NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: April 2011 | **Substance: Tetracycline**

Committee: Crops X Livestock ☐ Handling ☐ Petition is for: __

on the National List § 205.601_____

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

1. Impact on Humans and Environment — Yes ☐ No X N/A ☐
2. Essential & Availability Criteria — Yes ☐ No X N/A ☐
3. Compatibility & Consistency — Yes ☐ No X N/A ☐
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) — Yes ☐ No ☐ N/A ☐

B. Substance Fails Criteria Category: __ Comments:

C. Codex._____See following evaluation._____

_____

D. Proposed Annotation (if any): _____

_____

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

D. Recommended Committee Action & Vote, including classification recommendation (State Actual Motion):

_____

Classification of the material: Synthetic ____ ____ Non- synthetic_____ Absent:_____ Abstain _____

Motion by: _____ *Seconded:*_____ *Yes:* _____ *No:* _____ *Absent:* _____ *Abstain:* _____

Recommended Committee Action & Vote The majority of the Crops Committee recommends against the adoption of the petition to amend the listing for tetracycline by removing the expiration date on tetracycline so that the listing would state "tetracycline, for fire blight control only," thus allowing tetracycline's use to expire on October 21, 2012.

_____

Motion by: Jay Feldman *Seconded:* Tina Ellor *Yes:* 0 *No:* 5 *Absent:* 2 *Abstain:* 0

Crops	X	Agricultural		Allowed[1]	
Livestock		Non-Synthetic		Prohibited[2]	
Handling		Synthetic	X	Rejected[3]	x
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. _____Describe why material was rejected:

_____

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:

_____ _____

Committee Chair **Date**

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance: Tetracycline

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			TR1[1] 149-164 Daniels, 1982.[2] Manufacture results in discharges of solvents, detergents, disinfectants. Treated plants exude tetracycline.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X			Thiele-Bruhn and Beck, 2005.[3] See #6 below.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1) (B)(ii); 205.601(m)2]	?			
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	X			Burgos et al, 2003.[4] Bacteria with multiple resistance.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X			Thiele-Bruhn and Beck, 2005 Shifts fungal-bacterial balance at environmentally relevant concentrations.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			Xiujie Xie et al, 2010.[5] Tetracycline may be genotoxic to plant cells.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			See #10 below.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]	X			Daniels, 1982. Chander et al, 2005.[6] Halling-Sørensen et al, 2002.[7] Tetracycline is taken up by plants and appears in all tissues and in exudates. Soil-bound tetracycline maintains biological activity.

[1] TR1 is TR dated January 27, 2006.

[2] MJ Daniels, 1982. Editorial: Possible effects of antibiotic therapy in plants. Reviews of Infectious Diseases 4 (Supp): 167-170.

[3] Sören Thiele-Bruhn and Iris-Constanze Beck, 2005. Effects of sulfonamide and tetracycline antibiotics on soil microbial activity and microbial biomass. **Chemosphere**, Volume 59, Issue 4, April 2005, Pages 457-465

[4] Burgos JM, Ellington BA, Varela MF., 2005. Presence of multidrug-resistant enteric bacteria in dairy farm topsoil. J Dairy Sci. 2005 Apr;88(4):1391-8.

[5] Xie, X., Zhou, Q., Bao, Q., He, Z. and Bao, Y. , Genotoxicity of tetracycline as an emerging pollutant on root meristem cells of wheat (*Triticum aestivum* L.). Environmental Toxicology, n/a. doi: 10.1002/tox.20567

[6] Chander Y, Kumar K, Goyal SM, Gupta SC, 2005. Antibacterial activity of soil-bound antibiotics. J Environ Qual. 2005 Oct 12;34(6):1952-7. Print 2005 Nov-Dec.

[7] Halling-Sørensen B; Sengeløv G; Tjørnelund J, 2002. Toxicity of tetracyclines and tetracycline degradation products to environmentally relevant bacteria, including selected tetracycline-resistant bacteria. Archives of environmental contamination and toxicology 2002;42(3):263-71.

				Degradation products have same activity as parent.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)I; §6518 m.4]	X			TR163-71, 279-293 Lugo-Melchor et al, 2010.[8] Levy et al, 1976.[9] http://en.wikipedia.org/wiki/Tetracycline_antibiotics "Prop 65 list" http://www.oehha.org/prop65/prop65_list/files/P65single3405.pdf Workers are at risk of contracting tetracycline-resistant disease and suffering from allergic reactions. As a consequence of the widespread use of tetracyclines, the emergence and spread of tetracycline-resistant bacterial pathogens, among them the foodborne pathogen Salmonella enterica, has become a serious health hazard worldwide. Workers who handle feed with tetracycline have tetracycline-resistant flora in their intestines. Tetracyclines remain the treatment of choice for infections caused by chlamydia (trachoma, psittacosis, salpingitis, urethritis, and *L. venereum* infection), Rickettsia (typhus, Rocky Mountain spotted fever), brucellosis, and spirochetal infections (borreliosis, syphilis, and Lyme disease). In addition, they may be used to treat anthrax, plague, tularemia, and Legionnaires' disease. They may have a role in reducing the duration and severity of cholera, although drug-resistance is occurring, and their effects on overall mortality is questioned. Developmental toxin listed by the state of California.
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	

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

[8] Lugo-Melchor, Y., Quinones, B., Amezquita-Lopez, B.A., Leon-Felix, J., Garcia-Estrada, R., Chaidez, C. 2010. Characterization of tetracycline resistance in Salmonella enterica strains recovered from irrigation water in the Culiacan Valley, Mexico. Microbial Drug Resistance. 6(3):185-190.

[9] Stuart B. Levy, M.D., George B. FitzGerald, Ph.D., and Ann B. Macone, B.S., 1976. Changes in Intestinal Flora of Farm Personnel after Introduction of a Tetracycline-Supplemented Feed on a Farm. N Engl J Med 1976; 295:583-588.

Category 2. Is the Substance Essential for Organic Production? Substance:

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			TR1 304-312. Stockwell and Stack, 2007[10]
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			TR1 317-330
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			TR1 297-302, 335-343. Aldwinckle et al, 1998[11]. "Fireblight Management in the Pacific Northwest USA" (http://www.ncw.wsu.edu/treefruit/fireblight/principles.htm)

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

[10] Stockwell, V. O., and Stack, J. P. 2007. Using *Pseudomonas* spp. for integrated biological control. Phytopathology 97:244-249.

[11] H. Aldwinckle, J Norelli, and MT Momol, 1998. Fire blight: the search for better control. IDFTA Compact Fruit Tree, Vol. 31, No. 4

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

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, and biodiversity? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]				
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]				
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;				
b. toxins derived from bacteria;			X	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?				
d. livestock parasiticides and medicines?				
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?				

[1] 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. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	
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?			X	
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?			X	
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?			X	
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);			X	
b. Number of suppliers and amount produced;			X	
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;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			X	