National Organic Standards Board
Handling Subcommittee
L-Malic Acid Reclassification Proposal
Fall 2025

Introduction:
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 proposing to add synthetic L-malic acid to 7 CFR 205.605(b), in addition to retaining the nonsynthetic listing currently included at § 205.605(a). This change would align the regulations with current practice.

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]:

- **One-step process**: Fermentation using nonsynthetic carbohydrates.
- **Two-step process**:
    1. Production of fumaric acid
        a. Synthetically from petroleum products, or
        b. Nonsynthetically by fermentation of carbohydrates;
    2. Enzymatic conversion of fumaric acid to L-malic acid.

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 because of the availability of a nonsynthetic option.

The Handling Subcommittee noted in the Spring 2019 sunset document for L-malic acid that the material should be placed on § 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 consensus that the substance currently in use by many organic processors, derived from synthetic fumaric acid, is classified as "synthetic" and that if its use should continue, it should be listed at 205.605(b). This is reflected in the classification vote for L-malic acid made from synthetic fumaric acid. Other potential synthetic sources of L-malic acid have not been evaluated. The NOSB did not receive any comments at the Spring 2024 or Spring 2025 meetings 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."

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.

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).

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 and compatible with organic production (7 U.S.C. 6517(c)(1)), the Subcommittee proposes adding synthetic L-malic acid to 7 CFR 205.605(b). The Subcommittee does not propose removing nonsynthetic L-malic acid from § 205.605(a), as there may currently be nonsynthetic forms of L-malic acid in use. If commercial quantities of nonsynthetic L-malic acid become available, organic processors may shift to the nonsynthetic option, as long as the listing at § 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 and the extent to which excluded methods may be involved in fermentation. In light of the public comments discussed below, the Subcommittee does not recommend attaching the commercial availability restriction described in the Spring 2025 discussion document to the synthetic listing.

Public Comment:
The Subcommittee asked stakeholders for potential alternative approaches to addressing the disconnect between intention and practice for the current nonsynthetic L-malic acid listing.

Commenters agreed that L-malic acid derived from synthetic fumaric acid is synthetic and that there does not appear to be enough nonsynthetic L-malic acid to meet demand. It was noted that there is one OMRI-listed nonsynthetic L-malic acid, but that is not likely to be adequate to supply current demand.

Commenters raised questions about alternatives, ancillary ingredients, and use of excluded methods in production of L-malic acid. In particular, a commenter noted that if scaled up production of nonsynthetic L-malic acid were achieved, there is a high risk that it would rely on genetically modified bacteria that can survive in a high-acid environment. It was also noted that there are potential alternatives that could be used in place of L-malic acid and that ancillary ingredients were not identified or assessed in the 2019 TR.

Several commenters did not support attaching a commercial availability requirement to the synthetic listing, as recommended in the Spring 2025 discussion document. Commenters opposed this approach because it would be difficult for processors to determine the synthetic/nonsynthetic status of the material and for certifiers to enforce the requirement, and it is not clear that the extra work involved in verification would ultimately result in meaningful benefits.

Summary of Proposal:
The Subcommittee proposes adding synthetic L-malic acid to 7 CFR 205.605(b).

Classification Motions:
Motion to classify L-malic acid produced by fermentation and/or enzymatic conversion of carbohydrates as nonsynthetic.
Motion by: Allison Johnson
Second by: Kyla Smith
Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Motion to classify L-malic acid produced from synthetic fumaric acid as synthetic.
Motion by: Allison Johnson
Second by: Dilip Nandwani
Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1

National List Motion:
Motion to add synthetic L-malic acid to 7 CFR 205.605(b).
Motion by: Allison Johnson
Second by: Kyla Smith
Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1