

**National Organic Standards Board**  
**Handling Subcommittee Petitioned Material Discussion**  
**Pullulan**  
**June 5, 2018**

**Summary of [Petition](#):**

A petition has been submitted to add pullulan to the National List at §205.605(a) as an allowed non-agricultural, non-synthetic ingredient used in tablets and capsules for dietary supplements labeled “made with organic”. The petition was submitted by the Organic Trade Association (OTA) on behalf of its National List Innovation Working Group. The OTA states that the purpose of the petition is two-fold: to protect the continued production and availability of USDA-NOP certified dietary supplements and to support the commercial development of certified organic pullulan.

For dietary supplements, the capsule is considered an “ingredient” and must either be “certified organic” or made up of ingredients compliant with the National Organic Program’s (NOP) National List of Allowed and Prohibited Substances. Since the early 2000s accredited certifying agents have classified pullulan as agricultural and it was allowed in encapsulated dietary supplements certified in the “made with organic” category. Since the release in late 2016 of the NOP’s Classification of Materials guidance document (NOP 5033), certifying agents are in general agreement that pullulan should be classified as a non-agricultural and non-synthetic substance. Under this classification, pullulan would need to appear on the National List in order for it to be included in certified organic products.

There are no other NOP compliant vegetarian options available for producing organic encapsulated supplements. Organic pullulan is currently not commercially available in the United States. According to the petition, Capsugel is the owner of US patents covering pullulan capsules, and they are in the process of developing organic pullulan.

The only alternative practice for supplement manufacturers would be to use gelatin capsules. Gelatin is listed at §205.606 of the National List, but its use is problematic for consumers looking for a vegetarian, kosher, or halah product. Otherwise, to continue producing vegetarian products manufacturers would have to lose their organic certification. According to the petition, the 2018 forecast for pullulan capsules is approximately 2.5 billion capsules. They go on to calculate that a conservative estimate of \$10 per 30 count bottle would represent an economic value of over \$825 million.

In 2004, Capsugel submitted a petition to the NOSB to add pullulan to §205.605. The petition was put on hold and no recommendation was ever made. It is unclear why this is as no references to it were found in the NOSB meeting minutes.

The manufacturing process of pullulan is described in the OTA’s petition, page 3: Pullulan is produced by mesophilic fermentation of *A. pullulans* in a suitable starch syrup. During fermentation, pullulan is secreted extracellularly by the organism into the culture medium from which it is then recovered and purified. At the completion of fermentation, the resulting broth consists of microbial cells and cellular debris, as well as the extracellular metabolites produced and excreted during the fermentation (e.g., pullulan). The microbial cells and cellular debris are first removed by microfiltration. The cell-free filtrate is heat sterilized and then purified by a deionization process. The deionized solution is concentrated to a solids content of about 12%, treated with activated carbon to remove pigments and other impurities, and filtered using diatomaceous earth. The filtrate is

concentrated by evaporation to a solids content of about 30% and dried in a drum dryer. The dried pullulan is pulverized to a specified particle size and packaged.

According to the petition, there are no known negative environmental impacts resulting from the use or disposal of pullulan. It is a biodegradable polysaccharide that is easily metabolized by many microorganisms found in nature. Furthermore, pullulan may be used as a base material in novel flocculants that have been developed for the removal of contaminants in wastewater (Ghimici & Constantin, 2011).

The petition also cites a number of studies looking at the effects of pullulan on human health. The petition concludes that no adverse effects of toxicological significance have been observed for pullulan in a variety of assays. And that the safety of pullulan is supported by 30 years of human consumption in Japan and by the absence of adverse events in human trials at doses of 10g pullulan/day to evaluate metabolism and digestion.

### **Summary of Review:**

In April 2018 the Handling Subcommittee found the petition for pullulan to be sufficient. A request for a technical report was submitted by the Subcommittee to the NOP. At this time, the technical report is under development. This petitioned material discussion document is being put forward with the intent of gathering public comment and allowing for discussion by the full Board at the Fall 2018 NOSB meeting.

### **Questions:**

1. If you are currently using pullulan in a certified organic encapsulated supplement, what effect would the disallowance of pullulan be on your product/business?
2. Using the NOP's Classification of Materials guidance document (NOP 5033), do you consider pullulan to be agricultural or not? Please explain your rationale.

### **Subcommittee vote**

Motion to accept the discussion document on Pullulan

Motion by: Lisa de Lima

Seconded by: Tom Chapman

Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

**Approved by Lisa de Lima, Subcommittee Chair, to transmit to NOSB, August 24, 2018**