

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

Date: April 29, 2011

Subject: Calcium Acid Pyrophosphate

Chair: Tracy Miedema

The NOSB hereby recommends to the NOP the following:

Rulemaking Action
Guidance Statement
Other X

Statement of the Recommendation (Including Recount of Vote):

Not to add calcium acid pyrophosphate to § 205.605(b) of the National List.

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

The NOSB considered a petition to add Calcium Acid Pyrophosphate to the National List, section 205.605, and per board procedures, first made a determination as to whether the material should be classified as a synthetic or a non-synthetic. The Handling Committee recommended a synthetic classification, and the full board concurred with that recommendation in its vote at the full board meeting: Yes: 13; No: 1; Absent: 0.

This material was petitioned to the NOSB for use as a leavening agent in organic baked goods. The Handling Committee voted 5 no, 0 yes, and 2 absent for the listing of this material to the National List, thereby recommending it not be listed. The full board likewise rejected listing at its April 2011 NOSB meeting.

The manufacture of Calcium acid pyrophosphate (CAPP) involves the reaction of phosphoric acid produced from phosphate rock with Calcium oxide. Heavy metal contamination from mining operations is a concern, as is the environmental effect of the phosphoric acid component of the manufacture. The petition did not provide compelling evidence that the material is essential for organic production, even for its petitioned use as a leavening agent for organic baked products. Sodium acid pyrophosphate (SAPP) is already listed for use for this purpose, and although there is

mention of the fact that this material could be substituted for SAPP to reduce sodium content of organic baked items, there is no comparative discussion in the petition of what the actual sodium reduction would be, whether it would be significant enough to justify adding another synthetic material to the National List, or even if organic consumers desire lower sodium content in their baked goods. The TR states potential sodium reduction of up to 26%, but it is formula dependent. Calcium phosphates, also already listed materials, are also used in the leavening of bread and bakery products and do not contain sodium. There is no explanation as to the reasons for preference of CAPP over these materials, if one exists.

After publishing of the Handling Committee recommendation for the full board meeting, the petitioner submitted public comment opposing the committee viewpoint, but no other public comments were received in favor of listing the material. Several public comments were received opposing listing, agreeing with the committee recommendation.

NOSB Vote:

Moved: Steve DeMuri		Second: Mac Stone		
Yes: 5	No: 9	Abstain: 0	Absent: 0	Recusal: 0

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: **April 2011**

Substance: **Calcium Acid Pyrophosphate**

Committee: Crops ☐ Livestock ☐ Handling ☒ **Petition is for the addition of Calcium Acid Pyrophosphate to the National List § 205.605(b) "for use as a leavening agent" in baked goods.**

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

- | | | | |
|--|---|--|---|
| 1. Impact on Humans and Environment | Yes ☐ | No ☒ | N/A ☐ |
| 2. Essential & Availability Criteria | Yes ☐ | No ☒ | N/A ☐ |
| 3. Compatibility & Consistency | Yes ☒ | No ☐ | N/A ☐ |
| 4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) | Yes ☐ | No ☐ | N/A ☒ |

Substance Fails Criteria Category: 1 and 2. Comments: The manufacture of Calcium acid pyrophosphate (CAPP) involves the reaction of phosphoric acid produced from phosphate rock with Calcium oxide. Heavy metal contamination from mining operations is a concern, as is the environmental effect of the phosphoric acid component of the manufacture. The petition does not provide compelling evidence that the material is essential for organic production, even for its petitioned use as a leavening agent for organic baked products. Sodium acid pyrophosphate (SAPP) is already listed for use for this purpose, and although there is mention of the fact that this material could be substituted for SAPP to reduce sodium content of organic baked items, there is no comparative discussion in the petition of what the actual sodium reduction would be, whether it would be significant enough to justify adding another synthetic material to the National List, or even if organic consumers desire lower sodium content in their baked goods. The TR states potential sodium reduction of up to 26%, but it is formula dependent. Calcium phosphates, also already listed materials, are also used in the leavening of bread and bakery products and do not contain sodium. There is no explanation as to the reasons for preference of CAPP over these materials, if one exists.

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 Calcium Acid Pyrophosphate as a synthetic

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

Motion by: Steve DeMuri Seconded: Tracy Miedema Yes: 5 No: 0 Absent: 2 Abstain: 0

Recommended Committee Action & Vote: To add Calcium Acid Pyrophosphate to section 205.605(b) of the National List

Motion by: Steve DeMuri Seconded: Tracy Miedema Yes: 0 No: 5 Absent: 2 Abstain: 0

Crops		Agricultural		Allowed ¹	
Livestock		Non-Synthetic		Prohibited ²	
Handling	☒	Synthetic	☒	Rejected ³	☒
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:

Fails Categories 1 and 2 of the National List petitioned material evaluation criteria. See 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: Calcium 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 7, describes environmental concerns with the phosphoric acid used to produce the CAPP, and heavy metal contamination from phosphate rock mining, another input to the CAPP manufacturing process.
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 7
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.
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, not 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.
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, the substance may cause skin, eye, and respiratory tract irritation. Can be harmful if ingested in large quantities. TR page 8.

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			The substance is isn't listed as GRAS by the FDA, but was affirmed as GRAS by the SCOGS with no limitations other than Good Manufacturing Processes. TR page 5.
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. TR page 7.

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: Calcium 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			The typical manufacturing method described by the petitioner states that food grade phosphoric acid produced from phosphate rock is reacted with calcium oxide (lime) to precipitate calcium dihydrogen phosphate. The calcium dihydrogen phosphate is filtered and undergoes calcinations at 270°C to form CAPP. The material is then milled to a powder and packaged. TR page 4.
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 5, 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			SAPP is currently listed and used for the same purpose, but petitioner states CAPP would be a low sodium option. Calcium phosphates are already listed and used for the same purpose as well. No compelling rationalization provided, other than the sodium claim, as to why SAPP or Calcium phosphates don't suffice for the petitioned application.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Unleavened organic bakery products could be produced, by acceptability by organic consumers is unknown.

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: Calcium 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. It can have the benefit, however, of providing a low sodium leavening agent alternative for organic processors.
5. Is the primary use as a preservative? [§205.600 b.4]		X		Primary use would be as a leavening agent for organic baked goods, not preserving. TR page 6.
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 a leavening agent, not to recreate or improve quality attributes lost in processing. However, there is an indirect impact on the texture of baked goods as CAPP neutralizes baking soda and CO ₂ expands in the product during the baking process. TR page 6. The texture change is a result of processing, not a replacement function.
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: Calcium 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	