

**National Organic Standards Board
Handling Subcommittee
Polyalkylene Glycol Monobutyl Ether (PGME)
Discussion Document
August 20, 2013**

I INTRODUCTION

The purpose of this document is to seek public comment on the proposal that the petition for PGME be removed from the NOSB workplan after the Fall 2013 meeting, and that the NOP should notify the petitioner that PGME is not eligible for petition to 205.605 (b) because it is not used in direct contact with organic products.

II BACKGROUND

On December 27, 2012, the NOP received a petition requesting the addition of PGME to section 205.605 of the National List as a boiler water additive. Based on information in the petition, the NOP determined that the substance was eligible for petition to the National List. This decision was made based on the description of PGME as a processing aid that functions as a lubricant and surfactant within the pelleting process.

On January 28, 2013, the petition was sent to the NOSB Handling Subcommittee for review. The HS requested the development of a third-party technical report, which is posted on the NOP website.

The technical report, dated June 7, 2013, indicates that, since PGME is non-volatile, it remains in the boiler and does not come into direct contact with processed organic products.

The Handling Subcommittee prepared the Petitioned Material Checklist which was ready for final discussion and vote on August 20, 2013, at which time the Subcommittee determined that when used as a boiler additive, PGME is not required to be on the National List because it has no contact with organic products.

III RELEVANT AREAS OF THE RULE

§ 205.607 Amending the National List.

“(a) Any person may petition the National Organic Standard Board for the purpose of having a substance evaluated by the Board for recommendation to the Secretary for inclusion on or deletion from the National List in accordance with the Act.”

The petition requests addition of PGME to 205.605 – “Non agricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

§ 205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

“(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

(1) The substance cannot be produced from a natural source and there are no organic substitutes;

(2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;

(3) The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations;

(4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;

(5) The substance is listed as generally recognized as safe (GRAS) by Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; and

(6) The substance is essential for the handling of organically produced agricultural products.”

IV DISCUSSION

In reviewing PGME and developing the Materials Checklist the Handling Subcommittee found the following:

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 minimum molecular weight of 1500 in accordance with conditions required by 21CFR Section 173.310.

PGME functions to reduce foaming during production of pelleted livestock feeds 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. Thus PGME is not delivered with the steam, but remains in the boiler as a precipitate until the boiler cools below cloud point and thus PGME does not contact the feed.

PGME has very low toxicity, is not considered harmful to the environment or humans, and presently has a range of uses approved through the FDA. 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. IFOAM requires all additives to be declared. This material is regulated by FDA as a secondary direct food additive, and is not considered a GRAS substance.

There are no natural sources of PGME and there are not many natural anti-foam chemicals. Natural oils, such as cotton seed, lard, sunflower, safflower, palm oil, carnuba and peat waxes can be used, but none of them is as effective and none also provide lubricant properties during production. Some of the natural oils are available in organic form, but very little data is available on use of these oils.

When used as a boiler additive, the Handling subcommittee finds that PGME is not required to be on the National List because it has no direct contact with organic products.

V REQUEST FOR PUBLIC COMMENT

Based on the new information provided in the technical report, there are now questions about whether the original eligibility decision made by the NOP is still accurate. The original eligibility decision for this substance, which was based on the information contained in the petition only, may no longer be applicable.

This Discussion Document provides the opportunity for the petitioner to comment on the

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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.

Subcommittee Vote:

Motion: To accept the Discussion Document as amended August 20, 2013.

Moved: Tracy Favre

Second: Harold Austin

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

Approved by John Foster, Subcommittee Chair, to transmit to NOSB August 20, 2013