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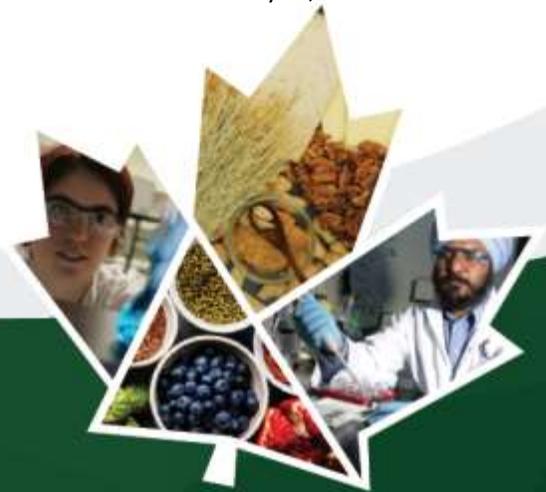
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# Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Lactase from *Bacillus subtilis* DH617 in Lactose-reducing Enzyme Preparations and Certain Dairy Foods

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0193

February 6, 2023



Canada

## Summary

Food additives are regulated in Canada under [Marketing Authorizations](#) (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 [Lists of Permitted Food Additives](#) that are incorporated by reference in the MAs and published on the Canada.ca website. A petitioner can request that Health Canada authorize a new additive, or a new source or a new condition of use for an already permitted food additive, by filing a food additive submission with the Department's Food Directorate. Health Canada uses this premarket authorization 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 authorization for the use of lactase from *Bacillus subtilis* DH617 to reduce lactose in milk and dairy products. Examples of foods of interest are cheese, condensed milk and sweet condensed milk, evaporated milk, flavoured milks, frozen dairy desserts, milk, milk shake, whey, yogurt and sweetened yogurt. The requested maximum level of use is "Good Manufacturing Practice".

According to the petitioner, lactase serves to catalyze the breakdown of the milk sugar lactose to its respective monosaccharides, glucose and galactose, and that its use would allow for the production of lactose-reduced and lactose-free dairy products. The petitioner also noted that the use of this enzyme could also increase the sweetness of dairy products as well as improve the texture of certain milk-derived products such as sweetened condensed milks and ice cream.

Most of these examples of dairy products of interest are standardized foods. Lactase from other sources is already permitted for use in flavoured milks, milk destined for use in ice cream mix and whey, which are all standardized foods. Lactase from other sources is also permitted in lactose-reducing enzyme preparations. Lactose-reducing enzyme preparations may, in turn, be used in unstandardized dairy products, including milk shake, yogurt and sweetened yogurt, and unstandardized frozen dairy desserts. Lactose-reducing enzyme preparations may also be used in dairy products that deviate from standardized dairy products by virtue of being lactose-reduced or lactose-free provided the common name reflects the deviation (e.g. "lactose-free milk").<sup>1</sup>

Prior to this notice, *B. subtilis* DH617 was not a permitted source for any food enzyme in Canada.

The results of the Food Directorate's evaluation of available scientific data support the safety of lactase from *B. subtilis* DH617 for use as requested by the petitioner. Therefore, Health Canada has modified the [List of Permitted Food Enzymes](#) to enable the use of lactase from this source by adding the text shown below to the list. For the definition of "Good Manufacturing Practice" set out in Column 4 as a Maximum Level of Use, see the [Marketing Authorization for Food Additives That May Be Used as Food Enzymes](#).

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<sup>1</sup> See the Canadian Food Inspection Agency's website [Labelling requirements for dairy products](#) and the Implementation and Enforcement section of this Notice of Modification.

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

The following text was added to the *List of Permitted Food Enzymes* (bold font not used in the list):

Item No.	Column 1 Additive	Column 2 Permitted Source	Column 3 Permitted in or Upon	Column 4 Maximum Level of Use and Other Conditions
L.1	Lactase	<b><i>Bacillus subtilis</i></b> <b>DH617</b>	(1) Lactose-reducing enzyme preparations	(1) Good Manufacturing Practice
			(2) (naming the flavour) Malted milk; (naming the flavour) Milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Partly skimmed milk with added milk solids; (naming the flavour) Skim milk; (naming the flavour) Skimmed milk with added milk solids	(2) Good Manufacturing Practice
			(3) Milk destined for use in ice cream mix	(3) Good Manufacturing Practice
			(4) Whey	(4) Good Manufacturing Practice

## Rationale

Health Canada's Food Directorate completed a premarket safety assessment of lactase from *B. subtilis* DH617 for use as a food enzyme to reduce lactose in foods as requested by the petitioner. The Directorate considered allergenicity, chemistry, microbiology, molecular biology, nutrition, and toxicology in the assessment. The results of the assessment supports the safety of lactase from *B. subtilis* DH617 for its requested use. Therefore, the Department has enabled the requested use of lactase from *B. subtilis* DH617 by adding to the *List of Permitted Food Enzymes* the new text shown in the above table.

## Other Relevant Information

Food additives such as lactase are required to meet food-grade specifications set out in Part B of the Regulations, where such specifications exist, or those set out in the most recent edition of the *Food Chemicals Codex* or the *Combined Compendium of Food Additive Specifications* where there are no specifications set out in Part B. The *Food Chemicals Codex* is a compendium of food grade specifications 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

Lactase from *B. subtilis* DH617 is being permitted for use in lactose-reducing enzyme preparations, as is already permitted for lactase from other sources. Manufacturers interested in using a lactose-reducing enzyme preparation to make a lactose-reduced or lactase-free version of a standardized dairy product that is not specifically permitted to contain lactase as shown by the *List of Permitted Food Enzymes* should consult the Canadian Food Inspection Agency's guidance on "Common names for lactose-free dairy products" at the Agency's website "[Labelling requirements for dairy products](#)".

The above modification came into force **February 6, 2023**, 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 new scientific information on the safety in use of any permitted food additive. Anyone wishing to submit an inquiry or new scientific information on the use of a permitted food additive may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically about lactase from *B.subtilis* DH617, please use the words "**lactase (NOM-0193)**" in the subject line of your e-mail.

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