

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

Date: May 1, 2024

Subject: Rye Pollen Extracts

NOSB Chair: Kyla Smith

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: None

Statement of the Recommendation:

The NOSB recommends not adding rye pollen extract [as petitioned] to the National List § 205.606

Rationale Supporting Recommendation:

The NOSB finds that the use of rye pollen extract (RPE), as petitioned, is incompatible with organic handling and suggests that the petitioner pursue section § 205.204(a), which allows nonorganic, untreated seed to be used for the production of an organic crop when an organically produced variety is not commercially available.

NOSB Vote:

Classification Motion:

Motion to classify rye pollen extracts as agricultural

Motion by: Carolyn Dimitri

Seconded by: Kyla Smith

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

Motion Passed

Listing Motion:

Motion to list rye pollen extracts [as petitioned] at §205.606

Motion by: Carolyn Dimitri

Seconded by: Jerry D'Amore

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

Motion Failed

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Rye Pollen Extract
January 16, 2024**

Summary of Petition [\[link\]](#):

The petition for rye pollen extract (RPE) was made by the Graminex company. Rye pollen extracts are an agricultural ingredient from *Secale cereale* pollen and are produced separately extracting the water and the lipid portions of rye (*Secale cereale*) pollen. The primary use of RPE is for vegan sweetener syrup, replacing honey from bees.

Summary of Review:

The Subcommittee discussed the petition and the Technical Report (TR) thoroughly. The Subcommittee paid particular attention the following section of the TR, line 330-335, page 7:

Section 7 CFR 205.301(b) permits nonorganically produced ingredients at less than 5% of a product's formulation when not available in organic form. The petitioner states that the specific high-pollen-producing rye breeder seed is unavailable in organic form. However, § 205.204(a) allows nonorganic, untreated seed to be used for the production of an organic crop when an organically produced variety is not commercially available. Certification of the petitioner's rye farm and processing facility may be possible, even if the specific seed used is not available in organic form.

The Subcommittee agreed that the petitioner has the option of obtaining rye pollen extract by using nonorganic seed raised on farmland under organic management.

Category 1: Classification

1. Substance is for: **Handling** **Livestock**
2. For HANDLING and LIVESTOCK use:
 - a. Is the substance **Agricultural** or **Non-Agricultural?**

Describe reasoning for this decision using [NOP 5033-2](#) as a guide: Following the decision tree: the product is not a mineral or bacterial culture, is not a microorganism, is derived from a crop, is not processed to the extent that its chemical substance has been changed, and thus meets the definition of an agricultural product.

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)]

The TR does not discuss the impact of rye pollen extract on other materials used in organic farming systems.

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)]

As petitioned, RPE adds pollen to vegan honey substitutes (sweeteners). The vast majority of the available literature on grass pollen extracts focuses on phytotherapy, or the use of plants to relieve symptoms related to disease. These studies typically do not describe the physical properties of the substance. The TR authors found no explicit physical descriptions of RPE raw material used in food products except that discussed in the petition.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

The TR cites research that indicates fertile rye produces a large volume of pollen with the ability to travel long distances. Consequently, extreme care is required in breeding programs since any genetic contamination leading to sterility can render an entire crop useless for future seed production.

The TR states there is little research examining the manufacturing process of pollen extracts.

Extraction of the water-soluble and lipid-soluble fractions of RPE are carried out via water extraction and supercritical CO₂ extraction, according to the petition. The TR indicates that both methods offer non-toxic alternatives with less environmental concerns compared to conventional organic solvent extraction methods.

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

The TR found no documented evidence of specific health risks or benefits related to the consumption of RPE as an ingredient in processed foods. Discussion of the reported effects on human health of the related materials bee pollen, raw rye pollen, and pollen extracts as therapeutic agents were included in the TR for broader consideration of strictly theoretical health implications related to consumption of the petitioned material.

The TR found no literature suggesting there is any clear toxicity risk associated directly with RPE. Several studies identified varying levels of lead, cadmium, and arsenic in bee pollen (see TR for specific citations).

The TR found no literature that indicated any clear allergen risk associated directly with RPE.

Rye, rye pollen, and rye pollen extract do not appear in any FDA Generally Recognized as Safe (GRAS) listings for human or animal uses, nor do they appear in the GRAS Notice Inventory. This does not necessarily mean that RPE is not permitted in food. The TR indicates that user of RPE would have to contact FDA about its use in food since it is not included in the *Substances Added to Food* inventory. The TR authors attempted to contact FDA but received no reply.

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 TR indicates that Impact studies on rye are limited. Farm level studies (see TR for specific details) compared the carbon and water dynamics of perennial rye and annual rye. The perennial rye demonstrated greater atmospheric carbon uptake compared to the annual rye. The terrestrial water balance was similar between both rye crops. The manufacturing process described in the petition suggests the use of annual rye.

Studies comparing conventional cereal crops for livestock feed indicate that among barley, rye, and sorghum, rye had the lowest environmental impact (see TR for specific citation). Rye is a common cover crop often planted to control soil erosion but can become a weed, particularly when planted before winter wheat (see citations in TR).

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

Conventional agriculture, through its reliance on synthetic chemicals, is thought to have a negative impact on biodiversity. The TR authors did not find research that examined rye crops as nesting sites or food sources for insects or other forms of biodiversity. Similarly, the authors did not find literature that indicated there was a negative impact on the environment or biodiversity resulting from the use of RPE in food.

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 TR offers several alternatives to the petitioned use:

- Continue to omit the ingredient in vegan honey alternatives.
- Obtain organic certification for this agricultural ingredient. § 205.204(a) allows nonorganic, untreated seed to be used for the production of an organic crop when an organically produced variety is not commercially available, the lack of available breeder stock should not pose a barrier to organic certification.
- Instead of RPE, vegan honey substitutes may be able to use extracts of bioactive compounds from plants and plant parts other than pollen.

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)]

The TR does not directly address this, but since RPE as petitioned would come from rye that is not grown organically, nonorganic farm production of rye is incompatible with a system of sustainable agriculture.

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

N/A – The questions in Category 4 are not relevant because this is an agricultural product.

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))
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 Categories 2, 3 and 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 the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?

The petitioner states that organic breeding stock with high pollen-producing potential is commercially unavailable, despite the availability of organic rye. The TR suggests the lack of high pollen producing organic rye seed may be the result of the fact that most rye breeding emphasizes grain yield rather than pollen production.

That said, the TR indicates that rye produced under conventional management is not necessary for organic handling; buying conventional seed and raising it under organic management is possible.

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?

The petition indicates that organic rye seed with high pollen-producing ability is unavailable. That said, as specified in the TR, there is no evidence supporting the need for RPE as petitioned in terms of form, quality, or quantity.

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?

The petition indicates that organic rye seed with high pollen-producing ability is unavailable. That said, there is no evidence supporting the need for RPE as petitioned in terms of form, quality, or quantity.

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 indicates that organic rye seed with high pollen-producing ability is unavailable. That said, there is no evidence supporting the need for RPE as petitioned in terms of form, quality, or quantity.

5. Does the industry information about unavailability include (but is not limited to) the following?:

There is no industry information about unavailability for reasons specified in this question. The challenge for the petitioner is lack of organic breeding stock of high pollen producing rye; conventional breeding stock with the necessary qualities does exist.

Regions of production (including factors such as climate and number of regions);

- a. Number of suppliers and amount produced;
 - 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;
 - c. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or
 - d. Other issues which may present a challenge to a consistent supply?
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](#))

In order to determine if a substance, its use, and manufacture are compatible with a system of sustainable agriculture and consistent with organic farming and handling, and in consideration of the NOSB Principles of Organic Production and Handling, the following factors are to be considered:

- Does the substance promote plant and animal health by enhancing the soil's physical chemical, or biological properties?
- Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop, livestock, and/or handling operations?
- Is the substance made from renewable resources? If the source of the product is non-renewable, are the materials used to produce the substance recyclable? Is the substance produced from recycled materials? Does use of the substance increase the efficiency of resources used by organic farms, complement the use of natural biological controls, or reduce the total amount of materials released into the environment?

- Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?
- Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?
- Does the substance allow for an increase in the long-term viability of organic farm operations?
- Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?
- If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?
- Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?
- Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?
- Is there adequate information about the substance to make a reasonable determination on the substance's compliance with each of the other applicable criteria? If adequate information has not been provided, does an abundance of caution warrant rejection of the substance?
- Does use of the substance have a positive impact on biodiversity?

The Handling Subcommittee finds that the use of RPE, as petitioned, is incompatible with Organic Handling and suggests that the petitioner pursue section § 205.204(a), which allows nonorganic, untreated seed to be used for the production of an organic crop when an organically produced variety is not commercially available.

Subcommittee Vote:

Classification Motion:

Motion to classify rye pollen extract as agricultural

Motion by: Carolyn Dimitri

Seconded by: Kyla Smith

Yes: 9 No: 0 Abstain: 0 Recuse: 0 Absent: 0

National List Motion:

Motion to add rye pollen extract [as petitioned] at § 205.606

Motion by: Carolyn Dimitri

Seconded by: Jerry D'Amore

Yes: 0 No: 9 Abstain: 0 Recuse: 0 Absent: 0