

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

ICE STRUCTURING PROTEIN PREPARATION

Issue

The Committee is invited to consider a draft opinion on Unilever's ice structuring protein preparation.

Background

1. Members first considered Unilever's application for the authorisation of an ice structuring protein (ISP) preparation derived from a genetically modified baker's yeast as a novel food ingredient at their July 2006 meeting (ACNFP/78/2). Members requested additional information from Unilever on this application. This was considered by Members in September 2006 and January 2007 (ACNFP/79/5 and ACNFP/80/2).
2. At the January meeting, the Committee concluded their assessment of this application and asked the Secretariat to prepare a draft opinion on the marketing of Unilever's ISP preparation (see **Annex 1**). The Committee recommended that the novel ingredient should be labelled as derived from a yeast source.
3. The Committee also queried whether the ISP preparation should be labelled as derived from a GM source. The Secretariat has consulted the Agency's experts on GM labelling who have advised that, in line with the conclusions recorded in a recent European Commission report to Council (**Annex 2**), the ISP does not need to be labelled as derived from a GM source because the GM yeast is being used as a processing aid and will not be present in the final product.
4. The Committee also agreed that allergy experts should consider a case report recently published in *The Annals of Allergy, Asthma and Immunology*. This paper is attached as **Annex 3**.

Committee Action Required

5. The Committee is asked whether it has any additional comments to make on the potential of the novel food ingredient to induce reactions in yeast allergic individuals in light of the information provided in the paper attached as Annex 3.
6. The Committee is asked whether it is satisfied with the proposed draft opinion.
7. If so, the Secretariat will publish this draft opinion on the Agency's website for a 10-day public consultation. Any comments received will be passed on to the Committee for its consideration.

8. If not, the Committee is asked to indicate what amendments are required.

**Secretariat
March 2007**

Annexes attached:

Annex 1 – Draft opinion (**restricted**)

Annex 2 – Extract of report from the Commission to the Council and the European Parliament on the implementation of Regulation (EC) no 1829/2003 of the European Parliament and of the Council on genetically modified food and feed

Annex 3 – K. Airola et al (2006). Case report. Clustered sensitivity to fungi: anaphylactic reactions caused by ingestive allergy to yeasts. *Annals of Allergy, Asthma and Immunology*. **97**, 294-297.

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Draft opinion (restricted)

**Secretariat
March 2007**

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Extract from the report from the Commission to the Council and the European Parliament on the implementation of Regulation (EC) no 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (October 2006)

Section 10 - Status of food or feed produced by fermentation using genetically modified micro-organisms not present in the final product

Available at: http://eur-lex.europa.eu/LexUriServ/site/en/com/2006/com2006_0626en01.pdf

**Secretariat
March 2007**

10. Status of food or feed produced by fermentation using genetically modified micro-organisms not present in the final product

10.1. Background

Upon the adoption of the Common Position regarding the proposal for the Regulation on GM food and feed, the following declaration was made “*The Council and the Commission agree that the status of food produced by fermentation using genetically modified micro-organisms not present in the final product, needs to be clarified, at the latest in the context of the report to be presented by the Commission as foreseen in Article [48] of the Regulation.*”

From the answers received from the Member States and stakeholders, one may conclude that there is a general opinion that a safety assessment of this type of products should be mandatory prior to their placing on the market. It is also mentioned that a great part of these products (for example food and feed additives) have already undergone an authorisation procedure that includes a safety assessment. All stakeholders were opposed to the GM labelling of this type of products. Few Member States are in favour while others are directly opposed to such a labelling.

10.2. Clarification of the status of food or feed produced by fermentation using genetically modified micro-organisms not present in the final product

The status of food or feed produced by fermentation using genetically modified micro-organisms has to be clarified in the light of the recital n° 16 of the Regulation. When the GM micro-organism is used as a processing aid, the food and the feed resulting from such production process are not to be considered as falling under the scope of the Regulation.

10.3. Application of the clarification to food products and processing aids

Article 1 of Directive 89/107/EC OJ L 40, 11.2.1989, p. 27. defines food processing aids as “any substance not consumed as a food by itself, intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect in the finished product”.

This may be the case, for example, when the micro-organisms are removed after the fermentation and that the produced food is further purified in the production process or when the micro-organisms are attached/fixed to a support/matrix in such a way that it is used during the treatment or processing of the food but it is not transferred into the final product as such or under an altered form.

When the GM micro-organisms are not removed during the production process, they are not used as processing aids. In these cases, the produced foods and food ingredients fall under the scope of the Regulation and have to be authorised and labelled accordingly.

It is to be underlined that an extended range of food produced using GM micro-organisms as processing aids are already subject to requirements consisting in a safety assessment and a pre-market approval, or will be subject to such requirements by the way of new proposed legislation in the near future. It is the case for food additives (subject to Directive 89/107/EC as amended), flavourings (subject to Directive 88/388/EC OJ L 184, 15.7.1988, p. 61.), and food enzymes. For these 3 types of substances, the Commission is finalising proposals to the European Parliament and the Council. It may also be the case for the placing on the market of food and food ingredients produced with new GM micro-organisms if they fall within the scope of Regulation (EC) No 258/97 OJ L 43, 14.2.1997, p. 1., and in particular art.1(2)(f) thereof: “foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances”.

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K. Airola et al (2006). Case report. Clustered sensitivity to fungi: anaphylactic reactions caused by ingestive allergy to yeasts. *Annals of allergy, asthma and immunology*. **97**, 294-297.

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