

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance Tetrasodium 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		TAP – Sodium Phosphates – 9/21/02, page 6 “ A primary concern is their release into water. However, this is primarily related to detergents and not as a food additive. Additionally: Page 3 and page 4 TAP.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		TAP – Sodium Phosphates – 9/21/02, page 6 “ A primary concern is their release into water. However, this is primarily related to detergents and not as a food additive. Additionally: Page 5 (top)
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		TAP – Sodium Phosphates – 9/21/02, page 6 “ A primary concern is their release into water. However, this is primarily related to detergents and not as a food additive.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			X	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		TAP – TSPP 7/02 page 3; The substance is used in production and would not interact directly with other materials used.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			X	Processing Material
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	Processing Material
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]			X	Processing Material
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]			X	Processing Material
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		TAP page 4: As noted, sodium pyrophosphate has been link to kidney damage However, TAP – Phosphates – 9/01 page 1; All reviewers shared the consensus that the levels used in food manufacture should not pose a serious risk for most consumers. TAP – TSPP- page 4; Most of the human health references are related to its medical, rather than food use. .
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		TAP: Page 3 NIEHS data
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]	X			TSPP – TAP page 6; 182.6789 GRAS when used in accordance with GMP’s. Tap page 5#5
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		TSPP – TAP page 5. Petition page 1 (characterization)

¹If 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 _____ TSPP _____

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is there a natural source of the substance? [§205.600 b.1]		X		TAP – Phosphates – 9/01 page 6 – TSPP TAP pg. 4; No documentation could be found of natural sources of food grade sodium phosphates.
2. Is there an organic substitute? [§205.600 b.1]	X			TSPP TAP pg. 4; lists organic lecithin as an emulsifier – not applicable since petitioned use is pH agent and dough conditioner.
3. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	X			Public Comment: 9/19/02; NOSB Meeting; Dr. Bassi. Page 7&8; Tested the following alternatives and all were not unsatisfactory do to poor quality, functionality, affordability, and unwanted discoloration and undesirable odor and foul taste. This product cannot be produced from natural sources and has no organic ingredients as substitutes. Note: Sodium phosphates currently allowed on the National List for Dairy foods. Petition: page 4 & 6, TAP page 11 (alternatives)
4. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		X		Public Comment: 9/19/02; NOSB Meeting; Dr. Bassi. Page 7&8; Tested the following alternatives and all caused poor quality, functionality, affordability, and unwanted discoloration and undesirable odor and foul taste. This product cannot be produced from natural sources and has no organic ingredients as substitutes. Petition: page 4 & 7, 9./ TAP: page 6 & 7
5. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		TSPP TAP page 1; All reviewers determined a synthetic
6. Is there any alternative substances? [§6518 m.6]	X			Public Comment: 9/19/02; NOSB Meeting; Dr. Bassi. Page 78; Tested the following alternatives and all caused poor quality, functionality, affordability, and unwanted discoloration and undesirable odor and foul tast. This product cannot be produced from natural sources and has no organic ingredients as substitutes. Sodium Hydroxide, Sodium Bicarbonate, Sulphur, Bisulfide, Sodium Phosphate, Disodium Phosphate, Sodium Polyphosphate, Sodium Trimetaphosphate. Per phone interview with NOSB processing committee also tested phosphates currently on national list. Note: Sodium phosphates currently allowed on the National List for Dairy foods Public Comment: 9/19/02 Tom Harding; As Dr Bassi has clearly stated, we have searched out and tested several other materials, some on the national list, and some recommended by the TAP reviewers. To date we have found no equals to TSPP, and none perform at these levels, and provide the functionality in quality of properties. Petition: page 4 & 9. TAP page 6 & 7. 6/11/02 – Letter to USDA.
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		Public comment and interviews with Processing committee validated no other practices or products would recreate the same product. Petition page 4 & 8, TAP: 6 & 7

¹If 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 _____ TSPP

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			<p>Sodium phosphates currently allowed on the National List for Dairy foods. Public Testimony 9/19/02; Dr. Bassi; There are products currently labeled certified organic in the marketplace. Public Testimony 9/19/02 – page 84; Tom Harding; All these organic products have high consumer acceptance, and are certified by responsible accredited certifiers.</p> <p>TAP – TSPP – 7/02; reviewer comment – page 11; Since the USDA has approved sodium orthophosphates with their inclusion in 205.605b(33) of the NOP with specific application to dair foods, there is minimal compelling scientific justification of not including all chemical forms requested in the petition for inclusion in the NOP. It should be noted that consistency is a very important component of the review process., it is difficult to scientifically oppose the use of pyrophosphates in the food systems.</p> <p>TAP – page 7 (Q2) Rev. 3, Page 11 (bottom)</p>
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]			X	<p>Handling Material. Sodium phosphates currently allowed on the National List for Dairy foods. Public Testimony 9/19/02; Dr. Bassi; There are products currently labeled certified organic in the marketplace. Public Testimony 9/19/02 – page 84; Tom Harding; All these organic products have high consumer acceptance, and are certified by responsible accredited certifiers.</p>
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	<p>Handling Material: Sodium phosphates currently allowed on the National List for Dairy foods. Public Testimony 9/19/02; Dr. Bassi; There are products currently labeled certified organic in the marketplace. Public Testimony 9/19/02 – page 84; Tom Harding; All these organic products have high consumer acceptance, and are certified by responsible accredited certifiers.</p>
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			<p>TAP TSPP 7/29/02 – reviewer comment – page 9; 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.</p> <p>TAP – Phosphates – 9/01 page 6 The primary adverse human health effect is the elevation of sodium levels and the substitution of sodium for calcium. However, does not appear to increase in normal healthy individuals.</p> <p>Petition: Page 4</p>
5. Is the primary use as a preservative? [§205.600 b.4]		X		<p>Petition; page 2; The petitioned use is as a buffer (pH agent) and dough conditioner for milled and processed grain products.</p> <p>TAP – Page 9: TAP – TSPP – reviewer comment; page 10; 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 & wine.</p>

				<p>Petition: page 4; Intended use as stated in the proposed annotation and specific uses in this petition are primarily not as a preservative, or to recreate flavor, color or texture. Its use as a dough conditioner and pH agent is indispensable because it greatly improves protein process flow.</p> <p>Reference Material – Functions of food phosphates; Astaris LLC – Table A; Tetrasodium Pyrophosphate – Alkalinity, Buffering Agent, Coagulant, Dispersing Agent, Emulsifying Agent, Protein Modifier, Sequestrant, Stabilizer.</p> <p>Reference Material – Functions of food phosphates; Astaris LLC – Bakery applications of Solutia Phosphates; Food Phosphates find many uses in baking; Leavening acidulants, Dough conditioners, pH and buffering. The phosphates used include ingredients tailored to meet the home and commercial baker’s specific leavening acid requirements. In addition to their role as the most commonly used acidulants for leavening formulas . Food phosphates contribute to bread production directly in dough improvers and yeast foods, as well as indirectly as acidifiers in the production of yeast. Leavening applications; SAPP; Breeding Batter Mixes, Cake Doughnut Mixes, Refrigerated Dough, Waffle Mixes. Primary use is a leavening acid.</p>
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		<p>TAP – TSPP – reviewer comment; page 5; Phosphates stabilize proteins during processing so the improve finished product texture.</p> <p>Petition: page 4; Intended use as stated in the proposed annotation and specific uses in this petition are primarily not as a preservative, or to recreate flavor, color or texture. Its use as a dough conditioner and pH agent is indispensable because it greatly improves protein process flow.</p> <p>Reference Material – Functions of food phosphates; Astaris LLC – Table A; Tetrasodium Pyrophosphate – Alkalinity, Buffering Agent, Coagulant, Dispersing Agent, Emulsifying Agent, Protein Modifier, Sequestrant, Stabilizer.</p> <p>Yes, the TAP does indicate that it use is for texture but it does not state to recreate texture.</p>
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:			X	Handling Material
a. copper and sulfur compounds;				
b. toxins derived from bacteria;			X	Handling Material
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	Handling Material

d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	

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

NOSB RECOMMENDED DECISION

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: _____	Substance: _____														
<p>A. Evaluation Criteria (Documentation attached; committee recommendation attached)</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;"></td> <td style="text-align: right;">Criteria Satisfied?</td> </tr> <tr> <td>1. Impact on humans and environment</td> <td style="text-align: right;">Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</td> </tr> <tr> <td>2. Availability criteria</td> <td style="text-align: right;">Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</td> </tr> <tr> <td>3. Compatibility & consistency</td> <td style="text-align: right;">Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</td> </tr> </table>			Criteria Satisfied?	1. Impact on humans and environment	Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)	2. Availability criteria	Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)	3. Compatibility & consistency	Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)						
	Criteria Satisfied?														
1. Impact on humans and environment	Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)														
2. Availability criteria	Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)														
3. Compatibility & consistency	Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)														
<p>B. Substance fails criteria?</p> <p>Criteria category: _____</p> <p>Comments: _____</p>	<p>C. Proposed Annotation: _____</p> <p>_____</p> <p>Basis for annotation: _____</p> <p>To meet criteria above: _____ Criteria: _____</p> <p>Other regulatory criteria: _____ Citation: _____</p>														
<p>D. Final Board Action & Vote: Motion by: _____ Second: _____</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; padding: 5px;"> <p><u>Vote:</u></p> <p>Yes: _____</p> <p>No: _____</p> <p>Abstain: _____</p> </td> <td style="width: 75%; border: 1px solid black; padding: 5px;"> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td style="width: 33%;">Agricultural</td> <td style="width: 33%;">Nonagricultural</td> <td style="width: 33%;">Crops</td> </tr> <tr> <td>Synthetic</td> <td>Not synthetic</td> <td>Livestock</td> </tr> <tr> <td>Allowed¹</td> <td>Prohibited²</td> <td>Handling</td> </tr> <tr> <td>No restriction</td> <td>Deferred⁴</td> <td>Rejected³</td> </tr> </table> </td> </tr> </table> <p style="text-align: center; margin-top: 5px;">1—substance voted to be added as “allowed” on National List</p> <p>Annotation: _____</p> <p style="text-align: center; margin-top: 5px;">2—substance to be added to “prohibited” paragraph of National List</p> <p>Describe why a prohibited substance: _____</p> <p style="text-align: center; margin-top: 5px;">3—substance was rejected by vote for amending National List</p> <p>Describe why material was rejected: _____</p> <p style="text-align: center; margin-top: 5px;">4—substance was recommended to be deferred</p> <p>Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up. _____</p>		<p><u>Vote:</u></p> <p>Yes: _____</p> <p>No: _____</p> <p>Abstain: _____</p>	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td style="width: 33%;">Agricultural</td> <td style="width: 33%;">Nonagricultural</td> <td style="width: 33%;">Crops</td> </tr> <tr> <td>Synthetic</td> <td>Not synthetic</td> <td>Livestock</td> </tr> <tr> <td>Allowed¹</td> <td>Prohibited²</td> <td>Handling</td> </tr> <tr> <td>No restriction</td> <td>Deferred⁴</td> <td>Rejected³</td> </tr> </table>	Agricultural	Nonagricultural	Crops	Synthetic	Not synthetic	Livestock	Allowed ¹	Prohibited ²	Handling	No restriction	Deferred ⁴	Rejected ³
<p><u>Vote:</u></p> <p>Yes: _____</p> <p>No: _____</p> <p>Abstain: _____</p>	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td style="width: 33%;">Agricultural</td> <td style="width: 33%;">Nonagricultural</td> <td style="width: 33%;">Crops</td> </tr> <tr> <td>Synthetic</td> <td>Not synthetic</td> <td>Livestock</td> </tr> <tr> <td>Allowed¹</td> <td>Prohibited²</td> <td>Handling</td> </tr> <tr> <td>No restriction</td> <td>Deferred⁴</td> <td>Rejected³</td> </tr> </table>	Agricultural	Nonagricultural	Crops	Synthetic	Not synthetic	Livestock	Allowed ¹	Prohibited ²	Handling	No restriction	Deferred ⁴	Rejected ³		
Agricultural	Nonagricultural	Crops													
Synthetic	Not synthetic	Livestock													
Allowed ¹	Prohibited ²	Handling													
No restriction	Deferred ⁴	Rejected ³													
<p>E. Approved by NOSB Chair to transmit to NOP:</p> <table style="width: 100%; border: none; margin-top: 10px;"> <tr> <td style="width: 50%; border-bottom: 1px solid black; text-align: center;">Dave Carter, NOSB Chair</td> <td style="width: 50%; border-bottom: 1px solid black; text-align: center;">Date</td> </tr> </table>		Dave Carter, NOSB Chair	Date												
Dave Carter, NOSB Chair	Date														
<p>F. NOP Action: Include in FR to amend National List: <input type="checkbox"/></p> <p>Return to NOSB <input type="checkbox"/> Reason: _____</p> <table style="width: 100%; border: none; margin-top: 10px;"> <tr> <td style="width: 50%; border-bottom: 1px solid black; text-align: center;">Richard H. Mathews, Program Manager</td> <td style="width: 50%; border-bottom: 1px solid black; text-align: center;">Date</td> </tr> </table>		Richard H. Mathews, Program Manager	Date												
Richard H. Mathews, Program Manager	Date														

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: _____ April 2004 _____	Substance: _____ TSP _____																																			
Committee: Crops <input checked="" type="checkbox"/> Livestock <input checked="" type="checkbox"/> Handling <input checked="" type="checkbox"/>																																				
<p>A. Evaluation Criteria (Documentation attached; committee recommendation attached)</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;"></td> <td style="text-align: right; font-weight: bold;">Criteria Satisfied?</td> </tr> <tr> <td>4. Impact on humans and environment</td> <td style="text-align: right;">Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)</td> </tr> <tr> <td>5. Availability criteria</td> <td style="text-align: right;">Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)</td> </tr> <tr> <td>6. Compatibility & consistency</td> <td style="text-align: right;">Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)</td> </tr> </table>			Criteria Satisfied?	4. Impact on humans and environment	Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)	5. Availability criteria	Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)	6. Compatibility & consistency	Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)																											
	Criteria Satisfied?																																			
4. Impact on humans and environment	Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)																																			
5. Availability criteria	Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)																																			
6. Compatibility & consistency	Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)																																			
<p>B. Substance fails criteria?</p> <p>Criteria category: _____</p> <p>Comments: _____</p>	<p>C. Proposed Annotation: _____</p> <p>_____</p> <p>Basis for annotation:</p> <p>To meet criteria above: _____ Criteria: _____</p> <p>Other regulatory criteria: _____ Citation: _____</p>																																			
<p>D. Recommended Committee Action & Vote: Motion by: _____ Andrea - Allow 205.605(b) _____</p> <p style="text-align: center;">Seconded: _____ Goldie _____</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"><u>Vote:</u></td> <td style="width: 15%;"></td> <td style="width: 15%; border: 1px solid black; text-align: center;">Agricultural</td> <td style="width: 15%; border: 1px solid black; text-align: center;">Nonagricultural</td> <td style="width: 15%; border: 1px solid black; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 15%; border: 1px solid black; text-align: center;">Crops</td> <td style="width: 15%; border: 1px solid black;"></td> </tr> <tr> <td>Yes: _____</td> <td style="text-align: center;">4</td> <td style="border: 1px solid black; text-align: center;">Synthetic</td> <td style="border: 1px solid black; text-align: center;">Not synthetic</td> <td style="border: 1px solid black; text-align: center;"><input checked="" type="checkbox"/></td> <td style="border: 1px solid black; text-align: center;">Livestock</td> <td style="border: 1px solid black;"></td> </tr> <tr> <td>No: _____</td> <td style="text-align: center;">0</td> <td style="border: 1px solid black; text-align: center;">Allowed¹</td> <td style="border: 1px solid black; text-align: center;">Prohibited²</td> <td style="border: 1px solid black; text-align: center;"><input type="checkbox"/></td> <td style="border: 1px solid black; text-align: center;">Handling</td> <td style="border: 1px solid black; text-align: center;">x</td> </tr> <tr> <td>Abstain: _____</td> <td></td> <td style="border: 1px solid black; text-align: center;">No restriction</td> <td style="border: 1px solid black; text-align: center;">Deferred⁴</td> <td style="border: 1px solid black; text-align: center;"><input type="checkbox"/></td> <td style="border: 1px solid black; text-align: center;">Rejected³</td> <td style="border: 1px solid black;"></td> </tr> <tr> <td>Absent: _____</td> <td style="text-align: center;">2</td> <td colspan="5"></td> </tr> </table> <p style="text-align: center;">1—substance voted to be added as “allowed” on National List</p> <p>Annotation: _____</p> <p style="text-align: center;">2—substance to be added to “prohibited” paragraph of National List</p> <p>Describe why a prohibited substance: _____</p> <p style="text-align: center;">3—substance was rejected by vote for amending National List</p> <p>Describe why material was rejected: _____</p> <p style="text-align: center;">4—substance was recommended to be deferred</p> <p>Describe why deferred; if follow-up is needed. If follow-up needed, who will follow up _____</p>		<u>Vote:</u>		Agricultural	Nonagricultural	<input checked="" type="checkbox"/>	Crops		Yes: _____	4	Synthetic	Not synthetic	<input checked="" type="checkbox"/>	Livestock		No: _____	0	Allowed ¹	Prohibited ²	<input type="checkbox"/>	Handling	x	Abstain: _____		No restriction	Deferred ⁴	<input type="checkbox"/>	Rejected ³		Absent: _____	2					
<u>Vote:</u>		Agricultural	Nonagricultural	<input checked="" type="checkbox"/>	Crops																															
Yes: _____	4	Synthetic	Not synthetic	<input checked="" type="checkbox"/>	Livestock																															
No: _____	0	Allowed ¹	Prohibited ²	<input type="checkbox"/>	Handling	x																														
Abstain: _____		No restriction	Deferred ⁴	<input type="checkbox"/>	Rejected ³																															
Absent: _____	2																																			
<p>E. Approved by Committee Chair to transmit to NOSB:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border-bottom: 1px solid black; text-align: center;">Committee Chair</td> <td style="width: 50%; border-bottom: 1px solid black; text-align: center;">Date</td> </tr> </table>		Committee Chair	Date																																	
Committee Chair	Date																																			