Decisions taken in the 89th meeting of the Genetic Engineering Approval Committee held on 8.10.2008.

The 89th meeting of the Genetically Engineering Approval Committee (GEAC) was held on 8.10.2008 in the Ministry of Environment and Forests under the Chairmanship of Dr. C. D. Mayee, Co-Chairman GEAC in the absence of Shri. B.S. Parsheera, Additional Secretary, Chairman GEAC, who was on leave.

The deliberations of the GEAC in respect of Agenda Item 4 are as follows:

Agenda Item No 4: Consideration of Proposals

4.1 Permission for manufacture and commercialization of recombinant Chymosin by M/s. Sudershan Biotech Ltd. Hyderabad.

4.1.1 The Committee considered the request of M/s Sudershan Biotech Ltd, Hyderabad for manufacture and commercialization of recombinant Chymosin in India. Chymet, developed by the applicant is a recombinant form of Chymosin used in manufacturing of cheese. Intended use of the product is to increase the shelf life of cheese consumed by human population

4.1.2 The Committee noted that the applicant has conducted pre-clinical toxicology studies from Indian Institute of Chemical Technology (IICT) to evaluate the potential toxicity of recombinant Chymosin, if any, on single and repeated doses of oral administration to mice, rats and rabbits. The preclinical toxicology report has been evaluated by the RCGM in its meetings held on 3.9.2007 and 25.1.2008. RCGM has recommended the proposal and directed the applicant to approach the GEAC for further approvals vide their letter dated 25.2.2008. The Committee also noted that the additional information sought by the expert member in the meeting held on 25.6.2008 has been provided to his satisfaction.

4.1.3 After detailed deliberations and taking into consideration the recommendations of the RCGM and comments of the Expert Members, the GEAC conveyed its "no objection" to the proposal.

4.2 Permission for import of recombinant CHY-MAX by M/s. Chr. Hasen (India) Pvt. Ltd Mumbai from M/s Chr. Hasen A/S, Denmark.

4.2.1 The Member Secretary, GEAC informed that the above proposal has been forwarded by the Ministry of Commerce and Industry seeking clarification on whether the product is GM or not. The Committee noted that the product was being imported under the HSN Code "3507- Enzymes, prepared enzymes not else where specified or included, 3507 90- other, 3507 90 99 – other-Free. In March 2007 the Custom Authorities in Mumbai disallowed import of this product under the above HSN Code. They felt that this should be classified under 35070000 which is prohibited under the present EXIM Policy. The Committee also considered the comments of DBT, Ministry of Agriculture, Department of Animal Husbandry, Dairying and Fisheries, National Dairy Development Board and National Dairy Research Institute, Karnal in this regard.

4.2.2 The Committee gave an opportunity to the applicant to present their case. The following points were noted:

i. CHY-MAX^{tm} is a milk clotting product containing: (i) a pure enzyme chymosin B, is the core and active molecule of the product and (ii) formulated with salt and a preservative to maintain its enzymatic and microbiological integrity.
ii. There is no "organism" in final product available in the market.
iii. The chymosin B was produced by a modified micro-organism but is not extracted from this micro-organism and therefore is not "derived from a GMO".

iv. The product is only composed of chymosin B. There is no fungal residue in the product available on the market and no trace of the fungus used to produce the enzyme.

v. The product is in the market since 1990. The product is being used in countries like France, Italy, Germany, Netherlands, USA, Canada, Japan and Australia. The same is being imported into India and used since the last 7-8 years by all major cheese producers namely; Amul, Britannia, Dynamix Dairy and Parag Milk.

vi. The safety documentation has been evaluated by the EU Scientific Committee on Food (SCF) and the Codex Expert committee, JECFA (JOINT FAO/WHO EXPERT Committee on Food Additives). All of them delivered favorable opinions on the same. JECFA's evaluation was published in its 37th report, 1991 (WHO technical report series vol. 806, pp 13-14).

vii. The product is neither subject to authorization nor to the labeling requirements as per the EU regulations.

4.2.3 After detailed deliberations and taking into consideration the views expressed by DBT, Ministry of Agriculture and other departments, the Committee conveyed its ` no objection' to the request for import of recombinant CHY-MAX.

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