Warangal Andhra Pradesh.**

2.3.1 The issues raised by the NGO regarding the adverse impact on cattle feeding with Bt cotton leaves was discussed in the GEAC meeting held on 1.6.2006 wherein the Committee decided to refer the matter to the State Department of Agriculture for a factual report on the allegation made by the NGOS and the findings of the post mortem report. It was noted that the response of the State Govt is awaited. The Committee also considered the representation dated 28th July 2005 received from Centre for Sustainable Agriculture forwarding the investigation report on sheep mortality and was of the view that comments of the State Government and IVRI needs to be obtained on the matter expeditiously.

2.3.2 The Committee sought clarification from the representative of DBT on the action taken regarding sponsoring a study to assess the problem at Warangal District with the help of local Veterinary Hospital in the district. It was informed that no proposal for conducting the study has been received. The Committee requested DBT to expedite the leaf toxicity studies study with the help of IVRI and local veterinary hospitals on a priority basis.

2.3.3 The Committee also requested the Chairman to take up the matter with the Principal Secretary, State Dept of Agriculture, Andhra Pradesh for expediting the factual report on the sheep mortality case at Warangal.

**3.0 Additional Agenda**

**3.1 Permission for 100 ha seed production of NCEH 2 R and NCEH 3 R Bt cotton by M/s Nath seeds.**

3.1.1 The Committee noted that the GEAC has approved conduct of LST with NCER 3 R Bt. in the Central Zone and NCEH 2 R Bt. in the South Zone subject to two years of LST and 10 ha seed production during first year LST. The Committee considered the request of the Company for 100 ha seed production.

3.1.2 The Member Secretary informed the Committee that a similar request was earlier received from M/s J.K.Seeds in respect of their hybrids JHCH 1050 Bt in North Zone, JKCH 666 Bt and JKCH 226 Bt. in Central Zone and JKCH 634 in the South Zone as these hybrids have completed 2 years ICAR trials. The request received from individual cases was referred by the GEAC to the Sub – Committee under Dr. C. D. Mayee, Chairman, ASRB and Co-Chair GEAC in the meeting held on 30.6,.2006. The Sub Committee in its meeting held on 12.7.2006 opined that cases which cannot be synchronized with the new procedure may be considered on a case to case basis based on one year LST and two year ICAR trial data. In cases such cases 100 ha seed production may be permitted during first year LST.

3.1.3 Since the request of M/s Nath Seeds is similar to that of J. K. Seeds, the Committee was of the view that the same decision would be applicable.

### 3.2 Permission for 100 ha. Seed production of Bt cotton hybrid Dhruv Bt (SCH 50064) by M/s Zuari seeds limited

3.2.1 The Committee noted that the GEAC in its meeting held on 2.5.2006 had approved conduct of LST with Dhruv Bt subject to 2 years LST and 10 ha seed production during first year LST. The Committee considered the request of the Company for 100 ha seed production on the ground that the hybrid has been recommended for notification during AICCIP workshop held at Dharwad during 7-9th April, 2006. The Committee noted that the recommendation for central notification is yet to be considered by the Central Varietals Release Committee of MoA only after which the hybrid can be notified.

3.2.2 After detailed deliberation the Committee opined that the case is pre-mature for consideration at this stage. The Applicant may be advised to submit their request along with the requisite details after issuance of the formal notification by MOA.

### 3.3 Permission for 100 ha. seed production of Bt cotton hybrid NCS 145 BG II (Bunny) and NCS 207 BG II (Mallika) by M/s Nuziveedu seeds limited

3.3.1 The GEAC in its meeting held on 4.2.2006, and 22.5.2006 had approved conduct of LST with NCS 145 BG II in all three Zones and NCS 207 BG II in the Central and South Zones subject to 2 years LST and 10 ha seed production during first year LST. The Committee considered the request for 1 year LST and 100 ha seed production with NCS 145 BG II (Bunny) and NCS 207 BG II (Mallika) on the grounds both the hybrids are Centrally Notified hybrids. As per the prevailing practice only one year of LST and one year ICAR trials is mandatory. In such cases 100 ha seed production is also permitted during first year LST. Since, NCS 145 and NCS 207 are centrally notified hybids, the Committee approved the request for one year LST and 100 ha seed production during first year LST.

### 3.4 Consideration of proposal for multi-locational trials recommended by RCGM in its meeting held on 31.7.2006.

3.4.1 In compliance with the Hon'ble Supreme Court Order dated 1.5.2006 in respect of WP NO 260/2005 – Aruna Rodrigues & Others vs Union of India, the Committee considered the recommendations made by RCGM in its meeting held on 31st July 2006 in respect of fifteen proposals for conduct of multi-location field trials of transgenic crops

3.4.2 After careful and in-depth consideration of the proposals and the recommendations of RCGM, the GEAC approved the proposals recommended by RCGM in the meeting held on 31.7.2006 and authorized Member Secretary, RCGM to issue the requisite communications in this regard.

### 3.5 Request for using different non Bt hybrids as refugia instead of the non Bt counterpart by M/s Rasi Seeds Ltd.

3.5.1 The Committee noted that sub-Committee on Bt Cotton and related issues has recommended that before taking a final view on the matter, it is advisable that studies on alternate IRM strategies be conducted with the help of SAU Punjab, CICR, Nagpur and SAU Dharwad for which RCGM may formulate different study modules. In view of the above the Committee opined that the request does not merit consideration at this stage.

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