

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

Date: April 2015

Subject: Petition to add Polyalkylene Glycol Monobutyl Ether (PGME) 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 Polyalkylene Glycol Monobutyl Ether (PGME) CAS 9038-95-3 as synthetic, passed

Statement of the Recommendation (Motion #2):

Motion to list Polyalkylene Glycol Monobutyl Ether (PGME) CAS 9038-95-3 at §205.605(b) with the annotation: with molecular weight greater than 1500, for use as a boiler additive in pelleted feed production, failed

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

In considering the OFPA criteria, additional criteria at 205.600(b), information from the petitioner, and public comment, the NOSB determined that PGME does come into contact with the organic product and that pelleted feed can be produced without the use of PGME.

Committee Vote:

Motion to classify Polyalkylene Glycol Monobutyl Ether (PGME) CAS 9038-95-3 as synthetic

Motion by: Jean Richardson

Seconded by: Tracy Favre

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

Motion passed

Motion to list Polyalkylene Glycol Monobutyl Ether (PGME) CAS 9038-95-3 at §205.605(b) with the annotation: with molecular weight greater than 1500, for use as a boiler additive in pelleted

feed production

Motion by: Jean Richardson

Seconded by: Tracy Favre

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

Motion failed

**National Organic Standards Board (NOSB)
Handling Subcommittee
Petitioned Material Proposal - Polyalkylene Glycol Monobutyl Ether (PGME)
February 24, 2015**

Summary of Proposed Action:

Polyalkylene Glycol Monobutyl Ether (PGME) polymeric fluid is a boiler steam additive petitioned for use in feed pellet mills. The petition is specifically for PGME with a requested restriction of a minimum molecular weight of 1500, in accordance with conditions required by 21CFR Section §173.310. The Petitioner is requesting that PGME be added to the National List of Approved Materials at §205.605. The National Organic Standards Board (NOSB) proposes not to add PGME to the National List as petitioned.

Background:

On October 9, 2012, Pellet Products, Inc. petitioned the USDA National Organic Program (NOP) to add polyalkylene glycol monobutyl ether (PGME) to the National List of Approved Materials under section §205.605. Following this, PGME was first considered by the National Organic Standards Board (NOSB) for use as a boiler water additive at the NOSB meeting in April 2013. Information provided in a Technical Report (TR) requested by the NOSB Handling subcommittee, dated June 7, 2013, indicated that PGME does not contact food. The report stated that this is because PGME is non-volatile; PGME precipitates at boiler temperatures and is not delivered with steam, but stays in the boiler as a precipitate until the boiler cools below the cloud point and it may be removed during boiler blow-down.

Based on the findings of the TR, the NOSB Handling Subcommittee developed a proposal on August 20, 2013 stating that PGME was not required to be on the National List because PGME in liquid water does not come into direct contact with organic food. However, public comment for the fall 2013 indicated that PGME may in fact come in to contact with organic product.

In the fall 2013, following the public comment period, there was no NOSB meeting due to the government shutdown. At the NOSB's next meeting on April 29, 2014, PGME was further discussed. Following review and public comment, the NOSB Handling Subcommittee requested an additional Technical Report of limited scope, as well as further information and clarification from the Petitioner. The Petitioner provided some additional information in a letter dated December 3, 2014. Meanwhile, the limited scope TR was received on January 28, 2015.

As requested by the NOSB, the limited scope TR addressed the following questions: 1) What evidence is there that there is entrainment of PGME in water droplets during normal use?; and 2) If used as petitioned, would PGME come into contact with the organic product (pelleted feed)?

Discussion:

Function of substance

PGME is added as a processing aid to water that is used to make steam for the production of pelleted livestock feeds. PGME functions to reduce foaming and also functions as a lubricant. PGME has the unique property of inverse solubility such that it dissolves easily in cold water, but at temperatures over 104F (cloud point) it is completely insoluble. (TR, 2013, lines 59-61) Thus, PGME is not delivered with the steam, but remains in the boiler as a precipitate until the

boiler cools below cloud point. The substance, therefore, has minimal contact with the pelleted feed. Precipitated PGME may also be removed during boiler blow-down (TR, 2013, lines 112-115).

Is there entrainment of PGME in water droplets during normal use?: Yes .

In a supplemental letter dated December 3, 2014, the Petitioner states the following: "PGME is introduced directly into steam lines prior to entering the conditioner whereby its nature acts as a wetting agent and lubricant for the pellet die. Due to the introduction site and the resulting increase in through-put and pellet Durability Index (PDI), it is evident that PGME is entrained in the water during normal use. It is metered based upon the through-put of the pellet mill. Under 21CFR Part 178 Subpart D Sec 178.3570, Certain Adjuvants and Production Aids, PGME can be safely used in and on machinery used for producing or processing feed. The metered amount of PGME is maintained at <3ppm, whereas the limit is not to exceed 10ppm."

However, the limited scope TR of January 28, 2015 states the following: "Thus, unlike solids that are dissolved in boiler water at steam-producing temperatures (e.g. sodium chloride), PGME is insoluble at steam production temperatures and unlikely to carryover dissolved in moisture entrained by steam." (lines 89-91). The report continues, "Entrainment traps and filtration devices incorporated in the 3-A system standard remove particulates, including PGME precipitate if it is present as a result of a boiler malfunction." (lines 107-109).

If used as petitioned, would PGME come in to contact with the organic product (pelleted livestock feed)? Yes.

The Petitioner states in his letter of December 3, 2014 that PGME "does come in to contact with the finished pelleted feed stock but well below limits set by 21 CFR...."

The limited scope TR of January 2013 provides the following: "However, steam that has entrained moisture may contain these solids as a result of carry over. Foaming is likely to enhance carryover of dissolved solids. The prevention of foaming prevents carryover. PGME prevents foaming eliminating one source of carryover. In addition, it is not soluble in water at steam-producing temperatures. Although, it does in fact come into contact with the water from which steam is produced, it does not evolve from the boiler into the steam as a particulate. PGME is not added directly to the pellet mash." (Lines 124-129)

Adverse impacts:

PGME polymers have a low degree of toxicity (TR 2013, line 80). Since they are generally non-toxic, PGME polymers have been approved for a variety of uses in which surfaces or water treated have the potential to come into contact with food. It has also been approved for a variety of foam control applications. In these applications only a potential exposure is assumed. (TR 2013, lines 86-92) Additionally, because PGME polymeric fluids are water-soluble and non-toxic at low concentrations, they are considered environmentally friendly compounds with respect to petroleum-based lubricants that are not water soluble. (TR 2013, lines 148-151). See also TR 2013 lines 494-502. There have been no reported effects of PGME on human health. (TR 2013 lines 526-et seq).

PGME presently has a range of uses approved by the FDA. However, Canadian, CODEX and Japanese standards do not address this additive. EEC standards require that processed feeds shall not have been processed with the aid of chemically synthesized solvents (TR 2013, 301-

302). Meanwhile, IFOAM requires all additives to be declared. PGME is not included in any IFOAM list, but would be considered a non-volatile water additive that is not likely to be entrained in steam (TR 2013, lines 318-320). Finally, The FDA's GRAS list does not address this material.

Manufacture:

PGME is manufactured from ethylene oxide, by chemical processes. PGME is commonly used in modern conditioning systems for pellet feed manufacturing, which includes the use of steam. In this process, steam is directly injected into the product with a tubular apparatus called a conditioner. This heat, plus water, pressure, and time to reach a physical state, facilitates compaction of the feed mash into pellets. This approach offers the manufacturer and the feeder various advantages which justify using additional energy for steam pelleting. Mainly, the process increases production capacity and positively affects the physical, nutritional, and hygienic quality of the produced feed. While dry pelleting is done at 40°C, the use of steam to raise temperatures to 65°C and 78°C results in increases in the production rate of 250% and 275%, respectively. Production rate increased only 9% when the conditioning temperature was raised from 65 to 80°C.

Steam conditioning also decreases fixed costs such as labor and maintenance of equipment. For example, die and roller replacements are another major cost in pelleting. Observing the temperature increase of mash pressed through the pellet die and the electrical energy used to pellet, it can be seen that steam conditioning decreases mechanical friction. A decrease in friction increases both die and roller life, reducing the frequency of replacement. Thus, while the main contribution of steam conditioning is improved nutrition of the pellets, its contribution to productivity and cost-savings is also significant. (TR 2013, lines 461-474)

Natural Sources and Alternatives:

There are no natural sources of PGME. Nor are there many natural antifoam chemicals for boilers, in general. Castor oil is a natural compound that has been used to prevent foam in boilers. However, if castor oil is used care must be taken to condition boiler water so that it is not alkaline. In the case of alkaline boiler water, castor oil will undergo hydrolysis to form the sodium soap of ricinoleic acid. Although not toxic, this soap may exacerbate foaming in the boiler. In addition to castor oil, and depending upon the specific boiler conditions, other natural oils such as lard, lard burning, soybean, corn, maize, cod liver, cottonseed, olive, sunflower, safflower, peanut, ground nut, grape seed, linseed, poppy seed castor and palm oil may be used. Carnauba and peat waxes also have been used as boiler antifoams. As a note, none of these natural chemicals is as effective or has the performance and characteristics provided by PGME. Extensive water treatment is also an alternative to using antifoam chemicals. Water can be treated using reverse osmosis filtration or ion exchange resins to reduce dissolved solids. (TR 2013, lines 628-638)

In considering all of the OFPA criteria, and additional criteria at 205.600(b), it appears that PGME does come into contact with the organic product and that pelleted feed can be produced without use of PGME.

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

- ✓ Impact on Humans and Environment
- N/A

Criteria Satisfied?

- Yes
- No

- ✓ Essential & Availability Criteria Yes No
 N/A
- ✓ Compatibility & Consistency Yes No
 N/A
- ✓ Commercial Supply is Fragile or Potentially Unavailable Yes No
 N/A
as Organic (only for §205.606)

**Substance Fails Criteria Category 2, 3
Subcommittee Action & Vote:**

Classification Motion: To classify Polyalkylene Glycol Monobutyl Ether (PGME) CAS 9038-95-3 as synthetic

Motion by: Jean Richardson
Seconded by: Tracy Favre
Yes: 7 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Listing Motion: To list Polyalkylene Glycol Monobutyl Ether (PGME) CAS 9038-95-3 on **§205.605 (b)** of the National List with the annotation: with molecular weight greater than 1500, for use as a boiler additive in pelleted feed production

Motion by: Jean Richardson
Seconded by: Tracy Favre
Yes: 0 No: 7 Absent: 1 Abstain: 0 Recuse: 0

Proposed Annotation: with molecular weight of 1500, for use as a boiler additive in pelleted feed production

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

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? PGME

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	x		PGME is manufactured from ethylene oxide, propylene oxide and butanol which are chemical products of the petroleum industry. Each of these chemicals is extremely toxic. (TR 2013, 519-520) Transport of PGME is unregulated. (TR 2013, 516)
2. Are there adverse effects on the environment or is there a probability of		x		See 1 above and TR 2013, 149-151

environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]				
3. Are there any adverse impacts on biodiversity? (§205.200)		x		PGME is not readily biodegradable (TR 2013, 504 and lines 513-520)
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	x		PGME is not readily biodegradable.
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		There have been no reported effects of PGME on human health (TR 2013, 526 et seq)
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]				GRAS does not address PGME. Title 21 CFR 178.3570 provides that PGME polymeric fluids may be used as a lubricant with incidental food contact at a concentration of less than 10 parts per million (TR 2013, 410-412)
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600(b)(5)]		x		Data was not found to substantiate the presence of detectable heavy metal contamination in PGME (TR 2013 487-488) and TR 2013, 480-487

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

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 2013 line 328, and lines 366-368 and line 374
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		See 2 above
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		x		See 2 above
5. Is there a natural source of the		x		There are no natural sources of PGME

substance? [§ 205.600(b)(1)]				(TR 2013, 394)
6. Is there an organic substitute? [§205.600(b)(1)]	x			Yes, there are a number of oils, such as sunflower , lard, soybean, corn, safflower etc which could be used, but very little data exists as to the efficacy of such oils for the purpose petitioned herewith(TR 2013, 665-668)
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]	x	x		Could use a mechanical piping design for the boiler, (TR 2013, 249-250) as required under Canadian standards for culinary steam. Can make pelleted feed without the use of PGME.
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		x		There are a range of oils as noted in 7 above (TR 2013, 665-668)
9. Are there any alternative substances? [§6518(m)(6)]	x			As in 8 above
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	x			Could try to make pellets without steam (TR 2013, 655-664) Could limit livestock feed to non-pelleted feeds and forage. Could use natural anti-foaming chemicals, but limited efficacy (TR 2013, 629-638)
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.				

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

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			Yes, Provided it is manufactured and used according to regulations
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	x	x		
4. Are the ancillary substances reviewed compatible with organic handling [?]				
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	x			TR 2013, 463-465

6. Is the primary use as a preservative? [§205.600(b)(4)]		x		Although not intended as a preservative, PGME addition to boiler steam improves steam quality, which improves pellet hardness (TR 2013, 423)
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		

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)] **PGME**

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	
5. Does the industry information about unavailability include (but is 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. Other issues which may present a challenge to a consistent supply?			x	