



BEYOND PESTICIDES

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October 3, 2014

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Re. HS: L-malic acid; MS: Workplan

These comments to the National Organic Standards Board (NOSB) on its Fall 2014 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and groups around the world.

Beyond Pesticides opposes the relisting of L-malic acid because the database does not support the decision to relist. The principal document of support is a Technical Advisory Panel (TAP) review of DL-malic acid, the synthetic form, which does not address the manufacture of L-malic acid by fermentation.

Our role as public interest commenters on the NOSB materials review process is to ensure that NOSB decisions are based on OFPA criteria, backed up with adequate documentation. We are disappointed that given the inadequacies of the documentation that the HS has not requested a supplemental TR to document environmental and health impacts as well as the need for the material. Nor has it requested any information from the industry or public concerning the manufacturing process. This lack of information and failure to request more information is especially disturbing because any information received after this meeting will be considered “untimely” according to the new NOP sunset policy. We submit additional information based on a patent, but urge the HS to seek more. In addition, we believe that some issues raised by the petition are beyond the purview of the HS and we request that the Materials/GMO Subcommittee (MS/GMO) add them to its workplan.

1. Health and Environmental Impacts

Documentation available to the HS on the health and environmental impacts of L-malic acid is sketchy at best. The following information comes from the patent¹ for manufacturing L-malic acid by fermentation. There are no restrictions on feedstock or fermenting organisms in the National List listing.

¹ 3,063,910 Method of Producing L-Malic Acid by Fermentation <http://www.google.com/patents/US3063910>

The patent says, “[A] substantial amount of l-malic acid can be accumulated in a culture medium by cultivating a strain of the species *Aspergillus parasiticus* Speare, *Aspergillus flavus* Link and *Aspergillus oryzae* (Ahl'ourg) Cohn.” The carbon source may be glucose, sucrose or molasses, fructose, maltose, mannose, galactose, sorbose, xylose, starch, sorbitol, glycerol, etc. It continues, Peptone, ammonium chloride, ammonium nitrate, urea, ammonium sulfate or sodium nitrate can be used in an amount of from 0.2 to 1.5% as nitrogen source. In addition to the carbon and nitrogen sources, 0.015% of potassium dihydrogen phosphate (KH PO 0.015% of Fatented Nov. 13, 1962 dipotassium hydrogen phosphate (Kg-IP0 0.01% of magnesium sulfate (MgSO 7H O), 0.01% of calcium chloride (CaCl -2H O), as well as 5 mgr./l. each of ferrous sulfate (FeSO -7H O) and sodium chloride are added to the culture medium. Further, 0.5 to 10% of organic acid, such as pyruvic and fumaric acid, or the salts thereof may be advantageously used together with the carbon source as fermentation accelerator. Additionally, 1 to 10% of sterile calcium carbonate or magnesium carbonate may be added.... After cultivation is completed, the mycelium is separated from the broth, containing l-malic acid, by filtration. The filtrate is then concentrated in vacuo, thereby yielding l-malic acid salt, such as calcium salt or magnesium salt.

It appears, therefore, that quite a variety of chemicals may be used in the manufacture of L-malic acid, and the NOSB should review them and the process for its impacts on human health and the environment. More about fermentation below.

2. Ancillary substances

According to the recommendation passed by the NOSB in the spring of 2013, the board defined “ancillary substances” as “additives added during the manufacturing of a non-organic substance and **not** removed.”

The NOSB went on to recommend the following policy:

The NOSB intends to review ancillary substances found in substances on and petitioned for the National List in accordance with OFPA criteria. Comprehensive review does not require these substances to be individually listed on the National List, however. The Board intends to follow the request by NOP to consider ancillary ingredients contained in substances as they come up for review or as new petitions are considered.

In each NOSB review checklist and recommendation cover sheet there will be a clear space to indicate what other ingredients are being reviewed and what restriction if any are placed on them as a result of the review. Restrictions on other ingredients will be included in an annotation and may be for specific individual components, for functional classes of ingredients, or by regulatory reference to another governmental agency such as FDA. The other ingredients restrictions may be incorporated into a permitted substances database for Handling, such as the one that is coming out for crops.

The NOSB recommendation will include a note that the other ingredients were reviewed and accepted. The review of other ingredients will distinguish between synthetic and

nonsynthetic ones, as well as agricultural ingredients that might be able to be organically produced. Any additional restrictions will be specified in an annotation.

Ancillary substances in general product categories that are currently on §205.605 and §205.606 and currently used in certified organic processed product will continue to be allowed until they go through their next sunset review and subsequent Rule amendment.

The ancillary substances associated with this material have not been reviewed or even listed. This is an important piece that needs to be incorporated into the review of every material during sunset. Maleic (<500 ppm) and fumaric (7.5 ppm) acids are impurities that should be considered.²

3. Essentiality

L-malic acid is used to acidify fruit juices, though it is not restricted to that use by its listing. As an acidulant, the TAP review points out that there are several alternatives available, including organic vinegar and lemon juice, as well as the nonsynthetic lactic acid and citric acid, which are also on the National List –and also produced by fermentation.

4. Compatibility

Although the main use of L-malic acid is acidification, the choice of L-malic acid as an acidulant is based on its ability to re-create and improve flavors, which is not consistent with organic processing.

5. Fermentation processes

This material raises issues that should be addressed by the NOSB: What criteria must be applied to determine whether fermentation products are acceptable as inputs in organic production and processing? What criteria must be applied in classifying the products of fermentation as agricultural/nonagricultural or synthetic/nonsynthetic? The draft materials classification guidance treats fermentation as a processing method that does not change the classification of the substrate from agricultural to non-agricultural or from nonsynthetic to synthetic. Yet fermentation processes vary widely from pickling, wine-making, and cheese-making to manufacture of substances that have no apparent relationship to the substrate. L-malic acid is an example of the last. Whole algal flour, glycerin, and gellan gum are other examples. The processes vary in nutrients added, physical methods of isolating the product, solvents used, and ancillary substances added. The fact that all of these processes involve the growth of microorganisms does not seem to be sufficient to treat them the same. Therefore, we request that the Materials/GMO Subcommittee add to its workplan the development of criteria for evaluating products of fermentation processes.

² <http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?cid=222656#x321>

6. Conclusion

We conclude that there is not sufficient information provided by the HS to support the relisting of L-malic acid. It is unfortunate that if such information is provided at this point, the public will not be able to comment on it in a “timely” way, according to the new sunset policy.

A word about the process of the Handling Subcommittee. It is critical that the subcommittee and Board prepare a more robust review for public discussion at the first meeting on a Sunset 2016 material. We believe that a supplemental Technical Review is critical to an assessment that evaluates compliance with OFPA criteria and should have been available and critiqued for this meeting. Since the Fall 2014 meeting is scheduled to be the only public NOSB meeting during which the Handling Subcommittee and Board members can share its thinking and receive “timely” public comment on the checklist and assessment of the material in accordance with OFPA criteria, the lack of prepared written analysis by the subcommittee for this meeting makes for an incomplete and truncated assessment process. Had this been done, the Subcommittee would have discovered that it needed a more complete TR to enable a complete assessment in accordance with OFPA criteria. Or, conversely, with a written prepared review, the subcommittee would have been able to share with the organic community its thinking on its decision on TR sufficiency and compliance with OFPA criteria. We appreciate the subcommittee’s question on essentiality of the material, but believe that the subcommittee and Board has a responsibility to bring to the public a comprehensive set of questions that address all OFPA criteria with a preliminary assessment of the data it has and should have prepared a preliminary checklist.

Under the current process, information brought to the Board at the Spring 2015 meeting will be considered “untimely.” While we recognize that the Board has embarked on a new two-stage process, the first stage, or first meeting on sunset materials, must be a more robust review process if the Board’s assessment of exempt prohibited materials, like this one, on the National List is to be viewed by the public, including users and consumers, as credible. The process requires this, if there is to be continuing and building public trust in the assessment process and the organic food label.

We have attached a checklist in which we provide the Board with answers to questions, based on the available TAP review and a patent, that are required to be considered as a part of a sunset review that is in compliance with the Organic Foods Production Act (OFPA) and the implementing regulations.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in cursive script, appearing to read "Terry Shistar".

Terry Shistar, Ph.D.
Board of Directors

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Checklist
L-Malic Acid**

[Date of Vote]

Summary of Proposed Action:

Listing is on 205.605(a)L-Malic acid (CAS # 97-67-6).

TAP reviews DL-malic acid (synthetic) and L-malic acid (nonsynthetic.) It recommends allowing only nonsynthetic L-malic acid.

The patent gives some information about manufacture (fermentation), but not enough to determine ancillary substances or waste stream.

Evaluation Criteria (see attached checklist for criteria in each category)

- | | Criteria Satisfied? |
|---|---|
| 1. Impact on Humans and Environment
N/A | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 2. Essential & Availability Criteria | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| 3. Compatibility & Consistency
N/A | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 4. Commercial Supply is Fragile or Potentially Unavailable
N/A
as Organic (only for §205.606) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> |

Substance Fails Criteria Category: [] **Comments:**

Subcommittee Action & Vote, including classification proposal (state actual motion):

Classification Motion: Move to classify [substance] as [synthetic, nonsynthetic, agricultural]

Motion by:

Seconded by:

Yes: # No: # Absent: # Abstain: # Recuse: #

Listing Motion: Move to list [substance] on section **205.6xx** of the National List [with the annotation]

Motion by:

Seconded by:

Yes: # No: # Absent: # Abstain: # Recuse: #

Proposed Annotation (if any):

Basis for annotation: To meet criteria above Other regulatory criteria Citation

Notes:

Approved by Subcommittee Chair to Transmit to NOSB

Name, Subcommittee Chair

Date

NOSB Evaluation Criteria for Substances Added To the National List Handling

Category 1. Adverse impacts on humans or the environment? Substance:

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]				
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]	?			<p>Manufacture is by fermentation –of glucose to fumaric acid, then from fumaric acid to L-malic acid. Details are not provided in TAP. No restrictions on feedstock or fermenting organisms in NL.</p> <p>[A] substantial amount of l-malic acid can be accumulated in a culture medium by cultivating a strain of the species <i>Aspergillus parasiticus</i> Speare, <i>Aspergillus flavus</i> Link and <i>Aspergillus oryzae</i> (Ahl'ourg) Cohn. Patent³</p> <p>Carbon source may be glucose, sucrose or molasses, fructose, maltose, mannose, galactose, sorbose, xylose, starch, sorbitol, glycerol, etc. "Peptone, ammonium chloride, ammonium nitrate, urea, ammonium sulfate or sodium nitrate can be used in an amount of from 0.2 to 1.5% as nitrogen source. In addition to the carbon and nitrogen sources, 0.015% of potassium dihydrogen phosphate (KH PO 0.015% of Fatented Nov. 13, 1962 dipotassium hydrogen phosphate (Kg-IP0 0.01% of magnesium sulfate (MgSO 7H O), 0.01% of calcium chloride (CaCl -2H O), as</p>

³ 3,063,910 Method of Producing L-Malic Acid by Fermentation <http://www.google.com/patents/US3063910>

				well as 5 mgr./l. each of ferrous sulfate (FeSO · 7H ₂ O) and sodium chloride are added to the culture medium. Further, 0.5 to 10% of organic acid, such as pyruvic and fumaric acid, or the salts thereof may be advantageously used together with the carbon source as fermentation accelerator. Additionally, 1 to 10% of sterile calcium carbonate or magnesium carbonate may be added.... After cultivation is completed, the mycelium is separated from the broth, containing l-malic acid, by filtration. The filtrate is then concentrated in vacuo, thereby yielding l-malic acid salt, such as calcium salt or magnesium salt." Patent Sources of raw materials?
3. Are there any adverse impacts on biodiversity? (§205.200)	?			
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]			X	
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c)(1)(A)(i); 6517 (c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]	?			Maleic (<500 ppm) and fumaric (7.5 ppm) acids are impurities. ⁴ Ancillary substances have not been reviewed.
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]	?			Maleic (<500 ppm) and fumaric (7.5 ppm) acids are impurities.
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 (b)(5)]	?			

⁴ <http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?cid=222656#x321>

**NOSB Evaluation Criteria for Substances Added To the National List
Handling**

Category 2. Is the Substance Essential for Organic Production? Substance:

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		Product of fermentation.
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]		X		
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			
4. Is the substance created by naturally occurring biological processes? [§6502(21)]	?			Unknown whether GMO-sourced organisms are used.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		Apples, other fruit.
6. Is there an organic substitute? [§205.600(b)(1)]		X		Organic apples and other fruit.
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]		X		Other acids are available. Malic acid matches certain combinations better.
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]			X	L-malic acid is considered natural.
9. Are there any alternative substances? [§6518(m)(6)]	X			Citric acid, lemon juice, etc.
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]				
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.		X		

**NOSB Evaluation Criteria for Substances Added To the National List
Handling**

Category 3. Is the substance compatible with organic handling practices? Substance:

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	?			
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]	?			
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]				
4. Are the ancillary substances reviewed compatible with organic handling [?]		X		Ancillary substances have not been reviewed.
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]				
6. Is the primary use as a preservative? [§205.600(b)(4)]		X		
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]	X	X		Major use is acidification, but choice of L-malic acid is based on recreating and improving flavors.

**NOSB Evaluation Criteria for Substances Added To the National List: Handling
 Category 4. Is the commercial supply of an organic agricultural substance fragile or
 potentially unavailable? [§6610, 6518, 6519, §205.2, § 205.105(d), §205.600(c)] **Substance:****

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?				
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?				
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling?				
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling?				
5. Does the industry information about unavailability include (but is not limited to) the following?: a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;				
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or				
e. Other issues which may present a challenge to a consistent supply?				