Barley Betafiber

Handling/Processing

Identification of Petitioned Substance

Chemical Names: ß-Glucan, ß-D-glucans from barley, Mixed linkage (1→3), (1→4) ß-D-glucans; (2S,3R,4S,5S,6R)-2-[(2R,4R,5R,6S)-4,5-dihydroxy-2-(hydroxymethyl)-6-[(2R,4R,5R,6S)-4,5,6-trihydroxy-2-(hydroxymethyl)oxan-3-yl]oxyoxan-3-yl]oxy-6-(hydroxymethyl)oxane-3,4,5-triol (Chembiofinder)

Other Names: Barley fiber isolates; barley fiber extracts; Mixed Linkage Beta Glucans; *Hordeum sativum*

Trade Names: Barlív®

CAS Numbers:
9041-22-9 [ß-D-glucans from any source]
55965-23-6 [Mixed linkage (1→3), (1→4) ß-D-glucans]

Other Codes:
ACX ID X1040144-0
International ID MC2866

Characterization of Petitioned Substance

<u>Composition of the Substance</u>:
Barley betafiber is described in the petition as a "polysaccharide of unbranched, linear, mixed-linkage ß-glucans" (Kolberg, 2011). Barley betafiber is described at 21 CFR 101.81(c)(2)(ii)(6) as the ethanol precipitated soluble fraction of cellulase and alpha-amylase hydrolyzed whole grain barley.

Barley betafiber is defined by the FDA as "the ethanol precipitated soluble fraction of cellulase and alpha-amylase hydrolyzed whole grain barley. Barley betafiber is produced by hydrolysis of whole grain barley flour, as defined in paragraph (c)(2)(ii)(A)(5) of this section, with a cellulase and alpha-amylase enzyme preparation, to produce a clear aqueous extract that contains mainly partially hydrolyzed beta-glucan and substantially hydrolyzed starch. The soluble, partially hydrolyzed beta-glucan is separated from the insoluble material by centrifugation, and after removal of the insoluble material, the partially hydrolyzed beta-glucan soluble fiber is separated from the other soluble compounds by precipitation with ethanol. The product is then dried, milled and sifted. Barley betafiber shall have a beta-glucan soluble fiber content of at least 70 percent on a dry weight basis" [21 CFR 101.81(c)(2)(ii)(6)].

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

Table 1:
Physical and Chemical Properties of Barley Betafiber

Physical or Chemical Property:	Value
Physical State	Solid
Appearance	White to Light Tan Powder
Taste	Bland
Solubility	Soluble in water.
Moisture	≤12%
Molecular Weight	Average of 50-400 kDaltons
Particle Size	<250µ
Beta-glucan content	≥ 70 g / 100 g (dry weight)

Sources: Cargill, 2006; Cargill, 2008; Kolberg, 2011; Food Chemicals Codex, 2010.

Specific Uses of the Substance:

Barley ß-glucan isolates such as barley betafiber enable food processors to incorporate the health benefits of barley in various foods without the problems created by whole grain barley in formulation (Fastnaught, 2009). The petition refers to it being used in a juice (Kolberg, 2011). Soluble barley betafiber is possible to use in other beverages (Zheng, et al., 2004). Other foods where barley betafiber has been added, at least experimentally if not commercially, include baked goods, pasta, ready-to-eat cereals, soups, stews, dairy products and meats (Newman and Newman, 2008; Fastnaught, 2009).

Approved Legal Uses of the Substance:

Barley betafiber is self-affirmed GRAS for use in food generally, except for infant formula and meat and poultry products (Cargill, 2006; Tarantino, 2006). Cargill also affirms that barley betafiber is GRAS for use as a texturizer in meat and poultry products (Cargill, 2010). The FDA referred Cargill to the Food Safety Inspection Service (FSIS) for an opinion on the use in products under USDA's jurisdiction (Cheeseman, 2011).

Action of the Substance:

Nutritional fiber has a wide range of technical and functional effects on food (Dreher, 2001; Sharma et al., 2008; Cho, 2009). Naturally occurring β-glucans can be classified as *Soluble Fibers*, while added or isolated β-glucans are potential *Functional Fibers*. Soluble and functional fibers have similar activity, but isolated ß-glucan extracts have a wide range of specific characteristics and functionality. Barley betafiber is distinguished by its low molecular weight (Zheng, et al., 2004). As discussed below, the primary health claim made related to the use of the petitioned substance is its ability to reduce the glycemic index of foods, help to maintain normal blood sugar levels, and lower cholesterol, decrease risk of diabetes, and "(potentially) promoting satiety" (Kolberg, 2011). The specific mode of action of the petitioned substance to achieve these activities is discussed under Evaluation Question #10 below.

Combinations of the Substance:

Barley betafiber can be used as an ingredient in a wide range of foods described in the GRAS notifications (Cargill, 2006; Cargill 2010).

Status

Historic Use:

Barley (*Hordeum vulgare*) has been cultivated for at least 8,000 years (MacGregor and Bhatty, 1993). It is believed by most, though not all archeologists to have been first cultivated in the Fertile Crescent, an area that includes parts or all of what is presently Iraq, Iran, Israel, Syria and Turkey (Newman and Newman, 2008).

Barley bran was isolated and incorporated in breakfast cereals for its beneficial health effects, particularly for diabetics (Kellogg, 1925). When the beneficial health effects of ß-glucan were validated by research, efforts to further isolate that polysaccharide were undertaken. Early attempts found it challenging to maintain the physiological properties of ß-glucan, particularly its viscosity (Newman and Newman, 2008).

Barley is known to be a rich source of ß-glucan. While most other grains have lower fiber in the endosperm than the whole grain, the soluble ß-glucan in barley endosperm is comparable to that of whole grain

(Henry, 1987). The variety "Prowashonupana" was identified in the early 1980s as a mutant hull-less waxy barley with a high ß-glucan content (Eslick, 1981). The ß-glucan in Prowashonupana is described as not soluble (WTARC, 2005). Other barley varieties selected for high soluble ß-glucan content are Apollo and Wanubet (Yoon et al., 1995). The petitioned substance is described as new and at this time, the only commercial products that use the petitioned substance are processed products that are not certified organic (Kolberg, 2011).

OFPA, USDA Final Rule

Barley betafiber is not listed anywhere in the Organic Foods Production Act (OFPA) [7 USC 6501 *et seq.*] or in the National Organic Program Final Rule [7 CFR 205]. Barley betafiber must be organic to be used in a processed product that is labeled as organic. Non-organic barley betafiber may be used in foods labeled as 'Made With Organic (Specific Ingredients or Food Group(s))' provided that it meets the requirements of 7 CFR 205.301(c). Specifically, it cannot be grown or processed using excluded methods [7 CFR 205.105(e)], handled with ionizing radiation [7 CFR 205.105(f)], and the barley cannot be produced from soil where sewage sludge has been applied [7 CFR 205.105(g)].

International

Canada - Canadian General Standards Board
Barley betafiber 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

For organic labeling, Codex provides guidelines, not standards. The Codex guidelines for the production, processing, labelling, and marketing of organically produced foods indicate that all ingredients of agricultural origin in 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 in sufficient quantity (§3.4) (Codex, 2001).

European Economic Community (EEC)

The European Council on Organic Production and Labelling of Organic Products (EC 834/2007) requires that 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 barley betafiber 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)).

The process begins with the production of high ß-glucan hull-less waxy barley. Barley can be produced either organically or non-organically and the petition is to permit non-organic barley products to be used in organic processed products. Non-organic barley is produced using conventional methods that include the use of synthetic fertilizers and pesticides. The resulting non-organic barley is a non-synthetic agricultural product.

Barley has a number of traits that are related to its ß-glucan content. The ß-glucan content of a variety is a poor indicator of malting quality (Henry, 1988b). Varieties are classified as 'waxy' and 'non-waxy' as well as covered and hull-less. Waxy varieties tend to have more total and more extractable ß-glucan (Xue, et al., 1991; Fastnaught et al., 1995; Beer et al., 1997). As ß-glucans are seen as interfering with the malting process, non-waxy varieties tend to be preferred for malting and brewing beer (Newman and Newman, 2008). Hull-less barley cultivars also tend to have higher fiber than those that have the seed covered with a hull (Fastnaught, 1995). Barley cultivars may be classically bred, selected from induced mutation or genetically improved by excluded methods (Ullrich, 2011). If barley betafiber was added to the National List at section 205.606, the specific variety used to produce barley betafiber would need to be publicly disclosed in order to verify that it was not genetically modified using excluded methods and to determine whether organic sources are commercially available.

The petition claims that there are "no other manufacturers of barley betafiber" (Kolberg, 2011). The petition notes that there other products on the market that extract ß-glucan from barley, but these are not considered barley betafiber by the FDA (Kolberg, 2011). The reviewers of the petition were given limited access to the confidential business information (CBI). Several patented processes may produce ß-glucan from barley (Inglett, 1992; Katta, et al., 2000; Zheng, et al., 2004; Morgan, 2006). Prowashonupana is a proprietary variety licensed to ConAgra and is used to make Sustagrain® (Arndt, 2006). The petitioner states that these other methods result in a different product and that there is currently only one source of barley betafiber on the market (Kolberg, 2011).

The petitioner has publicly disclosed that barley betafiber uses whole grain barley flour that has been cellulose- and α-amylase-hydrolyzed, and then precipitated using ethanol (Kolberg, 2011). Details are subject to CBI. The specific variety used is not stated in the petition; thus it is difficult to assess the organic availability or whether excluded methods were used to develop the variety. The manufacturing process does not provide enough information to confirm whether excluded methods are used in the process. Any non-organic ingredient used in a processed product labeled as 'Organic' cannot be produced or handled using excluded methods [7 CFR 205.105(e); 7 CFR 205.301(f)(1)]. Patents to produce the enzyme α-amylase by genetically engineered microorganisms have been granted to Novozyme (Bisgård-Frantzen, et al., 2005) and Genencor (Van Der Laan and Aehle, 2005). These have been commercialized. No information was provided in the petition to rule out the use of a genetically engineered source of α-amylase. Accredited Certification Agents (ACAs) would be obligated to ensure that enzymes from these and other genetically modified organisms are not used in the preparation of the barley betafiber. Similarly, ethanol may be produced from commodity corn that is likely to be produced using excluded methods.

Recovery rates of ß-glucans depend on a number of factors, including particle size, homogeneity, treatments with ethanol and with various enzymes (Benito, et al., 2010). Distiller's dry grain (DDG), the spent dried barley or other grains recovered after fermentation, can be used as a source of ß-glucans (Potter et al., 2001).

Evaluation Question #2: 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 substance barley betafiber and its constituents, including mixed linkage (1→3), (1→4) ß-D-glucans are naturally occurring constituents of barley and are non-synthetic when extracted by normal processing, including enzymatic hydrolysis.

Evaluation Question #3: 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 available from the petitioner.

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

Barley betafiber is self-affirmed Generally Recognized As Safe (GRAS) (Cargill, 2006; Cargill, 2010). The FDA had no questions when used as an ingredient in foods in general, except for infant formula and meat and poultry products, at levels consistent with current Good Manufacturing Practices (cGMP) (Tarantino, 2006). Use in meat and poultry products was referred to the USDA FSIS (Cheeseman, 2011).

Evaluation Question #5: 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 or purpose of the petitioned substance is as a soluble fiber (Kolberg, 2011). The petitioned substance is not a preservative. While some applications, particularly with baked goods, may cause greater stability because of greater moisture retention and possibly some antioxidant activity (Fastnaught, 2009).

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

The primary function is as a source of soluble fiber. Barley ß-glucan fractions appear to improved texture and structure and may also be used for that purpose (Newman and Newman, 2008). 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. Isolated soluble fiber may have textural or other functional effects, particularly in highly processed cereals and dairy products (Brennan and Cleary, 2005). The moisture and viscosity of the product may recreate or improve the sensory qualities of low-fat and fat-free products where lipids have been removed (Fastnaught, 2009).

<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)).

The effect on the nutritional quality of the food is an increase in the soluble fiber content. The petition substance can be used to justify a health claim that the foods in which it is included can reduce the risk of coronary heart disease [21 CFR 101.81].

To isolate the soluble fiber, practically all of the protein, fats, vitamins and minerals have been removed from the whole grain barley. The final product is about 95% carbohydrate, with 70% of those carbohydrates in the form of ß-glucan. Starches and sugars have been removed as well. The patent application describes barley betafiber as having low protein and fat content (Zheng, et al., 2004). Vitamin content of barley betafiber is not specified (Cargill, 2008c). Like other cereal grains, whole barley is generally considered a good source of B-complex vitamins (Newman and Newman, 2008)

Table 2
Nutritional Composition of
Barley Betafiber and Whole-Grain Hulled Waxy Barley

Item	Barley Betafiber	Hulless Waxy Barley
Protein	<3%	9.9%
Carbohydrates	<95%	77.7%
-As ß-glucan	≥70%	4.9%
-As Starch*	≤25%	45.5%
-As Sugar	<2%	4.2%
Fat	<0.1%	0.4%

Sources: Cargill, 2008c; Newman and Newman, 2008; NDL, 2012
*Calculated by subtracting ß-glucan from carbohydrates

<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)).

An analysis of heavy metals and contaminants was provided in the Confidential Business Information version of the petition (Kolberg, 2011).

The Technical Data Sheet for Barlív™ barley betafiber indicates that the product has less than 0.2 ppm lead (Cargill, 2008b). Quality control for pathogens specifies a total aerobic plate count of ≤10,000 cfu/g, negative for Salmonella per 375g, and <0.25 Deoxynivalenol (DON) (Cargill, 2008b).

Table 3 contains the EPA Tolerances for pesticide allowed in barley bran where available. When a separate tolerance was not established for barley bran, the tolerance for barley grain was used. No data on barley betafiber pesticide residues could be located. The extraction process may reduce the amount of residues in the soluble fiber.

Table 3
EPA Tolerances and FDA Action Levels for Pesticides in Barley Bran or Barley Grain

Pesticide	Tolerance (ppm)
Azoxystrobin	6.00
Bromoxynil	0.05
Carbofuran[a]	0.20
Carboxin	0.20
Carfentrazone-ethyl	0.80
Chlorsulfuron	0.10
Chlorpyrifos Methyl	90.00
Clopyralid	12.00
Cloquintocet-mexyl	0.10
Cyfluthrin	0.50
Cyhalothrin (λ & γ isomers)	0.20
2,4-D	4.00
Dicamba	6.00
Diclofop-methyl	0.10
Difenoconazole	0.10
Difenzoquat	0.25
Diflubenzuron	0.06
Diuron	0.70
Ethephon	5.00
Fenoxaprop-ethyl	0.05
Florasulam	0.01
Fluroxypyr 1-methylheptyl ester	0.50
Glyphosate	30.00
Imazalil	0.10
Imazamethabenz	0.10
Lindane	0.10
Malathion (post-harvest)	8.00
Mancozeb	20.00
MCPA	1.00
Mefenpyr-diethyl	0.05
Metalochlor	0.10
Metalaxyl	1.00
Methomyl (Lannate®)	1.00
Metconazole	2.50
Methyl Bromide (as inorganic bromide)	50.00
Methyl Parathion[b]	0.10
Metribuzin	0.75
Metsulfuron methyl	0.10
Paraquat	0.05
Phosphine	0.10
Picloram	0.50
Pinoxaden	1.60
Piperonyl Butoxide (post-harvest)	20.00
Propiconazole	0.60
Pyraclostrobin	1.40
Pyrasulfotole	0.02
Pyrethrins (post-harvest)	3.00
Quinclorac	2.00
Quizalofop ethyl	0.05
Spiromesifen	0.03
Sulfuryl fluoride (as inorganic fluoride)	45.00
Sulfuryl fluoride (post-harvest)	0.05
TCMTB	0.10

Pesticide	Tolerance (ppm)
Tebuconazole	0.15
Terrazole	0.10
Thiamethoxam	0.30
Thifensulfuron methyl	0.05
Tralkoxydim	0.02
Triallate	0.05
Triademanole	0.05
Triasulfuron	0.02
Tribenuron methyl	0.05
Trifluralin	0.05
Trifloxystrobin	0.05
Zinc Phosphide	0.05

Sources: 40 CFR 180; FDA, 2000.
[a]Revoked 12/31/2009
[b] Revoked 12/25/2010
[c] Expires 12/31/2013

The last years for which the USDA has data for barley sampled under the Pesticide Data Program (PDP) were 2002 and 2003. In 2002, 107 of 725 barley samples taken had at least one pesticide residue detected (14.8%). In 2003, 35 of 452 barley samples taken had at least one pesticide residue detected (7.7%) (Fry, 2012).

The CBI version of the petition raises several points where processing aids and incidental ingredients prohibited in organic production may be used to manufacture barley betafiber. Without additional information on these steps, it is not possible to predict what other contaminants may be in the food.

<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 relies heavily on monoculture and limited rotations, and uses fertilizers and pesticides that may be harmful to the environment and reduce ecological biodiversity. The environmental benefits of organic agriculture on small grain production systems generally compare favorably with conventional farming systems (USDA, 1980; Reganold, 1988; Pimentel et al., 2005; Teasdale, et al., 2007). Organic farming systems generally have greater biodiversity than conventional farming systems (Altieri, 1999; Mäder, et al., 2002; Hole et al. 2004). Organic farming enhances species richness, most notably of plants, birds and predatory insects in most cases when compared with conventional farming practices (Bengtsson, et al., 2005). Organic agriculture on a large scale has a proportionally greater improvement in biodiversity (Gabriel, et al., 2010).

The leading barley producing states in the US are Montana, North Dakota and Idaho. The prairie provinces of Canada are also a significant source of North American supply. Barley produced non-organically is typically fertilized with nitrogen fertilizers, including anhydrous ammonia (82-0-0), urea (46-0-0) and ammonium sulfate (21-0-0-24S) (McVay et al., 2009).

In general, pesticides used in conventional production may run off into streams and contaminate groundwater (Gilliom, et al., 2006). The impacts of water contamination by pesticides are subject to varying interpretations. Over 95% of all producers in the Pacific Northwest use herbicides (Hirnyck, 2004). Among the herbicides used include 2,4-D, Dicamba, diclofop methyl, glyphosate, MCPA, trifluralin (Treflan®), (Zollinger, et al., 2012). Most European producers of barley use herbicides, with the preferred herbicides in recent years being diflufenican and pendimethalin. In the UK, there were 22 different herbicides approved in 2008 for use on barley (Garstang and Spink, 2011). Herbicides by their very nature reduce the biodiversity of plants found in a field (Bengtsson, et al., 2005).

Barley grown in North America is susceptible to a number of fungal and viral diseases. Soil borne diseases, such as common root rot (*Cochliobolus sativus*), are usually controlled by rotation (Garstang, et al., 2011). Fungicide treated seed is also commonly used (McVay, 2009). Chemicals used to treat seed will often have an adverse impact on beneficial soil organisms (Huang and Chou, 2005). Foliar and head disease, such as net blotch (*Pyrenophora teres*), scald (*Rhychosporium secalis*) and fusarium head blight (*Fusarium graminearum*) may be controlled by application of fungicides in some cases (Hirnyck, 2004).

Insects are seldom a problem in North American barley production (Schillinger, et al., 2011). The cereal leaf beetle is the only pest where insecticides are used, but biological control has been largely successful (Glogoza, 2002). Pesticides registered for barley include malathion, methomyl (Lannate®) and carbofuran (Furdan®) Hirnyck, 2004).

Post-harvest losses to pests can be significant. Methyl bromide is still used to fumigate conventional barley in the United States. The maximum application rate is 3.0 lb ai/1000 ft3 and maximum exposure period is 24 hours (US 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). Sulfuryl fluoride is proposed as an alternative to methyl bromide (US EPA, 2006).

Biodiversity in barley is a subject of interest to scientific researchers and conservation of heritage varieties and land races is a growing concern (Bothmer, et al., 2003). Opportunities to cultivate varieties for purposes other than malting, feed and whole grain may help to increase biodiversity. However, reliance on one or two varieties for barley betafiber will limit the improvements.

A barley cultivar that is resistant to glyphosate and other herbicides has been transgenically produced with the ability to carry the trait of ß-glucan enhancement (Clark, 2011). This transgenic barley cultivar has not been commercially released at the time of this report. Any non-organic ingredient used in a processed product labeled as 'Organic' cannot be produced or handled using excluded methods [7 CFR 205.105(e); 7 CFR 205.301(f)(1)]. Without knowledge of the specific varieties claimed to be needed to produce barley betafiber, it is not possible to predict the long-run consequences of granting the petition. While transgenic barley is not now commercially released, such a release would require the establishment of an Identity Preserved (IP) market and verification by ACAs for any non-organic barley betafiber to be used in organic products if barley betafiber is added to the National List.

<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)).

As a source of dietary fiber, barley betafiber is beneficial to human health (IOM, 2005; Conway and Behall, 2005). An extensive review of the scientific literature showed that barley-derived soluble fiber beneficially reduced cholesterol and low-density lipid proteins (LDL), and triglycerides, but not high-density lipid proteins (Talati, 2009). The FDA permits barley betafiber to claim that it reduces risk of coronary heart disease [21 CFR 101.81(c)(2)(ii)(A)(5)]. Barley enriched with a barley ß-glucan extract was found to reduce plasma glucose and insulin response both in men (Behall, Scholfield and Hallfrisch, 2006) and women (Behall, Scholfield, Hallfrisch, and Liljeberg-Elmståhl, 2006). Barley fiber has been shown to lower cholesterol (McIntosh, et al., 1991). Barley with added ß-glucan may contribute to the cholesterol-lowering ability of barley (Bourdon, et al., 1999). Concentrated barley ß-glucan was found to be effective for improving blood lipids in men and women (Keenan, et al., 2007).

Given that it is a new ingredient, relatively few human or related species models have studied the health effects of the petitioned substance. Most of the research on barley fiber conducted either with whole barley or isolates other than those meeting the barley betafiber standard of identity established by the FDA. The studies submitted to FDA for GRAS status are publicly available (Cargill, 2006; Cargill 2010). Many of these studies cited for beneficial human health effects were conducted on model animals (e.g. Dongowski, et al., 2002; Jonker et al., 2010) or human fecal flora (e.g. Huth et al., 2000) rather than on human subjects. There is debate within the scientific community about how much can be extracted from studies that examine the health effects of whole foods for the sum of its parts (Morris, 1995).

One measure of a food's effect on blood sugar levels is the glycemic index (GI). The GI measures the effect of a carbohydrate on blood sugar levels, with glucose having a standard value of 100. Diets that are based on low-GI foods are correlated with reduced risk of type-2 diabetes and other chronic diseases that occur with aging (Chiu, et al., 2011). Whole grains in general reduce the risk of diabetes, and soluble fiber intake is one reason for that beneficial health effect (Liese, 2003). Barley betafiber can reduce the glycemic index of various foods. However, the response to various forms of ß-glucan can be variable (Chillo, et al., 2011).

Studies conducted with barley shorts showed that barley ß-glucan content was positively correlated with intestinal viscosity and a corresponding reduction in plasma cholesterol concentrations (Dikeman and Fahey, 2006). Fiber viscosity is highly variable in complex fluids like soluble fiber in solution (Morris, 1995). The structure and function of isolated fibers can be very different between whole grains, fractions high in fiber such as bran, and isolates like barley betafiber. High fiber whole grains lower post-prandial glucose, improves insulin responses (Liljeberg et al., 1996) and slows the rate of carbohydrate metabolism, and improves glucose tolerance (Liljeberg et al., 1999).

How ß-glucan achieves these health effects is still subject to study. One study suggests that the hypocholesterolemic property of β-d-glucan does not involve a simple binding of bile acid salt molecules to specific sites on the β-d-glucan polymer (Bowles, et al., 1996).

Rat studies concluded that consumption of concentrated barley β-glucan was not associated with any obvious signs of toxicity with the only finding of possible biological relevance was an increase in the number of circulating lymphocytes observed in males. However, the increase was not dose-dependent and was not observed in females (Delaney, et al., 2003).

<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)).

Barley betafiber is an agricultural ingredient that could be produced organically. The petitioner acknowledges this potential (Kolberg, 2011). Barley is organically produced and handled. As of January 31, 2012, there were 1,071 USDA Certified Organic producers and 73 handlers of certified organic barley (NOP, 2012). The petitioner has several divisions that are certified as USDA organic under the NOP, but none have barley listed as a certified organic commodity (NOP, 2010). Cargill has the Warminster Maltings division in the United Kingdom (Cargill, 2012b) that is certified organic for barley malt under the EU standards by the Soil Association and the Gambrinus division in British Columbia, Canada (Cargill, 2012a) that is certified organic by the Pacific Agricultural Certification Society under the Canadian Organic Regime (COABC, 2012). Specific varieties need to be grown to achieve soluble fiber that consists of over 75% ß-glucan.

The supporting documentation stating why specific varieties are needed was redacted from the CBI version of the petition. The petition does not explain why the specific varieties could not be organically grown, other than reference of the lack of organic seed (Kolberg, et al., 2011).

Processing is needed to isolate a 75% soluble fiber that makes it possible to fortify foods and beverages to a level where a heart-healthy claim can be made. Whether such fortified products are necessary is a matter of opinion that is subject to interpretation. Studies have found that some of the benefits claimed are also conferred by the consumption of whole barley, so it could be argued that further processing and isolation is not necessary (DeMoura, 2008). Whole grains provide the nutritional benefits of ß-glucan along with essential vitamins, minerals, complex carbohydrates and protein (Kantor, et al., 2001). The synergy of phytonutrients found in the whole grain package is difficult to replicate (Jones et al., 2002). High ß-glucan waxy hull-less barleys can be used for many applications (Arndt, 2006). Whole-grain food intake by a large middle-aged, multiethnic cohort was correlated with reduced risk of physical characteristics linked to atherosclerotic cardiovascular disease in a way that was not attributable to individual risk intermediates, single nutrient constituents, or larger dietary patterns (Mellen, et al., 2007).

The petition mentions numerous organic foods that are significant fiber sources, including whole grains, beans, fruits and vegetables (Kolberg, 2011). These are not soluble or isolated, so they are not seen as a practical way to fortify foods and beverages to levels needed to make a ‘heart healthy’ claim. Oats are another source of ß-D-glucan (Fennema, 1996). One patented method claims to be able to extract ß-glucans from either barley or oats that are colorless and free of undesirable flavor using enzymatic hydrolysis with α-amylase along with physical and mechanical methods (Inglett, 1992). Such a product could be produced from organic oats. There is at least one source of organic oat 70% ß-glucan made from on the market (Garuda, 2011). The product is certified under the NOP by the ACA BCS (NOP, 2010). There was no mention of organic oat 70% ß-glucan in the petition.

The effects of oat ß-glucan are comparable to barley ß-glucan. Health effects of ß-glucan from oats also improve post-prandial glucose and insulin in a way similar to barley betafiber (Behall, et al., 2006b). One study found the sensory quality of beverages that contained ß-glucans from oats to be comparable to beverages with soluble ß-glucans from barley, and the oat ß-glucans resulted in significantly lower total cholesterol concentrations compared with the barley ß-glucans (Biörklund, et al., 2005). Oat ß-glucan increased bile acid excretion more than barley, but barley ß-glucan increased cholesterol excretion somewhat more (Lia, et al., 1995). Oat ß-glucans in cookies lowered cholesterol (Kerckhoffs, et al., 2003). Barley ß-glucan levels may be higher than oats for certain varieties. Waxy wheat varieties are being developed with properties similar to waxy barley (Graybosch, 1998).

Soluble gums other than ß-D-glucans—such as guar gum—have similar effects on the gastrointestinal tract. Such gums can lower the level of cholesterol in the blood, but to different extents (Fennema, 1996). Guar gum is currently on 7 CFR 205.606 and also could potentially be organically produced.

In addition, it is possible that ß-glucans could be prepared within the specifications of a non-synthetic, non-agricultural ingredient that appears on 7 CFR 205.605(a). Yeast currently appears on 205.605, but it is unclear whether the substances used in hydrolysis would be permitted or would render the extract a different substance. Food grade microorganisms also appear on 7 CFR 205.605(a). Glucans can also be derived from various fungal masses comprised of *Aspergillus* spp., *Penicillium* spp., or *Mucor* spp. (Zhou, 2011).

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