

Decisions taken in the 71st Meeting of the Genetic Engineering Approval Committee held on 11.10.2006.

The 71st Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 11.10.2006 in the Ministry of Environment and Forests under the Chairmanship of Shri Desh Deepak Verma, Joint Secretary, MoEF and Vice - Chairman GEAC.

1.0 Consideration of Proposals.

1.1 Permission to import Soybean oil obtained from Round up Ready Soybean by M/s Solvent Extractors' Association of India, Mumbai.

1.1.1 The Committee noted that the GEAC in its meeting held on 2.5.2006 has 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.

1.1.2 The Member Secretary informed the Committee that the applicant has submitted the test results from SGS, an international laboratory as the institutions nominated by the GEAC are not coming forward to test the presence of GM events in Soybean oil.

1.1.3 The Committee considered the tests results conducted at Shriram Laboratories for conformity with PFA parameters in crude, refined oils and byproducts. The Committee noted that the tests results from Sri Ram Institute indicates that imported Crude degummed Soybean Oil and refined soybean oil obtained from Roundup Ready Soybeans seem be prima facie in conformity with the analytical requirements of PFA Rules.

1.1.4 The Committee also considered the test results from Shriram Laboratories on the glyphosate level in the Crude de-gummed Soybean Oil, refined soybean oil and its byproducts and noted that the Glyphosate content in refined oil was higher than the level in crude soybean oil. The Committee subsequently gave an opportunity to the applicant for presenting their views on this matter. It was informed that the Glyphosate in the refined oil and crude de-gummed soybean oil was subsequently tested in the Department of Entomology MPKV University at Rahuri. The data indicated that the levels of Glyphosate residues in different soybean oils ranged in between 0.197 and 0.350 ppm. Glyphosate residues were below the detection limit of 0.05 ppm in Soybean deodorized distillate. However, the Glyphosate level again showed higher value in the refined soybean oil as compared the de-gummed soybean oil. The reasons for such variations could not be explained and was attributed to the processing of soybean oil and properties of aromatic compounds. It was also noted that there is a significant variation in the Glyphosate level reported by Shriram Laboratories, Delhi and MPKV University Laboratory at Rahuri. During the discussion it was also clarified that Ministry of Health & Family Welfare, under PFA has not stipulated any norms form Glyphosate content in the oil. Neither there are any prescribed international standards.

1.1.5 After detailed deliberations it was decided that the presence of DNA / proteins and the Glyphosate level in the Crude de-gummed Soybean Oil, refined soybean oil and its byproducts needs to be tested either at CFTRI / NIN. The Committee authorized the Chairman, GEAC to take up the matter with Ministry of Health and Family Welfare for directing CFTRI / NIN to draw the samples and conduct the test for the above parameters on a priority basis to enable GEAC to take a view on the matter.

1.1.6 To a query on whether 'one time approval' for import of soybean oil would be obtained by the Oil Importers Association or individual importers it was decided that in the first instance a decision needs to be taken on whether the import of processed food like soybean falls under the purview of GEAC or not. Therefore, the matter may be discussed after receipt of the test results from CFTRI/NIN.

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

1.2.1 The Committee noted that the above request was considered by the GEAC in its meeting held on 17.8.2006 wherein it was decided to await the recommendation of RCGM on the containment facility which is mandatory prior to approval by GEAC as per Protocol I of the new procedure.

1.2.2 The Committee noted that the RCGM in its meeting held on 29.8.2006 has considered the recommendation of IBSC on the adequacy of the containment facilities and concluded that the containment facilities are adequate to meet the environmental safety regulation on cultivation of Genetically modified microorganisms and to purify recombinant Hepatitis C viral antigen. Based on recommendations of the RCGM, the Committee approved the above proposal.

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

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

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1.5 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.

1.3.1 The Committee noted that the above proposals were considered by the GEAC in its meeting held on 17.8.2006 wherein it was decided to await the recommendations of the Department of Animal Husbandry and Dairy, CFTRI and BARC. The Member-Secretary informed that comments have been received only from Dr A. K. Sharma, Baba Atomic Research Centre.

1.3.2 The Committee considered the recommendations received from BARC but was of the view that comments from CFTRI and Department of Animal Husbandry and Dairy may also be obtained. One of the expert members also pointed out that the phytase enzyme as poultry feed supplement has been banned in China and information on the reasons for banning the product also needs to be examined.

1.3.3 The Committee requested the Chairman, GEAC to take up the matter with CFTRI and Department of Animal Husbandry for submitting their comments expeditiously.

1.4 Approval for use of Non –Bt refugia not of the same hybrid during next Kharif.

1.4.1 The Committee considered the request made by M/s Rasi Seeds Limited vide their letter dated 27.9.2006 on the above subject. It was noted that based on the recommendation of the Sub-Committee on Bt Cotton and related issue which was adopted by the GEAC, the Company has organized production of popular non-Bt Cotton hybrid for meeting the requirement of refugia during Kharif 2007. Non – Bt seeds of the same Bt hybrid has not been produced.

1.4.2 In respect of the refugia, the sub-Committee had recommended "The non-Bt refugia seeds may not be of the same hybrid of Bt Cotton. Non Bt seeds of popular hybrids can be used as refugia".

1.4.3 The Member Secretary, RCGM explained that presently as per GEAC stipulation, non Bt seeds of the same Bt counterpart are provided by the Companies along with the Bt cotton seeds to farmers for planting the refugia. However, the non Bt seeds are used by farmers for gap filling instead of the stipulated refugia because of which it appears that many of the Bt plants have not germinated properly or are susceptible to bollworms. This is often construed by NGOs as a failure of Bt technology.

1.4.4 The Member Secretary GEAC further clarified that the present request is not for amendment of the conditions stipulated by the GEAC for maintaining the same non Bt counterpart as refugia but are for the next Kharif season. Views were also expressed that significant variation in the cotton quality may have an impact on trade as it may not fetch the optimum market price.

1.4.5 After detailed deliberations, the Committee was of the view that non Bt counterpart of the same species, similar duration and similar fibre quality may be used as refugia in place of the same non Bt counter part. The above decision would be applicable for all applicants during Kharif 2007.

2.0 Information Items:

2.1 Consideration of proposal for multi-locational trials recommended by RCGM in its meeting held on 29.8.2006.

2.1.1 The Committee considered 9 proposals for field trials of transgenic crops recommended by RCGM in its meeting held on 29.8.2006. However in accordance with Supreme Court order dated 22.9.2006 in respect of WP 260/2005 in IA NO 4/2006, directing the GEAC to withhold approvals until the matter has been heard and further directions are issued by the Court, decision on the 9 proposals forwarded by RCGM in accordance with the earlier Supreme Court order dated 1.5.2006 was deferred.

2.1.2 The Member Secretary GEAC informed that the matter has been listed for hearing on 13.10.2006 and MoEF is in the process of filing its counter affidavit for vacating the stay.

2.2 First meeting of the Expert Group on Bt Brinjal held on 25.9.2006 under the Chairmanship of Prof Deepak Pental, VC, Delhi University.

2.2.1 The Member Secretary informed the Committee that the first meeting of the Expert Committee on Bt Brinjal was held on 25.9.2006 under the chairmanship of Prof Deepak Pental Vice Chancellor of Delhi University. She briefly explained the deliberations of the meeting and informed the Committee that the experts have been requested to submit their views based on which a detailed reply to issues raised by stakeholders and recommendations to the GEAC would be prepared.
