

**Formal Recommendation by the
National Organic Standards Board (NOSB)
to the National Organic Program (NOP)**

Date: April 29, 2011

Subject: Sodium Acid Pyrophosphate

Chair: Tracy Miedema

The NOSB hereby recommends to the NOP the following:

Rulemaking Action
Guidance Statement
Other

Statement of the Recommendation (Including Recount of Vote):

Not to expand the current listing of Sodium Acid Pyrophosphate in section 205.605(b) of the National List for use as a sequestrant for cooked and uncooked produce.

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

The petition was to expand the allowed use of Sodium Acid Pyrophosphate (SAPP) on the National List § 205.605(b) to include its use as a sequestrant on cooked and uncooked produce. It is currently listed "for use only as a leavening agent". The TR mentioned 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. The petitioner did not provide compelling evidence that SAPP is necessary or essential to organic handling, and as a matter of fact, a Handling Committee survey of organic handlers who could potentially use this material did not reveal any who actually would if it was listed.

The Handling Committee recommended against expanded listing of the material. The vote was 0 yes, 6 no, and 1 absent for expansion of the listing. After the Handling Committee recommendation was published, the petitioner submitted public comments disagreeing with the committee recommendation, but no other comments in favor of the expanded listing were received. Several comments were received agreeing with the committee recommendation. The full board concurred with the Handling Committee recommendation at the April 2011 NOSB meeting with the vote for the expanded listing shown below.

NOSB Vote:

Moved: Steve DeMuri		Second: Mac Stone		
Yes: 0	No: 14	Abstain: 0	Absent: 0	Recusal: 0

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: **April 2011**

Substance: **Sodium Acid Pyrophosphate**

Committee: Crops Livestock Handling **Petition is to expand the allowed use of Sodium Acid Pyrophosphate on the National List § 205.605(b) to include it's use as a sequestrant on cooked and uncooked produce. It is currently listed "for use only as a leavening agent".**

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

- | | | | |
|--|---|--|---|
| 1. Impact on Humans and Environment | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. Essential & Availability Criteria | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 3. Compatibility & Consistency | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |

Substance Fails Criteria Category: 1 and 3. 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. The petitioner did not provide compelling evidence that SAPP is necessary or essential to organic handling, and as a matter of fact, a survey of organic handlers who could potentially use this material did not reveal any who actually would if it was listed.

Proposed Annotation (if any): N/A

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

B. Recommended Committee Action & Vote, including classification recommendation (State Actual Motion):

To classify Sodium Acid Pyrophosphate as a synthetic material.

Classification of the material: Synthetic: _____ Non-synthetic: _____

Motion by: Steve DeMuri Secoded: Katrina Heinze Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Recommended Committee Action & Vote To expand the listing of Sodium Acid Pyrophosphate on 205.605(b) to include use as a sequestrant on cooked and uncooked produce.

Motion by: Steve DeMuri Secoded: Katrina Heinze Yes: 0 No: 6 Absent: 1 Abstain: 0 Recuse: 0

Crops		Agricultural		Allowed ¹	
Livestock		Non-Synthetic		Prohibited ²	
Handling	<input checked="" type="checkbox"/>	Synthetic	<input checked="" type="checkbox"/>	Rejected ³	<input checked="" type="checkbox"/>
No restriction		Commercially Un-Available as Organic ¹		Deferred ⁴	

1) Substance voted to be added as "allowed" on National List to § 205._____ with Annotation (if any) _____

2) Substance to be added as "prohibited" on National List to § 205._____ with Annotation (if any) _____

Describe why a prohibited substance: _____

3) Substance was rejected by vote for amending National List to § 205. 605(b) Describe why material was rejected:

For the reasons described in the Criteria Category discussion in Section A above.

4) Substance was recommended to be deferred because _____

If follow-up needed, who will follow up: N/A

C. Approved by Committee Chair to transmit to NOSB:

Steve DeMuri
Committee Chair

April 29, 2011
Date

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance: Sodium Acid Pyrophosphate

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]	X			The TR, page 9, describes environmental concerns with the phosphoric acid used to produce the SAPP, and potential heavy metal contamination from phosphate rock mining, used to produce the phosphoric acid..
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			Heavy metal contamination of groundwater and estuaries possible during manufacture if not mitigated. These metals can be taken up by plants and marine life leading to concentration of heavy metals in food products. TR page 9
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		No evidence the substance itself is harmful. TR page 9.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1) (B)(ii); 205.601(m)2]		X		No evidence it contains these inerts.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		None identified in the TR.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			X	The substance is added to food as a leavening agent now, and has been petitioned to allow use as a sequestrant for vegetables. It is not applied to soil or crops.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			There can be an uptake of heavy metals from the phosphate rock component of the manufacturing process, but no evidence to suggest the material itself has detrimental physiological effects on soil organisms, crops, or livestock. TR page 9.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		None mentioned in the TR.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		No evidence of this in the TR.
10. Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)I; §6518 m.4]		X		According to the MSDS and TR, SAPP may cause body irritation in some individuals, but no evidence of it being acutely hazardous to human health.

11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		No evidence of such in the TR.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			TR page 6.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		There is no evidence that the substance contains heavy metals in excess of FDA tolerances.

¹ If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production?

Substance: Sodium Acid Pyrophosphate

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. 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). Phosphoric acid and sodium carbonate are the feedstock for producing SAPP.
2. 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 above
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		See # 1 above.
4. Is there a natural source of the substance? [§205.600 b.1]		X		Components of some of the manufacturing inputs are natural, but some are synthetic, rendering it a synthetic (not natural) substance.
5. Is there an organic substitute? [§205.600 b.1]		X		According to the petition and the TR, page 6, there are no organic substitutes known.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		May be useful as a reduced sodium leavening agent, but no compelling evidence is provided that it meets essentiality criteria, since other listed materials serve the same function.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		X		There is no evidence a natural substitute product exists. TR page 5.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		Used in handling, but IS synthetic and not organically produced.
9. Is there any alternative substances? [§6518 m.6]	X			Citric acid is used currently by some manufacturers to reduce oxidation on cut fruits and vegetables. There was no explanation in the petition as to why citric acid couldn't be used.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			A primary purpose for the material stated in the petition was for cut potatoes. An HC survey of major organic potato producers revealed that prompt production of manufactured potato products from raw potatoes greatly reduced the oxidation occurrence

			<p>on cut or peeled surfaces of the vegetables. Stored potatoes tend to oxidize more easily the longer they are held post harvest prior to further manufacturing. All organic potato handlers contacted stated they would not use the material even if listed, and would instead continue managing harvest and storage to reduce browning.</p>
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¹ If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 3. Is the substance compatible with organic production practices? Substance: Sodium Acid Pyrophosphate

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]	X			
2. Is the substance consistent with organic farming and handling, and biodiversity? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X		X	Consistent with Handling, but not applicable to farming and biodiversity, since it is not applied to soil or crops..
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	Petitioned for use in a Handling application.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			Nutritional quality is not negatively affected by it's use, per the TR, page 6.
5. Is the primary use as a preservative? [§205.600 b.4]		X		Primary use would be as an anti-oxidant to reduce browning in cut cooked or uncooked produce, not to limit microbial growth.
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		X		This substance, for the purpose petitioned, would act as an anti-oxidant on cut cooked or uncooked produce, not to recreate or improve factors lost during processing.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:			X	Not petitioned to this committee for use in organic production, just handling.
a. Copper and sulfur compounds;			X	See above
b. Toxins derived from bacteria;			X	See above
c. Pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	See above
d. Livestock parasiticides and medicines?			X	See above
e. Production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	See above

¹ If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]

Substance: Sodium Acid Pyrophosphate

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	This category pertains only to substances petitioned for addition to section 205.606. All questions in this category (4) not applicable.
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?			X	
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?			X	
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?			X	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			X	
a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	
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;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			X	