

**National Organic Standards Board
Handling Subcommittee Proposal
Additional listing of Tocopherols at §205.605(a)
September 14, 2016**

Summary of Proposed Action:

The Handling Subcommittee proposes an additional listing of Tocopherols at §205.605(a) of the National List.

Subcommittee Review

Tocopherols are listed at §205.605(b) of the National List with the following annotation: Derived from vegetable oil when rosemary extracts are not a suitable alternative.

Tocopherols function as antioxidants in foods, helping to preserve them and prevent rancidity. They are commonly extracted from distillates of vegetable oils. The term “tocopherols” refers to structurally similar compounds that occur in nature in four forms: alpha-, beta-, gamma-, and delta-tocopherol. Tocopherols that are derived from plant products are often referred to as “mixed tocopherols” because the mixture contains all four forms of tocopherol (CIR, 2002) (TR lines 41-43).

Tocopherols are separated from other compounds in vegetable oil distillate by multiple extraction and refining steps. These steps can include solvent extraction, chemical treatment, crystallization, complexation, and vacuum or molecular distillation (Burdock, 1997; EFSA, 2008; Torres et al., 2011) (TR lines 87-89). Using the draft Classification of Materials guidance from the NOP, even tocopherols derived from natural sources could be considered synthetic, depending upon their extraction and refining processes.

The NOSB completed review of tocopherols as part of its 2017 Sunset review and voted at the Fall 2015 meeting in Stowe, Vermont, to retain the listing on the National List at §205.605(b). However, during the initial public comment period, several commenters asserted that non-synthetic tocopherols are commercially available and should be used instead of synthetic versions. In the final Sunset proposal for tocopherols, the Handling Subcommittee indicated that it was considering a proposal to reclassify tocopherols to §205.605(a) and was seeking input regarding the impact of that on the industry. The second round of public comments brought forth several objections to a reclassification of tocopherols, citing their importance in food safety and voicing concerns regarding commercial availability of non-synthetic versions.

The Handling Subcommittee strongly encourages industry to move to non-synthetic, organic versions of tocopherols but does recognize that at present, there is insufficient commercial availability of organic tocopherols. For that reason, we are proposing a duplicate listing at 205.605(a) so that those manufacturers who wish to move to non-synthetic tocopherols – while waiting on commercial availability of organic versions – are incentivized to do so.

Determination of Synthetic/Non-synthetic Status of Tocopherols

In March, 2013, the National Organic Program issued draft guidance on the classification of materials used in Organic production in the document NOP 5033 - Classification of Materials. Background Section 3.1 states: “The Organic Foods Production Act of 1990 (OFPA) authorizes the USDA to establish the National List of Allowed and Prohibited Substances (National List). The National List is implemented in the USDA organic regulations at 7 CFR 205.600-607.

Under the OFPA, the National List must contain an itemization of each synthetic substance that is permitted and each natural substance that is prohibited for organic production. Due to this unique construction of the National List, definitions and classification are important to determine whether a substance is allowed or prohibited in organic production, whether it needs to be included on the National List, and where on the National List it should be placed. “

“For the handling or processing of organic agricultural products, the National List includes a list of agricultural and nonagricultural substances which are allowed in the handling of organic agricultural products. Nonagricultural substances are differentiated as either nonsynthetic (natural) or synthetic. Thus, the proper determination of a substance as agricultural or nonagricultural, or as synthetic or natural is important for proper placement on the National List.”

Section 4.3 under Inputs for Organic Processing and Handling, NOP 5033 states: “Petitioned ingredients and processing aids for handling and processing are classified by the NOSB to determine placement of substances on the National List, sections 205.605-205.606. Substances must first be classified as agricultural or nonagricultural according to the classification decision tree, [NOP 5033-2](#). Nonagricultural substances should be further classified as nonsynthetic or synthetic to determine placement on section §205.605(a) or §205.605(b), respectively.”

Section 4.6, Extraction of Non-Organic Materials, provides direction on the extraction of distillates such as those used in the creation of tocopherols: “For purposes of classification of a material as synthetic or nonsynthetic, a material may be classified as nonsynthetic (natural) if the extraction or separation technique results in a material that meets the following criteria:

- At the end of the extraction process, the material has not been transformed into a different substance via chemical change;
- The material has not been altered into a form that does not occur in nature; and
- Any synthetic materials used to separate, isolate, or extract the substance have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product.

While draft guidance NOP 5033 on classification of materials has not been finalized, the decision tree, [NOP 5033-2](#), as published on April 27, 2013, will be used to determine the non-synthetic/synthetic status of tocopherols until such time as NOP guidance may be finalized.

Vote in Subcommittee

Motion to list Tocopherols at §205.605(a) of the National List. Tocopherols – derived from vegetable oil

Motion by: Scott Rice

Seconded by: Jean Richardson

Yes: 8 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Harold Austin, Subcommittee Chair, to transmit to NOSB on September 6, 2016.