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.

Collagen Gel, Gelatin, and Casings

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
Collagen
Collagen Type I
Gelatin

Other Names:
Collagen I
Kollagene
Gelatine
Natural Casings
Intestinal Casings
Beef Casings
Pork Casings
Sheep Casings

Trade Names:
Galfoam
Gelatinfoam
Gelfoam
FreAlagin™ R gelatin
Prionex

CAS Numbers:
9007-34-5 (Collagen)
9000-70-8 (Gelatin)

Other Codes:
EC No. 232-697-4 (Collagen)

Summary of Petitioned Use

The petitioners are requesting to add collagen gel to Title 7 of the Code of Federal Regulations Section 205.606 (7 CFR 205.606) as a "nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as 'organic.'"

Collagen gel acts as an edible film in the production of processed meats (e.g., sausages). This is an alternative to preformed casings that have been traditionally used in both organic and nonorganic sausage manufacturing. Collagen gel is derived from the natural animal protein collagen, which is prevalent in the skin, bones, blood vessels, muscle, and connective tissue. When used as petitioned, a mixture of collagen, cellulose, and water will be applied to the sausage material in a coextrusion process. The meat product is then treated to form the fused casing. The use of collagen gel in the coextrusion process offers a more affordable, efficient, and sanitary means of manufacturing sausages (Barbut 2010, Djordjevic et al. 2015, Wang et al. 2015, Comaposada et al. 2018).

This report includes the petitioned collagen gel and a discussion about gelatin and natural casings, both of which have been approved for used by the United States National Organic Program (NOP) as "nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as 'organic,'" at 7 CFR 205.606. These substances are related to the petitioned substance, as they are largely composed of casings or derived from gelatin, the protein collagen. This report also serves as an update on the 2002 technical report on gelatin (USDA 2002).

Characterization of Petitioned Substance

Composition of the Substance:

Collagen Gel
The petitioned substance would be applied in the sausage manufacture process as a gel incorporated through the process of coextrusion. Collagen (3.0–4.5%) is the active ingredient accounting for most of the gel's characteristics. Collagen is a naturally occurring protein that is abundant in the connective tissue, bones, blood vessels, skin, and muscles of animals (Kim and Mendis 2006, Sahithi et al. 2013, Oechsle et al. 2014, Marousek et al. 2015). The unique structural properties of collagen's triple helix provide the desirable qualities of high-tensile strength and flexibility important to edible film casings (Oechsle et al. 2014, Oechsle et al. 2017).

The remainder of the gel is comprised of cellulose (<3.0%) and water (95.5–97.0%). 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.

Gelatin
Collagen is the source of gelatin, a substance that has a wide range of applications throughout the food, pharmaceutical, and biomedical industries (Gomez-Guillen et al. 2002, Kim and Mendis 2006, Karim and Bhat 2008). Gelatin is formed by the denaturation of the collagen triple helix through the application of heat and/or changes to pH (application of an acid or base). During this process, intermolecular forces are disrupted causing the helical structure to unwind, with the formation of a new structure resulting from the rewinding of portions of the helical structure (de Wolf 2003, Schrieber and Gareis 2007, Karim and Bhat 2008). The petitioned substance is applied as collagen gel; however, during the substance's processing and sausage encasement, the collagen is denatured to a state resembling gelatin and adheres to the encased meat product (Barbut 2010, Bombrun et al. 2014, Yang et al. 2016). Gelatin has been approved as a "nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as 'organic.'" at 7 CFR 205.606.

Casings
Natural casings formed from processed animal intestines have been traditionally used in the production of sausages and other meat products (Barbut 2010, Ioi 2013, Djordjevic et al. 2015). Natural casings are primarily composed of the natural protein collagen, whose natural characteristics of high tensile strength, flexibility, and gas/vapor permeability make the intestinal organs well suited as natural casings (Savic and Savic 2002, Barbut 2010, Harper et al. 2012, Oechsle et al. 2017). Following the slaughter of the animal, the intestines are cleaned and treated to remove fat. Next, the intestinal layers are removed (sliming), which acts to increase the permeability and flexibility of the casing (Barbut 2010, Ioi 2013, Djordjevic et al. 2015). The casing processing is completed with an additional wash using salt water, then drying and salting the final product (Barbut 2010, Ioi 2013, Djordjevic et al. 2015). Natural casings remain a major contributor in the production of commercial sausages and have been approved as "nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as 'organic.'" at 7 CFR 205.606 (Harper et al. 2012, Ioi 2013, Djordjevic et al. 2015).

Source or Origin of the Substance:

Collagen Gel
Collagen gel is isolated from the abundant animal protein collagen found in skin, bones, blood vessels, muscle and connective tissue (Kim and Mendis 2006, Sahithi et al. 2013, Oechsle et al. 2014, Marousek et al. 2015). Collagen is primarily obtained in the food industry as a precursor to gelatin, although there are also direct uses for the protein (Gomez-Guillen et al. 2002, de Wolf 2003, Kim and Mendis 2006, Schrieber and Gareis 2007, Karim and Bhat 2008).

Traditionally, collagen has been isolated from the skins (~95%) and bones (~5%) of cattle and pigs (Gomez-Guillen et al. 2002, Wassa et al. 2007, Karim and Bhat 2008, Silva et al. 2014, Marousek et al. 2015, Kumar and Suresh 2016, Oechsle et al. 2017). Collagen is typically isolated from livestock and food production by-products (Oechsle et al. 2017). Since most collagen and gelatin is isolated from bovine and porcine sources, they also present the primary means of organically-produced collagen and gelatin, with products available with USDA and Australian organic certifications (Changing Habits 2018, Gel-pro 2018, Vital Proteins 2018). The animal-based collagen source is partially hydrolyzed through enzymatic, thermal, or acid treatment from meat processing byproducts (Kim and Mendis 2006, Karim and Bhat 2008).

Despite efforts to diversify collagen sources, most collagen (and gelatin) remains bovine and porcine-based (Wassa et al. 2007, Silva et al. 2014, Kumar and Suresh 2016). Marine collagen is rarely used commercially due to its dark color and the persistence of a fishy odor (Wassa et al. 2007). Efforts to isolate collagen from marine sources are based on processing fish by-products, although these sources are not well-defined and may vary from bones and skins to including viscera and heads (Sadowska et al. 2003, Kim and Park 2004, Wassa et al. 2007, Karim and Bhat 2008, Silva et al. 2014, Kumar and Suresh 2016). Collagen may also be isolated by the enzymatic treatment or membrane filtration of wastewater from fish processing (Kim and Park 2004, Kim and Mendis 2006, Mohammad et al. 2011). Marine sources of collagen remain largely in the research stage; therefore, organic grade marine collagen is not currently available (Kumar and Suresh 2016).

Gelatin

Gelatin is not a naturally occurring substance, but rather is derived from denaturing the protein collagen (USDA 2002). The process of denaturing the collagen protein can be achieved through a variety of methods, including the application of heat and/or changing the pH of the protein with the addition of acid or base (USDA 2002, de Wolf 2003, Schrieber and Gareis 2007, Karim and Bhat 2008). The result is that the helical protein (collagen) unwinds due to the stresses of increased temperature and/or changes to the pH. Upon cooling, some of the helical strands are reformed. Their final structure, however, is altered from the initial collagen structure (de Wolf 2003, Schrieber and Gareis 2007, Karim and Bhat 2008).

Casings

Casings are derived from animal intestines that are processed following the slaughter of the animal (Barbut 2010, Ioi 2013, Djordjevic et al. 2015). The casings are processed immediately following the slaughter of the animal by cleaning, defatting, and removal of some intestinal layers (Barbut 2010, Ioi 2013, Djordjevic et al. 2015). The processing is completed with a salt water wash, then drying and salting the casings for storage until used in the production of sausage or other meat products (Barbut 2010, Ioi 2013, Djordjevic et al. 2015).

Properties of the Substance:

Collagen Gel and Casings

Since the collagen protein is the primary component of both collagen gel and natural casings, the following discussion of properties applies to both substances. Natural collagen is a fibrous protein found in the skin, muscle, bone, and connective tissues as a triple helix (Gomez-Guillen et al. 2002, Kim and Park 2004, Kim and Mendis 2006, Karim and Bhat 2008). This structure is formed due to the prevalence of glycine amino acid residues (approximately 1/3 of the protein) within the primary structure of the protein (amino acid order) (Gomez-Guillen 2002, Karim and Bhat 2008). The prevalence of glycine residues results in a flexible structure due to the rotational freedom of the small amino acid (-R sidechain = -H) and contributes to the thermal stability of the protein (Burjandze 2000, Gomez-Guillen et al. 2002, Oechsle et al. 2017). Within the triple helical structure, three chains of amino acids are woven together and stabilized by Van der Waals' forces, hydrophobic interactions, hydrogen bonding, and intermolecular forces between amino acid residues along the length of the chains (Privalov and Tiktopulo 1970, Usha and Ramasami 2004, Karim and Bhat 2008, Wu et al. 2017). The strength of the collagen biopolymer is further enhanced by natural crosslinking aldehydic residues such as lysine and hydroxylysine (Bateman et al. 1996, Gomez-Guillen et al. 2002).

Collagen Gel

Due to the site diversity of collagen in nature (e.g., skin, bones, blood vessels, muscle, and connective tissue), the amino acid sequence, degree of crosslinking, and structure are dependent on the type and age of the animal from which it is harvested, as well as the animal's age and environmental considerations (Gomez-Guillen et al. 2002, Kim and Park 2004, Kim and Mendis 2006). Therefore, the resulting properties of the isolated collagen (e.g., tensile strength and flexibility) are also dependent on these considerations (Hamada 1990, Miyauchi and Kimura 1990, Gomez-Guillen et al. 2002, Karim and Bhat 2008). Moreover, the properties of the collagen product are dependent on how it is processed and employed in its final application (Hamada 1990, Grossman and Bergman 1992, Haug et al. 2004, Karim and Bhat 2008, Djordjevic et al. 2015, Oechsle et al. 2015, Wang et al. 2015, Yang et al. 2016. Oechsle et al. 2017).

Gelatin

Gelatin has long been regarded as a unique and important substance in a variety of industries, including: food, pharmaceutical, biomedical, as well as non-food applications (USDA 2002, Karim and Bhat 2008). Gelatin forms thermally reversible gels when combined with water, being soluble with relatively low viscosity at high temperatures, while forming a hyper colloidal suspension when cooled to or below room temperature. At this point, the gelatin absorbs 5 to 10 times its weight in water (USDA 2002, Karim and Bhat 2008). The thermal reversibility of the gel is crucially below body temperature (<35 ^{o}C), providing a range of organoleptic properties, including a "melt-in-mouth" quality (Glicksmann 1969, Karim and Bhat 2008). Moreover, gelatin is noted as having minimal color and taste, allowing for the addition of important textural components without effecting the flavor or color profile (Food and Nutrition Board 1996, USDA 2002).

Like its collagen precursor, gelatin is produced from a wide range of sources (both in animal type and protein location/function within the animal) (Gomez-Guillen et al. 2002, Kim and Park 2004, Kim and Mendis 2006). The impact of collagen source also affects the properties of the resulting denatured protein (gelatin). This is most evident when comparing marine sources to mammalian sources, as the marine sources of gelatin typically exhibit reduced thermal stability of the gels (Gomez-Guillen et al. 2002, Kim and Park 2004, Karim and Bhat 2008, Wu et al. 2017). This result is likely due to differences in the amino acid composition in marine-sourced collagen, which reduces the amount of cross-linking capable between the helical strands (Gomez-Guillen et al. 2002, Karim and Bhat 2008, Wu et al. 2017).

Selected properties of collagen and gelatin are listed in Table 1.

Table 1: Properties of Collagen and Gelatin

Property	Collagen	Gelatin
CAS No.	9007-34-5	9000-70-8
Appearance	White fibres	Light yellow powder
pH	N/A	4.0 – 7 at 66.7 g/l at 60 ^{o}C
Solubility	Soluble in water	Soluble in hot water

Sources: Chemical Book 7663310, Chemical Book 9680379, Sigma-Aldrich 2014, Sigma-Aldrich 2018

Specific Uses of the Substance:

Collagen Gel

When used as petitioned, collagen would be applied to sausages manufactured through coextrusion. In the coextrusion method, the manufactured collagen casing is applied as a gel simultaneously to the extrusion of the sausage batter (Hoogenkamp 1994, Frye 1996, Marel Townsend). The treated casing acts as a replacement to natural (animal digestive tubes and bladders) or manufactured (formed from solubilized fibrous biomaterials (e.g., cellulose, collagen, alginate)) casings (Hoogenkamp 1994, Rantanavaraporn et al. 2008, Harper et al. 2012, Ioi 2013).

Once applied and processed via the coextrusion process, the sausage, the collagen gel fuses to the meat batter, forming a nonremovable edible film (Barbut 2010, Bombrun et al. 2014, Djordjevic et al. 2015). The resultant fused collagen casing acts as a protective barrier to the sausage product, reducing the movement of gases (e.g., oxygen), moisture, solvents, and prevents biological contamination (Debeaufort et al. 1998, Aloui and Khwaldia 2016, Hassan et al. 2018). Moreover, the edible casing contributes to the organoleptic properties of the sausage, and the delivery of coloration and flavorings (Savic and Savic 2002, Han and Gennadios 2005, Vasconez et al. 2009).

Gelatin

Gelatin has a wide range of uses in the food industry. Gelatin is used to change the properties and textures of foods due to its ability to form a thermally reversible gel. Such applications include use as a food additive in yogurt and gelatin desserts, instant gravy and soups, pastry toppings canned ham, luncheon meats, turkey and chicken rolls, and as a stabilizer in ice cream, cream cheese, cottage cheese, fruit salad, and food foams (McCormick 1987, Rose 1991, McWilliams 2001, USDA 2002). Gelatin is used as a beverage clarifier and fining agent for wine, beer, and fruit and vegetable juices (Tressler and Joslyn 1954, Peterson and Johnson 1978, Vine 1999, USDA 2002).

Gelatin has a variety of applications in non-food industries as well. In the pharmaceutical industry gelatin is used to bind and encapsulate tablets and gel-caps of medicines and nutritional substances (Ash and Ash 1997, USDA 2002). Gelatin is also incorporated into a range of pharmaceutical formulations, including vaccines (USDA 2002). Gelatin is used within the textile industry with applications, including: sizing, dressing, coating, and finishing a range of materials such as cotton, leather, silk, and wool (USDA 2002).

Casings

Natural casings are used as a natural and edible container for sausages and other meat products. Natural casings are derived from processed animal intestines and are stuffed with a meat mixture to yield the final product (Ioi 2013). The casing determines the size and shape of the sausage, while also providing structural integrity (Harper et al. 2012, Ioi 2013).

Approved Legal Uses of the Substance:

Collagen Gel

Collagen is permitted in a range of food and medical applications. Pork collagen is permitted for use as a binding agent with a limit of "3.5% of the product formulation," for "cured pork products," and "sausage," at 9 CFR 319.104 and 9 CFR 319.140, respectively. Collagen is also permitted in food products as collagen casings, in which collagen would appear on the ingredient list, and all products encased in regenerated collagen casings are required to disclose that information on product labels per §318.7 and §381.117.

The United States Food and Drug Administration (FDA) has permitted the use of collagen as a component in animal glues to be "used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food," at 21 CFR 178.3120. Collagen is also used in medical applications and has been approved by the FDA as a material "to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region," at §872.3930. The FDA has also approved collagen for use as a "biological coating" for "vascular graft prosthesis," at §870.3450.

The United States Environmental Protection Agency (EPA) has approved collagen as a component of glues as "inert ingredients permitted in minimum risk pesticide products," at 40 CFR 152.25.

Gelatin

Gelatin is derived by the denaturation of collagen and is widely used in the food, medical, and other non-food industries. Gelatin has been approved by the United States Department of Agriculture's (USDA) National Organic Program (NOP) as a "nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as 'organic.'" at 7 CFR 205.606(f). Gelatin is generally recognized as safe (GRAS) when used "to clarify juice or wine," at 27 CFR 24.246. The FDA has approved gelatin as an option ingredient in "pasteurized Neufchatel cheese spread with other foods," and "pasteurized process cheese spread," at 21 CFR 133.178 and 21 CFR 133.179, respectively. The FDA has also granted gelatin GRAS status for "substances migrating from cotton and cotton fabrics used in dry food packaging," at §182.70. Gelatin is approved for use as an ingredient in several "microcapsules for flavoring substances," at §172.230, and as a component of "peptones," at §184.1553. Gelatin is an approved ingredient in "canned boned poultry and baby or geriatric food," in "quantities not in excess of a total of 0.5% of the total ingredients," and must also "be included in the name of the product," as stated at 9 CFR 381.157. Gelatin is permitted as a binding agent in the manufacture of "turkey roll," however, if "added in excess of 3% for cooked rolls and 2% for raw rolls, the common name of the agent or the term "Binders Added" shall be included in the name of the product," as stipulated at §381.159. More generically, gelatin has been permitted "to bind and extend various poultry products," at §424.21.

Gelatin also has a range of uses in the medical and pharmaceutical industries. Gelatin has been approved as a component of "ophthalmic demulcents," with a maximum concentration of 0.01% at 21 CFR 349.12. Gelatin has been approved by the FDA as a material component of "partial ossicular replacement prosthesis," at §874.3450, and as a substance for "implantation or injectable dosage form new animal drugs," with the specification that "each 100 milliliters contains 8 grams of gelatin in a 0.85% sodium chloride solution," at §522.1020.

Casings

Casings are permitted "as containers of products," from "sheep, swine, or goats," without exception, and may be derived from cattle with the additional requirement that "if casings from cattle are derived from the small intestine, the small intestine must comply with the requirements in 9 CFR 310.22," as stated at 9 CFR 318.6. "Casings, from processed intestines," are designated by NOP as "nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as 'organic,'" at 7 CFR 205.606.

Action of the Substance:

Collagen Gel

Collagen is a natural protein found in the skin, bones, muscle, and connective tissue of animals (Kim and Mendis 2006, Sahithi et al. 2013, Oechsle et al. 2014, Marousek et al. 2015). In its natural state, the fibrous protein has a triple helix structure where crosslinking between the amino acid chains provides both strength and flexibility (Privalov and Tiktopulo 1970, Burjandze 2000, Gomez-Guillen et al. 2002, Usha and Ramasami 2004, Karim and Bhat 2008, Oechsle et al. 2017, Wu et al. 2017). These desirable attributes remain in place for collagen gels applied to sausage batter in the coextrusion process, resulting in an edible casing fused to the processed sausage that can endure the required thermal changes (e.g., freezing and cooking) (Hoogenkamp 1994, Frye 1996, Yang et al. 2016, Hassan et al. 2018). The collagen casing protects the meat product from oxidation and discoloration, by acting as a semipermeable membrane for gases, moisture, and other solvents (Savic and Savic 2002, Han and Gennadios 2005, Marousek et al. 2015). The casing also contributes to the organoleptic properties of the sausage, such as bite and texture, and serves as a means to deliver additional flavorings to the product (Savic and Savic 2002, Han and Gennadios 2005, Harper et al. 2012, Ioi 2013, Marousek et al. 2015).

Gelatin

When used for beverage clarification or fining, gelatin reacts with proteins that are soluble in the given solution (e.g., beer, wine, juices), in a binding type interaction (USDA 2002). Because of the gelling properties described earlier, the gelatin also absorbs water, causing the gelatin-protein structure to swell, and allowing for its removal through filtration of gravity settling (USDA 2002).

When used as a texturizing agent, the gelatin absorbs water through the formation of a hydrogen binding network. When the aqueous mixture is hot, the gelatin remains in solution, however, upon cooling gelation begins to occur caused by the crosslinking between gelatin strands (USDA 2002). Continued gelation occurs during storage and includes a rearrangement in the crosslinked strands to a more ordered state, consequently impacting the organoleptic properties of the gel (McWilliams 2001, USDA 2002). The structure (both initial and final) of the gel is dependent on the concentration of gelatin, with most food systems employing gelatin concentrations between 1.5 – 4% (McWilliams 2001).

Casings

Casings are used as "containers" for sausages and other meat products. Natural casings determine the size and shape of the formed sausage (Harper et al. 2012, Ioi 2013). The casing also provides the final product with structural integrity, due largely to the flexibility and tensile strength associated with its primary component, collagen (Oechsle et al. 2017). The casing also impacts the colors and flavors of the cooked sausage, which are influenced by the permeability characteristics of the casing. The casing permeability influences the migration of flavors, gases/vapors, and moisture in and out of the meat product during the preparation (seasoning) and cooking stages, with specific casings used for specific food types (Savic and Savic 2002, Ioi 2013, Djordjevic et al. 2015, Hassan et al. 2018). Furthermore, the type, size, and thickness of the casing influences the organoleptic properties of the sausage, most notably that of "bite quality" (Savic and Savic 2002, Han and Gennadios 2005, Harper et al. 2012, Ioi 2013, Marousek et al. 2015).

Combinations of the Substance:

Collagen Gel
The collagen gel being petitioned for organic use is a mixture of collagen (3.0-4.5%), cellulose (<3%), and water (95.5–97.0%). Cellulose has been approved for use as synthetic substance "in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid," for processed products labeled "organic or made with organic," at 7 CFR 205.605(b).

Cellulose has been historically used in regenerative casings and has also been applied with coextrusion technology (Hoogenkamp 1994, Feiner 2006, Djordjevic et al. 2015, Marel Townsend). In concert with the petitioned substance, the addition of cellulose to collagen mixtures has been reported to increase the strength and thermal stability of the casing (Harper et al. 2012, Hassan et al. 2018). Modification of collagen mixtures has been reported to influence the permeability, strength, flexibility, and thermal stability of the collagen casing (Savic and Savic 2002, Ioi 2013, Djordjevic et al. 2015, Hassan et al. 2018). These modifications can be made through changes to the collagen gel matrix by the inclusion of additional protein and crosslinking compounds, or changes to the manufacturing process (e.g., acid and brine type, smoke concentration, thermal treatments) (Barbut 2010, Bombrun et al. 2014, Djordjevic et al. 2015, Oechsle et al. 2017).

Additional proteins that have been reported for modifications to the collagen gel matrix includes soy protein, casein, and keratin (Wu et al. 2017). The incorporation of inorganic salts (e.g., sodium chloride, calcium chloride) and enzymes (e.g., transglutamase) have also been reported as additives to influence the crosslinking capabilities of the collagen gel (Oechsle et al. 2017, Wu et al. 2017, Comaposada et al. 2018). These substances (proteins and crosslinking promotors) have not been approved for use in organic processing and agricultural processes. Coextrusion process in sausage manufacturing remains relatively new, and research on the influence of protein and other additives to collagen casings applied via coextrusion is ongoing.

Gelatin
Gelatin is a unique substance. Its properties make it suitable for a range of applications across a variety of industries. Due to the many applications of gelatin, it can be combined with numerous other substances that vary depending on the given task. When used for beverage fining and clarification purposes, it is often applied in concert with other clarifying agents, specific to the type of beverage being treated, such as bentonite or tannins for juices (Tressler and Joslyn 1954, Peterson and Johnson 1978, USDA 2002). When used as a stabilizer or texturizer, sugars such as sucrose, or other substances such as agar, can be added to change the setting time and temperature characteristics of the gel (Stainsby 1987, USDA 2002). When used as an encapsulating agent for nutritional or medicinal tablets, other substances can be added to the hardness of the final gel (USDA 2002). These include a range of alcohols, including sorbitol, mannitol, and glycerol, that act as plasticizers, as well as aldehydes, including formaldehyde and glutaraldehyde to facilitate cross-linking between gelatin strands (Hutchinson et al. 1994, Cole 2000, Ledward 2000, USDA 2002).

Casings
Casings are produced from processed intestines. Their primary component is the protein collagen. The processing of casings includes several washing steps, as well as defatting and sliming (removal of one or more intestinal layers) (Barbut 2010, Harper et al. 2012, Ioi 2013, Djordjevic et al. 2015). In addition, the processed casings are dried and salted as the final processing steps prior to storage, meaning that the only additional components added to casings are salts from the second, salt-based washing, and from the final salting process (Barbut 2010, Harper et al. 2012, Ioi 2013, Djordjevic et al. 2015).

Status

Historic Use:
Natural casings (animal digestive tubes and bladders) have been used for hundreds of years in sausage preparation (Hoogenkamp 1994, Ioi 2013). In this process, the intestines or other digestive tubing from

sheep, hogs, or cattle, are removed after slaughter (Ioi 2013). The tubing undergoes "sliming," the removal of intestinal layers to increase the flexibility and permeability of the casing (Barbut 2010, Harper et al. 2012, Ioi 2013). The casing is then stuffed with minced or ground meat products or treated with salt or brine for later use (Savic and Savic 2002, Ioi 2013).

Manufactured collagen casings have served as an alternative to natural casings since their introduction in the 1920s and are now estimated to account for approximately 80% of the casing market (Amin and Ustunol 2007, Yang et al. 2016). Manufactured collagen casings are also referred to as "regenerated," since the collagen is isolated from a range of sources (e.g., skin, bones, muscle and connective tissue) and processed and reformed into a casing (Rantanavaraporn et al. 2008, Ioi 2013). Once isolated through a denaturing process (e.g., thermal, acid, base, or enzymatic treatment), it is most commonly reformed by extrusion (Barbut 2010, Yang et al. 2016). These manufactured casings have several advantages over natural casings, including more uniform thickness and strength, and the removal of the curing process and longer shelf-life (Savic and Savic 2002, Djordjevic et al. 2015). Moreover, the collagen casings offer improvements regarding sanitation concerns, as there is less human processing and, therefore, chance of contamination (Djordjevic et al. 2015).

The coextrusion process was developed in the 1960s as a cheaper and more efficient casing application method, although the process did not become widely used in the United States until the 1990s (Frye 1996). Like the collagen casings that changed the landscape of sausage manufacturing before it, the application of coextrusion processes offers improvements to efficiency and sanitation (Hoogenkamp 1994, Ioi 2013). In this process, a specialized extrusion cone is used to extrude the sausage batter in the center, while simultaneously coating it by the extrusion of collagen gel, or other casing (Hoogenkamp 1994, Frye 1996, Barbut 2010, Marel Townsend). The direct application of the casing to the extruded sausage batter further reduces handling and risk of contamination, while the automation of the coextrusion and subsequent treatment steps increase efficiency and reduce costs (Hoogenkamp 1994, Barbut 2010, Marel Townsend).

Gelatin has been historically used in a wide range of food applications. These include early attempts to replace natural casings for sausage production by dipping the meat mixtures in a gelatin solution (Hood 1987, USDA 2002). Gelatin is used as a stabilizer and texturizer in a range of foods and is a common component in dairy and gelatin-based desserts (USDA 2002). Gelatin has historic usage as a clarifying agent for a range of beverages including beer, wine, and fruit and vegetable juices (Tressler and Joslyn 1954, Peterson and Johnson 1978, Vine et al. 1999, USDA 2002).

Organic Foods Production Act, USDA Final Rule:
Collagen is not listed in the Organic Foods Production Act of 1990 (OFPA) or in USDA regulations.

Neither gelatin nor casings are listed in the OFPA. However, both gelatin and casings are listed in the USDA organic regulations under "nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as 'organic.'" at 7 CFR 205.606.

International

Canadian General Standards Board Permitted Substances List
Collagen is listed in the Canadian General Standards Board Permitted Substances List (CAN/CGSB-32.311-2015) in Table 6.4 as allowed for "ingredients not classified as food additives" in the form of "collagen casings." Collagen casings are required to "be derived from animal sources," and "if derived from cattle, shall be guaranteed free of specified risk materials." Moreover, collagen casings are permitted to include "other ingredients (such as, but not limited to: cellulose, calcium coatings, glycerin, etc.) added to collagen casings during their manufacture, which remain in the collagen casing."

Gelatin is listed in the Canadian General Standards Board Permitted Substances List (CAN/CGSB-32.311-2015) in Table 6.3 as allowed for "ingredients classified as food additives." Gelatin may be sourced from both plant and animal sources, with the requirement that "if derived from cattle, shall be guaranteed free of specified risk materials."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Neither collagen nor casings are listed in the CODEX (GL 32-1999).

Gelatin appears under CODEX (GL 32-1999) guidelines as an allowed substance in Table 2 "substances for plant pest and disease control," and Table 4 "processing aids which may be used for the preparation of products of agricultural origin."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Neither collagen, nor gelatin, nor casings are listed in EC No. 834-151 2007. Collagen is not listed in EC No. 889/2008.

Gelatin is listed in EC No. 889/2008 in Section B as a "processing aid, which may be used for processing of ingredients of agricultural origin for organic production."

Gelatin and casings are listed in EC No. 889/2008, stating that when derived from "aquatic organisms, not originating from aquaculture" is "permitted in no-organic foodstuffs preparation."

Japan Agricultural Standard (JAS) for Organic Production
Neither collagen nor casings are listed in the JAS for Organic Production.

Gelatin is listed in the JAS for Organic Processed Foods (notification no. 1606) in Attached Table 1 as a "food additive," with the restriction that it is "limited to be used for processed foods of plant origin."

International Federation of Organic Agriculture Movements (IFOAM)
Neither collagen nor casings are listed in IFOAM.

Gelatin is listed in IFOAM in Appendix 3 as a "crop protectant and growth regulator," and in Appendix 4, Table 1 as a "processing and post-harvest handling aid."

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Collagen Gel
Collagen is a natural animal protein found in skin, bones, muscle, and connective tissues (Kim and Mendis 2006, Sahithi et al. 2013, Oechsle et al. 2014, Marousek et al. 2015). Collagen is isolated from these animal sources through hydrolysis during treatment of the animal byproduct by thermal, acid, base, or enzymatic treatments to cleave the protein (Kim and Park 2004, Karim and Bhat 2008, Rantanavaraporn et al. 2008, Ioi 2013). Once cleaved, the collagen extract is decalcified and ground to uniformity within the collagen fibers (Harper et al. 2012, Ioi 2013, Hassan et al. 2018). The collagen fibers are then swollen with acid (typically hydrochloric (HCl) or sulfuric (H_2SO_4) acid) treatment before the extrusion process (Rantanavaraporn et al. 2008, Barbut 2010, Ioi 2013).

When used as petitioned, collagen would be applied to sausages manufactured through coextrusion. In the coextrusion method, the manufactured collagen casing is applied as a gel simultaneously to the extrusion of the sausage batter (Hoogenkamp 1994, Frye 1996, Marel Townsend). Once applied, the coextruded product is treated with a brine solution to firm the gel for the remainder of the processing (Hoogenkamp 1994, Frye 1996, Marel Townsend). Crosslinking is then established by treatment with acid, heat, and/or smoke exposure (Hoogenkamp 1994, Frye 1996, Marel Townsend). Smoke has been reported to be an especially effective promotor of crosslinking due to the presence of aldehyde groups (Bateman et al. 1996, Gomez-Guillen et al. 2002). Finally, the collagen casing adheres to the encased sausage batter through gelation, achieved by thermally denaturing the collagen proteins and reformation of portions of the triple helical structure (Ross-Murphy 1992, Karim and Bhat 2008, Yang et al. 2016, Hassan et al. 2018).

Gelatin

Gelatin is produced by denaturing sources of collagen through the application of heat or changes to pH. The specific method of denaturing is typically dependent on the source of the collagen and will be discussed separately based on source (fish, bovine, and porcine).

Gelatin prepared from fish is extracted from fish skins with the application of heat in conjunction with changes to pH by treatment with an acid (e.g., acetic acid, lactic acid, citric acid) to a base (e.g., sodium hydroxide) (USDA 2002). Once extracted, the gelatin mixture is concentrated and dried to yield the finished gelatin product (USDA 2002).

Gelatin prepared from porcine sources is obtained from pigskins that have been dehaired via exposure to steam, flame, and paddling (Farmer et al. 1982). The dehaired pigskins are then degreased by centrifugation and steam treatments, or exposure to organic solvents such as tetrachloroethylene (Hinterwaldner 1977, Norris 1982). The treated pigskins are soaked in a food grade mineral acid (e.g., hydrochloric acid (HCl), phosphoric acid (H_3PO_4), sulfuric acid (H_2SO_4)) during which the skins swell to two to three times the pretreatment size (Cole 2000, Ledward 2000, USDA 2002). The pigskins are then washed and extracted with hot water before filtration through an anion-cation exchange column for further purification (Hinterwaldner 1977, USDA 2002). Following filtration, the mixture is concentrated via evaporation and receives pH treatment to a final pH between 3.5 – 6, undergoes sterilization at 248 – 303 ^{o}F, and is dried to obtain the finished product (Hinterwaldner 1977, USDA 2002).

Gelatin prepared from bovine sources is derived from collagen isolated from the hides and bones of cattle. Cattle bones are crushed, cooked at 180 – 250 ^{o}F, centrifuged, dried, and degreased before they are used in the manufacture of gelatin (Stainsby 1987, Rose 1991, USDA 2002). Due to the high mineral content of bones, the treated bone mixture then undergoes a demineralization process via treatment with 4 – 6% hydrochloric acid (HCl) (USDA 2002). The demineralized bone mixture is washed to remove impurities and undergoes a liming process, which includes extended (35 – 70 days) treatment with lime (calcium hydroxide) in order to increase the pH of the slurry to 12 – 12.7 (USDA 2002). The liming process eliminates non-collagen components of the mixture, which undergoes additional washes before treatment with a mineral acid (e.g., hydrochloric acid (HCl), sulfuric acid (H_2SO_4)) to decrease the pH to 3. The gelatin mixture undergoes a hot water extraction, followed by further purification by filtration through diatomaceous earth or exposure to a de-ionizing resin. After a final pH adjustment to 5 – 7, the mixture is concentrated, sterilized at 280 – 290 ^{o}F, and dried to yield the finished product (USDA 2002).

Casings

Casings are produced from the intestines of animals following slaughter to aid in the defatting process and prevent bacterial contamination (Ioi 2013, Djordjevic et al. 2015). The casing then undergoes the sliming process (the removal of one or more layers of the intestinal lining) to increase the flexibility and permeability of the process casing (Ioi 2013, Djordjevic et al. 2015). The degree of the sliming process (number of intestinal layers removed) is dependent on the source of the intestine as well as the desired application (type of meat product) for the casing (Ioi 2013, Djordjevic et al. 2015). The casing undergoes subsequent washes with salt water to remove impurities and residual blood (Savic and Savic 2002). If not used immediately, the casings are cured by treatment with salt, and are dried to increase their shelf life (Savic and Savic 2002, Ioi 2013, Djordjevic et al. 2015). Following the drying process, natural casings are washed in water, then soaked (in water) for 3 – 5 hours prior to use in sausage production to remove excess salt content and increase the flexibility of the casing (Ioi 2013, Djordjevic et al. 2015). Moreover, the addition of dilute (~2%) organic acids (e.g., lactic acid) to the water acts to further increase the elasticity of the casing (Djordjevic et al. 2015).

Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a chemical process or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.

Collagen is a naturally occurring protein that is prevalent in animal skins, bones, muscle, and connective tissues (Kim and Mendis 2006, Sahithi et al. 2013, Oechsle et al. 2014, Marousek et al. 2015). Collagen is isolated from agricultural livestock sources, primarily of hog and cattle origin (Karim and Bhat 2008, Oechsle et al. 2017). However, with the rise of bovine spongiform encephalopathy (BSE), also known as foot-and-mouth-disease in the 1980s, there has been increased interest in alternative collagen sources (Sadowska et al. 2003, Kim and Park 2004, Karim and Bhat 2008, Oechsle et al. 2017). Collagen is typically isolated via an acid catalyzed hydrolysis of the protein-amide backbone (Savic and Savic 2002, Sadowska et al. 2003, Kim and Park 2004, Kim and Mendis 2006, Barbut 2010, Mohammad et al. 2012). The isolated collagen source is decalcified and homogenized before the fibers undergo further denaturation and "swelling" from acid treatment (typically hydrochloric (HCl) or sulfuric (H_2SO_4) acid) before the extrusion process to form manufactured casings, or coextrusion to form a non-removable edible film (Rantanavaraporn et al. 2008, Barbut 2010, Ioi 2013).

Gelatin is manufactured by additional processing of collagen, specifically through denaturation of the protein using heat and/or changes to pH. These changes disrupt the native-state structure of protein, causing the helix to partially unwind (de Wolf 2003, Schrieber and Gareis 2007, Karim and Bhat 2008). Upon cooling, new interactions between the unwound strands are formed, resulting in gelation of the mixture (de Wolf 2003, Schrieber and Gareis 2007, Karim and Bhat 2008).

Casings are produced from the processing of animal intestines. They are isolated following the slaughter of the animal, and undergo several washes, defatting, sliming, and curing procedures to yield the completed casing (Ioi 2013, Djordjevic et al. 2015).

Due to the common animal sources (bovine, porcine) for all substances, and the additional marine sources of collagen gel and gelatin, all substances can be considered as derived from agricultural sources (Sadowska et al. 2003, Kim and Park 2004, Djordjevic et al. 2015, Wu et al. 2017).

Evaluation Question #3: If the substance is a synthetic substance, provide a list of non-synthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

Collagen is a naturally occurring and abundant animal protein that is isolated from livestock and maritime (fish) sources (Sadowska et al. 2003, Kim and Park 2004, Karim and Bhat 2008, Oechsle et al. 2017). 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 (Rantanavaraporn et al. 2008, Barbut 2010, Ioi 2013). Due to the natural prevalence and low cost of natural animal sources, the petitioned substance is not manufactured on an industrial scale.

Gelatin is not a naturally occurring substance and is obtained by denaturing the protein collagen. The denaturing process occurs through the treatment of collagen with heat and/or changes to pH (de Wolf 2003, Schrieber and Gareis 2007, Karim and Bhat 2008). These denaturing processes disrupt hydrogen bonding and other native state protein interactions and result in the partial unwinding of the helical structure of the collagen protein (de Wolf 2003, Schrieber and Gareis 2007, Karim and Bhat 2008). Upon cooling, some of these interactions are re-established in gelatin, although in an altered chemical structure compared to the original protein, resulting in the formation of a gel (Ross-Murphy 1992, Karim and Bhat 2008, Yang et al. 2016, Hassan et al. 2018). While a wide range of gelatin alternatives have been explored, none have been identified as a full replacement for the versatile substance (Karim and Bhat 2008).

Casings are obtained through the processing of animal intestines and can be considered non-synthetic. Casing production includes: several washes, defatting of the intestine, sliming (removal of intestinal layers), subsequent washes, and finally drying and salting of the processed intestine (Barbut 2010, Ioi 2013, Djordjevic et al. 2015).

Evaluation Question #4: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.

Collagen has not been granted GRAS status by the FDA at 21 CFR Parts 182, 184, or 186. However, collagen, in the form of pork collagen appears on the FDA's "GRAS Notice Inventory," at GRN No. 21, with an intended use "in meat products as a binder and purge reducing agent at levels of 1.0 to 3.5 percent." The FDA has responded to the manufacturer notification with a letter containing no questions.

Gelatin has been granted GRAS status by the FDA for "substances migrating from cotton and cotton fabrics used in dry food packaging," at 21 CFR 182.70. Moreover, gelatin is generally recognized as safe (GRAS) when used "to clarify juice or wine," at 27 CFR 24.246.

Casings have not received GRAS status. The production of casings from bovine sources must be compliant with the guidelines outlined at 9 CFR 310.22 to demonstrate the risk evaluation of the cattle source for bovine spongiform encephalopathy (BSE), as stipulated at 9 CFR 318.6.

Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).

The primary use of collagen is not to act as a preservative. However, when used as petitioned, collagen would be applied to the sausage batter, and upon processing would act as an edible film encasing the sausage (Hoogenkamp 1994, Frye 1996, Yang et al. 2016, Hassan et al. 2018). Once established, the collagen casing is fused to the sausage batter and acts as a barrier to the movement of gases, moisture, solvents, and biological contamination, collectively preserving the product and extending its shelf-life (Frye 1996, Debeaufort et al. 1998, Marousek et al. 2015, Aloui and Khwaldia 2016, Hassan et al. 2018). The preservative characteristics of the collagen gel casing are also attributable to natural casings, which likewise act as a barrier for the migration of solvents, gases, moisture, solvents, and biological contaminants (Ioi 2013, Djordjevic et al. 2015). Like collagen gel and casings, gelatin does not function primarily as a preservative; however, it does have the ability to encapsulate a food product. This additional barrier provides some degree of enhanced protection from biological contamination and may extend the shelf life of the encapsulated food product (Hood 1987, USDA 2002).

Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

The primary use of collagen is not for the improvement of flavors, colors, textures, or nutritive values lost in processing. However, collagen gel applied to sausage manufacture via coextrusion has been reported to influence the organoleptic properties of the final product (Savic and Savic 2002, Han and Gennadios 2005, Vasconez et al. 2009). Likewise, the type, thickness, treatment, and permeability of natural casings influence the organoleptic properties of the sausage product (Barbut 2010, Harper et al. 2012, Ioi 2013, Djordjevic et al. 2015). Moreover, the formulation of the collagen gel and post application processes to the extruded sausage have been shown to affect the coloration and flavor profile of the final product (Savic and Savic 2002, Han and Gennadios 2005).

Gelatin is used in a wide range of applications within the food industry. One such application is as a texturizing agent (USDA 2002). Gelatin's mode of action as a texturizing agent is in the formation of thermally reversible gels, whose lower than body temperature ($<35\ ^{o}C$) thermal stability results in a "melt-in-mouth feel" (Karim and Bhat 2008). This property is due to the formation of new, but weaker hydrogen bonding and cross-linking interactions between unwound strands of the denatured collagen protein (gelatin). The structure of gelatin differs from the native state of the previous collagen protein, and the newly formed interactions are sufficiently weak to be disrupted at relatively low temperatures, which allow for unique textural changes upon ingestion of the gelatin-containing food product (USDA 2002, Karim and Bhat 2008).

Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).

Collagen is petitioned for use as a sausage casing applied via coextrusion with the sausage batter. The collagen gel applied in the coextrusion process is isolated from the animal protein collagen, found in skin, bones, blood vessels, muscle, and connective tissue (Kim and Mendis 2006, Sahithi et al. 2013, Oechsle et al. 2014, Marousek et al. 2015). Like all other proteins, the coextruded collagen casing is formed from, and would be metabolized to amino acids, the building block of human proteins and other biologically important molecules (Kim and Mendis 2006, Hassan et al. 2018). However, when used as petitioned, the coextruded collagen casing would account for approximately 0.15 – 0.25% of the finished product, making the nutritional contribution of the collagen negligible (USDA 2018). Like collagen gel, casings are primarily composed of collagen and would contribute to a small portion (<1%) of the final product, and as such, are unlikely to influence the nutritional content of the final food product.

Gelatin provides little nutritional and protein quality, primarily due to the absence of the amino acid tryptophan, and deficiencies in the amino acids isoleucine, threonine, and methionine (Potter and Hotchkiss 1998, USDA 2002). Based on the documented low nutritional value of gelatin, the effect of its addition to food products would be negligible.

Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 (b)(5)).

There are no published reports of heavy metals and other contaminants present in formulations of collagen gel and casings. However, gelatin has been reported as having the potential for contamination by chromium and pentachlorophenol, depending on the initial source of collagen (Food and Nutritional Board 1996).

Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

There are no published studies on the environmental persistence or impacts to biodiversity of collagen gel, gelatin, or casings. However, collagen and gelatin have been widely incorporated into a range of industries, including food and medicine, and are widely regarded as biocompatible and biodegradable (Schrieber and Gareis 2007, Karim and Bhat 2008). Based on the natural abundance of collagen (the primary component of collagen gel, gelatin, and natural casings), and its historic use in industrial settings, it is not anticipated to have a negative impact on the environment or biodiversity.

The primary source of collagen gel and natural casings is from treatment of livestock and fish byproducts, making its production unlikely to increase waste (Karim and Bhat 2008, Mohammad et al. 2012, Marousek et al. 2015). Conversely, the manufacture of collagen may result in reductions to livestock and fish wastes. This has been especially true for the treatment of fish byproducts, which were commonly dumped into the ocean before they began to be utilized for a source of collagen (Ciarlo et al. 1997, Kim and Park 2004, Kim and Mendis 2006, Mohammad et al. 2012). Since gelatin is produced by the denaturing of collagen, the previous discussion applies to both collagen gel and gelatin.

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

Collagen is a naturally occurring protein in humans and a range of other animals. There have been no published studies on the impact of collagen and gelatin on human health. However, collagen and gelatin have been widely incorporated into a range of industries, including food and medicine, and are widely regarded as biocompatible and biodegradable (Schrieber and Gareis 2007, Karim and Bhat 2008). Based on the natural abundance of collagen, and its long use in industrial settings, it is not anticipated to have a negative impact on human health. Since the primary component of natural casings is the protein collagen, the previous discussion also applies to casings.

Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

The manufacturing process for sausages requires a casing to provide structure to the encased meat product, and to regulate the movement of gases, moisture, solvents, and flavorings in and out of the sausage (Savic and Savic 2002, Barbut 2010). Moreover, the casing provides protection from biological contaminants and a mechanism for the delivery of texture and flavoring agents (Savic and Savic 2002, Han and Gennadios 2005, Vasconez et al. 2009).

Evaluation Question #12: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

There are two main alternatives to the petitioned substance and coextruded casings in general. These are the traditional sausage casings, both natural (digestive tubing) and manufactured (regenerated casings from collagen, cellulose, and other materials) (Hoogenkamp 1994, Rantanavaraporn et al. 2008, Harper et al. 2012, Ioi 2013). The use of certified organic livestock digestive tubing for natural casings is allowed under USDA organic regulations as well as nonorganically produced casings from processed intestines (7 CFR 205.606). Manufactured (regenerated) cellulose casings (classified as synthetic) are also allowed under USDA organic regulations at 7 CFR 205.605(b) in “organic” or “made with organic” products.

Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b) (1)).

Organic livestock digestive tubing (i.e., derived from organic livestock and handled organically) for natural casings is an alternative to nonorganically produced casings from processed intestines and for other casings (e.g., regenerative casings). It is possible to isolate both collagen and gelatin from wholly organic sources (using only organic livestock sources), demonstrated by bovine and porcine collagen and gelatin products that have been labeled as “organic,” with certifications from the USDA and Australian authorities (Changing Habits 2018, Gel-pro 2018, Vital Proteins 2018).

Report Authorship

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