Tetrasodium Pyrophosphate

Processing

Executive Summary

The NOSB received a petition to consider tetrasodium pyrophosphate (TSPP) as a pH buffer and dough conditioner for use in organic meat alternative products. The principal food uses for tetrasodium pyrophosphate are as an emulsifier, buffer, nutrient, dietary supplement, sequestrant, and texturizer in bread and cereal products. It may be prepared from processes involving neutralization of phosphoric acid using sodium carbonate or sodium hydroxide to produce dibasic sodium phosphate, which is further dehydrated molecularly to produce TSPP.

TSPP has not previously been reviewed by the NOSB. Sodium phosphates, a precursor, were reviewed in 1995 and again in 2001. The restriction on use established by the 1995 review—for use only in dairy products—was not extended to include other uses as petitioned in the 2001 review.

All reviewers agreed that Tetrasodium pyrophosphate is a synthetically produced food additive. A majority of reviewers agreed that the substance should not be added to the National List.

Identification

Chemical Name:
tetrasodium pyrophosphate

Other Names:
TSPP, pyro, sodium pyrophosphate, tetrasodium diphosphate; Diphosphoric acid, tetrasodium salt

Trade Names: Albrite TSPP Food Grade; Solutia TSPP; Nutrifos L-50 (with sodium tripolyphosphate); Wakal A601 (Ash and Ash, 1995).

CAS Numbers:
7722-88-5

International Numbering System (INS) Numbers:
452(i)

Other:
NIOSH Registry Number:
ACX #X10000138-0
RTECS UX735000

Summary of TAP Reviewer Analyses [1]

95% organic

Synthetic / Nonsynthetic:	**Allowed or Prohibited:**	**Suggested Annotation:**
Synthetic (3-0)	*Allowed (1)* *Prohibited (2)*	*None (3)*

Made with organic

Synthetic / Nonsynthetic:	**Allowed or Prohibited:**	**Suggested Annotation:**
Synthetic (3-0)	*Allowed (1)* *Prohibited (2)*	*None (3)*

[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.*

Characterization

Composition:
$Na_4P_2O_7$

Properties:
White crystalline solid (Ashford, 1994). Solubility in water at 0°C., 0.316 g/l (Budavari, 1996); Solubility in water at 25°C, 6.7 g/l (Ashford, 1994). The pH of a 1% solution is 10.2. Insoluble in alcohol (Budavari, 1996).

How Made:
TSPP can be prepared by molecular dehydration of dibasic sodium phosphate at 500°C. (Budavari, 1996). 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). Another way to prepare TSPP involves the calcination of sodium tripolyphosphate and a sodium salt (Hensler, 1989). The manufacture of the precursors is described in the review of triple superphosphate (OMRI, 2001c).

Specific Uses:
The specific use petitioned is as a pH buffer and dough conditioner for use in organic meat alternative products (Harding, 2002). Cereal and baked goods account for the greatest food use of phosphate additives (Branen, et al., 2002). The principal food uses for tetrasodium pyrophosphate are as an emulsifier, buffer, nutrient, dietary supplement, sequestrant, and texturizer (Astaris; FCC, 1996; Heidolph, et al., 2000). TSPP is also used in cleaning compounds, oil well drilling, rust removal, ink erasers, and in electrodeposition on metals (Budavari, 1996).

Action:
Phosphates in general interact with proteins, such as casein, to function as emulsifiers and prevent the separation of both fat and water in cheese (Gard, 1996). Casein is precipitated by pyrophosphates to form thick gels (Ellinger, 1972). This is believed to be the result of the negative ionic charge of pyrophosphate anions reacting with the positively charged cations in casein (Zittle, cited in Ellinger, 1972). Pyrophosphates are good sequestrants for copper and iron, which often catalyze oxidation in fruits and vegetables (Considine and Considine, 1982). 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).

Combinations:
Tetrasodium pyrophosphate is combined with calcium phosphates as leavening agents (Ellinger, 1972; FMC, no date). TSPP has a synergistic effect on various foaming agents, such as alkyl polycarboxylates and triethyl citrate (Sutton, 1960). Other salts, such as sodium chloride, can have a synergistic effect on water-holding capacity of sodium phosphates (Gordon and Klimek, 2000).

Status

Historic Use:
The interaction of shorter chain polyphosphates—including pyrophosphates—with proteins was first known in 1916 (Ellinger, 1972). Industrial manufacturing of pyrophosphates occurred as early as the 1920s (Dickerson, 1927). Commercial application of polyphosphates for preparing vegetable protein-polyphosphate compounds in food processing appears to date back to the late 1940s (Reviewed in Ellinger, 1972. See, for example, Horvath, 1947).

OFPA, USDA Final Rule:
The NOSB has previously reviewed sodium orthophosphates (NOSB, 1995a) and the USDA added them to section 205.605(b)(33) of the NOP National List of "Non-agricultural (nonorganic) ingredients allowed for use in organic processed products . . .Sodium phosphates—for use only in dairy foods." The NOSB reviewed sodium phosphates again in October, 2001 (see the TAP review at OMRI, 2001b) and declined a petition to expand the permitted uses to include soy products. The NOSB determined that pyrophosphates and other polyphosphates require separate TAP reviews.

Regulatory:
See Table 1, below, for FDA references to tetrasodium pyrophosphate.

EPA/NIEHS/Other Sources:
EPA –Inert ingredients List 4B (US EPA, 1995).

NIEHS – No listing in the National Toxicology Program database (NTP, 2002).

Status Among U.S. Certifiers:
No certifier lists tetrasodium pyrophosphate as allowed, but several list sodium phosphates. Although the NOSB clarified that the recommendation was only for sodium (mono-, di-, and tri) orthophosphates and only for dairy products, some certifiers may have considered this sufficient to allow sodium pyrophosphates and sodium polyphosphates. Tetrasodium pyrophosphates do not appear on the Organic Materials Review Institute (OMRI) *Generic Materials List* (OMRI, 2001a).

California Certified Organic Farmers (CCOF) Certification Handbook (2000), Section 8.3.3 Processing and Handling Materials, "Sodium phosphates - Allowed Non-Organic, Use as an ingredient restricted to dairy foods." The listing does not distinguish between ortho-, pyro-, and polyphosphates.

Oregon Tilth Certified Organic (OTCO) – The most recent available Standards Manual prior to the NOS Final Rule (1998) lists only "Sodium Phosphates" as an allowed synthetic in organic processing, and does not list ortho-, pyro-, or polyphosphates separately. The annotation accompanying sodium phosphates states "...for use only in dairy foods."

Organic Crop Improvement Association International (OCIA) International Certification Standards (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." The listing does not distinguish between ortho-, pyro-, and polyphosphates.

Quality Assurance International (QAI) – No reference.

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." The listing does not distinguish between ortho-, pyro-, and polyphosphates.

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." The listing does not distinguish between ortho-, pyro-, and polyphosphates.

International
CODEX – Not listed.
EU 2092/91 – Not listed.
Japan Ministry of Agriculture, Forestry and Fisheries (JMAFF, 2001) – 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.
One study reported that sodium pyrophosphate has a rat intraperitoneal LD_{50} of 233 mg/kg and an oral LD_{50} of greater than 4 g/kg (Datta, et al., 1962). As such, sodium pyrophosphate is less toxic than the orthophosphates, but has similar deleterious subacute effects. TSPP depressed weight gains, decreased hemoglobin concentration, and reduced liver iron values the greatest among several food additive phosphates tested on rats (Molins, 1991). A number of feeding studies that involved rodent models showed kidney damage and calcium deposits in test animals (Ellinger, 1972). 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). Emits toxic fumes of PO_x and Na_2O (Ash and Ash, 1995). Also see criterion 4 and processing criterion 3, below.

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

4. The effects of the substance on human health.

As noted above (criterion 2), sodium pyrophosphate has been linked to kidney damage. Extrapolation from rat models may overestimate kidney damage from sodium pyrophosphate as a food additive, but overall phosphate consumption may be more relevant because sodium pyrophosphate readily converts to orthophosphate (Datta, et al., 1962). Actual consumption data is scarce, and phosphate additives may be over- or under-estimated (Molins, 1991).

Inhalation of heavy dust may irritate nose and throat. Ingestion may injure mouth, throat, and gastrointestinal tract, resulting in nausea, vomiting, cramps, and diarrhea; pain and burning in the mouth may occur. Contact with eyes produces local irritation, and may lead to chronic damage. Contact with skin produces local irritation; repeated or prolonged contact can lead to dermititis (Cheremisinoff, 1999)

Most of the human health references are related to its medical, rather than food, use. 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.

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. TSPP used as a buffer in cattle diets increased the microbial alpha-amino N (microbial protein synthesis) more than any other buffer—nearly twice the control (Hall and Thomas, 1984). TSPP inhibits *Bacillus subtilis* and other organisms commonly found in soils (Davidson, 2000).

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

7. Its compatibility with a system of sustainable agriculture.
See processing criterion 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.
Alkali pyrophosphates are naturally produced in plants, animals, and microorganisms (Heinonen, 2001). No documentation could be found of natural sources of food grade tetrasodium pyrophosphate. Various nonsynthetic items that already appear on the National List could be possible substitutes as pH buffers, including calcium carbonate, calcium phosphates, and sodium orthophosphates. Sodium chloride (salt) is also used as a buffer. Lecithin from organic soybeans is a possible substitute for certain applications as an emulsifier. Sodium alginate was found to be a more effective stabilizer for whipped cream than TSPP (Rothwell, cited in Ellinger, 1972). Dairy cultures can be used to make buttermilk instead of TSPP. The process using TSPP takes 1-5 hours, while the dairy culture process takes 15-48 hours (van Wazer, cited in Ellinger, 1972).

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.
Because it is manufactured from sodium orthophosphates, and is used and disposed of in much the same manner, the impacts on the environment are similar. The manufacturing processes for sodium orthophosphates, sodium carbonate, and sodium hydroxide (see "How Made" section, above) are covered in previous TAP reviews for these materials. 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 (OMRI, 2001c).

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.

The process of extrusion creates high temperature and pressures. High-temperature treatment of proteins with polyphosphates (pyrophosphate is the simplest polyphosphate) creates stable complexes resistant to the action of microorganisms, acids and alkalis (Ellinger, 1972). If a protein-phosphate complex is this stable, it is foreseeable that the protein is less bioavailable than untreated protein. The biological quality of the processed protein needs to be assessed to determine if there has been a significant loss in protein quality.

The use of tetrasodium pyrophosphate raises nutritional concerns related to the formation of bone tissue because its addition raises both sodium and phosphorous levels in the food. 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).

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. In particular, TSPP inhibits *Bacillus subtilis Enterococcus faecalis, Clostridium sporogenes, C. bifermentans,* and *Staphylococcus aureus* (Davidson, 2000). Phosphates stabilize proteins during processing so they improve finished product texture (Yazici, et al., 1997). It is also used as a nutritional supplement to replace or enhance phosphate levels. Pyrophosphates are often be used to prevent discoloration of foods during preparation and storage (Considine and Considine, 1982).

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.
The Food Chemicals Codex (1996) specifications for sodium pyrophosphate are as follows:

Assay: Not less than 95.0% and not more than 100.5% of $Na_4P_2O_7$, calculated on an ignited basis.
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%
Loss on ignition: $Na_4P_2O_7$ (anhydrous): Not more than 0.5%; $Na_4P_2O_7 \cdot 10H_2O$ (decahydrate): between 38.0% and 42.0%.

Table 1
FDA References to Tetrasodium Pyrophosphate and Pyrophosphates

21 CFR	Section Heading	Notes / Limitations
133.169	Pasteurized process cheese	Optional ingredient as an emulsifier, not to exceed 3% by weight of the product.
133.173	Pasteurized process cheese food	Optional ingredient as an emulsifier, not to exceed 3% by weight of the product.
133.179	Pasteurized process cheese spread	Optional ingredient as an emulsifier, not to exceed 3% by weight of the product.
173.310	Boiler water additive	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	Not to exceed the amount required as a preservative in emulsion defoamer.
175.300	Resinous and polymeric coatings	Miscellaneous material.
181.29	Stabilizers	Sodium pyrophosphate classified as a stabilizer, when migrating from food-packaging material.
182.70	Substances migrating from cotton and cotton fabrics used in dry food packaging	Tetrasodium pyrophosphate is GRAS as a substance migrating to food from cotton and cotton fabrics used in dry food packaging.
182.6787	Sodium pyrophosphate	GRAS when used in accordance with GMPs.
182.6789	Tetra sodium pyrophosphate	GRAS when used in accordance with GMPs.
	Source: EAFUS (2002)	

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). Principles of organic handling adopted by NOSB in October, 2001 include the statement "Organic processors and handlers implement organic good manufacturing and handling practices in order to maintain the integrity and quality of organic products through all stages of processing, handling, transport, and storage." The NOSB considered a petition for the general use of sodium phosphates in 1995, and restricted that use to dairy products. The 2001 review of sodium phosphates made it clear that the only substances considered in the 1995 and 2001 petitions were the three sodium orthosphosphates, mono-, di-, and tri-.

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 refers to internal proprietary research and process development, but does not provide any data to support the case. The investigator is unable to evaluate the claims made in the petition without more information. There is also no information to determine the quantity needed.

In general, various alginates, lecithin, and sodium citrate, can be used to substitute for emulsification; calcium carbonate, calcium citrate, potassium carbonate, potassium citrate, sodium carbonate, and sodium bicarbonate can be used as pH buffers; and citric acid and sodium citrate can be used as sequestrants (Lindsay, 1996).

TAP Reviewer Discussion[2]

The TAP Reviewers were asked the following questions:
Q1.Is there any documentation on tetrasodium phosphate in organic processing?

Reviewer 1: No. A search of the internet found that TSPP is an ingredient of JELL-O brand instant pudding but no indication that organic foods contain TSPP.

Reviewer 2: I have never come across this material being used before for direct contact with organic foods, in my direct work with over half a dozen certifiers and indirect work with dozens more.

Reviewer 3: An additional computer search did not reveal any literature documenting the use of tetrasodium phosphate in organic products or in process operations.

Q2 . . . [Are there a]ny references to add in the discussion of the compatibility of imitation v. real products in organic?
Reviewer 1: A fundamental principle of processing organic food with a synthetic substance as an ingredient is that a determination has been made that no nonsynthetic substance is able to be used successfully in the processing. The petition and the accompanying documentation provide no evidence of the essentiality of TSPP in the application and also provide no evidence of an evaluation of any nonsynthetic materials in the application.

The application is stated to be the use of TSPP as a buffering agent and a dough conditioner for milled and processed grain products. "Dough conditioners" allowed by FDA in foods include diverse substances: sodium stearoyl lactylate, datem, ammonium sulfate, calcium sulfate, l-cysteine hydrochloride, ascorbic acid, potassium iodate, azodicarbonamide, l-cysteine, and enzymes; at least some of these may be compatible with organic. "Buffering agents" allowed in organic foods include sodium citrate and sodium bicarbonate. There are no data presented to indicate that these materials have been tested in the application.

The petition does not clearly identify the food product(s) in which TSPP is used. The petition refers to "good textured wheat gluten proteins" and "milled and processed grain products which are used as ingredients for organic meat alternative products." The letter of June 11, 2002, refers to an "extrusion process." An example of product packaging would be useful, as would a flow diagram of how the product(s) is made.

Another principle of processing organic food is "minimal processing." The temperatures and pressures generated during an extrusion process may be sufficient to create complexes of protein and phosphates with diminished digestibility and bioavailability. Protein quality should be evaluated.

Reviewer 2: I looked for references like this, but was not able to come up with any that satisfied me.

[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.*

Reviewer 3: Overall I do not feel any synthetic additive is compatible with the principle of organic food products except for one exception. For issues of food safety only would a synthetic be considered. However, the review process has allowed the use of synthetic additives for a host of technical issues. Therefore, the review process is a critical pathway to conduct a careful technical review so that the individual merits of each review can be evaluated. For example, the NOSB has approved the use of sodium orthophosphate. On a purely scientific basis it is difficult to argue against using tetrasodium phosphate, sodium diphosphate, or sodium pyrophosphate. It is critical to the review process that consistency is maintained and sound science be used for the basis of the review process. This is the baseline of judgment that I feel should be employed in the assessment of compatibility issues.

Q3. . . By definition, meat products are similar. However, there is a segment of consumers that demand organic vegan/vegetarian substitutes for meat products. How is this best explored and explained? In particular, do any of you have good references for the making of seitan or other gluten-based high protein meat substitutes?

Reviewer 1: It is important to distinguish between food labeling questions and food processing questions. "Imitation" is a term used in labeling and advertising, regulated by the Food and Drug Administration and the Federal Trade Commission, respectively. These other agencies are charged with enforcing true and non-misleading labeling and advertising, respectively, with regard to foods. So-called "imitation meat" is true food made from gluten-containing grains. Traditionally this food is called "seitan."

The questions at hand are (1) whether the production of "seitan" requires use of the synthetic substance TSPP and (2) whether such production is compatible with the requirements of the OFPA and its attendant regulations. Neither of these questions have been answered by the petition, the petitioner or the accompanying references.

Q4. What are the vegan or vegetarian alternatives to muscle meat and can they be organic?

Reviewer 1. "Seitan" [gluten dough washed free of carbohydrate] is claimed as a vegetarian substitute for meat. See various websites for preparation methods and recipes for its use.

Q5. How can "seitan" ("gluten meat") be produced?

Reviewer 1The modern method requires instant gluten flour, also known as pure gluten flour or vital wheat gluten. (Gluten flour is **not** the same as high-gluten bread flour.) Pure gluten flour has had its starch (and bran) removed, and doesn't act like ordinary flour at all. When mixed with water, it doesn't make dough, but instead makes something that looks like wet rubber. In fact, this rubbery stuff is raw gluten.

The traditional way to make seitan is to combine flour and water to make a dough and then rinse the dough in water to remove the starch. [information taken from http://home.teleport.com/]

Q6. Can "seitan" be produced without tetrasodium pyrophosphate?

Reviewer 1: According to Internet websites, Arrowhead Mills produces a "Seitan Quick Mix." Also, some health food stores sell 'wet' seitan in the refrigerated section. These products apparently do not contain TSPP. Thus, it appears that "seitan" can be prepared without TSPP.

Reviewer 2: As stated in my review, numerous cookbooks state how to do this very simply using water only. Probably can find a similar description in an industrial food process textbook. . .

Reviewer 3: Review of reference *Foods and Food Production Encyclopedia* (1982) . . . indicates that phosphates are used in production of texturized vegetable protein to enhance water binding. TVP (texturized vegetable proteins) are the basis of meat analogues used for the production of meat substitutes. Sources of vegetable proteins routinely are wheat gluten or soy protein. Therefore, it would seem reasonable that use of sodium pyrophosphate due to its high affinity to bind water molecules at low concentrations is a unique functional property that appears not to [affect] the hydrophilic/hydrophobic balance of the food system allowing TVP and phosphate to work in concert in binding water, flavor and other components of the meat analogue system.

Reviewer Comments

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

It is extremely difficult to evaluate the adequacy of the TSPP TAP Review because the petition is not clear on the particulars of use of TSPP or on the effect of not using it in the desired application. The petition (page 4 of 5, submitted September 2001) indicates that ". . . as a result of our internal proprietary research and process development, we have yet to find a material(s) equal to TSPP in overall functionality and process flow, at such minor amounts . ." but provides no details of this research that permit of an evaluation against point 7 of the Criteria established by the NOSB on February 10, 1999. Maintaining such information as a trade secret is inconsistent with the transparency required for a TAP Review.

Organic Ingredients as Substitutes

The application is very poorly described in the petition so it is virtually impossible to determine if an organic ingredient can substitute for TSPP.

Primary Purpose

The petition indicates that TSPP complexes metals and inhibits rancidity and fat oxidation.

Compatibility

The use of TSPP has not been established as necessary for the processing of an organic food. The nutritional impact of TSPP on protein quality has not been evaluated.

Conclusion

Tetra Sodium Pyrophosphate should NOT BE ADDED TO THE NATIONAL LIST as an ingredient allowable in a product labeled 95% organic or in a product made with organic ingredients (i.e, it should be PROHIBITED), because no use has been established as necessary for the processing of an organic food and because the nutritional impact of TSPP on protein quality has not been evaluated.

Reviewer 2 [West coast--Consultant to organic certifiers, extensive experience in processing]

Both phosphorous and sodium, while necessary and important components of human biochemistry, are readily available from a wide variety of nonsynthetic sources, both agricultural and non-agricultural. The literature is not conclusive one way or the other as to whether the addition of TSPP to the diet contributes adversely to human health. There is no compelling reason to believe, however, that the addition of synthetic TSPP to human foods is necessary in the diet or would in and of itself contribute positively to human health.

Nutritional Quality

The interaction of sodium and phosphorous in the body is intimately linked with metabolism of other ions as well, perhaps most notably calcium. Calcium levels in the body are suggested to be especially important when considering its effects on healthy bone maintenance. Uncertainty arises 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 and other bone-related diseases in the human population have not been well discerned to date.

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 TSPP 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 TSPP was allowed in organic systems as proposed by the petitioner.

Primary Use

The petitioner states that one of the main reasons to use TSPP is "for the texturization of the proteins which is also critical to the quality characteristics of the end-use products." This is essentially a desire to create or improve textures not normally found in the organic agricultural ingredients under handling practices that do not use the synthetic agent, and as such fails the criterion.

The petitioner also states that the sequestrate action of TSPP inhibits rancidity of the textured final products. This implies two things: (i) TSPP is acting as a preservative; and (ii) TSPP effects a chemical interaction with the organic agricultural ingredients, from which one might thus conclude that the final product is synthetic in itself. In these regards TSPP again fails the criterion.

Compatibility

Organic systems are in principle conceived to be as close a mimic to nature as possible. The removal of parts of the whole food during processing should therefore be considered carefully, as should the reaction of organic ingredients with synthetic ingredients. The creation of isolates or chemically altered foods as significant components of the human diet is a departure from the principles of organic production (although this might be considered a matter of degree, in some cases). Until chemistry can explain biology – which at this point in time it cannot adequately do – a precautionary approach is advisable when considering the inclusion of synthetic components on food production systems and consumer food products.

Regarding the overall impact on the organic food choices and the nutritional value of organic foods provided to the consumer, the benefits of allowing TSPP into organic food processing systems is questionable, in the opinion of this reviewer. The intention to create "fake" meats or similar products could, over the course of time and the spectrum of manufacturing possibilities, result in an array of products on the market that are increasingly further departures from the original agricultural foods used as starting ingredients. Allowing the use of a synthetic agent such as TSPP could result in the creation of protein isolates or otherwise potentially nutritionally unbalanced food products. Limiting such processed products to those which are produced using only nonsynthetic ingredients and traditional food preparation methods (such as are used to produce wheat gluten in Asian cuisines) is a closer approximation to organic production practices and principles, and is perhaps more harmonious with the evolutionary development of the human diet. The advantages of ease and speed of processing stated by the petitioner may be desirable, but these concerns should not outweigh these other principles.

While it is entirely possible to have a complete vegetarian diet, such a diet generally implies that the eater consumes a wide enough variety of foods to get complete nutrition. Meats are generally high in nutrients, but fake meat is not the same thing, and it might be inadvisable for the consumer to equate one with the other – yet this is what the manufacturers of such products might want imply, and what some uneducated consumers believe. Therefore, it does not seem appropriate to allow TSPP for foods labeled as "made with organic *[specified ingredients]*" either. Unless there are more strict guidelines on how said organic ingredients would be labeled – particularly in the case of isolates created in the process using TSPP – the consumer might easily be misled by such label declarations, thinking they were buying a product with the whole organic food or natural part of said food, as opposed to an isolate created using a synthetic agent. For example, such products labeled as "made with organic wheat" might not necessarily be as accurate as a product "made with proteins isolated from organic wheat."

Alternatives

Nonsynthetic methods have long been used to produce plant-based protein concentrates. Numerous cookbooks and simple food processing manuals give recipes and procedures for producing seitan and other wheat gluten products. Production of such foods is entirely possible without the use of synthetic agents. (Wheat gluten is traditionally produced using only water as a processing aid.) Defatted soy flour - made without the use of synthetic agents - is also readily available on the market as a "meat substitute."

Conclusion

Among the benefits put forward by the petitioner of allowing TSPP in organic systems is that it would provide alternatives to meats to the organic consumer, and would thereby increase the market demand of certain organic grains produced by farmers. These are worthy goals. However, in this case the end does not justify the means. The allowance of a synthetic agent to create a food product that has unknown, inconclusive, or questionable nutritional effects, or results in the creation of food products far removed from their natural substrates, is generally not compatible with organic production principles. Natural alternatives exist in a variety of aspects, as mentioned in the TAP database and this review. Consumers who do not wish to eat meat generally have ability to learn and prepare a wide variety of well-established vegetarian *[dishes]* from various world cuisines.

The petitioner's request, while specific to their intended food products, are not the only product formulations that will be affected by the decision on TSPP, and a long-range view should be taken. Allowance of this synthetic material for the types of purposes intended by the petitioner could be a significant precedent.

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

It should be noted that sodium pyrophosphate is also called sodium diphosphate and the listing of chemical forms of phosphate should be specifically listed to avoid potential co-mingling of the forms of phosphate considered during the review process.

Nutritional Quality
Additional dietary phosphate may contribute to phosphorylation reactions in vivo contributing to the formation of high-energy nucleotides such as adenosine triphosphate and therefore contribute to oxidative phosphorylation. The net effect would be maintenance of body's energy metabolism.

Primary Purpose
The . . . two phosphate atoms linked through a shared oxygenation is also used in the fermentation industry as a yeast nutrient for alcoholic fermentation of beer and wine.

Compatibility
Since the USDA has approved sodium orthophosphate with their inclusion in 205.605b(33) of the NOP with specific application to dairy foods, there is minimal compelling scientific justification of not including all chemical forms requested in the petition for inclusion in the NOP.

Alternatives
The class of sodium pyrophosphates under review is capable of performing specific functional properties in food systems. It must be noted that differences in solubility, moisture levels, fat levels and pH all in concert influence the activity of functional additives to enhance or stabilize food systems. For example, disodium phosphate (pyrophosphate) readily disassociates as a function of pH to bind divalent or monovalent cations which may cause beverage discoloration; phosphate anions serve as a nutrient source for Saccromycetes (yeast) in fermentation; phosphate anions react with water to form phosphoric acid in chemically leavened food products to form the acid component of the acid base chemical leavening system and phosphates contribute a high water binding capability in muscle foods enhancing their sensory value. I feel the example functional properties as cited specifically demonstrate that pyrophosphates are unique functional additives which are difficult to simulate with potential alternatives.

Conclusion
Due to the unique functional properties of tetrasodium pyrophosphate . . . in a wide range of food products and its potential use in organic vegetarian substitute foods the argument for approval is compelling.

The argument is further strengthened by previous NOSB approval of sodium orthophosphate. Therefore I am in favor of allowing its usage according to GRAS recommendations in organic food systems.

It should be noted that consistency is a very important component of the review process. Since sodium orthophosphate has been approved by the NOSB for dairy product usage only, it is very difficult to scientifically oppose the use of pyrophosphates in food systems. Overall, I feel credibility may be compromised when a product is approved for one food category.

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