



BEYOND PESTICIDES

701 E Street, SE ■ Washington DC 20003
202-543-5450 phone ■ 202-543-4791 fax
info@beyondpesticides.org ■ www.beyondpesticides.org

April 2, 2015

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 Spring 2015 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 Organic Foods Production Act (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 fully evaluate environmental and health impacts, the need for the material, or the details of the manufacturing process. Nor did it request any information at the fall 2014 meeting from the industry or public concerning the manufacturing process. Additionally, it does not appear that the HS considered the information that we provided. This lack of information, failure to request more information, and failure to consider submitted information is especially disturbing because any information received after that meeting will be considered “untimely” according to the new NOP sunset policy.

At the fall 2014 meeting, we submitted additional information based on a patent, but urged the HS to seek more. In addition, we believe that some issues raised by the substance are beyond

the purview of the HS and we request that the Materials/GMO Subcommittee (MS/GMO) add them to its workplan. This spring, the HS said,

Two other commenters expressed concern that the original TAP review evaluated DL-malic acid, the synthetic form, rather than L-malic acid, the non-synthetic form currently listed. However, a review of the 2003 TAP shows that the reviewers very clearly accounted for the fact that there are two forms of this substance, very clearly recommended that the synthetic form not be listed, and that L-malic acid be listed on 605(a).

Despite the fact that the TAP review mentioned L-malic acid, and recommended it over DL-malic acid, the TAP was not given complete information concerning the production of L-malic acid by fermentation, such as that which we provided last fall and repeat below in these comments. Furthermore, it appears that the HS has failed to consider this additional information after we provided it.

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 a patent¹ for manufacturing L-malic acid by fermentation. There are no restrictions on feedstock or fermenting organisms in the National List listing.

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, or others. 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 (KH₂PO₄), 0.015% of dipotassium hydrogen phosphate (K₂HPO₄), 0.01% of magnesium sulfate (MgSO₄-7H₂O), 0.01% of calcium chloride (CaCl₂-2H₂O), as well as 5 mgr./l. each of ferrous sulfate (FeSO₄-7H₂O) 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. In addition, since the result of the process is actually a salt of L-malic

¹ 3,063,910 Method of Producing L-Malic Acid by Fermentation <http://www.freepatentsonline.com/3063910.html>

acid, the HS needs to determine whether the process of recovering L-malic acid from the salt results in a synthetic substance.

See more about fermentation below and in our comments on fermentation processes.

2. Ancillary substances

The ancillary substances associated with this material have not been adequately reviewed. 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 if L-malic acid is synthetic.

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? Therefore, we request that the Materials/GMO Subcommittee add to its workplan the development of criteria for evaluating products of fermentation processes. Please see our comments on products of fermentation for more details.

An important issue in this case is whether, given the fermentation process as described above, or by other possible processes, L-malic acid is actually nonsynthetic. If it is nonsynthetic, then its use as a flavor enhancer and flavoring agent is not consistent with organic regulations at §205.600(b)(4).

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 the HS considers the information repeated here from our fall 2014 comments as new, that it will not be considered to be “timely,” according to the new sunset policy.

² <http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?cid=222656#x321> Section 8.2.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Shistar". The signature is written in a cursive style with a prominent flourish at the end.

Terry Shistar, Ph.D.
Board of Directors