Notice of Modification to the *List of Permitted Food Enzymes* to Enable the

Use of Lysophospholipase from *Trichoderma reesei* RF7206 in the

Production of Sugars and Dextrins from

Starch

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0172





# 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* (Regulations). Approved food additives and their permitted conditions of use are set out in the <u>Lists of Permitted Food Additives</u> that are incorporated by reference in the MAs and published on the Canada.ca 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's Food Directorate received a food additive submission seeking approval for the use of lysophospholipase from *Trichoderma reesei* RF7206 in starch used in the production of dextrins, dextrose, fructose syrups and solids, glucose (glucose syrup), glucose solids (dried glucose syrup), or maltose. The food enzyme is intended to be used at a level consistent with Good Manufacturing Practice<sup>1</sup>. Its purpose of use is to improve the efficiency of the starch processing.

Lysophospholipase is a type of phospholipase. Phospholipase from other microbial sources is already permitted for use in Canada as a food enzyme in certain foods, but not in the production of sugars and dextrins from starch. In addition, *T. reesei* RF7206 was not already a permitted source for any food enzyme in Canada.

The results of the Food Directorate's evaluation of available scientific data support the safety and efficacy of lysophospholipase from *T. reesei* RF7206 when used as requested by the petitioner. Therefore, Health Canada has modified the <u>List of Permitted Food Enzymes</u> to extend the use of lysophospholipase from *T. reesei* RF7206 by adding the entry shown below to the list.

#### Modification to the List of Permitted Food Enzymes

| Item<br>No. | Column 1<br>Additive     | Column 2<br>Permitted<br>Source | Column 3<br>Permitted in or Upon  | Column 4 Maximum Level of Use and Other Conditions |
|-------------|--------------------------|---------------------------------|---|--|
| P.5.2       | (i)<br>Lysophospholipase | Trichoderma<br>reesei RF7206    | Starch used in the production of dextrins, dextrose, fructose syrups and solids, glucose (glucose syrup), glucose solids (dried glucose syrup) or maltose | Good Manufacturing<br>Practice                     |

<sup>&</sup>lt;sup>1</sup> See the definition of Good Manufacturing Practice in the <u>Marketing Authorization for Food Additives That May Be</u> <u>Used as Food Enzymes</u>.

#### Rationale

Health Canada's Food Directorate completed a premarket safety and efficacy assessment of lysophospholipase from *T. reesei* RF7206 for use as a food enzyme. The Department concluded that information related to allergenicity, chemistry, microbiology and molecular biology, nutrition and toxicology supports the safety of lysophospholipase from *T. reesei* RF7206 for its requested use, and technical information indicate that the enzyme is effective for its intended purpose. Therefore, the Department has enabled the requested use of lysophospholipase from *T. reesei* RF7206 by adding to the *List of Permitted Food Enzymes* the new entry shown in the above table.

### Other Relevant Information

The Food and Drug Regulations require that food additives, such as lysophospholipase, that do not have food-grade specifications set out in Part B of the Regulations meet the food-grade specifications set out in the most recent edition of the Food Chemicals Codex or the Combined Compendium of Food Additive Specifications. The Food Chemicals Codex is a compendium of standards for purity and identity for food ingredients, including food additives, published by the United States Pharmacopeial Convention. Specifications in the Combined Compendium of Food Additive Specifications and its associated General Specifications and Considerations for Enzyme Preparations are prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), both of which are published by the Food and Agriculture Organization of the United Nations.

# Implementation and Enforcement

The above modification came into force **August 10, 2021**, the day it was published in the <u>List of Permitted</u> <u>Food Enzymes</u>.

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 new scientific information on the safety in use of any permitted food additive, including lysophospholipase from *T. reesei* RF7206. Anyone wishing to submit new scientific information on the use of this additive or to submit inquiries on this modification may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words "Lysophospholipase (NOM-0172)" in the subject line of your e-mail.

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