

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: November 2009	Substance: Eprinomectin
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Committee: Crops Livestock Handling **Petition is for:** Eprinomectin on the National List **§ 205.603**

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

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 checked="" type="checkbox"/>	No <input 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. Substance Fails Criteria Category: Fails A.2. (above) because there are already substances on the List which have the same properties.

C. Proposed Annotation (if any): _____

Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____

D. Recommended Committee Action & Vote (State Actual Motion): To add eprinomectin to 7CFR205.603 (the National List)

Motion by: Dan Giacomini Seconded: Jeff Moyer Yes: 0 No: 7 Absent: 0 Abstain: 0

Crops		Agricultural		Allowed ¹
Livestock	<input checked="" type="checkbox"/>	Non-Synthetic		Prohibited ²
Handling		Synthetic	<input checked="" type="checkbox"/>	Rejected ³
No restriction		Commercially Un-Available as Organic ¹		Deferred ⁴

1) Substance voted to be added as "allowed" on National List to § 205. _____ with Annotation (if any) _____

2) Substance to be added as "prohibited" on National List to § 205. _____ with Annotation (if any) _____

Describe why a prohibited substance: _____

3) Substance was rejected by vote for amending National List to § 205. 603 Describe why material was rejected: because there are already substances on the List which have the same properties.

4) Substance was recommended to be deferred because _____
 _____ If follow-up needed, who will follow up _____

E. Approved by Committee Chair to transmit to NOSB:

Hubert J. Karreman Committee Chair	9-09-09 Date
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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/A¹	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.
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			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.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]	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.
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 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.

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

Question	Yes	No	N/A ¹	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 streptomycetes 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			See #1 above
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		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			See answer to #5
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Cultural management practices and excellent nutrition would render the need for synthetic wormers to be minimized

¹If 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 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		Other agricultural practices and treatments are more consistent
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X	X		Other agricultural practices and treatment are more consistent yet this compound could help animals severely infested with internal parasites (animal health and welfare)
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		
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.

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 form 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 quality 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 quantity 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?				