

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

Date: April 26, 2019

Subject: Collagen gel

NOSB Chair: Harriet Behar

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: Yes

Statement of the Recommendation:

The NOSB recommends the addition of collagen gel to the National List at 7 CFR 205.606, nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic,”. The only use reviewed by the NOSB was as a co-extrusion system to enrobe sausage meat like a casing as the meat is extruded to hold the form of the meat product.

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

The substance increases opportunities to produce organic sausages and meat products that are not possible using existing production aids, and in particular allows production of single-species products that can meet the needs and preferences of different consumer populations, thereby expanding opportunities and markets to produce organically certified livestock. Collagen gel is used in similar fashion to casings, already listed under §205.606(b).

Collagen gel has no known toxicities and breaks down into its constituent amino acids upon digestion. It has no environmental persistence and use of collagen gel is unlikely to have any additional adverse impact on the environment. Listing of collagen gel could help build a bigger market for organically produced meat and is consistent with current regulations allowing up to 5% of nonorganic materials in processed food products labeled as “organic” or 30% in products labeled as “made with organic”. Listing of collagen gel is also consistent with the current listing of gelatin and casings as nonorganically produced animal products. Under §205.606, future availability of organic collagen gel source materials are encouraged.

NOSB Vote:

Classification Motion:

Motion to classify collagen gel casing as agricultural

Motion by: Asa Bradman

Seconded by: Harriet Behar

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

Listing Motion:

Motion to add collagen gel casing at \$205.606

Motion by: Asa Bradman

Seconded by: Tom Chapman

Yes: 11 No: 0 Abstain: 3 Absent: 0 Recuse: 0

Motion Passed

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Collagen Gel
February 21, 2019**

Summary of Petition 2018:

<https://www.ams.usda.gov/sites/default/files/media/CollagenGelPetition.pdf>

A petition has been submitted by Devro, Inc. to add collagen gel at 7 CFR 205.606, nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.” The NOP defines an agricultural product as “any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock...”.

The petitioned use is to produce sausage using a co-extrusion system. In these systems, collagen gel enrobes the sausage meat like a casing as the meat is extruded and holds the form of the meat product.

Summary of Review:

Based on the review of the petition and the 2019 Technical Report

(<https://www.ams.usda.gov/sites/default/files/media/CollagenGelGelatinCasingsTechnicalReport01282019.pdf>), collagen is a naturally occurring and abundant animal protein that is isolated from livestock and maritime (fish) sources. Collagen gel is derived from animal skins with some processing. The Handling Subcommittee had extensive discussions about whether the processing to produce collagen gel constituted a change to the chemical structure and might be considered non-agricultural. The Subcommittee ultimately concluded that the material is agricultural and eligible for listing at §205.606.

Cellulose powder, derived from plant sources, is an ancillary substance in collagen gel. Cellulose adds permeability to the sausage’s skin, allowing for the release of the meat emulsion’s oil and fats during the sausage’s cooking process. In finished collagen gel, cellulose is present in the range of 2 - 5%, depending on targeted product characteristics. Cellulose is currently approved for use as a synthetic substance “in regenerative casings [extruded collagen casing that is dried prior to use], as an anti-caking agent (non-chlorine bleached) and filtering aid,” and for processed products labeled “organic” or “made with organic,” at 7 CFR 205.605.

Collagen gel can be used in organic sausage production using a co-extrusion system. Typical products using this ingredient include cooked and smoked sausages. In these coextrusion systems, collagen gel enrobes the sausage meat like a casing as the meat is extruded and holds the form of the meat product. The collagen gel is considered an ingredient in the finished product. Collagen casings and gels are GRAS (Generally Recognized as Safe) for use in sausages and meat products.

Collagen gel has no known toxicities and breaks down into its constituent amino acids upon digestion. It has no environmental persistence and use of collagen is unlikely to have any adverse impact on the environment. Collagen is harvested from the skins of edible species of commercially harvested livestock processed at USDA inspected facilities following all pertinent regulations. It is a co-product of the animal production industry, thereby providing a raw material that otherwise has less value.

The Handling Subcommittee voted to classify the material as agricultural and list the material under 205.606.

Category 1: Classification

1. Substance is for: X **Handling** _____ **Livestock**
2. For HANDLING and LIVESTOCK use:
 - a. Is the substance ___X___ **Agricultural** or _____ **Non-Agricultural**?
Describe reasoning for this decision using NOP 5033-2 as a guide:

Collagen gels are derived from the corium layer of skins from cows, pigs, chickens and/ or turkeys and also maritime sources. The isolation process includes the partial hydrolysis of the protein, typically achieved with acid or base treatment, homogenization, and further denaturation with acid before final extrusion to form manufactured casings or coextrusion for direct application to extruded sausage batter.

The Handling Subcommittee had extensive discussions about whether processing steps to produce collagen gel constituted a change to the source protein chemical structure and might be considered non-agricultural. Because protein denaturation results from the disruption of non-covalent bonds that maintain the three-dimensional structure of the original protein, but leaves the peptide bonds intact, the Subcommittee ultimately concluded that the material has not been chemically changed and is thus agricultural.

In summary, based on the NOP 5033-2 decision tree, the material is derived from an animal; the substance is not a microorganism or enzyme, and not a product of a microorganism or an enzyme; the substance has not been processed to the extent that its chemical structure has been changed, and therefore is classified as agricultural.

3. For **Handling** use: Is the substance _X_ Non-synthetic or ___ Synthetic?
Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources?

As noted above, the Handling Subcommittee had extensive discussions about whether processing steps to produce collagen gel constituted a change to the chemical structure and might be considered non-agricultural. Because protein denaturation results from the disruption of non-covalent bonds that maintain the three-dimensional structure of the original protein, but leaves the peptide bonds intact, the Subcommittee ultimately concluded that the material has not been chemically changed and is thus agricultural

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?

There is little potential for the substance to have detrimental chemical interactions with 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 containments, and their persistence and areas of concentration in the environment?

There is no known toxicity of collagen gel. It is an edible product produced from animal skins.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance.

There is little probability of environmental contamination during manufacture, use, misuse, or disposal of collagen gel. Because the proposed petition is for nonorganically produced collagen gel, the material may be sourced from conventionally raised animals that have been fed GMO grain treated with pesticides as well as other materials not allowed in organic husbandry, such as antibiotic use.

4. Discuss the effect of the substance on human health.

Collagen gel is a food product with no known health effects.

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.

Collagen gel is unlikely to have any effects on biological and chemical interactions in the agroecosystem, including physiological effects on soil organisms.

6. Are there any adverse impacts on biodiversity?

Conventional production of animals used as source material for collagen gel may employ agricultural practices that adversely impact biodiversity. However, additional processing of these resources into collagen gel for organic sausage production will not add additional burdens on the environment.

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)]

Current options (casings, from processed intestines) will not function in this type of co-extrusion sausage production system. Nonorganically produced casings are allowed in sausages labeled as “organic” or “made with organic”.

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?

An organic form of collagen gel would be expected to perform similarly to nonorganic forms. Availability of organic collagen gel is a limiting factor.

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 form of available nonorganic versus organic animal source material for collagen gel is not relevant to the petitioned request for this material.

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 quality of available nonorganic versus organic animal source material for collagen gel is not relevant to the petitioned request for this material.

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?

According to the petitioner, collagen gel could theoretically be formed using skins from certified organic sources were they readily available in mass quantity and an identity preservation system in place. However, the quantity of organically raised animals required to satisfy the market demand may not exist. Organic options for collagen gel for meat production were not found based on internet searches and review of the USDA integrity database. Allowing the use of collagen gel could increase the market for organic meat and improve the potential for there to be sufficient organically raised animals to provide collagen gel source material. Under §205.606, future availability of organic collagen gel source materials are encouraged.

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;

Number of suppliers and amount produced is not readily available.

- 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 information is available on the impact of weather events.

- c. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or

No trade-related issues are available.

- d. Other issues which may present a challenge to a consistent supply?

None.

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](#))

Yes, the substance increases opportunities to produce organic sausages and meat products that are not possible using existing production aids, and in particular allows production of single-

species products that can meet the needs and preferences of different consumer populations, thereby expanding opportunities and markets to produce organically certified livestock. Collagen gel is used in similar fashion to casings, already listed under §205.606(b).

Collagen gel has no known toxicities and breaks down into its constituent amino acids upon digestion. It has no environmental persistence and use of collagen gel is unlikely to have any additional adverse impact on the environment. Collagen is harvested from the skins of edible species of commercially harvested livestock processed at USDA inspected facilities following all pertinent regulations. Because source material for production of collagen is usually produced from nonorganically raised livestock, there may be environmental and human health impacts from materials used to produce nonorganic grain and livestock. However, it is a co-product of the animal production industry, thereby providing a raw material that otherwise has less value, and helps support markets for organically produce meats.

In summary, listing of collagen gel could help build a bigger market for organically produced meat and is consistent with current regulations allowing up to 5% of nonorganic materials in processed food products labeled as “organic” or 30% in products labeled as “made with organic”. Listing of collagen gel is also consistent with the current listing of gelatin and casings as nonorganically produced animal products. Under §205.606, future availability of organic collagen gel source materials are encouraged.

Classification Motion:

Motion to classify Collagen gel as agricultural.

Motion by: Asa Bradman

Seconded by: Harriet Behar

Yes: 5 No: 0 Abstain: 1 Absent: 1 Recuse: 0

National List Motion:

Motion to add collagen gel as petitioned at §205.606.

Motion by: Asa Bradman

Seconded by: Tom Chapman

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Asa Bradman, Subcommittee Chair, to transmit to NOSB, February 24, 2019