

DRAFT

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance 6-Benzyladenine

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		The restricted entry level is 4 hours TAP pg 7; minimal to no possible environmental contamination expected TAP pg 13, 17, 19 & 20; neither materials used to produce substance is carcinogenic (Ostiguy)
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Not persistent; non toxic in environment where applied; slight toxicity to fish & aquatic invertebrates but not birds or bees TAP pg 6, 13, 17, 19
4. Does the substance contain List 1, 2, or 3 inert? [§6517 c (1)(B)(ii); 205.601(m)2]	X			The formulated substance contains unknown inerts; the TAP evaluated only the active ingredient, which does not have inerts.
5. Is there potential for detrimental chemical interaction with other materials used [§6518 m.1]		X		One material, Bt, has been specifically studied. No problems were observed when this compound and Bt were applied simultaneously TAP pg 6 “The chemistry of BAP is such that few detrimental interactions would be expected with any other substances” TAP pg 17; Incompatible with two chemical fruit thinners TAP pg 4
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		EPA classified substance as biochemical pesticide – no environmental fate studies required; no adverse effects on soil organisms or livestock observed; 7-9 wk 1/2 life; not phytotoxic; slight toxicity to aquatic organisms TAP pg 8, 14, 15, 18, 20
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		no adverse effects on soil organisms or livestock observed; 7-9 wk 1/2 life; not phytotoxic; TAP pg 8, 14, 15, 18, 20
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		Non toxic in environment where applied; slight toxicity to fish & aquatic invertebrates but not birds or bees; not phytotoxic TAP pg 6, 13, 17, 19
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		7-9 wk 1/2 life and no toxic breakdown products; does not bioaccumulate TAP 8, 14, 15, 18, 20
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		Exempt from tolerance when used for fruit thinning if application rate does not exceed 30 g active ingredient per acre in or on apples; temporary exemption from tolerance in or on apples at ≤ 182 g active ingredient per acre per season TAP pg 3; eye, skin and respiratory irritant, workers instructed to wear proper attire and adequate ventilation TAP pg 7
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 6-Benzyladenine

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			There are no products that are allowed in organic production; there other commercially available fruit thinners; a mixture of fish oil and lime sulfur (noxious odor) and water with salts of calcium and magnesium (CM) have been tested; some undesirable affects observed with sulfur applications and CM product was not efficacious TAP pg 9, 10, 20
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			There other commercially available fruit thinners TAP pg 8, 20; a mixture of fish oil and sulfur (noxious odor) was mentioned TAP pg 20; water with salts of calcium and magnesium have been tested but are ineffective TAP pg 20
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Manual thinning is the current method used in organic agriculture TAP pg 8; physical damage, e.g., trampling of roots and vegetation, incorrect pruning and hazards (falling) are possible with manual thinning TAP pg 20

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DRAFT

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

Substance 6-Benzyladenine

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)]		X		Substance reduces production cost by reducing labor TAP pgs 8, 10, 15; Substance may encourage preventive management by improving air circulation (as does mechanical thinking) thus reducing pests and disease TAP pg 2; “BAP is not compatible with sustainable agriculture” because “natural alternatives exist.” “Switching to chemical solutions as an alternative to farmers working in the field is not an example of sustainability regardless of the economic profitability.” TAP pg 15
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			Substance reduces production cost by reducing labor; this may increase the economic viability of a farm TAP pgs 8, 10, 15 [This answer depend upon whether or not economics is important for sustainability.]
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		
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			This is a production aid; thins fruit thus improving quality of fruit; improves air circulation thus reducing pests and disease; “enhances lateral bud break and lateral shoot growth, which leads to improved branching” TAP pg 2

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> 6-Benzyladenine </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: <u> Rose </u> Second: <u> Mark </u></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>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>6-Benzyladenine</u>																																
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