

# NOSB RECOMMENDED DECISION FORM

Form NOPLIST2. Full Board Transmittal to NOP

<b>For NOSB Meeting: November 2009</b>	<b>Substance: Eprinomectin</b>																								
<b>A. Evaluation Criteria</b> (Applicability noted for each category; Documentation attached) <span style="float: right;"><u>Criteria Satisfied? (see B below)</u></span>																									
1. Impact on Humans and Environment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																								
2. Essential & Availability Criteria	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/>																								
3. Compatibility & Consistency	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																								
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																								
<b>B. Substance fails criteria?</b>  Criteria category: A.2.  Comments: There are already substances on the List which have the same properties.	<b>C. Proposed Annotation:</b> _____  Basis for annotation:  To meet criteria above: ____ Criteria: _____  Other regulatory criteria: ____ Citation: _____																								
<b>D. Final Board Action &amp; Vote (State Actual Motion):</b> To add eprinomectin to 7CFR205.603 as a parasiticide  Motion: Hubert Karreman    Second: Tracy Miedema    Yes: 0    No: 13    Abstain: 0    Absent: 2																									
<table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Agricultural</td> <td style="width: 20px;"></td> <td style="padding: 5px;">Nonagricultural</td> <td style="width: 20px;"></td> <td style="padding: 5px;">Crops</td> <td style="width: 20px;"></td> </tr> <tr> <td style="padding: 5px;">Synthetic</td> <td></td> <td style="padding: 5px;">Not synthetic</td> <td></td> <td style="padding: 5px;">Livestock</td> <td></td> </tr> <tr> <td style="padding: 5px;">Allowed<sup>1</sup></td> <td></td> <td style="padding: 5px;">Prohibited<sup>2</sup></td> <td></td> <td style="padding: 5px;">Handling</td> <td></td> </tr> <tr> <td style="padding: 5px;">No restriction</td> <td></td> <td style="padding: 5px;">Deferred<sup>4</sup></td> <td></td> <td style="padding: 5px;">Rejected<sup>3</sup></td> <td></td> </tr> </table>		Agricultural		Nonagricultural		Crops		Synthetic		Not synthetic		Livestock		Allowed <sup>1</sup>		Prohibited <sup>2</sup>		Handling		No restriction		Deferred <sup>4</sup>		Rejected <sup>3</sup>	
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<b>Provide a summary narrative here or attach a more complete narrative, and attach the original committee recommendation that includes the evaluation criteria checklist:</b>																									
1—substance voted to be added as “allowed” on National List on National List to § 205. _____ with Annotation (if any): _____																									
2—substance to be added to “prohibited” paragraph of National List to § 205. _____ Describe why a prohibited substance: _____																									
3—substance was rejected by vote for amending National List to § 205.603 Describe why material was rejected: There exist synthetic materials on the List having essentially the same use (ivermectin).																									
4—substance was recommended to be deferred § 205. _____ Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up _____																									
<b>E. Approved by NOSB Chair to transmit to NOP</b>																									
Chair <u>Jeff Moyer</u>	Date <u>11/05/2009</u>																								
<b>F. NOP Action: Include in FR to amend National List:</b> Return to NOSB Reason: _____  _____ Date _____																									

**NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST**

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

**Substance - EPRINOMECTIN**

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			There is interaction between Eprinomectin and various species of avians, fish, algae and earthworms at various levels. To what degree this matches what would be excreted by the animal in the isomeric B <sub>1a</sub> form of Eprinomectin (the major isomer) isn't provided.
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X			Tightly bound to the soil, thus persistence may be an issue i.e. no breakdown of product noted in petition.
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		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X			No environmental impact statement was required by FDA during submittal of eprinomectin for official NADA approval.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			No data submitted for soil or crops. A battery of studies was completed on various animal species during the regulatory approval process (mice, rats, rabbits, dogs, cattle). Tightly bound to soil, therefore persistence is likely
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			Tightly bound to soil, therefore persistence is likely
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]	X			Tightly bound to soil, therefore persistence is likely.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	X			Minor skin irritation was noted during clinical testing of the product and that person had a history or skin irritations. The OTC directions clearly say to immediately wash any product off exposed skin.
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			X	

tolerances? [§205.600 b.5]				
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<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.

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

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X			It is semi-synthetic, derived from soil streptomyces and chemically altered to create the product.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	X			
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X	X		Part of the process is via fermentation but then various chemical processes are undertaken to create the end product.
4. Is there a natural source of the substance? [§205.600 b.1]			X	
5. Is there an organic substitute? [§205.600 b.1]	X	X		With internal parasiticides, this is always debatable in that there are many studies showing various botanical compounds providing some measure of efficacy when tested using in vivo models. However, the efficiency of the synthetic products is extremely high and therefore very easy to use.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X	X		See answer to #5
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		
9. Is there any alternative substances? [§6518 m.6]	X	X		See answer to #5
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X	X		Cultural management practices and excellent nutrition would render the need for synthetic wormers to be minimized

<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.

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

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	X		It is when thinking about animal welfare needs; it isn't when thinking about residues of synthetics in the environment.
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X	X		See #1 above
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X	X		It depends on your philosophy.
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;		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		

<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.

**Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable?**

[§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]

**Substance - \_\_\_\_\_**

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in organic handling?				
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate <b>form</b> to fulfill an essential function in a system of organic handling?				
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate <b>quality</b> to fulfill an essential function in a system of organic handling?				
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate <b>quantity</b> to fulfill an essential function in a system of organic handling?				
5. Does the industry information provided on material / substance non-availability as organic, include ( but not limited to) the following:				
a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;				
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or				

e. Are there other issues which may present a challenge to a consistent supply?

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