National Organic Standards Board
Handling Subcommittee Discussion Document
Reclassification of L-Malic Acid
February 19, 2020

Introduction:
The Handling Subcommittee is considering a change to the classification of L-malic acid from a nonagricultural (nonorganic) non-synthetic allowed substance to a nonagricultural synthetic allowed substance and move the substance from §205.605(a) to §205.605(b). This consideration responds to recommendations made in a number of comments submitted during the substance's sunset review at the Spring and Fall 2019 NOSB meetings. Additionally, this responds to the 2019 L-malic acid Technical Report (TR), which found that most commercial quantities of L-malic acid are derived in part via a process of enzymatic conversion of synthetic fumaric acid.

Background:
L-malic acid was first added to the National List in 2006 and its listing has been renewed at each subsequent sunset review. The substance underwent its most recent 5-year sunset review in 2019, during which it received support from stakeholders for continued inclusion on the National List. Several commenters opposed the relisting; these comments are addressed in the discussion section below. At its Fall 2019 meeting, the Board voted 13 in favor, with one member absent, to relist L-malic acid.

However, during the sunset review the Board acknowledged the many comments suggesting most commercial sources of L-malic are synthetic and that the listing for L-malic acid should be at §205.605(b). Because a listing cannot be changed nor can an annotation be added during sunset review, the Board noted it would address the placement of the substance outside of sunset review.

Relevant areas in the Regulation:
§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

Reference: 205.605(a) Nonsynthetics allowed: L-malic acid (CAS # 97-67-6).

Discussion:
L-malic acid occurs naturally in many fruits and vegetables, including apples and cherries and can be obtained by enzymatic conversion of fumaric acid and by fermentation of glucose and other carbohydrates. It is not economical to extract L-malic acid from natural foodstuffs such as apple juice.

In the first round of the sunset review in Spring 2019, a number of commenters questioned whether commercially available L-malic acid is indeed from nonsynthetic sources, as this listing restricts. Commenters noted that while supporting documentation may state L-malic acid is produced naturally via enzymatic fermentation, this statement refers to only the second half of the process.

Industrial quantities of L-malic acid are made using biological processes, with the major industrial process to produce L-malic acid being a two-step procedure:

1. Production of fumaric acid either synthetically from petroleum or by fermentation of carbohydrates; and
2. Enzymatic conversion of fumaric acid to L-malic acid by immobilized microbes producing the enzyme fumarase.

There are two options for obtaining the fumaric acid in the **first step** in this process; more detailed information on the two-step process can be found in Appendix A of the 2019 Technical Report.

1. The fumaric acid precursor is obtained through the fermentation of carbohydrates (i.e., Rhizopus spp.)
2. The fumaric acid precursor is obtained as a synthetic product from maleic acid of petroleum origin

Commercial quantities of nonsynthetic L-malic acid may also be produced using a one-step fermentation process through biological methods such as microbial fermentation using *Aureobasidium pullulans* and *Penicillium vitacola*, though it is not believed that this process is occurring on a scale that would accommodate the needs of the current market. The major commercial source of L-malic acid is enzymatic conversion of synthetic fumaric acid to L-malic acid by immobilized microbes (Chibata et al. 1983; Chi et al. 2016a; Dai et al. 2018). If the malic acid produced by this method is synthetic, most if not all, of the L-malic acid on the market is therefore synthetic (Goldberg et al. 2006; Chibata et al. 1983; Engel et al. 2008; Chi et al. 2016a; Dai et al. 2018).

A number of commenters noted that while there may have been nonsynthetic versions available in the past, it is unlikely that commercially available nonsynthetic quantities exist. As certifiers, material review organizations, and the 2019 TR attest, applying NOP Guidance 5033 and 5033-1 to this full production method would result in classifying L-Malic acid as a synthetic material. Until this material is reclassified, certifiers have been verifying the following for L-malic acid: that it is not made using the "big 3" (genetic modification, sewage sludge, irradiation); that it is L-malic acid (not DL- or D-); and that it is the form with the same CAS# as is identified on the National List.

Commenters opposing the relisting of L-malic acid during the 2019 sunset review believe it should be removed from the National List and then repetitioned for inclusion at §205.605(b), or listed at §205.605(a) with an annotation limiting use to forms produced through nonsynthetic fermentation methods. The Handling Subcommittee is keenly aware of the negative environmental and climate impacts of petroleum use and supports alternatives to its use in organic production. However, as noted by commenters during the 2019 sunset review and indicated in the 2019 TR, it does not appear that commercial quantities of nonsynthetic L-malic acid are sufficient to meet current demand.

Questions:
The Subcommittee is seeking feedback on the following questions to help inform its decision regarding the reclassification of L-malic acid and to gather further information on some of the comments expressed during the 2019 sunset review.

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

Subcommittee Vote:
Motion to accept the discussion document on reclassification of L-Malic Acid
Motion by: Scott Rice
Seconded by: Steve Ela
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Asa Bradman, Handling Subcommittee Chair, to transmit to NOSB, February 19, 2020