



BEYOND PESTICIDES

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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: Pullulan

These comments to the National Organic Standards Board (NOSB) on its Fall 2018 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 biological control

¹¹ 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.

agent in plants,² and in biotechnology for production of the polysaccharide pullulan and the antifungal aureobasidin A.³

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.⁴

In view of the data gaps –including definitive data on the lack of alternatives— and the fact that it was not listed on §205.606 and hence has not been reviewed by the NOSB, the HS should not act on the pullulans petition before receiving a technical review.

Thank you for your consideration of these comments.

Sincerely,



Terry Shistar, Ph.D.
Board of Directors

² 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.

³ 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.

⁴ 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.