



October 4, 2018

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2642-So., Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-18-0029

RE: Handling Subcommittee – Pullulan (Discussion)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Handling Subcommittee’s Discussion Document on the Pullulan Petition. The purpose of submitting this petition is to: 1) protect the production and availability of USDA-NOP “made with” certified encapsulated dietary supplements; and 2) support the commercial development of certified organic Pullulan.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Summary

The Organic Trade Association is the petitioner of this material. The petition was submitted on behalf of our organic trade members that are manufacturing and selling USDA-NOP certified dietary supplements that utilize Pullulan-based (vegetarian) capsules. The petition is for the *continued* allowance of non-organic Pullulan used in dietary supplements labeled “**made with organic (specified ingredients or food group(s)).**” The only alternative is a gelatin capsules (animal based), which is not appropriate for vegetarian products and may cause issues among kosher and halal consumers.

Pullulan is a product of microbial fermentation. It utilizes primarily agricultural source materials for its production, but it is a polysaccharide that is secreted extracellularly by the organism *Aureobasidium pullulans* into a culture medium from which it is then recovered and purified. From this perspective and using NOP’s Classification of Materials Guidance (NOP 5033), it should be classified as non-agricultural.

The petition was submitted in response to accredited certifying agents reclassifying Pullulan as “non-agricultural” in accordance with NOP’s Classification of Materials Guidance released in late 2016. Since the early 2000s, certifying agents have allowed its use in encapsulated dietary supplements certified to the “**made with” product category.** This allowance has significantly contributed to the growth of NOP certified dietary supplements. As a **non-agricultural** substance, Pullulan must now appear on the National List. If Pullulan is not placed on the National List, the continued allowance of NOP certified

vegetarian encapsulated supplement products will no longer be possible. Without its continued allowance and without an alternative vegetarian option, we estimate the economic impact to the organic dietary supplement sector would be over \$825 million.

We offer the following more detailed comments:

Background

Pullulan is a natural extracellular polysaccharide excreted by the yeast-like fungus *Aureobasidium pullulans*. It is not genetically modified, and it is commercially produced by a non-pathogenic and non-toxicogenic strain of the organism using a liquid starch syrup as the fermentation substrate. Pullulan can be made into very thin films with high tensile strength and stability over a range of temperatures, making it an ideal material to be used in the manufacture of empty capsules for encapsulating dietary supplements or as a coating for dietary supplement tablets.

Encapsulation of organic raw materials and active blends is essential to the handling of dietary supplements because it allows the delivery of materials without the use of excipients, and without the risk of damaging those materials through tablet compression. It also allows controlled dosage, which bulk powders do not, and the lack of heat used during processing helps preserve the bioavailability of the active compounds.

Encapsulated vegetarian dietary supplements certified under USDA's National Organic Program (NOP) rely on the use of Pullulan as the primary ingredient in the capsule. For dietary supplements, the capsule is considered an "ingredient" and must either be "certified organic," or comprised of ingredients compliant with the National List of Allowed and Prohibited Substances. The capsule, as an ingredient, also is counted in the weight of the total encapsulated product when calculating the organic percentage. The weight of a capsule always exceeds 5% so any encapsulated product utilizing a non-organic capsule will only qualify for the "made with" labeling category. For an encapsulated product to be certified and labeled as "organic," an organic capsule would need to be used.

Since the early 2000s, accredited certifying agents have classified Pullulan as "**agricultural**" and allowed its use only in encapsulated dietary supplements certified to the "**made with** product category. This allowance has significantly contributed to the growth of NOP certified dietary supplements. Currently, certified organic Pullulan is commercially unavailable in North America, and there are no other NOP compliant vegetarian options available. Gelatin capsules, while allowed under NOP, present consumer acceptance and GMO challenges.

In late 2016, NOP released a guidance document (NOP 5033) on the Classification of Materials. This document assists the National Organic Standards Board (NOSB), accredited certifying agents, and the organic industry in making 'Agricultural' vs. 'Non-agricultural' and 'Synthetic' vs. 'Non-synthetic' determinations. Given the information contained in the NOP guidance document, accredited certifying agents are now in general agreement that Pullulan should be classified as a "**non-agricultural, non-synthetic**" substance, and accordingly must appear on the National List at §205.605 to be allowed in NOP certified products.

In response to this new interpretation, we are requesting that Pullulan be added to the National List so that it may *continue* to be allowed as an ingredient in capsules for dietary supplements labeled "made with organic (specified ingredients or food group(s))."

VERY IMPORTANT CLARIFICATION: Please note that we are intentionally limiting the allowance of non-organic Pullulan to dietary supplements certified to the “made with” category. Any encapsulated dietary supplement sold or labeled as “certified organic (95%+) will need to use certified organic Pullulan. Although organic Pullulan-based capsules are not commercially available in North America, development is underway and they should be available in the future. **The end goal is the development and use of organic Pullulan.** The organic supplement sector is highly motivated to use organic Pullulan because it is the only way these products can qualify for the USDA Organic seal. **See pages 5 and 6 for more on organic alternatives.**

The Handling Subcommittee is asking the following 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?*

It is first critical to understand that non-organic Pullulan is not being used in “certified organic” encapsulated supplements. The weight of a non-organic capsule exceeds the 5% non-organic allowance in a product labeled as “organic.” The allowance of non-organic Pullulan-based capsules, previously and going forward, is only in products labeled as “**made with organic (specified ingredients or food group(s)).**”

If Pullulan is not placed on the National List, the continued allowance of NOP certified vegetarian encapsulated supplement products will not be possible. The 2018 forecast for Pullulan capsules, the only capsule currently allowed in the “made with organic” category, is approximately 2.5 billion capsules. A conservative estimate of \$10 per bottle of 30 would represent an economic value of over \$825 million. The addition of Pullulan at §205.605(a) will be **critical** to maintain the status of these products and avoid consumer confusion. Notably, there is no other alternative for a vegetarian, organic-compliant capsule. **Thus, companies would be forced to either lose organic certification without changing their formula, or switch to a (non-vegetarian) gelatin capsule.**

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.*

Pullulan is a product of microbial fermentation. It utilizes primarily agricultural source materials for its production but it is a polysaccharide secreted extracellularly by the organism *Aureobasidium pullulans* into a culture medium from which it is then recovered and purified. Historically, at the certifier level, Pullulan was thought to be a fermentation product made from plant material and considered agricultural, since the large majority of its production is based on plant starch (starch syrup, the substrate that feeds the microorganism). Additionally, some view (and continue to view) fermentation products in general to be agricultural, especially since it could be certified organic if organic substrate is used along with processing aids on the National List. In this particular case, “organic” pullulan is under development, so it begs the question of how Pullulan can be classified as “non-agricultural” yet still be certified to a regulation that certifies **agricultural** products. This is a long-running debate, but thankfully one that NOP has formally weighed in on via the Classification of Materials Guidance (NOP 5033), as informed by years of public comment.

The use of the 5033-2 Decision Tree, when applied to fermentation by-products, however, does present some challenges as we have pointed out below. However, if there is uncertainty or lack of agreement about the agricultural/non-agricultural status of Pullulan, the Organic Trade Association would prefer to see Pullulan go through the NOSB process, be placed on the National List and brought under the five-year Sunset Review cycle.

Using NOP Guidance Document 5033 and the Decision Tree for Classification of Agricultural and Non-agricultural Materials (5033-2):

1. Is the substance a mineral or bacterial culture as included in the definition of “non-agricultural substance” at section 205.2 of the USDA organic regulations?

No. Pullulan is not a bacterial culture. Pullulan is best described as a microbial metabolite that is isolated from a culture medium or fermentation broth. It is a polysaccharide that is secreted extracellularly by the organism *Aureobasidium pullulans* into a culture medium from which it is then recovered and purified.

YES = Non-agricultural

No = **Question Go to Question #2**

2. Is the Substance a microorganism (e.g., yeast, bacteria, fungi) or enzyme?

No, Pullulan is not a microorganism. It is the product of a microorganism. More specifically, it is a microbial metabolite of a yeast-like fungus.

Yes = Non-agricultural

No = **Go to Question #3**

3. Is the substance a crop or livestock product derived from crops or livestock?

No, Pullulan is derived from a microorganism utilizing crop material as the substrate.

Yes = Go to Question #4

No = **Non-agricultural**

GO TO SYNTHETIC / NON-SYNTHETIC DECISION TREE QUESTIONS

Has the substance been processed to the extent that its chemical structure has been changed?

No. At the completion of the fermentation process for Pullulan, 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 then heat-sterilized.

The filtrate is then purified by a deionization process using an ion exchange resin to remove the salt and protein contaminants¹. The deionized solution is concentrated to a solids content of

¹ Please note that some manufacturing descriptions found in research articles indicate that an additional step may be utilized prior to deionization using ion-exchange chromatography in which the filtrate is treated with an organic

about 12%, treated with activated carbon to remove pigments and other impurities by adsorption, and filtered using diatomaceous earth as a filter aid.

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 packed in sterilized polyethylene bags.

Pullulan is produced through a naturally occurring biological process (fermentation) and does not undergo a chemical change at any stage of the extraction or purification process. The purified substance is non-synthetic and has not been altered into a form that does not occur in nature. The processing aids used in the purification process are removed from the final substance such that they have no technical or functional effect in the final product. Furthermore, the microorganism as well as the substrate is not genetically modified and there are no ancillary substances added.

Is the chemical change a result of naturally occurring biological processes such as fermentation or use of enzymes; or a result of mechanical/physical/biological process described under section 205.270(a)?

N/A - Pullulan does not undergo a chemical change.

Based on the Classification of Materials Guidance and relevant Decision Trees, we believe that Pullulan is best classified as **non-agricultural** and **non-synthetic**.

We acknowledge that the Guidance does not perfectly address the spectrum of products produced via microbial fermentation. There is one question that asks if the substance is a bacterial culture and one that asks if the substance is a microorganism. The Decision Tree lacks a question about whether the substance is a product of a microorganism. In the Classification Guidance, wine is used as an example, and is classified as “agricultural” with the following explanation:

“Substance is a product of a microorganism and produced from agricultural media.”

A similar argument could be made for Pullulan. However, wine retains a large amount of the “agricultural media” in the finished product while Pullulan is recovered from the agricultural media and purified. The production of Pullulan is more analogous to citric acid or xanthan gum, both of which are classified as “non-agricultural” and appear on § 205.605(a) of the National List.

As stated earlier, if there is uncertainty or lack of agreement about the agricultural/non-agricultural status of Pullulan, the Organic Trade Association would prefer to see Pullulan go through the NOSB process, be placed on the National List, and brought under the five-year Sunset Review cycle.

To address the concept that Pullulan could be both “non-agricultural” AND certified organic, please refer to **NOP Guidance 5033**:

solvent (e.g., alcohol) to precipitate the pullulan. However, we have confirmed that Hayashibara Company’s manufacturing process does not use this step, and no organic solvents are used during their production.

Section 4.4 - Eligibility for Organic Certification:

This guidance does not determine the eligibility of a substance for organic certification. If a substance contains or is made up of agricultural ingredients and can meet the USDA organic production, handling, processing and labeling standards, it may be eligible to be certified under the USDA organic regulations.

Development of organic alternatives

At this time, organic Pullulan-based capsules are not commercially available for use in North America. A quick Internet search for organic Pullulan will produce results reflecting the availability from Bright Pharma Caps, Inc., JC Bright. However, Capsugel® is the owner of U.S. patents covering Pullulan capsules. Capsugel® sued JC Bright for patent infringement and false advertising related to JC Bright's sale of Pullulan capsules. Capsugel® obtained a consent judgment barring JC Bright from selling infringing organic and non-organic capsules. At this time, we are not aware of a legitimate source of Pullulan capsules in the U.S. other than Capsugel®

Because Pullulan is made via a fermentation utilizing agricultural source material, the manufacturing of **organic** Pullulan is possible and development is underway. Capsugel® is in the process of ramping up scale to meet the demand, and the availability of organic Pullulan for the U.S. market should occur in the near future. However, in the interim, no other vegetarian option that we are aware of is available. As mentioned earlier, the organic sector is motivated to use Organic Pullulan. Once it becomes available, we expect that companies selling products in the "made with organic" category will reformulate with organic pullulan capsules and move the product line to the USDA organic label.

National List alternatives

Gelatin-based capsules, informally called gel caps or gelcaps, are composed of gelatin **manufactured** from the collagen of animal skin or bone. Gelatin is listed on §205.606 of the National List and may be used as an ingredient in gelatin capsules for dietary supplements provided they are non-GMO and not available in organic form. However, because gelatin capsules are animal based and not appropriate for vegetarian products, they may cause issues among kosher and halal consumers.

Conclusion

The Organic Trade Association thanks the Handling Subcommittee for carefully considering the Organic Trade Association's petition to add Pullulan to the National List at 205.605(a) as a non-agricultural, non-synthetic substance that may be used in encapsulated dietary supplements labeled "**made with organic (specified ingredients or food group(s)).**"

Adding Pullulan to the National List is a timely and important action that will:

- ✓ Quickly address a new interpretation made by several accredited certifying agents in response to NOP's Classification of Materials Guidance (NOP 5033);
- ✓ Prevent widespread disruption and economically significant damage to the organic supplements sector;
- ✓ Bring the allowance of non-organic Pullulan under strict review of NOSB and the National List Sunset process;
- ✓ Support the commercial development of certified organic Pullulan that is highly sought by the supplement sector.



On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

A handwritten signature in black ink, reading "Gwendolyn V. Wyard". The signature is written in a cursive style with a large initial "G".

Gwendolyn Wyard
Vice President, Regulatory and Technical Affairs
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association