Consultation Document on Health Canada’s Proposal to Enable the Use of a New Food Additive, Ice Structuring Protein, to Modify the Texture of Unstandardized Edible Ices and Unstandardized Frozen Desserts

Notice of Proposal – Lists of Permitted Food Additives

January 03, 2014
Summary

Food additives are regulated in Canada under Marketing Authorizations (MAs) issued by the Minister of Health and the Food and Drug Regulations. Approved food additives and their permitted conditions of use are set out in the Lists of Permitted Food Additives that are incorporated by reference in the MAs. A petitioner can request that Health Canada approve a new additive or a new condition of use for an already approved food additive by filing a food additive submission with the Department's Food Directorate. Health Canada uses this premarket approval process to determine whether the scientific data support the safety of food additives when used under specified conditions in foods sold in Canada.

Health Canada has received a food additive submission seeking approval for the use of ice structuring protein, type III HPLC 12, obtained from Saccharomyces cerevisiae CEN.PK K338 (ice structuring protein type III), at a maximum level of use of 0.01% (100 parts per million), to modify the texture of unstandardized edible ices and unstandardized frozen desserts.

The results of Health Canada’s evaluation of available scientific data support the safety and efficacy of ice structuring protein type III when used for this purpose. Therefore, it is the intention of Health Canada to modify the List of Permitted Food Additives with Other Generally Accepted Uses by adding an entry to this list as indicated below.

Proposed Modification to the List of Permitted Food Additives with Other Generally Accepted Uses:

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Column 1 Additive</th>
<th>Column 2 Permitted in or Upon</th>
<th>Column 3 Purpose of Use</th>
<th>Column 4 Maximum Level of Use and Other Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.1</td>
<td>Ice Structuring Protein Type III HPLC 12 from Saccharomyces cerevisiae CEN.PK K338</td>
<td>Unstandardized edible ices; Unstandardized frozen desserts</td>
<td>To modify texture</td>
<td>100 p.p.m.</td>
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</tbody>
</table>

Rationale

Health Canada’s Food Directorate has completed a pre-market safety and efficacy assessment of ice structuring protein type III when used as described in the table above. The assessment considered toxicological, chemical, microbiological, nutritional and technical aspects of the proposal.
Ice structuring proteins are naturally occurring proteins found in a wide variety of organisms. These proteins protect the organism from damage caused by ice formation by lowering the temperature at which ice nuclei grow and by modifying the size and shape of ice crystals that are formed. Ice structuring proteins have been found in many freeze-tolerant organisms including cold water fish, higher plants such as wheat and rye grass, as well as lichen, insect larvae and bacteria.

The specific ice structuring protein that is the subject of this notice was first isolated in ocean pout, a species of cold water fish, and is qualified as “Ice Structuring Protein Type III HPLC 12”, based on its structure and form. To ensure a consistent, reproducible commercial supply of ice structuring protein type III, a production system was developed which produces the ice structuring protein type III based on fermentation using genetically modified baker’s yeast (Saccharomyces cerevisiae).

The ice structuring protein type III preparation is a mixture of ice structuring protein, glycosylated ice structuring protein (ice structuring protein bound to the sugar mannose), proteins and peptides from the yeast and sugars, acids and salts commonly found in food. It is this preparation that is intended to be added to unstandardized edible ices and unstandardized frozen desserts prior to freezing. When added to these foods, ice structuring protein type III does not prevent freezing but influences the growth and structure of ice crystals during their formation and hence the physical properties of these frozen foods. By changing the structure of ice in these foods, ice structuring protein type III delivers products with increased hardness that can be used to deliver novel texture or improved melt resistance.

The safety of ice structuring protein type III was demonstrated in studies that considered the potential toxicity of the ice structuring protein type III protein and the commercial preparation itself. The toxicological testing strategy is similar to that required for other food materials produced by fermentation (e.g., enzymes) and was considered adequate to substantiate the safety of the ice structuring protein type III preparation.

Using accepted testing strategies, no primary sequence similarities between ice structuring protein type III and the sequence of any known allergens, including fish allergens, were found. Evidence also indicated that the ice structuring protein type III and its glycoforms have a low level of resistance to intestinal enzymes. As such, the proposed use of the ice structuring protein type III preparation is not considered to pose an allergenic safety concern.

No microbiological or nutritional safety concerns have been identified for the proposed use of ice structuring protein type III.

Ice structuring proteins are naturally consumed in the diet through the consumption of fish, oats, rye, barley, wheat, carrot and potato. There is a history of safe human consumption of ice structuring protein type III protein at levels comparable to the proposed use of the ice structuring protein type III preparation.
Based on the results of the safety assessment, Health Canada's Food Directorate considers that the data support the safety of ice structuring protein type III when used under the conditions of use set out in the table above. The Department is therefore proposing to enable the use of ice structuring protein type III as described in the table.

Other Relevant Information

In the United States of America, a Generally Recognized as Safe (GRAS) notice for ice structuring protein Type III (GRN 000117) was submitted to the Food and Drug Administration (FDA) for review on October 23, 2002. In a response letter dated April 17, 2003, the US FDA did not raise any objections regarding the petitioner’s determination of GRAS status of its ice structuring protein preparation for use as a texturizer in frozen novelty desserts at a level of 0.01% (100 p.p.m.).

Australia and New Zealand permit the use of ice structuring protein Type III HPLC 12 in the manufacture of ice cream and edible ices at a maximum permitted level of 100 mg/kg (100 p.p.m.).

The European Union permits the use of ice structuring protein Type III HPLC 12 as a novel food for the preparation of edible ices (includes ice cream products) at a maximum use level of 0.01% (100 p.p.m.).

Ice structuring protein Type III is not listed in the Codex General Standard for Food Additives (GSFA).

Implementation and Enforcement

The proposed changes will be effective the day on which they are published in the List of Permitted Food Additives with Other Generally Accepted Uses. This will be announced via a Notice of Modification which will be published on the Food and Nutrition - Public Involvement and Partnerships section of Health Canada’s Website.

The Canadian Food Inspection Agency is responsible for the enforcement of the Food and Drugs Act and its associated regulations with respect to foods.

Contact Information

For additional information or to submit comments related to this proposal, please contact:

Bureau of Chemical Safety, Food Directorate

If communicating by e-mail, please use the words “ice structuring protein” in the subject line of your e-mail. Health Canada is able to consider information received by March 18, 2014, 75 days from the date of this posting.