ACNFP

THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Ice structuring protein (ISP) preparation derived from genetically modified baker's yeast *Saccharomyces cerevisiae*

The safety of this novel food ingredient was considered by the Advisory Committee on Novel Foods and Processes (ACNFP) between July 2006 and July 2007.

The aim of this fact sheet is to provide members of the public with information about this food ingredient and its proposed use in ice cream and other iced products.

Introduction

Unilever, one of the world's largest manufacturers of ice cream and other edible ices, has an interest in finding new ways of producing products, such as ice cream with fewer calories and less fat and sugar. But removing these ingredients is challenging as they have an important role in forming the texture and taste of ice cream.

Unilever has, therefore, carried out research into certain proteins that occur naturally in animals and plants living in cold climates. These proteins offer protection against very cold conditions by binding to ice crystals and controlling their growth, preventing tissue damage. These proteins are called ice structuring proteins (ISP) or anti-freeze proteins (AFP).

When ISP are used in the manufacture of frozen products they help with the formation of a large number of very small crystals, instead of the smaller number of relatively large ice crystals found in conventional frozen foods. These very small ice crystals provide a structure that differs from existing products allowing, for example, the production of ice cream with a low fat content.

Unilever's ISP preparation

Specifically Unilever looked at an ISP found in a cold water fish, the ocean pout (*Macrozoarces americanus),* which lives in deep waters off the North East American coast. Unilever decided that it was not sustainable or economically feasible to extract this protein from ocean pout. It therefore developed a strain of baker's yeast (*Saccharomyces cerevisiae*) that can produce the same ISP. This yeast has been genetically modified by inserting a synthetic gene that provides a "blueprint" for the ISP that is found in ocean pout. The genetically modified (GM) yeast is fermented under controlled conditions in sealed containers. The ISP preparation is then extracted from the fermentation mixture.

Similar fermentation processes using GM technology are used to make many other food ingredients including citric acid and food enzymes, such as the milk-clotting agent used in the manufacture of some vegetarian cheese.

The ISP preparation is a light brown liquid that contains about 20% proteins, including about 10% ISP. Other components are derived from the yeast and these will also be present in existing foods and ingredients that are derived from baker's yeast.

Risk assessment

The ACNFP considered the safety of Unilever's ISP preparation under the novel foods regulation, which requires any novel ingredient to comply with three criteria, namely:

- It must not present a danger to the consumer,
- It must not mislead the consumer,
- It must not be nutritionally disadvantageous compared with foods which it might replace.

Unilever's ISP preparation

Unilever's ISP preparation contains ice structuring proteins, yeast proteins, peptides, sugars, acids and salt. It is produced by using accepted principles of good manufacturing practice in order to ensure that it is microbiologically safe for consumption.

Unilever is planning to use its ISP preparation at levels up to 0.2% (equivalent to 0.01% of the ISP component) in a range of ice cream products including dairy ice cream, milk ice, water ice, fruit ice, sorbets, frozen desserts and iced smoothies. It will be used to facilitate the manufacture of ice cream products with reduced fat content whilst keeping their taste and mouthfeel acceptable. It will also help to keep the structure of ice cream product stable.

GM baker's yeast Saccharomyces cerevisiae

The production process is designed to remove all yeast cells from the ISP preparation and the final product does not contain any intact GM microorganisms although GM yeast proteins are present.. Unilever has tested its ISP preparation for contamination with DNA derived from the inserted ice structuring protein gene in the yeast and it has found no trace of DNA contamination.

Toxicity

Unilever has tested the safety of its ISP ingredient by carrying conventional toxicity studies. Unilever has additionally shown that its preparation has no effects on the immune system, whether inhibitory or stimulatory. These tests showed that the ISP preparation is safe for human consumption at the proposed level of use.

Allergenicity

- Fish allergy

Tests have been carried out to show that fish-allergic individuals do not react to the ISP preparation. Therefore, the ice structuring protein preparation can safely be consumed by people with existing allergy to fish.

- Yeast allergy

Some individuals have an allergy to yeast and suffer reactions when particles of yeast are inhaled into the lungs. The majority of people who react like this can still eat bread and other products containing yeast. Nevertheless, a small number of individuals do suffer reactions to yeast in food and the yeast proteins in the ISP preparation could provoke allergic reactions in these people.

Labelling

The use of the ISP preparation would be indicated in the ingredient list of any products that were manufactured using it. In view of the potential risk to people with yeast allergy, the ACNFP has advised that the source of the ISP preparation should be indicated.

The ISP protein is not manufactured from fish but from genetically modified yeast and it may therefore be acceptable to vegetarians..

The ACNFP has also considered the use of genetic modification in the manufacture of this ingredient. This use of GM technology is different from many other GM foods, which are typically prepared from GM crops such as maize or soya. Nevertheless, the ACNFP recognises that there is considerable public interest in the use of GM technology and has recommended that consumers should be informed that the ISP ingredient is manufactured using a genetically modified yeast.

ACNFP Conclusion

In July 2007, the ACNFP issued a positive opinion for the marketing of this novel ingredient in the EU.

Overall, the ACNFP was satisfied that Unilever's ISP preparation meets the criteria for acceptance of novel food ingredients and that it can be used in the range of ice cream products and other edible ices proposed by Unilever.

The ACNFP recommended that information should be provided in an easily-accessible format to consumers indicating that the ingredient is manufactured using a GM yeast, so consumers are adequately informed about the nature of the ISP ingredient in the products they are purchasing.

The ACNFP's full opinion is available at:
http://www.acnfp.gov.uk/assess/fullapplics/isp

What next

The ACNFP opinion on Unilever's ISP preparation is forwarded to the European Commission. The Commission will distribute this document to the other 26 Member States for a 60-day period during which they can comment or provide reasoned objections. If all are agreed, the applicant will be informed by the EC of the decision. If not, a decision will be taken by majority vote. Before any vote, any outstanding technical or scientific issues can be examined by the European Food Safety Authority (EFSA).

Note: Unilever's ISP preparation has already been authorised for use in Australia, New Zealand, Chile, Indonesia, Mexico, the United States and the Philippines under their local regulatory procedures. Edible ices containing this preparation have been on the market in the USA since 2003, with no reported consumer issues. Similar products have also been on sale in other countries such as the Philippines since 2004 and Australia since August 2006.

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Information on the ACNFP is available at:
http://www.acnfp.gov.uk/

Further information can be obtained by contacting the ACNFP Secretariat at the address below:

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