

National Organic Standards Board
Handling Subcommittee
L-Malic Acid Reclassification Discussion Document
February 4, 2025

Summary of Issue

Reclassification of L-malic acid has been on the National Organic Standards Board (NOSB) work agenda for a number of years, and it was put on hold in 2020. The Handling Subcommittee is attempting to resolve confusion and ensure consistency in use of this material by recommending the addition of synthetic L-malic acid to 7 CFR 205.605(b) with a commercial availability limitation, in addition to retaining the nonsynthetic listing currently included at 7 CFR 205.605(a). This change would align the regulations with current use practices, as well as codify a preference for the nonsynthetic version.

Background

L-malic acid can be obtained by enzymatic synthesis or fermentation ([2019 Technical Report \[TR\], lines 53-54](#)).

There are two main pathways for producing L-malic acid on a commercial scale (2019 TR, lines 282-292):

- **Two-step process:**
 1. Production of fumaric acid, either synthetically from petroleum or by fermentation of carbohydrates;
 2. Enzymatic conversion of fumaric acid to L-malic acid.
- **One-step process:** Fermentation using carbohydrates.

Under NOP Guidance 5033-1, natural substances that undergo strictly biological processes, including fermentation and enzymatic conversion, are determined to be nonsynthetic. Accordingly, the product of the one-step process is nonsynthetic L-malic acid. In addition, the fermentation and enzymatic conversion used in the two-step process are nonsynthetic processes. However, the synthetic/non-synthetic status of the product of the two-step process depends on how fumaric acid is produced. When fumaric acid is produced from fermentation of carbohydrates, the resulting L-malic acid is nonsynthetic (2019 TR, lines 361-386). The status of L-malic acid resulting from synthetically produced fumaric acid, however, depends on what is considered the “natural source” (2019 TR, lines 388-391). If synthetic fumaric acid is considered the “source,” the resulting L-malic acid is synthetic; if the “source” is the solution resulting from the microbial fermentation (the “culture broth”), from which the L-malic acid is extracted, the L-malic acid could be considered nonsynthetic (2019 TR, lines 392-394, 412). The 2019 TR notes that the starting material or growth medium have not been consistently used to categorize the non/synthetic status of materials (2019 TR, lines 418-419) – that is, that guidance on materials produced through fermentation has not placed restrictions on the use of synthetic growth media in the production of a nonsynthetic input.

There are several other ways to produce L-malic acid that are not commercially relevant options. L-malic acid occurs naturally in many fruits and vegetables, including apples and cherries (2019 TR, lines 85-87); however, it is not economical to extract L-malic acid from natural foodstuffs (2019 TR, line 282). L-malic acid may also be separated from synthetically produced DL-malic acid; however, this process is expensive and not used to make commercial quantities (2019 TR, lines 294-328).

DL-malic acid, the material that was [originally petitioned](#) for inclusion on the National List, is a mixture of L-malic acid and D-malic acid. Production of DL-malic acid starts with petroleum products and involves chemical changes that are not the result of naturally occurring biological processes (2019 TR, lines 294-314); the process is similar to that used to produce the synthetic fumaric acid that can feed

into the two-step process for L-malic acid production (2019 TR, lines 314-316). In the original [2003 TAP review](#), all three reviewers concluded that DL-malic acid is synthetic and should not be added to the National List because a non-synthetic alternative (L-malic acid produced by double fermentation) was viable (2003 TAP, p. 1). The TAP noted that L-malic acid is produced by fermentation of fumaric acid and that fumaric acid can be produced by fermentation from glucose (2003 TAP, p. 5). The reviewers recommended rejecting DL-malic acid because L-malic acid produced from fermentation of carbohydrates seemed like a potential non-synthetic alternative; however, they also noted that they did not have full information about the commercial availability of L-malic acid from a natural source (2003 TAP, pp. 8, 10, 12). None of the reviewers directly addressed L-malic acid derived from synthetic fumaric acid, but the emphasis on fermentation of glucose implies that they would have viewed the synthetic fumaric acid version as synthetic and incompatible with organic production.

The Handling Subcommittee noted in the [Spring 2019 sunset document](#) for L-malic acid that the material should be placed on 7 CFR 205.605(b), in light of the new information about the manufacturing process and role of synthetic fumaric acid described in the 2019 TR. However, the Subcommittee [noted](#) that reclassification could not be completed via sunset review and proposed to address reclassification separately at a future meeting. The Subcommittee then considered an [L-malic acid reclassification discussion document](#) in Spring 2020 that asked stakeholders for input on the classification question, the potential precedential impacts, and the availability of L-malic acid derived from different processes and raw materials. Questions raised in comments about the impact of this classification decision on review of other materials appear to have generated enough confusion that the NOSB ultimately put this work agenda item on hold.

Discussion

There appears to be general consensus that the substance currently in use by many organic processors is classified as “synthetic” and that if its use should continue, it should be listed at 7 CFR 205.605(b). 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 7 CFR 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).

The original review of this material resulted in addition of L-malic acid to only § 205.605(a), as an alternative to adding synthetic DL-malic acid to the National List. However, the NOSB’s recommendation appears to have been based on incomplete information about the commercial availability of L-malic acid produced from fumaric acid derived from fermentation, rather than fumaric acid derived from a synthetic process. Currently, there does not appear to be an adequate supply of nonsynthetic L-malic acid to meet demand for L-malic acid from organic processors.

Given that the original non-synthetic listing was based on a presumption of commercial availability that has not turned out to be accurate, and L-malic acid has repeatedly been determined necessary for organic production, the Subcommittee recommends adding synthetic L-malic acid to 7 CFR 205.605(b), with a commercial availability annotation. This change will accurately reflect the current practice of allowing L-malic acid produced from synthetic fumaric acid in organic food processing, while codifying a preference for the nonsynthetic version. The Subcommittee also recommends retaining the listing for nonsynthetic L-malic acid at 7 CFR 205.605(a), as there may currently be nonsynthetic forms of L-malic acid in use. If commercial quantities of non-synthetic L-malic acid become available, organic processors can shift to the nonsynthetic option, as long as the listing at 7 CFR 205.605(a) is retained. The ongoing sunset review of both versions will provide opportunities to continue to examine the availability of and

need for each form, as well as the environmental and health concerns associated with fumaric acid derived from petroleum.

The Subcommittee put forward a proposal at the Fall 2024 meeting, and the NOSB voted to return the proposal to the Subcommittee to clarify and address concerns raised in comments. The Subcommittee considered two key concerns:

1. **Precedent:** Because the need for reclassification turns on the lack of commercial availability of a nonsynthetic material (L-malic acid produced from fumaric acid derived from fermentation of glucose) that was originally listed based on a presumption of commercial availability, the implications of action taken will be specific and confined to L-malic acid. It would not establish a general precedent for adding synthetic materials to the National List. The NOSB will continue to identify and address areas where current practice does not align with the letter of the law and make recommendations to improve alignment and compliance with OFPA.
2. **Fermentation:** Commenters raised concerns about the implication of reclassification on other materials that are the product of fermentation. Reclassification of L-malic acid is consistent with NOP Guidance 5033-1, in that a synthetic material cannot become nonsynthetic even if it is subjected to additional nonsynthetic processes. The Subcommittee is not aware of any other materials currently included on the National List that are listed as nonsynthetic but derived from a synthetic primary source material. If there are other materials that may be in a similar situation, the Subcommittee welcomes that feedback and could address them accordingly. To the extent that there are broader questions about the synthetic/nonsynthetic mix of ingredients that may be included in growth media, those issues may be dealt with separately (and if necessary, applied to the L-malic acid listings at that time).

Questions for Stakeholders

1. Organic processors currently use L-malic acid derived from synthetic fumaric acid, and there does not appear to be sufficient supply of nonsynthetic L-malic acid to meet demand. The Subcommittee recommends updating the National List to align with current practice and attaching a commercial availability requirement to the use of synthetic L-malic acid, to drive use toward the nonsynthetic form if it becomes more widely available. Are there any alternative approaches to addressing this issue that the Subcommittee should consider?

Subcommittee Vote:

Motion to accept the discussion document on; 1) classifying L-malic acid produced from synthetic fumaric acid as synthetic, and 2) adding the following to 7 CFR 205.605(b): L-malic acid, when nonsynthetic L-malic acid is not commercially available.

Motion by: Allison Johnson

Second by: Dilip Nandwani

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