



Health
Canada

Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Information and Consultation Document on Health Canada's Proposal to Enable the use of the Food Additive 'Trisodium Pyrophosphate' in certain Standardized Meat, Poultry and Marine and Freshwater Products, and in Unstandardized Foods

October 2012

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada 

Table of Contents

Purpose.....	2
Background.....	2
Health Canada’s Assessment of Trisodium Pyrophosphate.....	3
Technical Efficacy.....	3
Chemical Assessment.....	3
Dietary Exposure	3
Toxicological Assessment.....	4
Nutritional Assessment.....	4
Rationale for Action.....	5
International Status	5
Previous Consultation.....	6
Recommendations	7
Comments.....	9

Purpose

This document provides information on Health Canada's proposal to permit the use of trisodium pyrophosphate in certain standardized meat, poultry, marine and freshwater products, and in unstandardized foods.

Background

In Canada, all food additives are regulated under the *Food and Drug Regulations (Regulations)* and are subject to rigorous controls under the *Food and Drugs Act*. Before a food additive is permitted for use, a submission must be filed with Health Canada's Food Directorate so the Department can conduct a thorough safety evaluation of the proposed use(s) of the additive. Food manufacturers are not permitted to use the additive in foods to be sold in Canada until it has been approved by Health Canada and steps have been taken to legally enable its use.

Health Canada received a submission requesting legal approval for the use of trisodium pyrophosphate in those standardized meat, poultry meat, marine and freshwater animal products and in unstandardized foods, where the use of tetrasodium pyrophosphate (sodium phosphate, tetrabasic) and/or sodium acid pyrophosphate is already permitted. Trisodium pyrophosphate is a phosphate that has a variety of technical functions and would be used in the place of other already-permitted phosphate salts.

The proposed maximum level of use of trisodium pyrophosphate in standardized meat, poultry and marine and freshwater animal products is 0.5% total added phosphate, calculated as sodium phosphate, dibasic. This maximum level of use would apply to the use of trisodium pyrophosphate when used singly as well as to combinations of trisodium pyrophosphate with other phosphate salts. The level of use in unstandardized foods is proposed to be at a use level consistent with Good Manufacturing Practice (GMP). These proposed maximum levels of use are the same as the levels of use that are currently legally prescribed for other already permitted phosphates in these foods.

Two of the currently permitted phosphates, namely sodium acid pyrophosphate and tetrasodium pyrophosphate, are very similar to trisodium pyrophosphate in that trisodium pyrophosphate is chemically equivalent to a 50:50 mixture of sodium acid pyrophosphate and tetrasodium pyrophosphate. However, trisodium pyrophosphate itself is not currently a permitted food additive in Canada. Legal provisions exist for various technological purposes for a number of other phosphate salts in certain meat, poultry, and marine and freshwater animal products. Specifically, certain phosphate salts are permitted at a maximum level of use of 0.5% total added phosphate, calculated as sodium phosphate, dibasic, either singly or in certain combinations with other phosphate salts, in the following products: solid cut meat; prepared meat, prepared meat by-product; solid cut poultry meat; prepared poultry meat, prepared poultry meat by-product; cured pork, beef and lamb cuts prepared with the aid of pumping pickle; cured poultry or poultry meat prepared by means of injection or cover solution; frozen fish fillets, frozen minced fish, frozen lobster, frozen crab, frozen clam and frozen shrimp; and canned seafoods. Unstandardized foods, pumping pickle for the curing of pork, beef and lamb cuts, and injection or cover solution for the curing of poultry or poultry meat, are permitted to contain certain phosphate salts at levels consistent with GMP.

Health Canada's Assessment of Trisodium Pyrophosphate

Food Directorate scientists at Health Canada conducted a detailed evaluation of the submission requesting approval of the use of trisodium pyrophosphate, focusing on safety and efficacy. Their evaluation considered the chemical, toxicological and nutritional aspects of the proposed use of trisodium pyrophosphate as a food additive and is described in the following sections.

Technical Efficacy

Phosphates are known to have a variety of technological functions. For example, in the case of frozen fish, phosphates act to inhibit protein denaturation during freezing which prevents water loss and protects flavour and colour. In the case of canned seafoods, the technical function of phosphate salts is to chelate ions that would otherwise negatively affect the quality of the canned product. For example, phosphate salts prevent the formation of struvite (magnesium ammonium phosphate crystals) in canned tuna and they prevent blue discoloration in canned crab meat by binding copper from crab blood. Phosphate salts have a variety of functions, including the chelation of ions, in meat and poultry products.

The petitioner who filed the submission suggested that the advantages of using this pyrophosphate over combinations of other already approved phosphates will vary depending on the application. Trisodium pyrophosphate is unique in comparison to sodium acid pyrophosphate and tetrasodium pyrophosphate in that one single product can be utilized where good binding qualities and a neutral pH are needed. Trisodium pyrophosphate can also be premixed in a dry salt marinade making it convenient for customers, whereas tetrasodium pyrophosphate cannot due to its poor solubility in water and concentrated salt solutions. The petitioner also suggested that while this phosphate provides the same benefits to meat processing as other phosphates (e.g., reduced cook loss, colour stability and improved texture), it also improves bite (resulting from a combination of the neutral pH and good solubility), and other characteristics important to the processing of meats.

Chemical Assessment

Food Directorate scientists have not identified any safety concerns, from a chemical perspective, in relation to the use of trisodium pyrophosphate in the foods, and under the conditions of use, proposed in the submission.

Dietary Exposure

Since the proposed areas and levels of use for trisodium pyrophosphate are the same as for those phosphate salts that are already legally permitted in Canada, and as it would likely be used in the place of other phosphates, it is not expected that trisodium pyrophosphate will increase dietary levels of phosphate or sodium for consumers. In addition, the meat, poultry, fish and seafood applications described here, where phosphate salts are permitted, prescribe maximum levels of use for the phosphate salts, whether added singly or in combination. As a result, this replacement would not affect the phosphorus level of the food supply. Furthermore, trisodium pyrophosphate is chemically equivalent to a 50:50 equimolar blend of sodium acid pyrophosphate and tetrasodium pyrophosphate (sodium phosphate, tetrabasic), both permitted food additives.

Toxicological Assessment

The safety of trisodium pyrophosphate was established as part of an assessment of phosphoric acid and phosphate salts by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1970. JECFA revisited the assessment in 1974, 1982 and 2001. The database that was evaluated included biochemical and metabolic studies; acute, short and long-term oral toxicity studies; teratology and reproductive toxicity studies; genotoxicity studies; and clinical studies.

The JECFA established a maximum tolerable daily intake (MTDI) of 70 mg/kg bw/day expressed as phosphorus, based on adverse kidney effects (nephrocalcinosis) in the most sensitive test animal (rat). This MTDI applies to the sum of phosphates naturally present in food and due to the use of food additives. The MTDI also assumes that adequate amounts of calcium are present in the diet (the ratio of phosphorus intake relative to calcium intake is a parameter that is considered in determining the safe use of phosphate).

In 2001, the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine in the United States set a tolerable upper intake level (UL) for phosphorus of 4000 mg/person/day for males and females between the ages of 9 to 70 years, a value consistent with the MTDI established by JECFA.

As noted previously, trisodium pyrophosphate is to be used in the place of other already-permitted phosphate salts and is chemically equivalent to a 50:50 mixture of sodium acid pyrophosphate and tetrasodium pyrophosphate, both of which are approved food additives. No additional phosphorus would be added to the diet.

Based on this information, Food Directorate scientists have no toxicological concerns with the use of trisodium pyrophosphate in those foods and under the conditions of use proposed in the submission.

Nutritional Assessment

Trisodium pyrophosphate is intended to replace other sodium-containing food additives such as sodium acid pyrophosphate and tetrasodium pyrophosphate. The maximum level of use for trisodium pyrophosphate will be the same as that for other currently permitted phosphates, either 0.5%, calculated as sodium phosphate, dibasic, or GMP, depending on the type of food.

Given the fact that trisodium pyrophosphate is a replacement additive, that its composition is equivalent to a 50:50 equimolar blend of two already-permitted sodium-containing additives (sodium acid pyrophosphate and tetrasodium pyrophosphate), and that its use will be regulated in the same manner as for currently permitted phosphate salts, there will likely be no significant increase in dietary consumption of either sodium or phosphorus, both of which are of nutritional interest.

Based on this information, Food Directorate scientists have no concerns from a nutritional perspective to the proposed use of trisodium pyrophosphate in those foods and under the conditions of use proposed.

Rationale for Action

Based on the evaluation conducted by scientists in Health Canada's Food Directorate, the information provided by the petitioner has satisfactorily met the requirements for a food additive submission outlined in Section B.16.002 of the Regulations. Therefore, it is proposed that trisodium pyrophosphate be approved as a food additive for use in those foods in which tetrasodium pyrophosphate (sodium phosphate, tetrabasic) and/or sodium acid pyrophosphate is already permitted. Enabling the use of this additive would allow manufacturers greater formulation flexibility.

International Status

Trisodium pyrophosphate (listed as its synonym, trisodium diphosphate) and a number of other phosphate salts and phosphoric acid are recognized in the European Union for use as food additives. They may be used individually or in combination (expressed as phosphorus pentoxide, P₂O₅) in a broad range of foods, including meat products, glazes for meat and vegetable products, unprocessed frozen and deep-frozen fish fillets, unprocessed and processed frozen and deep-frozen molluscs and crustaceans, canned crustacean products, surimi, and fish and crustacean paste ([European Parliament Council Directive No 95/2/EC](#); Regulation EC1333/2008 and Annex II adopted 11 Nov., 2011).

Food Standards Australia New Zealand (FSANZ) has provisions under the Australia and New Zealand Food Standards Code for the use of pyrophosphates in Schedule 2 (Miscellaneous additives permitted to GMP in processed foods specified in Schedule 1) where specifications recognized by FSANZ for the additives exist, in a wide variety of foods including processed meat, poultry and game products in whole cuts or pieces; processed comminuted meat, poultry and game products; edible casings; animal protein products; processed fish and fish products; semi preserved fish and fish products; and fully preserved fish including canned fish products. There is also specific provision for the use of certain phosphates, including pyrophosphates (INS 450), in unprocessed frozen fish at GMP under Schedule 1 (Permitted uses of food additives by food type).

Trisodium pyrophosphate is not listed in the U.S. Code of Federal Regulations (CFR) as generally recognized as safe (GRAS). However, on December 16, 2009, the U.S. Food and Drug Administration (FDA) responded to a GRAS notification filed by a food additive manufacturer who had notified that trisodium pyrophosphate is GRAS for use as a stabilizer, moisturizer and sequestrant in sausages (fine emulsions) and fish and seafood products (excluding catfish and scallops) at GMP levels (level of addition not to exceed 0.5%, expressed as phosphorus pentoxide, P₂O₅). The FDA indicated that it had no questions regarding the conclusion that trisodium diphosphate (trisodium pyrophosphate) is GRAS under the intended conditions of use. Further, the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) has listed trisodium pyrophosphate (as its synonym trisodium diphosphate) in an [FSIS Directive entitled *Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg products*](#), where it is listed as a stabilizer, moisturizer and sequestrant for use in sausages (fine emulsions).

Trisodium pyrophosphate (trisodium diphosphate; acid trisodium pyrophosphate; INS 450 ii) was included in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) 2001 evaluation of phosphates. It is recognized under four functional classes: stabilizers, leavening agents, emulsifiers and nutrients. Under the Codex General Standard for Food Additives (GSFA), provisions for specific phosphate salts in food are defined at the food additive group level, i.e., 'phosphates'. This means that any phosphate salt recognized in the GSFA is permitted for use in foods in which phosphates are allowed. Currently, twenty-nine phosphate salts are listed in the GSFA for use in many different foods, including frozen processed meat, poultry, and game products in whole pieces or cuts; processed comminuted meat, poultry, and game products; and crustacean and fish pastes. Trisodium pyrophosphate is recognized under the GSFA in three functional classes: emulsifier, raising agent and stabilizer.

As the Codex GSFA continues to be developed, it is expected that additional uses for phosphates will be listed as there are a number of proposed uses for phosphates in a variety of foods at Steps 3 and 6 of the Codex Step procedure. These proposals cover a variety of fresh and processed meats, poultry and game products; and frozen, battered, minced, creamed or cooked fish, fish fillets and fish products (including molluscs, crustaceans & echinoderms), among many others.

Previous Consultation

The approval of trisodium pyrophosphate as a food additive would permit its use in foods for which there are standards set out in Division 14 (Meat, its Preparation and Products), Division 21 (Marine and Freshwater Animal products) and Division 22 (Poultry, Poultry Meats, their Preparations and Products) of the Regulations. As such, the Canadian Meat Council (CMC), the Canadian Pork Council (CPC), the Canadian Poultry and Egg Processors Council (CPEPC), the Further Poultry Processors Association of Canada (FPPAC), the Fisheries Council of Canada (FCC), and the Food of Animal Origin Division and the Fish Seafood and Production Division of the Canadian Food Inspection Agency (CFIA), were consulted during the development of this proposal.

Responses were received from the CFIA, CMC, FCC and CPEPC. The CMC, FCC, and CPEPC have expressed their full support of legally enabling the use of trisodium pyrophosphate.

The Food of Animal Origin Division of the CFIA had no objections to the proposal, including the use of trisodium pyrophosphate in meat and poultry products where similar phosphates are already permitted under the various Sections of the *Regulations*. It was also noted that this proposal would not affect the 1990 *Meat Inspection Regulations* (MIR), as the specific chemical names of the different phosphates that may be used are not listed independently in Schedule 1 of the MIR.

The Fish Seafood and Production Division of the CFIA had no objection to enabling this additive in fish and fish products standardized under Division 21 of the *Regulations* provided trisodium pyrophosphate is only used in fish and fish products where other phosphates are already permitted, and that there is not a significant difference in water retention between fish products treated with trisodium pyrophosphate and the other phosphates currently permitted for use in Canada.

Recommendations

Health Canada has completed a detailed safety assessment of a submission requesting the approval of the use of trisodium pyrophosphate and determined that there are no health or safety concerns with the use of this additive in those standardized meat, poultry meat, marine and freshwater animal products, and in unstandardized foods where the use of certain phosphate salts is already permitted, and at the same levels of use as the currently permitted phosphates. The specific conditions of use are detailed below.

The use of trisodium pyrophosphate as an agent to reduce processing losses and to reduce thaw drip would be considered to be a “miscellaneous” food additive function (that is, it does not fall within other food additive functional classes). The conditions of use would be as shown in the table below:

Conditions of use of trisodium pyrophosphate as an agent to reduce processing losses and to reduce thaw drip

Additive	Permitted in or Upon	Purpose of Use	Maximum Level of Use
Sodium Tripolyphosphate	Frozen fish fillets; frozen minced fish; frozen lobster; frozen crab; frozen clams; frozen shrimp	To reduce processing losses and to reduce thaw drip	Used singly or in combination with sodium acid pyrophosphate and sodium pyrophosphate tetrabasic or in combination with trisodium pyrophosphate, total added phosphate not to exceed 0.5% calculated as sodium phosphate, dibasic
Trisodium pyrophosphate	Frozen fish fillets; frozen minced fish; frozen lobster; frozen crab; frozen clams; frozen shrimp	To reduce processing losses and to reduce thaw drip	Used in combination with sodium tripolyphosphate, total added phosphate not to exceed 0.5% calculated as sodium phosphate, dibasic

Trisodium pyrophosphate in canned seafoods functions as a sequestering agent. The conditions of use are described in the table below:

Information and Consultation Document on Health Canada's Proposal to Enable the use of the Food Additive 'Trisodium Pyrophosphate' as a Stabilizer in Certain Standardized Meat, Poultry and Marine and Freshwater Products, and in Unstandardized Foods

The conditions of use of trisodium pyrophosphate in canned seafoods functions as a sequestering agent

Additive	Permitted in or on	Maximum Level of Use
Sodium acid pyrophosphate	(1) Canned seafoods	(1) Used singly or in combination with sodium hexametaphosphate, sodium tripolyphosphate or trisodium pyrophosphate, total added phosphate not to exceed 0.5% calculated as sodium phosphate, dibasic
Sodium Hexametaphosphate	(1) Canned seafoods	(1) Used singly or in combination with sodium acid pyrophosphate, sodium tripolyphosphate or trisodium pyrophosphate, total added phosphate not to exceed 0.5% calculated as sodium phosphate, dibasic
Sodium Tripolyphosphate	(6) Canned seafoods	(6) Used singly or in combination with sodium acid pyrophosphate, sodium hexametaphosphate or trisodium pyrophosphate, total added phosphate not to exceed 0.5% calculated as sodium phosphate, dibasic
Trisodium pyrophosphate	(1) Canned seafoods (2) Injection or cover solution for the curing of poultry or poultry meat (3) Pumping pickle for the curing of pork, beef and lamb cuts (4) Unstandardized foods (5) Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product	(1) Used singly or in combination with sodium acid pyrophosphate, sodium hexametaphosphate, or sodium tripolyphosphate, total added phosphate not to exceed 0.5% calculated as sodium phosphate, dibasic (2) Good Manufacturing Practice, and in accordance with B.22.021(e) (3) Good Manufacturing Practice, and in accordance with B.14.009(f) and B.14.031(h) (4) Good Manufacturing Practice (5) 0.5% total added phosphate, calculated as sodium phosphate, dibasic

Information and Consultation Document on Health Canada’s Proposal to Enable the use of the Food Additive ‘Trisodium Pyrophosphate’ as a Stabilizer in Certain Standardized Meat, Poultry and Marine and Freshwater Products, and in Unstandardized Foods

Specific paragraphs within certain food standards would also require amendment by adding trisodium pyrophosphate to the lists of permitted phosphates in the following paragraphs: B.14.005(c), B.14.009(f), B.14.021(1)(b), B.14.031(h), B.21.003(a)(i), B.21.003(c), B.21.004, B.21.006(f), B.22.006(a), B.22.012(1)(b), and B.22.021(e).

Item 8 of the Table in B.01.010(3)(b) of the Regulations, which allows the ingredient declaration of certain phosphate salts by a common name, would also require amendment through the addition of trisodium pyrophosphate to the list of phosphates appearing in Column I, as follows:

Proposed update to Item 8 of the Table in B.01.010(3)(b) of the Regulations

<i>Item No.</i>	<i>Column I Ingredient or component</i>	<i>Column II Common Name</i>
8	any combination of disodium phosphate, monosodium phosphate, sodium hexametaphosphate, sodium tripolyphosphate, tetrasodium pyrophosphate, sodium acid pyrophosphate and trisodium pyrophosphate	sodium phosphate or sodium phosphates

Comments

Comments on this proposal may be submitted in writing, either electronically or by regular mail. If you are submitting your comments electronically, please use the words “trisodium pyrophosphate” in the subject box of your e-mail.

Comments must be received by 11:59 p.m. EST, December 29, 2012.

Mailing address:
Bureau of Chemical Safety
251 Sir Frederick Banting Driveway
Tunney’s Pasture, PL: 2203B
Ottawa, Ontario K1A 0L2

E-mail address: bcsc-bicp@hc-sc.gc.ca

For more information on this initiative, please contact the [Chemical Health Hazard Assessment Division](#) at bcsc-bicp@hc-sc.gc.ca, using the words “trisodium pyrophosphate” in the subject box of your e-mail