

September 20, 2013

National Organic Standards Board Fall 2013 Meeting Louisville, KY

## 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 would not come into direct contact with processed organic products, and was thus not eligible or required to be listed in the National List. The Handling Subcommittee requests public comment to help determine the eligibility status of PGME to the National List.

Beyond Pesticides believes that although PGME is non-volatile, contact with organic food is possible under this use through entrainment in water droplets. As a material that is added during production, PGME should be evaluated through the petition process for its appropriateness for use in 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.

PGME has been petitioned to be used in the manufacture of livestock feed pellets. It should be petitioned to be included in §205.603.

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, is in the form particles suspended in the water. (The TR talks about 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.

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>1</sup>

Data submitted to EPA by Union Carbide showed that PGME up to MW of 1590 caused convulsions in test animals.<sup>2</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>3</sup> Data submitted to EPA by Union Carbide showed eye injury, delayed deaths, and lethal dermal exposure.<sup>4</sup>

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 on the National List if used in organic production.

Because we believe the NOP sunset policy violates OFPA, and will therefore not subject Polyalkalene Glycol Monobutyl Ether (PGME) to the required assessment to determine re-listing at sunset in the future, we sincerely urge NOSB members to oppose this petition and any others where removal or annotation might conceivably be needed for health, environmental, and essentiality issues until the sunset process of OFPA and the Board is reinstated.

Thank you for your consideration of these comments.

Sincerely,

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Terry Shistar, Ph.D. Board of Directors

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<sup>&</sup>lt;sup>1</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.

<sup>&</sup>lt;sup>2</sup><u>http://yosemite.epa.gov/oppts/epatscat8.nsf/ALLIDS/612615DD19EBC8E085256930004CD868/\$FILE/889200103</u> 60.pdf?OpenElement

<sup>&</sup>lt;sup>3</sup><u>http://yosemite.epa.gov/oppts/epatscat8.nsf/ALLIDS/EDA417CD065152FA852571AF006B9A43/\$FILE/889200001</u> 05.pdf?OpenElement

<sup>&</sup>lt;sup>4</sup><u>http://yosemite.epa.gov/oppts/epatscat8.nsf/ALLIDS/78D0F9E3F0E645108525720C00685434/\$FILE/8892001090</u> 2.pdf?OpenElement