

October 26, 2016

National Organic Standards Board  
USDA-AMS  
1400 Independent Ave. SW  
Washington, D.C. 20250  
Re: AMS-NOP-16-0049

Docket # AMS-NOP-16-0049

Dear National Organic Standards Board Members:

The following comments are submitted to you on behalf of The Cornucopia Institute, whose mission is to support economic justice for family scale farming.

## **HANDLING SUBCOMITTEE**

### **Tocopherols Proposed Annotation Change and Additional Listing**

#### **SUMMARY**

The Handling subcommittee proposes an annotation change as well as an additional listing for Tocopherols:

- Amend the annotation for tocopherols listed at §205.605(b) of the National List to read as follows: “Tocopherols – Derived from vegetable oil.”
- List Tocopherols at §205.605(a) of the National List. Tocopherols – derived from vegetable oil.

The Cornucopia Institute **stands** neutral as to the annotation change and **supports** the listing of Tocopherols to §205.605(a). However, The Cornucopia Institute suggests a different annotation than what is proposed by the Handling Subcommittee:

- **Tocopherols – extracted without synthetic solvents and derived only from non-GMO vegetable oil.**

#### ***Rationale:***

The Cornucopia Institute supports the additional listing under §205.605(a), as proposed in our fall 2015 comments to the NOSB regarding the 2017 Sunset of tocopherols. The listing of tocopherols on §205.605(a) would incentivize the use of nonsynthetic tocopherols.

However, all nonorganic tocopherols, suitable for the proposed annotations of either listing, are extracted from a number of nonorganic vegetable oils, but mainly from soybean oil,<sup>1</sup> and the majority (94%) of soybeans grown in the USA are GMO.<sup>2</sup>

In addition, tocopherols are obtained through a multi-step process that involves extraction with synthetic solvents such as hexane.

- Non-solvent extracted tocopherols from non-GMO oil are currently commercially available.
- The main sources of tocopherols are conventionally grown oils, such as soybean, rapeseed (canola), sunflower, corn, and cottonseed oils. In reviewing the impact of their manufacture, the NOSB must consider the consequences of raising the nonorganic crops used to produce it, including GMO crops.
- Tocopherols are extracted from the distillate, resulting from the deodorization of vegetable oils via several steps, which can include extraction with volatile organic solvents.
- Hexane is a solvent commonly used to extract tocopherols from soybean oil. Other solvents may include ethanol, isopropanol alcohol, acetone, isopentane, isohexane, trichloroethylene, or petroleum ether.
- Solvent extraction is a prohibited method in organic production.

## DISCUSSION

Tocopherols are a group of fat-soluble phenolic antioxidants naturally occurring in a variety of plant species, encompassing cereal grains, oilseeds, nuts, and vegetables.<sup>3</sup> Tocopherols possess vitamin E activity, and are an antioxidant ingredient mainly used for the stabilization of food products containing fats or oils susceptible to oxidation damages, resulting in off-flavor (rancidity). Their action helps preserve the taste and nutritional value of the food. They are used as additives in a variety of food, including dairy products, cereals, frozen green vegetables, margarine, fresh and frozen sausages, vegetable oils, soft drinks, snacks and nuts, salad dressings, soup bases, seasonings, dehydrated potatoes, processed meats and poultry, and baked products.<sup>4</sup>

### *Human Health Concerns*

Tocopherols used as antioxidants in food are generally obtained from oil distillate, a deodorization by-product of vegetable oils (e.g., soybean, canola, sunflower, corn, or cottonseed)<sup>5</sup> through a series of extraction and refining steps, which can include **solvent**

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<sup>1</sup> <https://www3.epa.gov/ttnchie1/ap42/ch09/final/c9s11-1.pdf>

<sup>2</sup> <http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-adoption.aspx>

<sup>3</sup> Burdock, G.A. 1997. Tocopherols. In: Encyclopedia of Food and Color Additives, Volume III. CRC Press, Boca Raton, FL, pp. 2801-2803.

<sup>4</sup> Limited Scope TR, 2015 - Tocopherols. Page 4, line 109-115

<sup>5</sup> Burdock, G.A. 1997. Tocopherols. In: Encyclopedia of Food and Color Additives, Volume III. CRC Press, Boca Raton, FL, pp. 2801-2803.

**extraction, chemical treatment, crystallization, complexation, and vacuum or molecular distillation.**<sup>6</sup>

Soybean oil is often a source of mixed tocopherols, which are obtained from soybean oil by solvent extraction, **hexane** being a commonly used solvent. Other solvents may include ethanol, isopropanol, acetone, isopentane, isohexane, trichloroethylene, or petroleum ether.<sup>7</sup> In addition, various organic solvents, such as hexane, are traditionally used during extraction of tocopherols from plant products.<sup>8</sup> A 2009 study by The Cornucopia Institute found hexane residues in soybean oil.<sup>9</sup> Hexane is a neurotoxic petrochemical solvent, listed as a hazardous air pollutant by the EPA, and is “*harmful or fatal if swallowed*” according to the MSDS.<sup>10</sup>

The oil is first extracted using hexane, then the oil distillate, a by-product of the oil refining, is further processed with hexane to extract tocopherols. So, the oil distillate would most likely contain hexane residues, which would be further augmented during the hexane extraction of mixed tocopherols from soybean oil, and potentially from any other edible oils whenever hexane is used.

Considering the toxicity of hexane and of some of the other solvents used, and the fact that extraction using volatile solvents is a prohibited method under the organic regulations, it would be wise to ensure that **only natural tocopherols, obtained without solvents**, are used as antioxidants in processed foods to prevent long-term chronic exposure to hexane.

### *Alternatives & Essentiality*

#### Comments about commercial availability:

In 2014 there were already **several sources of non-solvent extracted natural tocopherols**. This was pointed out in the minority report on the tocopherols proposal for aquaculture, which was deliberated at the spring 2014 NOSB meeting:

“The minority also has concerns about the unnecessary presence of volatile synthetic solvents in tocopherols. The Livestock Subcommittee received a letter from Oh Oh Organics supporting the consistent availability of natural tocopherols extracted without synthetic solvents. The letter states, “*I have sold **Non-GMO, non-solvent extracted tocopherol since 2005**. Both BASF, an international ingredient manufacturer out of Germany and BTSA, a company specializing in non-GMO Tocopherols supply this material. It is consistently available and is broadly used in the food, cosmetic and household cleaning business. Additionally I have seen ISO certified documents for a supplier in China...so, I believe it available around the world.*”

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<sup>6</sup> Limited Scope TR, 2015 - Tocopherols. Page 4, line 87-89

<sup>7</sup> Limited Scope TR, 2015 - Tocopherols. Page 8, line 308-313

<sup>8</sup> Ogbanna, J.C. 2009. Microbiological production of tocopherols: current state and prospects. Applied Microbiology and Biotechnology 84(2): 217-225.

<sup>9</sup> <http://www.cornucopia.org/2009/05/soy-report-and-scorecard/>

<sup>10</sup> Registry, A., & Health, N. (2013). Public Health Statement for n-Hexane. Retrieved from <http://www.eoearth.org/view/article/51cbeebe7896bb431f699f7a>

In spite of this and several additional testimonies made to the NOSB at the spring and fall 2015 meetings, the NOSB chose to dismiss these evidences, which seem to clearly establish that a sufficient commercial supply of non-solvent extracted natural tocopherols appears to exist.

Instead, the NOSB stated:

*“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 nonsynthetic 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.”*

While the use of organic tocopherols is the most desirable outcome, the use of non-solvent extracted natural tocopherols derived from non-GMO oil would be very acceptable during a transitional period, until organic tocopherols become commercially available.

### ***Other Considerations***

**Many of the oils from which the tocopherols are extracted are often obtained from GMO crops**, including canola, soy, corn, and cottonseed. When reviewing this material, the NOSB must consider whether the manufacturing base was obtained from excluded methods.

**The main sources of tocopherols are conventionally grown oils.** In reviewing the impact of their manufacture, the NOSB must consider the consequences of chemical-intensive agriculture in the production of the nonorganic crops used to produce these oils.

**Tocopherols are commonly formulated with ancillary substances<sup>11</sup>**; only handling materials listed on the National List and additionally not obtained via excluded methods should be used in tocopherols formulations.

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<sup>11</sup> Limited Scope TR, 2015 - Tocopherols. Pages 5-6, line 175-191

## CONCLUSION

The Cornucopia Institute supports the listing of tocopherols under **§205.605(a) *Nonsynthetics allowed, Tocopherols – extracted without synthetic solvents and derived only from non-GMO vegetable oil.***

The Handling Subcommittee has made an encouraging first step – the proposal to create a separate listing for non-synthetic tocopherols; however, considering that pesticides, GMO oils, and dangerous synthetic solvents are part of the process to manufacture tocopherols, this proposal is not sufficient. **The NOSB should consider removing all exemptions for nonorganic tocopherols, particularly in light of the fact that non-solvent extracted tocopherols from non-GMO oil are already commercially available.**

Furthermore, the NOSB should encourage the production of organic tocopherols by placing an expiration date on the §205.605(a) and §205.605(b) listings.