

**Formal Recommendation**  
**From: National Organic Standards Board (NOSB)**  
**To: The National Organic Program (NOP)**

**Date:** November 27, 2016

**Subject:** Petitioned Material Proposal – Oat Protein Concentrate

**NOSB Chair:** Tracy Favre

**The NOSB hereby recommends to the NOP the following:**

Rulemaking Action:

Guidance Statement:

Other: X

**Statement of the Recommendation:**

The NOSB recommends that the petitioned material, Oat Protein Concentrate, not be added to the National List at §205.606.

**Rationale Supporting Recommendation (including consistency with OFPA and Organic Regulations):**

The NOSB felt the petitioned material, Oat Protein Concentrate, failed the evaluation criteria of essentiality & availability. The board saw no reason why an organic version of the petitioned substance could not be produced.

**NOSB Vote:**

**Classification Motion:** Move to classify oat protein concentrate as agricultural

Motion by: Lisa de Lima

Seconded by: Tom Chapman

Yes: 14 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**Listing Motion:** Move to list oat protein concentrate at §205.606

Motion by: Lisa de Lima

Seconded by: Scott Rice

Yes: 0 No: 14 Abstain: 0 Absent: 1 Recuse: 0

Motion Failed

**National Organic Standards Board  
Handling Subcommittee  
Petitioned Material Proposal  
Oat Protein Concentrate  
May 17, 2016**

**Summary of**

**Petition** <https://www.ams.usda.gov/sites/default/files/media/Oat%20Protein%20Concentrate.pdf>

Oat protein concentrate is being petitioned by manufacturer Tate & Lyle for addition to §205.606, as a natural component of oats, an agricultural commodity. According to the petition the substance is isolated from oat bran through a simple process of grinding, heating, and water extraction. No synthetic chemical additions or solvents are used in the manufacturing process (pH adjustment and/or solvent extraction) being petitioned. The only additives used in producing oat protein concentrate are water and enzymes. The alpha-amylase enzyme used is derived from a non-pathogenic, non-GE/GM microorganism.

Oat protein concentrate is a vegan, non-GMO protein source and is a good source of certain essential amino acids. The petition also notes that it has better digestibility than other cereal proteins because it is primarily composed of globulin proteins. Additionally, due to its bland flavor and low impact on texture it can be used to supplement protein content in a wide range of foods. Examples listed in the petition include vegan entrees, cereal bars, baked goods, breakfast cereals, pasta, and meal replacement shakes.

Overall oat protein concentrate appears to have no significant negative impacts on human health. Unlike other proteins used as supplements (milk, soy, egg), this ingredient can be used in foods targeted for individuals with these specific allergies.

The petition states that oat protein concentrate is used in handling, not crop production, and therefore it has no effect on soil, crops, or livestock. However, the Subcommittee would like to point out that according to the USDA pesticide data program there are 7 pesticide residues found on conventionally grown oats. Conventionally grown oats are what oat protein concentrate is derived from.

The petition states that currently there is no source of organic oat protein concentrate, despite organic oats and organic oat bran being widely available in the U.S. and Canada. Additionally the petition claims that in Nordic countries, where a large amount of oat protein concentrate is manufactured, organic oat quantities are limited. The petition goes on to state that if the demand for organic oat protein concentrate was to increase, the Nordic manufacturing facilities could purchase organic oats from the U.S. The petitioner thought this scenario was unlikely to happen anytime soon due to the undetermined demand for oat protein concentrate in organic form.

**Summary of Review:**

The Handling Subcommittee would like to point out that geographical location is not sufficient justification for arguing the commercial non-availability of a commodity. The Subcommittee sees no reason why oat protein concentrate could not be manufactured organically. Therefore, the Subcommittee recommends that the petitioned material, oat protein concentrate, should not be placed

on the National List as it fails the “Essentiality & Availability” criteria, as well as the “Commercial Supply is Fragile or Potentially Unavailable as Organic” criteria.

### Category 1: Classification

1. **Substance is for:** Handling
2. **For HANDLING use:**
  - a. Is the substance agricultural or non-agricultural? Substance is agricultural  
Describe reasoning for this decision using NOP 5033-2 as a guide:

Oat protein concentrate is extracted from whole oats. The oats are first de-hulled and then the oat bran and oat flour are separated through a dry milling process. Then the oat bran goes through a wet milling process, and using alpha-amylase enzyme the protein is separated from the bran.

The oat protein remains intact throughout the manufacturing process. The protein is isolated through grinding, heating, and water extraction. No synthetic chemicals additions or solvents are used.

### Category 2: Adverse Impacts

1. **What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]**  
N/A
2. **What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]**  
N/A
3. **Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]**  
N/A
4. **Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].**

Oat protein concentrate can be used to boost protein in content in foods that are suitable for vegetarians, vegans, and those with allergies to milk, soy, wheat or celiac disease.

5. **Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]**

The final substance does not have a direct effect on soil, but the conventional oats from which the oat protein concentrate is extracted, could. According to the USDA pesticide data program there are 7 pesticide residues found on conventionally grown oats.

**6. Are there any adverse impacts on biodiversity? (§205.200)**

The final substance does not have a direct effect on soil, but the conventional oats from which the oat protein concentrate is extracted, could. According to the USDA pesticide data program there are 7 pesticide residues found on conventionally grown oats.

**Category 3: Alternatives/Compatibility**

**1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]**

The alternative to using the substance would be to create an organic oat protein concentrate from organic oats. Additionally, there are other organic vegan proteins available on the market, for example: soy, hemp, pea, rice, quinoa, sunflower, pumpkin, mushroom, chia, amaranth, lentil, flax, goji, and peanut.

**2. For Livestock substances, and Nonsynthetic substances used in Handling: In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]**

No.

**Category 4: Additional criteria for synthetic substances used in Handling (does not apply to nonsynthetic or agricultural substances used in organic handling):**

N/A. Oat protein concentrate is agricultural

Describe how the petitioned substance meets or fails to meet each numbered criterion.

1. The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1))
2. The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2))
3. The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations; (§205.600(b)(3))
4. The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law; (§205.600(b)(4))
5. The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5))

Yes, oat protein is GRAS. Designated GRN No. 000575

6. The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))
7. In balancing the responses to the criteria in Category 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, [Compatibility with Organic Production and Handling, April 2004](#))

**Category 5: Additional criteria for agricultural substances used in handling** (review of commercial unavailability of organic sources):

1. **Is a comparative description given as to why the non-organic form of the material /substance is necessary for use in organic handling provided?**

Yes, but not persuasive.

2. **Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?**

No.

3. **Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling?**

No.

4. **Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling?**

The petition claims that in Nordic countries, where a large amount of oat protein concentrate is manufactured, organic oat quantities are limited. The Nordic manufacturing facilities could purchase organic oats from the elsewhere, if they determined the demand for organic oat protein concentrate was sufficient for justifying manufacture of the substance. Additionally, the subcommittee believes there are organic oats available in Europe.

5. **Does the industry information about unavailability include (but is not limited to) the following: Regions of production (including factors such as climate and number of regions);**

- a. Number of suppliers and amount produced;  
No.

- b. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;  
No.

c. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or  
No.

d. Other issues which may present a challenge to a consistent supply?  
No.

6. **In balancing the responses to the criteria in Categories 2, 3 and 5, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, [Compatibility with Organic Production and Handling, April 2004](#))**

No. The Handling Subcommittee sees no reason why an organic form of oat protein concentrate could not be produced. Additionally, oat protein concentrate does not appear to be necessary in organic handling.

**Classification Motion:**

Motion to classify oat protein concentrate as petitioned as agricultural.

Motion by: Lisa de Lima

Seconded by: Tom Chapman

Yes: 6 No: 0 Abstain: 0 Absent: 2 Recuse: 0

**Listing Motion:**

Motion to add oat protein concentrate as petitioned at §205.606

Motion by: Lisa de Lima

Seconded by: Scott Rice

Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0