March 26, 2020 – Draft1 – DO NOT CIRCULATE – OTA MEMBERS ONLY

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-19-0095

RE: Handling Subcommittee – L-Malic Acid (Discussion Document)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Handling Subcommittee's Discussion Document on L-Malic Acid. The Subcommittee is evaluating whether L-malic acid has been incorrectly classified as a non-synthetic, and whether the common manufacturing process is more appropriately classified as 'synthetic' based on NOP Instruction on Classification of Materials.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

The Handling Subcommittee is presenting four questions to inform its evaluation and proposal for the fall 2020 meeting. In summary:

- OTA's evaluation determined that the two-step production process that involves the synthesis of fumaric acid from petroleum products followed by enzymatic conversion of synthetic fumaric acid to L-malic acid renders it **synthetic**. In contrast, the two-step process involving production of non-synthetic fumaric acid by fermentation followed by enzymatic conversion to L-malic acid results in **non-synthetic** L-malic acid.

- OTA analyzed citric acid, lactic acid, gibberellic acid, yeast and xanthan gum. In doing so, we determined that the classification of L-malic acid, when synthesized as a two-step process starting with petroleum products, would not affect the classification of other substances on the National List. However, the exercise of running multiple substances produced via fermentation through the Classification Decision Tree (Synthetic/Non-synthetic) led us to conclude that there is a need for improved Classification Guidance for fermentation by-productions.

- The commercial source of L-malic acid that is predominantly being used in organic processed products is the synthetic form. There does not appear to be sufficient quantities of a non-synthetic L-malic acid available to meet current demand in organic production. More research, however, is needed. One option for addressing the issue as a whole is to list L-malic acid as "synthetic" with an annotated requirement to use a non-synthetic form when commercially available.

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We offer the following more detailed response to the Subcommittee's questions:

1. **There still appears to be some disagreement whether the process described in this document results in a synthetic form of L-malic acid. Is the determination that the two-step process described in this document and in the 2019 Technical Report results in a synthetic form of L-malic acid accurate?**

   The 2019 Technical Report (TR) presents a one-step fermentation process for L-malic acid as well as two variations of a two-step production process. In the one-step process, L-malic acid is produced via microbial fermentation of glucose (and other sugars) whereas the final isolated L-malic acid product has not been transformed into another substance (no chemical change). The one-step fermentation method, from our viewpoint, is unquestionably non-synthetic.

   In the two-step process for producing L-malic acid, fumaric acid is first produced and then it is enzymatically converted to L-malic acid. The TR presents two options for the production of fumaric acid: 1) fumaric acid is produced via glucose fermentation; and 2) fumaric acid is synthesized from petroleum products. The first option using fermentation, as described in the TR and by our analysis, is clearly non-synthetic. The point of disagreement, or rather discussion, is the status of L-malic acid when the precursor for enzymatic conversion is **synthetic** fumaric acid, derived from **petroleum products**. The question arises around the interpretation of NOP Guidance 5033-1 and what is considered the "natural source."

   In evaluation #2 of the TR, on Page 9, two interpretations are presented:

   a. If synthetic fumaric acid, as a microbial substrate, is considered the source, then L-malic acid is synthetic.
   b. If, however, the microbial product (i.e. column effluent) the L-malic acid is extracted from is considered the source, L-malic acid could be considered synthetic. As previously discussed, the second phase of this production methods involves conversion of fumaric acid to L-malic acid followed by extraction of L-malic acid using non-synthetic methods.

   The Organic Trade Association views the L-malic acid from synthetic fumaric acid production to be **SYNTHETIC**.

   First and foremost, we believe the two-step process needs to be viewed as <u>one process</u> with two steps. From this perspective, the "source" should be identified in the first step of the process. In the fermentation option, the L-malic acid is produced via a naturally occurring biological process. The source is ultimately glucose fermentation that produces non-synthetic fumaric acid that is converted to L-malic acid. In second option, the ultimate source of the L-malic acid is petroleum products whereas fumaric acid is synthesized from petroleum and converted to L-malic acid. In other words, we do not think the fumaric acid should be identified as the "source." Fumaric acid is an intermediate substance in a two-step process. Fumaric acid is, in fact, the substance or source that the L-malic acid is directly derived (converted) from, but it is a two-step production process from start to finish.

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To further address the question of whether fumaric acid is the microbial substrate or a microbial product (column effluent), we suggest it most closely resembles the reference to "microbial substrate." Fumaric acid is the substance that is enzymatically converted (the direct source), although it is part of a column effluent along with a preparation of immobilized cells that produce the fumurase (catalyst) that performs the enzymatic conversion to L-malic acid. In a microbial preparation for fermentation, as well as a preparation for enzymatic conversion, there are several starting inputs that make up the starting media / substrate / effluent. In all cases, however, there is the primary substrate or substance that is converted - glucose in the case of fermentation and fumaric acid in this case of enzymatic conversion. If fumaric acid is removed from the effluent, L-malic will not be produced.

2. **Would classification of L-malic acid when manufactured from synthetic fumaric acid as a synthetic substance affect the classification of other substances currently on 205.605(a)?**

We do not believe so, as long the synthetic form is clearly tied to L-malic acid produced from synthetic fumaric acid (as opposed to the fermentation methods). Our determination is based on an analysis we conducted looking at citric acid, lactic acid, gibberellic acid, yeast and xanthan gum. We reviewed the technical resources available for all substances and ran each one through the Classification Guidance for Synthetic / Non-synthetic (NOP 5033-1). The important distinction is that all of the National List examples listed above are produced via microbial fermentation, whereas the primary substrate is natural (typically glucose, sucrose or some other sugar or carbohydrate source). In no other non-synthetic example is the primary food source a petroleum product, or a synthetic substance converted from a synthetic source.

The exercise of running multiple substances produced via fermentation through the Classification Decision Tree (Synthetic/Non-synthetic) led us to conclude that there is a need for improved Classification Guidance for fermentation by-productions. The problem is that for fermentation and other naturally occurring biological processes, the starting material (referred to as the substrate, medium, culture broth, etc.) will typically involve multiple inputs that may be synthetic and non-synthetic. For example, starting inputs may include the microorganism, glucose, nitrogen source, oxygen source, trace minerals etc. In this case, the primary substrate or food source is glucose, but other proteinaceous and complex nutrients are also required and consumed by the organisms to successfully carry out the fermentation process. This relates to the question of "source" and how to distinguish one component of a substrate from another.

The first question of NOP 5033-1 asks, "Is the substance manufactured, produced, or extracted from a natural source?" This is a straight-forward question when the source is a plant, animal or mineral. However, when applied to a substance produced via fermentation, the question of source can be complex because it can include multiple food sources and inputs. In simple terms, we believe the primary focus for classification should be on the breakdown of the essential carbohydrate source, or in the case of hydrolysis, the substance that is being converted. Additional guidance on the classification of fermentation by-products and review of the substrate is an area NOSB could consider for further work.

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3. **If the Subcommittee recommends an annotation that limits sources of fumaric acid used in the production of L-malic acid to non-petroleum sources, are there sufficient quantities to meet current demand in organic production?**

The Organic Trade Association will need to continue to gather information to evaluate whether there are sufficient quantities of non-synthetic L-malic acid (non-petroleum source) to meet the demand in organic product. Based on the information NOSB received from certifiers during the spring 2019 meeting, we do not believe so. At that time, certifiers reported that it is unlikely that there are commercially available non-synthetic sources of L-Malic Acid. One certifier said they ""are confident that all commercially available sources are produced with petroleum as the starting material. Even when supporting documentation for L-malic acid says, "produced naturally via enzymatic fermentation," that only refers to the second half of the process.""

OTA is aware of at least 70 NOP certified operations that are using L-malic acid in NOP certified products; however, we do not have access to information detailing the exact form being used. Regardless, a classification change that would inadvertently prohibit the form(s) being used would have a significant and potentially harmful impact on many organic processors. Therefore, a well-informed answer to this question is critical. NOP certified products that currently use L-malic acid include wine, juices, dietary supplements, personal care products, energy drinks, granola, gummy products, spice blends and others.

One option is to retain the listing on § 205.605(a)(non-synthetic), and add an additional listing at §205.605(b)(synthetic) with an annotated requirement to use a non-synthetic form when commercially available. Alternatively, a listing on 205.605(b) with a requirement to use non-synthetic forms when commercially available would likely suffice. Both approaches would not only maintain an allowance for non-synthetic L-malic acid, but ***require its use*** unless commercially unavailable. Maintaining a listing on 205.605(a) would reflect a clear allowance for the non-synthetic form, as reviewed by NOSB, in addition to an allowance for the synthetic form when non-synthetic is commercially unavailable.

We recognize that commercial availability requires additional time and resources of certifiers and certified operators. Therefore, we do not take this suggestion lightly in the grand scheme of advancing organic. However, it does present a reasonable path for honoring the intent of the law ("natural" preference) should sufficient quantities of the natural form not be available. A classification and listing of L-malic acid as "synthetic" only could not only raise questions around the allowance of a natural form, but also remove the incentive to use the natural form.

4. **How much time would be required for the industry to meet current and expected commercial demand of non-synthetic L-malic acid produced using a one-step fermentation process through biological methods such as microbial fermentation using *Aureobasidium pullulans* and *Penicillium vitacola*?**

We are not yet able to answer this question. More research and outreach are needed. See our response to Question #3.

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On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

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Vice President of Regulatory and Technical Affairs
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
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