



# BEYOND PESTICIDES

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National Organic Standards Board  
Spring 2014 Meeting  
San Antonio, TX

## **Re. HS: Polyalkalene Glycol Monobutyl Ether (PGME) Discussion Document**

These comments are submitted on behalf of Beyond Pesticides. Beyond Pesticides, founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and groups around the world.

The subcommittee determined, based on the non-volatility of PGME at the boiling point of water, that under its petitioned use, PGME “does not come into direct contact with processed organic products,” and was thus not eligible or required to be listed in the National List of approved and prohibited substances. In its Discussion Document, the Handling Subcommittee requests public comment “on the accuracy of the technical description of PGME in the technical report and the opportunity for other members of the public to comment on the petition and technical report.” However, in addition, we believe that the HS errs in saying that because PGME “does not come into direct contact” with food to be labeled organic in the organic production process in which it would be used, that somehow PGME “is not required to be on the National List.” In fact, we believe this conclusion requires public comment and consideration of the NOSB because it is based on a misreading of the *Organic Foods Production Act* (OFPA) and the requirement of the Board to consider this material for listing on the National List.

In addition to our perspective that the ‘no direct contact with food’ position does not waive the requirement for a synthetic material used in handling to be put on the National List, we have concerns about exposure to PGME. Although PGME is non-volatile, there is a concern about possible contact with organic food through entrainment in water droplets, which has not been addressed by the subcommittee. In addition, as a material that is added during production, PGME should be evaluated through the petition process for its compatibility with organic production. PGME is made from highly toxic ethylene dioxide, and the TR identifies alternative production practices that do not require an additive like PGME. For example (lines 594-602):

Producers may choose to use an intermittent boiler chemical treatment program where chemicals not on the National List are absent from boiler water during organic pellet production runs. The safest approach for the production of clean steam is to use a steam generation system designed to eliminate the potential of volatile or carryover contamination. Here, steam from a primary boiler is used to heat water in a secondary steam generator where feed water quality and purity are carefully controlled and free of chemicals. Design is very important and feed water must be filtered free of contaminants and degassed prior to instruction into the generator. It is still possible to have water droplets contaminating steam in this type of system. The use of the water separators can resolve this issue and steam produced by this type of system will be free of chemical contaminants.

PGME has been petitioned to be used as a boiler water additive in the manufacture of livestock feed pellets. It must be petitioned to be included in §205.605(b),<sup>1</sup> on the National List of approved and prohibited substances. The Handling Subcommittee conclusion –“when used as a boiler additive, PGME is not required to be on the National List because it has no contact with organic products” – neglects to recognize that the Board’s review and listing recommendation responsibility calls for an evaluation of the manufacturing process, including health and environmental impacts, of the substances used in the production of food that carry the USDA organic food label.

When water is heated to boiling, it is not just steam that rises, but also droplets of water. At the boiling point of water, PGME is a solid, but given the movement of water caused by boiling, it is in the form of particles suspended in the water. The Technical Review, at lines 60-62, identifies a "cloud point," which is the temperature at which the PGME is no longer dissolved, but clouds up the water with particles.) So, if water is bubbling up and water droplets are carried into the air, they could be carrying "entrained" PGME. (TR, lines 624-626)

Although the petition portrays PGME as innocuous, and the TR indicates that only the lowest molecular weight (MW) forms are toxic, the scientific literature and test results submitted to EPA indicate otherwise. The petition requests listing for MW greater than 1500. An acute inhalation study found that PGME with a MW of 4000 was acutely toxic to test animals. “Significant pathological changes were limited to the lungs and were more common in animals which died prior to scheduled sacrifice. Grossly, these lung changes consisted of red discoloration, edema, emphysema, and surface irregularities. Microscopic findings in the lungs included acute congestion and hemorrhage and, less commonly, acute interstitial inflammation.”<sup>2</sup>

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<sup>1</sup> One could argue that because it is used to produce livestock feed that it should be petitioned to be on §205.603 instead, and we would not oppose consideration by the Livestock Subcommittee for that section.

<sup>2</sup> Hoffman GM, Newton PE, Thomas WC, Birnbaum HA, Kennedy GL Jr., 1991. Acute inhalation toxicity studies in several animal species of an ethylene oxide/propylene oxide copolymer (UCON 50-HB-5100), Drug Chem Toxicol. 14(3):243-56.

Data submitted to EPA by Union Carbide showed that PGME up to MW of 1590 caused convulsions in test animals.<sup>3</sup> Data submitted to EPA by Union Carbide showed that some PGME forms with MW above 1500 were among those that were highly toxic.<sup>4</sup> Data submitted to EPA by Union Carbide showed eye injury, delayed deaths, and lethal dermal exposure.<sup>5</sup>

As the Board knows, the exposure pattern associated with food contact of a material in organic systems is not the sole focus of NOSB review, given the broader set of review criteria that include food and material manufacture and captured in the checklists used to guide NOSB evaluations. Therefore, we believe that the possibility of PGME entrainment in water droplets combined with the potential hazards, including hazards to workers in manufacture and use of PGME, provide a *prima facie* case for requiring PGME to be evaluated for placement on the National List if used in organic production.

Direct contact with food is certainly a consideration in making a determination on a material recommendation, but NOSB review is required to be broader under the OFPA and the rules and regulations implementing the statute.

7 U.S.C. 6504 [National Standards for Organic Production] states,  
To be sold or labeled as an organically produced agricultural product under this title, an agricultural product shall—

- (1) Have been produced and handled without the use of synthetic chemicals, except as otherwise provided in this title.

7 U.S.C. 6510 [Handling] states,

- (a) In General.—For a handling operation to be certified under this title, each person on such handling operation shall not, with respect to any agricultural product covered by this title—
  - (1) add any synthetic ingredient not appearing on the National List during the processing or any postharvest handling of the product.

7 U.S.C. 6517 [National List] states,

- (a) In General.—The secretary shall establish a National List of approved and prohibited substances that shall be included in the standards for organic production and handling established under this title in order for such products to be sold or labeled as organically produced under this title.

...

- (c) Guidelines for Prohibitions or Exemptions.—

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<sup>3</sup>[http://yosemite.epa.gov/oppts/epatscat8.nsf/ALLIDS/612615DD19EBC8E085256930004CD868/\\$FILE/88920010360.pdf?OpenElement](http://yosemite.epa.gov/oppts/epatscat8.nsf/ALLIDS/612615DD19EBC8E085256930004CD868/$FILE/88920010360.pdf?OpenElement)

<sup>4</sup>[http://yosemite.epa.gov/oppts/epatscat8.nsf/ALLIDS/EDA417CD065152FA852571AF006B9A43/\\$FILE/88920000105.pdf?OpenElement](http://yosemite.epa.gov/oppts/epatscat8.nsf/ALLIDS/EDA417CD065152FA852571AF006B9A43/$FILE/88920000105.pdf?OpenElement)

<sup>5</sup>[http://yosemite.epa.gov/oppts/epatscat8.nsf/ALLIDS/78D0F9E3F0E645108525720C00685434/\\$FILE/88920010902.pdf?OpenElement](http://yosemite.epa.gov/oppts/epatscat8.nsf/ALLIDS/78D0F9E3F0E645108525720C00685434/$FILE/88920010902.pdf?OpenElement)

- (1) Exemption for prohibited substances in organic production and Handling operations. –  
The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this title only if—

Thus, we believe that the HS has erred in suggesting that “no direct food contact” excludes review of the “use of substances in an organic farming or handling operation” under the standards of the OFPA.

Therefore, we urge NOSB members to request the Handling Subcommittee to consider a petition to list PGME on the National List, as required by OFPA, by preparing a checklist review of the material with a subcommittee recommendation to be considered at the fall meeting of the Board. To do otherwise and allow PGME’s use in organic production would be a circumvention of the intent, spirit, and letter of OFPA. We look forward to full consideration of the health and environmental issues associated with the use of this material.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in cursive script, appearing to read "Terry Shistar".

Terry Shistar, Ph.D.  
Board of Directors