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Notice of Modification to the *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents, the List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents and the List of Permitted Sequestering Agents* to Enable the Use of Potassium Pyrophosphate, Tetrabasic in Unstandardized Foods

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: NOM/ADM-0128

March 5, 2019

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada

Notice of Modification to the *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents*, the *List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents*, and the *List of Permitted Sequestering Agents* to Enable the Use of Potassium Pyrophosphate, Tetrabasic in Unstandardized Foods

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 a food additive submission seeking approval for the use of potassium pyrophosphate, tetrabasic as a pH adjusting agent, a sequestrant and a texturizing agent at a maximum level of use of Good Manufacturing Practice (GMP) in unstandardized foods.

The sodium analogue of this additive, sodium pyrophosphate, tetrabasic, is already permitted for these uses in unstandardized foods at a level consistent with GMP. Potassium pyrophosphate, tetrabasic can be used as a partial or complete replacement for the sodium analogue or it can be used in place of other phosphate salts that are permitted in unstandardized foods. Other currently permitted food additive uses of potassium pyrophosphate, tetrabasic are shown in the *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents*, *List of Permitted Sequestering Agents*, and the *List of Permitted Food Additives with Other Accepted Uses*.

The results of the Food Directorate's evaluation of relevant scientific data support the safety and efficacy of potassium pyrophosphate, tetrabasic for use as requested by the petitioner. Therefore, Health Canada has enabled the requested uses of this additive by adding the entries shown below to the [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#), the [List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#), and the [List of Permitted Sequestering Agents](#).

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Modifications to the Lists of Permitted Food Additives

The existing entry in columns 2 and 3 for item P.11B has been renumbered to subitem “(1)” and a new subitem “(2)”, as shown in the table below, has 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
P.11B	Potassium Pyrophosphate, tetrabasic	(2) Unstandardized foods	(2) Good Manufacturing Practice

A new item “P.10B” has 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.10B	Potassium Pyrophosphate, tetrabasic	Unstandardized foods	Good Manufacturing Practice

A new subitem “(9)” has been added to Item P.3 in the [*List of Permitted Sequestering Agents*](#):

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
P.3	Potassium Pyrophosphate, tetrabasic	(9) Unstandardized foods	(9) Good Manufacturing Practice

Consequential Modification

The entries for potassium tripolyphosphate (Item P.5), sodium acid pyrophosphate (Item S.1), sodium hexametaphosphate (Item S.3), sodium potassium hexametaphosphate (Item S.5.1), sodium potassium tripolyphosphate (Item S.5.2), sodium pyrophosphate, tetrabasic (Item S.6), sodium pyrophosphate, tribasic (Item S.6.1) and sodium tripolyphosphate (Item S.7) in the [*List of Permitted Sequestering Agents*](#) specify that these phosphates are permitted in or upon the same foods, at the same levels and other conditions, as potassium pyrophosphate, tetrabasic. These entries also specifically permit their use in unstandardized foods at a level consistent with GMP. However, these entries for their use in unstandardized foods would be duplicative if retained

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because the three new entries shown in the tables above and the existing provisions for the use of each of the eight phosphates in the same foods as potassium pyrophosphate, tetrabasic have the effect of allowing them in unstandardized foods.

In order to avoid duplication, the specific references to “unstandardized foods” that appear as subitem (2) in each of those entries have been removed from columns 2 and 3 of items P.5, S.1, S.3, S.5.1, S.5.2, S.6, S.6.1, and S.7 and replaced with text indicating the removal date. These changes are consequential only and have no effect on the foods, maximum levels of use and other conditions for these eight phosphates. The use of these eight phosphates in unstandardized foods at levels consistent with GMP continues to be permitted.

Rationale

Health Canada’s Food Directorate completed a premarket safety assessment of the requested uses of potassium pyrophosphate, tetrabasic. The assessment concluded that information related to chemistry, nutrition, toxicology, allergenicity and efficacy supports the safety and efficacy of potassium pyrophosphate, tetrabasic for its requested uses. Therefore, the Department has enabled the requested uses of potassium pyrophosphate, tetrabasic by modifying the [*List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents*](#), the [*List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents*](#), and the [*List of Permitted Sequestering Agents*](#) as shown in first three tables above.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as potassium pyrophosphate, tetrabasic that do not have food-grade specifications set out in Part B of the Regulations meet the most recent food-grade specifications set out in 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.

Food additives and other ingredients generally must be declared in the list of ingredients on the label of pre-packaged foods sold in Canada. Some persons, such as individuals with kidney disease or those taking medications that could impair potassium or phosphorus excretion, need to follow a low potassium or low phosphorus diet. They therefore also need to know the amount of potassium or phosphorous in a food to make an informed food choice.

For this reason, Health Canada recommends that food companies voluntarily declare the total amount of potassium and phosphorus, and the percentage of the “daily value” for potassium and phosphorus, in the nutrition facts table when phosphorous- or potassium-containing ingredients have been added to a food. For foods that are offered for sale at retail and that are not required to

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carry a nutrition facts table, such as meat products offered at a deli counter, Health Canada recommends that the retailer be prepared to inform consumers upon request that the ingredient has been added to the food and provide them with the phosphorous and potassium content of the food.

Declaration of the potassium content of prepackaged foods in the nutrition facts table is scheduled to become mandatory as a result of proposed changes to food labeling requirements, published in Part I of the *Canada Gazette* on December 14, 2016.¹ Labels will be expected to comply with the new labeling requirements by December 2021 unless the deadline changes as a result of Health Canada's proposal for front of package labeling.²

Implementation and Enforcement

The above modification came into force **March 5, 2019**, the day it was published in the [*List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents*](#), the [*List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents*](#), and the [*List of Permitted Sequestering 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 any new scientific information on the safety in use of any food additive, including potassium pyrophosphate, tetrabasic. 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 "**potassium pyrophosphate, tetrabasic (NOM-0128)**" in the subject line of your e-mail.

[Bureau of Chemical Safety, Food Directorate](#)

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¹ [Canada Gazette, Part II, Vol. 150, No 25, December 14, 2016. SOR/DORS/2016-305](#)

² [Canada Gazette Part I, Vol. 152, No. 6, February 10, 2018](#)