

DRAFT

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance Ammonium Bicarbonate –

manufactured as described

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]				
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]				
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]				
5. Is there potential for detrimental chemical interaction with other materials used [§6518 m.1]				
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]				
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]				
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]				
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]				
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]				
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]				
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]				
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600b.5]				

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 Ammonium Bicarbonate

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)]				
5. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]				
6. Are there any alternative substances? [§6518 m.6]				
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]				

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 Ammonium Bicarbonate

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)]				
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]				
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				
b. toxins derived from bacteria;				
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?				
d. livestock parasiticides and medicines?				
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?				

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>March 2005</u>	Substance: <u>Ammonium Bicarbonate</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: 10px;">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: 10px;">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: 10px;">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>March 2005</u>	Substance: <u>Ammonium Bicarbonate</u>																				
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