

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date: April 2015

Subject: Petition to add Triethyl Citrate (TEC) at §205.605

NOSB Chair: Jean Richardson

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement:

Other: X

Statement of the Recommendation (Motion #1):

Motion to classify Triethyl Citrate (CAS# 77-93-0) as petitioned, as synthetic, passed.

Statement of the Recommendation (Motion #2):

Motion to list Triethyl Citrate (CAS# 77-93-0) as petitioned, at §205.605 without annotation, failed.

Rationale Supporting Recommendation (including consistency with OFPA and Organic Regulations):

Based on the technical report, TEC is produced from the reaction of citric acid and ethyl alcohol (ethanol), both of which are fermentation products from the microbial digestion of a carbon substrate." Thus TEC is considered synthetic. Additionally, there are non-synthetic alternatives currently on the National List that can be used for the same purpose.

Committee Vote:

Motion to classify Triethyl Citrate (CAS# 77-93-0) as petitioned, as synthetic.

Motion by: Jean Richardson

Seconded by: Zea Sonnabend

Yes: 14 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Motion passed

Motion to list Triethyl Citrate (CAS# 77-93-0) as petitioned at §205.605, without annotation.

Motion by: Jean Richardson

Seconded by: Zea Sonnabend

Yes: 0 No: 14 Absent: 1 Abstain: 0 Recuse: 0

Motion failed

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal - Triethyl Citrate
January 6 2015**

Summary of Proposed Action:

Triethyl Citrate (TEC), CAS# 77-93-0, is a synthetic substance petitioned to be added to the National List at §205.605 as a food additive for the intended use as a whipping enhancer for egg whites during processing. TEC is an ester of citric acid, a colorless, odorless liquid used as a food additive to stabilize foams, and especially as a whipping aid for egg whites. There are alternative non-synthetic substances that can be used for this purpose. Thus, the Handling Subcommittee proposes not to recommend that this material be added to the National List of Approved Substances.

Background:

The Petition, dated 2/10/14, was received by the National Organic Standards Board (NOSB) on 3/4/14. Following initial review, the Handling Subcommittee requested a Technical Report (TR) on 4/16/14. The TR was received on 11/6/14 and Sufficiency Review completed on 1/18/14. The petition includes no confidential business information (CBI).

Discussion:

The Petitioner states that Triethyl Citrate (TEC) is a “natural, organic compliant ingredient flavor and is also used by the egg industry as a pasteurized egg white whipping enhancer in baking, such as for angel food cakes.” However, the TR indicates that TEC may not meet NOP organic requirements for use as a flavor. The Petitioner states, and the TR concurs, that “the main reason that TEC is added to egg whites is to recreate textures and related properties which are lost during pasteurization.”

The Petitioner considers TEC nonsynthetic, based on 100% natural raw materials. However, the TR indicates that “commercial sources of TEC are produced from the reaction of citric acid and ethyl alcohol (ethanol), both of which are fermentation products from the microbial digestion of a carbon substrate.”

While there are no known commercial sources of non-synthetic or natural TEC, numerous plants and animals are non-commercial sources, including brown seaweed and tobacco. There are several alternative substances which can be used, such as sugar, some gums, and cream of tartar, which is potassium acid tartrate on the National List at §205.605(b).

TEC does not appear to have adverse impacts on human health or the environment. TEC is not permitted in organic processing in Canada, the EU or by IFOAM or the CODEX, and not listed in JAS.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for §205.606)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A

Substance Fails Criteria Category: 2, 3

Subcommittee Action & Vote

Classification Motion: Move to classify Triethyl Citrate, CAS# 77-93-0, as petitioned, as synthetic.

Motion by: Jean Richardson

Seconded by: Zea Sonnabend

Yes: 7 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Listing Motion: Move to list Triethyl Citrate, CAS# 77-93-0, as petitioned, at **§205.605** of the National List without annotation.

Motion by: Jean Richardson

Seconded by: Zea Sonnabend

Yes: 0 No: 7 Absent: 1 Abstain: 0 Recuse: 0

Proposed Annotation (if any): No annotation proposed

Approved by Harold Austin, Subcommittee Chair, to transmit to NOSB February 24, 2015

NOSB Evaluation Criteria for Substances Added To the National List – Handling

Category 1. Adverse Impacts on humans or the environment? Substance: Triethyl Citrate

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]		X		
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]		X		
3. Are there any adverse impacts on biodiversity? (§205.200)		X		
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		

5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c)(1)(A)(i); 6517(c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]		X		TR lines 423-441
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]		X		TR 3224-344
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600(b)(5)]		X		TR 325-344 TR 393-397 FDA stipulates no more than 3 ppm arsenic and 10 ppm lead. Major TEC sources meet FDA and FCC

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

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			TR 247-284 Esterization of citric acid and ethanol
3. 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		
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		
6. Is there an organic substitute? [§205.600(b)(1)]		X		
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]		X		

8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X			TR 318-319 – There are no known commercial sources of non-synthetic or natural TEC. Numerous plants and animals are non-commercial sources, including brown seaweed and tobacco. TR 529 and 560 et seq. suggests sugar, some gums and salt may be used.
9. Are there any alternative substances? [§6518(m)(6)]	X			TR 525-582 – the main used during the whipping stage to enhance egg white foaming characteristics is cream of tartar (potassium acid tartrate listed at 205.605(b)) Martha Stewart 2014. Could use sugar TR 560 et seq.
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	X			Could use non-pasteurized egg whites
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.	X			

Category 3. Is the substance compatible with organic handling practices?

Substance: Triethyl Citrate

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]		X		
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]	X			
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]		X		
4. Are the ancillary substances reviewed compatible with organic handling [?]			X	
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]		X		

6. Is the primary use as a preservative? [§205.600(b)(4)]	X	X		TR 354-357 The addition of TEC could be considered both to aid in the foaming process and help stabilize the whipped foam. Stabilization of foam could be considered a preservative function, although it prevents deterioration not of the egg itself but of the structure achieved by the whipping action.
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]	X			TR 368-369 et seq. The main reason TEC is added to egg white is to recreate textures and related properties lost during pasteurization.

Category 4. Is the commercial supply of an organic agricultural substance fragile or potentially unavailable? [§6610, 6518, 6519, §205.2, § 205.105(d), §205.600(c)]
Substance: Triethyl citrate

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?			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	

<p>5. Does the industry information about unavailability include (but is not limited to) the following?:</p> <p>a. Regions of production (including factors such as climate and number of regions);</p>			X	
<p>b. Number of suppliers and amount produced;</p>			X	
<p>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;</p>			X	
<p>d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or</p>			X	
<p>e. Other issues which may present a challenge to a consistent supply?</p>			X	