

COMMISSION DECISION

of 22 April 2009

authorising the placing on the market of Ice Structuring Protein type III HPLC 12 as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2009) 2929)

(Only the English text is authentic)

(2009/344/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients⁽¹⁾, and in particular Article 7 thereof,

Whereas:

- (1) On 8 June 2006 Unilever made a request to the competent authorities of the United Kingdom to place the Ice Structuring Protein type III HPLC 12 on the market as a novel food ingredient.
- (2) The Ice Structuring Protein (ISP) type III HPLC 12 is produced using a genetically modified yeast as a processing aid. Pursuant to recital 16 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council⁽²⁾, food and feed which are manufactured with the help of a genetically modified processing aid are not included in the scope of that Regulation. The Report from the Commission to the Council and the European Parliament on the implementation of that Regulation⁽³⁾ has clarified that the authorisation and labelling requirements set out in the Regulation are not applicable to food or feed produced by fermentation using genetically modified micro-organisms.
- (3) On 27 July 2007 the competent food assessment body of the United Kingdom issued its initial assessment report. In that report it came to the conclusion that the use of the Ice Structuring Protein as a food ingredient was acceptable.
- (4) The Commission forwarded the initial assessment report to all Member States on 1 August 2007.

(5) Within the 60-day period laid down in Article 6(4) of Regulation (EC) No 258/97 reasoned objections to the marketing of the product were raised in accordance with that provision.

(6) Therefore the European Food Safety Authority (EFSA) was consulted on 25 February 2008.

(7) On 9 July 2008, following a request from the Commission, the Panel on Dietetic Products, Nutrition and Allergies of EFSA adopted a Scientific Opinion on the safety of Ice Structuring Protein (ISP) type III HPLC 12 as a food ingredient. That Opinion was also adopted by the Panel on Genetically Modified Organisms on 2 July 2008. In the Opinion EFSA concluded that the use of the Ice Structuring Protein (ISP) type III HPLC 12 in edible ices is safe.

(8) On the basis of the scientific assessment, it is established that the Ice Structuring Protein (ISP) type III HPLC 12 complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Ice Structuring Protein type III HPLC 12 as specified in the Annex may be placed on the market in the Community as a novel food ingredient for the preparation of edible ices.

The content of the Ice Structuring Protein type III HPLC 12 in edible ices shall not exceed 0,01 %.

Article 2

The designation of the novel food ingredient authorised by this Decision on the labelling of the foodstuff containing it shall be 'Ice Structuring Protein'.

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.

⁽²⁾ OJ L 268, 18.10.2003, p. 1.

⁽³⁾ COM(2006) 626 final.

Article 3

This Decision is addressed to Unilever UK, Walton Court, Station Avenue, Walton-on-Thames KT12 1NT, Surrey, United Kingdom.

Done at Brussels, 22 April 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

Specifications of Ice Structuring Protein type III HPLC 12

The Ice Structuring Protein (ISP) preparation is a light-brown liquid produced by submerged fermentation of a genetically-modified strain of food-grade baker's yeast (*Saccharomyces cerevisiae*) in which a synthetic gene for the ISP has been inserted into the yeast's genome. The protein is expressed and secreted into the growth medium where it is separated from the yeast cells by micro-filtration and concentrated by ultra-filtration. As a result, the yeast cells are not transferred into the ISP preparation as such or under an altered form. The ISP preparation consists of native ISP, glycosylated ISP and proteins and peptides from the yeast and sugars as well as acids and salts commonly found in food. The concentrate is stabilised with 10 mM citric acid buffer.

Assay	Not less than 5 g/l active ISP
pH	2,5 to 3,5
Ash	Not more than 2 %
DNA	Not detectable
