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GRAS Notification
for
Sugar Beet Fiber

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Division of
Biotechnology and
GRAS Notice Review

Volume 1 of 1

Submitted by:

Nordic Sugar A/S
Langebrogade 1
P O Box 2100
Copenhagen K 1014
Denmark

May 1, 2012

000001.001

Cover Letter

Nordic Sugar
Member of Nordzucker Group

May 1, 2012

Moriama Ramos, Ph.D.
Division of Biotech and GRAS Notice Review (HFS 255)
OFAS/CFSAN/FDA
5100 Paint Branch Parkway
College Park, MD 20740

VIA: Federal Express

RE: GRAS Notification for Sugar Beet Fiber

Dear Dr. Ramos:

Nordic Sugar has determined that the use of its sugar beet fiber, Fibrex, is exempt from the premarket approval requirements of the Federal Food, Drug and Cosmetic Act because Nordic Sugar has determined that such use is GRAS. In accordance with proposed regulation, the following information is provided:

Proposed 21 CFR § 170.36 (c)(1)(I) The name and address of the notified:

Nordic Sugar A/S
Langebrogade 1
P.O. Box 2100
DK-1014 Copenhagen K
Denmark

Proposed 21 CFR § 170.36 (c)(1)(ii) The common or usual name of the notified substance:

Sugar beet fiber
Trade Name: Fibrex®

Proposed 21 CFR § 170.36 (c)(iii) The applicable conditions of use of the notified substance:

Sugar beet fiber is used in various food formulations as an anticaking agent; binding agent; bulking agent; dispersing agent; source of dietary fiber; stabilizing agent; texturizing agent; or as a thickening agent. The use is self-limiting because of the texture and taste of the sugar beet fiber. For most uses, the sugar beet fiber is about 1-3% of the food product; 1-5% for bread products, 1-10% for cereals and muesli, and 1-5% for meat products.

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Proposed 21 CFR § 170.36 (c)(1)(iv) The basis for the GRAS determination:

This GRAS determination is based on scientific procedures.

Proposed 21 CFR § 170.36 (c)(1)(v) Availability of information:

The data and information that are the basis for Nordic Sugar's GRAS determination are available for FDA review by request at Phoenix Regulatory Associates, Ltd. Copies of references and any additional information may be obtained by contacting:

Dr. Clyde A. Takeguchi, Ph.D.
Phoenix Regulatory Associates, Ltd.
21525 Ridgetop Circle, Suite 240
Sterling, VA 20166
Phone: (703)-406-0906
Fax: (703)-406-9513
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Sincerely,

(b) (6)

Lars-Erik Hansson
Business Manager, Fibrex®
Nordic Sugar
Langebrogade 1
P.O. Box 2100
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Enclosures: Original and two copies

cc: Phoenix Regulatory Associates, Ltd.

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GRAS Notification

GRAS Notification
for
Sugar Beet Fiber

1. Introduction

Nordic Sugar is the current manufacturer of Fibrex®, a sugar beet fiber that was self-affirmed as Generally Recognized as Safe (GRAS) in 1991. Fibrex® was originally manufactured by Swedish Sugar (Sockerbolaget), who then set up a separate subsidiary, Fibrex AB. It was sold in 1997 and incorporated into Danisco Sugar. In 2009 it was sold to Nordzucker. Nordic Sugar, the current manufacturer of Fibrex® was established by Nordzucker for the production and sale of sugar and sugar products.

Delta Fibre Foods (Delta) is a US company that had the license to manufacture Fibrex® in North Dakota. Delta obtained the sugar beet pulp from Minn-Dak Farmers Cooperative, its parent company. Delta submitted a GRAS petition in 1991 for Fibrex® sugar beet fiber. In 1997, FDA issued a proposed rule to convert the GRAS affirmation petition process to a notification process and invited individuals who had filed a GRAS petition at that time to convert it to a notification. Fibrex and Delta decided at that time that self-affirmation was sufficient and decided not to convert the petition to a notification. Nordic Sugar has decided to submit a GRAS notification for sugar beet fiber with recent information and incorporates the GRAS petition by reference.

2. Identity and Specifications

The sugar beet fiber, Fibrex® is produced from the sugar beet pulp obtained after extracting the sugar from the sugar beets. Three reviews on sugar beet fiber in food (Harland 1993, Thibault et al, and Ralet, et al., 2009) summarized the polysaccharide composition of the sugar beet fiber, including pectin, hemicellulose, and cellulose. The Fibrex® process is a non-destructive process and Fibrex® continues to be a rich source of pectin. The ratio of insoluble to soluble fiber for Fibrex® sugar beet fiber is two (2) to one (1).

Food grade specifications for sugar beet fiber (Fibrex®) is listed in the Food Chemicals Codex (FCC) for use as an anticaking agent; binding agent; bulking agent; dispersing agent; source of dietary fiber; stabilizing agent; texturizing agent; and a thickening agent. The specifications listed in the FCC monograph reflect the current specifications for sugar beet fiber manufactured with sugar beet pulp grown in Sweden.

GRAS Notification for Sugar Beet Fiber (continued)
2. Identity and Specifications (continued)

Sugar Beet Fiber

Total Fiber	Not less than 62%
Soluble Fiber	Not less than 20.0%
Lead	Not more than 1 mg/kg
Ash (total)	Not more than 6.0%
Loss on Drying	Not more than 10.0%
pH	4.0 to 5.0

Nutritional Data (per 100 g)*

Energy	800 kcal/200 kJ
Protein	8 g
Fat (saturated)	1 g (< 1 g)
Carbohydrates (sugar)	5.5g
Fiber Hemicellulose (42%) Cellulose (28%) Pectin (27%) Lignin (3%)	67 g
Minerals	4 g
Sodium	0.05 g

* Appendix 1

Synonyms: Fibrex®, sugar beet fiber, sugar beet powder, sugar beet flakes, beet fiber, dietary fiber from beets, dietary plant fiber, sugar beet pulp, sugar beet parenchyma, vegetable fiber, vegetable pulp.

3. Manufacturing Process

Sugar beets are washed, sliced, and soaked in hot water to extract the sugar and other water soluble components. The sugar solution is filtered and the pulp is mechanically pressed to remove the remaining water. The beet pulp from the sugar extraction process is the starting material for production of the sugar beet fiber used in food. The Fibrex® process is to dry with hot air and steam and grind/mill the fiber to specific grades. No chemicals are added in this process. Information on the Fibrex® manufacturing process and the Hazard Analysis & Critical Control Points (HACCP) plan are provided in Appendix 2.

Nordic Sugar has a monitoring and analysis program to verify the safety of their products and that these products are in compliance with relevant EU requirements for pesticides and contaminants in foodstuff (Appendix 3). The analysis program is based on random samples of all product types provided to an international external laboratory for the sample analyses. The yearly program is made up of two parts. The first part consists of analyzing a wide range of commonly recognized contaminants, i.e., heavy metals, environmental contaminants, pesticides and mycotoxins. The second part varies depending on factors like new legislation, new scientific or technical information, or customer requests.

Mycotoxins are controlled and monitored in three steps during the harvesting and processing of sugar beets for the production of sugar and sugar products, including sugar beet fiber. First, the amount of damaged beets by frost, mold, etc., delivered to the sugar factory is minimized through price incentives to the farmers and is checked at the point of delivery. Second, the beet pulp is disinfected at the start of the sugar production process. Third, mycotoxin testing is included as part of the Nordzucker Residual Monitoring Program and each batch of Fibrex® is analyzed for the presence of mycotoxin. Mycotoxin was not detected for three of the last five years, and detected for two years at levels within the EU limits for cereals (zearalenone 75 μg/kg).

4. Conditions of Use

Sugar beet fiber is used in various food formulations as an anticaking agent; binding agent; bulking agent; dispersing agent; source of dietary fiber; stabilizing agent; texturizing agent; or as a thickening agent. The use is self-limiting because of the texture and taste of the sugar beet fiber. For most uses, the sugar beet fiber is about 1-3% of the food product; 1-5% for bread products, 1-10% for cereals and muesli, and 1-5% for meat products.

Sugar beet fiber is used in the following products:

- Non-standardized meat products such as beef and poultry patties, sausages, chicken links, etc.
- Fish products
- Bakery products
- Ready meals
- Pasta
- Cereals, mueslis
- Snacks
- Soups
- Fruit fillings
- Beverages
- Fiber tablets
- Supplements

Based on 2010 consumption data from Nordic Sugar (Martensson, 2012), a total of 215,000 pounds of sugar beet fiber was consumed by humans. Of this, about 30% (65,000 lb) was consumed in cereals and bakery products, 9% (20,000 lb) in meat and poultry products, and 60% (130,000 lb) in health products.

Based on 2010 census data (Howden and Meyer 2011), the U.S. population was 309 million, and about 40% of the population consisted of people 45 ears of age or older, who are most likely to consume such products. We calculate that in 2010, each person consumed 1.92×10^{-6} lb sugar beet fiber per day. Assuming that the fraction of the population most likely to consume sugar beet fiber-containing products would be people 45 years of age or older, we calculate that this group would consume 4.79×10^{-6} lb per day, or $2.17 \text{ g} \times 10^{-3}$ g per day. Assuming 60 kg as the weight of a person over 45 years of age, the estimated exposure is 0.036 mg/kg/day.

5. Safety

A. Regulatory Status

USA

Fibrex® sugar beet fiber was self-affirmed as GRAS in 1991. A GRAS petition was submitted to FDA in 1991 (GRASP 2G0378).

The FCC approved the monograph on sugar beet fiber and it was published in FCC 5, Supplement 1. The monograph was amended in FCC 7 to reflect specifications for the product currently made in Sweden.

The USDA/FSIS acknowledged that sugar beet powder, flakes or granules are allowed in non-standardized meat and poultry products [Appendix 4].

Nordic Sugar submitted a Petition for Inclusion of sugar beet fiber onto the National List (7 CFR 205.606) to allow the use of sugar beet fiber in or on processed products labeled as "organic" in September 2009. The petition was amended in response to additional questions in February 2011 and is awaiting a review by the National Organic Standards Board.

Canada

The Health Protection Branch, Health and Welfare, Canada confirmed the use of Fibrex® sugar beet fiber as a source of dietary fiber in food in 1989 [Appendix 5].

EU

Fibrex® is considered as a food ingredient and a fiber in Europe. The definition of "fibre" in Directive 90/496/EEC states:

For the purposes of this Directive "fibre" means carbohydrate polymers with three or more monomeric units, which are neither digested nor absorbed in the human small intestine and belong to the following categories:

- *edible carbohydrate polymers naturally occurring in the food as consumed;*
- *edible carbohydrate polymers which have been obtained from food raw material by physical, enzymatic or chemical means and which have a beneficial physiological effect demonstrated by generally accepted scientific evidence;*
- *edible synthetic carbohydrate polymers which have a beneficial physiological effect demonstrated by generally accepted scientific evidence.'*

GRAS Notification for Sugar Beet Fiber (continued)
5. Safety (continued)

Nordic Sugar sent an application to the European Food Safety Authority (EFSA) on the following individual claims for sugar beet fiber.

- Helps to maintain healthy cholesterol levels.
- Helps to balance blood glucose levels / reduce postprandial glycaemic responses.
- Ensures a healthy digestive system/function and promotes regularity.

EFSA considered sugar beet fiber as sufficiently characterized in relation to the claimed effects.

EFSA concluded that it is the pectin in sugar beet fiber, which is the active part to maintain a normal blood LDL-cholesterol concentration. Pectin itself has been approved earlier and as 6g/day is needed to obtain the claimed effect, EFSA concluded that 30g/day intake of sugar beet fiber is needed to have the same effect due to the ratio of pectin in sugar beet fiber (EFSA 2010). When using this health claim on sugar beet fiber, one should refer to the active substance pectin.

EFSA rejected sugar beet fiber to balance blood glucose levels and reduce postprandial glycaemic responses, mainly since there are not enough human studies for sugar beet fiber on this subject (EFSA 2011a).

The claim for digestive health was resent to EFSA in 2011 with new studies identified since the initial application was sent in 2008. The EFSA concluded that a cause and effect relationship has been established between the consumption of sugar beet fiber and increasing fecal bulk (EFSA 2011b). To use the claim, food must be at least "high in fiber," or at least 6 g fiber per 100 g of food.

B. Recent Studies since the GRAS Petition

Literature searches have been conducted on sugar beet fiber through January 2012. The databases searched included Medline, Cab Abstract, Foodline (Science) and Food Science & Technology Abstract. A bibliography of relevant literature associated with safety and technical effects of Fibrex® and other sugar beet fibers is summarized below and are included in the list of references.

Dongowski et al., (1998) fed groups of 15 male rats food ad libitum for four (4) weeks with a standard diet containing 0, 2.5, 5.0 and 10% sugar beet fiber in the diet. They found no toxic effect based on urinary, hematological and serum parameters.

GRAS Notification for Sugar Beet Fiber (continued)
5. Safety (continued)

Harland (1993) provided the case history of Beta Fibre, the fiber from sugar beet that is dried after standard sugar extraction techniques using a process by British

Sugar. The fiber includes three main fractions, pectins, cellulose and arabinose polymers, of which about 30% are soluble. Nutritional studies demonstrated that it is highly digestible and increased both wet and dry fecal mass. In clinical trials, it was shown to reduce postprandial blood glucose, reduce blood cholesterol by reducing the LDL cholesterol so enhancing the LDL:HDL ratio and had no adverse effect on the availability of bivalent metals. Beta Fibre increased the satiating effect of a meal with energy intake being reduced for up to 24 hours after consumption. All of the trials demonstrated that Beta Fibre was safe to consume even at extremely high levels of fiber intake. The author reported that animal studies with up to 15% Beta Fibre was a nutritionally acceptable fibrous food ingredient and had no significant adverse effects on the availability of other nutrients. The author noted that the intake of sugar beet fiber by animals is generally tenfold or higher than the extreme level of intake assumed for humans and provides the assurance of product safety.

Thibault, et al. (2001) reviewed the production, composition, physicochemical properties, physiological effects, safety, and food applications of sugar beet fiber. They concluded that beet fiber has been one of the most extensively studied and documented fiber for its nutritional and functional qualities because of the research and efforts by all sugar beet companies to produce a high-quality fiber. They stated that sugar beet fiber may fulfill a need and be a good complement to other dietary fibers.

Ralet and her colleagues (2009) reviewed the production, characteristics, applications, and physiological effects of sugar beet fiber and included documentation that the sugar beet fiber has been extensively studied and has been used in many functional and nutritional studies. The fiber has a high natural concentration of dietary fibers (about 70%) and a high soluble fiber content (about one-third (1/3)), which is due to its high pectin content. This high fiber content and its high water-holding capacity provide a basis for its use in many food applications, such as high-fiber extruded products, coatings, bread and baked goods, and in meat products. They stated that potential toxic effects of sugar beet supplementation has not been extensively investigated and referenced Dongowski et al.,(1998) where sugar beet levels of up to 10% in rats were well tolerated.

GRAS Notification for Sugar Beet Fiber (continued)
5. Safety (continued)

Based on the study by Dongowski et al., the NOAEL is estimated at 11 mg/kg bw/day, or 1.8 mg/kg/day human equivalent dose (HED). We believe that the history of use of sugar beet fiber as an animal feed at more than 10 times the estimated human intake and the similarity with other vegetable-based carbohydrates, neutralizes the safety factor for species differences, and a safety factor of 1 is reasonable. Based on the 2010 exposure level, we calculate a 50-fold safety factor (1.8/0.036).

Bosch and Mirocha (1992) identified 55 *Fusarium* isolates from stored moldy sugar beets. All isolates were cultured on autoclaved rice grains and tested for toxicity by feeding weanling female rats the ground-rice cultures of the isolates in a 50% mixture with a regular diet for 5 days. In most cases, toxicity could not be accounted for by the known mycotoxins found. *F. equiseti* was the predominant species found on visibly molded beets in the field. Six of 25 moldy sugar beet root samples collected in the field contained zearalenone in concentrations ranging between 12 and 391 ng/g, whereas 10 samples from commercial stockpiles were negative for zearalenone. Zearalenone was detected in 31 of 75 sugar beet fiber samples (13-4650 ng/g). Three of 31 samples contained cis-zearalenone (1-8 ng/g), and 2 contained trace amounts of trans-α- and trans-ß-zearalenol. This is the first report of zearalenone in sugar beet roots and fiber.

Human and animal studies have reported that sugar beet fiber has a potential as a dietary aid in the treatment of hypercholesterolemia and constipation. Similar to other studies where patients have been fed dietary fiber, researchers have also reported that the consumption of sugar beet fiber did not inhibit absorption of minerals such as iron and zinc, and resulted in a lowering of LDL cholesterol. In addition, feeding sugar beet fiber to non-insulin-dependent diabetic patients resulted in a beneficial effect to blood glucose and triglyceride levels.

Functionality Studies

Sakac et al., (2009) estimated the physico-chemical characteristics of sugar beet fibers extracted with sulfurous acid (untreated fiber-UTF), fiber treated with hydrogen peroxide (treated fiber-TF), and Fibrex®. These fibers were tested using: Folin-Ciocalteu reagent, 1,1-diphenyl-2-picrylhydrazyl (DPPH) radical scavenging assay, antioxidant activity/ß-carotene bleaching test (AOA), chelating activity on Fe^{2+} and Fe^{3+}/Fe^{2+} reducing power. The results demonstrated antioxidant activity from all ethanol extracts, with the lowest from TF and the same amount of chelating activity for all fiber extracts. DPPH scavenging activities was about two (2) times

higher for TF compared to the other two (2) fibers but much lower than BHT and α-tocopherol. The reducing activity was lowest for TF, and the other two (2) fibers had similar activity.

Sakac et al., (2011) compared the functional characteristics and shelf-life of cookies made with the addition of 0, 7, 9, and 11% TF and Fibrex® as a substitute for wheat flour in a cookie formulation. The antioxidant properties of cookies were tested every seven (7) days during six (6) weeks of storage at room temperature. The results indicated that substitution of wheat flour with Fibrex® upgraded the antioxidant activity of the cookies and could prolong the shelf life compared to control or TF-enriched cookies.

Application Studies

Ozboy and Koksel (2000) added sugar beet fiber to corn grits at levels of 10, 20, 30, and 40% to produce high fiber extruded products. The results obtained suggest that addition of sugar beet fiber decreased the expansion ratio, increased bulk density, and decreased both brittleness and hardness values. Fiber addition caused significant changes in various properties of extruded products, but the finished products were acceptable by sensory testing results up to a level of 20%.

Lue, et al., (1991) varied the particle size of sugar beet fiber and the amount mixed with corn meal and compared the results by varying the extruder screw speed. They determined the expansion properties, dietary fiber contents, and total and gelatinized starch contents of the extruded products. Increasing the percentage of sugar beet fiber resulted in less radial expansion and more elongation of the products. Decreasing the particle size improved both radial and longitudinal expansion. Increased screw speed favored elongation but decreased radial expansion. The starch was completely gelatinized after extrusion regardless of the fiber content (0-30%). The insoluble, soluble, and total dietary fiber were not significantly different among extruded products containing 30% sugar beet fiber.

GRAS Notification for Sugar Beet Fiber (continued)
5. Safety (continued)

Karlovic and co-workers (2009) analyzed the texture, elasticity, and oil uptake of coating mixtures for deep-fried chicken meat. The authors compared textural qualities of coating mixtures containing 0.5, 1.5 or 2.5% dietary fiber (sugar beet fiber (Fibrex®) or pectin (citrus)) to a basic coating consisting of corn flour and rice starch. Oil uptake and texture properties were tested after frying the coated chicken in palm oil for five (5) minutes at 180°C. Addition of pectin or sugar beet fiber to mixtures resulted in a significant decrease in oil uptake (up to 30%). Sugar beet fiber absorbed less oil than pectin. Water loss from the meat decreased with pectin or sugar beet fiber coatings than for samples without dietary fiber coating. Hardness of samples decreased up to 38% with coatings containing sugar beet fiber and 47.5% for samples with coatings containing pectin. They concluded that the addition of dietary fiber to coating formulations have a positive influence on textural properties of meat and oil uptake.

Jezek et al., (2009) studied the effects of the addition of rice starch and dietary fibers (pectin and Fibrex®) on the porosity of basic frying mixture formulations (corn flour, salt, spices) and oil uptake of coated chicken meat. Porosity of the fried breaded chicken meat was calculated from particle and bulk density. Pore size and particle size distribution were determined using microscopy image analysis and particle density by mercury intrusion porosimeter. Since there was a wide range of particle diameters, significant differences in pore size distribution were found. Also, pore structure appeared to be affected by oil absorption. Mercury entrapment in pores decreased significantly during eight (8) minutes of frying. The results show that porosity of the samples is different for different frying mixture formulations and indicate that there is a difference in the extent of oil uptake for different formulations due to film-forming capabilities of dietary fibers (pectin and Fibrex®).

The Nutrition and Food Safety Research Institute of the University of Barcelona (INSA·UB 2009, unpublished) conducted a study to investigate the effect of Fibrex® sugar beet fiber to reduce frying losses in beef patties. A standard beef-patty formulation was compared to patties with dosages of 0.8, 1.2, and 1.5% Fibrex® 595 or a common wheat fiber. Physical and sensory analyses were employed to measure performance. The incorporation of Fibrex® resulted in a reduction in the loss of weight that the beef patties undergo during the frying process by more than 30% and resulted in a reduction of the shrinkage (length, width and diagonal distance) that the meat patties undergo during cooking. The patties incorporated with Fibrex® performed better than the ones incorporated with wheat fiber with regards to frying loss but there was no significant difference in shrinkage.

GRAS Notification for Sugar Beet Fiber (continued)
5. Safety (continued)

The American Institute of Baking (AIB 1998, unpublished) made a series of tests with the objective of testing the effectiveness of Fibrex® in reducing fat pick-up and extending shelf-life of fried cake donuts. Fibrex® was added to donut batters at the levels of 1.2, 1.8, and 2.4% based on flour quantity. The amount of water added to each batter was 3.3 times the weight of added Fibrex®, to compensate for the water-binding properties of Fibrex®. Crumb firmness of the cake donuts increased with the addition of Fibrex®. AIB concluded that the addition of Fibrex® at all dosage levels, reduced the fat content and increased the moisture content of the fried donuts.

The AIB (1990, unpublished) has conducted a study evaluating the functionality of Fibrex® 595 in improving the shelf-life of white pan bread. Fibrex® was added at levels 2.5 and 5% based on the flour quantity. AIB concluded that a seven-day old Fibrex®-containing bread had the crumb firmness of a four-day old control bread and that breads containing Fibrex® demonstrated a moister mouthfeel after storage. The optimum level of Fibrex® usage in white pan bread is between two (2) to three (3) percent based on flour weight.

The Bremerhavener Institute fur Lebensmitteltechnologie und Bioverfahrenstechnik (BILB 2000, unpublished) conducted a study on the effect of Fibrex 595 on the dough and baked goods properties of wheat rolls from various deep-freezing production processes. They found that 0.5% Fibrex® was optimal and they were able to meet the following results: 1) guarantees the easy processing of dough, 2) a greater level of freshness develops in the baked goods that ensures and optimizes the quality properties, 3) improves the aroma and taste of interrupted baking products, 4) a drastic reduction in the rate of cracking in semi-baked frozen products, 5) greater freezing/defrosting stability of doughs and baked products, and 6) longer preservation of freshness and very good crumb composition.

Animal Studies

Klopfenstein (1990) reported that sugar beet fiber had potential as a dietary aid in the treatment of hypercholesterolemia and constipation. Eight (8) groups of ten (10) male Wistar rats were fed casein-based diets containing 5% α cellulose, hard red winter wheat bran (course and fine) or sugar beet fiber (course and fine) for six (6) weeks. At the end of six (6) weeks, total serum cholesterol levels were lower in animals fed beet fiber than those on the cellulose diet. Animals fed the wheat bran diet had cholesterol levels intermediate between the animals fed cellulose and beet fiber. Serum triglyceride concentrations did not differ significantly among groups

but rats fed sugar beet fiber had lower liver triglyceride concentrations than animals from the other groups. No differences were found in fecal water-holding capacity among rats fed wheat bran and sugar beet fiber, but feces of rats fed 5% cellulose had a significantly lower water-holding capacity.

Hagander et al. (1988a) also conducted some animal studies to support the metabolic responses reported in humans. The suspension of beet fiber bread was given to male Sprague-Dawley rats by oro-gastric intubation. The result was a lower blood glucose response than a control bread suspension at 15 and 30 minutes, but a similar insulin response. The authors suggest that this is due to an effect of beet fiber on the rate of carbohydrate absorption.

Health Effects

Lampe et al., (1991) reported a reduction in total cholesterol due to significant lowering of LDL cholesterol in a study with 34 subjects consuming six (6) controlled diets of wheat bran (0, 10, and 30 g), mixed vegetable fiber (10 and 30 g), and sugar beet fiber (30 g) for three (3) weeks each. They reported reduction in total cholesterol with sugar beet fiber largely due to significant lowering of LDL cholesterol.

Israelsson et al., (1993) studied 30 women (55-56 years old) with 30 g sugar beet fiber (Fibrex®) or placebo in a placebo controlled, double blind crossover study after a one (1) month "run in". Compared to the control group, intervention with sugar beet fiber resulted in a reduction of serum cholesterol by 0.26 mmol/l after two (2) weeks and 0.2 mmol/l after four (4) weeks. Reduction was restricted to LDL cholesterol which decreased by 0.22 mmol/l after two (2) weeks and by 0.30 mmol/l after four (4) weeks without much change in the HDL cholesterol level.

Cossack and Musaiger (1991) conducted a study to test the effect of fiber supplementation (Fibrex®) for hyperecholesterolaemia in desert Nomads. They studied ten (10) males in three (3) phases: 1) baseline with the normal diet (two (2) weeks), 2) fiber supplementation (26 g/day) for five (5) weeks, and 3) four (4) weeks where the fiber supplementation was withdrawn. The intake of nutrients, body weight, and HDL cholesterol levels did not change significantly. There was a significant decrease in total serum cholesterol (10 and 13%), LDL cholesterol (14 and 17%), and the LDL/HDL ratio (5 and 10%) after two (2) and five (5) weeks on the fiber supplementation. Serum triglycerides did not change significantly after two (2) weeks but decreased about 10% after five (5) weeks of supplementation.

GRAS Notification for Sugar Beet Fiber (continued)
5. Safety (continued)

Hagander et al., (1986) evaluated the effect of sugar beet fiber (Fibrex®) on the response of glucose in nine (9) non-insulin-dependent diabetic (NIDD) patients and its relation to plasma levels of pancreatic and gastrointestinal hormones. Standardized breakfasts with or without 10.9 g sugar beet fiber (Fibrex®) resulted in a lower glucose plateau level and area under the curve than the control meal and a slower glucose decrease compared to the control. There were no notable differences with the plasma levels of insulin, C-peptide or glucagon. The gastric inhibitory polypeptide response was greater during the first part of the curve while the somatostatin response after the fiber meal displayed a significantly larger total area below the curve. The results suggested that the diminished glycemic response after the beet-fiber meal is associated with an increased response of somatostatin, giving a reduced glucose absorption and a delayed gastrointestinal transit time.

Hagander et al., (1988a) have reported an effect on the rate of carbohydrate absorption, expressed as a lower insulin response in eight (8) healthy volunteers three (3) hours after they were fed 10.9 g sugar beet fiber (Fibrex®).

Hagander et al., (1988b) evaluated the metabolic effects of dietary fiber without changing energy intake or proportions of protein, fat and carbohydrates in a group of 14 NIDD patients whose diabetes was controlled satisfactorily by diet alone and found a beneficial effect. The high-fiber diet induced lower fasting blood glucose levels and decreased the ratio of low-density lipoproteins to high-density lipoproteins. Continuous glucose monitoring also showed a difference in fasting glucose levels that remained after identical low-fiber test meals. The incremental glucose responses did not differ. The fasting and incremental postprandial levels of insulin, C-peptide, glucagon, and somatostatin did not change, while the mean triglyceride concentrations were lower after the high-fiber diet.

Hagander et al., (1989) conducted a study on the influence of a sugar beet fiber-enriched (Fibrex®) diet on blood pressure, plasma lipoproteins and glycemic control in 12 NIDD patients. The fiber-enriched and control diets were given in randomized order for eight (8) weeks each. After both diet periods, the total plasma cholesterol and triglyceride levels were decreased. Blood glucose levels and glycosylated hemoglobin were not affected during the two (2) different diet periods. The postprandial insulin levels were lower after the fiber diet compared to the control diet in obese patients.

GRAS Notification for Sugar Beet Fiber (continued)
5. Safety (continued)

Morgan, et al., (1988) investigated the effect of sugar beet fiber (SBF) on glucose tolerance, insulin, gastric inhibitory polypeptide (GIP) secretion, and circulating lipids in comparison with guar gum and wheat bran. Postprandial peak arterialized blood glucose concentration was significantly reduced by a 100 g carbohydrate meal supplemented with 10 g guar gum or SBF, compared with an unsupplemented control. Plasma insulin fluctuation was reduced by guar gum but not by SBF. Plasma GIP levels were significantly reduced by guar gum and increased by SBF at 40 minutes when insulin and glucose levels were maximal. Volunteers also consumed bread incorporated with one (1) of the fibers as part of the diet for 14 days. Fasting blood samples were taken weekly for 14 days before, during, and for 14 days after each fiber supplementation period. Plasma total cholesterol levels were reduced by 11.7 and 4.6% by guar gum and SBF, respectively, but were unchanged by bran.

Thorsdottir et al., (1998) investigated the effects of sugar beet fiber (Fibrex®) in formula diet on blood glucose, serum insulin and serum hydroxyproline in 15 healthy male volunteers (mean age 25, range 21-42). Two (2) formula test meals with and without 7 g of sugar beet fiber were fed to the subjects on two (2) mornings in a clinic after a 12 hour fast. Blood samples were drawn before and after the test meals and terminated 155 minutes after ingestion. The test formula with sugar beet fiber reduced the postprandial blood glucose response, serum insulin response, and serum hydroxyproline response compared to the control formula. The sugar beet fiber in the formula lowered incremental areas over one (1) hour for glucose, insulin and hydroxyproline by 24%, 23%, and 21%, respectively, and by 19% and 21% for glucose and insulin over two (2) hours.

Frape and Jones (1995) questioned whether a dietary fiber supplement known to lower fasting plasma cholesterol concentrations can also lower the postprandial plasma cholesterol, glucose and insulin concentrations when it is administered just before a meal. Two (2) studies were conducted in healthy middle-aged volunteers of both sexes who had fasting plasma total cholesterol concentrations above normal. In the first study, four (4) males and eight (8) females with no prior exposure to the dietary fiber were provided with 2.2g of psyllium and a psyllium-citrus pectin mixture and compared with controls (no added dietary fiber). The meals were high-fat breakfasts and lunches. In the second study, eight (8) males and eight (8) females were fed sugar beet fiber supplements (6 g) three (3) times daily for three (3) weeks and compared to control diet (2 g cellulose). In the first experiment, there were no significant effects on the postprandial measurements of plasma glucose, insulin:glucose ratio, total-, LDL- and HDL-cholesterol, and triacylglycerol (TAG). In the second study, sugar beet fiber significantly decreased

the area under the glucose response curve by 6.9%, the area under the insulin response curve was lower by 9.6%, although not significantly, and the post-glucose meal HDL-cholesterol concentration was significantly (12%) higher. Additionally, the three-week treatment with sugar beet fiber significantly lowered the fasting total- and LDL-cholesterol concentrations by 8.5% and 9.6% respectively.

Ulmius et al., (2009) conducted a study to study the effects of meals enriched with soluble dietary fibers (oats, rye bran, and sugar beet fiber) on postprandial glucose, insulin and triglyceride concentrations. Eighteen healthy volunteers (ten (10) men and eight (8) women) were recruited for the study. Fourteen completed the five-week study and one (1) was excluded due to illness and low compliance, resulting in 13 subjects (six (6) men, seven (7) women, ages 20-28 years) included in the study. The subjects were fed test meals and a control meal in random order after an overnight fast, once a week. The meals contained oat powder (62 g, 2.7g soluble fiber), rye bran (31 g, 1.7 g soluble fiber), sugar beet fiber (19 g, 5 g soluble fiber), a mixture of the three (3) fibers (74 g 5 g soluble (1.7 g from each source)), or the control with no added fiber, with all adjusted to contain the same total amount of available carbohydrates. Blood samples were drawn before each meal and every 30 minutes after the meal up to 180 minutes. The researchers found that meals with rye bran gave a lower postprandial glucose effect when compared with the control, and this effect was more pronounced in women compared to men. Oat powder gave a higher incremental glucose peak concentration compared to rye bran and sugar beet fiber, and higher insulin incremental area under the curve compared to control. Postprandial triglyceride levels tended to be higher after all fiber-rich meals, but was significant only for oat powder and the mixed meal when compared with control.

Langkilde et al., (1993) studied the effect of sugar beet fiber (Fibrex®) on sterol excretion from the small intestine in nine (9) ileostomy subjects. They were given a low-fiber diet in two (2) three-day periods with and without 32 g sugar beet fiber per day in random order. The addition of sugar beet fiber increased net cholesterol excretion and decreased bile acid excretion. This effect is different from the pattern associated with other fiber sources, and the authors concluded that the interaction between dietary fiber and sterol metabolism may be mediated by different mechanisms depending on the fiber source.

GRAS Notification for Sugar Beet Fiber (continued)
5. Safety (continued)

Phytic acid, present in relatively high concentration in cereal brans, inhibit the absorption of the minerals, iron and zinc. Sandstrom and coworkers (1987) used isotope-labeled zinc (^{65}Zn) in composite meals with and without Fibrex® using 39 volunteers and measured whole body retention of the radioisotope. Low zinc chicken meals with 150 g white bread or 225 g potatoes, carrots, turnips, cabbage, or green peas were studied. The mean percentage absorption from the chicken meals with bread, carrots and cabbage was significantly different from the meals with potatoes, turnips and green peas. When the amount of Zn in the meals was taken into account a slightly higher absorption was observed from the bread meal compared with the meals with potatoes and cabbage, while no differences were seen between the vegetable meals. The effect of a beet-pulp-fiber preparation used as a breakfast cereal, in bread and as a meat extender was also studied. The beet-pulp-fiber preparation did not affect the extent of Zn absorption when used as a meat extender. The absorption of Zn was higher when the beet fiber was included in bread than when used as a muesli. The authors concluded that the results suggest that besides the low Zn content in vegetables, a large intake of vegetables or a pure vegetable fiber preparation has no significant effect on Zn availability from animal protein-based meals.

Hallberg (in manuscript) demonstrated that there was no inhibiting effect on the absorption of iron and zinc in meals containing Fibrex®. Hallberg fed ten (10) volunteers spaghetti with meat sauce with and without Fibrex®. Using isotope-labeled iron (^{59}Fe), no difference was found between groups when monitoring absorption of the minerals after two (2) weeks.

Hamberg et al., (1989) reported that dietary fibers (wheat bran, sugar beet fiber, and pea fiber) impaired the absorption of wheat starch, and thereby increased the amount of starch-derived carbohydrate available for colonic fermentation. Eight (8) healthy subjects were fed bread made from 100 g wheat flour and were compared with each dietary fiber fed simultaneously. Hydrogen excretion in the breath was measured after the test meals and compared. Concurrent ingestion of the bread with either wheat bran, sugar-beet fiber, or pea fiber increased the fraction of unabsorbed starch to 12.5%, 12.5%, and 12%, respectively. All three (3) fibers decreased mouth-to-caecum transit time. Bread made from 100 g of low gluten wheat flour only escaped small bowel absorption in three (3) subjects with a maximal fraction of 6%.

GRAS Notification for Sugar Beet Fiber (continued)
5. Safety (continued)

Giacosa et al., (1990) conducted a study in 27 patients (18 females and nine (9) males) ranging in age 21 to 42 years (mean 42 years) complaining of chronic constipation. The study was to evaluate the efficacy, safety, and compliance of sugar beet fiber, which contains high proportions of soluble and non-soluble components. The sugar beet fiber was pressed into tablets containing 750 mg of product. The daily dose was nine (9) tablets consumed in three (3) equal doses during meals after four (4) days of a progressive consumption (four (4) tablets on days 1 and 2, and six (6) tablets on days 3 and 4). Stool frequency and composition were assessed before study initiation, and at 15 and 30 days after full consumption (nine (9) tablets/day). The study was completed by 26 of 27 patients. The stool behavior evaluation demonstrated a marked decrease of severe and moderate constipation after 15 and 30 days of treatment. Initially, 11 patients were assessed with severe constipation and 15 with moderate constipation. After 15 days, two (2) were assessed with severe constipation, eight (8) with moderate constipation, and 16 had normal stools. On the 30th day, one (1) was assessed with severe constipation, three (3) with moderate constipation, and 22 with normal stools. Seven (7) patients with cholesterol greater than 230 mg/dl were studied after 30 days. Initially these patients had a cholesterol level of 258 ±14, and after 30 days of the study, resulted in a significant decrease to 220 ± 18. The tolerance and compliance of the patients to sugar beet fiber were good. In two (2) cases, multiple liquid stools were reported after days 12 and 14. Reducing the dose from nine (9) to six (6) tablets per day normalized the effect.

Burley et al., (1993) conducted a study with 18 non-obese subjects (nine (9) male and nine (9) female) to determine the effects of a breakfast supplemented with sugar beet fiber on satiety. The subjects consumed a control or a fiber-supplemented breakfast. Each breakfast consisted of orange juice, milk, grilled tomato, butter, jam, breakfast cereal, bread, crispbread, and English sausages and served with a hot beverage. The cereal, bread, crispbread, and sausages were prepared with and without sugar beet fiber to generate 29 g additional non-starch polysaccharide per breakfast. The subjects recorded their perceived level of hunger on an hourly basis after breakfast. Direct assessment of motivation to eat was made by the administration of an *ad libitum* test lunch 4.5 hr after breakfast, and further food intake was recorded in a food diary for 36 hours. A 14% lower energy intake was observed at the test lunch following the high-fiber breakfast compared to control, and this was supported in the food diaries after the two (2) breakfasts.

GRAS Notification for Sugar Beet Fiber (continued)
5. Safety (continued)

Lampe et al., (1993) compared the gastrointestinal effects of sugar beet fiber (SBF) and wheat bran (WB) in 17 healthy men (17 of 20) who completed a randomized cross-over design study. The fibers were milled to similar particle sizes and consumed as supplements to self-selected (SS) diets by each subject. Transit times were similar among the diets. Fecal wet and dry weights were greater on the fiber diets compared to the SS diet ($P < 0.05$); wet weights were similar with WB and SBF; dry weights were greater with WB than SBF ($P<0.001$); and moisture content was lower with WB than SBF ($P<0.01$). Fecal pH was lower with WB than SBF ($P<0.025$). WB and SBF provided similar fecal bulking effect; however, the contribution of fecal dry matter and fecal water content to increased bulk differed between fibers.

Castiglia-Delavaud, et al., (1998) conducted a study to determine whether differences in metabolizable energy (ME) and net energy (NE) contents were similar for insoluble and soluble non-starch polysaccharide isolates (NSP). Nine (9) healthy young men were offered three (3) diets with three (3) repetitions: control diet (C), control plus sugar beet fiber (B, 50g/day) and control plus inulin (I, 50g/day). After a 16 day adaptation period, food intake was controlled and feces and urine were collected for eight (8) days. NSP-isolate ingestion induced significant increases in the number of defecations and stool weight resulting from increases in water, DM and microbial mass excretion. After deduction of microbial N, differences in fecal N excretion between diets were not significantly different. Urinary N excretion was slightly decreased with diets B and I, but the N balances for the diets were not significantly different.

Cherbut et al., (1991) evaluated the effects of five (5) dietary fibers on intestinal transit time, wheat bran (WB), sugar beet fiber (B), Maize (M), pea hulls (P), and roasted cocoa (C). They evaluated the chemical composition, physicochemical and *in vitro* fermentative properties (total and soluble fiber), water-binding capacity, and *in vitro* fermentation of the five (5) fibers and related their effects on intestinal (orocaecal and orofaecal) transit time (OCTT and OFTT) in healthy volunteers. The results showed that there were no simple relationships between the chemical and physicochemical properties of the fibers and their effect on intestinal transit time. The results suggested that the water-binding capacity might be involved in the OCTT and that the non-fermented fibers, such as maize fibers, could change the OFTT by a mechanical effect. The fermentable fibers also might change the OFTT as a result of production of propionic and butyric acids during fermentation.

GRAS Notification for Sugar Beet Fiber (continued)
5. Safety (continued)

C. Conclusions on Safety

1. Sugar beets and the pulp after extraction of the sugar have long history of food and feed use.

2. The sugar beets are monitored during harvesting and the production of sugar and sugar products, including sugar beet fiber for a wide range of contaminants, including heavy metals, pesticides and mycotoxins to verify the safety of the sugar beet fiber.

3. The manufacturing process for the isolated fiber is a non-destructive process and retains the ratio of insoluble to soluble fiber as two to one.

4. Based on the rat study, the HED is 1.8 mg/kg/day. With an estimated exposure of 0.036 mg/kg/day in 2010, we have a 50-fold safety factor.

5. The recommendations of the 1991 GRAS Expert Panel that the use of sugar beet fiber in food is safe are still valid.

6. Nordic Sugar concludes that the new information obtained since the Expert Panel report supports the conclusion reached in 1991 that the uses of sugar beet fiber are considered as GRAS.

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7. Appendices

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4. Letters from USDA/FSIS:

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   - December 23, 1998 letter from Labeling and Additives Policy Division, FSIS to Hesco, Inc.
   - September 12, 2002 letter from Labeling and Consumer Protection Staff, FSIS to International Fiber Corporation.

5. July 5, 1989 letter from Nutrition Evaluation Division, Bureau of Nutritional Science, Health Protection Branch to Canadian Fibre Foods, Inc.

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Nordic Sugar
Member of Nordzucker Group

PRODUCT DESCRIPTION - PD 228905-5.0EN

Fibrex

Valid from: November 22, 2010

Description

Sugar beet fibre

Ingredients

Sugar beet pulp

Physical/Chemical specifications

Dry matter	approx 92 %
Water holding capacity	3.5 - 4.0 g water/g
Particles <0.032 mm	Fibrex 575
Particles <0.125 mm	Fibrex 595
Particles <0.50 mm	Fibrex 600
Particles <2.0 mm	Fibrex 608
Particles 0.4-1.4 mm	Fibrex 610
Particles 1.0-2.0 mm	Fibrex 615
Coarse, not milled	Fibrex 620
Flake	Fibrex 630

Microbiological specifications

Analysis accordning to NMKL methods:

Total plate count	< 1000 CFU/g
Yeasts	< 100 CFU/g
Moulds	< 100 CFU/g
Enterobacteriaceae	< 10 CFU/g
E.coli	negative
Salmonella	negative
Bacillus cereus	< 100 CFU/g
Clostridium perfringens	< 10 CFU/g

Nutritional data

per 100 g

Energy	800 / 200 kJ / kcal [1]
Protein	8 g
Carbohydrate	5.5 g
of which sugars	5.5 g
Fat	1 g
of which saturated	< 1 g
Fibre	67 g [2]
of which	
- Hemicellulose (42%)	
- Cellulose (28%)	
- Pectin (27%)	
- Lignin (3%)	
Minerals	4 g
Sodium	0.05 g

[1] The energy value is corrected according to Commission Directive 2008/100/EC and Codex Alimentarius.
[2] According to AOAC 45.4.07/NMKL 129. Some hemicelluloses, particularly arabans are exceptionally soluble in alcohol and therefore not recovered in the fibre analysis. However, their degree of polymerisation is well above 10 and they are therefore fibre according to current Codex Alimentarius and EU definitions. Taken this into account, the total fibre content is approx. 73%.
Fibrex is a product of nature, with natural variations according to place of growth of the sugar beet, weather conditions etc. The specifications parameters on composition can therefore by definition not be bindning, but must be seen as a guideline.

Storage recommendations

Shelf life in unbroken packaging: 8 years

Keep dry, relative humidity < 65 %

Results from analyses are obtained using Good Laboratory Practice.Deviations from the data specified above might occur due to normal uncertainty in sampling and methods of analysis.

Nordic Sugar
Member of Nordzucker Group

PRODUCT DESCRIPTION - PD 228905-5.0EN

Fibrex

Valid from: November 22, 2010

Packaging

57522 / 22 kg, 660 kg/pallet
59522 / 22 kg, 660 kg/pallet
59422 / 22 kg, 990 kg/pallet
59500 / Big bag
60022 / 22 kg, 660 kg/pallet
60122 / 22 kg, 924 kg/pallet
60822 / 22 kg, 660 kg/pallet
61022 / 22 kg, 660 kg/pallet
61522 / 22 kg, 660 kg/pallet
62014 / 14 kg, 420 kg/pallet
63016 / 16 kg, 480 kg/pallet

Fibrex is delivered on Europallets in 2-sheet Semiclupac or Duplex bags, (1x90g/m2 + 1x80g/m2).

Produced in

Sweden

Kosher information

The product is Kosher. Certificate is available on request.

Halal information

The product is Halal. Certificate is available on request.

GMO information

The product does not contain or consist of GMOs and is not produced from or contain ingredients produced from GMOs as defined in Regulations (EC) No 1829/2003 and 1830/2003.

Allergen information

The product does not contain any allergens as listed in Directives 2003/89/EC (Annex IIIa), 2005/26/EC (Annex) and 2006/142/EC (Article 1).

Additional information

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PO Box 2100
1014 Copenhagen K
Denmark
Phone: +45 32 66 25 00
Fax: +45 32 66 21 50

Results from analyses are obtained using Good Laboratory Practice.Deviations from the data specified above might occur due to normal uncertainty in sampling and methods of analysis.

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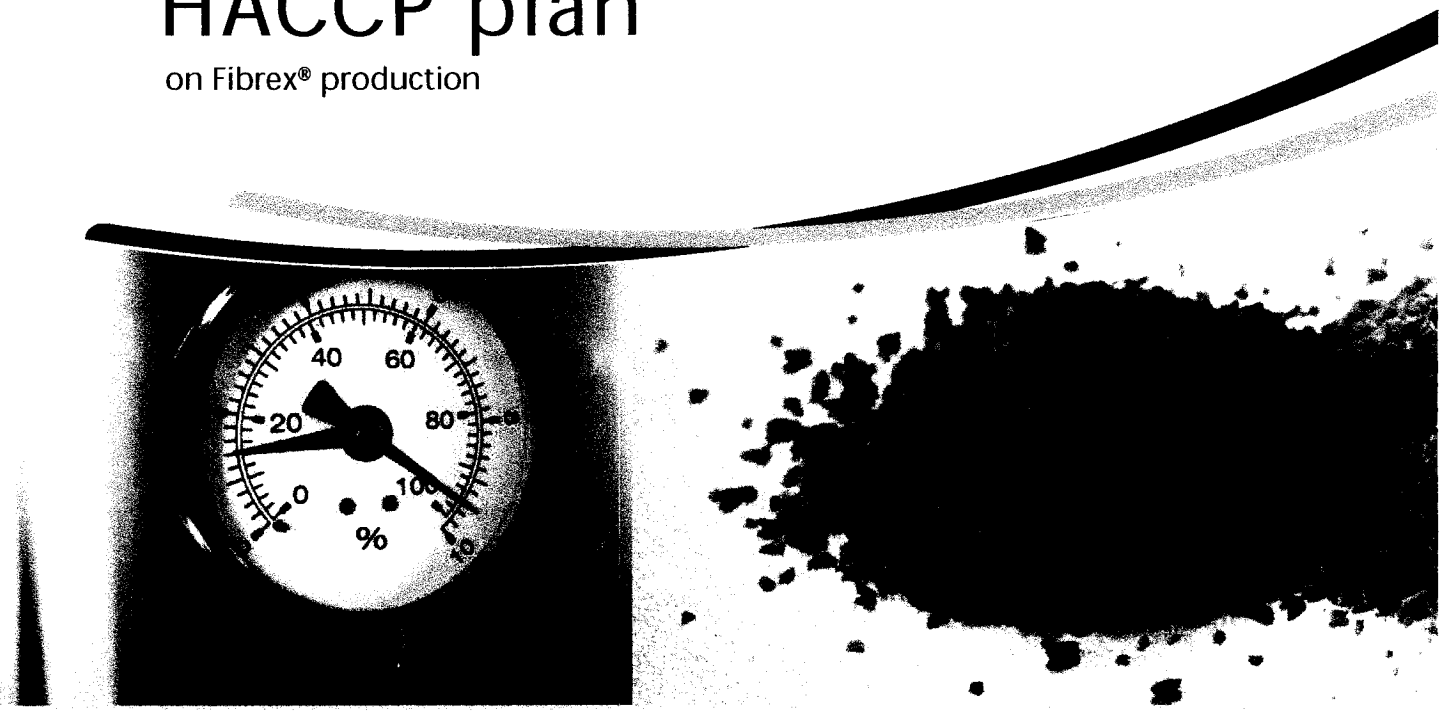
Nordic Sugar
Member of Nordzucker Group

HACCP plan

on Fibrex® production



000037

Content

1. Objectives
2. The method
3. Identification of CCPs and POAs
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1. Objectives

The objectives with this booklet are to

1. Explain and introduce Nordic Sugar's HACCP work to customers and authorities
2. Exchange general experiences with HACCP plans throughout the organisation
3. Create a common understanding of the HACCP method (calibration between factories)

The current HACCP plan adresses product safety associated with production of Fibrex®

2. The method

The HACCP plans at Nordic Sugar are based on the GMP+ method (International Feed Ingredients Standard - IFIS) and the international food safety standard ISO 22000. We have taken every identified hazard in the whole process chain and evaluated them with regard to three basic steps in this method (the fourth step below is the verification of the system). This procedure has clarified where the hazard should be controlled, how the hazard should be controlled and what verification procedures are necessary.

1. Identification of chemical, physical, biological and allergenic hazards in each step of the process chain.
2. In a risk assessment (2.2.) the severity and probability of each identified hazard are combined to determine the risk class and the type of control method necessary.
3. By using the decision tree (2.3.) we have identified where the hazards should be controlled along the production chain. Based on the risk classes the decision tree is used to determine whether a given process step is a critical control point (CCP), a point of attention (POA/GMP) or just a periodic measure (PM).
4. Apart from product specifications, process diagrams, risk analysis tables and summary tables, also activities towards verification of the HACCP system are documented. These activities are e.g. audits, sampling and analysis of products, analysis of deviations and customer complaints.

2.1. Severity and probability

The severity of every possible hazard in the production chain has been estimated by the Nordic Sugar HACCP Reference Group independent of the current production process. The probability of each hazard is very closely associated with the processes and the current process equipment. The probability has therefore been determined by the local HACCP group at the factory.

2.2. Risk assessment matrix

Probability* \ Severity	Small	Medium	Great
Great	3 POA Specific measures	4 CCP Critical measures	4 CCP Critical measures
Medium	2 PM General measures	3 POA Specific measures	4 CCP Critical measures
Small	1 No measures	2 PM General measures	3 POA Specific measures

* Refers to the probability of the hazard being present in the end product e.g. at the moment of consumption.

2.3. Decision tree

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Where will the hazard be controlled?

Q1: Are there identified hazards present which have a harmful effect on the safety of the product and/or can the hazard exist or increase to unacceptable levels?
Yes → Q2, No → stop!

Q2: Which type of control measures are necessary according to the risk assessment?
Critical measures (class 4) → Q3, Specific measures (class 3) → include measures as POA and in verification procedures,
General measures (class 2) → include measures as PM and in verification procedures or no measures (class 1) → stop!

Q3: Are the critical control measures referred to present?
Yes → Q4, No → Modify the process or product and start again at Q1.

Q4: Has this process step been specifically developed to eliminate the risk or reduce it to an acceptable level? No → Q5, Yes → CCP!

Q5: Will the risk be eliminated in a subsequent process step or will it be reduced to an acceptable level? Yes → Stop, No → CCP!

3. Identification of CCPs and POAs

The way Nordic Sugar differs between a CCP and a POA

CCP

- A high risk step, which is likely to get out of control
- Critical (and possible/applicable) control measures are needed in order to prevent, eliminate or reduce food & feed safety hazards to an acceptable level
- If measures are out of control the corrective actions must include isolation of product batch, retesting, decontamination or destruction
- The hazard is not eliminated or reduced to an acceptable level at a later stage in the process
- If not in control the end product consitutes a serious health risk

POA

- A moderate risk step
- Specific control measures essential to control the likelihood of introduction, contamination and/or proliferation of food & feed safety hazards
- The hazard may be reduced at a later stage in the process
- If measures are out of control the corrective actions include reevaluating procedure and/or checking equipment

In total two POAs and one CCP have been identified for the production of Fibrex.
(see 3.1. Fibrex production process).

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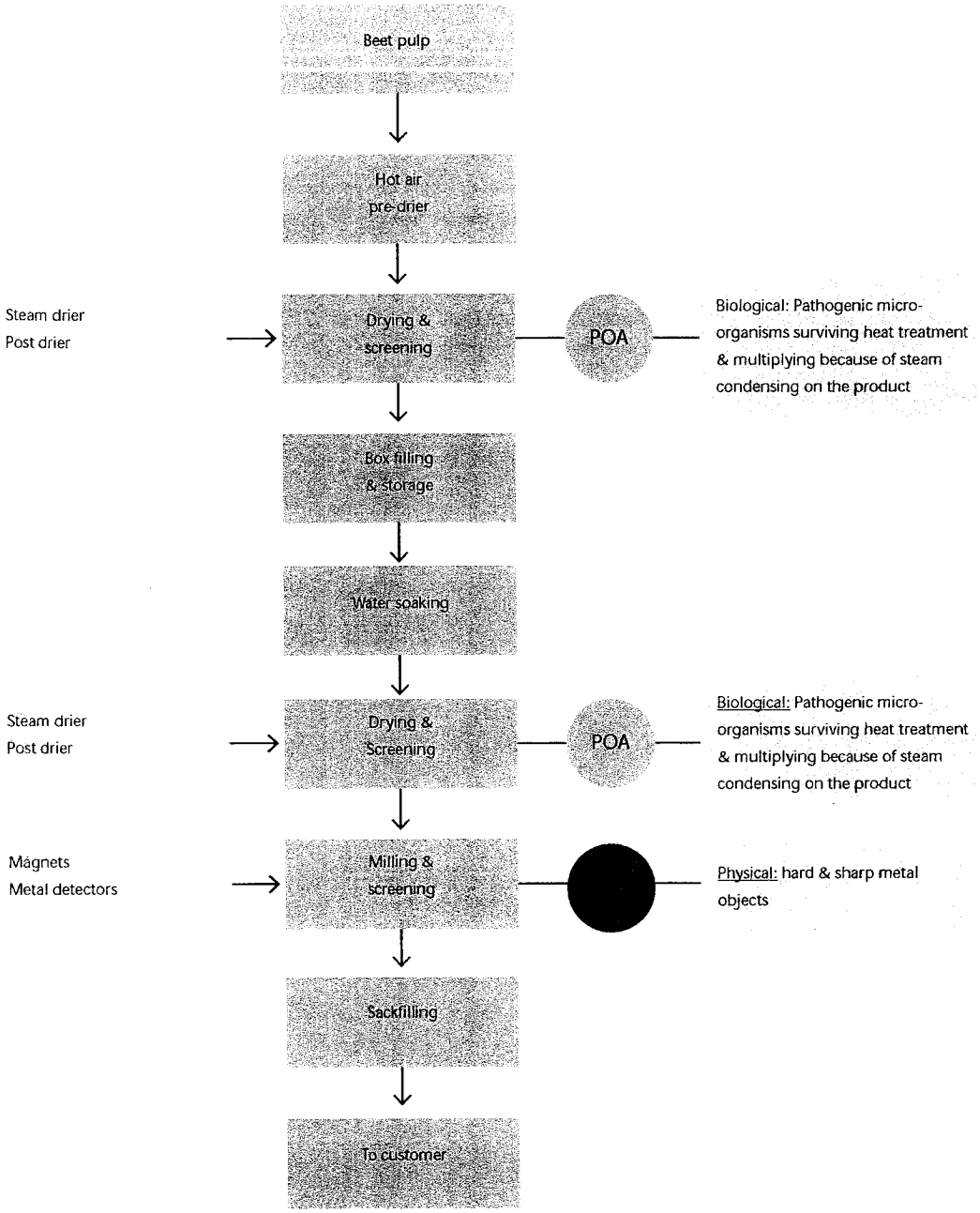
3.1. Fibrex production process

General process steps and description of CCPs and POAs



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See description of hazards, control measures, action limits and corrective actions for these process steps in table 3.2. and 3.3.

3.2. Hazard analysis table (risk evaluation)

Processing step		Potential Hazards	Control measures
		introduced,crontrolled or enhanced at this step	applied at this step to prevent/reduce/ eliminate the hazard.
1	Drying & screening	(B) Mycotoxin producing fungi or pathogenic bacteria surviving heat treatment. Multiplication of these microorganisms later in the process if steam condensing on the product	Processing control Right temperature & pressure
2	Drying & screening	(B) Mycotoxin producing fungi or pathogenic bacteria surviving heat treatment. Multiplication of these microorganisms later in the process if steam condensing on the product	Processing control Right temperature & pressure
3	Screening	(P) Presence of hard & sharp metal objects 3 - 25 mm.	Continuous screening with magnets & metal detectors

* Refers to the questions in the Decision tree (see 2.3. Decision tree).

B=Biological

C=Chemical

P=Physical

SM=Specific measures

CM=Critical measures

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Is this step a critical control point?

Evaluation of hazard Severity and probability in the risk assessment matrix gives the risk class	Decision tree questions 1 / 2 / 3 / 4 / 5*	CCP/POA/PM Comm. / Ref.
Great x small = 3	Yes / SM → POA	Drying (steam & post drier) is a POA for microbiological hazards
Great x small = 3	Yes / SM → POA	Drying (steam & post drier) is a POA for microbiological hazards
Medium x great = 4	Yes / CM / Yes / Yes → CCP	Screening with magnets & metal-detectors is a CCP for metal hazards

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3.3 HACCP Summary table

CCP or POA	Process step	Hazard to control	Control Method	Frequency
1 POA	Drying & screening	I. Survival of pathogenic microorganisms II. Mycotoxin production	I. Temperature & pressure control II. Dry matter (DM) content	I. Every 2 hour II. Every 2 hour
2 POA	Drying & screening	I. Survival of pathogenic microorganisms II. Mycotoxin production	I. Temperature & pressure control II. Dry matter (DM) content	I. Every 2 hour II. Every 2 hour
3 CCP	Screening	Presence of hard & sharp metal objects	Specific method to check the magnet or metal detector efficiency (test objects identified or caught)	Every shift

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Action limit	Corrective action - when action limit is exceeded	Responsible	Reference
I. According to norm. II. DM < 87%	I. Rework II. Rework	Drier operator	Local instruction for activities covering this area
I. According to norm. II. DM < 87%	I. Rework II. Rework	Drier operator	Local instruction for activities covering this area
Target limit: The test objects are being identified in product flow Action limit: Test objects not identified by metal detector in the product stream	Rework	Drier operator	Local instruction for activities covering this area

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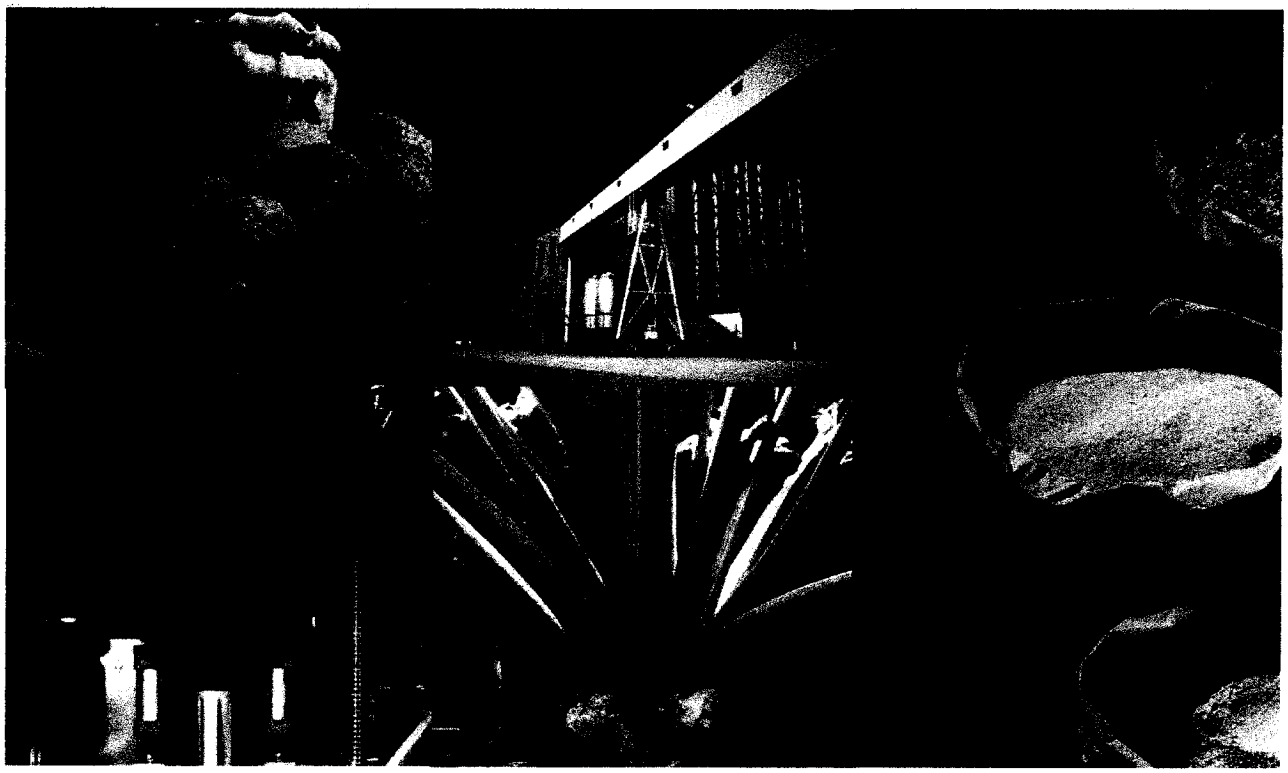
4. Verification process

Sustaining a high quality and secure HACCP system requires continuous evaluation and review of the system. A Nordic Sugar review of the risk analysis and verification of the HACCP plans consists of the following elements:

- Trend analyses of monitoring of POAs and or CCPs e.g. how often do we identify broken sieves
- Sampling and analysis of end products as a part of our quality program.
- Evaluation of complaints and/or emergencies reported to Nordic Sugar.
- Internal and external audits.

Audits -with focus on e.g. hygiene and HACCP are performed by internal and external parties.

These elements are used to verify the current HACCP plans at the different production sites. The verification is done whenever necessary and at least once a year.

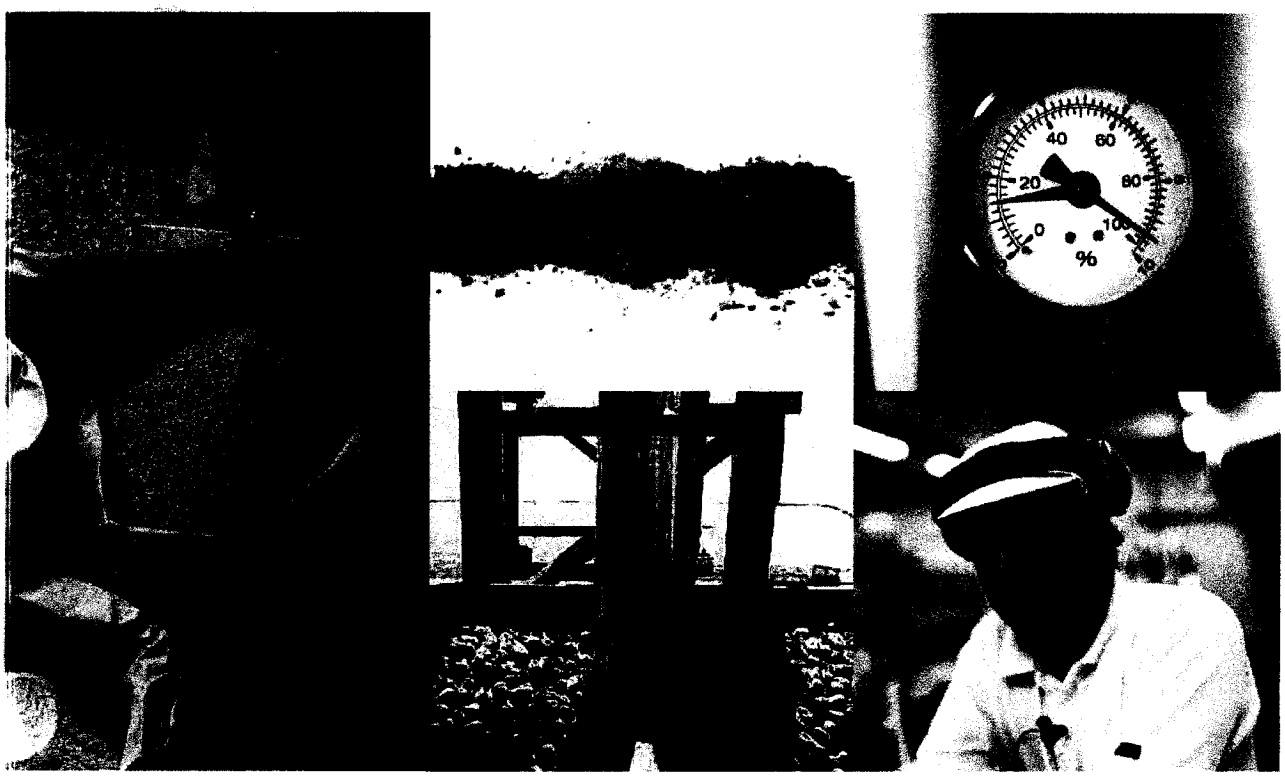


5. Documentation

In the description of our HACCP system the following documents are included:

- HACCP team documents (members and areas of expertise)
- Flowcharts i.e. process diagrams
- Hazard analysis tables
- HACCP summary tables (comprising exclusively POAs and CCPs)

These documents are handled in the document management system (DMS) for each factory. The product safety manager located at the production site supports the management and updates the documentation. Deviations from criteria set for CCPs/ POAs are reported and registered in a Deviation Database and/or the Laboratory Information Management System (LIMS) or Production Information Management System (PIMS). Deviations identified at the factories (at e.g. audits) are reported and communicated in a Deviation Database. Customer complaints are registered in a similar database, "Sugar Complaints for sugar, Fibrex and animal feed products".



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Member of Nordzucker Group

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Langebrogade 1
PO Box 2100
1014 Copenhagen K
Denmark

Copenhagen, 27 april 2012

Residues and contaminants

Residuals Food English 09.03.2009

In response to your enquiry regarding undesirable residues and contaminants in

Fibrex 610

we want to inform you, that Nordic Sugar has a monitoring and analysis programme with the purpose of verifying the safety of our products and the compliance with relevant EU legal requirements (e.g. those laid down in Regulation 178/2002 and specifically in Regulation (EC) 1881/2006, Regulation (EC) 396/2005 (as amended) and the recommendations of WHO (Codex Alimentarius).

The analysis programme is based on random samples of all product types taking the results of the previous years in consideration. An international external laboratory carries out the analyses. The programme is made up of two parts carried out on a yearly basis. One part comprises analyses of a wide range of commonly recognized contaminants, i.e. heavy metals, environmental contaminants, pesticides and mycotoxins. The type of analyses comprised by the other part varies depending on factors like new legislation, new scientific or technical information, or customer requests. The programme also includes the control of residues of various process aids, for example sulphur dioxide, applied in the production. Based on the results of the analyses conducted under this programme and to the best of our knowledge the above-mentioned product does not pose a health risk and complies with above mentioned EU legislation and recommendations.

Should any circumstances arise that affect this conclusion you will be informed. This document supersedes all previous statements on residues and contaminants relating to the above-mentioned product. The above information is given in respect of Nordic Sugar's policy of openness and transparency with its customers.

Nordic Sugar A/S
(b) (6)

Birgitta Hermansson

Product Manager

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United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

MAR 25 1993

Mr. Sid Arends
Director of Sales & Marketing
DELTA Fibre Foods
435 Ford Road
Suite 315
Minneapolis, MN 55426-4911

Dear Mr. Arends:

This in response to your letter of February 19, 1993, concerning the status of your ingredient "sugar beet pulp granules" (or "flakes") and its use in non-standardized meat and poultry products.

Based on the technical data you provided, sugar beef pulp powder, flakes, or granules may be used in non-standardized meat and poultry products, e.g., "beef patties," "chicken links," or products identified by Policy Memo 121 (copy enclosed). The ingredient may be used at levels consistent with the functional effect of binding. Additionally, the ingredient must be declared by the name "sugar beet pulp powder (granules or flakes)" in the ingredients statement of products like beef patties or as part of the product name per Policy Memo 121.

I hope this letter has adequately responded to your request. If you have additional questions, please write or contact Dr. Jim Rasekh, Food Standards and Ingredients Branch, at Area Code (202) 205-0003.

Sincerely,

(b) (6)

Robert C. Post, Branch Chief
Food Standards and Ingredients Branch
Product Assessment Division
Regulatory Programs

Enclosure

United States Department of Agriculture

Food Safety and Inspection Service

Office of Policy, Program Development and Evaluation

Washington, D.C. 20250-3700

DEC 23 1998

Mr. Sid Arends
Hesco, Inc.
P.O. Box 815
118 South maple Street
Watertown, SD 57201

Dear Mr. Arends:

This is in response to your request for permission to use Hesco AS-20 Fiber and Hesco AS-25 Fiber in non-standardized meat and poultry products as a binder.

The data provided in your December 11, and December 18, 1998, facsimile letters, sufficiently identify Hesco AS-20 and Hesco AS-25 as Sugar Beet Pulp powder. Sugar Beet Pulp powder may be used as a binding agent in non-standardized meat and poultry products, e.g., " beef patties", "chicken links", and other products identified by Policy Memo 121. Ingredients classified as binders are subject to Federal meat and poultry regulations found in 9 CFR 318.7(c)(4) and 381.7 (f)(4). The quantity of Sugar Beet Pulp powder added to non-standardized meat and poultry products should not exceed the amount necessary to achieve the desired technical effect in that meat and poultry food product. This level is typically 3.5 percent or less of product formulation. Above this level, e.g., at above 10 percent, concerns about product characteristics may warrant the inclusion of Sugar Beet Pulp Powder in the product name.

The labels of non-standardized meat and poultry products containing Hesco AS-20 and/or Hesco AS-25 must declare the ingredient by the name "Sugar Beet Pulp Powder (granules or flakes)." Sugar Beet Pulp powder products may not be identified by the term "Sugar Beet Flour" or "Vegetable Flour" on meat and/or poultry labels.

If you have additional questions, you may contact Susan Zuk, Labeling and Additives Policy Division, at Area Code (202) 205-0279.

Sincerely,

(b) (6)

Robert C Post, Ph.D., Director
Labeling and Additives Policy Division

United States Department of Agriculture
Food Safety and Inspection Service
Office of Policy, Program Development
Washington, D.C. 20250/3700

Mr. Sid Arends
Regional Account Manager
International Fiber Corporation
50 Bridge Street
North Tonawanda, NY 14120

SEP 12 2002

Dear Mr. Arends:

I am responding to your faxed letter of July 30, 2002, in which you requested approval to use FIBREX Sugar Beet Powder in non-standardized meat and poultry products.

In your letter, you indicated that FIBREX Sugar Beet Powder is made up of sugar beet pulp powder, granules or flakes. This ingredient may be used in non-standardized meat and poultry products such as "beef patties," "chicken links," or products identified in Policy Memo 121. Fibrex may be used at levels consistent with the functional effect of binding. The ingredients must also be declared by the name "sugar beet pulp powder (granules, or flakes)" in the ingredients statement of products, such as beef patties, or as part of product name e.g., according to Policy Memo 121.

If we can be of further assistance, please do not hesitate to contact Tawana Duncan, Program Analyst, at Area Code (202) 205-0623.

Sincerely,

(b) (6)

Robert C. Post, Ph.D., Director
Labeling and Consumer Protection Staff

5

Health and Welfare Canada | Santé et Bien-être social Canada

Health Protection Branch | Direction générale de la protection de la santé

Bureau of Nutritional Sciences
Food Directorate
Tunney's Pasture
Ottawa, Ontario
K1A 0L2

July 5, 1989

Mr. K.V. Galland
Canadian Fibre Foods Inc.
1530-1176 West Georgia St.
VANCOUVER, British Columbia
V6E 4A2

Dear Mr. Galland:

This in reference to your submission regarding the use of FIBREX sugar beet fibre as a dietary fibre ingredient in foods.

We have reviewed all the information provided by you, and can now confirm that we would have no objection to the use of FIBREX sugar beet fibre as a source of dietary fibre in foods, provided that, as previously discussed, the following recommendations are followed:

1. It should be incorporated into products similar to those tested, and at similar levels and particle sizes to those of products tested for physiological efficacy.

2. Based on the data provided in your letter of May 9, 1989 and a maximum potential use level of FIBREX of 7% in bread and other bakery products, the lead and cadmium levels in FIBREX are not considered to pose a hazard to health. You mentioned that in order to keep lead and cadmium levels low, the fines are removed from FIBREX during production. Please ensure that this procedure and the specifications cited above are consistently maintained.

.../2

3. With respect to the chemical analysis, please note that, in order to satisfy the requirements of Section B.15.002 of the Food and Drug Regulations, the total content of each agricultural chemical and its derivatives may not exceed 0.1 ppm.

4. The energy value of dietary fibre sources, including FIBREX, must be included in the calculation of the energy value of foods containing them. The Branch's position in this regard are set out in the Guidelines on Nutrition Labelling.

5. With regard to finely ground (particle size of less than 0.125 mm) fibre sources, we should point out that since we have not had the opportunity to evaluate results of safety and efficacy studies, e.g. laxation studies, we are not yet in a position to comment on their acceptability in foods. Further efficacy data would be required, therefore, to comment on the acceptability of all very finely ground (or microground) fibre sources, including FIBREX products with particle sizes of less than 0.125 mm.

6. The use of FIBREX in extruded products would require demonstration of efficacy, since the extrusion process could significantly alter the fibre properties (as discussed at our meeting on June 6, 1988).

7. With respect to the promotional material for manufacturers, we have the following comments: At this time, claims to the effect that FIBREX will lower blood sugar content after meals or reduce blood cholesterol may not be made, since these claims would bring FIBREX within the definition of a drug for purposes of the Food and Drugs Act and are unacceptable for foods. (We would, however, have no objection to the listing of published studies about the effects of FIBREX). Descriptions relating fibre in food to diseases such as gallstones and cancer, included in the "general information about food fibre and FIBREX", are not acceptable for a food. The differential method is not considered acceptable for dietary fibre analysis. Information Letter No. 736 lists those methods considered acceptable e.g. Prosky et al., 1985 or equivalent (Asp et al, 1983).

.../3

Comparative claims, e.g. "more food fibre than wheat bran", would have to be supported by efficacy studies comparing the two products. We would refer you to Section 21 of Part C of the Guide for Food Manufacturers and Advertisers, published by the Department of Consumer and Corporate Affairs, for a more detailed discussion of claims for dietary fibre.

As research on the properties and physiological efficacy of FIBREX progresses, we would be pleased to evaluate new data. Please do not hesitate to call us if you have further questions at this time.

Yours truly,

(b) (6)

M.C. Cheney, Ph.D
Chief
Nutrition Evaluation Division

SUBMISSION END