Gelatin

processing

Executive Summary

The NOSB was petitioned to consider gelatin derived from fish used to clarify tea. Gelatin can be made from many different sources of collagen. Cattle bones, hides, pigskins, and fish are the principle commercial sources. As such, it may come from either agricultural or non-agricultural sources. Gelatin is also used as a fining agent in wine, and as a stabilizer, thickener, and texturizer for a range of products. Gelatin can be used as either a processing aid or an ingredient. In some cases, gelatin will comprise over 5% of a food.

Gelatin may be prepared in a way that is more like cooking and could be considered nonsynthetic. However, gelatin may also be processed in ways that would render it synthetic. Some forms are chemically modified (e.g., cross-linked) or possibly involve the use of substances derived from genetically modified organisms. These forms and processes are considered excluded from this review. Irradiated gelatin is also not covered. Gelatin is often combined with other ingredients. Each of these other ingredients would either need to appear on the National List or be from an organic source to be used in a product labeled as 'organic.'

Unprocessed fish bladders, known as isinglass, are a possible substitute for more processed gelatin and may want to be considered for a separate listing. Isinglass is covered under the current TAP review, although this is technically a different substance from gelatin.

Two Reviewers recommended that gelatin be added to the National List. One recommended that it be prohibited for use in organic processing and handling.

Identification

Chemical Name: gelatin

Other Names:
bovine gelatin (type B gelatin), fish gelatin, porcine gelatin (type A gelatin), food-grade gelatin, edible gelatin, kosher fish gelatin, dried fish gelatin, bloom fish gelatin, HMW fish gelatin, isinglass(?), gelatine.

Trade Names (selected list):
Gelfoam, Puragel, Norland Fish Gelatin, Gel-caps, Emagel, Gelafusal, Gelatine, Gelita Sol E Gelita-Collagel, Gelita-Sol P, Gelita-Tec,Gelodan G, Gelofusine, Gelrite, Glutins (gelatins), Grindsted G GX 45L404, IK, IK (gelatin), K 16096, K 7598, Knox Unflavored Gelatin, KV 3000, KV 3000 (gelatin), KV 3029, M 394, M 396, M 400 (gelatin), MGP 9066 Neosoft GE 82, Nikkol CCP 4, Nitta 750, Nittait GF 600A, Calfskin Gelatin, Crodyne BY-19, Flavorset® GP-2, Flavorset® GP-3, Gummi Gelatin P-5, Gummi Gelatin P-7, Gummi Gelatin P-8, Margarine Gelatin, Quickset® D-4, Spa Gelatin, Tenderset® M-7, Tenderset® M-8, Tenderset® M-9; Biofine P-19® (isinglass), Hausengranulat Drifine® (isinglass).

CAS Number: 9000-70-8

Other Codes: EINECS 2325546

Summary of TAP Reviewer Analysis[1]

Agricultural / Non-agricultural	**Synthetic / Non-Synthetic:**
From fish: Non-agricultural (3-0) *Isinglass* Non-agricultural (3-0) *From cattle bones:* Agricultural (2-1) *From tanned cattle hides:* Non-agricultural (3-0) *From pigskins:* Agricultural (2-1)	*From fish treatd with food acids:* Non-synthetic (2-1) *Isinglass:* (Not considered gelatin) Non-synthetic (2-1) *From cattle bones:* Non-synthetic (2-1) *From tanned cattle hides:* Synthetic (3-0) *From pigskins:* Non-synthetic (2-1)

95% organic

Allowed or Prohibited:	***Suggested* Annotation:**
Allowed (2) *Prohibited* (1)	(1) From animal bones and animal skins prepared with agricultural products and items on the National List (7 CFR 205.605) and not chemically modified. (2) Allowed with the exception of hard gelatin capsule applications. No sulfur dioxide or hydrogen peroxide allowed in the process. (3) Prohibited without annotation.

made with organic

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Characterization

Composition:

Gelatin is a heterogeneous mixture of water-soluble proteins of high molecular weight (Budavari, 1996). On a dry weight basis, gelatin consists of 98 to 99% protein. The molecular weight of these large protein structures typically ranges between 20,000 and 250,000 (Kennan, 1994), with some aggregates weighing in the millions (Poppe, 1997).

Coils of amino acids are joined together by peptide bonds. The predominant amino acid sequence is Gly-Pro-Hyp (Poppe, 1997). As a result, gelatin contains relatively high levels of these amino acids: glycine (Gly) 26-34%; proline (Pro) 10-18%; and hydroxy proline (Hyp) 7-15% (Veis, 1964; Poppe, 1997). Other significant amino acids include: alanine (Ala) 8-11%; arginine (Arg) 8-9%; aspartic acid (Asp) 6-7%; and glutamic acid (Glu) 10-12%. (Hudson, 1994; Poppe, 1997).

Gelatin is not a nutritionally complete protein. It contains no tryptophan and is deficient in isoleucine, threonine, and methionine (Potter and Hotchkiss, 1998). The other sulfur-containing amino acids—cysteine and cystine—are deficient or absent as well. Percent of water will vary between 6 to 9% (Alais, 1991; US FDA, 1997a). Ash content is 0.1 to 3.25% (Veis, 1964).

Properties:

Gelatin is nearly tasteless and odorless (Food Chemicals Codex, 1996). Physical and chemical properties noted: colorless or slightly yellow, transparent, brittle, odorless, tasteless sheets, flakes, or powder; soluble in hot water, glycerol, and acetic acid; and insoluble in organic solvents (Budavari, 1996). Gelatin swells and absorbs 5-10 times its weight of water to form a gel in aqueous solutions between 30-35°C. Gelatin extracted from fish will have a gel point in the range of 5-10°C. (Food Chemicals Codex, 1996). These gels have increasing viscosity under stress (thixotrophic) and are thermally reversible. Gelatin has a unique protein structure that provides for a wide range of functional properties (Hudson, 1994). These proteins form a compound (triple) helix in aqueous solution (Veis, 1965).

[1] *This Technical Advisory Panel (TAP) review is based on the information available as of the date of this review. This review addresses the requirements of the Organic Foods Production Act to the best of the investigator's ability, and has been reviewed by experts on the TAP. The substance is evaluated against the criteria found in section 2119(m) of the OFPA [7 USC 6517(m)]. The information and advice presented to the NOSB is based on the technical evaluation against that criteria, and does not incorporate commercial availability, socio-economic impact or other factors that the NOSB and the USDA may want to consider in making decisions.*

Gelatin is amphoteric (Budavari, 1996), meaning that it is neither acidic nor alkali, but possesses both properties depending on the nature of the solution. The pH at which gelatin's charge in solution is neutral is known as the isoelectric point. The isoelectric point of gelatin ranges between 4.8 and 9.4, with acid processed gelatins having higher isoelectric points than alkali processed gelatins (Poppe, 1997).

Gelatin forms a gel at a minimum concentration of 0.5% through the pH range of 4 through 8. The pH in water solutions for type A is between 4.5 and 6, and the pH range for type B is from 5 to 7 (see below for types) (US FDA, 1997a). Bloom is an ascending index used to measure gel strength (Bloom, 1925). Commercial gelatin will vary from 90 to 300 grams Bloom (Igoe, 1983).

In addition to origin, fish gelatin is distinguished from beef or pork gelatin by its low melting point, low gelation temperature, and high solution viscosity. These physical properties are not as strongly correlated to Bloom strength (Leuenberger, 1991). One study found fish gelatin to have similar physical and chemical properties compared to porcine gelatin and to be rated superior in a blind sensory test (Choi and Regenstein, 2000).

How Made:
All manufacturing operations extract and hydrolyze collagen found in fish skins, bovine bone, and porcine skin with subsequent purification, concentration, and drying operations. These can be either simple or complicated operations.

Gelatin is formed during the simple cooking of meat, particularly in low-quality cuts that are high in collagen (Foegeding, et al., 1996). Collagen is an important product of rendering cattle and hog slaughter by-products (Boehme, 1982). Fish swim bladders are often simply dried to make isinglass (Ockerman, 1991; Leather et al., 1994; Hickman et al., 2000). Various applications will require certain specific sources, or processing steps, to achieve certain functionalities or grades. Some may be based on religious preference—e.g., porcine gelatin is forbidden for Halal or Kosher. Others depend on additional processing steps that provide an appropriate type, strength, viscosity, and water-absorption capacity. Comestible grades are selected based on (neutral) flavor and texture (Choi and Regenstein, 2000).

Genetically engineered sources of collagen and gelatin are also being researched. At the present time, most of the research appears to involve transgenic animals that produce human collagen for grafting (Ferguson, 2001; Fibrogen, 2001). One patented source of recombinant human collagen is expressed in milk of non-human animals (Berg, 1997). These are intended for therapeutic and medical use to replace damaged human tissue. Another patent claims that collagen-like polypeptides are produced by yeast as the host organism (Weber and Herz, 1998). This would be suitable for conversion to gelatin, although it might also be considered a gelatin substitute. The intended application is for photography. At present, it is unclear whether any GMO sources of collagen are commercially available.

Fish Gelatin Process
Gelatin is extracted from fish skins (Kosher) with heat and water and acetic acid (the acid found in vinegar) to control pH. The soluble extract is filtered, concentrated by evaporation, dried, and milled into standard particle size (40 mesh), then blended and packaged (Kenney and Ross, no date). Various other food acids can be used, such as citric or lactic (Gómez-Guillén, M.C. and P. Montero. 2001). The source of the fish, including species and whether farmed or wild-caught, was not specified. Various species may be used, and a number of these species may be farmed. Alkali hydrolysis may speed the process and increase Bloom strength, but alkali does not appear to be used in the manufacture of most fish-based fining gelatins. Sodium hydroxide appears to be the alkali of choice used by the exceptional alkali processors.

Isinglass
When fish bladders are dried, this forms a substance known as 'isinglass.' The bladders can come from either wild-caught or farmed fish. Sturgeon (Ockerman, 1991), channel catfish (Eun, Chung, and Hearnsberger, 1994), and tilapia, megrim, cod, and tuna (Gilsenan and Ross-Murphy, 2000) have all been used at various times. Commentators differ as to whether isinglass is a gelatin or a raw collagen. One food science reference defines isinglass as "[a] refined *gelatin* obtained from the collagen of the outer layer of the dried swim bladder of a fish (e.g., sturgeon) and used as an edible jelly, to preserve eggs, and for clarifying wine and beer" (Ockerman, 1991, emphasis added; see also Light, 1989). Other sources consider it to be raw collagen, but indicate that the collagen can be turned into gelatin simply by heating, without a synthetic chemical reaction (Hickman, et al., 2000). Adding fruit juice and various spices, heating, cooling, and filtering can also reduce isinglass to a stable, consistent gelatin (Cooper, 1845). Isinglass is unique among collagens in that it possesses many of the chemical and functional properties of gelatin without being denatured by processing with synthetics. Many common tests are unable to distinguish whether isinglass is a collagen or a gelatin. One study prepared a denatured gelatin from isinglass by treatment in a waterbath at 60°C. (140°F.) (Leather, et al., 1994).

(Note: In 1995, the NOSB received a petition for isinglass that it did not refer to the TAP for review.)

Acid Pretreatment Process or Porcine Gelatin (Type A Gelatin)

Acid pretreatment is invariably used for porcine gelatin. Pigskins are first dehaired, usually by a combination of steam, rubber paddles, and flame (Farmer, et al., 1982). The pigskins may then be degreased by various methods, such as centrifuged in a rotating drum heated with steam to temperatures between 60° and 65° C. or approximately 150°-160°F. (Hinterwaldner, 1977a). Petroleum-based solvents such as tetrachloroethylene (TCE) may also be used to degrease animals, but this is less common than steam and mechanical methods because of safety and environmental issues (Norris, 1982). Hydrogen peroxide may be used to remove grease passed through a chopper or macerator to cut the skin into uniform sizes (Keenan, 1994). The skins are then soaked at a pH of 1 to 4 with a food-grade mineral acid such as hydrochloric (HCl), phosphoric (H_3PO_4), or sulfuric (H_2SO_4) acid for 8 to 30 hours (Hinterwaldner, 1977b; Keenan, 1994; Cole, 2000; Ledward, 2000). This treatment causes the material to swell to two to three times its pre-treatment volume (Ledward, 2000). The acid-treated pigskins are then washed with water to remove impurities. The skins are then extracted with hot water and the extract is filtered through an anion-cation exchange column to reduce ash or mineral levels. The gelatin extract is vacuum concentrated or ultra filtered to a concentration of between 15 and 35%, filtered, pH adjusted to between 3.5 and 6, evaporated to 50% solids, sterilized at temperatures between 248-303°F. for up to 13 seconds, chilled and extruded into noodles approximately 1/8 inch diameter, dried through a multi zone oven at 158°F., and milled to the specified particle size and packaged (Hinterwaldner, 1977a). Acid pretreatment is sometimes used for beef ossein, but this is relatively uncommon (Rose, 1990).

Alkali Process or Bovine Gelatin (Type B Gelatin)

Bovine gelatin is obtained from collagen from cattle, primarily hides and bones. In the U.S., 98% of the bone used for gelatin extraction is obtained from USDA inspected plants and 2% is obtained from Argentina (US FDA, 1997a). If chromium-tanned hides are used, steps are taken to remove the chromium from the hides (Rose, 1990). Because of the mineral content of bones, a great deal more processing time is needed (Stainsby, 1987). The bone is crushed, cooked at 180-250°F., centrifuged, and dried at 160-270°F. This extracted bone is degreased prior to gelatin manufacture. The degreased bone meal is de-mineralized with 4-6% HCl for a period of 5 to 7 days. Shorter times can be achieved by continuous processes (Garono, et al., 1956). The de-mineralized bone is now called ossein. The ossein is washed with multiple rinses of water to remove impurities. The next step is called the liming process where ossein is treated with a 1 to 4% lime (calcium hydroxide) slurry to adjust the pH to 12 to 12.7 for periods from 35 to 70 days, with agitation and weekly lime changes to remove all non-collagen components. The ossein is then washed at the rate of 50 to 100 lb. of water per pound of gelatin. During the wash process, a mineral acid is added (HCl or H_2SO_4) to neutralize excess lime and to adjust the pH to 3. The final pH after all wash operations is between 5 and 7. Gelatin is then extracted from the ossein by de-mineralized hot water extraction. To further remove impurities, the liquid gelatin solution may be filtered through a cellulose/diatomaceous earth plate and frame filter and de-ionized using an anionic-cationic resin bed. The gelatin solution is evaporated to a concentration between 15 and 45%. The concentrated gelatin is filtered, pH adjusted to between 5 and 7, and sterilized between 280-290°F. for 8 to 12 seconds, cooled, and hot air dried for periods of 1 to 3 hours. It is then milled to 80 to 30 mesh size and packaged (US FDA, 1997a). The alkaline process may take up to 20 weeks (Poppe, 1997).

Enzymatic Process

Collagen resists proteinase attack, but a number of collagenase enzymes have been isolated (Cole, 2000). Several processes have been developed to produce gelatin by the use of naturally occurring enzymes (e.g., Vernon, Glass, and Weaver, 1939). Proteolytic enzymes such as pepsin and pronase are often used in conjunction with chemical treatment methods to increase the efficiency and reduce processing time for Type A gelatin (Hinterwaldner, 1977b). An early approach to process collagen into gelatin without mineral acids or bases involved the sterilization of pigskins with hydrogen peroxide, followed by the introduction of a yeast culture, such as baker's yeast or brewer's yeast, along with a sugar as an energy source for the yeast (Keil, 1956). The yeast produced enzymes that digested the collagen, and converted that substrate to gelatin after being denatured. Since then, a more refined approach has been patented that introduces proteolytic enzymes produced by non-pathogenic bacteria, rather than the fermentation organisms (Petersen and Yates, 1977). Both sodium hydroxide and a bactericide were also used in the example, but was not claimed as essential to the process. Enzymatic methods to produce gelatin continue to evolve and have succeeded in demineralizing collagen from ossein with improved predictability of quality and yield (Rowlands and Burrows, 1998). Earlier TAP reviews on enzymes have noted the development of enzymes from genetically modified organisms.

Capsules

'Gelatin' capsules are made from gelatin and various other ingredients. These are manufactured by a number of different methods (see various patents, and Jones, 1987). The earliest reference to gelatin capsules makes no specific mention of any ingredients other than the medicines encapsulated (Cauhaupe, 1874). However, current gelatin capsule formulations contain a wide variety of other ingredients. Each ingredient needs to be addressed on its own merits. One of the earliest improvements was the addition of sodium carbonate to correct for stomach acidity (Heineman, 1891). At about the same time, it was discovered that formaldehyde (formic aldehyde) and other aldehydes can be used to harden gelatin capsules and enable them to pass from the stomach to the intestine (Weyland, 1899). A number of other ingredients have been introduced to harden both soft- and hard-capsules since that invention, but the most extensively studied has been formaldehyde (Jones, 1987). Improved methods to detect formaldehyde cross-linking are of interest because trace levels of formaldehyde may have an adverse effect on the capsule contents (Gold, et al., 2001a, and Gold, et al., 2001b).

Specific Uses:

Gelatin has a considerable number of applications and uses (Hudson, 1994; Keenan, 1994; Cole, 2000; Poppe, 1997; Ledward, 2000). The petitioned use is in foods as a beverage clarifier (Gass, 2001). Gelatin is also used as a fining agent for white wine (Vine, 1999), as a beer clarifier (Brewers Resource, 2001), and to clarify fruit and vegetable juice, especially for clarified apple juice (Tressler and Joslyn, 1954; Peterson and Johnson, 1978) and pear juice (Lee and Lee, 1999). Gelatin is used in desserts at 8 to 10% of the dry weight (e.g., Jell-O™), in yogurt at 0.3 to 0.5% as a thickener, in ham coatings at 2 to 3%, and in confectionery and capsules (vitamin supplements) at 1.5 to 2.5 % (Igoe, 1983). Further uses include fruit toppings for pastry, instant gravy, instant sauces and soups, edible films for confectionery products (McCormick, 1987), as a stabilizer in ice cream, cream cheese, and cottage cheese as well as in food foams and fruit salads (McWilliams, 2001). Overall functional uses include as a stabilizer, thickener, and texturizer.

Gelatin and animal glue are closely related (Torr, 1954; Keenan, 1994). Gelatin-based glues are also used as adhesives to put those little 'organic' stickers on fruits and vegetables. Gelatin is also used in prepared meat products such as canned ham, luncheon meats, turkey, and chicken rolls where it helps to maintain consistency and moisture (Rose, 1990). Textile applications include use as a sizing, coating, dressing, or finishing agent for cotton, leather, silk, and wool (Naghski, 1982).

Gelatin capsules (gel-caps) are commonly used to encapsulate various foods, nutritional supplements, and medicines (Ash and Ash, 1995). Various forms of gelatin are common excipients in pharmaceutical formulations, including vaccines, and are used as a binder for tablets (Zanowiak, 1996).

Action:

For juice applications, gelatin in combination with bentonite causes a dense precipitate or coagulum with soluble proteins in the juice, which facilitates the clarification process by allowing the protein haze to be filtered out from the juice. The petition states, "added directly to beverage in conjunction with other clarifiers to cause(s) binding of haze causing components which can then be filtered out along with the gelatin" (Gass, 2001).

Gelatin in aqueous food systems readily forms a hydrogen bond with water because of many exposed polar regions. As gelatin binds with water, it swells and absorbs water. It can then be dispersed in hot water and with other ingredients. The formation of a gelatin gel is endothermic and occurs gradually as the energy of the system dissipates. A surface film forms as some of the gelatin molecules cross link in a compact configuration. When the interior begins to gel, the molecules of gelatin are in random configuration. As gelation continues, a more organized arrangement evolves after storage. The gelatin gel is a dynamic colloidal dispersion and is subject to change (thixotrophy) and decreased tenderness during storage. As the concentration of gelatin increases, the rate of gelation also increases, thereby increasing the firmness and decreasing tenderness. If the concentration is too high, the texture becomes too firm and rubbery. An acceptable gel for most food systems can be formed with gelatin concentrations of between 1.5 and 4% (McWilliams, 2001).

When gelatin is used as a clarification agent for white wine, it is able to bind negatively charged tannins by gelatin's net positive charge in acidic solution. The two bind electrostatically and form an insoluble complex that can be filtered or gravity settled from the wine.

Combinations:

The literature is filled with references to combinations for gelatin. These are not necessarily used as ingredients in food, and may involve use for photography, textiles, or other non-food applications. All forms of gelatin may be subjected to further chemical treatment to change the functional, textural, or keeping qualities. The review below will focus on food uses, but will also make references to pharmaceutical applications given the need to consider the use of gelatin as an excipient / carrier for animal drugs, and the packaging of organic nutraceuticals and functional foods. Some non-food applications pose contamination concerns and are noted as control points for safe food-grade gelatin manufacture (Cole, 2000).

<u>Preservatives</u>

Dry gelatin, kept dry, can keep for years (Hinterwaldner, 1977b). However, under certain conditions, bacteria readily consume gelatin because it is pure protein. Hydrogen peroxide is also used (Cole, 2000; Ledward, 2000). Pentachlorophenol may be used for non-edible industrial-grade gelatin, but is prohibited for food-grade gelatin (Food Chemicals Codex, 1996). Isinglass may be packaged with tartaric acid to balance the pH and produce a positive charge; metabisulfite may be also used as a stabilizer (Quest, 2001). Gelatin may also be irradiated (9 CFR 424.21; see 21 CFR 179 for general provisions).

Fining Agents

The petition states, "…added directly to beverage in conjunction with other clarifiers" (Gass, 2001). Gelatin is combined with bentonite for juice clarification (Peterson and Johnson, 1978). Tannin is often added to apple juice and other juices with low tannin content (Tressler and Joslyn, 1954). Sugar as sucrose is frequently added to increase the set time of the gel.

Comestible Gelatin

Gelatin may also be irradiated. Agar is used with gelatin to create a phase-separated system that maintains the texture of meat and fish despite changes in room temperature (Stainsby, 1987). Sugar-gelatin mixtures can be directly added to hot aqueous liquids without preliminary hydration in cold water.

Capsules

Various plasticizing and hardening agents are added to the gelatin used to make capsules or microcapsules. Glycerol (glycerin) is a plasticizer most widely used to make soft gel capsules. Other plasticizers used with or instead of glycerol include various alcohols, propylene glycol, sucrose, and acacia (Ledward, 2000). Sorbitol is the most widely used alcohol, but other alcohols have been explored, including various polyethylene glycols (PEGs) (Hutchinson, et al., 1998), mannitol, ethylene glycol (Sano et al., 2001), and tetrafurfuryl alcohol (Brox and Gabler, 1990). Various starches can be used as disintegrants and to improve adhesion of a secondary coating (Hutchinson, et al., 1998). Hard capsules use aldehydes to cross-link and stiffen the structure of gelatin. Formaldehyde and glutaraldehyde are used as hardening agents for microencapsulation of flavors (Cole, 2000). Hard capsules rarely use a plasticizer (Ledward, 2000). The introduction of formaldehyde to the gelatin may involve an emulsification of lanolin and mineral (petroleum) oil (Palermo and McMillion, 1951). Capsules can also be coated with various substances to give a smooth finish, to increase dispersion and dissolution, for flavoring, and for identification. Various surfactants, such as various polysorbates, can be used to increase dispersion. Natural and artificial flavors and sweeteners can also be incorporated into the shells or coatings of gelatin capsules. Sucrose (sugar) has been the most widely used, but coatings may include acesulfame K, aspartame, and saccharin (Hutchinson, et al., 1998).

Status

Historic Use: The practice of consuming collagen films as edible gut parts of slaughtered animals, filled with their original contents or comminuted meat, dates to the ancient Babylonians and Homer's Odyssey in 800 B.C. (Hood, 1987). Gelatin, derived from collagen, was among the first commercial raw materials suitable as a contact preservative for meat and meat products. Several U.S. patents covering topical applications of gelatin were granted in the mid nineteenth and early twentieth centuries (e.g. Henley, 1872). Gelatin was also reported to be used in the earliest individual sausage casings in 1864 as a coating applied by dip treatment of textile or cotton bags or tubes (Hood, 1987). The technology for gelatin production intensified during the period of 1940 through the 1950's when commercial processes were developed and refined (Pearson and Bailey, 1985).

Gelatin was widely used in Europe to clarify juice, but because of difficulties in controlling use and the large amounts of sediments formed, use in the U.S. was limited (Tressler and Joslyn, 1954). Gelatin remains unpopular in fruit juice clarification because it creates a haze (Shaw, 1994).

Fish gelatin has been used to clarify coffee for over a century (Tucker, 1871). The literature contains few references to methods to clarify tea, including the use of gelatin. The use of gelatin to stabilize green tea extract and product was patented (Ekanayake, Kirksey, and Pultinas, 1995). Gelatin capsules have been used to encapsulate nutritional supplements as well as medications since at least the second half of the 19^{th} century (Cauhape, 1874).

OFPA, USDA Final Rule: Not mentioned in the final rule.

Regulatory: Meets USP and European Pharmacopoeia standards. FDA approved as GRAS.

EPA/NIEHS/Other Sources

EPA – Inert ingredients List 4A.

While gelatin and the collagen from which it is derived are both not considered hazardous, a number of the chemical agents used to treat the collagen to form gelatin are considered hazardous (US EPA, 1998b). Hydrochloric acid, sulfuric acid, and sodium hydroxide are all reportable under the Emergency Planning and Community Right-to-know Act (EPCRA) (EPA, 1998a).

NIEHS – (National Toxicology Program Database) no monograph on gelatin appeared on the day of the search (NTP, 2001). There were several cross-references about compounds combined with gelatin.

Hazardous components-none
Fire and explosion data- not applicable
Reactivity Data- stable
Conditions to avoid- none
Hazardous decomposition products- none

Other Sources – None found.

Status Among U.S. Certifiers

California Certified Organic Farmers, Oregon Tilth Certified Organic, and Washington State Department of Agriculture (WSDA) Organic Food Program — Not mentioned.

Organic Crop Improvement Association International (OCIA) — International Certification Standards, effective date July 1, 2001, 9.4.3 Processing Materials List: allowed as a processing production aid for fruits and vegetables and in winemaking.

Texas Department of Agriculture (TDA) Organic Certification Program — Organic Certification Program Materials List 2000; lists as gelatin waxes—may be used as an aid in processing organic fiber if removed by final scouring.

International

EU 2092/91 — Annex VI — Gelatin is listed under "Processing aids and other products which may be used for processing of ingredients of agricultural origin" in Section B and under "Ingredients of Agricultural Origin Which Have Not Been Produced Organically" in Section C.

Codex Alimentarius — Guideline for the Production, Processing, Labelling, and Marketing of Organically Produced Foods CAC/GL 32-1999, Table 2 Substance for Plant Pest and Disease Control, 1. Plant and Animal: listed. Table 4: Listed under "processing aids which may be used for the preparation of products of agricultural origin."

IFOAM — Basic Standards for Organic Production and Processing, September 2000, Appendix 4 List of Approved Ingredients of Non Agricultural Origin and Processing Aids Used in Food Processing, Processing Aids and Other Products: listed for use in fruit & vegetable products and wine.

Ministry of Agricultural, Forestry and Fisheries of Japan (MAFF) — Japan Agricultural Standard, Notification #60, Table 2 of food additives: allowed, with no annotation.

Canada — Canadian General Standards Board National Standard for Organic Agriculture (CAN/CGSB-32.310-99), June 1999: permitted as a clarifying agent.

Certified Organic Associations of British Columbia (COABC) — British Columbia Certified Organic Production Operation Policies and Farm Management Standards, Section 9.14 Processing and Handling Materials List, March 2001: non-hydrolysed or hydrolysed, regulated as a processing production aid; Either form of gelatin maybe used as a product processing aid, for now, but the producer must submit to the certifying agency written details of their search to replace the hydrolysed gelatin format with a non-hydrolysed gelatin or a completely different product. Allowed for fruits and vegetables and in winemaking.

Naturland, Germany — Listed in the August 1999 General Processing Standards in the "List of Permitted Ingredients, Additives, and Auxiliary Products" as "food gelatin without additives (exclusively for cream-like masses)."

Miscellaneous

Organic Grapes into Wine Alliance (OGWA) — Lists 'Fish based fining agents' and 'Non-hydrolized bone gelatin' as 'Tolerated clarifying materials.' 'Hydrolized gelatin' is prohibited.

Section 2119 OFPA U.S.C. 6518(m)(1-7) Criteria

1. *The potential of the substance for detrimental chemical interactions with other materials used in organic farming systems.*
   Fish, bovine, and porcine gelatin are used directly in value-added food products and juice and wine processing and therefore would not interact directly with other materials used in organic farming systems. The petition notes that the spent gelatin and bentonite are spread as fertilizer (Gass, 2001). There is no indication of detrimental interactions from this application.

2. *The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.*

There is no information available on the toxicity or mode of action of gelatin. Since gelatin is a protein, it can be readily broken down by proteolytic enzymes in foods such as papain, bromealin, and ficin, or in the stomach by pepsin or chymotrypsin to shorter chain peptides and amino acids. Chromium and pentachlorophenol from gelatin recovered from hides could be possible contaminants.

3. *The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.*
This is covered under processing criteria 2 below.

4. *The effects of the substance on human health.*
Fish gelatin may be contaminated with *Clostridium botulinum* and the consumption of fish gelatin has resulted in documented fatal cases of botulism (Miller, 1975). These incidents do not appear to be related to gelatin prepared by Good Manufacturing Practices.

Another human-health concern is allergenicity to gelatin. Beef, pork, and fish gelatin all have been reported to cause allergenic reactions (Sakaguchi, Hori, Ebihara, et al., 1999). Fish proteins can cause allergic reactions at very low levels (Aas, 1966). Although no allergic reactions to fish gelatin in processed, packaged foods have been documented, some caution is noted in labeling foods that contain gelatin (Taylor and Hefle, 2001). Fish-sensitive patients exposed to fish gelatin had allergic reactions. Gelatin labeling may be required for certain products even if the product contains only incidental amounts of an allergen (Taylor & Hefle, 2001). Fish vary by species in their allergen composition and the reactivity of sensitive patients (de Martino, et al., 1990). The use of gelatin as an excipient in various vaccines and medications may result in immediate severe allergic reactions—including anaphylactic shock—when the vaccinations are administered to patients who have recently eaten food containing gelatin (Sakaguchi, et al., 1996; Wahl and Kleinhans, 1989; Kelso, et al., 1993). Reactions were noted with both bovine gelatin (Sakaguchi, Hori, Ebihara, et al., 1999; Sakaguchi, Hori, Hattori, et al., 1999) and fish gelatin (Sakaguchi, Toda, et al., 2000). The commercialization of soft, chewy (gummi) candies increased gelatin consumption world-wide beginning around 1992 (Keenan, 1994). The increase in reactions to gelatin as an excipient in vaccines administered in Japan may be related to but not entirely explained by an increase in the consumption by children of candy that contains gelatin (Nakayama, Aizawa, and Kuno-Sakai, 1999). Adult patients have had similar reactions (Sakaguchi, Kaneda, and Inouye, 1999).

Finally, the most recent human health concern to arise from gelatin use has been the possible transmission of spongiform encephalophathy (Mad Cow Disease) from infected animals through the production and manufacturing operations (US FDA, 1997a). The FDA has not concluded that there is a potential risk to humans from BSE transmitted from infected bovine animals through gelatin, but has prohibited using sources of animal by-products for gelatin manufacture if those sources were obtained form BSE positive countries. Conclusions drawn from this study indicate that no sources of bovine or porcine animal by-products from countries where there have been outbreaks have been used for gelatin manufacturing. Since in the U.S. 98% of all bovine gelatin is obtained from USDA Food Safety Inspection Service (FSIS) inspected plants and 2% from Argentina, risk is very minimal on the transmission of this disease via gelatin manufacture. The FDA now requires a certificate of origin for gelatin coming in from non-BSE affected countries and the certificate of origin must be endorsed by the veterinary service of the country where the gelatin is manufactured, relating to the species and processing of the gelatin. Additionally, there have been a few studies conducted to determine if the infectious agent (prion) can retain its biological activity after undergoing process manufacturing conditions since there is no diagnostic method available other then direct inoculation. To date, all reported cases of BSE have been bovine in origin, with no reported cases derived form porcine or fish. BSE concerns have led manufacturers to replace bovine gelatin with other hydrocolloids (Ledward, 2000).

5. *The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock.*
Gelatin is a food ingredient and is not applied to the soil or otherwise released into the agroecosystem, except as an inert ingredient and carrier in various formulations.

6. *The alternatives to using the substance in terms of practices or other available materials.*
See processing criteria 7 below.

7. *Its compatibility with a system of sustainable agriculture.*
See processing criteria 6 below.

Criteria From the February 10, 1999 NOSB Meeting

A PROCESSING AID OR ADJUVANT may be used if:

1. *It cannot be produced from a natural source and has no organic ingredients as substitutes.*

Gelatin is not found in nature, but is derived from collagen, a naturally occurring protein (Budavari, 1996). One possible exception may be undenatured isinglass (Ockerman, 1991) or isinglass that has been denatured by thermal treatment (heating) (Hickman, et al., 2000). It is not clear if organic collagen is commercially available, but it would ordinarily be considered an agricultural commodity. Since gelatin is a purified, extracted protein if derived from certified organic animals, its organic integrity would need to be evaluated as a function of process operations. Kosher fish skins, prepared with natural acids, and isinglass may be considered natural sources. However, collagen—a natural protein—is converted to a biologically different protein, gelatin, by cooking. The other ingredients used in preparation may be nonsynthetic or synthetic.

2. *Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA.*

As a slaughter product, gelatin creates a number of environmental impacts related to meat production. The major consideration during the manufacture of all forms of gelatin is the large amount of process waste effluents generated during manufacturing, which would contain mineral components and lipid material (Hinterwaldner, 1977). This creates a high biological oxygen demand (BOD). Waste effluents would be alkaline or acidic. Gelatin recovered from leather tanning operations may generate chromium contaminated waste. Irradiation with gamma rays may involve the use of radioactive material.

Gelatin capsules may involve the use of polyacrylamide, various aldehydes such as formaldehyde or glutaraldehyde, and other synthetic compounds to harden and cross-link the structures to make the capsules rigid.

3. *If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.*

Gelatin is notable for its low nutritional value and poor protein quality, and is often used as a textbook example for that purpose. It is one of the few foods that has a negative protein efficiency ratio (PER). That is, the test animals (rats) lost weight per gram of protein in the form of eaten gelatin (Johnson and Peterson, 1974). This anomaly is attributed to the fact that gelatin contains no tryptophan, and is deficient in isoleucine, threonine, and methionine (Potter and Hotchkiss, 1998). During the 1970s, the low protein quality of collagen-based 'Liquid Protein' diet products led to Federal regulatory action (Vanderveen and Mitchell, 1981). The Food and Drug Administration investigated the deaths of 17 relatively young people, 13 with diets whose sole caloric intake came from a liquid collagen or gelatin solution. The FDA subsequently developed regulations that modified the label requirements of such diet products (US FDA, 1990).

Despite its low nutritional value, gelatin is not considered hazardous by applicable government regulations. It is considered a food rather than a food additive. This covers all three forms of gelatin--fish, bovine and porcine. Also see OFPA criteria 4, above.

4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.*

The primary use of fish gelatin as described in the petition is for use as a processing aid to be used in combination with bentonite to clarify the haze found in tea (Gass, 2001). Gelatin also has a significant number of additional food uses based on its protein functionality in gelation, water binding, emulsification, adhesion, film formation, cyrstallization control, thickening and stabilization, whipping and foam generation, other beverage fining, and glaze formation (Hudson, 1994). Gelatin appeared to be 'among the first commercial raw materials suitable as a contact preservative for meat and meat products' (Henley, 1872; Hood, 1987). Certain applications of gelatin are textural in nature, such as use as an ingredient in confectionary and jelly desserts (Poppe, 1997), in yogurts and other dairy products (Ledward, 2000), and as a thickener in soup (Cole, 2000). Gelatin is particularly prized over possible substitutes for its texture and mouth-feel (Stainsby, 1987).

5. *Is Generally Recognized As Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.*

The FDA recognizes gelatin as "Generally Recognized as Safe" (GRAS). Because gelatin is considered a food, rather than a food additive, it is GRAS by prior approval. Gelatin is listed as GRAS under 21 CFR 182.70, 'substances migrating from cotton and cotton fabrics used in dry food packaging.'

The FDA references to gelatin include:

FDA References to Gelatin	
21 CFR	**Title**
133.178	Pasteurized Neufchâtel cheese spread with other foods.
133.179	Pasteurized process cheese spread.
172.230	Microcapsules for flavoring substances.
172.255	Polyacrylamide.
172.280	Terpene resin.
182.70	Substances migrating from cotton and cotton fabrics used in dry food packaging.
Source: EAFUS, 21 CFR.	

Sulfur dioxide used as a biocide is often a contaminant (Cole, 2000). Chromium and pentachlorophenol are regarded as potential contaminants of food-grade gelatin (Food Chemicals Codex, 1996) due to the use of leather as a source of collagen (Rose, 1990).

Food Chemicals Codex requirements for gelatin are:
Identification:
A. Gelatin forms a reversible gel when tested as follows: Dissolve 10 g in 100 ml of hot water in a suitable flask, and cool at 2°C. for 24 h. A gel forms. Transfer the flask to a water bath heated to 60°C. Within 30 minutes, upon stirring, the gel reverts to the original liquid state.
B. To a 1 in 100 solution of the sample, add trinitrophenol TS or a 1 in 1.5 solution of potassium dichromate previously mixed with about one-fourth its volume of 3 N hydrochloric acid. A yellow precipitate forms.
Ash: Not more than 3.0%
Chromium: Not more than 10 mg/kg
Fluoride: Not more than 0.005%
Heavy metals (as Pb): Not more than 0.002%
Lead (as Pb): Not more than 1.5 mg/kg
Loss on drying: Not more than 15.0%
Microbial limits:
  E coli: Negative in 25 g.
  Salmonella: Negative in 25 g.
Pentachlorophenol limit: Not more than 0.3 mg/kg
Protein: the specification conforms to the representations of the vendor.
Sulfur dioxide: Not more than 0.005%.

Gelatin also has the potential to transmit pathogens. Fish gelatin from Alaska has plate-tested positive for *Clostridium botulinum* type E, a source of botulism (Miller, 1975). The Animal and Plant Health Inspection Service (APHIS) mandated a certificate of origin on all imported gelatin from non-BSE countries (9 CFR 94.18).

'Gelatin' capsules are GRAS conditional upon their other ingredients. Each of these would also need to be GRAS. Microcapsules used for flavoring may contain any substance that FDA recognizes as GRAS 'for the purpose' [21CFR 172.230(a)(1)]. The FDA also allows the following for microcapsules:

Substances Considered GRAS for use in Gelatin Capsules		
21 CFR	**Substance**	**Limitation**
172.230(a)(2)	succinylated gelatin	Succinic acid content of the gelatin is 4.5 to 5.5 percent.
172.230(a)(2)	arabinogalactan	Complying with Sec. 172.610; as adjuvant.
172.230(a)(2)	silicon dioxide	Complying with Sec. 172.480; as adjuvant.
172.230(a)(3)	glutaraldehyde	As cross-linking agent for insolubilizing a coacervate of gum arabic and gelatin.
172.230(a)(3)	n-Octyl alcohol	As a defoamer.
172.230(a)(4)	petroleum wax	Complying with Sec. 172.886. Not to exceed 50 percent by combined weight of the microcapsule and spice-flavoring substance.
172.255	polyacrylamide	Not more than 0.2 percent of acrylamide monomer may be safely used as a film former in the imprinting of soft-shell gelatin capsules when the amount used is not in excess of the minimum required to produce the intended effect.
172.280	terpene resin	As a moisture barrier for gelatin capsules, at a level not to exceed 0.07% of the weight of the capsule.

Source: EAFUS, 21CFR.

6. Its use is compatible with the principles of organic handling.

The petition is requesting approval for its use as a processing aid to form a gelatin-bentonite complex to bind with soluble protein extracted in the tea. The gelatin does not remain in the tea but precipitates out in the form of a complex and is not carried over in the final organic product. This is also true for application of gelatin in beer, juice, and white wine clarification. However, for many other uses in food systems gelatin would be present as a specific functional ingredient in that product formulation and would have to be listed on the label of the product. Increasing numbers of consumers of organic wine request wine fined without animal products, but in general production of wine to vegetarian standards is not considered a requirement (Elliot, 2000).

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.*
Gelatin has some unique functional properties that are similar, but not identical in a number of other gels. The long molecular strands and partially stacked triple helixes found in gelatin offer a strength and flexibility not found in, say, alginate, cornstarch, or carrageenan (Walstra, 1996). These vegetable-based substitutes lack the 'melt-in-the-mouth' and elastic properties of gelatin (Cole, 2000).

The petition states, "We have found a gelatin bentonite combination to work best in removing the haze causing proteins found in tea, while hot processing. In addition, gelatin fining can be used in conjunction with diatomaceous earth filtration which is less expensive and more versatile than membrane or ultra-filtration for the range of teas and botanicals that Tazo filters. Other clarifying agents that can be used are silica gel, and tannic acid. Tannic acid requires cold processing, and finding an exact-dosage is difficult. Silica fining agents require settling, and would also work best in conjunction with gelatin" (Gass, 2001).

Fruit juice clarification and fining wine can be carried out with enzymes, diatomaceous earth (Shaw, 1994), rice hulls, egg whites, bentonite clay, pectin, and cellulose. Pectolytic enzymes are probably the most common and reliable method for apple juice clarification (USDA, 1982). Apple juice can also be physically clarified by flash heat, electrokinetic adsorption, and filtration (USDA, 1982). The use of gelatin has an advantage over pectin in that it does not foul the membranes used to filter juice. Tannin shares this advantage (Riedl, Girard, and Lencki, 1998).

Wine that has been fined is qualitatively different from unfined wine. Various fining agents also produce different results in fining. One study indicated that the use of gelatin enabled a more accurate determination of sulfite levels in white wine by the removal of interfering polyphenols (Matsumoto, et al., 1989). The minimum active gelatin dosage needed to fine wine depends on both the wine's and the gelatin's parameters. Home winemakers use between 0.25 and 2 grams of gelatin per gallon of red wine and between 0.0825 and 0.25 grams per gallon of white wine. The amount of isinglass typically ranges between 0.05 to 0.3 grams per gallon, with white wine typically receiving about one gram per gallon (Eisenmann, 1999). Polyphenol content, turbidity, color intensity, and brown polymers content in the wine creates a greater demand for fining agents. Ellagic acid may be a special concern with muscadine wine (Lin and Vine, 1990). The gelatin's capacity to aggregate and remove the undesired properties depends on the degree of hydrolysis expressed as the distribution of molecular weights and the net charge density of the gelatin (Versari, et al., 1998). Most of the same substitutes can be used in clarifying juice can also be used to fine wine: bentonite clay, colloidal silica, diatomaceous earth, casein, and egg whites (Eisenmann, 1999). While these do not create identical finishes to gelatin and isinglass, they are able to remove the tannins, lees, and other particles and impurities that are removed by gelatin and isinglass.

One study compared undenatured isinglass (crude swim bladders), thermally denatured and purified isinglass, and bovine collagen treated with acetic acid and the enzyme pepsin. The undenatured isinglass was found to be more effective at aggregating yeast and other insoluble particles found in beer than the denatured fish gelatin. Bovine hide collagen was found the most effective treatment (Hickman et al., 2000).

Gelatin fining can be used with diatomaceous earth filtration. Additionally, fish gelatin may be more cost effective especially in comparison to process ultra filtration, which would be capital intensive (Gass, 2001). Because excessive amounts can lead to discoloration and—particularly in the case of fish gelatin—off-flavors, gelatin is used sparingly (Tressler and Joslyn, 1954). These drawbacks have led to gelatin's replacement in many processes.

For beer, irish moss, bentonite, papain, egg whites, isinglass, silica gel, and other materials are possible clarifiers and fining agents (Brewers Resource, 2001). Fungally-derived gellan gum is also described in an abstract to be a potential replacement for isinglass (Dartey, 1993).

Fish gelatin can serve as a substitute for various dairy products as oil-in-water emulsifiers, with certain limitations (Dickinson and Lopez, 2001). Of the emulsifiers included in the study, sodium caseinate performed the best. This implies that sodium caseinate, casein hydrolyzate, and whey protein isolate may be used as substitutes for fish gelatin. Consumer demand for vegetable-based substitutes has created incentives to develop alternatives to gelatin that are similarly low in fat. Researchers have explored various hydrocolloids and fluid gels, including carrageenans, agars, agarose, alginates, pectins, and gellans (Norton, Foster, and Brown, 1998). While pectin and sodium alginate combined may have comparable rheological qualities to gelatin, the pectin used in one experiment was been chemically treated by amidation with an unspecified agent (Madsen, 2000).

Cellulose can substitute for gelatin in the making of vegetarian / vegan capsules. See the cellulose TAP review.

TAP Reviewer Discussion[2]

Reviewer 1

*[*Ph.D, Biochemistry with food industry experience. Eastern U.S.*]*

Identification

. . . Strictly speaking, isinglass is not "gelatin," although it has similar properties and similar applications. The 'title' of this material review should be "**Gelatins and Isinglass**."

Characterization

The fish gelatin manufacturing procedure is unequivocally described here as involving only food acids (acetic, lactic or citric). The excellent literature sources accompanying the TAP Review speak only to "acid" and usually mineral acid (sulfuric and hydrochloric) in describing production of gelatin from young animal (including fish) skins.

For isinglass, most commentators would agree that "gelatin" is the material extracted from collagen by hot water. Since isinglass (a) is used directly without extraction, (b) is not extracted with hot water and (c) loses much of its functionality when treated with hot water, it should be treated on its own merits ("gelatin substitute") and not as gelatin.

The presentation to FDA by the U.S. manufacturers of porcine gelatin and the review by Hinterwalter (1977a) make it clear that economic and effluent disposal issues are driving Type A porcine gelatin manufacture to simpler and less environmentally impactful processes. The basics of the process – soak food grade skin in acid to swell the collagen (similar to pickling cucumbers or making sauerbraten), rinse to neutralize the acid, extract the gelatin with hot water – seem to me compatible with organic processing.

The alkali process is well-described. My reservation here is that the bone-to-ossein-to-gelatin process is lumped with the process for chromium-tanned hides. The ossein process is somewhat more drastic than the acid process, since strong acid and a lower pH are needed to dissolve the bone mineral. The alkali soak using calcium hydroxide is analogous to the original way of making masa (lime water soaking of corn). Other alkalis (e.g., sodium hydroxide) would be less acceptable. Chromium-tanned hides are synthetic materials, unlike animal bones and animal skins, which are agricultural products.

The enzymatic processes do not seem to be commercially important.

Gelatin CAPSULES do not belong in this section or in this document. Gelatin capsules routinely comprise other ingredients. Rarely are they 'pure' gelatin. Capsules merely represent an ingestible product (food, supplement or drug) of which gelatin is an ingredient.

Cross-linked gelatins can be chemically modified (thus synthetic) or enzyme-modified (synthetic if the enzyme is produced by a GMO). They should be the subject of a separate TAP Review.

Status

It is significant that the USDA Grading Manual for Canned Apple Juice specifically mentions the "Gelatin-tannin Method" for clarifying apple juice. The petitioned use of gelatin for tea clarification is an exemplification of the same principle.

It also is significant that the BATF regulations for "Storage, Treatment and Finishing of Wine" [27 CFR 24.246] permit the use of gelatin (food grade) to clarify juice or wine. The same regulations permit use of isinglass to clarify wine and indicate that isinglass is GRAS per FDA advisory opinion dated 02/25/1985.

[2] *OMRI's information is enclosed is square brackets in italics. Where a reviewer corrected a technical point (e.g., the word should be "intravenous" rather than "subcutaneous"), these corrections were made in this document and are not listed here in the Reviewer Comments. The rest of the TAP Reviewer's comments are edited for any identifying comments, redundant statements, and typographical errors. Text removed is identified by ellipses […]. Statements expressed by reviewers are their own and do not reflect the opinions of any other individual or organizations.*

It would be useful to know exactly which of the materials used in preparing bones, hides, or skins are reportable under the EPCRA, in order to judge the significance of this mention.

OFPA Criteria

Criterion No. 1: The petition mentions that the filter cake, comprising gelatin, bentonite and diatomaceous earth in addition to juice or tea tannins, proteins, etc., are applied to the land as 'fertilizer,' which takes advantage of the nitrogen in the gelatin.

Criterion No. 2: The chromium, which is present in tanned hides, is toxic. Use of tanned hides to manufacture gelatin for use in organic food processing is incongruous at the least. Note that pentachlorophenol appears to be used only in inedible gelatin manufacture.

Criterion No. 3: The petition and the TAP review do not get deeply into the issue of environmental contamination related to the gelatin manufacturing process. The two industry presentations to FDA in 1997 indicate that the economic costs of pollution control are forcing the industry in developed countries to take various steps to reduce the environmental impact. For example, solvent extraction of fat from skins, hides, and bones is being replaced by steam and physical methods.

Criterion No. 4: Gelatin is GRAS [Generally Recognized As Safe]. Commercial porcine and bovine gelatins are sterilized prior to noodle creation and drying. The allergy issue is becoming a greater concern. Since there is always some carry-over into the finished food, species labeling of processing aids makes sense. The BSE [Mad Cow Disease] is not an issue in North America at this moment with regard to gelatin.

Criterion No. 5: The TAP Review is not complete on this criterion at this point in the TAP Review. Gelatin is used to filter natural beverages and it is logical to expect that the resulting filter cake will be composted or applied directly to land as a useful soil amendment (one with a substantial nitrogen content). This is a good thing.

Criterion No. 6: Although other methods for clarifying juices and other beverages exist, the use of gelatin, alone or with other substances (tannin for apple juice, diatomaceous earth for tea, etc.), appears to offer advantages in certain circumstances [see petitioner statement].

Criterion No. 7: Making gelatin from pigskins, cattle hides, and cattle bones is compatible with sustainable agriculture. These practices go back hundreds to thousands of years, and use as starting materials animal tissues that would otherwise not be used, thus lowering the cost of meat.

NOSB Criteria

NOSB Criterion 1: Gelatin is produced from a natural source – pigskins, fish skins, cattle hides, and cattle bones. Organic gelatin could be produced from organically raised hogs and cattle, depending on the process. The acid process induces little or no chemical change in the collagen and the collagen is converted to extractable gelatin by 'cooking' in hot water. Cooking is allowed as a process in OFPA.

NOSB Criterion 2: The TAP Review does not provide sufficient detail on the industrial disposal problems resulting from gelatin manufacture as it is performed in the U.S. in the Twenty-first Century. See OFPA Criterion No. 3 above.

NOSB Criterion 3: The TAP Review discussion treats gelatin as if it is only and always the sole protein in the diet. In its normal use as a food ingredient (where it is about 2.5% of a dessert product) and in its normal use as a processing aid (where it is removed totally from the beverage to achieve its intended clarifying effect), gelatin has a minimal impact on an individual's protein nutrition. Edible gelatin is a FOOD; it is not a food additive.

NOSB Criterion 4: In beverage processing (clarification), gelatin has the effect of improving color (it removes turbidity). In gelatin desserts, gelatin creates the texture. In meats, the effect of gelatin can best be described as improving texture, since it binds the water of cooking. The same holds true for yogurts, soups, and other semi-liquid products.

NOSB Criterion 5: Gelatin is a food. Gelatin is GRAS. Isinglass also is GRAS.

NOSB Criterion 6: The TAP Review is not accurate in limiting beverage clarification uses of gelatin to tea and wine [see "all other uses in food systems"]. Gelatin is also used to clarify beer, fruit juices, and, historically, coffee. Directing attention to the criterion itself, using Type A fish or porcine gelatin (prepared by the acid method) or isinglass, all of which are non-synthetic agricultural substances, to clarify beverages seems imminently compatible with the principles of organic handling.

NOSB Criterion 7: Other means of clarifying juices, wine, and tannin-containing beverages (tea, coffee, beer) exist but each has advantages depending on the system. Economically and functionally, it is important to use the minimum quantity required to achieve the intended effect, since using more can actually create turbidity in the final product.

Recommendation: List as nonsynthetic, and allowed. Annotation: From animal bones and animal skins prepared with agricultural products and items on the National List (7 CFR 205.605) and not chemically modified.

Reviewer 2
[PhD. Food science, organic and natural foods industry consultant, Western U.S.]

My determination is that gelatin is a non-agricultural substance and should be considered non-synthetic for both 95% organic and Made with Organic. It should be allowed as a texturizer, coating and binder (no hard capsule applications); no sulfur dioxide or hydrogen peroxide allowed in the process.

For the most part (see comments regarding questions below), I agree with the information contained in the TAP review and I feel that it is generally complete.

….. Fish gelatin, in particular, seems to use only natural processes for extraction. The pre-treatments in acid or base for beef or pork gelatin are harsh, but are primarily used to make the extraction more efficient and do not chemically participate in the reaction. Gelatin capsules should be considered synthetic, unless available without chemical hardening agents and not allowed. Soft gel capsules, which only use glycerol as a plasticizer, may be okay.

Gelatin used as a texturizer or coating agent is compatible with organic production. The issue of animal versus vegetable products is one that is consistent with its application as a fining agent. Since animal products are certified organic, there should be no reason why gelatin would not be compatible with organic processing.

There are many other fining agents that can be used, some of which are mentioned in the petition.

Vegetarian/vegan gel caps are made of hydroxypropylmethylcellulose, which although cellulose-derived, would be considered synthetic. Chemically modified celluloses were not considered in the cellulose TAP review. [1] You can get more information at www.vegicaps.com, made by RP Scherer or at www.capsugel.com, who make a competitive product called Vcaps.

Gelatin may be used as a texturizer and coating agent. It may also be used in capsules, although I believe the process renders the product synthetic and incompatible with organic.

It would be preferred that they not come from genetically engineered organisms. These products should be run through OMRI's decision tree on genetic modification as a first step for the determination of whether they should be considered excluded to be consistent with other processes and determinations.

The issues around nutritional quality are really only applicable where gelatin is the sole source of protein as in the liquid protein diets. They could be another excluded application, I suppose. The use of gelatin at the usage levels for texturization or coating is not sufficient to cause nutritional quality degradation. It technically could be possible to create an organic [gelatin dessert] from organic animals, organic cane sugar, and organic flavor. It would only be a problem if someone tried to live on organic [gelatin dessert] alone.

I am not sure what additional information is needed from an exhaustive review of fining agent articles. It seems to be an acceptable process if the gelatin is processed correctly.

Reviewer 3
[Academic researcher with experience as a public health official, East Coast]
I agree with the TAP Review with regard to gelatin itself, but perhaps processing criteria 2 and 5 should be referenced here, since there are issues of environmental contamination related to substances attendant to the manufacture, use, misuse, or disposal of gelatin.

1. *The effects of the substance on human health.*
There appear to be a variety of human health risks related to gelatin. I have put them in four general categories for purposes of this discussion. The nature and magnitude of these risks vary depending on the species of animal from which

[1] Cellulose TAP review, 9-29-01 did discuss process for microcrystalline cellulose, a more highly modified form. TAP reviewers and NOSB did not recommend this form for approval.

the collagen (the raw material for gelatin) is derived, the part of the animal that is used, the end-use of the gelatin, and the process by which the gelatin is extracted and treated, and many other factors. For purposes of this discussion, I have limited my consideration to those factors that bear most directly on the decision at hand.

BSE: According to the FDA in 1997, about 55% of gelatin consumed in the US was derived from pigs, and about 45% from cattle. As of May 1997, gelatin was being imported from the a number of countries, primarily Argentina, Australia, Belgium, Brazil, Columbia, Germany, Mexico, New Zealand, South Africa, and Sweden (anonymous, 1997). Since that time only Argentina, Australia, Brazil, and New Zealand remain as countries generally considered without risk for BSE.

In December 2000, the World Health Organization (WHO) announced that 500,000 tons of meat and bone meal produced by the European Union had been exported over the last 10 years to Eastern Europe, Asia, and the US (International Herald Tribune, 17 March 2001). According to a recent report from The Institute of Food Science & Technology (IFST), the United Kingdom's independent professional qualifying body for food scientists and technologists, WHO has stated that over 100 countries are at risk for BSE and countries throughout Europe have now reported cases of BSE. According to WHO, countries can be placed in four categories of risk that live cattle could be infected with the BSE agent and incubating the disease. Only 14 countries are in Category I (highly unlikely to present a BSE risk). The US, along with Canada, is in Category II (unlikely but a BSE risk cannot be excluded). Category III countries are comprised mostly by Eastern Europe and are likely to present a BSE risk or have a low level of confirmed risk. Category IV countries have a confirmed risk at a high level such as the United Kingdom (UK) (IFST, 2001).

BSE has recently spread to Asia as well, as cases have been reported in Hong Kong and Korea (Medical Industry Today, 17 August 2001). In the fall of 2001, the first case in Japan was reported (IFST, 2001).

Governments are scrambling to tighten their borders and the level of prohibition of feed sources in an effort to bolster public confidence. Currently, the European Commission (EC) has a total suspension in effect for member states on the feeding of processed animal protein to farmed animals used for the production of food. Among the few exceptions allowed to member states are fishmeal for non-ruminant feed and gelatin of non-ruminant animals for coating additives (EC,2001). Japan extended their ban on ruminant meat and bone meal in cattle feed to include an extensive list of animal protein products banned from use in swine and poultry feed as well as fertilizers. The list includes fishmeal except if it is made at plants where no animal protein other than fishmeal is produced, and gelatin from collagen excluding that derived from skin/hide and treated in a certain manner (Japan Ministry of Agriculture, Forestry and Fisheries press release, 2 October 2001).

In a little heralded fact, BSE has already appeared in North America as a single cow imported from Britain died of BSE in Canada (Johnson and Gibbs, 1998). In addition, between 1980 and 1989, 334 animals were brought from the UK to the US. The USDA traced the disposition of these animals and determined that 161 were disposed of in a manner that poses no risk to humans or other animals, but it cannot make this conclusion about the other 173 animals (USDA, 2001).

Unfortunately, no amount of government action may restore consumer confidence. The BSE Inquiry conducted by the UK government issued its final report in the fall of 2001 and identified a number of problems with the handling of the BSE outbreak: excessive government secrecy and unjustified public reassurances; inadequate communication among government departments; inadequate handling of hazard and uncertainty; lack of foresight and planning; ineffective enforcement of control measures; lack of correct use of scientific advisory committees; and, inadequate coordination of research (IFST, 2001).

The lack of faith in regulatory barriers is evident throughout the food industry, and not only in the UK. Major food-processing and grocery store chains in Europe and the US are requesting written guarantees and "traceable evidence" from beef suppliers (including those based in the US) that no meat or bone meal is used as feed. This has had the direct effect of inducing commercial feed companies in England to rely increasingly on vegetable proteins, in particular organic soybean meal (Preston, 2001). US cattle producers organized a private meeting with the FDA and USDA to improve compliance and the American Feed Industry Association set up an independent third-party certification program after FDA released a report in early 2001 revealing the occurrence of numerous violations of labeling requirements and the lack of system safeguards to keep ruminant and non-ruminant by-products separated (Center for Science in the Public Interest, 2001).

A risk analysis conducted by Harvard for the USDA theorizes that in the unlikely event that BSE should be introduced to this country, control measures already in place would ensure that few if any animals would get sick and that the disease would soon die out. The authors of the study admit that this assumes the disease is spread through the feeding of infected rendered animals to susceptible animals. It further acknowledges that violations of the feed ban have occurred and that many unknowns, including the exact origin of the disease, remain unresolved. It cannot say that the disease will never occur here (USDA 2001).

Urgent research needs remain – the exact mechanism of transmission, whether muscle meat or milk, carry infectivity at too low a level to be measured or detected by existing methods, and what is the infective dose, or whether it is a single dose or cumulative (IFST, 2001). A member of FDA's BSE Advisory Committee stated that perhaps the most practical way to gauge the risk presented by gelatin in the US is on a scale of relative risk, where the highest risk would be from bovine-bone gelatin, produced by a non-alkaline process in countries with BSE or unknown BSE status and the lowest risk would be from pork skin gelatin from US produced pork (SCRIP # 2228, 2 May 1997).

Another unresolved issue is whether the risk is confined entirely to bovine by-products. Pork has been linked to increased risk of CJD in at least two studies (Hansen, 1999). Another recent study in rodents indicates that the species barrier may not be as protective as previously thought, permitting speculation "…that chickens, pigs, or other livestock fed BSE-infected animal feed may be silent carriers of the disease" (Balter, 2000). One case of nvCJD was a strict vegetarian as of 1985 onward, indicating that the person was exposed before the clinical recognition of BSE in 1986, or there was occult exposure from prepared/processed foods, pharmaceuticals or cosmetics (Collinge, 1999).

Unfortunately, even fishmeal is a focus of concern in Europe, at least, for cross-contamination with potentially BSE-infected materials from other species of rendered animals. For carnivorous farm fish, such as salmon (a commonly used fish for isinglass according to the petition), blood meal, liver meal, meat and bone meal, and poultry by-products are all considered substitutes for fishmeal, although their commercial availability is unknown (Goldburg and Triplett, 1997).

Allergy: Fish and shellfish are among the most commonly allergenic foods. Cod is one of the most commonly allergenic fish. Cod skins are a common source of fish gelatin (Taylor and Hefle, 2001). Many food ingredients are made from commonly allergenic sources, including fish gelatin. The threshold to allergenic residues is unknown, although it is reasonably well documented that food-allergic individuals can react to mere traces of the offending food (Taylor and Hefle, 2000). While some fish apparently elicit greater reactivity in sensitive individuals, recent evidence indicates that there is cross-reactivity of such individuals to gelatins from various fishes (Sakaguchi et al, 2000). The Codex Alimentarius says that fish and shellfish are commonly allergenic and should be listed as ingredients no matter what amount results in the final product (Taylor and Hefle, 2001).

Recent evidence indicates that there is cross-reactivity of individuals sensitive to fish gelatin to bovine gelatin, albeit at a low level (Sakaguchi et al, 2000). Even though beef and pork are rarely considered to be allergenic foods (Taylor and Hefle, 2001), bovine and porcine gelatin have been associated with the production of anaphylaxis in vaccinated children with doses containing as little as 1 mg. of gelatin (Sakaguchi et al, 1996). The CDC regards the risk of gelatin anaphylaxis seriously enough to recommend that vaccination of children with a history of anaphylaxis to products containing gelatin should be pursued with extreme caution and suggests that skin-testing is available (US CDC, 2000).

In my opinion, residue tests have limits of detection and the quantum of substance exposure required for inciting anaphylaxis is not known, so definitive statements concerning the presence or absence of any allergenic particles in the final products can't really be justified, even if the substance is only used for processing.

Microbial Contamination: My review of the US Centers for Disease Control (US CDC) database did not reveal any additional references to the risk of Clostridium botulinum infection from fish gelatin beyond those already mentioned in the TAP review. As far as the risk of food-borne microbial contamination from gelatin overall, the risk appears to be low considering the volume of use. A white paper from FDA's Center for Food Safety and Applied Nutrition (September 1999) included a literature review of food-borne disease caused by food handling practices from 1975-1998, indicated that gelatin glazes, such as those in baked goods or aspic glazes used to preserve the shelf-life of cold foods, occasionally were implicated as sources of contamination (Guzewich and Ross, 1999).

Aflatoxins are a problem for farm fish according to FDA, but whether this can result in contamination of meat from animals fed on aflatoxin-infected grain does not seem to have been addressed. Occasionally, however, meat samples do contain aflatoxins, but what the cause is remains the question (FDA, Food Residue Program reports, various years).

Environmental Contaminants: In 1991, FDA said that the harvest of farmed fish had increased four-fold from 10 years ago (FDA Food Residue Monitoring Program report, 1991). In 1992, FDA said that 10% of the total seafood harvest was from aquaculture. The majority species were catfish, trout, salmon, crawfish, shrimp, clams, and mussels. Twenty-five percent of the aquaculture samples tested by FDA had detectable pesticide residues including DDT, dieldrin, and chlordane at 25, 20 and 10 times the FDA Action Levels, respectively (FDA Food Residue Monitoring Program report, 1992).

Farm fish are treated with a number of products such as disinfectants, herbicides, vaccines, parasiticides, and drugs. A fish commonly used for isinglass is catfish (see materials with petition), which also comprises 50% of all aquaculture in the US. These are typically fed a commercially prepared pelleted feed, high in protein, and consisting of soybeans, corn, wheat, and fishmeal (FDA Consumer Magazine, 1991).

Summary: In general, the human health risks for the 3 sources of gelatin can be summarized as follows:

Bovine – very low risk of contamination with BSE, low risk of microbial contamination, low risk of environmental contaminants, and low risk of allergenicity;
Porcine – negligible risk of BSE, low risk of microbial contamination, low risk of environmental contaminants, and low risk of allergenicity;
Fish – only theoretical risk of BSE, some risk of microbial contamination, low risk of environmental contaminants, and some risk of allergenicity.

<u>Processing criteria</u>

1. *It cannot be produced from a natural source and has no organic ingredients as substitutes.*
   Not withstanding the possibility of organic collagen being commercially available or deriving gelatin from Kosher fish skins with minimal processing, my opinion is that the products we are considering fall into the category of "nonagricultural substances," as defined in the Federal Register (65 FR 80,640 [2000]). The key words in that definition that appear to characterize gelatin are "… that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction."

2. *Its manufacture, use and disposal do not have any adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA.*
   In addition to the information provided in the TAP review already, there are four processes that have recently been proposed for the sterilization of gelatin by the European Commission (EC) Scientific Steering Committee (SSC) on TSE Risks from Gelatin Derived from Ruminants. Three of them involve various applications of chemicals such as hydrochloric acid, saturated lime, and sodium hydroxide, but a fourth is autoclaving (a heat/pressure/time process). (EC SSC Updated Opinion, 6-7 September 2001)

   The waste materials resulting from the rendering of 50 billion lbs. of animal protein each year are voluminous (USDA, transcript of press conference on release of Harvard BSE risk analysis, 2001).

3. *If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.*
   I don't have much to add to the TAP Review for this question, except that gelatin's role in food processing does not appear to be nutritive. My comments on the adverse health effects can be found under OFPA criteria 4 above.

4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.*
   My reading indicates that gelatin's function in food processing can be characterized generally as preservative, textural, and esthetic enhancement.

5. *Is Generally Recognized As Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.*
   The FDA's advisory committee seems to leave the continued status of gelatin as uniformly GRAS in doubt. As of the spring of 1998, FDA was leaning towards no longer considering gelatin GRAS if its derivation came from BSE countries (SCRIP #2328, 22 April 1998). The 1997 FDA Guidance document states that the majority opinion of the advisory committee is that gelatin should no longer continue to be exempted from restrictions placed on other bovine materials from BSE countries (FDA Guidance 1997). It is still listed as GRAS as of the April 2001 publication of the CFR under the same category as noted in the TAP Review (21 CFR 182.70).

   On the question of whether sulfur dioxide is added as a biocide added to gelatin, I only came across a reference that it protects beer against bacterial spoilage in addition to slowing down the rate at which staleness and haze develop. A new area of research is to induce yeast to produce natural sulfite during the fermentation process (Simpson, paper presented at Institute of Brewing Africa Section workshop, 1999).

6. *Its use is compatible with the principles of organic handling.*

The use of gelatin may be counter to principles of organic handling because of the potential for human health risks and consumer deception (albeit unintentional). All sources of gelatin carry some health risks, with fish gelatin probably being the highest in terms of incidence and bovine being the most grave and fear-inducing in terms of consequence. The potential for consumer deception arises because some consumers (e.g., vegetarians and Halal/Kosher adherents) who have an aversion to products formulated with meat or fish (possibly containing traces of these substances), will be ingesting such products unknowingly.

As food ingredients, gelatin's uses do not appear to be essential enough to outweigh its incompatibility with organic principles due to the human health risks. As clarifying agents for beverages, there is an element of consumer misinformation involved in their use and some unquantifiable public health risk, in which the incidence is low, but the consequences are severe. In addition, there is the concept that what gelatins actually do for beverages is act as preservatives or appearance enhancers, and hence constitute an unnecessary production input incompatible with sustainable agriculture and organic principles, given that gelatin is not an organic ingredient and carries other possible risks. As coatings for animal products, there is some risk of BSE transmission, and alternatives appear to exist or be commercially feasible.

In addition, several commentators have indicated that animal-derived gelatin is increasingly viewed with disfavor by various sectors of the food industry. More and more brewers will abandon the use of animal finings in the future because risks outweigh benefits (Simpson, Institute of Brewing workshop, 1999). BSE concerns have led manufacturers to replace bovine gelatin with other hydrocolloids (TAP Review). The drawbacks of fish gelatin relative to off-flavors and discoloration have led to gelatin's replacement in many processes (TAP Review). Gelatin remains unpopular in fruit juice clarification because it creates a haze (TAP Review).

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.*
There are at least three companies pursuing production of genetically engineered gelatin (two in California and one in the Netherlands) (Biocentury Report, 22 January 2001). Fibrogen was expected to begin large-scale commercial production using yeast and genetically altered tobacco plants as of the second half of 2000 (Food Industry News website, 21 December 2001). However, from the brief descriptions that I have seen of these processes in the sources cited as terms such as "transgenic" and "recombinantly" were used, thus apparently bringing them within the purview of "excluded methods" according to my reading of the regulation (65 FR 80, 639 [2000]).

Coatings - Most gelatin used in vaccines is derived from pigskin, while tablets and capsules use a mixture of bone and pigskin because a capsule made solely from pigskin gelatin would become brittle. As coatings for animal supplements and medications, gelatin may play a role that may be more difficult to duplicate with materials compatible with organic principles. However, some substitutes such as cellulose coatings are mentioned in the TAP Review. Furthermore, non-capsule formulations, e.g. powders, may be feasible alternatives.

Food uses - Gelatin's "useful" properties appear to be mainly preservative, esthetic, or textural, which can be replaced in general by mechanical processing or biologically inert substances, possibly of organic origin.

Wine Clarifying Agent – The COABC recommends natural settling and racking but "tolerates": isinglass, non-hydrolyzed bone gelatin, bentonite, kaolin, pure casein, diatomaceous earth, fresh egg whites, cellulose plate filters, centrifugation, sterile filtration with membrane filters, and cross-flow filtration.

Beer Clarifying Agent – As beer ages it develops haze. Older haze control agents such as papain and tannins are being replaced by ones allowing haze control for up to 18 months. This is not necessarily a good thing as it permits marketers to label their products with longer shelf life than it really deserves because the appearance of freshness is maintained. Other drawbacks specific to gelatin are that some consumers who are vegetarians or otherwise concerned about the use of animal products may be averse to these food-processing agents, despite dubious protestations that they do not survive into the final product – an assertion that can be evaluated by a hydroxyproline test (Simpson, Institute of Brewing workshop, 1999).

Other Beverages – Alternatives are discussed in both the TAP Review and the information submitted with the petition.

Recommendation for NOP Listing:
My recommendation is that gelatin should be prohibited as a Processing Production Aid. If prohibition is not feasible because there are no better alternatives for certain uses, then the allowed status listing should have an annotation limiting it to certain uses and requiring precautionary labeling that informs customers that a specific type of gelatin was used in processing.

[end of TAP Reviewer comments]

TAP Conclusion:
Gelatin can be made from a variety of different sources by a number of different processes. Some gelatin sources are agricultural and some are non-agricultural. The petitioned source appears to be non-agricultural. Some of the processes result in synthetic reactions and some are more like cooking in ways that the NOSB has not considered to be synthetic under OFPA. The process used to prepare the petitioned material appears to be nonsynthetic. Isinglass from wild-caught fish also appears to be non-agricultural and nonsynthetic.

Two TAP Reviewers wanted to allow gelatin with limitations; one thought that gelatin should be prohibited for use in organic handling and processing. The two reviewers who advised that it be recommended for inclusion on the National List both wanted to allow only gelatin produced by certain manufacturing processes. The review appears to support the inclusion of isinglass and fish gelatin from fish processed with food acids and substances on the National List under 205.605(a) as nonsynthetic and non-agricultural; Type A (porcine) gelatin would be considered agricultural and non-synthetic if it were processed only with items on the National List. Therefore, porcine gelatin could be listed as commercially unavailable under 7 CFR 205.606. The NOSB might want to consider further restrictions on bovine sources of gelatin, to restrict to sources not derived from hides tanned with chromium or treated with other synthetic substances such as pentachlorophenol; or further modified and cross linked. If the NOSB decides to permit use of some types of gelatin based on production method— such as non-chemically modified or cross-linked, not derived from chromium tanned hides—processors and certifiers will need to verify that the source meets the standard.

(Although the TAP review does not specifically address livestock applications, gelatin is used as a carrier for vitamin formulations, similar to use in human food supplements. The NOSB may want to consider whether gelatin would be considered a slaughter by-product, based on the information provided about manufacturing sources.)

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*Note: * = included in packet*

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