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Notice of Modification to the Lists of Permitted Food Additives to Extend the Use of Three Food Additives to Certain Plant Protein Isolate-based Products

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0168

July 22, 2021



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 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 three food additive submissions, two seeking approval for the use of gellan gum and nisin, respectively, in a liquid plant protein isolate-based product, and the third seeking approval for the use of transglutaminase from *Streptovorticillium mobaraense* S-8112 in the same liquid product as well as in the manufacture of a solid ("patty") plant protein isolate-based product.

These products resemble egg products, but are not equivalent to egg products with respect to nutrient composition and protein quality. The liquid product is to be cooked prior to consumption to make a food similar to an omelet or scramble made from eggs. The solid "patty", which resembles an egg omelet, essentially starts as the same liquid plant protein isolate-based product, without the nisin and gellan gum, but is baked by the manufacturer, sold in a frozen format, and re-heated in an oven by a restaurant, institution, or consumer.

Gellan gum and nisin are to be used in the liquid product at a maximum level of 0.2% and 25 ppm, respectively. Transglutaminase is to be added to the liquid mix at Good Manufacturing Practice, prior to the liquid mix being baked to make the "patty".

In Canada, gellan gum, nisin, and transglutaminase are already permitted for use as food additives in a variety of other foods.

The results of the Food Directorate's evaluation of available scientific data support the safety and efficacy of these three additives for use as set out in the tables below. Therefore, Health Canada has modified the [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#), Part 2 of the [List of Permitted Preservatives](#) and the [List of Permitted Food Enzymes](#), to extend the use of these three food additives to plant protein isolate-based products that resemble egg products by adding the entries shown below to the respective Lists. In addition, the name of the source for transglutaminase has been updated from "*Streptovorticillium mobaraense*" to "*Streptomyces mobaraensis*" to reflect its latest taxonomic classification.

Modifications to the Lists of Permitted Food Additives

The following new sub-item (13) was added to item G.2 in the [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#):

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
G.2	Gellan Gum	(13) Liquid plant protein isolate-based products that resemble egg products	(13) 0.2%

The following new sub-item 7 was added to item N.1 in Part 2 of the [List of Permitted Preservatives](#):

Item No.	Column 1 Additive	Column 3 Permitted in or Upon	Column 4 Maximum Level of Use and Other Conditions
N.1	Nisin	(7) Liquid plant protein isolate-based products that resemble egg products	(7) 25 p.p.m.

The following new sub-item 13 was added to item T.01 in the [List of Permitted Food Enzymes](#) and the name of the permitted source in Column 2 of item T.01 was updated to the entry shown below

Item No.	Column 1 Additive	Column 2 Permitted Source	Column 3 Permitted in or Upon	Column 4 Maximum Level of Use and Other Conditions
T.01	Transglutaminase	<i>Streptomyces mobaraensis</i> S-8112 (previous name: <i>Streptoverticillium mobaraense</i> S-8112)	(13) Liquid or solid plant protein isolate-based products that resemble egg products	(13) Good Manufacturing Practice

Rationale

Health Canada’s Food Directorate completed a premarket safety and efficacy assessment of the requested use of each of gellan gum, nisin and transglutaminase. The assessment considered, where applicable to the additive, aspects related to allergenicity, chemistry, molecular biology, microbiology, nutrition, toxicology, and technical function, and concluded that the safety and efficacy of these food additives for their requested use is supported.

Therefore, the Department has enabled the requested uses of these food additives by adding the entries shown in the tables above to the [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#), Part 2 of the [List of Permitted Preservatives](#), and the [List of Permitted Food Enzymes](#).

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as gellan gum, nisin and transglutaminase 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. 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) and published by the Food and Agriculture Organization of the United Nations.

Implementation and Enforcement

The above modifications came into force **July 22, 2021**, the day they were published in the [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#), Part 2 of the [List of Permitted Preservatives](#) and 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, including gellan gum, nisin and transglutaminase. Anyone wishing to submit new scientific information on the use of these additives 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 "**Food additives in plant protein isolate-based products (NOM-0168)**" in the subject line of your e-mail.

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