Sodium Phosphates

processing

Executive Summary

Sodium orthophosphates (mono-, di-, and tri-sodium phosphates) have a wide variety of uses in conventional food processing, but is currently restricted to dairy products only for organic processing. The petition requests soy-based dairy substitutes be allowed to use sodium phosphates for purposes similar to those allowed for dairy products.

The TAP Reviewers all agreed that sodium orthophosphates are synthetic. The reviewers all agreed that the current National List refers only to sodium orthophosphates, and that any other sodium phosphates should be considered and listed separately. While two reviewers were in favor of permitting broader use of this additive, they were not able to reach consensus on the appropriate annotation.

The reviewers concluded that the petitioner did not adequately justify that sodium phosphates are essential for use in soy products. Each cited alternative methods to produce similar products. Two raised concerns about possible nutritional imbalance between calcium and phosphorus due to the addition of sodium phosphates in foods. However, all reviewers shared the consensus that the levels used in food manufacture should not pose a serious health risk for most consumers.

Of the two reviewers who thought it should be listed as a permitted use, one suggested changing the existing annotation to place stringent conditions on all uses of sodium orthophosphates. This would allow all FDA permitted uses, but only with a case-by case determination of need, essentiality, nutritional impact, and alternatives.

The other reviewer in favor of listing the material suggests allowing their use in any product, limited only by 21 CFR requirements. This reviewer felt that since dairy use is permitted it is only consistent that all uses should be permitted.

The reviewer opposed to listing the material found that the combination of concerns was enough to recommend prohibition for all uses in organic products. This reviewer suggested that sodium phosphates be prohibited in all products labeled organic, but permitted in products labeled "made with organic ingredients."

All reviewers agreed that sodium orthophosphates should be permitted in all products labeled "made with organic" (70% or greater organic ingredients).

Identification

Chemical Name:
sodium phosphates (mono-, di-, and tri-)

Other Names:
monobasic, dibasic, and tribasic sodium phosphate; mono- di- or tri-sodium phosphate; di-hydrogen sodium phosphate (monosodium); monohydrogen sodium phosphate (di-sodium); MSP (mono-), DSP (di-), TSP (tri-); sodium orthophosphates.

Trade Names: Many, often contained in blends with calcium phosphates, polyphosphates, and other mixes.

CAS Numbers:
monobasic: 7558-80-7; dibasic: 7558-79-4;
tribasic: 7601-54-9

International Numbering System (INS) Numbers:
339 sodium phosphates
339(i) monosodium orthophosphate
339(ii) disodium orthophosphate
339(iii) trisodium orthophosphate

Other:
NIOSH Registry Number: WC4600000

Summary of TAP Reviewer Analyses [1]

95% organic

Synthetic / Non-Synthetic:	Allowed or Prohibited:	Suggested Annotation:
Synthetic (3-0)	*Allowed (2)* *Prohibited (1)*	*Reviewer 1:* Any of the three salts of Sodium Orthophosphate should be allowed for use as direct additives in foods labeled as organic when used in accordance with good manufacturing practice provided that: (a) the use is established as necessary for the processing of the food; (b) the use is established as having no adverse nutritional impact on the "target population" intended to consume the food; and (c) no non-synthetic, "less synthetic" or environmentally less impactful substance can be used in place of the sodium phosphate salt. *Reviewer 2:* prohibited, no annotation. *Reviewer 3:* allowed as listed in 21 CFR.

Made with organic

Synthetic / Non-Synthetic:	Allowed or Prohibited:	Suggested Annotation:
Synthetic (3-0)	*Allowed (3-0)*	See the 95%+ annotation for Reviewer 1 and 3. Reviewer 2: no annotation.

Characterization

Composition:
monosodium phosphate: NaH_2PO_4
disodium phosphate: Na_2HPO_4
trisodium phosphate: Na_3PO_4

Properties:
All forms are either anhydrous or contain one or more molecules of water of hydration. The anhydrous forms are white, crystalline powders or granules. The hydrated forms occur as white or transparent crystals or granules. The anhydrous form is hygroscopic. It is freely soluble in water and insoluble in alcohol (Budavari, 1996). The pH of the three orthophosphates ranges from the moderately acid monosodium phosphate (pH=4) to the slightly alkaline disodium phosphate (pH=9) to the strongly alkaline trisodium phosphate (pH=12) (Considine and Considine, 1982).

How Made:
Sodium phosphates are generally prepared by the partial or total neutralization of phosphoric acid using sodium carbonate or sodium hydroxide (Ashford, 1994). Crystals of a specific hydrate can then be obtained by evaporation of the resultant solution within the temperature range over which the hydrate is stable (Gard, 1996).

Specific Uses:
Sodium phosphates are used as antimicrobials (Davidson, 2000), pH control agents (buffers), boiler water additives, cleaners, coagulants, dispersants, leavening agents, stabilizers, emulsifiers, sequestrants, texturizers, nutrients, and dietary supplements. Sodium phosphate (mono-, di-, and tri-) is used as a buffering salt in foods. The principal use is for pH stabilization of food systems for fruit and vegetable product systems (Fennema, 1985). Monosodium phosphate is used as an acidulent (Ashford, 1994) and also in medicine as a cathartic, an excipient, and in saline solutions (Budavari, 1996). The petition states, "The addition of sodium phosphates increases the shelf life of soy products" (Amin, 2001).

[1] *This Technical Advisory Panel (TAP) review is based on the information available as of the date of this review. This review addresses the requirements of the Organic Foods Production Act to the best of the investigator's ability, and has been reviewed by experts on the TAP. The substance is evaluated against the criteria found in section 2119(m) of the OFPA [7 USC 6517(m)]. The information and advice presented to the NOSB is based on the technical evaluation against that criteria, and does not incorporate commercial availability, socio-economic impact or other factors that the NOSB and the USDA may want to consider in making decisions.*

Action:
The emulsification abilities of sodium phosphates are not completely understood, but the phosphate interacts with proteins, such as casein, to function as emulsifiers and prevent the separation of both fat and water in cheese (Gard, 1996). The addition of sodium phosphate (tri) to evaporated milk prevents separation of the butter fat and aqueous phases and prevents gel formation (Fennema, 1985). One source notes considerable debate about the mechanisms of phosphate functionality, with reference to water holding capacity of meat and fish (Miller, 1996). The addition of phosphates to muscle food homogenates, raw and cooked meats, in sausages, hams, poultry and seafood will decrease the amount of drip loss, enhance waterbinding and water holding capacity resulting in enhanced sensory characteristics (Fennema, 1985). Orthophosphates can bind with and sequester metals (Considine and Considine, 1982). Sodium phosphate salts can be used as chelating agents (sequesterant) that act to bind to metallic and alkaline earth ions to form complexes that alter the properties and stability of foods such as by binding copper and ferrous ions to slow down the rate of lipid oxidation in foods (Fennema, 1985).

Combinations:
Sodium phosphates are combined with calcium phosphates as leavening agents (Horsford, 1864; Ellinger, 1972; FMC, no date). Sodium orthophosphates are often combined with insoluble sodium metaphosphate (IMP) and various polyphosphates (Ellinger, 1972; FMC, no date). The addition of other salts, such as sodium chloride, can have a synergistic effect on water-holding capacity (Gordon and Klimek, 2000). Typical commercial mixtures contain 30-60% soluble orthophosphates and 40-70% IMP (Gard, 1996). Starches are often used as carriers (Ashford, 1994). Trisodium phosphate used for cleaning is often combined with sodium hypochlorite (bleach) (Ashford, 1994). Sodium aluminum phosphate and sodium acid pyrophosphates are also used as a leavening agents (Food Chemicals Codex, 1996). The sodium phosphates are often used in combination with various gels such as agar, alginates, carageenan, pectins, and various gums (Ellinger, 1972).

The previous sodium phosphates TAP Review (NOSB, 1995) only reviewed the forms mono-, di-, and tri-sodium phosphates. . This TAP Review does not cover other forms such as metaphosphates, pyrophosphates, polyphosphates, or combinations of sodium phosphates with any elemental constituents other than hydrogen.

Status

Historic Use:
The earliest documented use of refined sodium phosphates was with a double salt with calcium phosphates in baking powder (Horsford, 1864).

One reference states that the use of phosphate emulsifiers in cheeses began in the 1890s and cited Kraft's patent as the source for that information (Heidolph and Gard, 2000). However, Kraft's patent makes no reference to sodium phosphate or any other phosphate emulsifier (Kraft, 1916). The historical use of phosphates in soy-based dairy substitutes is not well documented. The historical use of sodium phosphates in organic dairy products does not appear to predate the NOSB's recommendation in 1995.

OFPA, USDA Final Rule:
Section 205.605(b)(33) synthetics allowed: sodium phosphates— for use only in dairy foods.

Regulatory:
See Table 1, below, for FDA references to sodium phosphates.

EPA/NIEHS/Other Sources:
EPA – Both disodium phosphate and trisodium phosphates are considered hazardous materials under the Comprehensive Environmental Response, Cleanup, and Liability Act (CERCLA) with reportable quantities of 5,000 pounds (USEPA, 1998b). Disodium and trisodium phosphates are designated hazardous substances under the Clean Water Act (40 CFR 116.4). Disodium phosphate were reclassified to EPA List 4B (60 *Fed. Reg. 35397).* The EPA's List of Pesticide Product Inert Ingredients also classifies monosodium phosphate and trisodium phosphate as EPA List 4B, but a corresponding *Federal Register* notification of reclassification was not found. (EPA, 1995).

NIEHS – National Toxicology Program database (NTP, 2001):
Toxicity
Acute Toxicity:

Type Dose	Mode	Species	amount unit
LD_{50}	orl	rat	12,930 mg/kg
LD_{lo}	ipr	rat	1,000 mg/kg

*Sax toxicity evaluation: not available
*carcinogenicity: not available
*mutagenicity: not available
*teratogenicity: not available

ipr=intraperitoneal
LD_{50}=lethal Dose for 50% of the test organisms
LD_{lo}=lowest published lethal dose
orl=oral

Standards, Regulations & Recommendations:
OSHA: none
ACGIH: none
NIOSH criteria document: none
NFPA hazard rating: health (h): none
flammability (f): none
reactivity (r): none
Other toxicity data: not available
Acute/chronic hazards:
Toxic. May cause irritation on contact. Hazardous decomposition.
Minimum protective clothing: not available
Recommended glove materials: Permeation data indicate that latex gloves may provide protection from contact with this compound. Latex over latex gloves is recommended. However, if this chemical makes direct contact with your gloves, or if a tear, hole or puncture develops, remove them at once.

Recommended respirator: Where the neat test chemical is weighed and diluted, wear a NIOSH-approved half face respirator equipped with an organic vapor/acid gas cartridge (specific for organic vapors, HCl, acid gas and SO2) with a dust/mist filter.

Spills and leakage: If you spill this chemical, you should dampen the solid spill material with water, then transfer the dampened material to a suitable container. Use absorbent paper dampened with water to pick up any remaining material. Seal your contaminated clothing and the absorbent paper in a vapor-tight plastic bag for eventual disposal. Wash all contaminated surfaces with a strong soap and water solution. Do not reenter the contaminated area until the safety officer (or other responsible person) has verified that the area has been properly cleaned.

Skin contact: Immediately flood affected skin with water while removing and isolating all contaminated clothing. Gently wash all affected skin areas thoroughly with soap and water. If symptoms such as redness or irritation develop, immediately call a physician and be prepared to transport the victim to a hospital for treatment.

Inhalation: Immediately leave the contaminated area; take deep breaths of fresh air. If symptoms (such as wheezing, coughing, shortness of breath, or burning in the mouth, throat, or chest) develop, call a physician and be prepared to transport the victim to a hospital. Provide proper respiratory protection to rescuers entering an unknown atmosphere. Whenever possible, self-contained breathing apparatus (scba) should be used; if not available, use a level of protection greater than or equal to that advised under respirator recommendation.

Eye contact: First check the victim for contact lenses and remove if present. Flush victim's eyes with water or normal saline solution for 20 to 30 minutes while simultaneously calling a hospital or poison control center. Do not put any ointments, oils, or medication in the victim's eyes without specific instructions from a physician. Immediately transport the victim after flushing eyes to a hospital even if no symptoms (such as redness or irritation) develop.

Ingestion: Do not induce vomiting. If the victim is conscious and not convulsing, give 1 or 2 glasses of water to dilute the chemical and immediately call a hospital or poison control center. Be prepared to transport the victim to a hospital if advised by a physician. If the victim is convulsing or unconscious, do not give anything by mouth, ensure that the victim's airway is open and lay the victim on his/her side with the head lower than the body. Do not induce vomiting. Immediately transport the victim to a hospital.

Other Sources – Disodium phosphate is subject to state Right-to-Know laws in Massachusetts, New Jersey, and Pennsylvania.

Status Among U.S. Certifiers:

California Certified Organic Farmers (CCOF) – CCOF Certification Handbook (2000), Section 8.3.3 Processing and Handling Materials, "Allowed Non-Organic, Use as an ingredient restricted to dairy foods."

Oregon Tilth Certified Organic (OTCO) – OTCO Generic Materials List (April 30, 1999), Processing Materials, "Allowed, Non-Organic Ingredient, Use as an ingredient restricted to dairy foods." The petition included a letter from OTCO stating, "OTCO has considered your request for use of di-sodium phosphate in soymilk drink to prevent protein coagulation upon heating. The reason for using di-sodium phosphate and the lack of alternatives was clearly explained by Mr. Amin, from Carousel Foods. OTCO would extend allowance of the use of sodium di-phosphate to soymilk... ." (OTCO, 2000).

Organic Crop Improvement Association International (OCIA) – OCIA International Certification Standards, effective date July 1, 2001, Section 9.4.3, regulated for use in the NOI (non-organic ingredient) class with specifications "use as an ingredients restricted to dairy foods."

Quality Assurance International (QAI) – Petition included a letter from QAI stating, "According to the current organic practices, di-sodium phosphate is allowed in the processing of soy products... .When the National Organic Program goes into effect this will no longer be an allowed material... ." (QAI, 2000).

Texas Department of Agriculture (TDA) Organic Certification Program – TDA Organic Certification Program Materials List (February 2000), restricted for use in processing with comments, "Use as a non-organic ingredient is restricted to dairy foods."

Washington State Department of Agriculture (WSDA) Organic Food Program – Chapter 16-158-060 WAC (rev. January 18, 2001), listed in the section "Minor Ingredients and Processing Aids" as "sodium phosphate—for dairy processing only."

International

CODEX – Not listed.
EU 2092/91 – Not listed.
Japanese Agricultural Standard – Not listed.
IFOAM – Not listed.
Canada – Not listed.
Other International Certifiers – Could not find any that allow any sodium phosphates for any purpose.

Section 2119 OFPA U.S.C. 6518(m)(1-7) Criteria

1. The potential of the substance for detrimental chemical interactions with other materials used in organic farming systems.
The substance is used in processing and therefore would not interact directly with other materials used in organic farming systems.

2. The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.
The toxicity of sodium phosphates is generally related to the sequestration of calcium and the subsequent reduction of ionized calcium (Gosselin, et al., 1984). Ingestion may injure the mouth, throat, and gastrointestinal tract, resulting in nausea, vomiting, cramps, and diarrhea (Chermishinoff, 2000). Feeding studies on human subjects showed no adverse chronic effects. However a number of feeding studies that involved rodent models showed kidney damage and calcium deposits in test animals (Ellinger, 1972). Also see processing criteria 3, below.

3. The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.
See processing criteria 2, below.

4. The effects of the substance on human health.
Most of the human health references are related to its medical, rather than food, use. The Reviewers considered the literature citations of the effect of sodium phosphate purgatives to be not directly relevant to food use. However, for the sake of completeness, these studies are briefly noted, but not exhaustively reviewed. A number of the adverse health effects are related to the use of phosphates purgatives. In a number of cases, bowel cleansers were not used according to label instructions or were given to patients with reduced renal function where the use of phosphate purgatives is medically contraindicated.

Because phosphates react slowly, systemic reactions are unlikely. Low calcium (hypocalcemia) has been reported in certain susceptible individuals (Gosselin, et al., 1984; Boivin and Kahn, 1998). Continuous contact may cause skin irritation and can be minimally to moderately irritating to unwashed eyes.

Trisodium phosphate is caustic (Gosselin, et al., 1984). Most of the adverse reactions reported in the medical literature involve the use of relatively high levels of sodium phosphate administered to patients where such use is contraindicated. Also, trisodium phosphate reportedly promotes bladder cancer initiated by an experimental nitrosoamine in rats, while monosodium phosphate does not (Shibata et al., 1991, cited in Shibata, et al., 1993). See also processing criteria 3 and 5, below.

5. The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock.
This is a processing material that is not applied to soil.

6. The alternatives to using the substance in terms of practices or other available materials.
See processing criteria 1 and 7, below.

Its compatibility with a system of sustainable agriculture.
See processing criteria 6, below.

Criteria From the February 10, 1999 NOSB Meeting

A PROCESSING AID OR ADJUVANT may be used if:
1. It cannot be produced from a natural source and has no organic ingredients as substitutes.
No documentation could be found of natural sources of food grade sodium phosphates. Lecithin from organic soybeans is a possible substitute for certain applications as an emulsifier.

2. Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA.
The manufacturing processes for sodium carbonate and sodium hydroxide (see "How Made" section, above) are covered in previous TAP reviews. Sodium hydroxide and sodium carbonate were reviewed by the NOSB and added to the National List. Manufacture of food-grade phosphoric acid involves the removal of heavy metals and radioactive waste. The environmental impact of mining calcium phosphate is covered in the TAP review for triple superphosphate.

A primary environmental concern of sodium phosphates is their release into water. Phosphate detergents caused algal blooms and eutrophication of the Great Lakes. This was remedied by the development of low-phosphate detergents and bans on high-phosphate detergents in the states that drain into the Great Lakes (US EPA, 1997). This is primarily related to trisodium phosphate used as a detergent or cleaner, and is generally not related to use as a food additive.

3. If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.
Calcium and phosphorous are metabolically linked by their common absorptive mechanism through Vitamin D. Vitamin D_3 stimulates absorption of calcium in the intestine. This maintains the homeostasis of calcium and phosphorus in bone formation from those two minerals (Watkins, 2000). The distribution of phosphorous in foods is so wide that deficiencies do not seem to exist. It is always linked to calcium in skeletal mass and exists as a phosphate salt in bone as phospho proteins, phospho lipids and nucleic acids in the cell (Alais and Linden, 1991). Its addition raises both sodium and phosphorous levels in the food.

Nutritional disorders are of particular concern with infants and children raised on a vegan diet and are being fed soy beverages as a milk substitute (Anil, et al., 1996; Carvalho, et al., 2001). One Reviewer raised the concern that soy beverages are not nutritionally equivalent to milk and soy-based dairy substitutes also have different nutritional compositions.
An additional review of health effects (not included in original materials sent to Reviewers) reported on a study that examined the effect of an intentionally high phosphate additive diet (potato chips, processed cheese carbonated beverages, etc) This resulted in measurably lower calcium serum levels. (Bell, cited in Molins, 1991) This report also estimated that phosphate additives in the ordinary American diet may increase P intake on the order of 25-100%.

Disodium phosphate anhydrous is not considered hazardous by known governmental definitions (FMC, 1996).

The primary adverse human health effect is the elevation of sodium levels and the substitution of sodium for calcium. Sodium phosphate does not appear to increase the amount of calcium excreted in urine (calciuria) in normal healthy individuals (Whiting, Andersen, and Weeks, 1997). One text in food chemistry provides the following quote (de Man, 1990):

> "The importance of phosphates in the diet as it relates to the absorption of calcium depends on the amount of calcium, iron, strontium and aluminum present in the diet. The literature suggests that a diet containing more phosphorous than calcium can be as detrimental as a simple calcium deficiency. The ratio of calcium to phosphorous in the bone is 2:1. In early infancy the ratio should be 1.5:1, in adults 1:1. The estimated annual per capita intake in the US is 1-g calcium and 2.9-g phosphorous; thus providing a ratio of 0.35. Therefore a danger in raising phosphorous levels in the diet may increase the unavailability of calcium."

4. Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.

Sodium phosphates possess antimicrobial properties (Davidson, 2000). The primary purpose in the petition is not as a preservative. The specific functionality is not described in any detail in the petition (Amin, 2001). However, the primary petitioned function could possibly be described as 'textural.' Phosphates stabilize proteins during processing so they improve finished product texture (Yazici, et al., 1997).

The primary use, as described in the petition, would be to make dairy product substitutes (Ellinger, 1972). Monosodium phosphate can be used to impart a certain flavor (Tidridge, 1962). It is also used as a nutritional supplement to replace or enhance phosphate levels.

5. Is Generally Recognized As Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.

M\Mono-, di-, and tri-basic sodium phosphates are all considered GRAS as multiple purpose ingredients (21 CFR 182.1778). The Food Chemicals Codex (1996) specifications for all three forms are as follows:

Identification: A 1 in 20 solution gives positive tests for Phosphate and Sodium.

Arsenic: Not more than 3 mg/kg	Fluoride: Not more than 0.005%
Heavy metals (as Pb) Not more than 10 mg/kg	Insoluble substances: Not more than 0.2%

Table 1 summarizes the FDA references to sodium phosphates in the EAFUS database. Note that polyphosphates and pyrophosphates are covered under separate references.

Table 1
FDA References to Sodium Phosphates

21 CFR	Section heading	Form*	Notes/Limitations
73.85	caramel color	1,2,3	Salts that may be employed to assist caramelization, in amounts consistent with good manufacturing practice.
133.169	pasteurized process cheese	1,2,3	Optional ingredient as an emulsifier, not to exceed 3% by weight of the product.
133.173	pasteurized process cheese food	1,2,3	Optional ingredient as an emulsifier, not to exceed 3% by weight of the product.
133.179	pasteurized process cheese spread	1,2,3	Optional ingredient as an emulsifier, not to exceed 3% by weight of the product.
135.110	ice cream and frozen custard	2	Optional ingredient.
137.305	enriched farina	2	Optional ingredient at not less than 0.5 percent and not more than 1 percent by weight. The enzymes pepsin and papain may be used as substitutes to reduce cooking time.
139.110	macaroni products	2	Optional ingredient in a quantity not less than 0.5 percent and not more than 1.0 percent of the weight of the finished food. When disodium phosphate is used the label shall bear the statement "Disodium phosphate added for quick cooking."
150.141	artificially sweetened fruit jelly	1,2,3	Optional ingredient in an amount not exceeding 2 ounces avoirdupois per 100 pounds of the finished food.
150.161	artificially sweetened fruit preserves and jams	1,2,3	Optional ingredient in an amount not exceeding 2 ounces avoirdupois per 100 pounds of the finished food.
160.110	frozen eggs	1	Optional ingredient not to exceed 0.5 percent of the weight of the frozen eggs.
172.892	food starch-modified	1	Residual phosphate in food starch-modified not to exceed 0.4 percent calculated as phosphorus.
173.310	boiler water additive	1,2,3	The amount of additive is not in excess of that required for its functional purpose, and the amount of steam in contact with food does not exceed that required to produce the intended effect in or on the food.
175.210	acrylate ester copolymer coating	2	Not to exceed the amount required as a preservative in emulsion defoamer.
175.300	resinous and polymeric coatings	2	Miscellaneous material.
178.1010	sanitizing solutions	1,3	Approved for use in combination with sodium hypochlorite, sodium lauryl sulfate, and potassium permanganate (b)(37); limitations described in detail at 21 CFR 178.1010(c)(32)(ii).
181.29	stabilizers	2	Disodium hydrogen phosphate classified as a stabilizer, when migrating from food- packaging material.
182.1778	sodium phosphate	1,2,3	Multiple Purpose GRAS Food Substances. GRAS when used in accordance with GMPs.
182.6085	sodium acid phosphate	1	Sequestrants: GRAS when used in accordance with GMPs.
182.6290	disodium phosphate	2	Sequestrants: GRAS when used in accordance with GMPs.
182.6778	sodium phosphate	1,2,3	Sequestrants: GRAS when used in accordance with GMPs.
182.8778	sodium phosphate	1,2,3	Nutrients: GRAS when used in accordance with GMPs.

* 1= sodium phosphate, monobasic (CAS #7558-80-7); 2= sodium phosphate, dibasic 7558-79-4; 3= sodium phosphate, tribasic (CAS #7601-54-9)

Source: EAFUS.

6. Its use is compatible with the principles of organic handling.

Additives used for stabilization and prolonging shelf life have generally not been considered compatible with principles of organic processing (Raj, 1991). Draft principles of organic handling proposed by NOSB in June, 2001 include the statement "Organic products are handled using processing methods that maintain the organic integrity and quality of the products." The NOSB considered a petition for the general use of sodium phosphates in 1995, and restricted that use to dairy products. A reasonable argument could be made that the same logic could be applied to plant-derived dairy substitutes. A counter-

argument could be made in support of real dairy products being more natural and therefore more compatible with organic principles than plant-derived substitutes that require synthetic additives. (Sodium phosphates are not used in fluid milk, but are more likely to be used in frozen milk products or shelf stable dairy creamers.)

Imitation products have historically been regarded as less 'organic' than the real product they seek to imitate, particularly when synthetic chemical additives are necessary to give the impression to the consumer that the imitation is similar to the real product. A clear consensus is not available on current consumer preference regarding use of stabilizers and other additives in organic products, and could be further investigated.

7. There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.

The petition states, "Our lengthy research and development has determined that the sodium phosphates provide essential and incomparable functionality in our organic soy products... . Without the use of sodium phosphates in producing our soy food and beverage products similar to dairy products, we would not be able to create products acceptable to consumers" (Amin, 2001). Information included with the petition focused more on dairy products and other applications and only included data on sodium hexametaphosphate (not reviewed in this TAP review).

Soy milk and other soy-based dairy substitutes in the US are evaluated by comparison with cow's milk rather than the traditional product of soy milk (Wong, 1964; Shurtleff and Aoyagi, 1985). Therefore, the question of what is a 'similar' product is more difficult to resolve than usual, given that the petition explicitly requests to be evaluated as 'similar to or equivalent to' dairy products, rather than as soy products (Amin, 2001). The logical conclusion is that an organic dairy product is, by definition, similar.

Traditional Chinese recipes involved the soaking of soybeans in water, grinding them into a slurry, cooking, and filtering to remove the insoluble cell wall and hull fractions, with no mention of sodium phosphates or any other chemical sequestrants (Piper and Morse, 1923, cited in Wong, 1964; Hui, 2000). Product development researchers explored a number of processing modifications in the 1960s and 1970s, with an extensive number of references that compared the resulting products to dairy foods rather than to the traditional Asian beverage (Wong, 1964; Shurtleff and Aoyagi, 1985). This included methods to make blander flavors or to produce a yogurt-like texture (Wong, 1964). Later efforts went into creating frozen desserts, such as ice creams (Shurtleff and Aoyagi, 1985). Soybean variety selection appeared to be more significant than either preparation methods or the use of additives in eliminating what were deemed off-flavors in at least one series of experiments (Wong, 1964).

Potassium citrate is a viable alternative cited in a comparative study of the effects of sodium hexametaphosphate and potassium citrate on 'soymilk' heat stability. The authors found, "on a weight-for-weight basis, potassium citrate provided higher heat stability compared to sodium hexametaphosphate." In their abstract, the authors state that "samples with 1.25% potassium citrate had the best heat stability" (Yaziki, et al., 1997).

Sodium citrate is an alternative to trisodium phosphate in condensed, evaporated, and non-fat milk processing (Ellinger, 1972) and in processed dairy cheese manufacture (Rippen, 1986). Calcium citrate, sodium citrate, and potassium citrate are all Federally approved emulsifiers to make processed cheese and permitted under the organic rules [21 CFR 133.173(e)(1) and 7 CFR 205.605(b)(5, 26, 31)].

Di-potassium phosphate could be used to prevent coagulation in non-dairy creamers (Considine and Considine, 1982; FMC, no date). This would limit the non-dairy creamer to a 'made with organic' claim [7 CFR 205.605(b)(29)].

Organic ice cream producers make ice cream without added stabilizers and emulsifiers by producing in small batches with low over-run (Wright, 1994).

Sodium phosphates are not listed in any of the recipes and formulations contained in one of the few references devoted to soy dairy substitutes (Shurtleff and Aoyagi, 1985). Among the ingredients used in formulations described that are already on the National List include guar gum [205.606(b)] and lecithin [205.605(b)(15) and 205.606d]. Agar, alginic acid, pectins, potassium alginate, sodium alginate, and starches are also possible emulsifiers, stabilizers, and thickeners (Considine and Considine, 1982). Calcium sulfate (Buena Park, 2001) and carageenan (NOSB, Orlando, 1995) were not included on the National List; both were recommended for inclusion by the NOSB.

TAP Reviewer Discussion[2]

Reviewer 1 *[East Coast--Ph.D. in biochemistry with food industry experience]*

1. The three salts of Sodium Orthophosphate, FCC, are SYNTHETIC.

2. The three salts of Sodium Orthophosphate are already on the National List.

3. Any of the three salts of Sodium Orthophosphate should be allowed for use as direct additives in foods labeled as organic when used in accordance with good manufacturing practice provided that:

(d) the use is established as necessary for the processing of the food;
(e) the use is established as having no adverse nutritional impact on the "target population" intended to consume the food; and
(f) no non-synthetic, "less synthetic" or environmentally less impactful substance can be used in place of the sodium phosphate salt.

4. Assessment as to the completeness and accuracy of database and evaluation.

Criterion 3 [nutritional quality and adverse effects on human health]. This aspect is not adequately addressed in the document, particularly as it relates to the petitioned use of sodium orthophosphate in soy beverages purported to be nutritionally equivalent to cows' milk.

Relevant analyses were not provided on the effect of sodium phosphate use in a soy beverage purported to be nutritionally equivalent to cows' milk (a so-called "soymilk") and specifically on the overall mineral balance of the product. Soy is rich in phosphorus and poor in calcium. A varying proportion of the phosphorus is present as phytate (inositol hexaphosphate), which binds minerals like calcium and reduces their bioavailability. Adding phosphates can aggravate a nutritional imbalance between calcium and phosphorus. Similarly, adding sodium salts can create an imbalance between sodium and potassium.

Vegan parents sometimes feed soy beverages to their toddlers and small children as "milk." To gauge the nutritional impact of the use of sodium phosphate in these foods requires chemical analysis of the major minerals (calcium, phosphorus, magnesium, sodium, potassium, and chloride) in a soy beverage purported to be nutritionally equivalent to milk.

It may be that added phosphates are necessary for nutritional reasons, to meet compositional requirements for a soy beverage labeled as "soymilk" should FDA establish a standard of identify for foods so labeled.

Criterion 4 [technical effect in the food] is specified in the petition.

Criterion 5 [compatibility with organic handling]. The same reasoning that culminated in allowance of sodium orthophosphates for dairy products should hold for soy-based foods, except where nutritional considerations become critical due to the intended use and labeling of the food.

Criterion 7 [availability of alternative means]. The intended effect of sodium phosphate is to stabilize protein during heating or acidification. The petitioner so states: "The use of phosphates is always considered an essential part of a food formula whenever the food formulation contains protein that is subjected to heat or an acidic environment" (page 8, NOSB Petition of March 21, 2001).

However, this statement is an untrue overgeneralization in its use of the words "always," "essential" and "whenever." The petitioner has provided no objective evidence that alternative sequestrants (e.g., potassium citrate, sodium citrate, potassium phosphate, and potassium acid tartrate) cannot substitute for sodium phosphate. I am personally aware that citrates can replace phosphates in at least some of these applications (e.g., evaporated milk). . . . Thus, to paraphrase the language of the NOSB, "there is another way to produce the product without its use . . . " The citrate salts are more environmentally friendly and more sustainable than the phosphates, and they are already on the National List and allowed for use in organic foods.

[2] *OMRI's information is enclosed is square brackets in italics. Where a reviewer corrected a technical point (e.g., the word should be "intravenous" rather than "subcutaneous"), these corrections were made in this document and are not listed here in the Reviewer Comments. The rest of the TAP Reviewer's comments are edited for any identifying comments, redundant statements, and typographical errors. Text removed is identified by ellipses [...]. Statements expressed by reviewers are their own and do not reflect the opinions of any other individual or organizations.*

Comments on the petition.

The term "soymilk" is not universally accepted as the "common or usual name" of the beverage made with whole soybeans. The *FDA Consumer* magazine has published articles on soy. According to one article, "*'Soymilk,'* the name some marketers use for a soy beverage, is produced by grinding dehulled soybeans and mixing them with water to form a milk-like liquid. It can be consumed as a beverage or used in recipes as a substitute for cow's milk. Soymilk, *sometimes fortified with calcium*, comes plain or in flavors such as vanilla, chocolate and coffee. For lactose-intolerant individuals, it can be a good replacement for dairy products." (*FDA Consumer)* [Emphasis the reviewer's.]

In 1997, the Soyfoods Association of North America (SANA) filed a citizen petition requesting that FDA issued a regulation to recognize the term "soymilk" as the common or usual name for these products. See FDA/CFSAN Docket No. 97P0078/CP. SANA also proposed compositional specifications for products bearing the name of "soymilk." However, in May 2000, only 1 in 8 commercially available "soymilk" products met the compositional requirements for "soymilk" proposed by SANA [May 24, 2000, letter of C. Burnett of White Wave, Inc. to FDA].

The TAP document not withstanding, the petitioner is requesting allowance of far more than just the sodium salts of orthophosphate. The petitioner makes the statement "These phosphates . . . may be composed of aluminum . . . or sodium salts" (page 9). EAFUS and 21CFR 182.1781 show that "sodium aluminum phosphate" is allowed in food. Several recipes in the petition contain "sodium phosphate" but it is sodium ***aluminum*** phosphate . . . [*in*] Fanny's fat-free foods Ingredient Statement pages, and others. [Emphasis the reviewer's.]

The TAP document not withstanding, the petitioner is requesting allowance of sodium salts of far more than just orthophosphoric acid. The "Selected Definitions" page shows "sodium hexametaphosphate." Other recipes show sodium acid pyrophosphate and sodium tripolyphosphate. "Polyphosphates are made by heating mixtures of orthophosphates to high temperatures where they condense into phosphate chains." (FMC "Food Phosphates" document). This latter statement indicates that a separate TAP review of polyphosphates and pyrophosphates is needed due to the more drastic conditions required for their production.

The petitioner points out four abstracts as being critical but included none of the full articles in the petition. The abstracts are not detailed enough for thorough evaluation.

Reviewer 2 *[West coast--Consultant to organic certifiers]*

CHEMICAL/PROCESSING PROPERTIES, CATEGORIZATION AS SYNTHETIC OR NON-SYNTHETIC:

Sodium phosphates are easily soluble in water. They have a variety of uses in food processing, as mentioned in the database. This reviewer has not found any sources that describe sodium phosphates as being derived from natural sources. Rather, production comes from a neutralization of phosphoric acid by sodium hydroxide or sodium carbonate (Davidson, 2000). As such, sodium phosphates should be considered synthetic materials under OFPA guidelines.

NOSB processing criterion #1 states: "A synthetic processing aid or adjuvant may be used if it cannot be produced from a natural source and has no organic ingredients as substitutes." This is partially fulfilled for the case of sodium phosphates. There are no non-synthetic sources available. However, non-synthetic additives do exist that have similar effects on soy products as requested by the petitioner. Also, organic ingredients could conceivably be used – examples might be lecithin, oils, and starches, either by themselves or in combination, with or without inclusion of non-synthetic additives, to achieve the desired effect. For example, soymilk has been manufactured for many years without sodium phosphates. Additional ingredients to the soybeans include such things as calcium carbonate, lecithin, vegetable oils, kombu, and others. See below under "Uses/Essentiality/Compatibility" for more discussion.

ENVIRONMENTAL CONSIDERATIONS:

Manufacture of sodium phosphates is an industrial process. . . Production of sodium phosphates from the reactants involves yet more processes, each having concomitant added environmental impact.

Sodium phosphates are readily soluble in water into their ionic components. These ions are found in all organisms, and in and of themselves do not necessarily pose a significant environmental hazard, unless they occur at abnormally high levels. The control of effluent from sites of high sodium phosphate concentration could have detrimental impact on soils due to increased sodium content. Release of large amounts of phosphates into aquatic systems has been shown to cause algal blooms that in turn result in the death of higher species, as the algae deprive the other organisms of oxygen and other nutrients necessary for survival. This would be the case more for trisodium phosphate than for the mono- and di-sodium forms. . .

The amounts and concentrations proposed for use in the processing of organic foods do not necessarily approach the toxic levels needed to cause the results mentioned above. Presumably discharge of such concentrations into the environment could and should be regulated by other governmental agencies.

There are some precautions to be taken when handling certain sodium phosphates (Cherimishinoff, 1999), but these do not appear to be unduly onerous, especially when compared with other materials one might encounter in a processing facility that manufactures both conventional and organic products.

NOSB processing criterion #2 is, in the opinion of this reviewer, fulfilled.

NUTRITIONAL / HUMAN HEALTH EFFECTS:

Both phosphate and sodium are essential ions in human metabolism. Some studies offered by the database suggest that sodium taken in the diet as sodium phosphates may be correlated to displacement of calcium from the body (Boivin and Kahn, 1998), but there is equally compelling data which suggest that perhaps this is not a significant threat (Whiting, et al, 1997).

Elevated sodium intake is widely known to contribute adversely to a number of circulatory and other diseases in humans, but the amounts afforded by the proposed use of sodium phosphates is not deemed by this reviewer to constitute a significant added threat, especially if normal food labeling guidelines are followed by the manufacturer, whereby sodium content of the food product would be noted. Furthermore, concerns about sodium content in the human diet should not be based solely on one type of food product. Overall dietary consumption of sodium is part of a larger regimen; those persons concerned with excessive sodium intake should simply avoid foods made with extra sodium, and many alternatives exist, even if sodium phosphates were allowed in organic systems as proposed by the petitioner. . .

In the types of processes and amounts proposed for use by the petitioner, there is no reason to suspect any short-term negative consequences of their inclusion in human food, from a nutritional or health standpoint. Again, the long-term effects of ingestion are not conclusive. It is the opinion of this reviewer that NOSB processing criterion #3 is fulfilled to an extent that would not categorically prohibit the use of sodium phosphates from processing of organic foods.

On the other hand, there is nothing presented in the database or by the petitioner that indicates any positive nutritional or health effect from use of sodium phosphates in processing of organic food. It is clear that phosphate and sodium both can be gained in the diet through a multitude of other more unquestionably beneficial food sources. In summary, evaluations of the effects of sodium phosphates in the human diet are at best neutral, and may in time be shown to be detrimental, either slightly or more significantly so.

Uses / essentiality / compatibility with organic systems and principles:

One of the petitioner's reasons for wanting to use sodium phosphates is that they increase the stability of soy-based products. Such functions as they pertain to preservative types of actions should be construed as not meeting NOSB processing criterion #4 ("...it is not used as a preservative... "). . .

The petitioner does not dispute such ideas when considering more traditional soy-based products, but rather presents other rationale for the use of sodium phosphates. This rationale is based on the desire to produce certain food products whose organoleptic characteristic differ from those soy-based products that are made using already accepted additives (such as magnesium chloride, nigari, calcium sulfate, lecithin, other emulsifiers, oils, already approved non-synthetic non-organic ingredients, etc.). This may in fact be the case for certain formulated products that the petitioner wishes to market as organic. The combination of the sodium phosphate(s) with certain ingredients and using specific manufacturing techniques may indeed result in products with different textures and usability than those made without it. What the petitioner seems to be claiming is that use of sodium phosphates is essentially creating characteristics of the final food that would otherwise not be possible.

NOSB/OFPA criteria for evaluation of materials used in processing of organic foods do not specifically address such proposals. NOSB criterion #4 refers to the re-creation of flavors, textures, etc., but not the actual creation of new or otherwise unachievable characteristics. Organic certification is a process-based certification. The basis of standards is therefore not a list of materials, but rather is a set of practices, the materials being a support to that, and not vice versa. The question then arises as to whether or not such additives in organic foods are appropriate, given the fact that sodium phosphates are synthetic materials arising from industrial processes that themselves have environmental impact, and have not evolutionarily been included as part of the human diet. This is especially relevant when considering the uncertainty of the human health effects caused by more regular intake of sodium phosphates, as noted earlier in this review.

The petitioner claims that the essentiality of sodium phosphates in the formulations desired for marketing in the organic sector are manufactured as such so that they may mimic and compete with similar products that are dairy-based (Amin, 2001).

From such considerations as elaborated in the preceding two paragraphs, this reviewer is of the opinion that NOSB processing criterion #6 ("its use is compatible with the principles of organic handling") is not met.

Furthermore, to label such formulations as "organic food" seems to fail NOSB criterion #7, which states: "there is no other way to produce a **similar** product without its use and it is used in the minimum quantity required to achieve the process" (emphasis added). The petitioner claims that their food products made with additives other than sodium phosphates do not adequately equal traditional dairy-based counterparts, even though the products are in fact similar. On the other hand, labeling such foods as being "made with organic ingredients" would be a true statement."

Conclusion: 95% organic— synthetic, prohibited, no annotation. Made with organic— synthetic, allowed, no annotation.

Reviewer 3 *[West Coast–Ph.D., Food Science and Nutrition professor with inspection and certification experience]*

Overview

All life forms known to exist contain phosphorus as the phosphate anion. Polyphosphates to include di- and tri-phosphates play a central role in energy metabolism since it is the transfer of one phosphate of adenosine triphosphate that provides the means of energy transfer for every living cell. Phosphorous in the form of the phosphate anion is a constituent of nearly every type of food consumed by living organisms (Ellinger, 1972). Therefore the role of phosphorous in human cell bioenergetics is well established in the biochemical literature.

Phosphate in Food Processing

Functionality of phosphates in food depends on their ability to form complexes and reaction products with constituents of foods.

Phosphates have been used in food in the preparation of beverage powders, as leavening acids in chemical leavening systems, in cheese and dairy product beverages, puddings, coffee whiteners, whipped toppings, ice cream products, cream cheese and cheese spreads, and egg products. Additionally, phosphates are used in the refining of food oils, and reduction in the rate of lipid oxidation in muscle food systems. Phosphates have also shown to function as microbiological inhibitors Therefore, phosphates in the mono, di and tri forms have been and are used extensively in many food systems (Considine, 1982).

Regulatory Status

The US Food and Drug Administration considers use of sodium mono, di and tri phosphates as generally recognized as safe. Initially some types of phosphate were thought not to be safe. For example the cyclic metaphosphates showed upon ingestion a high urinary output. Further research has shown that the metaphosphate must first be hydrolyzed to the triphosphate and then to the orthophosphate before it can be absorbed (Ellinger, 1972). Sodium phosphate in the mono, di and tri basic forms are provided GRAS status (Ellinger, 1972).

Nutritional and Toxicological Issues

Sodium phosphate in all of its chemical forms has been approved as a dietary supplement (Ash and Ash, 1995). However, recent evidence suggests that there may be a relationship between high dietary levels of protein and phosphate that may increase urinary calcium excretion. Additionally, a recent report indicated that oral sodium phosphate when taken for bowel preparation (i.e. examination) may cause electrolyte shifts in patients resulting in death of elderly or seriously ill patients (Boivin and Kahn, 1998). Additionally, a study comparing bladder tumor promoting characteristics of sodium phosphate and sodium diphosphate with preformed nitrosamines showed that sodium phosphate, a urine alkalizer, demonstrated tumor promoting activity in rats initiated by N-butyl-N-4hydroxy butyl nitrosamine (BBN) (Shibata, et al, 1993). The authors suggested further study to better understand how the sodium phosphate in the presence of carcinogens such as nitrosamines function to possibly act as tumor promoters.

Overall, the literature contains many studies on the nutritional and potential toxicological effects of phosphates in food. However, after over forty years of research, few definitive conclusions have been made.

Additional Effects of Phosphates

It is well known that phosphate detergents may play a significant role in eutrophication. However, a database may be useful if detergents and/or cleaning compounds containing phosphate come up for review. Additionally, I think it would be wise to collect basic information on phosphate mining, sodium hydroxide and sodium carbonate manufacture...

Summary of Findings

Sodium phosphate in its mono-, di-, and tri- forms is being petitioned for inclusion on the NOP. Presently it is approved for use in dairy products. Sodium phosphate (mono, di and tri) is GRAS as determined by FDA [XXX note this conflicts with his answer below] Overall, since the NOSB approved its use for dairy products, it is hard to argue on any scientific basis why it cannot be used in other food systems. It is clearly a synthetic food additive that should have been prohibited in 1995 if only organic principles were applied. Therefore, I feel that on a purely scientific basis, sodium phosphate (mono-, di-, and tri-) should be classified as synthetic, allowed with a suggested annotation to the usage levels as required by FDA 21 CFR, inclusive of any product categories (i.e., not just dairy and soy).

The TAP Reviewers were also asked the following questions:

Similar questions were posted to the OMRI web site, and no information was received from the public by the deadline. Where a Reviewer is not mentioned, the Reviewer did not have comments on the question.

1) *Additional references requested.*
All three reviewers provided additional references that were integrated into the TAP review. Other comments:

Reviewer 1: The petitioner failed to include references establishing the essentiality of "sodium phosphate" for a purported "soymilk" manufacture. Thus, specific references documenting the use of sodium phosphates in "soymilk' cannot replace specific references that should prove that sodium phosphates are essential for "soymilk" manufacture.

The literature citations of effects of sodium phosphate purgatives are not relevant to food use. This is especially true when the bowel cleansers were not used according to label instructions and were given to patients where the use of phosphate purgatives was medically contraindicated.

Relevant literature was not provided on the effect of sodium phosphate use in a so-called "soymilk" on the overall mineral balance of the product. Soy is rich in phosphorus, with a varying proportion of it bound as phytate (inositol hexaphosphate). Adding phosphates can create a nutritional imbalance between calcium and phosphorus. Similarly, adding sodium salts can create an imbalance between sodium and potassium.

Reviewer 3: Review of the literature provides little evidence of the ability of phosphates to function as tumor promoters and play a role in carcinogenisis.

2) *OMRI did not include numerous references to dairy products for which the petitioner is substituting. If any of these are particularly relevant, please let OMRI know. Ellinger's 1972 survey has over 1,000 references, and many more references have come out since then. Very few seem to specifically address what is in the petition or the OFPA criteria.*

Reviewer 1: The physical and technological effects may be quite similar but the nutritional impact of added sodium phosphate on a calcium-rich milk system with a balanced calcium-to-phosphorus ratio is very different than the impact of added sodium phosphate on a calcium-poor so-called "soymilk" containing a lot of phosphorus.

Reviewer 3: According to the petition page 4, there are no other acceptable substitutes for phosphates, perhaps based on cost, functionality, product stability requirements during large scale manufacturing operations, and required product stability for shelf life considerations. I am sure that the soymilk I may make at home does not require phosphates because it is consumed in a matter of hours or days without any further processing. Therefore the petition seems to suggest that commercial manufacture requires the soymilk to be stabilized and therefore lies the nature or reason for the petition.

3) *Is there any documentation on sodium phosphates' uses in certified organic products prior to the 1995 NOSB recommendation for use in dairy products?*

Reviewer 1: I believe that the answer is yes, according to my recollection of the correspondence to the NOSB from industry in 1992-1995 on soy-based beverages.

Reviewer 2: A wide variety of soy-based products have been manufactured for a very long time without the use of sodium phosphates. From this standpoint, the need for sodium phosphates could be deemed to not be essential.

Reviewer 3: I have no references to document use of sodium phosphate in certified organic product prior to 1995.

4) *What do other soy milk manufacturers use?*

Reviewer 2 did not answer this question regarding soy milk but provided considerable comment on ingredients used in various other dairy substitutes.

5) *There is substantial literature on the medical applications and health effects of sodium phosphates that OMRI has not summarized in the TAP review, other than to note that it exists. Some potential areas to include for OFPA criteria question 4--The effects of the substance on human health:*

Reviewer 1: The health effects discussion in the document is too heavily weighted to pharmacological, pharmaceutical and toxicological aspects and not enough to the nutritional aspects.

Reviewer 3 did not respond to any of the items below in reference to 5, but instead verified the references used for processing criteria question 2 and suggested that it may be appropriate to cite additional references.

a) *One source describes trisodium phosphate as a tumor promoter, but it is not listed as such by NTP or IARC. Are there any additional references of any of the sodium phosphates?*

Reviewer 1: Trisodium phosphate is an extremely caustic material; note the pH value of 12 described in the base document. In a food system the use of a sodium phosphate is 'normally' at levels consistent with good manufacturing practices. I can think of no foods with a pH of 12 (equivalent to 0.01 N sodium hydroxide).

Reviewer 2: . . . the OMRI database includes reference to promotion of bladder cancer in rats fed trisodium phosphate (Shibata, et al), but this study in and of itself does not seem to be strong enough evidence to support significant concern of the petitioner's proposed use of sodium phosphates.

Reviewer 3: Review of the literature provides little evidence of the ability of phosphates to function as tumor promoters and play a role in carcinogenisis.

b) *What is the connection between sodium phosphates and osteoporosis? Specifically, do sodium phosphates increase, decrease, or have no effect on osteoporosis? Is there a difference between use in dairy foods and soy foods based on the different calcium and phosphate levels contained in those foods?*

Reviewer 1: I believe that the evidence is convincing that a high phosphate, low calcium diet will predispose to osteoporosis. More critically, a high calcium intake prior to menarche increases the bone calcium level in women. Thus, the use of added phosphate salts in a so-called "soymilk" needs to be guided by nutritional considerations of calcium-to-phosphorus ratio, etc.

Reviewer 2: Questions have been posed as to whether or not increased ingestion of sodium phosphates contributes in some way to osteoporosis, but there is no conclusive research offered to show that this is absolutely the case. These issues may be part of a larger question regarding the intake of phosphates in general, and their relation to calcium use by the body.

Uncertainty stems from several factors, among which are: (i) The interactions of phosphates and calcium in the body is not completely understood. Balance of the two is also dependent on a variety of other physiological factors, including hormone and vitamin levels (Vander, 1980). Much of the interactions on a cellular and wider physiological level are simply not adequately known. (ii) Individual human metabolism varies considerably from one person to another, based on genetics, body type, diet, lifestyle, and environmental exposure. (iii) Patterns of osteoporosis in the human population have not been well discerned to date. It is possible that increased documentation of the incidence of osteoporosis in the population over the next generation or so will reveal more convincing patterns. . . .

Reviewer 3 provided references that were incorporated in, and made the following statement:
In principle I am not in favor of the use of any synthetic additive or ingredient in organic food systems. In reality a decision was made to allow phosphates for use in dairy products. The literature warns us of the effects of increased phosphorous in the diet and its negative effect on calcium absorption and retention in bone. However, the usage levels as mandated by FDA mitigate this concern..
. . . [U]se of phosphates, in my opinion will contribute to the amount of phosphorous in the diet and may contribute to less calcium being absorbed. This is especially important in young children and older people who may be in osteoporatic conditions. It would be interesting to know what the ratio of calcium to phosphorous is in soymilk with and without the

added sodium phosphates. Without this data, it would be difficult to assess the specific availability of calcium from soy food and beverage products.

c) *Does sodium phosphate increase the excretion of calcium in [urine]? Most studies seem to suggest that it does not, but individual cases have been reported in the literature. Should the adverse health impact on a subgroup of the population be listed, even if adverse health impacts are not observed on most people?*

Reviewer 1: The chronic (rather than acute) effects of "soymilk" consumption by children and adolescents (rather than by elderly individuals with kidney failure) are much more relevant to the OFPA criteria in evaluating sodium phosphate use in a food labeled as "soymilk."

Reviewer 2: There is the possibility that increased intake of phosphates in the diet may lead to calcium depletion from the body, but this could likely be due to all types of phosphates as opposed to only sodium phosphates. For example, the increased consumption, especially by female youths and teenagers, of soft drinks containing phosphoric acid (in the diet in place of milk, fruit juices, plain water, or other non-synthetic drinks) may eventually show itself convincingly to be part of a pattern that leads to such diseases as osteoporosis. However, despite the possible validity of such concern, without some solid epidemiological or similar public health data, it is too early to actually draw such conclusions. For these reasons, it does not seem reasonable to this reviewer at this time to dwell on adverse health effects of sodium phosphates as recorded in individual cases, or to assume that the problems linked to dietary intake of phosphates (sodium or otherwise) is that simple or straightforward.

d) *Any other medical and health effects that should be included in the TAP review?*
None of the reviewers suggested anything specific. Reviewer 1 referred to the response to 5c.

6) *Compatibility (Processing criteria question 6: Its use is compatible with the principles of organic handling.): Any references to add in the discussion of the compatibility of imitation v. real products in organic?*

Reviewer 1: I believe that the regulators best make this value judgment. "Soymilk" is not a legal term, since "milk" has a legal definition. What we refer to as "soymilk" is a "soy beverage." These foods are 'real' soy beverages. Should the FDA ever create a standard of identity for "vegetable milk," this would be the forum for substantive and philosophical comments.

7) *Alternatives (Processing criteria question 7: There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.): By definition, dairy products are similar. However, there is a segment of consumers that demand organic vegan substitutes for dairy products. How is this best explored and explained?*

Reviewer 1: Potassium citrate can replace sodium phosphate in both dairy and in soy beverage processing, with some documentation available on a case-by-case basis.

The Food and Drug Administration and the Federal Trade Commission are charged with enforcing true and non-misleading labeling and advertising, respectively, with regard to these foods. Thus, this question is outside the aegis of both the NOSB and the USDA except as it relates to the use of the term 'organic'.

Reviewer 2: The choice of some consumers to buy and eat non-dairy foods is valid. However, the need to market such foods as being functionally and organoleptically equivalent to their dairy-based analogues is, in this reviewer's opinion, questionable. The need for consumers to have substitute or "mock" products so that they can alter their nutritional intake by simply substituting their habitual food choices with "fake" analogues is questionable. Consumers of organic food might consider a more broad or holistic approach to food preparation to satisfy their own dietary choices. The NOSB might want to address the question, Do such substitutions result in as complete a diet and nutrition for the consumer? As a simplistic example, soymilk is not recommended to replace dairy milk for feeding infants. It must be acknowledged that despite continual advances, mankind's knowledge of his nutritional requirements is incomplete. Compliance with organic certification requirements often demands creativity of the farmer, and of the processor... .

Reviewer 3: In review of the petition and from review of the literature I am not aware of a suitable alternative to sodium phosphate that possesses the same functionality, cost, availability and usage levels. In my opinion there is not available any non-synthetic alternative.

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*Note: * = included in packet*

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