Cellulose

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
β(1→4) linked D-glucose;
Polyanhydroglucuronic

Other Names:
Powdered cellulose; alpha-cellulose, flour cellulose; cellulose fibers, paper, linters. Microcrystalline cellulose, MCC, (derived from cellulose) is also called cellulose gel; cellulose (Spanish)

Trade Names:
Alphacel; Arbocel; Avicel; Heweten; JustFiber; QualFlow; Rayophane, Viskase; Vitacel; Vivapur

CAS Numbers:
9004-34-6 (cellulose powder);
68442-85-3 (regenerated cellulose)

Other Codes:
EINECS 232-674-9 (cellulose powder), 270-493-7 (regenerated cellulose);
SMILES: Cc1ccc(C)c2c1CC(C)C2

Summary of Use

Cellulose is currently allowed under the National Organic Program (NOP) regulations at 7 CFR 205.605(b) for use in regenerative casings, as an anti-caking agent, and as a filtering aid. Cellulose is the main component of higher plant cell walls and is also one of the most abundant organic compounds on earth. It can be derived from several sources using a number of techniques that are considered synthetic, and some that might be considered nonsynthetic (natural). Cellulose is available in many forms for different functional purposes in food products. This report considers two forms that are currently permitted for use in organic processing and handling: amorphous powdered cellulose and inedible cellulose casing.

Various forms of cellulose have many other uses permitted by the FDA, including as a fat substitute and bulking agent in low calorie foods, a texturizer, emulsifier and extender. These uses are not currently permitted under the NOP regulations, and are beyond the scope of this report. Other forms of cellulose, including microcrystalline cellulose, nanoparticle cellulose, and various cellulose derivatives such as carboxymethylcellulose and cellulose gums are also beyond the scope of this report.

Characterization of Petitioned Substance

Composition of the Substance:
Cellulose is a polysaccharide of the monomer $(C_6H_{10}O_5)n$ with the glucose units linked by cellobiose (Merck 2015).

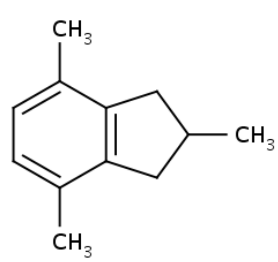


Figure 1: Cellulose Monomer (US EPA 2015a)

In its simplest form, cellulose is a linear, insoluble polymer of D-glucose units joined by hundreds or thousands of glycosidic linkages, and is considered a polysaccharide. As a polymer, it can take on six different distinct structures, known as polymorphs, and also appears in amorphous forms (O'Sullivan 1997). Cellulose molecules form long chains in polycrystalline fibrous bundles that contain crystalline as well as amorphous regions. These different forms are able to perform various functions, and not all cellulose is suitable for every application.

Source or Origin of the Substance:

Cellulose is the main structural component of all higher plant cell walls and one of the most abundant organic compounds on earth (EMBL 2015). It is also formed by some algae, fungi, bacteria and marine animals (Whistler and BeMiller 1997; French et al. 1993).

Most commercial sources of cellulose are from cotton linters and wood. Most food grade applications require a high degree of purity. Cotton fibers are about 98% cellulose, while wood is 40-50% cellulose (Whistler and BeMiller 1997; Ockerman 1991). Linters are the short fibers that remain on cottonseeds after the long fibers used for textile production are removed. Cellulose obtained from cotton linters needs only a treatment with a hot sodium hydroxide solution that removes the protein, pectic substances and wax to produce high quality cellulose (Whistler and BeMiller 1997).

Wood requires more extensive processing to solubilize the hemicelluloses and lignins (delignification). The most common manufacturing process is described in Evaluation Question 1. Cellulose can be made as a co-product with ethanol from fermented wood (Frederick et al. 2008) and opportunities are growing with the increase in the production of biofuels.

Cellulose can also be produced from various other plant fibers, such as corn cobs or stalks, soybean hulls, bagasse (sugar cane stalks), oat hulls, rice hulls, wheat straw, sugar beet pulp, bamboo, and fibers such as jute, flax, and ramie among others (Franz and Blaschek 1990; French et al. 1993).

Recycled paper and cardboard account for a growing source of cellulose, and 63% of all paper and cardboard generated was recovered for recycling in 2013. This rate of recovery is up from just under 50% in 2005 and triple the recovery rate in 1980 (US EPA 2015b). Recycling technologies continue to improve, and the ability to increase recycling recovery and efficiency depends as much on building adequate capacity as it does on the collection of recyclable material (Roberts 2007).

For economic reasons, different sources of cellulose are used for different purposes. Pulp and paper are usually produced from wood, while textile fibers are generally not isolated from woody fibers. Cotton fibers are a biological source of almost pure cellulose, but this is not usually used in food grade cellulose. Cotton fibers are used instead for various cellulose derivatives for pharmaceutical or chemical engineering uses, such as chromatography, paints, and explosives (Franz and Blaschek 1990).

Cellulose technology continues to evolve. Microbially produced cellulose can be made from fermentation of sugars with bacteria or microalgae. Bacterial sources of cellulose have also been developed using *Acetobacter xylinum* that ferments substrates of glucose from corn syrup (French et al. 1993; Delmer and Amor 1995).

Cellulose is also currently the subject of research and development in nanotechnology. Cellulosic nanocrystals have a number of physical and chemical characteristics that go beyond microcrystalline cellulose in terms of strength, directionality for making structured composites, and hydrophilic / hydrophobic capacity (Hubbe et al. 2008). Cellulose impregnated with nanosilver (Ag NP) has been researched as packaging for meats, although this would not be allowed for use in organic products. The Ag NP migrates into meat, providing preservative properties (Martirosyan and Schneider 2014).

Properties of the Substance:

The physical and chemical properties of cellulose are summarized in Table 1.

Table 1: Properties of Cellulose

Property	Characteristic / Value	Source(s)
Molecular Formula:	$(C_6H_{10}O_5)n$	(Merck 2015)
Molecular Weight:	~162 (monomer); 200-250 (purified cotton); 336,100 (softwood)	(Krässig 1993; Ellis and Smith 2008)
Percent Composition:	~44-45% C, 6-6.5% H, 48-49% O	(Krässig 1993)
Physical state at 25°C / 1 Atm.	Solid	(Merck 2015)
Color	White	(Merck 2015)
Odor	Odorless	(Royal Society of Chemistry 2015)
Density / Specific Gravity	0.940-0.950	(Merck 2015)
Melting point	360°C	(Merck 2015)
Boiling point	380°C	(Merck 2015)
Solubility	Insoluble	(Merck 2015)
Vapor pressure	1 mm Hg @ 714° C	(Royal Society of Chemistry 2015)
pH	5.0 – 7.5	(Food Chemicals Codex Committee 2011)
Corrosion characteristics	Corrosive to metal and tissue	(Royal Society of Chemistry 2015)

Specific Uses of the Substance:

The specific uses of cellulose are summarized in Table 2.

Table 2: Uses of Cellulose (French et al. 1993; Whistler and BeMiller 1997)

Powdered cellulose	Anti-caking agent, used in shredded cheese and spices Filtering aid Moisture retention Non-caloric bulking agent used in reduced calorie products Texturizer, dispersing agent Emulsifier, used in frozen products to maintain texture through freeze - thaw cycles
Regenerated cellulose casing	Casing for skinless sausages and hot dogs

Uses of powdered cellulose other than as an anti-caking agent and as a filtering aid are not allowed for organic processed products or organically produced ingredients. Regenerated cellulose casings may be used for products such as skinless sausages and hot dogs.

Approved Legal Uses of the Substance:

Cellulose is approved by the FDA by prior sanction as a food ingredient and additive used before the passage of the 1958 amendments to the Food and Drug Act (Mitchell 1986). Anti-caking agents in grated cheeses are specifically referenced at 21 CFR 133.146(b)(4). The uses in Table 2 all appear to be approved. For organic processing and handling, the only uses that are allowed are as a filtering aid, an anti-caking agent, and in regenerative casings in accordance with 7 CFR 205.605(b).

Action of the Substance:

Cellulose can absorb water, oil, and other liquids, binding 4-9 times its own weight in water (Saltmarsh 2000). It is also porous when saturated, permitting liquids to pass while retaining solids. Powdered cellulose prevents agglomeration of some solids like flour, spices, and shredded cheeses by absorbing, binding and retaining moisture.

Combinations of the Substance:

Cellulose takes on many forms and performs a wide range of functions. Food-grade cellulose filters composed of either 100% or food-grade 99%+ cellulose without ancillary ingredients are commercially available (ErtelAlsop 2015; Purifiber 2015; International Fiber Corporation 2015). However, the inclusion of other ingredients may reduce labor costs and could increase the functional efficiency of cellulose for certain processes. Specifically, various polymers and co-polymers can be combined with cellulose to improve absorption, increase or decrease viscosity, and to increase yield (Adams and Hoftiezer 1968; Lassen 1976; Oechsle, Baur, and Gottkehaskamp 1994). Food grade filtering systems composed mainly of cellulose may also include various polymers or substances like fiberglass for ease of handling, or to increase throughput (Parker 2008). Silica hydrogels may be combined with cellulose to increase the removal of proteins and reduce chill hazing of beer (Fernyhough 1994).

Sometimes preservatives such as natamycin, sorbates or enzymes are added to improve the shelf life of the grated cheeses that use cellulose as an anti-caking agent (International Fiber Corporation 2015). While natamycin and sorbates would be prohibited under the NOP, enzymes are listed at 7 CFR 205.605(a). Cellulose without these additives is commercially available and clearly identified (International Fiber Corporation 2015).

Sausage casings, including those made from regenerated cellulose, may be lubricated with vegetable, animal or mineral oil in the shirring process (Clement 1966). Various releasing agents may be used to reduce the time for peeling, retain moisture, or to permit the addition of smoke flavor (Viskase 2013). Synthetic sausage casings may be formulated with various binders and plasticizers. These may include mineral oil, propylene glycol and lecithin (OMRI 2001). Regenerated cellulose sausage casings are also commercially available without additives (Viskase 2013).

Status

Historic Use:

The use of cellulose as a filtering aid and food additive predates the Food and Drug Act. Powdered cellulose was petitioned to FDA for GRAS status as a cheese anti-caking agent in 1986 (International Fiber Corporation 2015). Organic certification agents first approved that use for organic food in 1994 (OMRI 2001). Regenerated cellulose casings were first used in meat processing in the 1930s (Knudsen 1931; Paddock 1939).

Organic Foods Production Act, USDA Final Rule:

Cellulose appears at 7 CFR 205.605(b) as a nonagricultural (nonorganic) synthetic substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” with the following annotation: “for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.” The NOP regulations did not include cellulose on the original list of synthetic substances allowed for use in processed organic products (USDA Agricultural Marketing Service 2000). Cellulose was added to the National List with the current annotation on November 3, 2003 (USDA Agricultural Marketing Service 2003).

International

Cellulose is permitted by most organic standards outside of the U.S., for at least some uses and applications. However, it is not referred to in the Codex Alimentarius organic guidelines or the Japanese Agricultural Standard.

Canada - Canadian General Standards Board Permitted Substances List – Allowed as a filtering aid (non-chlorine bleached) and for use in inedible regenerative sausage casings (CAN/CGSB 2015).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) – Not found.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 – Cellulose appears in Annex VIIIa, "Products and substances authorised for use or addition in organic products of the wine sector" in the centrifuging and filtration of wine. It is authorized only for use as an inert filtering aid (EU Commission 2008).

Japan Agricultural Standard (JAS) for Organic Production – Not found.

IFOAM – Organics International (IFOAM) – Cellulose appears in Appendix 4, Table 1 "List of approved additives and processing / post-harvest handling aids" as a processing and post-harvest handling aid with no annotation (IFOAM 2014).

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)).

Most commercial sources of cellulose are from cotton linters and wood. Cellulose obtained from cotton linters needs only a treatment with a hot sodium hydroxide solution that removes the protein, pectic substances and wax to produce high quality cellulose (Whistler and BeMiller 1997). Wood requires more extensive processing to solubilize the hemicelluloses and lignins (delignification).

Pulping process

Most wood species contain approximately 40-45% cellulose, with the remainder consisting of hemicellulose and lignin (Sjostrom 1993). The pulping process separates the cellulose from the lignin and hemicellulose (structurally unrelated polysaccharides), leaving it in a fibrous form that is purified, dried, and shipped in large rolls. The lignin portion, which is the fraction most resistant to pulping, may comprise as much as 36% in some species (French et al. 1993).

In the wood pulp processing, timber is debarked and cut into chips. These are mechanically ground and then digested (cooked) chemically using either a sulfite or an alkali process at elevated temperatures in pressure vessels or digesters (Johnson and Peterson 1974). Either process can be modified to produce higher purity cellulose that is not only free of lignins and hemicellulose, but also broken down to smaller molecules, lighter products and simpler derivatives (French et al. 1993). Various sulfite processes are used for delignification of the pulp, including the bisulfite process, which uses calcium bisulfite in the presence of sulfur dioxide at a pH range of 2-6 on various wood species.

Alkali processes use either caustic soda (dilute sodium hydroxide) as the pulping agent, or sodium sulfate (Kraft process) as the source of alkali. Kraft process pulping liquor contains caustic soda and sodium sulfide, and increases the delignification and also pulp strength. Chemicals used in the pulping process are potential pollutants that may be recovered, adding costs to the mill investment. New mills are designed to consider energy efficiency, chemical recovery and water pollution.

Another method for breaking down lignocellulose (other than the Kraft or sulfite process) is steam explosion. This uses moisture saturated wood chips subjected to high pressure and temperatures, or may involve milder conditions for paper manufacture and molded building materials (French et al. 1993).

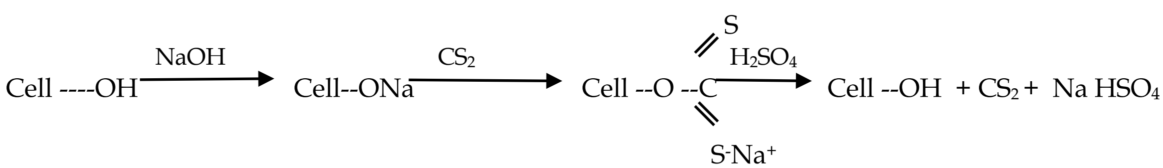
After pulping, several steps are required, including bleaching and alkali extraction, to develop products with the desired molecular weight and physical length of the fibers. Bleaching may include up to twelve steps of chlorination, hypochlorite bleaching, chlorine dioxide bleaching, and extraction with concentrated sodium hydroxide, along with intermediate alkaline extraction by washing after each oxidative stage. It must be purified and bleached to meet the specifications of the Food Chemicals Codex (Food Chemicals Codex Committee 2011). Purification may involve the addition of surfactants in another hot, weakly alkaline extraction step after chlorination. Companies also offer unbleached cellulose products to their customers. Another option is to treat pulp with another bath of 6-10% sodium hydroxide after the bleaching is finished. Final stages in most purification plants include the use of sulfuric acid and optional multicomponent solvents (such as chelating agents) to accelerate dissolution, increase yields, and remove impurities such as heavy metals, depending on the grade and intended use (French et al. 1993).

Powdered cellulose

Powdered cellulose is made from dried wood pulp that is pulverized at various elevated temperatures (Demon et al. 1955). The process separates cellulose from hemicellulose and lignins. Fiber length varies from 0.5 to 3.0 mm and moisture content is 15% or less.

Regenerated cellulose

Cellulose can be regenerated by a number of different methods. The original process was called the viscose method, which converts cellulose fibers into regenerated fibers and films (C. F. Cross, Bevan, and Beadle 1892; C. Cross, Bevan, and Beadle 1894; Vautier and Fay 1938). The resulting polymer is used for packaging and casings, as well as to produce viscose silk, also known as Rayon®. With some minor modifications, the same basic chemical process is still used to this day (Franz and Blaschek 1990; Nicholson et al. 1994; Pierce 2001; OMRI 2001). The basic process for making viscose was invented in the 1890s *(*Cross et al. 1894*)*. Insoluble cellulose fibers (Cell-OH) in a highly refined purified wood pulp are laid out in sheets. These sheets are then dissolved in sodium hydroxide, which forms alkali cellulose (Cell-ONa). Excess sodium hydroxide is removed by pressing. The Cell-ONa is then aged and dissolved in carbon disulfide to form cellulose xanthate (Cell—O–C), which is an unstable salt or ester. Cell—O–C is then dissolved in aqueous sodium hydroxide before it is filtered, aged and the air is removed. It is then extruded and pumped though a regeneration and coagulation bath containing aqueous sulfuric acid and sodium sulfate, which convert cellulose xanthate in viscose form back into regenerated cellulose that is extruded in tubular form.



Seamless regenerated cellulose in tube form is then washed free of salts and chemical byproducts, plasticized with glycerin, dried, and wound to form reels of casing. Finished casing reels are shirred on rods to form pleated or folded casings. As originally described, shirring is strictly a mechanical process (Dietrich 1935). Shirring solutions may be used to facilitate removal, and may be formulated with ingredients such as carboxymethylcellulose (CMC), glycerine (glycerol), propylene glycol, polyol, and mineral (petroleum) oil (Shiner and Brounstein 1961; A. D. Stall 1998; A. Stall 2000).

Casings are then compressed and pleated to form a hollow-bored stick 12-25 inches long. The sticks are packaged and sold to food processors for manufacture of the skinless hot dog and other sausage products. The casings are injected with meat into the center of the casing tube, which are then tied off into links. Filled casings are cooked, then mechanically peeled. The casings from frankfurters and sausages are often removed before they are packaged for retail sale (McClure and McClure 1950; Allen and Nack 1961; Culp 1965).

<u>Evaluation Question #2:</u> 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.

While cellulose occurs in nature, most cellulose used in food processing is extracted, purified, and made into a useful form. It is manufactured by an industrial process that involves the use of various chemicals and steps that would be considered chemical processes. Evaluation Question #1 describes in detail the processes and chemicals involved. An increasing amount of cellulose is produced from the recycling of paper. Cellulose has been previously classified as synthetic as indicated by its listing at 7 CFR 205.605(b) as an allowed synthetic.

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

Cellulose occurs naturally in great abundance and is found in all higher plants to varying degrees, but in a wide range of different forms and structures (O'Sullivan 1997). The purest natural form of cellulose is the fiber from cotton (*Gossypium* spp.), which is approximately 90% cellulose (Merck 2015). Wood consists of 40-50% cellulose (EMBL 2015). Other fiber-producing plants include linen (*Linum usitatissimum*), hemp (*Cannabis sativa*), jute (*Corchorus* spp.), kenaf (*Hibiscus cannabinus*), ramie (*Boehmerie* spp.) and straw from various grains. However, these alternative plant sources are limited by technical considerations and production capacity (Ververis et al. 2004). Although it is theoretically possible to use cotton and other natural fibers as sources of cellulose for filtering, making food-grade cellulose in a functional form requires synthetic processes.

<u>Evaluation Question #4:</u> 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.

The FDA determined that cellulose was GRAS under the provisions of 21 CFR 121.101 (LSRO 1973). The Select Committee on GRAS Substances (SCOGS) concluded that "[t]here is no evidence in the available information on [cellulose] that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current or might reasonably be expected in the future" (SCOGS 2015). Powdered cellulose is considered to belong in the "prior sanctioned category" as a food addition in use prior to the passage of the Food Additives Amendment in 1958. It is considered "grandfathered" and permitted (Mitchell 1986).

<u>Evaluation Question #5:</u> 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)).

Cellulose has no antimicrobial activity by itself and it does not serve as a preservative. Its functionality is more often as packaging, protecting the food surface from contamination by potential pathogens and spoilage organisms.

<u>Evaluation Question #6:</u> 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)).

Cellulose is generally tasteless, non-digestible and is not used to recreate or improve flavors, colors, or nutritive values. When cellulose is used as a filtering aid or a peelable sausage casing, it does not have impact on texture. However, cellulose is used to achieve certain specific structural and textural effects when used as an anti-caking agent with baked goods, spices and dairy products by retaining moisture and preventing agglomeration. For example, cellulose will improve the crumb structure and gas exchange of muffins, cakes and doughnuts (Saltmarsh 2000). Cellulose combined with guar gum can also increase the thickness of certain liquid products, such as salad dressings. Such a use would not comply with the current annotation at 7 CFR 205.605(b).

<u>Evaluation Question #7</u>: 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)).

Use as an anti-caking agent or a regenerative sausage casing is not expected to have any effect on the nutritional quality of food or feed.

<u>Evaluation Question #8:</u> 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)).

Food grade specifications for powdered cellulose are listed in Table 3.

Table 3. Food grade specifications for powdered cellulose (Food Chemicals Codex Committee 2011)

Chlorine	Not more than 0.05%
Lead	Not more than 3 mg/kg
Sulfur	Not more than 0.01%
Total Ash upon combustion	Not more than 0.3%
Loss on Drying	Not more than 7%
pH	Between 5 and 7.5
Water soluble substances	Not more than 1.5%

<u>Evaluation Question #9:</u> 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)).

Cellulose may be derived from many sources. If the original source of cellulose is taken into account, then the environmental impacts of logging need to be considered. Natural ecosystems have been cleared and replaced with plantations of fast-growing species harvested for paper, threatening biodiversity (Roberts 2007). Genetically engineered trees have been released in China for the purpose of producing paper and other cellulose products. Their release has raised environmental concerns, and transgenic trees are expected to contribute to cellulose production in the U.S. in the near future (Roberts 2007).

The traits for which trees are being genetically modified include reduced lignin and higher cellulose content (Pilate et al. 2002), insect and disease resistance (Hu et al. 2001; Mentag et al. 2003; Merkle et al. 2007), and rapid growth, among other traits (Harfouche, Meilan, and Altman 2011). Excluded methods such as genetic modification are prohibited under 7 CFR 205.105(e). Recycling and the use of alternative crops would mitigate the impact of cellulose manufacturing on biodiversity (Roberts 2007).

Pulp and paper processing involves the emission of various airborne pollutants and effluents into water. The process for manufacturing pulp and paper is regulated under the Clean Air Act and the Clean Water Act and their respective regulations (40 CFR 63 and 40 CFR 430). The paper industry is the largest user of water per ton of industrial product (Roberts 2007). Forest products ranked third for both energy use and greenhouse gas emissions among all U.S. industries, with the pulp and paper subsector accounting for most in both categories (Energetics 2012).

The environmental problems caused by waste cellulose generated from food processing are not well documented. The cellulose that is removed in peelable casings or spent filtration aids could potentially be composted, recycled, regenerated or converted to ethanol. However, data is not available that compares how much cellulose as a by-product of food processing is landfilled versus put to another use. Conversion of cellulosic food wastes into useful products has been the subject of research. Most is based on food by-products, but in some cases the research involves the filtration aids or spent casings that comprise a small fraction of the waste stream generated by food processing. The research is based more on seeking to add value, but is also driven by environmental concerns, rising disposal costs and government regulations (Das and Singh 2004).

<u>Evaluation Question #10:</u> 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)).

Studies on both animal models and human subjects found cellulose to be non-toxic. Rats fed cellulose at the highest doses possible suffered no mortalities (LSRO 1973). Long-term feeding studies on rats showed higher weight gain in rats fed cellulose, possibly due to greater water retention. The slight adverse effects on reproductive ability were attributed to the reduced nutritional intake in the cellulose diet. Cellulose is not considered a carcinogen by the International Agency for Research on Cancer (IARC 2014) or the California Proposition 65 list of known carcinogens (Cal-EPA 1997), and does not appear on the Toxics Release Inventory (TRI) Basis of OSHA Carcinogens (US EPA Toxics Release Inventory Program 2015).

Although cellulose is not explicitly listed as GRAS in 21 CFR 184, the Select Committee on GRAS Substances concluded that "[t]here is no evidence in the available information on pure and regenerated cellulose, including micro-crystalline cellulose, that demonstrates or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are current, or might reasonably be expected in the future" (SCOGS 2015).

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

Mechanical filtration can be a substitute for the use of cellulose as a filtering aid. However, many of these filters are also synthetic, such as various cross-linked polymers.

Methods to prepare sausages without casings using appropriate heat and pressure in a stuffing horn have been commercially available since the 1930s (Paddock 1939). Sausages can also be made without casings using agricultural ingredients as binding agents, as well as pressure. Common ingredients used as binders in elongated meat products made without casings include vegetable oil and lecithin (Powers et al. 2012).

<u>Evaluation Question #12:</u> 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)).

Silicon dioxide can also be used as an anti-caking agent. Silicon dioxide can be nonsynthetic, although most food-grade sources would probably be considered synthetic. Nonsynthetic silicon dioxide is not listed at 7 CFR 205.605(a), but the synthetic form is listed at 7 CFR 205.605(b) with the annotation, "Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available."

Diatomaceous earth is nonsynthetic and can be used as a nonsynthetic filtering aid per 7 CFR 205.605(a).

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

Because cellulose is found in all plants, a large number of crops are used to produce cellulose (French et al. 1993). The most important is cotton, followed by linen, which is the same plant that is used to produce flaxseed. Hemp was once a major source. Hemp fiber can be imported into the U.S., but domestic production is currently illegal under Federal law. A significant amount of research and development has gone into the adoption of kenaf as a source for cellulose. Switchgrass (*Panicum virgatum*) is another promising agricultural source (Reddy and Yang 2007). However, certain uses are unlikely to be replaced by agricultural sources, and mass production is anticipated to continue to rely on a combination of recycled and woody sources. Cellulose content of the agricultural alternatives to cotton is relatively low by comparison. For example, hemp stalks consist of approximately 45% cellulose (EMBL 2015). However, most cellulose and regenerated cellulose is produced from wood pulp (French et al. 1993).

Potato starch and other vegetable starches can be used as anti-caking agents in various food products. The main drawback to using starch is that it can get moldy (OMRI 2001). Rice hulls can also be used as anti-caking agents due to the siliceous fraction of the hulls (Hammond and Peirce 2013).

Rice, oat, barley and spelt hulls can be used to filter fruit juices, wine and other beverages (Luh 1991; Bates, Morris, and Crandall 2001). .

Alternatives for sausage and hot dog casings include those made of natural intestine, or collagen, which is an animal by-product derived from skins and hides. These types of casings are left on the sausage, and are used in breakfast sausages, bratwurst, or similar style sausages. Casings from processed intestines are listed at 7 CFR 205.606(a).

References

Adams, James W, and Henry W Hoftiezer. 1968. Cellulosic copolymer filter material. US Patent Office 3,366,582, issued January 30, 1968.

Allen, WM, and H Nack. 1961. Method for manufacturing skinless sausages. US Patent Office 2,995,449, issued August 8, 1961. https://www.google.com/patents/US2995449.

Bates, Richard Pierce, JR Morris, and Philip G Crandall. 2001. *Principles and Practices of Small-and Medium-Scale Fruit Juice Processing*. 146. Food & Agriculture Org.

Cal-EPA. 1997. “Prioritized Candidate Chemicals under Consideration for Carcinogenicity Evaluation.” Sacramento, CA: California Environmental Protection Agency, Office of Environmental Health Hazard Assessment. http://www.oehha.ca.gov/prop65/pdf/batch1.pdf.

CAN/CGSB. 2015. *Organic Production Systems: Permitted Substances List*. 32.311-2015. Ottawa, ON, Canada: Canadian General Standards Board. http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/normes-standards/internet/bio-org/lsp-psl-eng.html.

Clement, WJ. 1966. Method of shirring synthetic tubular sausage casing. US Patent Office 3,266,911, issued August 1966. http://www.google.com/patents/US3266911.

Cross, CF, EJ Bevan, and C Beadle. 1894. Plastic compound of cellulose. US Patent Office 520,770, issued June 5, 1894. https://www.google.com/patents/US520770.

Cross, Ch F, EJ Bevan, and C Beadle. 1892. Viscose. British Patent Office 8,700, issued 1892.

Culp, Ercel. 1965. Method of making annular sausages. US Patent Office 3,180,737, issued April 27, 1965.

Das, Himanish, and Sudhir Kumar Singh. 2004. “Useful Byproducts from Cellulosic Wastes of Agriculture and Food Industry—a Critical Appraisal.” *Critical Reviews in Food Science and Nutrition* 44 (2): 77–89.

Delmer, Deborah P, and Yehudit Amor. 1995. “Cellulose Biosynthesis.” *Plant Cell* 7 (7): 987–1000.

Demon, GA, LC Van Der Ven, J Andriessen, and H Van Der Ven. 1955. Process of manufacturing cellulose powder. US Patent Office 2,709,045, issued May 1955. https://www.google.com/patents/US2709045.

Dietrich, EH. 1935. Tube-packaging machine and method. US Patent Office 2,010,626, issued August 1935. https://www.google.com/patents/US2010626.

Ellis, Bryan, and Ray Smith. 2008. *Polymers: A Property Database*. Boca Raton, FL: CRC Press.

EMBL. 2015. “Chemical Entities of Biological Interest.” http://www.ebi.ac.uk/.

Energetics. 2012. “US Manufacturing Energy Use and Greenhouse Gas Emissions Analysis.” Oak Ridge, TN: Oak Ridge National Laboratory. http://energy.gov/sites/prod/files/2013/11/f4/energy_use_and_loss_and_emissions.pdf.

ErtelAlsop. 2015. “Filter Paper.” https://ertelalsop.com/filter-media/filter-paper/.

EU Commission. 2008. *Organic Production and Labelling of Organic Products with Regard to Organic Production, Labelling and Control*. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R0889-20140416&qid=1446510177884&from=EN.

Fernyhough, R. 1994. Treatment of alcoholic beverages. EP Patent 391,687, issued August 10, 1994. https://www.google.com/patents/EP0391687B1?cl=en.

Food Chemicals Codex Committee. 2011. *Food Chemicals Codex*. Rockville, MD: US Pharmacoepial Convention.

Franz, G, and W Blaschek. 1990. "Cellulose." In *Methods in Plant Biochemistry, Vol. 2: Carbohydrates*, edited by PM Dey and JO Harbourne. London, UK: Academic Press.

Frederick, WJ, SJ Lien, CE Courchene, NA DeMartini, AJ Ragauskas, and Kristiina Iisa. 2008. "Co-Production of Ethanol and Cellulose Fiber from Southern Pine: A Technical and Economic Assessment." *Biomass and Bioenergy* 32 (12): 1293–1302.

French, AD, NR Bertoniere, OA Battiste, JA Cuculo, and DL Gray. 1993. *Cellulose Kirk-Othmer Encyclopedia of Chemical Technology, Vol. 5*. Interscience, new york.

Hammond, Neal A. and J, Steve Peirce. 2013. "Biogenic silica from silica-containing plant material such as rice hulls." US Patent 8,492,444 B2, filed February 2, 2009, published July 23, 2013.

Harfouche, Antoine, Richard Meilan, and Arie Altman. 2011. "Tree Genetic Engineering and Applications to Sustainable Forestry and Biomass Production." *Trends in Biotechnology* 29 (1): 9–17.

Hubbe, Martin A, Orlando J Rojas, Lucian A Lucia, and Mohini Sain. 2008. "Cellulosic Nanocomposites: A Review." *BioResources* 3 (3): 929–80.

Hu, JJ, YC Tian, YF Han, L Li, and BE Zhang. 2001. "Field Evaluation of Insect-Resistant Transgenic Populus Nigra Trees." *Euphytica* 121 (2): 123–27.

IARC. 2014. "Agents Classified by the IARC Monographs." http://monographs.iarc.fr/ENG/Classification/.

IFOAM. 2014. *IFOAM Norms*. Bonn, Germany: IFOAM.

International Fiber Corporation. 2015. "Cheese Anti-Caking." http://www.ifcfiber.com/applications/cheese/cheese.php.

Johnson, AH, and MS Peterson. 1974. "Carbohydrates." *Encyclopedia of Food Technology*.

Knudsen, FW. 1931. Method of producing skinless sausage. US Patent Office 1,825,528, issued September 29, 1931. https://www.google.com/patents/US1825528.

Krässig, Hans A. 1993. *Cellulose: Structure, Accessibility and Reactivity*. New York: Gordon & Breach.

Lassen, F.O. 1976. Method of making filaments and webs of chemically modified cellulose fibers. US Patent Office 3,997,647, issued December 1976. https://www.google.com/patents/US3997647.

LSRO. 1973. "Evaluation of the Health Aspects of Cellulose and Certain Cellulose Derivatives as Food Ingredients." GRAS PB274667. Bethesda, MD: Federation of American Societies for Experimental Biology, Life Sciences Research Office.

Luh, BS. 1991. "Rice Hulls." In *Rice Utilization. Vol II*, edited by BS Luh, 269–94. Westport, CT: AVI.

Martirosyan, Alina, and Yves-Jacques Schneider. 2014. "Engineered Nanomaterials in Food: Implications for Food Safety and Consumer Health." *International Journal of Environmental Research and Public Health* 11 (6): 5720–50.

McClure, ER, and AL McClure. 1950. Means of producing frankfurters. US Patent Office 2,514,660, issued July 11, 1950. https://www.google.com/patents/US2514660.

Mentag, R, M Luckevich, M-J Morency, and A Seguin. 2003. "Bacterial Disease Resistance of Transgenic Hybrid Poplar Expressing the Synthetic Antimicrobial Peptide D4E1." *Tree Physiology* 23 (6): 405–11.

Merck. 2015. *The Merck Index Online*. Cambridge, UK : Royal Society of Chemistry,. http://resolver.library.cornell.edu/misc/8496923.

Merkle, SA, GM Andrade, CJ Nairn, WA Powell, and CA Maynard. 2007. "Restoration of Threatened Species: A Noble Cause for Transgenic Trees." *Tree Genetics & Genomes* 3 (2): 111–18.

Mitchell, BL. Letter to WB Miller. 1986. "Letter to Mr. William B. Miller, James River Corporation, Berlin NH from B.L. Mitchell, Assistant to the Director, Division of Regulatory Guidance," August 26.

Nicholson, M.D., E.M. Kajiwara, P.E. Ducharme, M.E. McCallister, and J.R. Walta. 1994. Method of making a cellulose food casing. US Patent Office 5,277,857, issued January 1994. http://www.google.com/patents/US5277857.

Ockerman, Herbert W. 1991. *Food Science Sourcebook*. 2nd ed. New York: Van Nostrand Reinhold.

Oechsle, D., W. Baur, and L. Gottkehaskamp. 1994. Method of filtering beverages and chemical, pharmaceutical, or similar liquids. US Patent Office 5,300,234, issued April 5, 1994. https://www.google.com/patents/US5300234.

OMRI. 2001. "Cellulose." Technical Advisory Panel Review. Washington, DC: USDA National Organic Program. http://www.ams.usda.gov/sites/default/files/media/Cellulose%20TR%202001.pdf.

O'Sullivan, AC. 1997. "Cellulose: The Structure Slowly Unravels." *Cellulose* 4 (3): 173–207.

Paddock, LS. 1939. Preparation of sausage. US Patent Office 2,182,211, issued December 5, 1939. https://www.google.com/patents/US2182211.

Parker. 2008. "Process Filtration: Filtration Products for Industrial Applications." Oxnard, CA: Parker Hannifin Corp. https://www.parker.com/literature/Process%20Advanced%20Filtration%20Division/Industrial%20Catalog%20Feb%202008.pdf.

Pierce, JL. 2001. “Petition for Amending the National List of the USDA’s National Organic Program for the Inclusion of Cellulose Fibers.” LaFarge, WI: CROPP Cooperative. http://www.ams.usda.gov/sites/default/files/media/Cellulose%20Petition.pdf.

Pilate, Gilles, Emma Guiney, Karen Holt, Michel Petit-Conil, Catherine Lapierre, Jean-Charles Leplé, Brigitte Pollet, et al. 2002. “Field and Pulping Performances of Transgenic Trees with Altered Lignification.” *Nature Biotechnology* 20 (6): 607–12.

Powers, R., A.E. Anderson, and P. Hardenburger. 2012. Method and apparatus for production of elongated meat products without casings. US Patent Office 8,241,686, issued August 14, 2012. https://www.google.com/patents/US8241686.

Purifiber. 2015. “Food Industry.” http://www.purifiber.com/industrial/food-industry.html.

Reddy, Narendra, and Yiqi Yang. 2007. “Natural Cellulose Fibers from Switchgrass with Tensile Properties Similar to Cotton and Linen.” *Biotechnology and Bioengineering* 97 (5): 1021–27.

Roberts, J. 2007. “The State of the Paper Industry: Monitoring the Indicators of Environmental Performance.” Asheville, NC: Environmental Paper Network. http://www.greenpressinitiative.org/documents/StateOfPaperInd.pdf.

Royal Society of Chemistry. 2015. “Chemspider.” http://www.chemspider.com/.

Saltmarsh, M. 2000. *Essential Guide to Food Additives*. Leatherhead, UK: Leatherhead.

SCOGS. 2015. “SCOGS Database.” *Select Committee On GRAS Substances Database*. http://www.accessdata.fda.gov/scripts/fdcc/?set=SCOGS.

Shiner, EA, and CJ Brounstein. 1961. Method for producing cellulosic sausage casings and product. US Patent Office 2,999,757, issued September 12, 1961. https://www.google.com/patents/US2999757.

Sjostrom, Eero. 1993. *Wood Chemistry: Fundamentals and Applications*. San Diego: Academic Press.

Stall, A.D. 1998. Cold temperature shirring. US Patent Office, issued July 21, 1998. https://www.google.com/patents/US5782683.

Stall, AD. 2000. Shirring solution for cellulosic sausage casings. US Patent Office 6,086,929, issued July 11, 2000. https://www.google.com/patents/US6086929.

US EPA. 2015a. “ACToR Database.” http://actor.epa.gov/.

———. 2015b. “Advancing Sustainable Materials Management: Facts and Figures 2013.” Washington, DC: US EPA Office of Resource Conservation and Recovery. http://www3.epa.gov/epawaste/nonhaz/municipal/pubs/2013_advncng_smm_rpt.pdf.

US EPA Toxics Release Inventory Program. 2015. “Toxics Release Inventory (TRI) Basis of OSHA Carcinogens.” Washington, DC: US EPA. http://www2.epa.gov/sites/production/files/2015-03/documents/osha_carcinogen_basis_march_2015_0.pdf.

USDA Agricultural Marketing Service. 2000. "National Organic Program: Final Rule with request for comments." *Federal Register* 65(246): 80548-80684. Washington DC: USDA-AMS-NOP. December 21. http://www.gpo.gov/fdsys/pkg/FR-2000-12-21/pdf/00-32257.pdf.

———. 2003. "National Organic Program; Amendments to the National List of Allowed and Prohibited Substances: Final Rule." *Federal Register* 68(212): 62215 -62218. Washington DC: USDA-AMS-NOP. November 3. https://federalregister.gov/a/03-27416.

Vautier, LPG, and RE Fay. 1938. Cellulosic structure and method for preparing same. US Patent Office 2,141,776, issued December 1938. http://www.google.com/patents/US2141776.

Ververis, C, K Georghiou, N Christodoulakis, P Santas, and R Santas. 2004. “Fiber Dimensions, Lignin and Cellulose Content of Various Plant Materials and Their Suitability for Paper Production.” *Industrial Crops and Products* 19 (3): 245–54.

Viskase. 2013. “Casing Solutions Worldwide.” Darien, IL: Viskase Corp. http://viskase.com/wp-content/uploads/2013/10/homepage-brochure31.pdf.

Whistler, Roy Lester, and James N BeMiller. 1997. *Carbohydrate Chemistry for Food Scientists*. St Paul, MN: Eagan.