Cellulose

processing

Executive Summary

Cellulose is the main component of higher plant cell walls and one of the most abundant organic compounds on earth. It can be derived from a number of sources using a number of techniques that are considered synthetic, and some that might be considered nonsynthetic (natural). It is available in many forms for different functional purposes in food products. This review considers three forms that have been petitioned for various uses: powdered cellulose, regenerated cellulose casing, and microcrystalline cellulose. Petitioned uses in food products include as a processing aid for filtration of juices, as an anti-caking agent ingredient for shredded cheese, and as a processing aid in the form of peelable hot dog casings. Various forms of cellulose have many other permitted FDA uses, including as a fat substitute and bulking agent in low calorie foods, as a texturizer, emulsifier, and extender.

These materials are commercially available in forms that are predominantly derived from wood pulp after a chemical delignification process. Reviewers agreed that most forms of cellulose are synthetic, though one reviewer finds that sources derived from cotton linters might be considered nonsynthetic, as are those derived from non-genetically engineered bacteria.

All reviewers recommend an allowance as processing aids used for peelable hot dog casings, provided no additional additives not on the National List are used. Reviewers felt the petition did not strongly support the use of powdered cellulose in some applications and suggested different annotations. Reviewers stated a preference for alternatives such as rice flour, non-GMO derived bacterial cellulose, and cellulose derived from cotton when used as an ingredient. One reviewer supported all sources of powdered cellulose as a filter aid. All reviewers considered microcrystalline cellulose to be a highly processed material not compatible with organic handling systems.

While most of the reviewers supported use of all forms other than GMO derived sources for use in products labeled "Made with Organic", one reviewer pointed out that there are no established criteria or guidelines for this type of annotation and requested guidance from NOSB in order to be able to make such a recommendation.

Identification

Chemical Name(s):
Cellulose, ß-1-4-D-glucan

Other Name(s):
powdered cellulose; alpha-cellulose, flour cellulose; cellulose fibers.
Microcrystalline cellulose, MCC, (derived from cellulose) is also called cellulose gel.

Cellulose casing, regenerated cellulose.

Trade Name(s):
JustFiber L20, Vitacel L600-30, Avicel, Arbocel, Cellulon, Alphacel, Novagel (MCC)

CAS Number: 9004-34-6- alpha cellulose

Other Codes:
INS numbers:
460 cellulose
460(i) microcrystalline cellulose
460(ii) powdered cellulose

Summary of TAP Reviewer Analysis

95% organic

Form	Synthetic / Non-Synthetic:	Allowed or Prohibited:	Suggested Annotation:
Regenerated Casings	Synthetic (3)	Allowed (3)	Regenerated cellulose sausage casing: All additives must appear on the National List (3)
Powdered	All forms Synthetic (1)	Prohibit (2)	Powdered cellulose: Only as a filtration aid (1) Prohibit, no annotation (2)
Derived from cotton linters or bacterial cellulose (non GMO derived)	Non-synthetic (2)	Allowed (2)	Only as a filtration aid (1) Must be derived from cotton linters and be from an organic source when commercially available (list under 205.606) or non-GMO bacterial cellulose (list under 205.605(a)(1)
Microcrystalline	Synthetic (3)	Prohibited (3)	Prohibited with no annotation (3)

Made with organic (70% or more organic ingredients)

Form	Synthetic / Non-Synthetic:	Allowed or Prohibited:	Suggested Annotation:
Regenerated Casings	Synthetic (3)	Allowed (3)	No annotation: (2) All additives must appear on the National List (1)
Powdered	All forms Synthetic (2)	Allowed (2) Prohibit (1)	No annotation (3)
Microcrystalline	Synthetic (3)	Allowed (2) Prohibit (1)	No annotation (3)

Characterization

Composition:
$(C_6H_{10}O_5)n$

Properties:
Powdered cellulose - a purified white powder; odorless; consisting of fibrous particles in various grades and degrees of fineness ranging from a dense, free flowing powder to a coarse, fluffy, non-flowing material. It is insoluble in water, in dilute acids and most organic solvents, slightly soluble in sodium hydroxide. Fibers vary in length from 0.5 to 4mm and in width from 0.005 to 0.35 mm.

Microcrystalline cellulose is purified, partially depolymerized cellulose. A fine, white, odorless crystalline powder. Insoluble in water, in dilute acids, in most organic solvents, also insoluble in dilute sodium hydroxide solutions (FCC 1981).

How Made:
Cellulose is the main component of higher plant cell walls and one of the most abundant organic compounds on earth. It is also formed by some algae, fungi, bacteria, and marine animals (Whistler, 1997; Kirk-Othmer, 1993). It is a linear, insoluble polymer of D-glucose unit joined by glycosidic linkages, and considered a polysaccharide. Cellulose molecules form long chains in polycrystalline fibrous bundles that contain crystalline as well as amorphous regions.

Commercial sources of cellulose include wood pulp or cotton linters; the short fibers remaining on cottonseeds after the long fibers are removed. Cotton fibers are about 98% cellulose, while wood is 40-50% cellulose (Whistler, 1997; Ockerman, 1991). 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 (Hanna, 2001; Ang, 2001; Franz, 1990).

Different sources of cellulose are used for different purposes, for economic reasons. 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 and are used instead for various cellulose derivatives, pharmaceutical, or chemical engineering uses, such as chromatography, paints, and explosives (Franz, 1990; Mallinckrodt-Baker, 2001). Bacterial sources of cellulose have also been developed using *Acetobacter xylinum* that ferment substrates of glucose from corn syrup (Son, 2001; Kirk-Othmer, 1993; Okiyami, 1993). These produce cellulose of small particle diameter with more surface area than powdered cellulose derived from wood pulp. They have high tensile strength and water holding capacity and currently are used as a high-value specialty chemical with applications ranging from acoustical speakers, high quality paper, diet foods, and artificial skin (Son, 2001; Okiyami, 1993).

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, 1997). Wood requires more extensive processing to solubilize the hemicelluloses and lignins (delignification). In addition, there are relatively small quantities of bacterial-derived cellulose commercially available, but reportedly have not been used for food applications. (Clark, 2001)

Pulping process

Wood contains approximately 50% cellulose, 30% hemicellulose, and 20% lignin. 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.

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 alkali process at elevated temperatures in pressure vessels or digesters (Johnson, 1974). Either process can be modified to produce higher purity cellulose that is not only free of lignins and hemicellulose, but also further degraded to result in reduced molecular weight products and derivatives (Kirk-Othmer, 1993; Whistler, 1997). 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 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. A newer oxygen alkali system avoids the use of sulfur compounds, but the fibers have lower tear strength.

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 and involves milder conditions for paper manufacturer and molded building materials. (Kirk-Othmer, 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 (washing) after each oxidative stage. It must be purified and bleached to meet the specifications of Food Chemicals Codex. Purification may involve addition of surfactants in another hot weakly alkaline extraction step after chlorination. 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 chelating agents (Kirk-Othmer, 1993).

Powdered cellulose

Manufacturers of powdered forms receive the wood pulp in the dried form from pulp mills and further mechanically process it to attain the desired fiber length, varying from 0.5 to 4 mm.

Cellulose quality is measured by the content of alpha-cellulose, which is that portion insoluble in 18% alkali. Highly purified forms (over 99% alpha cellulose) are used to make derivatives such as the cellulose gums, including sodium carboxymethylcellulose, methylcellulose and hydroxypropylmethylcellulose. However, powdered food grade cellulose is not required to reach that level of purity, because all cellulosic cell-wall materials are components of all fruits, vegetables, and cereals.

Microcrystalline cellulose (MCC)

The utility of pulverized or powdered cellulose is limited due to the highly fibrous forms, that results in poor "mouthfeel." Cellulose in its more native state has both amorphous and crystalline regions, and the amorphous regions are attacked first by solvents and chemical reagents. MCC production uses an additional step involving hydrolysis of the purified wood pulp, using hydrochloric acid to reduce the degree of polymerization. This leaves only the tiny, acid-resistant crystalline regions. It can be spray-dried, and is then termed "powdered MCC." This produces average particle sizes ranging from about 20-90 μ-m. Another form is colloidal MCC, which is water dispersible and has properties similar to water soluble gums. It requires the use of mechanical energy after hydrolysis to tear apart microfibrils and provides a major proportion of colloidal sized aggregates (less than 0.2μm in diameter) (Kirk- Othmer, 1993; Whistler, 1990).

Cellulose casings

The viscose method is used to convert cellulose fibers into regenerated fibers and films used for packaging and casings as well as to produce viscose silk (Rayon®) (Franz, 1990; Nicholson, 1991; submitted petition, Portnoy, 2001). A related process produces cellophane (Johnson, 1974). Basically this involves taking the insoluble cellulose fibers, dissolving them in alkali solutions, and regenerating them in a tubular form. The manufacturers start with a highly refined and purified wood pulp cellulose in sheet form. This wood pulp is soaked in sodium hydroxide solution to form dissolved alkali cellulose, and excess sodium hydroxide is removed by pressing. This is then shredded to form a fluffed alkali cellulose crumb. This is aged and dissolved in carbon disulfide to form a cellulose xanthate (a salt or ester of the unstable acid form). This cellulose xanthate is then dissolved in aqueous sodium hydroxide before it is filtered, aged, deaerated, and extruded and pumped though a regeneration and coagulation bath containing aqueous sulfuric acid and sodium sulfate, which converts cellulose xanthate in viscose form to regenerated cellulose that is extruded in tubular form.

$$\text{Cell ----OH} \xrightarrow{\text{NaOH}} \text{Cell--ONa} \xrightarrow{CS_2} \text{Cell --O --C}{\overset{\displaystyle S}{\underset{\displaystyle S^-Na^+}{}}} \xrightarrow{H_2SO_4} \text{Cell --OH} + CS_2 + \text{Na }HSO_4$$

The resulting seamless tube of regenerated cellulose is washed free of salts and chemical byproducts, plasticized with glycerine, dried, and wound to form reels of casing. In finishing, reels of casing are shirred ('scrunched') onto rods to form pleated or folded casing. The resulting stick of casing contains 50 feet or more of casing compressed and pleated to form a hollow-bored stick 12-25 inches long. Sticks are packaged and sold to food processors for manufacture of the skinless hot dog and other sausage products. These are then filled with ground meat products injected into the center of the casing tube, which is then tied off into links. The filled casings are then cooked and the casing peeled mechanically, as this cellulose product is not edible.

Specific Uses:

Powdered cellulose	Anti-caking agent, used in shredded cheese and spices Filter aid Retains moisture Non-caloric bulking agent used in reduced calorie products Texturizer, dispersing agent Emulsifier, used in frozen products to maintain texture through freeze - thaw cycles
Microcrystalline cellulose	Anti-caking agent and flavor carrier in grated and shredded cheese Stabilizes foams Stabilizes emulsions Replaces fats and oils, is used in low fat hot dogs, reduced fat ice cream Forms gels, improves adhesion (cling) of sauces, salad dressings Modify texture- thickens with favorable mouth feel Improves quality of low-solids tomato sauces Freeze thaw stability, retards ice crystal growth Suspending agent in ice cream Extends starches Vegetable fat whipped toppings - improves body, texture, stability Other food uses: Barbecue sauces, frozen cheese lasagna, frozen guacamole, marshmallow topping, liquid diet products, sandwich spreads, low calorie mayonnaise Tabletting agent
Regenerated cellulose casing	Casing for skinless sausages and hot dogs

Sources: Whistler, 1997; Kirk-Othmer 1993; CODEX 1999.

Uses mentioned by petitioner includes as an anti-caking agent for shredded or grated cheese, as a filtering aid in fruit processing and as a processing aid in the form of cellulose sausage casings for the production of skinless wieners (hot dogs)(Pierce 2001, Shea 2001, Ellerstson 2001.)

Use in juice filtering

As described by a supporting letter to the petition (Ellertson, 2001), powdered cellulose is used as a filtration aid to act a s shield on a filter coated with diatomaceous earth to prevent the DE from penetrating the filter, causing cloudiness of the juice product. Filtration aids are used in clarified products as a second mechanical step after initial screening to remove solids as well as mucilaginous materials. The use of the correct grade and amount of filter aid increases the effectiveness and rate of filtration. Diatomaceous earth, expanded perlite, or blends of these minerals with cellulose fibers are the most commonly used aids to filtration (Bump, 1989). Cellulose used may be the highly refined alpha-cellulose, or slightly more impure unbleached material. Different types of equipment are used, including pressure leaf, rotary vacuum, frame, sock or bag, and membrane filters (Somogyi, 1996). Those that use filter aids are reportedly the best types for filtration of apple juice (Bump, 1989). DE filtration is a three-step process: 1) a thin protective precoat layer of the cellulose filter aid is built up on the filter septum; 2) the use of a correct amount of DE over this layer; and 3) is the separation of the spent filter cake from the septum prior to the next filter cycle (Somogyi, 1996).

Other cellulose derivatives

Many other derivatives have been developed from cellulose, involving more drastic chemical modification of the basic cellulose molecule (Whistler, 1990). Various reaction products with methyl chloride are known as the methyl celluloses. This group includes carboxymethylcellulose (CMC) or cellulose gum; hydroxypropylmethylcellulose (HPMC) or carbohydrate gum; and methyl cellulose (MC) or modified vegetable gum (Whistler, 1997). These derivatives are beyond the scope of this TAP review.

Action:
Powdered cellulose is a white flavorless powder that is insoluble, but can hold large amounts of water, up to seven times its weight. It does not add undesirable flavors, does not mask desirable flavors, and is chemically inert (Ory, 1991).

Combinations: Powdered cellulose increases the viscosities of solutions of guar gum, sodium carboxymethylcellulose (CMC), and xanthan. Microcrystalline cellulose (MCC) is used in combination with CMC, or methylcellulose, which act as protective colloids. MCC is combined with starch to improve thickening with less masking of flavor.

Cellulose casings may optionally be treated with processing aids in a finishing process as the casings are shirred into stick form. These are added to facilitate peeling ('E-Z Peel'®), and can include mineral oil, propylene glycol, CMC, and lecithin. Casings are also available in colors to monitor thorough peeling or for adding color to product when desired (Viskase, 1998; Portnoy, 2001).

Status

Historic Use: The petition reports that peelable cellulose casings have been approved by Oregon Tilth Certified Organic (OTCO) since 1999. Quality Assurance International (QAI) and OTCO have allowed powdered cellulose in shredded cheese since 1994, according to the petition.

OFPA, USDA Final Rule:
Cellulose may be considered a synthetic ingredient as per 7 USC 6510(a) or considered a processing aid, and allowed if on the National List as stated at 7 USC 6510(a)(4) depending on use. It might also be considered a packaging material as described under 7 USC 6510(a)(5).

Cellulose does not appear on the National List of allowed non-organic ingredients or 7 CFR 205.605 or as a non-organically produced agricultural products allowed as ingredients in or on processed products at 7CFR 205.606.

Regulatory: Cellulose, powdered cellulose, and microcrystalline cellulose do not appear in 21CFR as regulated or GRAS. 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 (FDA, 1986).

FDA also lists "cellulose, regenerated" as approved under 21CFR 176.170, Indirect Food Additives, Components of paper and paperboard in contact with aqueous and fatty foods. Identity standards for hot dogs are described at 9 CFR 319.80 (FSIS, 2000.)

CMC, methyl cellulose, and cellulose acetate are all listed as GRAS when used in accordance with good manufacturing practice. The Association of American Feed Control Officials (AAFCO) lists powdered cellulose at 87.14 as a "special purpose product (anti-caking agents, color additives, condiments, grinding agents, pelleting agents, etc.)."

EPA/NIEHS/Other Sources

EPA – includes alpha cellulose on List 4B, "Inerts which have sufficient data to substantiate they can be used safely in pesticide products."

NIEHS – No listing in the NTP Chemical Repository. No evidence or reference of listing as a carcinogen. Not listed in the Carcinogenic Potency Database (CPDB, 2001).

NIOSH Recommended Exposure Limits
DHHS (NIOSH) Publication No. 92-100
Listed Name(s): Cellulose, respirable fraction
Cellulose, total dust
REL (Total dust): 10 mg/m3 TWA
REL (Respirable fraction): 5 mg/m3 TWA
Health Effects: Eye, skin, and physical irritation.

OSHA Permissible Exposure Levels
Code of Federal Regulations (CFR) v.29 Sections 1910.1000 (1996)
Listed Name(s): Cellulose
(Total dust): 15 mg/m3 PEL
(Respirable fraction): 5 mg/m3

Status Among U.S. Certifiers

Not listed in any published standards.

International

CODEX – Not listed. Microcrystalline cellulose was proposed by a member country prior to the May 2001 meeting, but was not adopted.

EU 2092/91 – Not listed.

IFOAM – Not listed. (IFOAM IBS 2000)

Canada – (1999). Not listed in Appendix C, Permitted Substances for Processing. .

International - Uses of anti-caking agents in cheese products appears to be prohibited in Belgium, Canada, Denmark Finland, Italy, France, Japan, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, UK, and West Germany (Branen, 1990).

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.*
   This material is being considered for use in processing applications and does not directly interact with farming systems. Spent cellulose casings derived as waste from the processing industry have been studied for disposal by composting and for use as ruminant feed (Gentry, 1995). This study found that rapid composting and use as a livestock feed material are both possible. Livestock feed use as a carbohydrate source is not sanctioned under AAFCO or FDA at present.

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.*
   See processing criterion number 2.

3. *The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.*
   See processing criterion number 2.

4. *The effects of the substance on human health.*
   See processing criterion number 3.

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.*
   Not intended for use in soil systems.

6. *The alternatives to using the substance in terms of practices or other available materials.*
   See processing criteria numbers 1 and 7.

7. *Its compatibility with a system of sustainable agriculture.*
   See processing criterion number 6.

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.*

Cellulose is a widely abundant natural material, however the processing of fiber sources to remove other natural constituents results in a purified material that can be considered synthetic. As stated under description of manufacturing, it is possible to extract cellulose from agricultural commodities, including fibers such as cotton, hemp, ramie, linen, and jute as well as sugar cane, corn stalks and cobs, straw, soybean hulls, among others. Cellulose is commercially available from cotton linters and could be produced and processed organically. No known organic source has been identified at this time. See discussion of alternatives under number 7.

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 6510 of the OFPA.*

Cellulose pulp manufactured from wood products historically has many environmental concerns. Recovery of waste chemicals, such as caustics, sulfites, and bleaching agents are important to avoid water pollution. The organic waste liquor substances may be disposed of by combustion, resulting in odors and air pollution (Kirk-Othmer, 1993). Conventional production of microcrystalline cellulose results in production of acid wastes due to the use of hydrochloric and other acids (Hanna, 2001). The use and disposal of cellulose powder itself is not reported to have any adverse environmental effects as synthetic cellulose is similar to that found naturally in the environment.

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.*

Cellulose is regarded as an inert, non-nutritive component of food products because no forms of cellulose are digested by humans. However as dietary fiber it does serve important functions (Whistler, 1997; Ory, 1991). Cellulose was found to be protective against colon cancer in 6 out of nine studies. Vegetable fiber was found to reduce the risk of colon cancer more than cereal fibers in an epidemiological study (Jones, 1991).

Interactions between fiber in the diet and some nutrients can reduce availability of some, especially calcium. Insoluble fibers can bind calcium more than soluble fibers such as pectins and gums. Vegetarian diets that have a higher proportion of various fiber constituents including pectin, lignin, and cellulose and may have a lower availability of calcium than in omnivorous diets. Ionic calcium was lower in the presence of soy protein, wheat bran, lignin, or cellulose, compared to fiber free controls (Blaney, 1996).

Cellulose is non-toxic and non-carcinogenic. Hazards from direct use are related to its status as nuisance dust and require appropriate respiratory protection during formulation.

Regenerated cellulose films may be formulated with softeners and plasticizers that can migrate into food. These include mono, diethylene and polyethylene glycols (PEG). PEG was found in food that had been wrapped in cellulose at levels approaching German statutory limits of 50mg/kg. (Castle, 1988). Regenerated cellulose casings were less permeable than natural skin casings and transmitted less benzo-pyrene compounds into sausage products after air-smoke treatment (Fedonin, 1974).

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.*

Cellulose and its derivatives have many uses that include manipulation of textures. They do not have an impact on flavor, color, or nutritive value. Microcrystalline cellulose and cellulose gums are used to substitute for fat in many reduced fat products, including low-fat sausages and hot dogs (Whistler, 1997; Mittal, 1993; Barbut 1996) and reduced fat cheese (Bullens, 1994). Microcrystalline cellulose is used to reduce moisture loss when cooking. Low fat meat products typically have increased brittleness, gumminess, and chewiness, which can be improved by addition of a MCC or CMS. Low fat cheese products may suffer from whey and water separation due to the removal of fat, or effects on protein structure formation due to High Temperature Short Time pasteurization (HTST). MCC combined with carrageenan can be used to overcome these problems, as MCC forms a spherical particle that simulates body and mouthfeel of fat globules (Bullens, 1994).

Powdered cellulose may be added to bread to provide noncaloric bulk. It is also used in reduced-calorie baked goods to stay moist and fresh longer, and provide an increased content of dietary fiber. Powdered cellulose can be added to frozen novelty ice pops to maintain texture through freezing and thawing cycles. It provides a smooth creamy texture and increased cling and viscosity for sauces (Whistler, 1997).

Cellulose used as a filtering aid, or as a peelable sausage casing, do not have impact on texture. Anti-caking agents do have an impact on texture, as they act to retain moisture and prevent clumping of cheese or allow flowing of spices.

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.

FDA considers powdered cellulose to be "an extremely highly refined substance which may be obtained from any plant fiber source" that was in use prior to the Food Additives Amendment in 1958, and as such "prior sanctioned" and permitted for use. Many references cite a limitation of 2% in shredded or grated cheese, but this does not appear in the current 21CFR 17.

Food Chemical Codex standard of identity includes the following limits (1981):

<u>Powdered cellulose</u>:

Assay: not less than 97% and not more than the equivalent of 102% of carbohydrate, calculated as cellulose.
Arsenic: (As) Not more than 1 ppm (does not appear in the 1996 edition of FCC)
Ash (total) not more than 0.3%
Chloride: not more than 0.05%
Heavy metals: (as Pb) not more than 10ppm
pH: between 5.0 and 7.5
Sulfur (total): not more than 0.01%
Water Soluble substances: not more than 1.5%

<u>Cellulose, microcrystalline (cellulose gel)</u>

Assay: not less than 97% and not more than the equivalent of 102% of carbohydrate, calculated as cellulose on a dried basis.
Arsenic: (as As) Not more than 3 ppm. (does not appear in the 1996 edition of FCC)
Heavy metals: (as Pb) not more than 10ppm
Loss on drying: not more than 5%
pH: between 5.5 and 7.0 for samples having a sieve fraction greater than 5% retained on a 37μm screen, between 5.0 and 7.0 for other samples.
Residue on ignition: not more than 0.05%
Water Soluble substances: not more than 0.16% (changed to 0.242 in 1996)

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

A basic principle of organic handling is to minimize the use of additives. The use of a non-organic additive to replace fat or provide texture characteristics not present in the natural food is not compatible with criteria 1 and 4. Reviewers believe that natural sources such as bacterial cellulose (non GMO source) or cellulose derived from cotton using a less synthetic process would be more compatible with organic principles for this type of direct additive use. Use as a processing aid, when the material does not become a component of the food, such as for casings or as a filter aid is considered compatible by most of the reviewers.

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.

Alternatives for use as an anti-caking agent: Potato starches or other starches and also rice or corn flours may be used in shredded cheese products. According to a cellulose supplier (Benbold, 2001) potato starch is cheaper but does not absorb as much moisture and is not as effective a flowing agent as powdered cellulose. The petitioner also noted problems with mold contamination of potato and other starch products. FDA GRAS listed anti-caking agents including several silicates, such as aluminum calcium silicate and calcium silicate magnesium silicate. These are not included on the National List at 7CFR 205.605 and would need to be petitioned.

Silicon dioxide is listed as GRAS at 7 CFR 172.480 when less than 2% for use "in only those foods in which the additive has been demonstrated to have an anti-caking effect." Silicon dioxide is included on the National list, and is used currently as an anti-caking agent for spices. According to a supplier, the silicates are used only in very limited amounts for shredded cheese, and silicates are more hazardous to formulate due to particulates and OSHA requirements for worker exposure. (Ang, 2001) Silicates or silicon dioxide may not be as desirable an anti-caking agent in some products, such as spices due to the abrasive qualities that can affect product structure or texture.

Alternatives for filtering aids: One source lists alternatives for juice that include activated carbon, diatomaceous earth, isinglass finings, paper shavings, rice hulls, silica compounds, carrageenans. (Branen, 1990) As described under Specific Uses, cellulose when combined with diatomaceous earth is the preferred filtering method for apple juice and for certain types of filtration equipment. Another alternative would be to market un-clarified juice forms only.

Alternatives for sausage casings: Cellulose casings are non-edible and designed to be removed from the product before sale. 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 sausage that has a "bite" to the skin (Rice, 1994; Portnoy, 2001).

TAP Reviewer Discussion[2]

Reviewer 1

[Ph.D, Food Science and nutrition professor with inspection and certification experience, Western U.S.]

Assessment of the completeness and accuracy of database and evaluation.
[Reviewer agreed with the database characterization]

Additional information regarding NOSB Processing Criteria]

1. *It cannot be produced from a natural source and has no organic ingredients as substitutes.*
   The only other potential source has been identified as bacterial.

6. *Its use is compatible with the principles of organic handling.*
   It must be articulated that cellulose products when used as a casing or filler aid do not become ingredients of that product. Therefore cellulose is a short term packaging material and cellulose when used as a filtering aid, should be considered as a processing aid, not an ingredient since it is not present in any form in the final product.

Additional Comments
Cellulose is a linear polymer of ß (beta) linked D glyco- pyranosyl units and is the most abundant naturally occurring substance. (Johnson, 1974) In humans it is not digested since we do not possess the beta amylase enzymes required to breakdown or hydrolyze cellulose to glucose as we can for starches that are structurally in an alpha D glyco-pyranosyl (Ockerman, 1991).

This petition focuses on a petition for the use of cellulose fibers, micro crystalline and powdered cellulose manufactured by the viscose process using wood pulp and sodium hydroxide and carbon disulfide to form a cellulose xanthate crumb further dissolved n aqueous sodium hydroxide which is then further physically processed by extrusion to produce cellulose casings. (Viskase, in Pierce, 2001) This process and product are Kosher certified and as for powdered cellulose ingredients approved by the FDA since it was used as a food additive prior to the passage of the food additives amendment in 1958. Therefore use of powdered cellulose is grandfathered as "prior sanctioned"(FDA, 1986).

Additionally, bacterial cellulose has been developed as a newer form of cellulose having functional properties as a food stabilizer and non-caloric bulking agent. Bacterial cellulose has been produced from Acetobacter sp. A-9 (Son, 2001; Okiyama, 1993).

A number of cellulose derivatives are also used as FDA approved food applications. The most commonly used are carboxy methyl cellulose (CMC), methyl cellulose, hydroxypropylmethyl cellulose as well as microcrystalline cellulose (MCC). All of these cellulose derivatives are produced and manufactured using additional chemical modification of cellulose (Pomeranz, 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.*

Therefore, for this TAP review as a function of the contents of petition the following forms of cellulose will be reviewed: Cellulose casings, Powdered cellulose, and Microcrystalline cellulose.

Conclusion Reviewer 1

Since cellulose extracted from natural wood sources is used for limited term storage of smoked organic sausages, I would classify this product as a short-term packaging material. At no time does it become a component of the organic food. Additionally, it has been shown to reduce the uptake of 3-4 benzopyrene, a powerful carcinogen. Therefore cellulose casings are non-edible. I would favor approval of cellulose as used for casings as a synthetic packaging material as long as it is not stored or transported in propylene glycol since softening agents such as propylene glycol may be added to casings to insure softness and pliability with resulting migration into the organic product.

Therefore I would recommend cellulose as used for sausage casings as an approved synthetic packaging material.

The use of powdered cellulose has been used in the industry as a process filtration aid that is mixed with diatomaceous earth. Cellulose does not contribute any additional filtration capacity but serves as an aid to help remove the diatomaceous earth from the filtering plate after filtration of the juice or liquid has been conducted. Additionally, powdered cellulose will function to help retain the diatomaceous earth on the filter bed minimizing the risk of diatomaceous earth particles passing through the filter and into the juice. Since the powdered cellulose is not present in the final product, I would recommend that powdered cellulose be approved as a synthetic processing aid specifically for filtration operations.

Incorporation of any form of microcrystalline cellulose into organic products should be prohibited. It is clearly a chemically modified form of naturally occurring cellulose. Microcrystalline cellulose has undergone additional hydrolysis with additional breakage of covalent Betal-4 bonds causing a complete structural and functional change from its native form. Therefore, it should be classified as a synthetic prohibited food additive.

Recommendation Advised to the NOSB, Reviewer 1:

1. Cellulose Powder/Fibers Used for Casings: *Synthetic, Should be added to the National List of Allowed Non-organic Ingredients (includes processing aids).*

Suggested Annotation

Must only be used according to FDA CFR and must not contain any softening agents such as propylene glycol.

2. Powdered Cellulose, Synthetic Should be added to the National List of Allowed Non-organic Ingredients (includes processing aids). *Suggested Annotation* Must only be used according to FDA 21CFR as a filtering aid. May be used for all FDA approved uses in products labeled "made with organic" ingredients.

Justification

Not suitable as ingredient for anti-caking, natural alternative sources are preferred.

3. Microcrystalline Cellulose, Synthetic, Should not be added to the National List of Allowed Non-organic Ingredients (includes processing aids).

Justification:

This product is clearly synthetic and further chemically modified. Manufacturer is advised to consider conducting research on storage and sensory testing using more organically compatible ingredients. Allowed only in products labeled "made with organic ingredients."

Reviewer 2

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

I. Cellulose, powdered forms

Assessment of the completeness and accuracy of database and evaluation.

The discussion of bacterial cellulose in the TAP Review was inadequate, given this reviewer's belief that bacterial cellulose, which was commercialized about 10 years ago under the brand name "CELLULON," is a non-synthetic substitute for 'normal' 'commercial' cellulose manufactured from wood pulp and for microcrystalline cellulose. The references were adequate to provide good background.

A detailed description of the process for fermenting A. xylinum to make cellulose can be found in U.S. Patent No. 4,960,763. A GRAS (Generally Recognized As Safe) petition was accepted for filing by FDA in 1992 (Food Product Design, 1997).

NIEHS reviewed some aspects of the toxicology of bacterial cellulose in its review of cellulose insulation. Schmitt and coworkers (NTP, 1991) found that Cellulon fiber which is produced by a bacterial fermentation process employing a strain of *Acetobacter aceti xylinum* and most closely resembles powdered and microcrystalline cellulose, exhibited no genotoxic potential in four assays. At 66.7 - 2500 μg/plate, Cellulon did not cause increases in histidine revertants in *Salmonella typhimurium* strains TA98, TA100, TA1537 or TA1538 both with and without metabolic activation. Cellulon was negative for inducing chromosomal aberrations in Chinese hamster ovary (CHO) cells at 1990 - 8000 μg/ml both with and without metabolic activation. At 501 - 5010 μg/ml Cellulon was inactive in the *in vitro* rat primary hepatocyte UDS assay. Cellulon fiber was negative for inducing forward mutations at the HGPRT locus in CHO cells at 0.25 - 5 mg/ml both with and without metabolic activation (NTP,1994).

The "Characterization" section has all the information required to differentiate between cellulose from pulp by chemical means and cellulose from cotton linters by a simple alkali wash. .... The Kirk-Othmer discussion leads me to believe that the "steam explosion" process may yield clean cellulose without the use of harsh chemicals. If this is true, wood cellulose from the "steam explosion" process may be acceptable for inclusion on the National List. The temperatures involved, 200ºC to 250ºC (392ºF to 482ºF), are within the capability of a home oven [mine goes to 550ºF] so the NOSB might consider it acceptable.

OFPA Criteria Issues

Criterion 1: The BSE (bovine spongiform encephalitis; "mad cow disease") concern makes ruminant feed use of spent hot dog and sausage casing unacceptably risky, to avoid spreading a contagious disease. I believe that this use has been discontinued. Composting still is acceptable.

Criterion 2. Cellulose is not toxic and decomposes in the environment.

Criterion 3. The chemical treatment of wood pulp to manufacture cellulose and the acid hydrolysis of cellulose to make microcrystalline cellulose can be severely environmentally unfriendly. However, other processes for making cellulose are much less damaging to the environment. This needs to be pointed out.

Criterion 4. Cellulose is benign unless inhaled, injected or implanted. Note that SCOGS [Select Committee on GRAS Substances] issued a report in 1973, entitled "Evaluation of the Health Aspects of Cellulose and Certain Cellulose Derivatives as Food Ingredients" (SCOGS-25, Bethesda MD, Federation of American Societies for Experimental Biology, 27 pp.). This [is available from] National Technical Information Service (NTIS) of the Department of Commerce.

Criterion 5. Cellulose can be composted, given a source of nitrogen.

Criterion 6. The petition requests allowance of cellulose for use as an anti-caking ingredient (up to 2%) in shredded cheese products. One petition supporter (Horizon Organic Dairy) indicated that rice powder and oat powder were unacceptable alternatives. The TAP Review correctly indicates that potato and starch products introduce mold concerns.

Criterion 7. Isolating cellulose from cotton linters or fermenting *A. xylinum* on corn steep liquor are consistent with sustainable agriculture.

NOSB Processing Criteria Issues

Criterion 1. Cellulose is produced from a natural source. The TAP Review discussion is adequate.

Criterion 2. See OFPA Criterion 3 discussion above. The chemical treatment of wood pulp to manufacture cellulose and the acid hydrolysis of cellulose to make microcrystalline cellulose are environmentally unfriendly. However, other processes for making cellulose are much less damaging to the environment. The differential aspects of the environmental impacts of the several ways of producing cellulose need to be set forth. The TAP Review is inadequate in this regard.

Criterion 3. Adding non-nutritive fiber at a low level is nutritionally neutral or slightly benign. The TAP Review discussion is adequate.

Criterion 4. Cellulose is being petitioned as an anti-caking agent added to cheese to keep the cheese from compacting into a non-saleable mass. The uses cited in the TAP Review are valuable to know because there seems to be no reason for any limitation on the use of cellulose in food other than current Good Manufacturing Practices.

Criterion 5. The TAP Review could be supplemented with the summary from the 1973 SCOGS evaluation of the health effects of cellulose as a food ingredient.

Criterion 6. The use of 2% of a natural substance such as cellulose (if the manufacturing process can keep it non-synthetic) to enable shredded organic cheese to retain its marketability is compatible with the principles of organic handling.

Criterion 7. One petitioner indicated that cellulose is not routinely added to shredded cheese: only if the batch requires it.

Recommended Vote – Reviewer 2 – Cellulose in powdered forms

1. The following substances are SYNTHETIC:
   - Cellulose prepared from wood pulp and other vegetable matter by sulfite, Kraft or other chemical processes.
   - Microcrystalline cellulose produced by hydrochloric acid digestion of cellulose.
   - Bacterial cellulose prepared by fermentation of genetically modified organisms.

   These materials should not be added to the National List of substances allowed as ingredients in or on processed products labeled as organic or made with organic ingredients because of the following reasons:
   - the drastic treatment and environmental impact of the manufacturing of cellulose from wood pulp;
   - the availability of cellulose made from cotton linters, an acceptable substitute for wood pulp-derived cellulose;
   - the chemical changes produced by the acid hydrolysis process used to make microcrystalline cellulose;
   - the availability of bacterial cellulose made by a native microorganism, an acceptable substitute for microcrystalline cellulose; or
   - the bacterial cellulose produced by a genetically engineered microorganism is antithetical to organic integrity.

2. Cellulose, produced from conventional cotton linters (which are 98% cellulose) by a process that consists of no chemical exposure other than washing with a warm sodium hydroxide solution to remove minor amounts of protein, pectic substances and wax, with a final water rinse to remove residual sodium hydroxide, is a non-organically produced agricultural product. It is NON-SYNTHETIC. It should be allowed as an ingredient in or on processed products labeled as organic or made with organic ingredients. (An analogous material currently listed in 7CFR205.606 is "Cornstarch (native)".)

   The only chemical exposure permissible is to a dilute solution of a sodium hydroxide, an Allowed Non-Organic Ingredient [7CFR205.605(b)(32)].

   Cellulose currently produced from conventional cotton linters could be made commercially from linters of organic cotton. Section 7CFR205.606 foresees this eventuality. Assigning this regulatory status to cellulose from cotton linters creates an incentive to produce organic cellulose.

3. Bacterial cellulose prepared by non-genetically engineered cellulose-producing bacterial (e.g., Acetobacter aceti xylinum) fermentation of carbohydrate substrates is a NON-SYNTHETIC non-agricultural substance. It should be allowed as an ingredient in or on processed products labeled as organic or made with organic ingredients. (An analogous material currently listed in 7CFR205.605 is "Citric acid – produced by microbial fermentation of carbohydrate substrates".)

   Bacterial cellulose is purified by washing with a warm sodium hydroxide solution to remove bacterial cell bodies, and with a final water rinse to remove residual sodium hydroxide. The only chemical exposure permissible is to a dilute solution of a sodium hydroxide, an Allowed Non-Organic Ingredients, 7CFR 205.605(b)(32).

   Note that bacterial cellulose inherently has the functional properties of microcrystalline cellulose.

Recommended Annotation: the two non-synthetic cellulose materials made by the indicated methods of production appear acceptable. Other production methods described are unacceptable. There appears to be no rationale for limiting cellulose use in food to other than current Good Manufacturing Practice.

[Reviewer 2] II. Regenerated (Viscose) Cellulose Sausage Casing

Title 21, Code of Federal Regulations, Section 176.170, entitled "Components of paper and paperboard in contact with aqueous and fatty foods," cites regenerated cellulose as acceptable without reservation. Although cellulose casing would not qualify as either paper or paperboard, this section has relevance in establishing that FDA has determined that regenerated cellulose packaging is safe when in contact with fatty food like a hot dog.

Title 7, Code of Federal Regulations, Paragraph 205.270(a) states: "the packaging . . or otherwise enclosing food in a container may be used to process an organically produced agricultural product for the purpose of retarding spoilage or otherwise preparing the agricultural product for market." Filling regenerated (viscose) cellulose sausage casing with a meat emulsion in order to facilitating cooking/smoking of the hot dog represents such an action.

Title 7, Code of Federal Regulations, Paragraph 205.105(a) requires all products to be produced and handled without the use of non-organic substances except as provided in 205.605-205.606. This requirement creates a burden to establish that, in the course of the handling or processing of an organic product (including the packaging), (1) no substance not on the National List has migrated into the product and (2) any substance that has migrated into the food is on the National List. This is because any migrating substance becomes, unintentionally, an <u>ingredient</u> of the food.

The Current Facts:
The petitioned casing material is “pure” “cellulose casing.” This is distinguished from “fibrous casing” comprised of "a flexible fibrous composite . . made of long-fibered abaca hemp. . formed into a tube and bonded with a cellulose xanthate (viscose) solution"(Nicholson, 1991). Casing manufacturers make both kinds of “cellulose” casings so it is important to make this distinction.

Cellulose casing is inedible and is stripped from the cooked sausage (e.g., frankfurter, wiener, hot dog) after cooking or smoking to produce a “skinless hot dog.” Consequently, the cellulose in the cellulose casing is not an ingredient of the fully processed food. Note that there is no other means of producing a “skinless hot dog.” “Skinless hot dogs” are the most popular of all categories of hot dogs.

(Collagen casing, produced from beef skin, can be used to produce a hot dog with a skin (“skin-on hot dog”). In this case the collagen casing is consumed so the collagen casing is an ingredient of the organic product; DeWeid, 2001).

Cellulose casings can be treated with substances that migrate to the food during the cooking or smoking process. A polyol (glycol) plasticizer additive is required to keep the regenerated cellulose casing from becoming brittle and suffering a loss in performance. Low molecular weight plasticizers migrate into the food. Of the various polyols used for cellulose casings (propylene glycol, glycerol, etc.), only glycerol (glycerin produced by hydrolysis of fats and oils) is on the National List [see 7CFR205.605(b)(13)]. Thus, glycerol produced by hydrolysis of fats and oils is the only acceptable plasticizer for cellulose casing used for handling and processing organic foods.

Any other additive to the cellulose casing should be documented as having zero migration to the food [see test methods at 21CFR176.170(c) and (d)] or it should be on the National List. Thus, for example, if a substance listed in Section 21CFR 178.3297, “Colorants for polymers,” is used to color the cellulose casing for internal control purposes (e.g., identifying organic versus non-organic hot dogs in the smoke room), any colorant used in the casing of the organic hot dogs must be established as not migrating to the food or, if it does migrate, the substance must be petitioned for inclusion on the National List.

The supplier must provide a detailed and complete listing of <u>**all**</u> substances added to the cellulose casing, in order to enable the processor (and the certifying agent) to determine the suitability of the casing for processing an organic product.

<u>Reviewer 2 Conclusion – Cellulose casing</u>:

1. Use of a regenerated (viscose) cellulose sausage casing for smoking or cooking skinless hot dog production constitutes “otherwise enclosing food in a container . . . to process an organically produced agricultural product” in the sense of 7CFR 205.270.
2. Regenerated (viscose) cellulose sausage casing contains non-agricultural and non-organic substances capable of migrating into an organic food. The cellulose casing itself is inedible, non-migrating and removed during processing.
3. Substances that migrate into the food become “ingredients”.
4. Non-agricultural and non-organic ingredients in organic products must appear on the National List.

<u>Recommended Vote</u>: Regenerated cellulose sausage casing containing no additive other than glycerin (glycerol) produced by hydrolysis of fats and oils is acceptable for the processing of organic skinless hot dogs.

<u>Reviewer 3</u>

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

Assessment of the completeness and accuracy of database and evaluation

Cellulose may be derived from bacterial sources as well. The process has been well characterized, although commercialization so far has been for non-food uses. Trade name was formerly Cellulon, the company CP Kelco has the rights for this product now and have recently had additional inquires for food use applications (Clark, 2001). It may be another alternative (Brown, 1995).

NOSB Processing Criteria Evaluation
[Reviewer agreed with the evaluation and offered the following additional points:]

1. *It cannot be produced from a natural source and has no organic ingredients as substitutes.*
It appears that cellulose could be potentially produced from a natural source, bacterial sources, but it is currently in limited commercial production. I was not able to find commercial sources that are derived from cotton linters.

Additional commercial anti-caking alternatives for shredded and grated cheeses include rice and corn flours, with rice flour being the preferred alternative as it is non-GMO at the present time. Theoretically, according to the supplier, these anti-caking agents could be derived from organic crops, as they involve physical, not chemical modification of the flours for this purpose (IMAC 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.
The very small amount of fiber used for these applications would not have a beneficial effect on the diet, since fiber needs to be consumed in gram quantities per serving.

6. Its use is compatible with the principles of organic handling.
As a processing aid and casing, it may be compatible. As an anti-caking agent, it is used at low quantities, similar to silicon dioxide, already on the National List.

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.
Rice and/or corn flour may be used for shredded or grated cheeses. This needs to be objectively evaluated. There is no evidence that other filtration aids, already mentioned, have been evaluated and rejected. There do not seem to be other alternatives to "peelable" casings at the present time.

<u>Reviewer 3 Conclusion</u>
Based on the above criteria, it appears that there may be alternatives to cellulose for anti-caking application in shredded cheeses and possibly as a filtration aid.

Since there is no current alternative to "peelable" casings, other than natural casings, with a different consumer perception, it may be agreeable to add cellulose to the National List for that purpose only.

<u>Recommendation Advised to the NOSB, Reviewer 3</u>
The substance is synthetic and should be added to the National List ONLY for "peelable" sausage casings, since the casing is actually removed from the product and the casing may be composted to minimize its effect on the environment. I strongly believe in restriction for only one purpose, and that only because there appear to be no other alternatives for "skinless" franks.

Additional work should be carried out to properly evaluate the use of alternatives to cellulose as an anti-caking agent in cheeses and as a filtration aid to apple juice. In addition, the potential commercialization of a non-GMO bacterial source of cellulose should be investigated as the production of cellulose from wood has a significant negative impact on the environment.

In the absence of criteria or guidelines for assessment of the "Made with Organic" category from the NOSB or NOP, I am not able to make a separate recommendation. Therefore I recommend the same votes and annotations for this category.

Additional questions asked of reviewers
Similar questions were posted on the OMRI website.

1. *Should cellulose be considered an agricultural ingredient and potentially listed under 205.606 or a non-agricultural ingredient listed in 205.605?*
   Reviewer 1:Cellulose as long as it is used with application to food processing and packaging of food products, would be listed as an agricultural processing aid or packaging material.

   Reviewer 3: Since it is processed from wood pulp, I would consider it a non-agricultural ingredient listed under 205.605 or potentially a packaging material.

2. *Any additional information regarding alternative materials used as anti-caking agents, filtering aids, or sausage casings.*
Reviewer 1: Cellulose has been used as a filtering substrate (Tressler, 1991) as well as a filtering aid when mixed with diatomaceous earth (Rider, 2001) to facilitate diatomaceous earth removal from the filter plate and reduce the risk of diatomaceous earth particles (fines) going into the clarified juice (Rider, 2001). However cellulose powder functions as a process aid since it does not migrate into the final juice product.

Reviewer 3: See above: rice and/or corn flour for anti-caking.

3. *Are you aware of any other uses for cellulose currently in use in organic production?*
Reviewer 1: I am not aware of any other uses of cellulose used in organic products.

Reviewer 3: No.

4. *Is silicon dioxide viable as an anti-caking agent for cheese products? Are other silicates used at all, and what are the FDA limitations?*
Reviewer 1: Silicon dioxide is pure quartz or sand. It has an inherent gritty texture if used at too high a level. Commercial preparations such as Cab-o-sil and Syloid have long been used in the industry as free-flowing agents or anti-caking agents particularly in the bakery and snack food business.

Reviewer 3: Not aware that silicon dioxide is used for cheeses.

5. Do *you think powdered cellulose alone would meet the needs petitioned, or do you think microcrystalline is needed for certain applications?*
Reviewer 1: I think the functionality of powdered cellulose is much different microcrystalline cellulose. Chemically, they are different. Cellulose and/or cellulose fibers have been used as filtering aids and as process aid in developing short term packaging materials for sausage and meat emulsion products (i.e., hot dogs). Microcrystalline cellulose is incorporated directly into the product as an anti-caking or water binding agent. Please refer to [my] conclusions of TAP review.

Reviewer 3: I do not see a need for MCC. It is often used for texture modification, which should be petitioned separately.

References

*Note: * = included with TAP review delivered to NOP.*

Ang, J. 2001. International Fiber Corporation, Tonawanda NY. pers. communication.

Barbut, S., G.S. Mittal. 1996. Effects of three cellulose gums on the texture profile and sensory properties of low fat frankfurters. Intl. J. of Food Science and Tech. 31: 241-246.

Benbold, R. 2001. Kelly Supply, Inc. Abbotsford, WI. pers. communication.

*Blaney, S. J.A. Zee, R. Mongeau, ,J. Marin. 1996. Combined Effects of Various Types of Dietary Fiber and Protein on *in Vitro* Calcium Availability. J. Agric. Food Chem,. 4: 3587-3590.

Branen A. P., M Davisdon, S. Salimen. 1990 Food Additives. Marcel Dekker NY and Basel. pp 548- 550*, filter aids. pp. 537-546; anticaking agents.

*Brown, R. M. Position Paper: (1995) Microbial Cellulose: A New Resource for Wood , Paper, Textiles, Food and Specialty Products. University of Texas, http://www.botany.utexas.edu/facstaff/facpsages/mbrown/position1.htm

*Bullens, C. G. Krawczyk, and L. Geithman. 1994. Reduced-Fat Cheese Products Using Carageenan and Microcrystalline Cellulose. Food Technology, Jan. 79-81.

*Bump, V. L. 1989. Filtration of Apple Juice, in *Processed Apple Products* edited by D. L. Downing. Van Nostrand Reinhold, NY. p 126-136.

*Castle, L. H.R. Cloke, C. Crews and J. Gilbert. 1988. The migration of propylene glycol, mono-di-, and triethylene glycols from regenerated cellulose film into food. Zeitschrift fuer Lebensmittal Untersuchung und Forschung. 187(5) 463-467. (German, abstract in English)

Clark, Ross. 2001. CP Kelco, personal communication with TAP reviewer. Website is www.CPKelco.com

CPDB 2001. The Carcinogenic Potency Database (CPDB). Supported by the National Institute of Environmental Health Sciences through the NIEHS Center, University of California at Berkeley, and by the Department of Energy (DOE) through E. O. Lawrence Berkeley National Laboratory. http://potency.berkeley.edu/cpdb.html

CODEX 1999. CCFAC - Codex Committee on Food Additives and Contaminants. Class Names and the International Numbering System for Food Additives (INS). http://www.codexalimentarius.net/standard/stan01e.htm

CODEX 2001. Guidelines For The Production, Processing, Labelling And Marketing Of Organically Produced Foods (Gl 32 – 1999, Rev. 1 – 2001).

Dewied International, Inc. 2001. Casing Products. http://www.dewied.com/casing/htm.

Ellertson, K. 2001. Letter to NOSB, on behalf of J. M. Smucker Co. in support of cellulose petition.

EPA, 2001. Lists of Other (Inert) Pesticide Ingredients http://www.epa.gov/opprd001/inerts/lists.html

Fedonin, V.F. T. Bershova, V. Kuznetsov, A.M. Mevedev, 1974. Passage of 3,4-benzopyrene through the sausage skin during heat treatment with smoke-air mixture. Mosk. Tekhnol. Inst. Myasn. Molochn. Prom. Moscow USSR. Myasn.Ind. SSSR (8) 27-8. Journal in Russian (abstract in English).

*FDA, 1986. Letter to Mr. William B. Miller, James River Corporation, Berlin NH from B.L. Mitchell, Assistant to the Director, Division of Regulatory Guidance, CFSAN dated Aug. 26, 1986.

* FDA. 1999. 21 CFR 176.70. Components of paper and paper board in contact with aqueous and fatty foods.

Food Chemicals Codex, 1981. Third Edition. National Academy Press, Washington DC. Pp 79-81.

Food Chemicals Codex, 1996 . Fourth Edition. National Academy Press, Washington DC.

*Food Product Design, March 1997. Reducing Fat, A Cutting –Edge Strategy. "Microbial web." http://www.foodproductdesign.com/archive/1997/0397CS.htm

*Francis, F. Encyclopedia of Food Science and Technology. 2nd Ed. 2000. John Wiley and Sons, Inc. pp. 745-756.

*Franz, G. and W. Blaschek. 1990. Cellulose, in *Methods in Plant Biochemistry, Vol. 2 Carbohydrates*. Academic Press, Harcourt Brace Janovich, London. pp 291-322.

*FSIS 2000. Food Safety and Inspection Service, USDA. Consumer Education and Information. Focus on Hot Dogs. http://www.fsis.usda.gov/OA/pubs/focushotdog.htm

*Gentry, J.L., H.S. Hussein, L.L. Berger, and G.C. Fahey, Jr., 1996. Spent Cellulose Casings as Potential Feed Ingredients for Ruminants. *Journal of Animal Science*. 74:663-671.

*Hanna, M., G. Biby, V. Miladinov, 2001. United States Patent: 6,228,213. Uses corn cobs and soybean hulls to make microcrystalline cellulose. Appl. no. 154376.

IFOAM, 2001. IFOAM comments to the proposed draft guidelines for Organic Livestock of Codex Alimentarius, ALINORM 01/22, APPENDIX IV, Sections on Bees and Additives. 27-03-01. Tholey-Thely, Germany.

* IMAC, 2001. International Media and Cultures, Inc., Denver, CO. Anti caking agents, and Product specification sheet for 200-102 ("No Dust™") White Anticaking Agent, Rice Based. www.askimac.com, 800-783-4615.

*Johnson, A.H., M. S. Peterson. 1974. Encyclopedia of Food Technology. Carbohydrates p. 154 -155.

*Jones, J.M. 1991 Nutrition. *Cereal Foods World* 36; 579-580.

*Kirk Othmer. Encyclopedia of Chemical Technology, 4th Ed. vol 5. Cellulose, p. 476-496.

Mallinckrodt Baker Chemicals, 2001. Phillipsburg NJ. Personal communication, Technical Support.

*Mittal. G. S., S. Barbut. 1993. Effects of Various Cellulose Gums on the Quality Parameters of Low-Fat Breakfast Sausages. *Meat Science* 35: 93-103.

*Nicholson, M.D. 1991. Flexible nonwoven composites for food packaging. *TAPPI Journal*, May 91: 227-231.

*NTP. 1994.Cellulose Insulation. Document prepared for NTP by Technical Resources International, Inc., under NCI Contract No. N01-CP-56019 (6/95).pp. 12-16.

*Ockerman, H. W. 1991. Food Science Sourcebook, 2nd Ed. AVI, NY p. 153.

*Okiyami, A. M. Motoki, and S. Yamanaka.. 1993. Bacterial cellulose IV. Application to processed foods. Food Hydrocolloids. 6:503-511.

*Ory, R. L. 1991. Grandma Called it Roughage-Fiber Facts and Fallacies. Amer. Chem.Soc. Washington DC. Pp. 11-17.

OSHA, 2001; Limits for Air Contaminants. http://www.osha-slc.gov/OshStd_data/1910_1000_TABLE_Z-1.html

OSHA 2001 TABLE Z-3 Mineral Dusts - 1910.1000TABLEZ-3 http://www.osha-slc.gov/OshStd_data/1910_1000_TABLE_Z-3.html

*Pierce, J. 2001 Petition for Amending the National List of the USDA's National Organic Program for inclusion of: Cellulose Fibers.

*Pomeranz, Y. 1985 Functional Properties of Food Components. Academic Press. NY, NY. Pp. 96-102.

Portnoy, N. 2001. Viskase Corporation, Willowbrook Ill. pers. communication.

* Rice, J. 1994. What's New in Edible Films*? Food Processing.* July: p. 61-62.

Rider, Tom. 2001. co-owner H.A. Rider and Sons, Watsonville, CA. Personal communication with Reviewer 1.

*Shea, K. 2001. Letter to NOSB on behlaf of Horizon Organic, in support of cellulose petition.

*Somogyi, L.P, D. M. Barret, Y. H. Hui, ed. 1996. Major Processed Products. pp. 17-18. Technomic Publishing Co. Lancaster PA, Basel.

*Son H.J., M.S. Heo, Y.G. Kim, and S.J. Lee. 2001. Optimization of fermentation conditions for the production of bacterial cellulose by a newly isolate *Acetobacter sp.* A9 in shaking cultures. *Biotechnol. Appl. Biochem* 33: 1-5.

*Tressler, D., M.A. Josyln 1961. Fruit and Vegetable Juice Processing Technology. AVI Publishing Co. Westport, CT pp. 260-264.

*U.S. Patent No. 4,960,763, Bacterial cellulose, excerpt on harvesting bacterial cellulose. http://patft.uspto.gov

*Viskase, 1998. Nojax® Casings Technical Data. Viskase Corp specification sheet, submitted with petition.

*Whistler R and J. R Daniel, 1990. Functions of Polysaccharides in Foods, in *Food Additives*, A. L. Branan, P. M Davidson, S. Salinen Eds. Marcel Dekker, inc. NY and Basel. pp. 395-409.

*Whistler, R. and J. N. BeMiller. 1997. *Carbohydrate Chemistry for Food Scientists*. Chapter 7 - Cellulosics. Eagen Press, St Paul, MN.

This TAP review was completed pursuant to United States Department of Agriculture Purchase Order 40-6395-0-2900.