

**Formal Recommendation by the
National Organic Standards Board (NOSB)
to the National Organic Program (NOP)**

Date: October 28, 2010

Subject: Ethylene Glycol (CAS# 107-21-1)

Chair: Daniel G. Giacomini

The NOSB hereby recommends to the NOP the following:

Rulemaking Action
Guidance Statement
Other Not list Ethylene Glycol on §205.601

Statement of the Recommendation (Including Recount of Vote):

The recommendation to list Ethylene Glycol on the National List §205.601 FAILED by a vote of 14 no and 0 yes. Ethylene Glycol was classified as synthetic by a vote of 14 yes, and 0 no.

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

The board found ethylene glycol to be synthetic with many alternative materials and practices that may be employed. See attached crops committee recommendation.

NOSB Vote: Motion is to consider Ethylene Glycol to be synthetic. Motion passed.

Moved: Jeff Moyer		Second: Tina Ellor			
Yes: 14	No: 0	Abstain: 0	Absent: 0	Recusal: 0	

Motion is to list Ethylene Glycol on the National List §205.601. Motion Failed.

Moved: Jeff Moyer		Second: Tina Ellor			
Yes: 0	No: 14	Abstain: 0	Absent: 0	Recusal: 0	

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: October 2010

Substance: Ethylene Glycol

Committee: **Crops X** Livestock Handling Petition is for: To add Ethylene Glycol to 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 | <input type="checkbox"/> |
| 2. Essential & Availability Criteria | Yes | <input type="checkbox"/> | No | X | N/A <input type="checkbox"/> |
| 3. Compatibility & Consistency | Yes | <input type="checkbox"/> | No | X | 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 X |

B. Substance Fails Criteria Category: 1,2,3 Comments: Material is a synthetic with many alternative materials and practices that may be employed and was previously listed on EPA's list 3 inerts.

Proposed Annotation (if any): _____
 Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____

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

Ethylene Glycol be classified as synthetic for crop production _____

Classification of the material: Synthetic 5 Non-synthetic 0 Absent: 2 Abstain 0

Motion by: Keven Englebert Seconded: Tina Ellor

D. Recommended Committee Action & Vote (State Actual Motion): Motion is to add Ethylene Glycol to the National List §205.601.

Motion by: Jeff Moyer Seconded: Tina Ellor Yes: 0 No: 6 Absent: 1 Abstain: _____

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. 601 with Annotation (if any) _____

2) Substance to be added as "prohibited" on National List to § 205. 601 with Annotation (if any) _____

Describe why a prohibited substance: _____

3) Substance was rejected by vote for amending National List to § 205. 601 Describe why material was rejected: Material was rejected for reasons listed above and on the attached forms – alternatives already exist on the national list and practices that make this material unnecessary exist. _____

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:

Tina Ellor
 Committee Chair

July 26, 2010
 Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance - Ethylene Glycol

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			TR lines 208 – 238 Millions of gallons enter the environment through general manufacture and use. This includes entry to surface water and soil.
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X			TR lines 252 – 299 Lethal to fish, volatilizes into the air and is highly mobile in soil.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]	X			Ethylene glycol is being petitioned as an inert and was listed on the EPA list 3.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	X			TR lines 303 – 336 Several materials already on the national list of allowed synthetics have the potential for interaction
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X			TR lines 341 - 348 Ethylene Glycol has been designated an air pollutant and has the ability to persist in the environment for several weeks.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			TR lines 353 – 386 Terrestrial animals are most susceptible yet are least likely to be exposed. Soil microbes are most likely to be exposed but are less susceptible.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			TR lines 391 – 426 Ethylene Glycol is toxic to humans but is not listed as a carcinogen.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]	X			TR lines 431 – 445 Yes, Ethylene Glycol is highly mobile in the soil and breaks down at various rates depending on temperature and is broken down by microorganisms.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	X			TR lines 450 – 468 Toxic to humans
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 – Ethylene Glycol

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			TR lines 176 - 189
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			TR lines 195 – 195 There are no natural sources of this material
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X	X		TR lines 200 – 203 While ethylene glycol can be released into the soil by naturally occurring processes; however there are no natural processes that are of commercial use.
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			TR lines 473 – 482 Both ethyl alcohol and isopropyl alcohol, already listed on the national list can be used as a substitute for this material.
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			TR lines 487 – 512 Many materials are already listed.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			TR lines 518 – 547 There are many cultural practices such as crop rotations, sanitation, mechanical cultivation, flaming, and use of materials already on the list to name a few.

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 - Ethylene Glycol

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 is a synthetic and there are many substitute materials and alternative practices that can be employed.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		
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		

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 - Ethylene Glycol

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	