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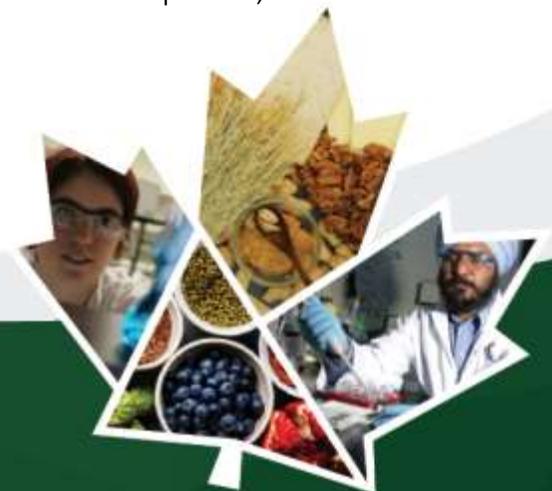
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Notice of Modification to the Lists of Permitted Food Additives to Extend the Use of Certain Food Additives to Human Milk Fortifiers

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0164

April 14, 2021



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.

Human milk fortifier (HMF) is a food whose composition includes at least one added vitamin, mineral nutrient or amino acid that is labelled or advertised as intended to be added to human milk to increase its nutritional value in order to meet the particular requirements of an infant in whom a physical or physiological condition exists as a result of a disease, disorder or abnormal state. Providing HMFs to infants who are born prematurely or for other infants as medically required (e.g. small for gestational age, high protein needs) is a best practice in clinical care. It is used under close medical supervision and monitoring, mostly in neonatal intensive care units of hospitals and occasionally at home as required.

Health Canada has new regulations that permit the sale of HMF¹. Prior to this, certain HMF products that were assessed for safety by Health Canada were allowed to be sold under an agreement between the Department and the Canadian Food Inspection Agency. The safety assessment for those products considered six food additives,² all of which were already permitted for use in infant formula, and found them to be safe for use in HMF. Now that HMF is defined in the Regulations, the Lists of Permitted Food Additives must be modified to permit the use of these food additives in HMF. In addition, Health Canada's Food Directorate received a food additive submission seeking approval for the use of gellan gum as a stabilizing agent in liquid HMF based on hydrolysed proteins. The requested maximum level of use for gellan gum is 225 parts per million (ppm), which is equivalent to 0.00415% in the human milk containing the HMF as consumed.

The Food Directorate has assessed the safety of these seven food additives for use in HMF and concluded that there are no safety concerns with their use as set out in the tables below.

Therefore, Health Canada has modified the [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#) and the [List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#) to extend the use of these food additives to HMF by adding the entries shown below to the Lists.

Modifications to the Lists of Permitted Food Additives

The following entries have been added to 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
C.15	Carrageenan	(19) Human milk fortifier	(19) 0.006% in the human milk containing the human milk fortifier as consumed

¹ *Regulations Amending the Food and Drug Regulations (Human Milk Fortifiers)*, [Canada Gazette Part II, SOR/2021-57](#), 2021-04-14.

² These additives are carrageenan as a stabilizing agent, lecithin and monoglycerides as emulsifying agents, and potassium citrate, potassium hydroxide and sodium citrate as pH adjusting 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	(12) Human milk fortifier based on protein hydrolysates	(12) 0.00415% in the human milk containing the human milk fortifier as consumed
L.2	Lecithin	(12) Human milk fortifier	(12) 0.03% in the human milk containing the human milk fortifier as consumed
M.4	Monoglycerides	(14) Human milk fortifier	(14) 0.034% in the human milk containing the human milk fortifier as consumed

The following entries have been added to the [*List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents*](#).

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
P.7	Potassium Citrate	(5) Human milk fortifier	(5) Good Manufacturing Practice
P.9	Potassium Hydroxide	(8) Human milk fortifier	(8) Good Manufacturing Practice
S.9	Sodium Citrate	(6) Human milk fortifier	(6) Good Manufacturing Practice

Rationale

Health Canada's Food Directorate assessed the safety of carrageenan, gellan gum, lecithin, monoglycerides, potassium citrate, potassium hydroxide, and sodium citrate for use in HMF. The assessments concluded that information related to allergenicity, chemistry, microbiology, nutrition, and toxicology support the safety of these food additives for use as shown in the tables above. Therefore, the Department has enabled the uses of these food additives shown in the above tables by adding them to the [*List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents*](#) and the [*List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents*](#).

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as carrageenan, gellan gum, lecithin, monoglycerides, potassium citrate, potassium hydroxide, and sodium citrate 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*, which contains specifications prepared by the Joint FAO/WHO

Expert Committee on Food Additives (JECFA), is published by the Food and Agriculture Organization of the United Nations.

Implementation and Enforcement

The above modifications came into force **April 14, 2021**, the day they were published in the [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#) and the [List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#).

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 carrageenan, gellan gum, lecithin, monoglycerides, potassium citrate, potassium hydroxide, and sodium citrate. 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 Human Milk Fortifier (NOM-0164)**" in the subject line of your e-mail.

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