

DRAFT

EVALUATION CRITERIA FOR SUBSTANCES PROHIBITED TO THE NATIONAL LIST

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

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		
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		The amounts are used are very small, thus any impact would be small, Supplemental TAP pg 1
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		Mineral chelation is used to increase the bioavailability of minerals in animal food. Only livestock would have access to the chelated minerals.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		No interactions are expected; Supplemental TAP pg 2
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		The quantities of minerals (e.g., copper and zinc) in livestock feed, along with the protein chelate, is so small that any interaction with soil, soil organisms, or crops is unlikely.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			There can be if concentration is high; there may be negative impacts on soil and soil organisms. Zinc and copper are only slowly removed from soil. Supplemental TAP pg 3
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]	X			If the amounts used in livestock feed were excessive (unlikely due to cost) then some of the minerals, e.g., zinc and copper are only slowly removed from the soil. Supplemental TAP pg 3
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		
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? [§205.600 b.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 Proteinated Chelates

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		Non-chelated minerals but this would require more of the mineral to be added to feed, Supplemental TAP pg 1
5. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
6. Is there any alternative substances? [§6518 m.6]	X			Non-chelated minerals but this would require more of the mineral to be added to feed, Supplemental TAP pg 1
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		Well-balanced nutritious soil would be a substitute but this is not available for all animals at all times (e.g., during a health crisis).

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

Substance Proteinated Chelates

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			Proteinated chelates do not have a sufficient quantity of protein to act as a supplement; they only increase bioavailability of mineral, Supplemental TAP pgs 1, 2
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			Preventative management is enhanced as the livestock will obtain minerals added to feed more readily not only improving animal health but decreasing the risk of contamination from inorganic mineral supplements; The use of proteinated mineral complexes will have a positive influence on animal health and welfare; the economic viability of organic farm operations will be promoted
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:	X			Chelated minerals include copper, TAP and Supplemental TAP
a. copper and sulfur compounds;				
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		

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>Chelates Minerals</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 checked="" type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)</td> </tr> <tr> <td>2. 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>3. 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?	1. Impact on humans and environment	Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)	2. Availability criteria	Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)	3. Compatibility & consistency	Yes <input checked="" type="checkbox"/> No <input checked="" 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: 20%; padding: 5px;"> <p><u>Vote:</u></p> <p>Yes: _____</p> <p>No: _____</p> <p>Abstain: _____</p> </td> <td style="width: 80%; border: 1px solid black; padding: 5px;"> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td style="width: 25%;">Agricultural</td> <td style="width: 25%;">Nonagricultural</td> <td style="width: 25%;">Crops</td> <td style="width: 25%;"></td> </tr> <tr> <td>Synthetic</td> <td>Not synthetic</td> <td>Livestock</td> <td>X</td> </tr> <tr> <td>Allowed¹</td> <td>Prohibited²</td> <td>Handling</td> <td></td> </tr> <tr> <td>No restriction</td> <td>Deferred⁴</td> <td>Rejected³</td> <td></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: 25%;">Agricultural</td> <td style="width: 25%;">Nonagricultural</td> <td style="width: 25%;">Crops</td> <td style="width: 25%;"></td> </tr> <tr> <td>Synthetic</td> <td>Not synthetic</td> <td>Livestock</td> <td>X</td> </tr> <tr> <td>Allowed¹</td> <td>Prohibited²</td> <td>Handling</td> <td></td> </tr> <tr> <td>No restriction</td> <td>Deferred⁴</td> <td>Rejected³</td> <td></td> </tr> </table>	Agricultural	Nonagricultural	Crops		Synthetic	Not synthetic	Livestock	X	Allowed ¹	Prohibited ²	Handling		No restriction	Deferred ⁴	Rejected ³	
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NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: <u>April 2004</u>	Substance: <u>Chelates Minerals</u>																												
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<p>D. Recommended Committee Action & Vote: Motion by: <u>George Simeon</u></p> <p style="text-align: center;">Seconded: <u>Mike Lacy</u></p> <p>Per recommendation from May 2002 NOSB meeting we reviewed chelated minerals. We recommend continued use of chelated minerals.</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 20%;">Vote:</td> <td style="width: 20%;"></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;"><u>4</u></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;"></td> <td style="border: 1px solid black; text-align: center;">Livestock</td> <td style="border: 1px solid black; text-align: center;"><input checked="" type="checkbox"/></td> </tr> <tr> <td>No:</td> <td style="text-align: center;"><u>0</u></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;"></td> <td style="border: 1px solid black; text-align: center;">Handling</td> <td style="border: 1px solid black;"></td> </tr> <tr> <td>Abstain:</td> <td style="text-align: center;"><u>0</u></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;"></td> <td style="border: 1px solid black; text-align: center;">Rejected³</td> <td style="border: 1px solid black;"></td> </tr> </table>		Vote:		Agricultural	Nonagricultural	<input checked="" type="checkbox"/>	Crops		Yes:	<u>4</u>	Synthetic	Not synthetic		Livestock	<input checked="" type="checkbox"/>	No:	<u>0</u>	Allowed ¹	Prohibited ²		Handling		Abstain:	<u>0</u>	No restriction	Deferred ⁴		Rejected ³	
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