

**National Organic Standards Board
Handling Subcommittee
L-Malic Acid Reclassification Proposal
July 16, 2024**

Summary of Issue.

Reclassification of L-Malic Acid has been on the National Organic Standards Board (NOSB's) work agenda for a number of years, and the Handling Subcommittee (HS) is attempting to resolve the ongoing classification issue at this sunset review of L-Malic Acid. The sunset review can be found in a separate document. This proposal focuses squarely on classification of L-Malic Acid and whether it should be listed at 7 CFR 205.605(a) or 7 CFR 205.605(b).

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 comes 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 only to 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.

More detailed information on the two-step process can be found in Appendix A of the [2019 Technical Report](#).

There are two options for obtaining the fumaric acid in the first step in this process: 1) The fumaric acid precursor is obtained through the fermentation of carbohydrates (i.e., *Rhizopus spp.*) or, 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 will also be synthetic (Goldberg et al. 2006; Chibata et al. 1983; Engel et al. 2008; Chi et al. 2016a; Dai et al. 2018).[All citations from 2019 TR]

L-malic acid can also be made from ethanol and biodiesel production waste but, again, this is not the production method that commonly supplies the market. Thin stillage is a byproduct of corn fermentation in the production of ethanol from which *Aspergillus niger* ATCC 9142 can produce L-malic acid (West 2017). Another L-malic acid production process is the fermentation of crude glycerol obtained from production of biodiesel. Non-engineered *Ustilago trichophora* can be used for high yield production. *A. niger* MTCC 281 can also produce L-malic acid from crude glycerol (Iyyappan et al. 2018ab).

L-malic acid can also be produced by microbes in a one-step fermentation process fueled by glucose or other carbohydrates. Reaction conditions are adjusted to cause overproduction of L-malic acid, which is an essential product of microbe metabolism. While this production process is possible, it is not clear how much is produced and whether it will be able to produce sufficient quantities to supply handlers currently relying on the L-malic acid produced by the synthetic process.

The production of DL-malic acid is a synthetic process according to [NOP Guidance 5033-1](#); the malic acid undergoes a chemical change that is not the result of a naturally occurring biological process (USDA 2016b). Note this is similar to the method of production for synthetic fumaric acid used as precursor for industrial L-malic production.

Discussion

The ongoing discussion around L-malic acid is not whether it is essential to organic handling or if it has detrimental effects on the environment or human health. In fact, there is broad agreement that it is essential, particularly to juice manufacturers, and there is no evidence to suggest that it does not meet National List criteria. However, as the organic material review process has become more refined and the production methods of L-malic acid has changed, we now see that much of the L-malic acid used in organic processing is “synthetic” while L-malic acid is currently listed at 7 CFR 205.605(a) as a “nonsynthetic” substance.

Previous Handling Subcommittees have suggested relisting L-malic acid at §205.605(b) as a “synthetic” substance to accurately reflect the predominant production method, and to ensure that the classifications inherent to the National List of nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” are consistent with NOP material classification guidance.

This Subcommittee agrees with the previous Board and suggests adding L-malic acid to §205.605(b) to reflect that most L-malic acid used in organic food processing is synthetic in origin. However, the Subcommittee has declined to recommend L-malic acid be removed from §205.605(a), as there may be nonsynthetic forms of L-malic acid in use, and should commercial quantities of nonsynthetic L-malic acid become available, organic processors may show a preference for a nonsynthetic option.

The NOSB did not receive any comments at the Spring 2024 meeting that quantified the amount of nonsynthetic L-malic acid currently in use, but commenters confirmed that most of what is currently in use would be classified as ‘synthetic.’ There were numerous opinions regarding how ‘synthetic’ L-malic acid should be considered or added to the National List. Some commenters preferred adding L-malic at §205.605(b) and keeping the nonsynthetic listing at §205.605(a). Some commenters preferred removing L-malic from §205.605(a) and requiring a petition to add it at §205.605(b). There appears to be general consensus that the substance currently in use by organic processors is classified as ‘synthetic’ and its allowance should be reflected by inclusion at §205.605(b). However, there is disagreement about whether the nonsynthetic listing should remain or if NOSB should recommend addition at §205.605(b) as part of the L-malic acid classification work agenda item or if a petition should be required for the reclassification.

The HS does not see any justification for removal of L-malic acid during this sunset review and views the classification as a critical revision that must be made. However, the classification of L-malic acid used by organic processors (e.g. synthetic or nonsynthetic) does not impact the substance’s compatibility with National List criteria, and L-malic acid should remain on the National List. At this sunset review, the HS proposes an additional classification and listing motion, so the National List accurately reflects the classification of the substance in use in organic processing. These motions are not contingent in any way

on the motion to remove L-malic as part of the OFPA mandated sunset review process, but they are discussed in the HS sunset recommendation for clarity and ease of reference. The HS believes that L-malic should remain at §205.605(a) to clarify that nonsynthetic forms of this substance remain allowed in organic processing. Should, in future sunset reviews, new information raise clear concerns about either the nonsynthetic or synthetic form of the substance, the NOSB will have the option to remove it with a decisive vote.

Classification Motion:

Motion to classify L-malic acid produced by fermentation of fumaric acid as synthetic

Motion by: Nate Lewis

Second by: Kyla Smith

Yes: 9 No: 0 Abstain: 0 Recuse: 0 Absent: 0

National List Motion:

Motion to add L-malic acid at 205.605(b)

Motion by: Nate Lewis

Second by: Kim Huseman

Yes: 9 No: 0 Abstain: 0 Recuse: 0 Absent: 0

