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Health Canada's Proposal to Enable the Use of Tripotassium Phosphate (Potassium Phosphate, Tribasic), Potassium Tripolyphosphate, Sodium Potassium Tripolyphosphate and Sodium Potassium Hexametaphosphate in Various Standardized and Unstandardized Foods

Notice of Proposal – *Lists of Permitted Food Additives*

September 11, 2014

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada 

Summary

Food additives are regulated in Canada under [Marketing Authorizations](#) (MAs) issued by the Minister of Health and the *Food and Drug 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 Health Canada's 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 received five food additive submissions that together seek approval for the use of tripotassium phosphate (which would be referred to in the Lists of Permitted Food Additives as potassium phosphate, tribasic), potassium tripolyphosphate, sodium potassium tripolyphosphate and sodium potassium hexametaphosphate in those foods where trisodium phosphate (referred to in the Lists of Permitted Food Additives as sodium phosphate, tribasic), sodium tripolyphosphate and sodium hexametaphosphate are already permitted. The requested levels and conditions of use of these potassium and sodium potassium phosphates were the same as for the already permitted sodium analogue.

Canada's Lists of Permitted Food Additives are organized by technological function. Phosphates exert multiple technological functions (e.g., sequestering agent, protein stabilizer, emulsifier, pH modifier, texturizer) in foods and are therefore listed for use in a wide variety of foods in the [Lists of Permitted Food Additives](#).

The new phosphate additives could be used as substitutes for their permitted sodium analogues to reduce the sodium content of the food without changing the intended technical or functional effect of the phosphate in the food. While the potassium or sodium potassium analogues indicated above could be used as replacements for their sodium counterparts, food manufacturers would be able to continue using the sodium versions of these additives. Thus, manufacturers would have more choice and greater flexibility in food formulation.

The results of Health Canada's evaluation of available scientific data support the safety and efficacy of these additives when used as requested by the petitioners.

In addition, Health Canada reviewed some of the foods and levels of use for the already approved phosphate additives. There are a variety of approved phosphates and different combinations are permitted in different foods. Health Canada's review took into consideration the recognized technical functions, which are determined by the pH and the chain length, of the phosphate. The review was limited to the use of phosphates in meat, fish and poultry. As a result, certain extensions of use of already permitted phosphates are being proposed. This would provide greater consistency among the permitted uses of certain phosphate additives.

Based on the outcome of this assessment, Health Canada intends to modify the [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#), the [List of Permitted Food Additives with Other Generally Accepted Uses](#), the [List of Permitted pH Adjusting Agents, Acid Reacting Materials and Water Correcting Agents](#), the [List of Permitted Sequestering Agents](#) and the [List of Permitted Starch-Modifying Agents](#) as described below.

Proposed Modifications to the Lists of Permitted Food Additives

List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents:

- Permit the use of potassium phosphate, tribasic in the same foods and with the same maximum levels of use and other conditions as sodium phosphate, tribasic.
- Permit the use of sodium potassium hexametaphosphate in the same foods and with the same maximum levels of use and other conditions as sodium hexametaphosphate.
- Permit the use of potassium tripolyphosphate, sodium potassium tripolyphosphate and trisodium pyrophosphate in a blend of prepared fish and prepared meat referred to in paragraph B.21.006 (n) of the *Food and Drug Regulations* (FDR).
- Extend the use of potassium pyrophosphate, tetrabasic and sodium acid pyrophosphate to a blend of prepared fish and prepared meat referred to in paragraph B.21.006 (n) of the FDR.
- For the phosphates (i.e. potassium pyrophosphate tetrabasic, potassium tripolyphosphate, sodium acid pyrophosphate, sodium hexametaphosphate, sodium potassium hexametaphosphate, sodium potassium tripolyphosphate, sodium pyrophosphate tetrabasic, sodium tripolyphosphate, and trisodium pyrophosphate) permitted for use in a blend of prepared fish and prepared meat referred to in paragraph B.21.006 (n) of the FDR, the following maximum level of use is being proposed: “0.15% calculated as sodium phosphate, dibasic. If used in combination with other phosphates, total added phosphate not to exceed 0.4%, calculated as sodium phosphate, dibasic.” This is consistent with current maximum use levels of already permitted phosphates in this food but is expressed on the basis of sodium phosphate, dibasic.
- For the use of sodium potassium hexametaphosphate in infant formula, a maximum level of use of 0.05% in the product, as consumed, is being proposed. When sodium potassium hexametaphosphate is to be used in combination with sodium hexametaphosphate, the combined total amount of these two additives would be set at 0.05%.

List of Permitted Food Additives with Other Generally Accepted Uses:

- Permit the use of potassium tripolyphosphate and sodium potassium tripolyphosphate in frozen clams, frozen cooked shrimp, frozen crab, frozen fish fillets, frozen lobster, frozen minced fish, frozen shrimp and frozen squid with the purpose of use “To reduce

processing losses and reduce thaw drip". These food additives would be enabled for use singly or in combination providing the total added phosphate does not exceed 0.5%, calculated as sodium phosphate, dibasic.

- Permit the use of sodium potassium hexametaphosphate in the same foods and at the same maximum levels of use as sodium hexametaphosphate. Since these two additives can be used in combination, it is proposed that the total amount of the two additives when used in combination be set at 2% and 0.2%, respectively, for gelatin intended for marshmallow composition and beef blood.
- Extend the use of potassium pyrophosphate, tetrabasic to frozen clams, frozen cooked shrimp, frozen crab, frozen fish fillets, frozen lobster, frozen minced fish, frozen shrimp and frozen squid with the purpose of use "To reduce processing losses and reduce thaw drip". This food additive would be enabled for use singly or in combination with other permitted phosphates providing the total added phosphate does not exceed 0.5%, calculated as sodium phosphate, dibasic.
- Extend the use of sodium acid pyrophosphate, sodium hexametaphosphate and sodium pyrophosphate, tetrabasic to frozen cooked shrimp at a maximum level of use such that total added phosphate does not exceed 0.5% calculated as sodium phosphate, dibasic.
- Extend the use of sodium pyrophosphate, tetrabasic to frozen squid at a maximum level of use such that total added phosphate does not exceed 0.5% calculated as sodium phosphate, dibasic.
- Permit the use of trisodium pyrophosphate in frozen squid and frozen cooked shrimp at a maximum level of use such that total added phosphate does not exceed 0.5% calculated as sodium phosphate, dibasic.
- Permit the use of sodium carbonate in combination with either sodium hexametaphosphate or sodium potassium hexametaphosphate or both and extend the use of sodium carbonate, in combination with either sodium hexametaphosphate or sodium potassium hexametaphosphate or both, to frozen squid and frozen cooked shrimp.
- Add the use of sodium hexametaphosphate in frozen minced fish at a maximum level of use of "total added phosphate, not to exceed 0.5% calculated as sodium phosphate, dibasic" as a corrective modification to reflect the standard set out in B.21.003 (b).
- Replace the term "frozen fish" in column 2 of item S.7 Sodium phosphate, dibasic with "glaze for frozen fish" in order to use a more appropriate term.

List of pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents:

- Permit potassium phosphate, tribasic in ale, beer, malt liquor, porter, stout and unstandardized foods at a maximum level of use consistent with good manufacturing practice.

- Permit potassium tripolyphosphate, sodium potassium hexametaphosphate and sodium potassium tripolyphosphate in unstandardized foods at a maximum level of use consistent with good manufacturing practice.
- In the French version of the list, the name of the food additive identified as item P.10 is proposed to change from “phosphate bipotassique” to “phosphate dipotassique” for consistency.
- In the French version of the list, the name of the food additive identified as item S.22 is proposed to change from “polyphosphate trisodique” to “tripolyphosphate de sodium” for consistency.

List of Permitted Sequestering Agents:

- Permit the use of potassium tripolyphosphate and sodium potassium tripolyphosphate in the same foods with the same maximum level of use and other conditions of use as sodium tripolyphosphate.
- Permit the use of sodium potassium hexametaphosphate in the same foods and the same maximum level of use and other conditions of use as sodium hexametaphosphate.
- Extend the use of potassium phosphate, monobasic; potassium phosphate, dibasic; sodium acid pyrophosphate; sodium hexametaphosphate; sodium phosphate, dibasic; sodium phosphate, monobasic and trisodium pyrophosphate to meat tenderizers at a maximum level of use consistent with good manufacturing practice.
- Extend the use of potassium pyrophosphate, tetrabasic and sodium pyrophosphate, tetrabasic to canned seafood at a maximum level of use such that total added phosphates do not exceed 0.5% calculated as sodium phosphate, dibasic.
- Extend the use of potassium pyrophosphate, tetrabasic; potassium phosphate, monobasic and potassium phosphate, dibasic to injection or cover solutions for use in the curing of poultry or poultry meat, and pumping pickle for the curing of pork, beef and lamb cuts.

List of Permitted Starch-Modifying Agents:

- Permit the use of potassium tripolyphosphate and sodium potassium tripolyphosphate in starch at a maximum level of use such that total residual phosphate does not exceed 0.4% calculated as phosphorus.

Rationale

Health Canada's Food Directorate has completed its pre-market safety and efficacy assessment of potassium phosphate, tribasic (also known as tripotassium phosphate), potassium tripolyphosphate, sodium potassium tripolyphosphate and sodium potassium hexametaphosphate

when used as described above. The assessment considered toxicological, nutritional and technical aspects of the proposal.

Since these additives could be used as replacements for sodium-based phosphates, there would be no change on the phosphate level in the food supply. However, the use of these additives could result in an increase in potassium intake. Available information suggested a complete replacement of the sodium analogues with the potassium or sodium potassium analogues would result in the mean potassium intake increasing by approximately 200 mg but remaining below the adequate intake (AI) of 4700 mg for adults. It was also noted that this would also result in a comparable reduction in the sodium intake.

Based on the results of the safety assessment, Health Canada's Food Directorate scientists consider that the data support the safety of potassium phosphate, tribasic (tripotassium phosphate), potassium tripolyphosphate, sodium potassium tripolyphosphate and sodium potassium hexametaphosphate when used in the same foods and at the same levels of use as their sodium analogues. Health Canada is therefore proposing to enable the use of potassium phosphate, tribasic (tripotassium phosphate), potassium tripolyphosphate, sodium potassium tripolyphosphate and sodium potassium hexametaphosphate as described above.

International Environment

Tripotassium phosphate and potassium tripolyphosphate are listed in the Codex General Standard for Food Additives (GSFA) for use in foods where all other phosphates are allowed. While sodium potassium tripolyphosphate and sodium potassium hexametaphosphate are not specifically listed in the GSFA, the sodium analogue and potassium analogues of these two additives are listed.

All four additives are considered Generally Recognized as Safe (GRAS) and are permitted for various food uses in the United States.

The European Union permits the use of tripotassium phosphate and potassium tripolyphosphate in many processed foods, including certain meat, poultry, fish and seafood applications. Although sodium potassium tripolyphosphate and sodium potassium hexametaphosphate are not specifically listed for use in foods, both their sodium and potassium analogues are permitted for use.

The Australia New Zealand Food Standards Code provides for the use of sodium, potassium, calcium, ammonium and magnesium phosphates; the pyrophosphates; the triphosphates; and the polyphosphates. These provisions would include tripotassium phosphate, potassium tripolyphosphate, and may include sodium potassium tripolyphosphate and sodium potassium hexametaphosphate (where specifications exist in primary or secondary sources recognized by Food Standards Australia New Zealand), in a variety of foods, including certain meat, poultry, fish and seafood applications.

Potassium phosphate, tribasic (tripotassium phosphate), potassium tripolyphosphate, sodium potassium tripolyphosphate, and sodium potassium hexametaphosphate that would be used in foods sold in Canada would need to meet the food-grade specifications set out in the most recent edition of the *Food Chemicals Codex* (FCC). The FCC is a compendium of standards for purity and identity of food ingredients, including food additives, which is published by the United States Pharmacopeial Convention.

Implementation and Enforcement

The proposed changes will be effective the day on which they are published in the *Lists of Permitted Food Additives*. This will be announced via a Notice of Modification which will be published on the [Food and Nutrition - Public Involvement and Partnerships](#) section of Health Canada's Website.

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

For additional information or to submit comments related to this proposal, please contact:

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

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If communicating by e-mail, please use the word "**phosphates**" in the subject line of your e-mail. Health Canada is able to consider information received by **November 24, 2014**, 75 days from the date of this posting.