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Submitted via [Regulations.gov](https://www.regulations.gov).

RE: Docket # AMS-NOP-19-0095

NOSB Handling Subcommittee Discussion Document: Reclassification of L-Malic Acid

Dear NOSB members:

Thank you for the opportunity to provide comments on the Discussion Document for the Reclassification of L-Malic acid. MOSA certifies approximately 2,155 organic operations throughout the United States, including 315 handling operations. Our feedback below on the Handling subcommittee's questions #1 and #2 considers the certification review process of L-malic acid. Questions three and four are best directed toward the industry.

NOSB subcommittee 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 TR results in a synthetic form of L-malic acid accurate?*

We agree with the interpretation in the 2019 TR in lines 412-416 [emphasis added]:

“Identifying the culture broth (i.e. extracellular metabolic product) as the “natural source” as opposed to the beginning growth substrate used is a commonly applied interpretation of the 5033-1 Decision Tree. For example, citric, lactic, and gibberellic acid are all nonsynthetic substances extracted from the fermentation medium produced by the growth of various microorganisms. In this interpretation, the culture broth produced by a microorganism is considered biological matter and a natural source material.”

We do not require review of substrate materials (“culture broth”) for any material unless required by the National List. Yeast is an example of a material that requires additional verification regarding substrate materials:

“Yeast—.....Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented.”

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)?*

Yes, such a decision would have tentacles. Yeast is a similar example on .605(a), with the manufacturing processes for various types of yeast covered well in the [2014 Technical Report](#). Yeast is generally categorized as a nonsynthetic regardless of manufacturing substrate, however, the rule prohibits specific production substrates:

“Growth on petrochemical substrate and sulfite waste liquor is prohibited.”

Several citations outline the nonsynthetic status of yeast. Lines 500-508 along with Tables 6 and 7 cover the manufacturing substrates known for yeast. Lines 596-611 answering Evaluation Question #2 clearly covers that yeast is nonsynthetic regardless of manufacturing substrate. Lines 640-641, the first line of the answer for Evaluation Question #3 specifically identifies yeast as nonsynthetic unless genetically modified.

“Yeast is considered a nonsynthetic microorganism with exceptions where yeast which has been genetically modified.”

The decision to deem l-malic acid a synthetic would also affect the review of numerous other materials such as citric acid, lactic acid, enzymes, dairy cultures, etc. As with yeast, the technical reports for other materials indicate review requirements for substrates only where applicable. The National List clearly outlines the materials where additional scrutiny is needed. If the NOSB decides that additional review criteria is needed for the review of l-malic acid substrate materials, we would look for a change to the National List to add a restricting annotation.

Thank you for your work on this topic. We are available to answer any questions you have.

Respectfully submitted,

The MOSA Certification Team