

DRAFT

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance Urea

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	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		In large quantities can foster excessive growth of algae or damage seedlings and inhibit germination TAP pg 7; recommended agricultural BMPs should reduce harm to environment; based upon petitioned use no harm expected. (Committee)
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Urea is non-toxic to aquatic organisms; can foster excessive growth of algae; in large quantities can damage seedlings and inhibit germination TAP pg 7; recommended agricultural BMPs should reduce harm to environment; based upon petitioned use no harm expected (Committee)
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]	X			There are no inert materials discussed in the petition. Material may contain inerts.
5. Is there potential for detrimental chemical interaction with other materials used [§6518 m.1]		X		Urea may have detrimental interaction with sodium nitrate (low likelihood) and hypochlorites (very likely), which are approve for use” in organic production. The proposed application reduces the likelihood of any interactions. TAP pg 6, 13, 16, 19
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		Highly mobile; rapidly hydrolyzes to CO ₂ and ammonia TAP pg 8; as a pest attractant there is little if any concern of the compound entering the water/soil TAP pg 14, 17, 20
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		Rapid degradation by soil organisms and used as a nitrogen source by plants and microorganismsTAP pg 13
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		No toxic or other adverse action or breakdown products (CO ₂ and ammonia) expected for petitioned use; ammonia accumulation is problematic when urea is applied as a fertilizer TAP pg 7, 13, 16, 19
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		Rapid biodegradation (6-14 days at 20 C), low persistence; breakdown products are carbon dioxide and ammonia; ammonia accumulation is problematic when urea is applied as a fertilizer TAP pg7,13,16,19
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	X			Eye, skin, and respiratory irritant Petition pg 4; headache, nausea, vomiting, transient confusion and electrolyte depletion, coughing, skin redness and itching, TAP pg 7, 8, 13, 16; At concentrations used for an attractant in traps, no adverse effects are expected TAP pg 20
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			X	
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]			X	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600b.5]			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.

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

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	
2. Is there an organic substitute? [§205.600 b.1]			X	
3. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
4. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			Pheromones have been approved for use as insect attractants and ammonium carbonate has been approved as a bait in insect traps, TAP pg 9; insecticidal soaps TAP pg 14
5. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
6. Are there any alternative substances? [§6518 m.6]	X			Pheromones have been approved for use as insect attractants and ammonium carbonate has been approved as a bait in insect traps, TAP pg 9; insecticidal soaps TAP pg 14
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Pheromones have been approved for use as insect attractants and ammonium carbonate has been approved as a bait in insect traps, TAP pg 9; insecticidal soaps TAP pg 14

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

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Category 3. Is the substance compatible with organic production practices?

Substance Urea

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? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]				Minimal pollution results but one raw material is natural gas; it is non-toxic to aquatic organisms; promotes algae growth, can cause damage to seedlings and inhibit seed germination TAP pg 9; insect traps are compatible with sustainable agriculture; minimal environmental risk TAP pg 14, 17, 18, 20
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]				Minimal pollution results but one raw material is natural gas; it is non-toxic to aquatic organisms; promotes algae growth, can cause damage to seedlings and inhibit seed germination TAP pg 9; insect traps are compatible with sustainable agriculture; minimal environmental risk TAP pg 14, 17, 18, 20
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]			X	
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	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:				
a. copper and sulfur compounds		X		
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?	X			“Urea is being petitioned for use as an insect (fruit fly) attractant in sticky traps” TAP pg 1
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			“Urea is being petitioned for use as an insect (fruit fly) attractant in sticky traps” TAP pg 1

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: <u> May 2004 </u>	Substance: <u> Urea </u>																				
<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)												
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<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: 15%; padding: 5px;">Vote:</td> <td style="width: 25%; border: 1px solid black; text-align: center;">Agricultural</td> <td style="width: 25%; border: 1px solid black; text-align: center;">Nonagricultural</td> <td style="width: 25%; border: 1px solid black; text-align: center;">Crops</td> <td style="width: 10%; border: 1px solid black; text-align: center;">X</td> </tr> <tr> <td style="padding: 5px;">Yes: _____</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;">Livestock</td> <td style="border: 1px solid black;"></td> </tr> <tr> <td style="padding: 5px;">No: _____</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;">Handling</td> <td style="border: 1px solid black;"></td> </tr> <tr> <td style="padding: 5px;">Abstain: _____</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;">Rejected³</td> <td style="border: 1px solid black;"></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>		Vote:	Agricultural	Nonagricultural	Crops	X	Yes: _____	Synthetic	Not synthetic	Livestock		No: _____	Allowed ¹	Prohibited ²	Handling		Abstain: _____	No restriction	Deferred ⁴	Rejected ³	
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<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																		
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<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																		
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NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: <u>April 2004</u>	Substance: <u>Urea</u>																												
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