FORMAL RECOMMENDATION BY THE
NATIONAL ORGANIC STANDARDS BOARD (NOSB)
TO THE NATIONAL ORGANIC PROGRAM (NOP)

Date: November 30, 2007

Subject: Sodium Ferric Hydroxy EDTA

Chair: Andrea M. Caroe

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:	X
Guidance Statement:	
Other:	

Statement of the Recommendation (including Recount of Vote)**:**

Add Sodium Ferric Hydroxy EDTA as snail and slug bait to the National List §205.601(h).

NOSB Vote: Motion: Gerald Davis Second: Jeff Moyer

Board vote: Yes - 0 No- 15 Abstain- 0 Absent - 0

Rationale Supporting Recommendation (including consistency with OFPA and NOP)**:**

Is not consistent with environmental and compatibility with organic farming OFPA criteria primarily due to the behavior of EDTA in the environment and the toxic chemicals used to manufacture.

Response by the NOP:

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Novermber 2007	Substance: Sodium Ferric Hydroxy ETDA

Committee: Crops X Livestock ☐ Handling ☐ Petition is for: adding sodium Ferric Hydroxy EDTA as snail and slug bait to the National List § 205.601(h)

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 **X**

B. Substance Fails Criteria Category: 1,2, and 3 Comments: Ferric phosphate is already listed for this use, harm to humans and the environment, not consistent with organic farming and handling.

C. Proposed Annotation (if any): _____

_____

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

D. Recommended Committee Action & Vote (State Actual Motion): Motion is to add Sodium Ferric Hydroxy EDTA to the National List on 205.601(h) as a slug and snail bait.

9/12/ 07 *Motion by: Jeff Seconded: Tina Yes: 0 No: 6 Absent: 0 Abstain 0*

11/29/07 1st: Rigo; 2nd Tina: yes 5 No 0 Absent: 1

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. 601(h). Describe why material was rejected: Sodium Ferric Hydroxy EDTA failed categories 1, 2, and 3.

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:

Gerald Davis _____ **9/12/07** _____

Committee Chair **Date**

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? **Substance –** Sodium Ferric Hydroxy EDTA

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			Petition pg. 13—petitioner says no, but with ingredients like hydrogen cyanide, formaldehyde and sulfuric acid it seems intuitive that there would be adverse effects from the manufacture.
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X			Not enough information. Pg 9 of the petition only addresses iron and not SFH EDTA. The EDTA clearly has the potential to be harmful to the environment (EU Commission risk assessment on EDTA)
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]				Not enough Info. Ferric sodium EDTA is a list 4B, but this is not the petitioned compound
5. Is there potential for detrimental chemical interaction with other materials used?[§6518 m.1]		X		Pg 9 of the petition iron and only how the petitioned substance should react in an organic system.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X			Page 15 of the petition had conclusions based on iron and ferric sodium EDTA. EDTA can result in the detrimental movement of metals in soils and river sediments (EU Commission Risk Assessment on EDTA)
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]				Insufficient information provided in the petition. Once again, the information in the petition are based on iron, EDTA, and ferric sodium EDTA, none of which are the petitioned compound.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			Also, add in the reference used in #10: Page 14 of petition, but eye irritant page 15, and possible chronic iron overload. EDTA is a very strong metal chelating agent, especially for calcium. It is poorly absorbed in mammalian GI tract and concerns have been raised that excessive usage in food could deplete the body of Ca and other minerals. It is a FDA GRAS direct food additive, but the maximum amounts in different foods are regulated. It is also added to some food systems as a Na2Ca salt rather than the Na form to prevent Ca depletion (O. R. Fennema 1985, Food Chemistry, 2'ed edition, pp. 641 - 642).
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]	X			EDTA is not degraded rapidly in the environment and is the most abundant anthropogenic chemical in some European surface waters http://en.wikipedia.org/wiki/EDTA#_note-1 accessed 1 August 07). Its strong chelating power can enhance the movement of metals such as Zn, Cd, Ni, Cr, Cu and Fe in soil and river sediments. EDTA is very soluble in water and is not sequestered in municipal sewage treatment plants (Frank and Rau 1990, in petition). The biodegradation rate strongly depends on the metal complexed to the EDTA. Ca and Mg complexes are easier to degrade than Cu and Fe for example (see EU Commission risk assessment on EDTA p 12 in petition). Photo degradation appears easier. However, the high solubility in water can limit the time exposed to sunlight. Since EDTA is inert under some environmental conditions and rapidly degrades under other conditions (very alkaline water - such as in waste water treatment from paper pulp mills (EU Commission risk assessment on EDTA), some environmental accumulations must occur.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	X			Page 14 of petition, but eye irritant page 15, and possible chronic iron overload. EDTA is a very strong metal chelating agent, especially for calcium. It is poorly absorbed in mammalian GI tract and concerns have been raised that excessive usage in food could deplete the body of Ca and other minerals. It is a FDA GRAS direct food additive, but the maximum amounts in different foods are regulated. It is also added to some food systems as a Na2Ca salt rather than the Na form to prevent Ca depletion (O. R. Fennema 1985, Food Chemistry, 2'ed edition, pp. 641 - 642).

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.

Category 2. Is the Substance Essential for Organic Production? Substance – Sodium Ferric Hydroxy EDTA

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			Page 22, Page 8, page 13 of the petition and summarized below. It is commercially produced in either a single or two step process. The single step process is most widely used commercially. The synthesis starting with ethylenediamine (2-a aldehyde and sodium cyanide to form a Na EDTA salt and ammonia and a Na salt of NTA (nitrilotriacetic acid) by reaction between the ammonia and the starting materials. Acidification precipitates the EDTA, leaving the NTA in solution. Hydrochloric or sulfuric acids are used. The NTA is considered a waste product, although the NTA can also be used as a chelator in detergents. Excess ammonia is either volatilized or recovered (see Ullmann's Encylopedia of industrial chemistry vol. A10 for details). The two step process uses the same starting materials and forms a Na salt of EDTA, and ammonia (no NTA) Formaldehyde and sodium cyanide are hazardous chemicals
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		Page 13 of the petition-tetra sodium salt is a synthetic reacted with ferric sulfate to give ferric sodium EDTA.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		Page 13 of the petition summarized above.
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	
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			Page 20 of the petition-diatomaceous earth, barriers, physical controls.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
9. Are there any alternative substances? [§6518 m.6]	X			Ferric Phosphate
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Petition page 20 copper tape, diatomaceous earth, barriers, physical and cultural controls.

[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 3. Is the substance compatible with organic production practices? Substance –Sodium Ferric Hydroxy EDTA

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		It's a synthetic material that does not present a compelling need for it as well as the toxic substances necessary for its manufacture.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		EDTA is inert under some circumstances and can build up in soil. It is the most abundant anthropomorphic chemical in some European surface waters. It can enhance the movement of metals in soil and river sediments.(EU commission risk assessment on EDTA)
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;			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	

[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 – Sodium Ferric Hydroxy EDTA

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;				
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	