

Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Cellulase, Glucanase and Xylanase Obtained from *Rasamsonia emersonii* (previous name: *Talaromyces emersonii*) as Food Enzymes in Brewers' Mash

Notice of Modification – Lists of Permitted Food Additives

**Reference Number:** [NOM/ADM-0042]

December 3, 2014



Bureau of Chemical Safety Food Directorate Health Products and Food Branch











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#### **Summary**

Food additives are regulated in Canada under <u>Marketing Authorizations</u> (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 MA's 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 a food enzyme preparation containing cellulase,  $\beta$ -glucanase and xylanase from *Rasamsonia emersonii* (previous name: *Talaromyces emersonii*) in brewers' mash at a maximum level of use consistent with good manufacturing practice.

All three enzymes in this preparation (cellulase,  $\beta$ -glucanase and xylanase) are permitted for use as food enzymes in certain foods in Canada. Glucanase, which includes  $\beta$ -glucanase, is permitted for use in ale, beer, malt liquor, porter and stout. However, *Talaromyces emersonii* has not previously been approved as a source organism for glucanase or any other permitted food enzyme. Several other enzymes are already approved for use as food enzymes in brewers' mash, but neither cellulase, glucanase, nor xylanase are among them.

The results of Health Canada's evaluation of available scientific data support the safety and efficacy of cellulase, glucanase and xylanase from *Rasamsonia emersonii* (previous name: *Talaromyces emersonii*) when used in brewers' mash as requested by the petitioner. Therefore, Health Canada has modified the *List of Permitted Food Enzymes* to extend the use of these three enzymes by adding the entries 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
C.2	Cellulase	Rasamsonia emersonii (previous name: Talaromyces emersonii)	(1) Brewers' Mash	(1) Good Manufacturing Practice

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Item No.	Column 1 Additive	Column 2 Permitted Source	Column 3 Permitted in or upon	Column 4 Maximum Level of Use and Other Conditions
G.2	Glucanase	Rasamsonia emersonii (previous name: Talaromyces emersonii)	(1) Brewers' Mash	(1) Good Manufacturing Practice

Item No.	Column 1 Additive	Column 2 Permitted Source	Column 3 Permitted in or upon	Column 4 Maximum Level of Use and Other Conditions
X.1	Xylanase	Rasamsonia emersonii (previous name: Talaromyces emersonii)	(1) Brewers' Mash	(1) Good Manufacturing Practice

# Rationale

Health Canada's Food Directorate completed a premarket safety assessment of the petitioner's proposed use of cellulase, glucanase and xylanase from *Rasamsonia emersonii* (previous name: *Talaromyces emersonii*) in brewers' mash. The assessment considered microbiological, toxicological, chemical and technical aspects relevant to the petitioner's request.

Based on the results of this assessment, Health Canada's Food Directorate considers that the data support the safety of cellulase, glucanase and xylanase from *Rasamsonia emersonii* (previous name: *Talaromyces emersonii*) when used under the conditions of use set out in the tables above. The Department has therefore enabled the use of cellulase, glucanase, and xylanase from *Rasamsonia emersonii* (previous name: *Talaromyces emersonii*) as described in the above tables.

# **Other Relevant Information**

The *Food and Drug Regulations* (FDR) require that all food additives, including food enzymes, meet the food-grade specifications set out in the most recent edition of the *Food Chemicals Codex* (FCC) where such specifications exist and when there are no specifications in the FDR. The FCC is a compendium of standards for purity and identity of food ingredients, including food additives, which is published by the United States Pharmacopeial Convention.

### **Implementation and Enforcement**

The above modification came into force December 3, 2014, the day it was published in the *List* of *Permitted Food Enzymes*.

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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 permitted food additive including cellulase, glucanase and xylanase from *Rasamsonia emersonii* (previous name: *Talaromyces emersonii*). Anyone wishing to submit new scientific information on the use of this 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 words "**Cellulase, glucanase and xylanase**" in the subject line of your e-mail.

Bureau of Chemical Safety, Food Directorate

251 Sir Frederick Banting Driveway Tunney's Pasture, PL: 2202C Ottawa, Ontario K1A 0L2 E-mail: <u>bcs-bipc@hc-sc.gc.ca</u>