

United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet

<https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>

Document Type:

National List Petition or Petition Update

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

Technical Report

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

PETITION FOR THE ADDITION OF COLLAGEN GEL to 7 CFR 205.606

ITEM A.1

Devro, Inc is petitioning for the inclusion of collagen gel in Section 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...”. Collagen gel is derived from skins from cows, pigs, chickens, and/or turkey and is therefore an agricultural product.

ITEM A.2 OFPA Category – Crop and Livestock Materials

Not applicable.

ITEM A.3 Inert Ingredients

Not applicable.

ITEM B

1. Substance name

Collagen Gel (from either cattle, pigs, chicken, and/ or turkey)

2. Petitioner and Manufacturer Information

Devro, Inc.

P.O. Box 11925

Columbia, SC 29211

Phone: 803-796-9730

Fax: 866-637-5343

3. Intended or Current Use

Collagen gel has the potential to be used in organic sausage production using a co-extrusion system. Typical products produced 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. The collagen gel is considered an ingredient in the finished product. Current organic options (casings, from processed intestines) will not function in this type of co-extrusion sausage production.

4. Intended Activities and Application Rate

Collagen casings and gels are GRAS for use in sausages and meat products. For Devro's purposes, the collagen gel will function as a coating/casing in sausages, hot dogs, and other meat products manufactured using co-extrusion production systems. Casings/coatings are vital to holding the form of the meat product.

5. Manufacturing Process

Collagen gels are derived from the corium layer of skins from cows, pigs, chickens and/ or turkeys [Step 1].

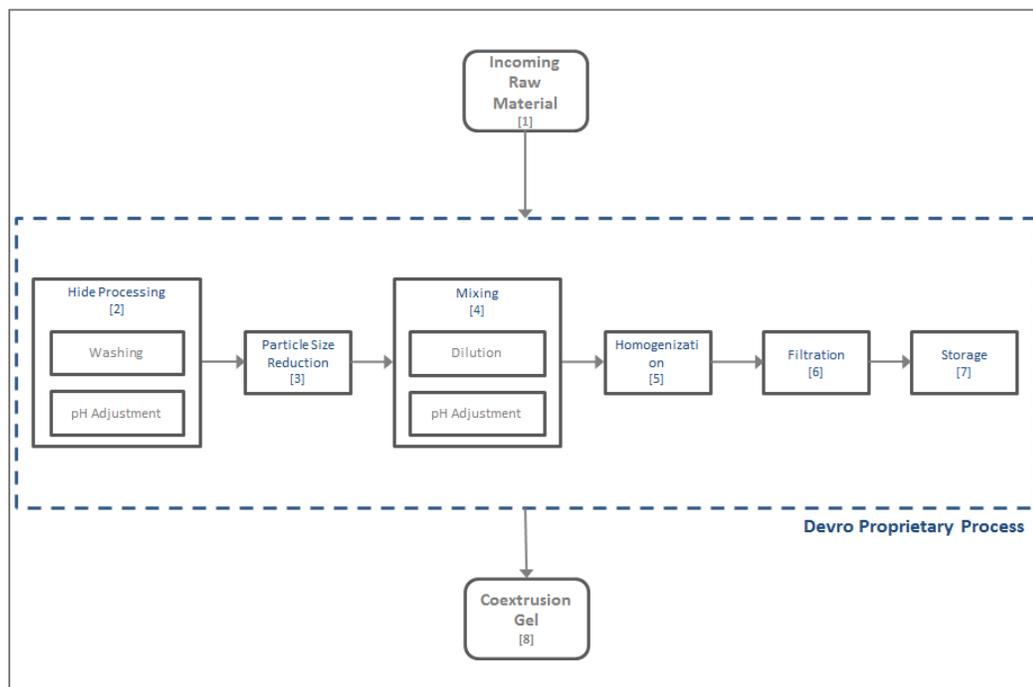
Skins are washed and treated to adjust pH in preparation for further production into collagen gel [Step 2]. pH adjustment is achieved from the treatment of Acetic acid, Lactic acid and/ or Hydrochloric acid, depending on targeted product characteristics; target pH range is 6.0 – 9.0.

Washed and treated skins are physically sieved through a two stage particle size reduction, resulting in a collagen pulp [Step 3].

Water is added and the pH reduced which causes the collagen to absorb water; the blend is physically agitated to produce a collagen gel [Step 4]. pH adjustment is achieved from treatment of Acetic acid, Lactic acid and/ or Hydrochloric acid, depending on targeted product characteristics; target pH range is 2.4 – 2.8.

The collagen gel is physically worked [Step 5] and pushed through a filter [Step 6] to produce a fine gel.

The finished collagen gel is packaged and stored in cold storage [Step 7].



6. Ancillary Substances

Cellulose powder, derived from plant sources, is an inert substance in collagen gel. Cellulose’s functionality is however critical once collagen gel has been coextruded into an enrobed extruded sausage. 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.

7. Previous Reviews

There is no previous review in regards to organic status.

8. Regulatory Authority

The FAO/WHO CODEX Alimentarius recognizes edible casings (e.g. sausage casings) as a food category: 08.4 Edible casings (e.g. sausage casings): Casings or tubing prepared from collagen, cellulose, or food-grade synthetic material or from natural sources (e.g. hog or sheep intestines) that contain the sausage mix.

Collagen is listed on the FDA’s “Everything added to food” list with no specific species.

<https://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?filter=collagen&sortColumn=&pt=eafuslisting>

9. Chemical Abstract Service (CAS) Number and Product Labels

CAS 9007-34-5

The attached product specification sheet has been attached in place of a product label, attached as Appendix A.

Examples of finished sausage product ingredient statements are shown below (Producer and brand names excluded for discretion).

Brand X Turkey Smoked Sausage

| |
|---|
| <p>Ingredients</p> <p>TURKEY, WATER, MECHANICALLY SEPARATED TURKEY, CORN SYRUP, CONTAINS 2% OR LESS OF: NATURAL FLAVORS, SALT, DEXTROSE, ISOLATED SOY PRODUCT, ISOLATED SOY PROTEIN, MONOSODIUM GLUTAMATE, SODIUM ERYTHORBATE, SODIUM NITRITE. MADE WITH BEEF COLLAGEN CASING. CONTAINS: SOY</p> |
|---|

Brand X Chicken Smoked Sausage Basil Pesto

| |
|---|
| <p>Ingredients</p> <p>Chicken, Water, Corn Syrup, Contains 2% Or Less: Salt, Isolated Soy Product, Flavor, Isolated Soy Protein, Dehydrated Cheddar Cheese (Cultured Pasteurized Milk, Salt, Enzymes), Yeast Extract, Sundried Tomatoes (Tomatoes, Salt), Dextrose, Lemon Juice Solids, Sodium Nitrite. Made with Beef Collagen Casing. Contains Soy, Milk</p> |
|---|

Brand X Beef Smoked Sausage

| |
|--|
| <p>Ingredients</p> <p>Beef, Water, Corn Syrup, Contains 2% or less of: SALT, ISOLATED SOY PRODUCT, Natural FLAVORS, DEXTROSE, ISOLATED SOY PROTEIN, SODIUM PHOSPHATE, Monosodium Glutamate, SODIUM ERYTHORBATE, Sodium Nitrite. Contains: Soy</p> |
|--|

Note: “Made with Beef Collagen Casing” is not listed as an ingredient as beef is the majority ingredient.

10. Physical and Chemical Properties

The attached SDS for collagen gel describes physical properties, attached as Appendix B.

a) chemical interactions with other substances, especially substances used in organic production

No distinct chemical reactions are known to occur

b)toxicity and environmental persistence

Collagen is a naturally occurring protein present in all living organisms, providing structural integrity. It has no known toxicities and breaks down into its constituent amino acids on digestion. It has no environmental persistence.

c) environmental impacts from its use or manufacture

Collagen is harvested from the skins of edible species of commercially harvested livestock such as cows, pigs, chickens and turkeys. All are harvested 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.

d) effects on human health

Collagen is a naturally occurring structural protein made up of essential amino acids. These amino acids are essential for growth and repair. Collagen is often sold as a protein supplement for good health.

e) effects on soil organisms, crops, or livestock.

Not applicable. Collagen is a food ingredient and is not applied to soil, crops, or livestock.

11. Safety Information

The attached SDS for collagen gel describes safety properties, attached as Appendix B.

12. Research Information

a) Research Review

Collagen is one of the most common proteins in the animal kingdom, existing as the major constituent of skin, tendon and other connective tissues; therefore, it is a significant component of meat. As such, it has existed as a natural food product throughout the history of man. Although collagen is used directly in the food industry, it is more widely used in its denatured form, as gelatin. Collagen is the native form of gelatin and chemically the two are indistinguishable. The two forms of this single protein are only separated by their physical structure; collagen retains the natural triple helical structure that defines it in nature. As gelatin, collagen is widely used in the food industry to form gels, gums, emulsifiers and as a polyelectrolyte to aid flocculation. It is also widely used in the pharmaceutical industry, e.g., as a binder in tablets and manufacture of capsules for supplements and pharmaceuticals. Besides its direct consumption as a natural meat component, purified collagen has also been used for decades in the manufacture of sausages. In the 1930's collagen was originally used to make non-edible sausage casing. Since the 1950's it has also been used in the manufacture of edible casing; approximately 10 billion meters of collagen casing are now being consumed around the world per annum. The native collagen has either been used as a dry tube, or since the 1960's, as a gel coated onto the meat mix at the point of extrusion. Beyond sausages, collagen films have been used in the manufacture of cheese, sweets, hams and beef round steaks.

b) Research Bibliography

Baldwin, E.A; Hagenmaier, R.; Bai, J. (2012): Edible Coatings and Films to Improve Food Quality - Second Edition. CRC Press

Berg, Jefferey (2006): The ultimate in biomaterials - common collagen. In *Biomedical Business & Technology*, pp. 16–19.

Brodsky, Barbara; Werkmeister, Jerome A.; Am Ramshaw, John (2005): Collagens and gelatins. In *Biopolymers Online*.

Chvapil, M.: Industrial uses of collagen. (Ed.): *Fibrous Proteins. Scientific, Industrial and medical Aspects*, pp. 247–269.

- Davis, Patricia (1998): Universal Body Builder. In *New Scientist-Inside Science* May, pp. 1–4.
- Farouk, M. M.; Price, J. F.; Salih, A. M. (1990): Effect of an Edible Collagen Film Overwrap on Exudation and Lipid Oxidation in Beef Round Steak. In *J Food Science* 55 (6), pp. 1510–1512.
- Gennadios, A. (Ed.) (2002): Protein-based films and coatings. Boca Raton: CRC Press.
- Krochta, J.M; Baldwin, E.A; Nisperos-Carriedo, M. (1994): Edible Coatings and Films to Improve Food Quality. Technomic Publishing Co
- Mitchell, J.R; Ledward, D.A (1985): Functional Properties of Food Macromolecules. Elsevier
- Phillips, G.O and Williams, P.A. (1994): Handbook of Hydrocolloids: CRC Press
- Savic, Z.; Savic I. (2002): Sausage Casings. 1st ed. Victus Publishing

13. Petition Justification Statement

Casing is a critical component in the production of sausages, encasing the sausage meat in a protective skin. Without casing, sausage products would be impossible to manufacture and be unacceptable to consumers.

Six types of sausage casing exist: non-edible plastic casings, peelable cellulose casings, natural casings (processed gut / intestine casings), shirred collagen casings, coextruded collagen gels and alginate coatings.

Non-edible plastic casings are thermally resistant plastics used to contain the sausage meat prior to cooking and setting. Once cooked, the plastic casing is removed.

Peelable cellulose casings are a tubular formed casing derived from cellulose sources such as cotton linters or wood pulp. These casings are stuffed with meat emulsion into a finished sausage product; sausages produced from this type of casing typically have their casing removed following the cook step.

Natural casings are the processed intestines of cows, pigs and/ or sheep. These casings are cleaned to remove manure and salted prior to being stuffed with meat emulsion into a finished sausage product; sausages produced from this type of casing are customarily eaten with their casing on.

Shirred collagen casings are a tubular formed casing derived from the hide / skin of cows, pigs, chickens and/ or turkeys. These casings are stuffed with meat emulsion into a finished sausage product; sausages produced using this type of casing are customarily eaten with their casing on.

Coextruded collagen gels are derived from the hide / skin of cows, pigs, chickens and/ or turkeys. These skins are cleaned and then macerated and pH-adjusted to form gels which are extruded simultaneously with meat emulsion. The use of a collagen gel

extruded with the sausage meat creates a whole sausage at the time of extrusion, bypassing the need for a separate casing; sausage products produced from this type of casing must be consumed with their casing.

Alginate coatings are a polysaccharide extract from seaweed origin that is functional within some coextrusion processes and finished products. However; this coating is not currently a viable option for processors making fully cooked sausages that are accepted by the marketplace.

Coextrusion systems that produce sausage products are continuous processes. These systems rely on simultaneous extrusion of collagen gel and meat emulsions to create enrobed extruded sausage. Of the six types of casings, only coextruded collagen gels can be used for this type of system. The other alternatives are only suited to semi-continuous and/ or batch processing such as hand and automated stuffing. Coextrusion systems allow manufacturers who have attained critical mass to meet market demands in an economical fashion as the market is shifting and demanding differentiated higher quality products. Coextruded collagen sausage products have attained broad consumer acceptance; approximately half of the fully cooked retail sausage category is comprised of collagen coextruded sausage products.

Shirred collagen casing and coextruded collagen gels are sourced from the same natural raw material. Shirred collagen casings are extruded and further processed from collagen gels. The critical difference is that coextrusion collagen gels are considered “not more than minimally processed.” Based on this, USDA FSIS has “determined that the use of collagen gel co-extrusion casings described in [this letter]¹ are acceptable for use in meat and poultry products labeled as ‘natural’.” In addition, collagen gel is far less degraded than gelatin, a material already accepted as suitable for organic production (included on the National Organic Program National List).

Of the six types of casings, only “natural casings” (processed gut / intestine derived casings) are currently on the National Organic Program’s National List, 7 CFR §205.606, added in 2007 (identified on the list as “Casings, from processed intestines”); therefore, permitted for use in organic sausage products. During the petition process for natural casings, it was noted:

“no casing manufacturer has ever attempted to make natural casings from organic slaughter stock due primarily to the inability to amass enough organic runners for an identity preserved run. While organic natural casings could easily be produced and would certainly be required for use in products labeled as organic the size of the organic sausage market is a long way from being substantial enough for a natural casing manufacturer to find it attractive enough a market.”

¹ Murphy-Jenkins, Rosalyn. Director, Labeling Program and Delivery Staff. United States Department of Agriculture, Food Safety and Inspection Service. (2014, March 23). [Letter to P. Hergarten].

A similar scenario applies to coextrusion collagen gel; collagen gel could theoretically be formed using skins from organic certified 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 does not exist. Therefore, collagen gel is not commercially available in organic form. Until organic slaughtered animal skins are available and collectible in sufficient quantity, processors using coextrusion systems currently have no opportunity to participate in the organic sausage sector in any form, quantity or quality.

This restriction impacts a rapidly growing segment of the sausage category: chicken sausage. This product group provides consumers with a better-for-you sausage option, as well as an alternative to beef or pork-based sausages. For manufacturers/marketers that wish to offer consumers an organic chicken sausage, the only casing option is natural casing (processed pig intestines, primarily). Consumers interested in organic chicken sausage have no option other than ones encased in pig intestine. Coextrusion collagen gels will provide a solution to this restriction when permitted for use in organic sausages.

In the current state, coextrusion collagen gel is the limiting factor preventing these processors from producing organic sausages, since organic meat emulsion, seasonings and other sausage ingredients are available. In a finished sausage product, however, the casing extruded from coextrusion collagen gels represents a very small percentage of the total weight: approximately 0.15 – 0.25% of the sausage's composition.

Importantly, the National Organic Program's List already permits gelatin, which is the same material as collagen gel, except collagen gel is a more natural state which is less processed, refined or degraded. Gelatin is produced by hydrolyzing collagen; thus, collagen is, in effect, a pre-gelatin.

Based on the justification above, Devro Inc. respectfully submits this petition for the addition of collagen to the National List of agricultural products allowed as ingredients in or on processed products labeled as "organic" under Section 7 CFR 205.606. We eagerly await the response of the National Organic Standards Board and look forward to participating in future dialogues.

Appendix A

Collagen Gel Product Specification Sheet



DEVRO

Date: 10/16/2017

Subject: Devro Collagen Gel Specification

Product Description:

Acidified collagen gel derived exclusively from bovine skin collagen harvested at government inspected slaughterhouses. The collagen was subsequently processed into gel at our FDA inspected facility located in Sandy Run South Carolina. This is a food grade product intended for use in the co-extrusion of sausage products.

Product Code Designations: C371V10

Ingredients:

| | |
|-------------|---------------|
| Water | 95.5% - 97.0% |
| Collagen | 3.0% - 4.5% |
| Cellulose | < 3.0% |
| Total Acid* | < 1.0% |

Physical Properties: Extremely high viscosity pumpable solid free of clumps.

Chemical Parameters: pH: 2.60 +/- 0.40

Storage/Shelf Life: Devro collagen gel should be stored in a clean dry environment at a temperature of 32°- 40° F. Storage at temperatures of less than 32° F could result in freezing which will negatively impact the performance of the gel during extrusion. Storage at temperatures above 40° F will reduce the overall shelf life of the gel. Under our recommended storage conditions, the shelf life of collagen gel should be up to one year.

Virginia Clement
Regulatory Affairs Manager

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Appendix B

Collagen Gel Product Specification Sheet



Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: COLLAGEN GEL

Manufacturer:
Devro, Inc.
PO Box 11925
Columbia, SC 29211

Emergency Phone Numbers:
803-796-9730
800-845-2119

2. HAZARDS IDENTIFICATION

| EMERGENCY OVERVIEW |
|---|
| As part of good industrial and personal hygiene as well as safety procedures, avoid all unnecessary exposures. Ensure prompt removal from skin, eyes, and clothing. |

POTENTIAL HEALTH EFFECTS:

| | |
|----------------------------|-------------------------------------|
| <u>Inhalation:</u> | No adverse effects expected. |
| <u>Eye Contact</u> | No adverse effects expected. |
| <u>Skin Contact</u> | No adverse effects expected. |
| <u>Ingestion</u> | No adverse effects expected. |
| <u>Chronic</u> | No adverse health effects expected. |

None of the contents are considered carcinogens.

HMIS Label:

| |
|-----------------------|
| <u>0</u> Health |
| <u>0</u> Flammability |
| <u>0</u> Reactivity |



Safety Data Sheet

3. COMPOSITION/INFORMATION ON INGREDIENTS

| Component | CAS# | % | Exposure Limits | |
|-----------|-----------|-------------|-----------------|-----------|
| | | | OSHA PEL | ACGIH TLV |
| Water | | 95.5 – 97.0 | N/A | N/A |
| Collagen | 9007-34-5 | 3.0 – 4.5 | N/A | N/A |
| Cellulose | 9004-34-6 | < 3.0 | N/A | N/A |

4. FIRST AID MEASURES

Inhalation: None required for usual conditions of use.

Eye Contact: Flush with water for 15 minutes then seek medical attention if irritation persists.

Ingestion: No hazard.

5. FIRE FIGHTING MEASURES

Flashpoint: NA

Flammable Limits: NA

Autoignition Temperature: Not considered to be a fire hazard.

Extinguishing Media: Use any means suitable for extinguishing surrounding media.

Fire Fighting Instructions: In the event of fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus.



Safety Data Sheet

6. ACCIDENTAL RELEASE MEASURES

Pick up and place in suitable container for disposal at approved landfill. Material is biodegradable.

7. HANDLING AND STORAGE

Keep in tightly closed container. Store in cool or refrigerated conditions.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: None required.

Respiratory Protection: None required.

Skin Protection: None required.

Eye Protection: None required.



DEVRO

Safety Data Sheet

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|------------------------------------|----------------|---------------------------------|----------|
| <u>Vapor Pressure:</u> | Close to water | <u>Vapor Density:</u> | NA |
| <u>Specific Gravity:</u> | Close to water | | |
| <u>Solubility in Water:</u> | Insoluble | <u>Evaporation Rate:</u> | NA |
| <u>pH:</u> | 2.4 - 2.8 | | |
| <u>Boiling Point:</u> | NA | <u>Freezing Point:</u> | NA |
| <u>Viscosity:</u> | Solid | | |
| <u>Color:</u> | White | <u>Odor:</u> | Odorless |

10. STABILITY AND REACTIVITY

General: Stable under ordinary conditions of use and storage.

Incompatible Materials and Conditions to Avoid: Oxidizers.

Hazardous Decompositions: Material will not polymerize.



Safety Data Sheet

11. OTHER INFORMATION

Date of Preparation: May 17, 2016

To the best of our knowledge, the information contained herein is accurate. However, Devro, Inc. does not assume a liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.