



BEYOND PESTICIDES

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April 1, 2019

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

Docket ID # AMS-NOP-18-0071-0001

Re. HS: Pullulan

These comments to the National Organic Standards Board (NOSB) on its Spring 2019 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 the world.

Pullulan is an extracellular polysaccharide excreted by the yeast-like fungus *Aureobasidium pullulans*. It is currently used to make capsules labeled “made with organic” ingredients. Certifiers who previously classified pullulan as an agricultural now classify it as a natural non-agricultural substance. Pullulan is created by vat fermentation, and is another example of the need for NOSB guidance on the classification and listing of products of fermentation.

Pullulan was classified as an agricultural material and used in products labeled “made with organic,” but it was not listed on §205.606 and hence has not been reviewed by the NOSB. Hence, although OTA’s petition frames this as a continued use of a material already present in made with organic products, it must be considered anew.

The petition characterizes *Aureobasidium pullulans* as “non-pathogenic and non-toxicogenic.” This is a vast oversimplification. *Aureobasidium pullulans* exists in many strains with a large variety of ecological niches, including (as stated in the petition) “forest soil, fresh and

sea water, plant and animal tissues.” It is known as a human pathogen,¹ a human allergen,² a biological control agent in plants,³ and in biotechnology for production of the polysaccharide pullulan and the antifungal aureobasidin A.⁴

A review of pullulan by the European Food Safety Authority (EFSA) found no evidence of acute toxicity and some effects in subchronic tests that were possibly due to large doses of non-digestible carbohydrate. EFSA found no available data on carcinogenicity, reproductive toxicity, or developmental toxicity. Experiments in human volunteers resulted in increased feeling of fullness, increased carbohydrate malabsorption, and increased bifidobacteria in feces. Although *Aureobasidium pullulans* is associated with allergic reactions and infections in immunocompromised individuals, there is no evidence that pullulan causes such reactions.⁵

While the petition requests the listing of pullulan for the specific use in tablets and capsules for dietary supplements, pullulan is also used for many other purposes, such as films to extend the shelf life of various foods. The motion proposing listing of pullulan should specify its use in dietary supplement tablets and capsules.

Although the TR appears to consider other vegetarian capsule materials as poor substitutes for pullulan, other sources appear to view HPMC—hydroxypropyl methylcellulose—as the standard.⁶ HPMC is produced from cellulose from pine, poplar, or spruce. Presumably, HPMC would need to be listed on the National List in order to be used in made with organic capsules, so the question of need is not really resolved.

Beyond Pesticides continues to call for NOSB guidance on classification and listing of products of vat fermentation. In view of the problems that may arise from exposure to the parent organism, *Aureobasidium pullulans*, the use of pullulan should not be expanded beyond

¹ See, for example, van Houghenhouck-Tulleken, W.G., Mathole, G., Karstaedt, A., Govind, N., Moodley, M., Seetharam, S., Govender, N.P. and Menezes, C.N., 2016. Disseminated fungal infection in an HIV-infected patient due to *Aureobasidium pullulans*. *Southern African Journal of Infectious Diseases*, 31(3), pp.71-73.

² Niedoszytko, M., Chełmińska, M., Jassem, E. and Czestochowska, E., 2007. Association between sensitization to *Aureobasidium pullulans* (*Pullularia* sp) and severity of asthma. *Annals of Allergy, Asthma & Immunology*, 98(2), pp.153-156.

³ See, for example, Di Francesco, A., Calassanzio, M., Ratti, C., Mari, M., Folchi, A. and Baraldi, E., 2018. Molecular characterization of the two postharvest biological control agents *Aureobasidium pullulans* L1 and L8. *Biological Control*, 123, pp.53-59.

⁴ Gostinčar, C., Ohm, R.A., Kogej, T., Sonjak, S., Turk, M., Zajc, J., Zalar, P., Grube, M., Sun, H., Han, J. and Sharma, A., 2014. Genome sequencing of four *Aureobasidium pullulans* varieties: biotechnological potential, stress tolerance, and description of new species. *BMC genomics*, 15(1), p.549.

⁵ EFSA, 2004. Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to Pullulan PI-20 for use as a new food additive. *EFSA Journal* (2004) 85: 1-32.

⁶ See, for example: <https://www.herbaffair.com/blogs/blog/gelatin-vs-vegetarian-capsules-whats-the-difference>; <https://www.herbaffair.com/pages/vegetarian-capsule-information>; <https://www.capsugel.com/product-suites/vegetarian-products>.

the current use, and pullulan must be listed on labels of made with organic supplement tablets and capsules.

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, flowing style.

Terry Shistar, Ph.D.
Board of Directors