Sugar Beet Fiber

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
Sugar beet fiber

Other Names:
Sugar beet pulp, dried beet pulp, spent cossettes, molasses pulp, beet pulp shreds

Trade Names:
Betafiber Atlantis, DuoFiber, Fibrex®

CAS Numbers:
No CAS Number

Other Codes:
IFN 4-00-669

Characterization of Petitioned Substance

<u>Composition of the Substance</u>:

Sugar beet fiber is the dried pulp of sugar beets after the sucrose has been extracted. It consists mostly of dietary fiber (Ralet, 2009; Nordic Sugar, 2011). The soluble fiber content is generally between 10 % and 20%, which is relatively high compared with other dietary fiber sources (Thibault, 2001). The principle fibers are cellulose, hemicellulose and pectin, with the lignin content relatively low (Thibault, 2001).

<u>Properties of the Substance</u>:

Table 1
Physical and Chemical Properties of Sugar Beet Fiber

Physical or Chemical Property:	Value
Physical State	Solid
Appearance	Untreated beet fiber can be various shades of brown. Fibrex® is described as 'natural beige or off-white.' Other sugar beet fibers may be chemically treated to nearly white.
Odor	Untreated beet fiber has an earthy aroma and distinct beet flavor. Various treatments can neutralize odors and flavors.
Solubility	Partly soluble in water.
Water Holding Capacity	3.5-4.0 g water/g
Relative Density	0.3-0.7 g/cm^3
pH	4.5±0.5
Calories	800/200 kJ/kcal
Protein	8 g/ 100g
Fat	1 g / 100g
Carbohydrates	5.5 g/ 100g
Fiber	67 g / 100 g
Hemicellulose	28g / 100g
Cellulose	19g / 100g

Compiled by The Organic Center for the USDA National Organic Program
Purchase Order #AG-6395-C-11-0146

Physical or Chemical Property:	Value
Pectin	18g / 100g
Lignin	2g / 100g
Minerals	4g /100g
Sodium	0.5g / 100g
Ash	Not more than 6%

Sources: Nordic Sugar, 2011; Food Chemicals Codex, 2010.

Specific Uses of the Substance:

The petitioned use is as a dietary fiber. Other food functions include anticaking, binding, bulking, stabilizing, texturizing, thickening and dispersion (Food Chemicals Codex, 2009). The biggest use of sugar beet pulp is as livestock feed, particularly dairy cattle.

Approved Legal Uses of the Substance:

The product used as food and feed is self-affirmed as Generally Recognized As Safe (GRAS) for human food use in accordance with FDA-permitted procedures (US FDA, 1991) and is now codified in the Food Chemical Codex (Food Chemicals Codex, 2010).

Action of the Substance:

Sugar beet pulp consists mainly of hemicellulose, cellulose and pectin. The cell walls of sugar beets are thin, supple and hydrophilic. The pectin is high in galacturonic acid and acetic acid. Sugar beet pulp is also distinguished from cereal fiber by its lack of phytic acid (Ralet, 2009).

The fibers have a relatively high surface area. The mode of action is believed to be two-fold. First is the absorptive capacity of sugar beet fiber and the hydration properties. Sugar beet fiber can hold 9-12 times its weight in water (Ang and Crosby, 2003). Secondly, sugar beet fiber is negatively charged and behaves as monofunctional cation exchange resins with an approximate cation exchange capacity (CEC) of 0.5 mEq/g (Thibault, 2001).

Combinations of the Substance:

The fiber will inevitably contain some unextracted sugar (Ralet, 2009). Food fibers are sometimes blended to achieve a certain texture and flavor profile (Cho, 2009; Klosterbuer and Roughead, 2011). Since most beet pulp is used as animal feed and does not contain balanced nutrients for any livestock species, it is mostly blended with other feedstuffs to make a complete ration. The petitioner claims that no preservatives are used in Fibrex® (Nordic Sugar, 2011). Beet pulp made by manufacturing processes other than contained in the petition may in some cases be further preserved by sulfiting agents, such as sodium sulfite, sodium bisulfite, sodium metabisulfite or sulfur dioxide (Beale, et al., 1984).

Status

Historic Use:

The beet (*Beta vulgaris*) and its wild relatives are believed to have been a part of the human diet for over 4,000 years. However, the discovery that sucrose can be isolated from beets is credited to the German chemist Andreas Margraff in the mid-18th century, (Harveson, 2011). Commercial production in Germany began in 1801 in Cunern, Silesia, what is today Poland. The first commercially successful sugar factory in North America was located near what is today Union City, California. Sugar beet fiber as a by-product of sucrose was commonly fed to livestock (Morrison, 1948).

Various high fiber breakfast cereals have been made with sugar beet fiber as an ingredient. However, use of sugar beet fiber for human consumption was not common until the 1980s, when techniques to remove undesirable flavors and colors were sufficiently improved for processors to manufacture palatable and attractive products (Thibault, et al., 2001).

OFPA, USDA Final Rule:

Sugar beet fiber is not currently on 7 CFR 205.606 and is currently required to be from an organic source if used as an ingredient in an organically processed product. Non-organic sugar beet fiber may be used in products labeled as "made with organic (specified ingredients or food group(s))" subject to the requirements of 7 CFR 205.301(f)(1). However, the National List includes high methoxy pectin, which could be obtained from sugar beets [7 CFR 205.606(s)].

International

Canada - Canadian General Standards Board
Sugar beet fiber does not appear on the Permitted Substances List as a permitted non-organic ingredient not classified as a food additive (CGSB, 2009a, Table 6.4).

Organic processed products are required to use agricultural ingredients of organic origin. The use of a non-organic agricultural ingredient is subject to the provisions of §8.2.3 of CGSB 32/310 which states: "[w]hen an organic product contains 95% or more organic ingredients, a maximum of 5% non-organic ingredients may be used only if not commercially available in an organic form, and the cost of organic ingredient(s) is not to be used as a criterion for commercially available." A non-organic ingredient is further required by §8.2.6 not to be genetically engineered, from a cloned animal, or treated with ionizing radiation (CGSB, 2009b).

CODEX Alimentarius Commission
Codex requires that all ingredients of agricultural origin in an organic products meet the standards for being organically produced (§3.3(b)). Derogations may be made to use certain non-organic ingredients of agricultural origin within the limit of maximum level of 5% of the total ingredients excluding salt and water in the final product where such ingredients of agricultural origin are not available, or insufficient quantity (§3.4) (Codex, 2001).

European Economic Community (EEC)
The European Council on Organic Production and Labelling of Organic Products (EC 834/2007) requires organic processed foods be made with organic ingredients. Non-organic agricultural ingredients may be used only if they have been authorized for use in organic production if they are on a list of ingredients or have been provisionally authorized by a Member State (Article 19, Section 2(c)) (EC, 2007). The list referred to in the regulation appears in Annex IX of EC 889/2008. As amended through April 10, 2011, sugar beet fiber does not appear on Annex IX and would need to be from an organic source unless a provisional authorization is granted by a Member State. Article 29 describes the criteria for a Member State to give provisional authorization. The reviewers could find no documentation of sugar beet fiber being granted such a provisional authorization.

International Federation of Organic Agriculture Movements (IFOAM)
Agricultural ingredients are required to be from organic sources according to §6.2.1, with a derogation for standard setting bodies to permit the use of non-organic ingredients where organic ingredients are not available in sufficient quality or quantity (IFOAM, 2005).

Japan Agricultural Standard (JAS) for Organic Production

JAS requires ingredients in organic food to be of organic agricultural origin, but allows for exceptions provided that those ingredients are not produced using "recombinant DNA technology" or "ionizing radiation" (JMAFF, 2000).

Evaluation Questions for Substances to be used in Organic Handling

<u>Evaluation Question #1:</u> 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)).

Sugar beet processing operations comprise several steps. These steps include diffusion, juice purification, evaporation, crystallization, dried-pulp manufacture, and sugar recovery from molasses. The diffusion and dried pulp manufacturing steps are the most relevant to the petition.

The harvested beets are cleaned, washed and sliced into long, thin strips, known as 'cossettes.' The cossettes are conveyed to continuous diffusers, where hot water is used to extract sucrose from the cossettes. The water temperature in the diffuser is typically maintained between 50°C and 80°C (122°F and 158°F) (Cleary, 2000). Various designs are used to extract as much of the sucrose from the beet as possible, while removing impurities. The sugar-enriched water that flows from the outlet of the diffuser contains between 10%-15% sugar. This raw juice proceeds to the juice purification operations. The remaining pulp from the processed cossettes leaving the diffuser is conveyed to the dried-pulp manufacture operations.

Sugar beet fiber in commerce—including soluble forms—may be extracted, processed and handled by methods different from those described in the petition (Desforges, et al., 1993; Ang and Crosby, 2003). The petitioner claims that no preservatives are used in their process. Microbial activity on sugar beet fiber is a concern noted in their Hazard Analysis and Critical Control Point (HACCP) Plan (Nordic Sugar, 2009). Surfactants are also commonly used during the diffusion process (Cleary, 2000). Microbial and chemical contaminants are addressed in the HACCP plan provided by the petitioner (Nordic Sugar, 2009). Other producers should have similar systems in place if they follow Good Manufacturing Practices.

Sugar beet pulp used for human consumption is usually further processed to remove sand, reduce odor and lighten the color (Thibault, et al., 2001). The Fibrex® process uses steam superheated to over 130°C under pressure to extract moisture, sand and color from the fiber. In order to modify the color by superheated steam, the fiber must be dried to at least 80% dry matter (Miranda Bernardo, et al., 1990).

<u>Evaluation</u> <u>Question #2:</u> Is the substance synthetic? 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)).

The petitioned sugar beet fiber is the unreacted and insoluble portion of the beet that remains after the sucrose has been extracted by basic hydrolysis. As such, it is chemically unchanged and is physically or mechanically processed and may be considered a non-synthetic agricultural ingredient.

Sugar beet fiber may be chemically treated with a number of different substances in order to remove undesirable color, odor, and flavor. Operations that use sulfites reduce the probability of undesirable colors that may result from Maillard reactions (Cleary, 2000). The calcium hydroxide solution removes some of the color (Cleary, 2000). Various solvents may be used to remove colors and flavors (Cagley, 1992). One process uses alcohol as a solvent (McGillivray, et al., 1993). Hydrogen peroxide may also be used to remove the undesired color via oxidation (Bayer, 1979).

Other methods to remove the color, odor and flavor may involve isopropyl or ethyl alcohol cis-3-hexenol; trans-2-heptenal; trans, cis-2,6-nonadienal; trans-2-nonenal; trans, trans-2,4-heptadienal (Cagley, et al., 1992a; Cagley, et al., 1992b). Another method uses either isopropyl or ethyl alcohol (Michel, et al., 1988; McGillivray, et al., 1993). Other experimental attempts to modify the structural and functional characteristics include potassium oxalate, hydrochloric acid and potassium hydroxide (Bertin, et al., 1988).

Beet fiber modified by synthetic chemicals is likely to be rendered “synthetic.”

<u>Evaluation Question #3:</u> Provide a list of non-synthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

The substance is a non-synthetic agricultural product.

<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. What is the technical function of the substance?

Sugar beet fiber produced by the method described in the petition is self-declared and self-affirmed as Generally Recognized As Safe (GRAS) (FDA, 1991).

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

The primary function of the petitioned substance is to serve as a dietary fiber. Sugar beet fiber does not function as a preservative in the anti-microbial sense of the word. However, products made with sugar beet fiber appear to be more stable in some cases because of its texture and moisture holding capacity. Sugar beet fiber is also claimed to prolong the freshness in bread and other baked goods (Ralet et al., 2009).

<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)).

The primary function claimed in the petition is as a source of dietary fiber for people. Sugar beet fiber is used as a texturizing agent and may also be used for that purpose. The ingredient may be used to replace fiber in foods where fiber has been reduced, such as with grains that have been milled to remove the bran.

<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)).

There is no evidence from surveys of the literature that sugar beet fiber has any adverse effect on the uptake of nutrients (Thibault, 2001; Ralet, 2009). Various studies of specific nutrients have had consistent findings with this. Zinc uptake was not significantly changed by beet fiber (Sandstrom, et al., 1987). Short-term feeding studies on rats showed that fecal losses of iron and calcium were reduced by feeding sugar beet fiber (Klopfenstein, 1990).

Sugar beet fiber has a claimed beneficial effect on digestion, nutrient retention and uptake, and the metabolism of various nutrients. Sugar beet fiber in a formula diet was found to reduce postprandial blood glucose, serum insulin and serum hydroxyproline (Thorsdottir, et al., 1998). Starch absorption was also inhibited in human subjects (Hamberg, et al., 1989).

Findings related to cholesterol were mixed, but generally supportive of the general hypothesis that increased fiber consumption reduces cholesterol. Studies found that serum cholesterol and low-density lipoprotein (LDL) in human subjects were reduced by sugar beet fiber consumption (Cossack and Musaiger, 1991). Sugar beet fiber increased the excretion of cholesterol (Langkilde, et al., 1993).

<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)).

The limit for lead in food grade beet fiber is not more than 1 mg/kg (Food Chemicals Codex, 2010).

Beet fiber is not routinely tested by the USDA's Pesticide Data Program. Table 2 contains the US EPA thresholds and FDA Action Levels for pesticides found in sugar beet roots and /or sugar beet pulp.

Table 2: EPA Tolerances and FDA Action Levels for Pesticides in Sugar Beet Pulp or Sugar Beet Roots

Pesticide	Tolerance (ppm)
Acetochlor	0.05
Aldicarb[d]	0.05
Aldrin	0.10
Boscalid	0.10
Carbaryl	0.50
Carbofuran[a]	0.10
Chlordane	0.10
Chloroneb[c]	0.20
Chlorpyrifos	5.00
Clethodim	0.20
Clopyralid	2.00
Clothianidin	0.03
Cyfluthrin	1.00
Cypermethrin	0.05
DDT, DDE and TDE	0.20
Desmedipham	0.10
Dieldrin	0.10
Difenoconazole	1.90
Dimethenamid	0.01
Endothall	1.50
Esfenvalerate	0.05
Ethofumesate	0.30
S -Ethyl cyclohexylethylthiocarbamate	0.05
S -Ethyl dipropylthiocarbamate	0.40
S-(2-(Ethylsulfinyl)ethyl) O,O-dimethyl phosphorothioate	0.30
Fenbuconazole	1.00
Fluazifop-P-butyl	1.00
Flutriafol	0.08
Glufosinate	0.90
Glyphosate	25.00
Imidacloprid	0.05
Malathion	1.00
Mancozeb	2.00

Pesticide	Tolerance (ppm)
Metalaxyl	0.50
Metconazole	0.70
Methyl Bromide (as inorganic bromide)	30.00
Metolachlor	0.50
Naled	0.50
Quizalofop ethyl	0.10
Paraquat	0.50
Phenmedipham	0.50
Phorate	0.30
Propiconazole	1.00
Prothioconazole	0.25
Pyraclostrobin	1.00
Pyrazon	0.20
Pyriproxyfen	3.00
Spiromesifen	0.03
Thiabendazole[b]	0.25
2-(Thiocyanomethylthio)benzothiazole	0.10
Thiophanate-methyl	0.20
Triallate	0.20
Triflusulfuron-methyl	0.05
Trifloxystrobin	0.40
Triphenyltin hydroxide	0.05
Terbufos	0.05
Zinc Phosphide	0.05

Sources: 40 CFR 180; FDA, 2000; EPA, 2010.
[a]Revoked 12/31/2009
[b]Revoked 12/25/2010
[c]Expires 4/16/2012
[d]Scheduled to be revoked 8/31/2018

In addition, beet fiber that is not properly dried or handled is subject to contamination by various mycotoxins, in particular those produced by *Fusarium* spp. and *Gibberella zeae* (Berlakoti, et al., 2008; Christ, 2011). The petitioner provides a HACCP Plan that identifies the risk and establishes procedures to prevent mycotoxins producing organisms (Nordic Sugar, 2009a). Among the mycotoxins reportedly found in moldy beets and beet fiber are zearalenone, chlamydosporol, moniliformin, deoxynivalenol (DON), 15-acetyldeoxynivalenol, diacetoxyscirpenol, monoacetoxyscirpenol, scirpenetriol, T-2 toxin, HT-2 toxin, neosolaniol, and T-2 tetraol (Bosch and Mirocha, 1992; Burlakoti, 2008). Microbial and chemical contaminants are addressed in the HACCP plan provided by the petitioner (Nordic Sugar, 2009). It is not clear what other producers of sugar beet fiber do.

The petitioner claims no preservatives are used. Other non-organic beet sugar processing operations may use various disinfectants to inhibit microbial growth. A 40 percent solution of formaldehyde—known as formalin—is sometimes added to the diffuser water (EPA, 1997). While formaldehyde is banned in the US and in many other countries, it appears to still be in use in some countries (Asadi, 2007). Sulfur dioxide, chlorine, ammonium bisulfite, or commercial FDA-approved biocides may also be used as disinfectants (Walker, 1985; EPA, 1997). Thiocarbamate fungicides and glutaraldehyde may also be used as anti-microbials (Cleary, 2000).

<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)).

The petitioned substance is a conventional agricultural product. Conventional farming may rely heavily on monoculture and limited rotations, and uses fertilizers and pesticides that may be harmful to the environment and reduce ecological biodiversity. Organic farming systems generally have greater biodiversity than conventional farming systems (Altieri, 1999; Mäder, et al., 2002; Hole, et al., 2005; Gabriel, et al., 2005). Swedish researchers found evidence that organic farming usually enhances species richness, most notably of plants, birds and predatory insects (Bengtsson, et al., 2005).

Beet sugar production is among the vegetable processing operations cited as responsible for high levels of pollution (Arvanitoyannis and Varzakas, 2008). Sugar beet processing has long been noted for voluminous wastewater that has high biological oxygen demand (BOD) (Woodroof, 1975). Air pollution and emissions are other concerns for sugar beet processing (EPA, 1997). While most of the pollutants emitted would be the same whether the processing meets organic standards, certain pollutants found in some conventional sugar processing are prohibited for use in organic sugar processing. Specifically, sugar beet mills were identified by IARC as a work place with significant exposure potential to formaldehyde (IARC, 2006). Sodium sulfite, ammonium bisulfite used in conventional processing and not organic processing of sugar beets are also a concern (EPA, 1997). There are a number of other synthetic substances used in sugar beet flume water that are not included on the National List at 7 CFR 205.605(b). In the United States, these include α-alkyl- omega -hydroxypoly-(oxyethylene), Linear undecylbenzenesulfonic acid, dialkanolamide, monoethanolamine, triethanolamine, ethylene dichloride, ethylene glycol monobutyl ether and tetrasodium ethylenediaminetetraacetate [21 CFR 173.315(a)(4)]. The same or similar surfactants, defoamers and deflocculants are commonly used to process conventional sugar beets in other countries. While flume water may be recirculated and dewatered, eventually some liquid effluent needs to be released and dewatering may further concentrate some of these compounds, requiring further treatment to meet discharge requirements (IFC, 2007).

The petition indicates that the Fibrex system uses a special steam drying process, but does not document if there is direct contact with steam. If there is direct contact of the sugar beet fiber with steam and volatile amine boiler additives are used in the boiler feed water, there is a potential source of contamination by the volatile amines prohibited for direct contact with organic food.

Conventional sugar beet production relies on chemical fertilizers, herbicides, insecticides, and fungicides (Cattanach, et al., 1991). Current pesticide usage statistics are difficult to assess, but historically conventional sugar beets are commonly grown with herbicides, insecticides and fungicides prohibited for use in organic farming. The release of these farm chemicals may have adverse effects on the environment and on biodiversity. This is also true in Sweden, where the petitioners get their sugar beets (Wivstad, 2012).

Swedish sugar beet seeds are commonly treated with imidacloprid. The main herbicides used are metamitron (Goltix), fenmedipham and desmedipham (Betanal Power) (Elfstrom, 2012). The most recent years for which data are available in Sweden, sugar beets received, on average, 1.00 kg/Ha of bis-carbamate herbicides, 0.3 kg/Ha pyridazinone herbicides and 0.2 kg/Ha cyclohexanedione herbicides (EC, 2007). Best practices for Swedish sugar beet production are followed by the contract growers (Nordic Sugar, 2012). A life-cycle assessment of the Swedish sugar industry found that the discontinuation of organic production reduced biodiversity in and around the farms where sugar beets were cultivated (Ness, 2011). Among the pesticides registered for use on sugar beets in the United States are aldicarb (Bayer, 2010), EPTC (Drexel, 2010) and methyl bromide (EPA, 2006).

Sugar beets have moderately high demands as heavy feeders over a long growing season. Nitrogen efficiency in sugar beet production has improved over the past 20 years, but the recommendation for Red River Valley producers is to have between 100 and 130 units of nitrogen available during the growing season. The main sources of nitrogen fertilizer for conventional sugar beet production are ammonium nitrate (33-0-0), anhydrous ammonia (82-0-0), monoammonium phosphate (11-52-0), urea-ammonia nitrate

(UAN) (Cattanach, et al., 1991; Lamb, et al., 2001; Blumenthal, 2008). Nitrogen fertilizers applied to sugar beets may volatilize or result in gaseous loss of ammonia to the atmosphere (Blumenthal, 2008). Sugar beet cultivation may also use soluble phosphate fertilizers (Cattanach, 1991; Blumenthal, 2008). Soluble phosphate is known to runoff into surface waters and cause eutrophication (EPA, 1978).

Pesticide pollution from sugar beet production is a global concern. For example, pesticides used in sugar beet production have been detected in the surface waters of catchments in southern Sweden (Kreuger and Nilsson, 2001).

Integrated Pest Management Program specialists reported that approximately a third of all of Idaho's sugar beet acres were treated with aldicarb in 1997 (Traveler and Gallian, 2000). Aldicarb no longer meets the EPA's food safety standards and may pose unacceptable dietary risks, especially to infants and young children (EPA, 2010). EPA intends to revoke aldicarb for sugar beet use by December 31, 2014. The product can continue to be sold until the end of 2016 and used by growers until August 31, 2018 (EPA, 2010). Carbofuran is a carbamate pesticide that—like aldicarb—is systemic in nature and a cholinesterase inhibitor. EPA cancelled all uses for carbofuran in 2011(EPA, 2011).

Methyl bromide continues to be permitted for use for soil used to grow sugar beets at a maximum application rate of 3.0 lb ai/1000 ft^3 and a maximum exposure period of 4 hours (EPA, 2006). The Montreal Protocol has identified methyl bromide as an ozone depleting chemical that is a priority substance to be phased out (UNEP, 2009).

Sugar beets have been genetically engineered to be resistant to or tolerant of the herbicides glyphosate (Shah, et al., 1990; Barry and Kishore, 1995) and glufosinate (Goodman and Donn, 1992). Aventis voluntarily stopped research, development and commercialization of glufosinate (Liberty Link) sugar beets because of cross-pollination with non-GMO sugar beets (Royal Society of Chemistry, 2001).

Industry sources estimated that genetically engineered sugar beets account for 95% of the sugar beets planted in the United States (Sugar Industry Biotechnology Council, 2010). The USDA has prepared an Environmental Impact Statement (EIS) that addresses this concern (USDA/APHIS, 2011). The draft EIS and subsequent *Federal Register* notice asked questions about organic sugar beet production and the potential impacts of the release of Roundup Ready Sugar Beets (RRSBs). The European Union has authorized the importation of food and feed products from RRSBs (DG SANCO, 2007). An application to permit the cultivation of RRSBs in the EU is pending before the European Food Safety Agency (KWS/Monsanto,). Statistics on RRSB plantings in Sweden and the rest of Europe were not available in time for this review. Non-organic sugar beet fiber would need to come from identity preserved (IP) non-GMO sources in order to meet the requirements of 7 CFR 205.105(e) if placed on the National List at 7 CF 205.606 and RRSBs are commercially released.

<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)).

The reported human health effects are beneficial and are summarized accurately in the petition for available references and abstracts (Nordic Sugar, 2011). The reviewers did not have access to the studies that were in progress or published in older journals with limited circulation. Other surveys of the literature offer consistent findings with the petition (Thibault, et al., 2001; Ralet, et al., 2009).

Sugar beet pulp softens stools, decreases transit time, and relieves constipation (Ralet, et al., 2009). These effects are consistent with the benefits of dietary fiber in general and are not limited to sugar beet fiber (Dreher, 2001; Cho, 2009; Klosterbuer and Roughead, 2011).

The effect of sugar beet fiber on mineral absorption is either neutral or beneficial. There is no evidence from studies to suggest that the absorptive capacity of sugar beet fiber inhibits mineral metabolism (Ralet, et al., 2009). In particular, no adverse effect on zinc uptake was shown (Sandstrom, et al., 1987). In this sense, the petitioners claim that sugar beet fiber is superior to fibers from cereals that contain phytic acid, known to inhibit zinc uptake (Nordic Sugar, 2011). Studies reviewed point out the significant mineral content of sugar beet fiber.

Studies regarding the anti-carcinogenic properties of sugar beet fiber have yielded mixed results. Fecal bile acid has been correlated with colorectal cancer (McPherson, 1987). Several fiber sources tested—including sugar beet fiber—resulted in greater fecal mass and lower fecal bile acid concentration (Gallaher, et al., 1992). Sugar beet fiber reduced the excretion of fecal bile acid (Lampe, et al., 1991; Langkilde, et al., 1993).Tests on laboratory animals with experimentally induced colorectal cancer yielded mixed results. In some cases, the number of precancerous lesions was reduced, while in other cases there is no significant difference between the treatment and control groups (literature survey in Ralet, et al., 2009).

Sugar beet fiber may be beneficial to diabetics and individuals who are prone to hyperglycemia by moderating the levels of glucose released into the bloodstream (Hagander, et al., 1986; Hagander et al., 1988a). Studies regarding lipid uptake are mixed, but generally favorable to reducing LDL cholesterol levels linked with heart disease (Cossack and Musaiger, 1991; Lampe, et al., 1991).

The only study found that conducted feeding studies to evaluate toxicity concluded that no toxic effects were related to dried fiber prepared from sugar beet (Dongowski, et al., 1998).

<u>Evaluation Information #11:</u> Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b)(1)).

The substance is an agricultural product that could be organically produced and processed. The petitioner produced certified organic sugar beet fiber in the past but discontinued due to market conditions (Nordic Sugar, 2011). Weed management is seen as the biggest production challenge to organic sugar beet production in Sweden (Fogelberg, 2001).

As of January 25, 2012, the NOP database listed 415 certified organic operations that listed 'beet' or 'beets' as a product produced (NOP, 2012). Most of the operations produce table beets, but some just list 'beets' and have the equipment and capacity needed to produce sugar beets. The petitioner claims that there are no known sources of certified organic sugar beets in Northern Europe (Nordic Sugar, 2011). The Yareskivskiy Sugar Factory in the Ukraine is certified organic by ETKO under the NOP for the production of beet sugar (NOP, 2012). In addition, Control Union has certified as organic the Dutch handler of sugar beet syrup Canisius Henssen BV (NOP, 2012). It is not clear what is done with the pulp from the extraction of the organic sugar beet syrup. In addition, Agrana in Austria reports growing beets for sugar according to the EU organic standards beginning with the 2008-09 campaign (Agrana, 2012).

In addition to organic beets, there are numerous other sources of organic vegetable fiber. Sugar beet fiber has some relatively unique characteristics, but other fibers could potentially be used as substitutes in many situations. Among these are oat bran, rice bran, barley fiber, wheat bran, citrus pulp, and psyllium (Dreher, 2001; Cho, 2009; Klosterbuer and Roughead, 2011). In addition, there are some functional and commercially available fiber sources that already appear on 7 CFR 205.605, including alginates, gellan gum, and low-methoxy pectin (Klosterbuer and Roughead, 2011). Fructooligosaccharides (FOS), gum Arabic, guar gum, oligo-fructose enriched inulin and high methoxy pectin currently appear on 7 CFR 205.606. Resistant starches also offer some of the same functions and properties as sugar beet fiber (Sharma, et al., 2008).

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