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Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Amylase Produced by *Bacillus licheniformis* JS1252 in Bread, Flour, Whole Wheat Flour and Unstandardized Bakery Products

Notice of Modification – Lists of Permitted Food Additives
Reference Number: NOM/ADM-0003

December 19, 2012

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada 

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Summary

Food additives are regulated in Canada under the *Food and Drug Regulations* and [Marketing Authorizations \(MA\)](#) issued by the Minister of Health. 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 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 the enzyme amylase produced by *Bacillus licheniformis* JS1252 that carries a modified gene from *Pseudomonas stutzeri* at a level consistent with Good Manufacturing Practice (GMP) in bread, sweet dough products and cakes. Sweet dough products and cakes are considered to fall under the category of “unstandardized bakery products” in Canada.

Amylase produced by *B. licheniformis* JS1252 is a variant of amylase produced by *B. licheniformis* MDT06-228, an enzyme that is currently permitted for use in Canada in bread and unstandardized bakery products at a level consistent with GMP.

The results of Health Canada’s evaluation of the available scientific data support the safety of the use of the enzyme amylase produced by *B. licheniformis* JS1252 in the food products requested by the petitioner as well as other unstandardized bakery products, flour and whole wheat flour when used at a level consistent with GMP. Therefore, Health Canada has modified the [List of Permitted Food Enzymes](#) to extend the use of amylase expressed produced by *B. licheniformis* JS1252 by adding the entry shown below to the list.

Modification to the *List of Permitted Food Enzymes*

| Item No | Column 1 Additive | Column 2 Permitted Source | Column 3 Permitted in or Upon | Column 4 Maximum Level of Use and Other Conditions |
|---------|-------------------|--------------------------------------|---|--|
| A.1 | Amylase | <i>Bacillus licheniformis</i> JS1252 | (1) Bread; Flour; Whole wheat flour | (1) Good Manufacturing Practice |
| | | | (2) Unstandardized bakery products | (2) Good Manufacturing Practice |

Rationale

Health Canada's Food Directorate has completed a pre-market safety assessment of the enzyme amylase expressed produced by *B. licheniformis* JS1252. The assessment considered the microbiological, nutritional and toxicological aspects of the enzyme when used as requested in the food additive submission.

Amylase expressed produced by *B. licheniformis* JS1252 is a variant of amylase produced by *B. licheniformis* MDT06-228, which is already permitted for use in bread and unstandardized bakery products according to the *List of Permitted Food Enzymes*. Amylases produced by *B. licheniformis* JS1252 and *B. licheniformis* MDT06-228 have protein sequences that are 97.9% identical. Based on function and physical similarities, these amylase enzymes are considered substantially equivalent.

The food additive submission demonstrated that *B. licheniformis* JS1252 is a production strain that is microbiologically safe and suitable for enzyme production. Food Directorate scientists reviewed specifications related to the microbiological safety of the enzyme preparation and data demonstrating compliance with these specifications. They also conducted a toxicological evaluation based on a conservative estimated intake from its proposed use in bread and unstandardized bakery products. In addition, a comparison of the amino acid sequence of the amylase produced by *B. licheniformis* JS1252 and known allergens found no significant similarities, which indicates that it is unlikely that the enzyme poses an allergic risk.

Other Relevant Information

- All enzymes used as food additives must meet the specifications for enzyme preparations set out in the most recent edition of the *Food Chemicals Codex*.
- There are standards of identity and composition for bread, flour, and whole wheat flour set out in sections of Division 13 (Grain and Bakery Products) of the *Food and Drug Regulations* (Part B). Given that these products are standardized foods in Canada, Health Canada consulted with the Canadian Food Inspection Agency about the use of amylase from *B. licheniformis* JS1252. The Agency did not express an objection.
- Several alpha-amylases, including alpha-amylase from *B. licheniformis*, are listed in table three of the *Codex General Standard for Food Additives (GSFA)*. Additives listed in Table Three may be used in foods in general, unless otherwise specified, in accordance with GMP. This standard provides for the use of alpha-amylase in bread, bakery products and flour prepared from common wheat (*Triticum aestivum* L.). However, the Codex Standard for Durum Wheat Semolina and Durum Wheat Flour (CODEX STAN 178-1991) does not permit the use of any additives in these types of flour.

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Based on the results of the safety assessment, Health Canada's Food Directorate considers that the data demonstrate the safety in use of amylase produced by *B. licheniformis* JS1252, at a maximum level of use consistent with GMP in bread, flour, whole wheat flour and unstandardized bakery products. The Department has therefore enabled the use of amylase produced by *B. licheniformis* JS1252 as described in the above table.

Implementation and Enforcement

The above modification came into force the day it was published in the [*List of Permitted Food Enzymes*](#).

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

Contact Information

For additional information or to submit information related to this modification of the *List of Permitted Food Enzymes*, please contact:

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If communicating by e-mail, please use the words “**Amylase produced by *Bacillus licheniformis* JS1252**” in the subject line of your e-mail.