Notice of Modification to the List of Permitted Food Enzymes to Enable the Use of Transglutaminase from Streptoverticillium mobaraense S-8112 in Bread, Flour, Whole Wheat Flour, and Unstandardized Bakery Products

Notice of Modification – Lists of Permitted Food Additives

Reference Number: [NOM/ADM-0071]

April 11, 2016
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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 and published on Health Canada’s website. 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 received a food additive submission seeking approval for the use of transglutaminase from *Streptoverticillium mobaraense* S-8112 as a food enzyme in bread, flour, whole wheat flour, and unstandardized bakery products at a maximum level of use of consistent with Good Manufacturing Practice.

Transglutaminase from *Streptoverticillium mobaraense* S-8112 is already permitted for use in Canada as a food enzyme in unstandardized prepared fish products, simulated meat products, certain unstandardized dairy products, and certain standardized meat and poultry products.

The results of Health Canada’s evaluation of available scientific data support the safety and efficacy of transglutaminase from *Streptoverticillium mobaraense* S-8112 when used as requested by the petitioner. Therefore, Health Canada has modified the List of Permitted Food Enzymes to extend the use of transglutaminase from *Streptoverticillium mobaraense* S-8112 by adding the entries shown below to the list.

Modification to the List of Permitted Food Enzymes

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Column 1 Additive</th>
<th>Column 2 Permitted Source</th>
<th>Column 3 Permitted in or upon</th>
<th>Column 4 Maximum Level of Use and Other Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>T.01</td>
<td>Transglutaminase</td>
<td><em>Streptoverticillium mobaraense</em> S-8112</td>
<td>(9) Bread; Flour; Whole wheat flour (10) Unstandardized bakery products</td>
<td>(9) Good Manufacturing Practice (10) Good Manufacturing Practice</td>
</tr>
</tbody>
</table>
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Rationale

Health Canada’s Food Directorate completed a pre-market safety assessment of the requested uses of transglutaminase from Streptoverticillium mobaraense S-8112. The assessment considered microbiological, toxicological, nutritional, chemical and technical aspects of this additive, and found that the requested uses are acceptable from a food safety perspective. Therefore, the Department has enabled the requested uses of transglutaminase from Streptoverticillium mobaraense S-8112 by modifying the List of Permitted Food Enzymes as described in the above table.

Other Relevant Information

The Codex General Standard for Food Additives (GSFA) contains few provisions for food enzymes, none of which are for transglutaminase. Similarly, the Codex General Standard for Wheat Flour (CODEX STAN 152-1985) provides for the use of some enzymes, but not transglutaminase. However, transglutaminase from Streptomyces mobaraensis (synonym for Streptoverticillium mobaraense) is listed in the “IPA Database by CCFA”1 (listed as “Protein-glutamine γ-glutamyltransferase”; IUBMB 2.3.2.13).

In Australia and New Zealand, food enzymes are regulated as processing aids under Standard 1.3.3 of the Australia New Zealand Food Standards Code. Transglutaminase (EC 2.3.2.13) from Streptomyces mobaraensis (synonym for Streptoverticillium mobaraense) may be used in the course of manufacturing any food.

In Europe, the use of food enzymes is subject to national legislation. Transglutaminase from Streptoverticillium mobaraense S-8112 is specifically permitted for use in France.

In the United States of America, there are standards2 for bread, rolls, and buns; and whole wheat bread, rolls, and buns, which permit the use of “enzyme active preparations”. Also, the U.S. Food and Drug Administration (FDA) has no questions about “self-affirmed” GRAS determinations that have been issued for the use of transglutaminase from Streptoverticillium mobaraense in pasta, bread, and pastry products, and in foods in general including flour and bakery products (GRN Nos. 55, 95).

The Food and Drug Regulations require that food additives such as transglutaminase from Streptoverticillium mobaraense S-8112, which do not have specifications set out in the Regulations, meet the food-grade specifications set out in the most recent edition of the Food Chemicals Codex (FCC). The FCC is a compendium of standards for purity and identity for food ingredients, including food additives, which is published by the United States Pharmacopeial Convention.

1 See http://ipa.ccfa.cc/substance?task=detail&substance_id=866
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**Implementation and Enforcement**

The above modification came into force **April 11, 2016**, the day it was published in the *List of Permitted Food Enzymes*.

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**

Health Canada's Food Directorate is committed to reviewing any new scientific information on the safety in use of any food additive, including *Transglutaminase*. Anyone wishing to submit new scientific information on the use of this food additive or to submit any inquiries may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the word “*Transglutaminase*” in the subject line of your e-mail.

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