

# DRAFT

## EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

### Category 1. Adverse impacts on humans or the environment?

Substance   Moxidectin  

Question	Yes	No	N/A <sup>1</sup>	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			Binds tightly to soil, long half life – up to six months, lipophilic - 26% excreted as active parent compound, adverse effects on non-target soil organisms, TAP pgs 5 & 6
4. Does the substance contain List 1, 2, or 3 inerts?[§6517 c (1)(B)(ii); 205.601(m)2]			X	Contains excipients
5. Is there potential for detrimental chemical interaction with other materials used [§6518 m.1]		X		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		No adverse biological or chemical interaction in agroecosystem have been found using the route of administration approved for this material TAP pg 4; reviewer 1 comments: "...there is limited possible interactions with other materials used in organic farming systems", TAP pg 9 reviewer 3 comments "I agree with the criterion evaluation" on the lack of potential for detrimental interactions with other materials used in the organic farming system TAP pg14
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			Reported adverse effects on several non-target soil organisms, TAP pg 6
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			Binds tightly to soil, long half life – up to six months, lipophilic - 26% excreted as active parent compound, adverse effects on non-target soil organisms, TAP pgs 5 & 6 Reported adverse effects on several non-target soil organisms, TAP pg 6
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]	X			Long half life – up to six months, TAP pg 5
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? [§205.600b.5]			X	

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

**DRAFT**

**Category 2. Is the Substance Essential for Organic Production?** Substance Moxidectin

Question	Yes	No	N/A <sup>1</sup>	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 potential alternatives but their safety and efficacy are unknown. TAP pg 8
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			Ivermectin is on the National List; Ivermectin has more adverse impacts on the environment; restricted to prior to breeding age
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Grazing management techniques, Mixing younger and older animals or mixing species, biological control (nematodes to decrease number of larvae in feces), stock selection, stocking rate, adequate nutrition

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

**DRAFT**

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

Substance   Moxidectin  

Question	Yes	No	N/A <sup>1</sup>	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			If other methods to control parasites are used first; this is a last resort, TAP pg 8, reviewers TAP pgs 10 & 15 “Organic livestock producers in the US rely on non-chemical methods such as herd management, grazing management and proper nutrition to control parasite infections within their herds, but these methods are not always effective.” Pg 8 TAP
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			Substance has a positive influence on the health and welfare of animals, promotes the economic viability of organic farm operations, is consistent with substances on National List.
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		
a. copper and sulfur compounds;				
b. toxins derived from bacteria;	X			TAP pg 2
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?	X			TAP pg 1 & 2; petition pg 1
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		

<sup>1</sup>If 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>Moxidectiin</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 &amp; 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)												
	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)																				
<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 &amp; Vote: Motion by: _____ Second: _____</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%; padding: 5px;"><u>Vote:</u></td> <td style="width: 20%; border: 1px solid black; text-align: center;">Agricultural</td> <td style="width: 20%; border: 1px solid black; text-align: center;">Nonagricultural</td> <td style="width: 20%; border: 1px solid black; text-align: center;">Crops</td> <td style="width: 20%; border: 1px solid black;"></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; text-align: center;">X</td> </tr> <tr> <td style="padding: 5px;">No: _____</td> <td style="border: 1px solid black; text-align: center;">Allowed<sup>1</sup></td> <td style="border: 1px solid black; text-align: center;">Prohibited<sup>2</sup></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;">Deferred<sup>4</sup></td> <td style="border: 1px solid black; text-align: center;">Rejected<sup>3</sup></td> <td style="border: 1px solid black;"></td> </tr> </table> <p style="text-align: center; margin-top: 10px;">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>		<u>Vote:</u>	Agricultural	Nonagricultural	Crops		Yes: _____	Synthetic	Not synthetic	Livestock	X	No: _____	Allowed <sup>1</sup>	Prohibited <sup>2</sup>	Handling		Abstain: _____	No restriction	Deferred <sup>4</sup>	Rejected <sup>3</sup>	
<u>Vote:</u>	Agricultural	Nonagricultural	Crops																		
Yes: _____	Synthetic	Not synthetic	Livestock	X																	
No: _____	Allowed <sup>1</sup>	Prohibited <sup>2</sup>	Handling																		
Abstain: _____	No restriction	Deferred <sup>4</sup>	Rejected <sup>3</sup>																		
<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;"></td> <td style="width: 50%; border-bottom: 1px solid black;"></td> </tr> <tr> <td>Dave Carter, NOSB Chair</td> <td>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 checked="" type="checkbox"/></p> <p>Return to NOSB <input checked="" type="checkbox"/> Reason: _____</p> <table style="width: 100%; border: none; margin-top: 10px;"> <tr> <td style="width: 50%; border-bottom: 1px solid black;"></td> <td style="width: 50%; border-bottom: 1px solid black;"></td> </tr> <tr> <td>Richard H. Mathews, Program Manager</td> <td>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: <u>April 2004</u>	Substance: <u>Moxidectin</u>																												
Committee: Crops <input type="checkbox"/> Livestock <input checked="" type="checkbox"/> Handling <input 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;">Criteria Satisfied?</td> </tr> <tr> <td>1. Impact on humans and environment</td> <td style="text-align: right;">Yes <input 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 type="checkbox"/> (see B below)</td> </tr> <tr> <td>3. Compatibility &amp; consistency</td> <td style="text-align: right;">Yes <input checked="" 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 checked="" type="checkbox"/> (see B below)	2. Availability criteria	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)	3. Compatibility & consistency	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)																				
	Criteria Satisfied?																												
1. Impact on humans and environment	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)																												
2. Availability criteria	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)																												
3. Compatibility & consistency	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)																												
<p>B. Substance fails criteria?</p> <p>Criteria category: <u>1</u></p> <p>Comments: concern about half life and impact on soil organisms; less problematic than ivermectin</p>	<p>C. Proposed Annotation: <u>control of internal parasites only;</u></p> <hr/> <p>Basis for annotation: natural, effective controls for external parasites; reduces impact on humans and the environment</p> <p>To meet criteria above: <u>X</u> Criteria: <u>1</u></p> <p>Other regulatory criteria: _____ Citation: _____</p>																												
<p>D. Recommended Committee Action &amp; Vote: Motion by: <u>Mike Lacy</u></p> <p style="text-align: center;">Seconded: <u>Rebecca Goldberg</u></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 20%;"><u>Vote:</u></td> <td style="width: 20%; border: 1px solid black; padding: 2px;">Agricultural</td> <td style="width: 10%; border: 1px solid black; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 20%; border: 1px solid black; padding: 2px;">Nonagricultural</td> <td style="width: 10%; border: 1px solid black;"></td> <td style="width: 20%; border: 1px solid black; padding: 2px;">Crops</td> <td style="width: 10%; border: 1px solid black;"></td> </tr> <tr> <td>Yes: <u>5</u></td> <td style="border: 1px solid black; padding: 2px;">Synthetic</td> <td style="border: 1px solid black; text-align: center;"><input checked="" type="checkbox"/></td> <td style="border: 1px solid black; padding: 2px;">Not synthetic</td> <td style="border: 1px solid black;"></td> <td style="border: 1px solid black; padding: 2px;">Livestock</td> <td style="border: 1px solid black; text-align: center;"><input checked="" type="checkbox"/></td> </tr> <tr> <td>No: <u>0</u></td> <td style="border: 1px solid black; padding: 2px;">Allowed<sup>1</sup></td> <td style="border: 1px solid black;"></td> <td style="border: 1px solid black; padding: 2px;">Prohibited<sup>2</sup></td> <td style="border: 1px solid black;"></td> <td style="border: 1px solid black; padding: 2px;">Handling</td> <td style="border: 1px solid black;"></td> </tr> <tr> <td>Abstain: <u>0</u></td> <td style="border: 1px solid black; padding: 2px;">No restriction</td> <td style="border: 1px solid black;"></td> <td style="border: 1px solid black; padding: 2px;">Deferred<sup>4</sup></td> <td style="border: 1px solid black;"></td> <td style="border: 1px solid black; padding: 2px;">Rejected<sup>3</sup></td> <td style="border: 1px solid black;"></td> </tr> </table> <p style="text-align: center;">1—substance voted to be added as “allowed” on National List</p> <p>Annotation: <u>control of internal parasites only</u></p> <hr/> <p style="text-align: center;">2—substance to be added to “prohibited” paragraph of National List</p> <p>Describe why a prohibited substance: _____</p> <hr/> <p style="text-align: center;">3—substance was rejected by vote for amending National List</p> <p>Describe why material was rejected: _____</p> <hr/> <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> <hr/>		<u>Vote:</u>	Agricultural	<input checked="" type="checkbox"/>	Nonagricultural		Crops		Yes: <u>5</u>	Synthetic	<input checked="" type="checkbox"/>	Not synthetic		Livestock	<input checked="" type="checkbox"/>	No: <u>0</u>	Allowed <sup>1</sup>		Prohibited <sup>2</sup>		Handling		Abstain: <u>0</u>	No restriction		Deferred <sup>4</sup>		Rejected <sup>3</sup>	
<u>Vote:</u>	Agricultural	<input checked="" type="checkbox"/>	Nonagricultural		Crops																								
Yes: <u>5</u>	Synthetic	<input checked="" type="checkbox"/>	Not synthetic		Livestock	<input checked="" type="checkbox"/>																							
No: <u>0</u>	Allowed <sup>1</sup>		Prohibited <sup>2</sup>		Handling																								
Abstain: <u>0</u>	No restriction		Deferred <sup>4</sup>		Rejected <sup>3</sup>																								
<p>E. Approved by Committee Chair to transmit to NOSB:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border-top: 1px solid black; border-bottom: 1px solid black;">Committee Chair</td> <td style="width: 50%; border-top: 1px solid black; border-bottom: 1px solid black;">Date</td> </tr> </table>		Committee Chair	Date																										
Committee Chair	Date																												