



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: Sodium Acid Pyrophosphate

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 sodium acid pyrophosphate (SAPP), based on the information available to us and the Handling Subcommittee (HS). We note that the principal document available to the committee is a technical advisory panel (TAP) review of sodium phosphates in response to a petition for use in soy milk. The technical review (TR) focuses on a proposed expanded use of SAPP, and does not address the current listed use. We have added some additional toxicity information in the attached checklist.

Our role as public interest commenters on the NOSB materials review process is to ensure that NOSB decisions are based on OFPA criteria, backed up with adequate documentation. We are disappointed that given the inadequacies of the documentation, the HS has not requested a supplemental TR addressing the use of SAPP as a leavening agent. This lack of documentation is especially disturbing because any information received after this meeting will be considered “untimely” according to the new NOP sunset policy.

1. Health and Environmental Impacts

The TR says no data was found on the material itself that indicated it posed potential negative impact on human health or the environment, but it did discuss that one of the primary inputs in the manufacture of SAPP, phosphoric acid, does pose a threat if waste is not carefully managed. According to the TAP review for sodium phosphates, the manufacture of food grade phosphoric acid involves the removal of heavy metals and radioactive waste. This creates a hazardous waste stream. A primary environmental concern of sodium phosphates is their release into water, though this is only likely to be a problem with this use in the case of a spill. When heated to decomposition, it emits toxic fumes.

[S]odium pyrophosphate has similar subacute effects to the more toxic orthophosphates, including kidney damage and calcium deposits in test animals. According to the TAP review, “The toxicity of sodium phosphates is generally related to the sequestration of calcium and the subsequent reduction of ionized calcium. It is an irritant, and ingestion may injure the mouth, throat, and gastrointestinal tract, resulting in nausea, vomiting, cramps, and diarrhea.”

2. Essentiality

SAPP is an acid that reacts with baking soda to act as a leavening agent. Other sources of acid – buttermilk, yogurt, molasses, lemon juice, vinegar – are commonly used alternatives. Besides those above, other acids on the National List for use in food include potassium acid tartrate (cream of tartar) and ammonium bicarbonate. Whipped egg whites and yeast are alternative methods of leavening.

3. Compatibility

SAPP is a synthetic chemical that is not essential for organic processing and whose manufacture creates a hazardous waste stream. It should therefore be viewed as incompatible with organic production and handling.

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 sodium acid pyrophosphate because it does not meet the criteria of lack of harm to the environment and human health, essentiality, and compatibility.

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. Had this been done, the Subcommittee would have discovered that it needed a more complete TR to enable a complete assessment in accordance with OFPA criteria. Or, conversely, with a written prepared review, the subcommittee would have been able to share with the organic community its thinking on its decision on TR sufficiency and compliance with OFPA criteria. 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 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". The signature is written in a cursive, flowing style.

Terry Shistar, Ph.D.
Board of Directors

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Checklist
Sodium Acid Pyrophosphate**

[Date of Vote]

Summary of Proposed Action:

Listed on 205.605(b)

Sodium acid pyrophosphate (CAS # 7758-16-9)—for use only as a leavening agent.

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

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

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)]	X			When heated to decomposition, it emits toxic fumes.(ToxNet ¹)
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			The TR mentions no data was found on the material itself that indicated it posed potential negative impact on human health or the environment, but it did discuss that one of the primary inputs in the manufacture of SAPP, Phosphoric acid, does pose a threat if waste is not carefully managed. TR lines 311-336. 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	X			A primary environmental concern of sodium phosphates is their release into

¹ <http://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+hsdb:@term+@rn+@rel+7758-16-9>

breakdown products in the environment? [§6518(m)(2)]				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			An irritant to skin, eyes, and mucous membranes. ² [S]odium pyrophosphate is less toxic than the orthophosphates, but has similar deleterious subacute effects. 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). TAP, p. 5. Emits toxic fumes of PO _x and Na ₂ O (Ash and Ash, 1995). 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	?		SAPP is GRAS. Ancillary substances unknown.
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 (b)(5)]	?			No information was identified to suggest that SAPP contains residues of heavy metal or other contaminants in excess of FDA tolerances. TR lines 282-283.

² Toxnet: <http://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+hsdb:@term+@rn+@rel+7758-16-9>

³ <http://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+hsdb:@term+@rn+@rel+7758-16-9>

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		See #2 below.
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			SAPP is manufactured by (1) partial neutralization of phosphoric acid (H ₃ PO ₄) with sodium hydroxide (NaOH) or sodium carbonate (Na ₂ CO ₃) to form monosodium phosphate (NaH ₂ PO ₄) and then (2) dehydration of monosodium phosphate at approximately 250° C to form SAPP (Na ₂ H ₂ P ₂ O ₇). TR lines 143-146
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		See #2 above.
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		See #2 above.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		TR line 214.
6. Is there an organic substitute? [§205.600(b)(1)]		X		See above.
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]		X		
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X			SAPP is an acid that reacts with baking soda to act as a leavening agent. Other sources of acid –buttermilk, yogurt, molasses, lemon juice, vinegar—are commonly used alternatives.
9. Are there any alternative substances? [§6518(m)(6)]	X			Besides those in #8 above, other acids are listed for use in food that could be used: potassium acid tartrate (cream of tartar), ammonium bicarbonate
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	X			Biological leavening with yeast or physical leavening with egg whites.
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.		X		

**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)]	?			
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]	?			
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	?			
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			Excessive use might cause excessive phosphorus in food, but not likely as a leavening agent.
6. Is the primary use as a preservative? [§205.600(b)(4)]		X		It can be used as a sequestrant, but that is not an allowed use in organic processing. TR line 229-234.
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		As a sequestrant it would be, but that use is not allowed. TR lines 241-262.

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?				