



BEYOND PESTICIDES

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October 2, 2014

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Re. HS: Tetrasodium Pyrophosphate (TSPP)

These comments to the National Organic Standards Board (NOSB) on its Fall 2014 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and groups around the world.

Beyond Pesticides opposes the relisting of tetrasodium pyrophosphate (TSPP) because it fails to meet the criteria in the Organic Foods Production Act for health and environmental effects, essentiality, and compatibility with organic handling practices.

The principal documentation available to the committee includes a 2001 technical advisory panel (TAP) review of sodium phosphates for use in soy milk, a 2002 TAP review of TSPP for use as a pH buffer and a dough conditioner for organic meat substitutes, and a 2014 limited-scope technical review (TR) addressing alternatives for the current use “in meat analog products.” Unless otherwise specified, “TAP review” below refers to the 2002 review.

1. Health and Environmental Impacts

TSPP is made from phosphoric acid and sodium carbonate. Manufacture of food grade phosphoric acid involves the removal of heavy metals and radioactive waste. This produces a waste stream of hazardous substances. A primary environmental concern of sodium phosphates is their release into water. TSPP emits toxic fumes when heated to decomposition.

According to the Technical Advisory Panel review,

[S]odium 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. A number of feeding studies that involved rodent models showed kidney damage and calcium deposits in test animals. The toxicity of sodium phosphates is generally related to the sequestration of calcium and the subsequent reduction of ionized calcium. Ingestion may injure the mouth, throat, and gastrointestinal tract, resulting in nausea, vomiting, cramps, and diarrhea.

2. Essentiality

The TAP review points out that several nonsynthetic items on the National List are substitutes for the various functions of TSPP. The 2014 technical review is focused on the listed use of TSPP in “meat analog products” and demonstrates that TSPP is not necessary.

3. Compatibility

We agree with the concern raised by the Handling Subcommittee:

The subcommittee has also raised the concern about the sole function of this input being to restore texture after complex processing and this runs counter to §205.600(4): "The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law".

This is further supported by the TAP review, “Phosphates stabilize proteins during processing so they improve finished product texture.”

In addition, we agree with observation in the TAP review,

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.

4. Ancillary Substances

According to the recommendation passed by the NOSB in the spring of 2013, the board defined “ancillary substances” as “additives added during the manufacturing of a non-organic substance and **not** removed.”

The NOSB went on to recommend the following policy:

The NOSB intends to review ancillary substances found in substances on and petitioned for the National List in accordance with OFPA criteria. Comprehensive review does not require these substances to be individually listed on the National List, however. The Board intends to follow the request by NOP to consider ancillary ingredients contained in substances as they come up for review or as new petitions are considered.

In each NOSB review checklist and recommendation cover sheet there will be a clear space to indicate what other ingredients are being reviewed and what restriction if any are placed on them as a result of the review. Restrictions on other ingredients will be included in an annotation and may be for specific individual components, for functional classes of ingredients, or by regulatory reference to another governmental agency such as FDA. The other ingredients restrictions may be incorporated into a permitted substances database for Handling, such as the one that is coming out for crops.

The NOSB recommendation will include a note that the other ingredients were reviewed and accepted. The review of other ingredients will distinguish between synthetic and nonsynthetic

ones, as well as agricultural ingredients that might be able to be organically produced. Any additional restrictions will be specified in an annotation.

Ancillary substances in general product categories that are currently on §205.605 and §205.606 and currently used in certified organic processed product will continue to be allowed until they go through their next sunset review and subsequent Rule amendment.

The ancillary substances associated with this material have not been reviewed or even listed. This is an important piece that needs to be incorporated into the review of every material during sunset.

5. Conclusion

Beyond Pesticides opposes the relisting of tetrasodium pyrophosphate (TSPP) because it fails to meet the criteria in the Organic Foods Production Act for health and environmental effects, essentiality, and compatibility with organic handling practices.

A word about the process of the Handling Subcommittee. It is critical that the subcommittee and Board prepare a more robust review for public discussion at the first meeting on a Sunset 2016 material. Since the Fall 2014 meeting is scheduled to be the only public NOSB meeting during which the Handling Subcommittee and Board members can share their thinking and receive “timely” public input on the checklist and assessment of the material in accordance with OFPA criteria, the lack of prepared written analysis by the subcommittee for this meeting makes for an incomplete and truncated assessment process. We appreciate the subcommittee’s question on essentiality of the material, but believe that the subcommittee and Board have a responsibility to bring to the public a comprehensive set of questions that address all OFPA criteria with a preliminary assessment of the data it has and should have prepared a preliminary checklist.

Under the current process, information brought to the Board at the Spring 2015 meeting will be considered “untimely.” While we recognize that the Board has embarked on a new two-stage process, the first stage, or first meeting on sunset materials, must be a more robust review process if the Board’s assessment of exempt prohibited materials, like this one, on the National List is to be viewed by the public, including users and consumers, as credible. The process requires this, if there is to be continuing and building public trust in the assessment process and the organic food label.

We have attached a checklist in which we provide the Board with answers to questions, based on available TAP reviews, that are required to be considered as a part of a sunset review that is in compliance with the Organic Foods Production Act (OFPA) and the implementing regulations. Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Shistar".

Terry Shistar, Ph.D.
Board of Directors

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Checklist
Tetrasodium Pyrophosphate (TSPP)**

[Date of Vote]

Summary of Proposed Action:

[Insert narrative describing vote, review of material, discussion, etc.]

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for §205.606)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

Substance Fails Criteria Category: [] **Comments:**

Subcommittee Action & Vote, including classification proposal (state actual motion):

Classification Motion: Move to classify [substance] as [synthetic, nonsynthetic, agricultural]

Motion by:

Seconded by:

Yes: # No: # Absent: # Abstain: # Recuse: #

Listing Motion: Move to list [substance] on section **205.6xx** of the National List [with the annotation]

Motion by:

Seconded by:

Yes: # No: # Absent: # Abstain: # Recuse: #

Proposed Annotation (if any):

Basis for annotation: To meet criteria above Other regulatory criteria Citation

Notes:

Approved by Subcommittee Chair to Transmit to NOSB

Name, Subcommittee Chair

Date

NOSB Evaluation Criteria for Substances Added To the National List Handling

Category 1. Adverse impacts on humans or the environment?

Substance:

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]				
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]	X			TSP is made from phosphoric acid and sodium carbonate. Manufacture of food grade phosphoric acid involves the removal of heavy metals and radioactive waste. 2001 TAP sodium phosphates This produces a waste stream of hazardous substances.
3. Are there any adverse impacts on biodiversity? (§205.200)				
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]			X	
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		A primary environmental concern of sodium phosphates is their release into water. TAP, p. 4.
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c)(1)(A)(i); 6517 (c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]	X			[S]odium pyrophosphate is less toxic than the orthophosphates, but has similar deleterious subacute effects. TSP 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). TAP, p. 3. Ancillary substances unknown.
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]		X		TAP, p. 5 for TSPP. Ancillary substances are unknown.
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600(b)(5)]		X		TAP, p. 5.

**NOSB Evaluation Criteria for Substances Added To the National List
Handling**

Category 2. Is the Substance Essential for Organic Production? Substance:

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			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. TAP, p. 1.
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]		X		
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		
6. Is there an organic substitute? [§205.600(b)(1)]	?			
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]		X		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. TAP, p. 4.
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X			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. TAP, p. 4.
9. Are there any alternative substances? [§6518(m)(6)]	X		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, p. 6.
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	X		In addition to the alternatives above, the TAP discusses the production of seitan without TSPP. P.7.
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.		X	Ancillary substances are not known.

NOSB Evaluation Criteria for Substances Added To the National List Handling

Category 3. Is the substance compatible with organic handling practices? Substance:

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]		X		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.” TAP, p. 6.
2. Is the manner of the substance’s use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]		X		See above #1 and Category 1, #2.
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]		X		Preservative –see #6 below.
4. Are the ancillary substances reviewed compatible with organic handling [?]		?		Ancillary substances not reviewed.
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]		X		Impact on protein quality unknown. Possible impact on calcium use by body.
6. Is the primary use as a preservative? [§205.600(b)(4)]	X			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. TAP, p. 8.
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]	X			Sodium phosphates possess antimicrobial properties. In particular, TSPP inhibits <i>Bacillus subtilis</i> <i>Enterococcus faecalis</i> , <i>Clostridium sporogenes</i> , <i>C. bifermentans</i> ,

				and <i>Staphylococcus aureus</i> (Davidson, 2000). Phosphates stabilize proteins during processing so they improve finished product texture (Yazici, et al., 1997). TAP, p. 5.
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NOSB Evaluation Criteria for Substances Added To the National List: Handling
Category 4. Is the commercial supply of an organic agricultural substance fragile or potentially unavailable? [§6610, 6518, 6519, §205.2, § 205.105(d), §205.600(c)] **Substance:**

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?				
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?				
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling?				
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling?				
5. Does the industry information about unavailability include (but is not limited to) the following?:				
a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;				
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or				
e. Other issues which may present a challenge to a consistent supply?				