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PETITION FOR THE ADDITION OF

OAT BETA-GLUCAN

OAT β-GLUCAN

TO THE NATIONAL LIST OF ALLOWED SUBSTANCES IN ORGANIC FOODS 7 CFR 205.606

Full Petition
Confidential Business Information

Respectfully submitted by:

TATE & LYLE
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Petition to Add to the National List 205.606:

Oat β-Glucan

>30% β-glucan content, water extracted,
no chemicals including those for pH adjustment and/or solvent extraction

Item A

1. Category

Non-organically produced agricultural products allowed in or on processed products labeled as "organic" – 7 CFR 205.606.

2. Justification for this category

The petitioned substance is a natural component of an agricultural commodity: oats. There are some bonds broken in the manufacture of the product but this occurs only through the use of an enzyme treatment. The soluble oat fiber remains in its natural state and is therefore non-synthetic. This substance is isolated through a simple process grinding, enzyme treatment, water extraction and drying; the process does not require any synthetic chemical additions or solvents. The only additives used in the manufacture of oat β-glucan are water and amylase enzyme.

Additional processing steps can be included to further purify soluble oat fiber including the addition of alkaline and acidic substances and solvent extraction. This further processing with synthetic chemicals is not part of this petition. This petition only requests addition of soluble oat fiber concentrates that are isolated through grinding, enzyme treatment, water extraction and drying (no chemicals including those for pH adjustment and/or solvent extraction).

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Item B

1. The common name of the substance.

Oat beta-glucan or oat β-glucan. Also labeled as: oat bran soluble fiber, oat fiber, oat soluble fiber, oat bran fiber.

2. The manufacturer – name, address, phone number, contact information

PromOat® Oat β-glucan

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There is at least one manufacturer, Garuda International, with a product called B-CAN™ 70% Oat Beta Glucan, that further purifies a soluble oat fiber through solvent extraction (GRAS Assessment, July 19, 2012 http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-foods-gen/documents/document/ucm316626.pdf). This further processing, solvent extraction, is not part of this petition. This petition only requests addition of soluble oat fiber concentrates that are isolated through grinding, enzyme treatment, water extraction and drying (no solvent extraction).

There is also another known US supplier of oat β-glucan in which the soluble oat fiber has been specifically extracted from the oats (exceeding 30% soluble fiber content). Nurture, Inc. manufactures a product called OatVantage™ that has been on the market for over 10 years. It is made through water extraction in a process that is claimed to be entirely natural, however Nurture has at least two patents for the manufacture of oat β-glucan (Method for Concentrating Beta-Glucan US 6,323,338 and Method for Concentrating Beta-Glucan Film US 6,624,300) in which they specifically mention pH adjustments made by adding alkali such as sodium carbonate and acid such as hydrochloric acid. For this reason, OatVantage™ has also not been included in this petition.

Petition to Add to the National List 205.606:

Oat β-Glucan

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3. The intended or current use of the substance.

Oat β-glucan is a soluble fiber ingredient which is used to supplement food products to provide the positive effects recognized for whole oats yet at a much lower use level:

- Helps maintain healthy blood cholesterol levels
- Promotes normal post-meal glycemic response; low glycemic effect
- Helps promote digestive/intestinal health
- Supplies fiber which may help promote satiety
- Helps rebalance recipe fat and calorie content due to fat mimicking properties

PromOat® Oat Beta Glucan, the product manufactured by Tate & Lyle, has been used in a wide range of food products including biscuits and cakes, bread, cereals, bars, soups, shakes, smoothies and supplements.

Appendix 1: Product Information for Oat Beta-glucan Products

Tate and Lyle - Product Bulletins for PromOat® Oat Beta Glucan:

- Product Data Sheet: PromOat® Beta Glucan
- PromOat® Beta-Glucan – "The natural, heart-healthy, functional oat ingredient" - provides more detail information about these effects. Numerous references provide supporting technical information.
- PromOat® Beta-glucan – "Give your food and beverages the goodness of oats" – provides general information on the use of oat beta-glucan in a variety of foods.

Due to the high level of β-glucan in these oat concentrates, 4.3 grams of the oat β-glucan concentrate PromOat® can be added to a 10 oz entrée yielding a final product with 1.5 grams of β-glucan (1.5% of the formula as PromOat®). At this level, which is half the daily amount of 3 grams identified in the FDA health claim, the β-glucan has been shown to have positive physiological effects. In addition, this use level can comply with the NOP composition requirements for "Organic" foods. With water and salt at less than 65% of the formula, the oat β-glucan concentrate level would be <5% in this entrée which is consistent with the composition requirements for non-organic ingredients in "Organic" foods.

Petition to Add to the National List 205.606:

Oat β-Glucan

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4. The handling activities for which the substance will be used and its mode of action.

Oat β-glucan is used as a source of soluble fiber to help promote healthy blood cholesterol levels and thereby reduce the risk of coronary heart disease. It may also be added to foods for other health benefits that are supported by clinical trials including: promotes low glycemic index, promotes normal blood sugar response after a meal and promotes satiety, which is a useful tool for weight management.

Oat β-glucan is consumed and not digested. It impacts health through its presence in the intestinal tract. Several mechanisms have been suggested as to how β-glucan lowers cholesterol including binding to the bile acids in the intestine, fermentation by colonic bacteria to produce beneficial short chain fatty acids that inhibit cholesterol synthesis, and interfering with the digestion of dietary fat. One or more of these likely results in the beneficial effects demonstrated by oat β-glucan.

5. The source of the substance and a detailed description of its manufacturing or processing procedures.

Oat β-glucan is extracted from whole oats

Confidential Business Information (CBI) Deleted

Appendix 2 shows the stepwise manufacture of PromOat® Oat Beta Glucan.

6. A summary of any available previous reviews of the petitioned substance by State or private certification programs or other organizations.

To the best of our knowledge, oat β-glucan has not been reviewed by State or private certification programs in the past. A GRAS determination was prepared and submitted to the FDA in 2014 (see point 7). As indicated in the GRAS determination, there is a long history of the safe use of oats and products derived from oats. Expert scientists agree that publically available scientific literature is sufficient to support the safety of oat β-glucan that is produced consistent with current Good Manufacturing Practices.

Petition to Add to the National List 205.606:

Oat β-Glucan

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7. Information regarding EPA, FDA, and State regulatory authority registrations.

A GRAS determination was prepared and submitted to the FDA in 2014. See Appendix 3.

8. The Chemical Abstract Service (CAS) numbers of the substance and labels of products that contain the petitioned substance.

Chemical Abstracts Service (CAS) Registry Number for "β-glucan" of any origin (specifically including oats) is 9041-22-9. The CAS number for the mixed linkage (1-3),(1-4)-β-D-glucan is 55965-23-6.

PromOat® Oat Beta-Glucan was launched in Europe and Australia within the last five years. This conventional oat β-glucan is currently used in a number of healthy products as a soluble fiber supplement. These are examples of products using this ingredient:

- Switzerland – Farmer Joghurt with 1 gram of oat β-glucan per 225 gram serving (1.3% PromOat®)
- Switzerland - Sponser Pro Mass Gainer with 1 gram of oat β-glucan per 60 gram serving (4.8% PromOat®)
- UK – Hovis Hearty Oats Bread with 1 gram of oat β-glucan per 88 gram serving (3.2% PromOat®)
- UK – Marks & Spencer – Super Juice with 0.75 grams of oat β-glucan per 300 gram serving (0.7% PromOat®)

Appendix 4, Tate & Lyle Oat Ingredients – Launches in the Market with Beta-Glucan, contains information on a range of products which contain PromOat® Oat Beta-Glucan.

Petition to Add to the National List 205.606:

Oat β-Glucan

>30% β-glucan content, water extracted,
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9. The substance's physical properties and chemical mode of action including:

(a) chemical interactions with other substances, especially substances used in organic production;

Oat β-glucan (specifically the type specified in this petition) is extracted from oat bran with water and then separated from the oat protein which is made insoluble through a heat treatment. There are no known reports of it interacting with other substances in nature to form other compounds.

(b) toxicity and environmental persistence;

Oat β-glucan is non-toxic. It exists in nature as a natural component of oats. There are no issues of environmental persistence. It is environmentally harmless.

(c) environmental impacts from its use or manufacture;

The manufacture of oat β-glucan involves only substances found in nature. Separation of oat β-glucan from oat bran has two objectives:

- isolate the soluble oat fiber for use as a nutritional supplement
- separate off the oat protein for use as a protein supplement

There is no residual in this process that must be discarded.

(d) effects on human health;

The positive effect of oat β-glucan in human health has been reported in numerous studies on various β-glucans over the past 25 years. Initial studies involved the positive impact of barley and oat β-glucan on lipid metabolism. More recent studies have involved the ability of barley and oat β-glucan to reduce glycemic and insulinemic responses in foods and help enhance satiety.

In passing through the digestive tract, β-glucan is not absorbed to any significant degree because of its large molecular size. Therefore, the benefits of β-glucan occur through associations with other components and microorganisms in the digestive tract. See Appendix 3 for the Report of the Expert Panel on the Generally Recognized as Safe (GRAS) Status of PromOat® Oat Beta-Glucan.

The following section taken from the GRAS Determination (Appendix 3, page 21) summarizes one of the beneficial contributions of oat β-glucan:

> *The Federal Register Notice acknowledges the beneficial contribution from β-glucan (FDA, 1997): Based on its review of evidence submitted with comments to the proposal, as well as of the evidence described in the proposal, the agency has concluded that the type of soluble fiber found in whole oats, i.e., beta (β)-glucan soluble fiber, is primarily responsible for the association between consumption of whole oats, including oat bran, rolled oats, and whole oat flour, and an observed lowering of blood cholesterol levels... (I)ntakes of β-glucan soluble fiber at or above 3 g per day were more effective in lowering serum lipids than lower intake*

levels.

Petition to Add to the National List 205.606:

Oat β-Glucan

>30% β-glucan content, water extracted,
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Over the years, there have been more positive physiological effects identified with the consumption of oat β-glucan and β-glucan in general. The GRAS Determination summarizes a significant amount of detailed information on clinical trials using β-glucan (Appendix 3, pages 22 – 33). These are the specific topics covered regarding human health in the GRAS Determination:

- Studies of the Cholesterol-Lowering Effect of Beta-Glucan
- Studies on the Modulation of Blood Glucose and Insulin by Beta-Glucan
- Studies of Immune-Modulating Effects of Beta-Glucan
- Additional Protective Effects of Beta-Glucan
- Tolerance Studies in Human Volunteers
- Interaction with Nutrient Absorption
- Allergenicity

The few negative impacts on human health attributed to oat β-glucan are:

- mild, transient gastrointestinal effects such as flatulence and abdominal discomfort NOTE: these gastrointestinal effects commonly occur following a shift from a low- to high-fiber diet (IOM, 2005).
- mild allergic reactions in some individuals generally attributed to contamination of oats with gluten containing grains

The physiological benefits of oat β-glucan far outweigh the few minor negative impacts identified in numerous clinical trials.

(e) effects on soil organisms, crops, or livestock.

Oat β-glucan is used in handling, not crop production. It has no effect on soil organisms, crops or livestock.

Petition to Add to the National List 205.606:

Oat β-Glucan

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10. Safety information about the substance.

Oats are a traditional food with a long history of safe use. Removal of some of the components from oats results in concentrates that are as safe as the oats from which the components were extracted.

There is a thorough review of safety information in the GRAS Determination Section 5.0 Safety (Appendix 3, pages 16 - 33).

The MSDS (Material Safety Data Sheet) for PromOat® Oat Beta Glucan is provided in Appendix 5.

11. Comprehensive research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions.

While we were able to find information on fiber contents from organic food sources, we were not able to find an article that identified organic sources for high levels of β-glucan that are suitable for use as a soluble fiber supplement

The numerous articles cited in the GRAS petition provide a clear picture of the beneficial physiological impacts from the consumption of β-glucan.

Petition to Add to the National List 205.606:

Oat β-Glucan

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12 ``Petition Justification Statement'' which provides justification for inclusion of a non-organically produced agricultural substance onto the National List 205.606

A wide range of studies and clinical trials have consistently revealed that fiber-rich diets are associated with significant reductions in cardiovascular disease risk. Fiber-rich diets, particularly those high in soluble fiber, have also been identified as providing physiological benefits such as:

- Reducing blood cholesterol
- Reducing glycemic response
- Promoting digestive/intestinal health
- Promoting satiety / weight management

While most consumers are aware there are benefits to eating products that contain fiber, consumers generally do not eat the daily recommended amount. According to USDA and NHANES, Americans consume only about 65% of the recommended daily intake fiber (based on a Daily Value of 25 grams of fiber for a 2000 calorie diet). As shown in Appendix 6 USDA NHANES Nutrient Intakes from Food 2009 – 2010, we eat an average of about 16 grams of fiber a day. Americans need to increase the amount of fiber in their diets to achieve the full health benefits associated with this dietary component.

Organic consumers justifiably believe that consuming organic foods is both beneficial to the earth as well as beneficial to their health. Product selection for organic consumers can include more nutritious products because these consumers are more likely to select whole foods (fruits, vegetables, whole grains, etc.). However, the need for convenient foods that are either ready to consume or easy to prepare means that organic consumers will continue to select some processed foods for their diets.

Processed foods can contain fewer nutrients such as fiber because they are formulated to provide optimum flavor and texture as well as product stability on the shelf. Fiber is removed from ingredients such as wheat flour and rice to make them more acceptable to the consumer.

Organic food formulators now have a wide range of organic whole foods available to them which are high in fiber: beans, broccoli, whole wheat flour, oats, barley. However, in many cases, it is difficult to build fiber content beyond the foods already used in the recipe. Specific formulas will not always be palatable and/or meet target flavor profiles with high levels of currently available fiber rich organic foods. Organic processors would have more opportunities to build fiber levels in their products if they had an ingredient available that is high in fiber, has bland flavor and can be added at a level of physiological significance without impacting the flavor or texture of the finished product. Due to its high soluble fiber content, bland flavor and minimal impact at low use levels, oat β-glucan (>30% β-glucan) is an ideal ingredient to supplement fiber content in a wide range of food products.

The FDA acknowledges that the soluble fiber β-glucan helps to maintain healthy blood cholesterol levels and is effective in reducing the risk of coronary heart disease. A health claim is authorized by the FDA for products containing 0.75 grams of oat and/or barley β-glucan fiber as defined in 21 CFR 101.81:

Petition to Add to the National List 205.606:

Oat β-Glucan

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(c) (iii) Nature of the food eligible to bear the claim.

(A) The food product shall include: (*1*) One or more of the whole oat or barley foods from paragraphs (c)(2)(ii)(A)(*1*), (*2*), (*3*), and (*5*) of this section, and the whole oat or barley foods shall contain at least 0.75 gram (g) of soluble fiber per reference amount customarily consumed of the food product.

Appendix 7 contains 21 CFR 101.81 Health claims: Soluble fiber from certain foods and risk of coronary heart disease (CHD).

The table shown below provides a general summary of options that were investigated to fortify one 12 oz beverage with 0.75 grams of β-glucan (or the equivalent to give the same effective level in reducing the risk of heart disease).

Source of Soluble Fiber	Trade Name	Soluble Fiber Content (approx per 100 g)	Amount Needed to Meet Health Claim (0.75 g β-glucan, 1.7 g psyllium)*	Formula % if Used in 12 oz Beverage	Impact on Finished Beverage
Sources of β-Glucan and Psyllium Fiber Currently Available for Use in Organic Foods					
Organic Oats or Barley	Generic	5	15 grams	4.3%	Unpalatable
Organic Oat Bran	Generic	7	11 grams	3.1%	Unpalatable
Organic Psyllium Husk*	Generic	70	2.4 grams	0.7%	Gelatinous, unpalatable
Sources of β-Glucan Proposed for Use in Organic Foods in this Petition					
Oat β-glucan	PromOat®	35	2.1 grams	0.6%	Minimal

* FDA allows the health claim for psyllium husk as that allowed for 0.75 grams of oat β-glucan however the required quantity is higher. 21 CFR 101.81 (c) (iii) (*3*) Psyllium husk...shall contain at least 1.7 g of soluble fiber per reference amount customarily consumed of the food product.

As the table indicates, while there are currently certified organic crops that do provide a source of fiber to consumers and processors that will reduce the risk of coronary heart disease, all are relatively lower in fiber and/or have functional properties that make them difficult to use in processing/food formulation.

This demonstrates that the current sources of organic oat soluble fiber are not suitable for use in formulating a wide range of supplemented "Organic" foods. In addition, at this time, there are no concentrated sources of soluble fiber on the National List 205.606, i.e., there are no conventional sources of soluble fiber that are allowed in "Organic" foods.

Petition to Add to the National List 205.606:

Oat β-Glucan

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In addition to reducing the risk of coronary heart disease, oat β-glucan has a number of other health benefits that have been demonstrated in studies completed by a number of independent researchers. Appendix 8 provides an overview of the health benefits and product applications for PromOat® Oat Beta Glucan.

Clearly, the organic consumer and processor alike can benefit from the availability of a source of soluble fiber that is concentrated, versatile and palatable – a source that can easily provide a physiological impact through the addition of only 0.75 grams of soluble fiber. Oat β-glucan (>30% β-glucan, water extracted, no chemicals including those for pH adjustment and/or solvent extraction) is an ideal ingredient to meet this need and, because of its high content of soluble fiber, can be used at a level that would be consistent with the organic rules (i.e., use level can remain under 5% of the formula – less water and salt).

There is currently no source of organic oat β-glucan. While oat bran and oats are widely available as organic in the US and Canada, there is no organic oat processor that is making oat β-glucan. In addition, there is no manufacturer of oat β-glucan that has a processing facility making certified organic products.

This is also true in the Nordic countries where a large amount of oat β-glucan is manufactured. There are sources of organic oats and organic oat bran in this region but quantities are limited and require further development. Due to the equivalency arrangement, organic oats / organic oat bran could now be purchased from the USA for use in this Swedish manufacturing facility and this facility could become certified to make organic oat β-glucan, however, this is not likely to occur soon due to an undetermined demand for oat β-glucan in an organic form.

Should the use of oat β-glucan be successful in "Organic" foods (as a conventional ingredient authorized on the National List), sources of oat β-glucan would likely be developed from organic oats originating in the USA and/or the Nordic region.

Petition to Add to the National List 205.606:

Oat β-Glucan

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Comments Relative to Similar Petition for Oat Bran Concentrate

In 2007, GTC Nutrition submitted a petition to request the addition of oat bran concentrate to the National List (OatVantage™ listed as example, the petitioned substance was a concentrate of oat β-glucan). A copy of the petition (without appendices) is included as Appendix 7 along with the NOSB Committee Recommendation dated May 2008.

In the petition, the justification statement provided little information about the nutritional benefits of the oat β glucan and it did not elaborate on the reason there was no organic equivalent product available. This is the GTC Nutrition justification statement:

> OatVantage Petition justification statement: The product falls under the category §205.606 Agricultural (nonorganic) nonsynthetic substances allowed in or on processed products labelled as "organic" or "made with organic (specified ingredients)." There are currently no organic equivalents of the product available. The product is not synthetic, it is a naturally occurring oat bran source produced from whole oats. Therefore OatVantage™ should be included on the National List, as it provides a valuable source of beta-glucan. OatVantage™ is easily incorporated into a wide range of foods, snacks, beverages and dietetic foods and leads to interesting documented health benefits at low inclusion levels.

The NOSB committee reviewed the petition and rejected oat bran concentrate for inclusion on the National list 205.606 for the following reason:

> The petition did not provide information demonstrating that this material cannot be obtained organically in the appropriate form, quantity, or quality.

Seven years have passed since the original similar petition was submitted. During the time since the petition was filed and rejected, no organic oat bran concentrate / oat β-glucan has been made available on the market. The organic industry has not had the advantage of using this physiologically functional component known to have significant health advantages over the last seven years. It is likely that physiologically functional substances such as oat β-glucan will not be manufactured in an organic form until it can be demonstrated that the Organic industry is interested in developing processed products that contain concentrates/isolates of known health advantage. Adding an ingredient like oat β-glucan to the National List encourages the development of organic alternatives.

In the 2007 petition, the processing information for OatVantage™ was part of the confidential business information. A review of patents granted to Nurture, the manufacturer of OatVantage™, indicates that this product is pH adjusted with chemicals such as sodium carbonate and hydrochloric acid. Therefore, this specific product is not included in this petition.

This petitioner has provided additional information beyond that submitted in 2007 in order to elucidate the nutritional value of oat β-glucan to the organic market and consumer. In addition, the petitioner has explained the reasons the organic industry could benefit from a concentrated form of oat β-glucan. If use of this component is allowed for companies manufacturing "Organic" products, it would prompt the development of an organic oat β-glucan.

Petition to Add to the National List 205.606:

Oat β-Glucan

>30% β-glucan content, water extracted,
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13. Confidential Business Information Statement

The manufacturing process for PromOat® Oat Beta Glucan (Appendix 2) is confidential business information. Two versions of the petitions have been provided, one containing Confidential Business Information (CBI) and one with CBI Deleted.

Petition to Add to the National List 205.606:

Oat β-Glucan

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Appendices

Appendix 1: Product Information for Oat Beta-Glucan Products

Appendix 2: Stepwise Process for Manufacture of PromOat® Oat Beta Glucan

Appendix 3: GRAS Determination of Oat Beta-Glucan for Use in Food
Submitted by: Tate & Lyle, September 5, 2014

Appendix 4: Tate & Lyle Oat Ingredients
Launches in the Market with PromOat® Oat Beta Glucan

Appendix 5: Material Safety Data Sheet (MSDS) for PromOat® Oat Beta-Glucan

Appendix 6: USDA NHANES Nutrient Intakes from Food, 2009 – 2010.

Appendix 7: 21 CFR 101.81 Health claims: Soluble fiber from certain foods and risk of coronary heart disease (CHD)

Appendix 8: Beta-Glucan: Health Benefits and Product Applications (Tate & Lyle)

Appendix 9: Oat Bran Concentrate Petition for Inclusion on the
National List of Allowed Substances

NOSB Committee Recommendation: Oat Bran Concentrate, May 2008

Petition to Add to the National List 205.606:

Oat β-Glucan

>30% β-glucan content, water extracted,
no chemicals including those for pH adjustment and/or solvent extraction

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Petition to Add to the National List 7 CFR 205.606: Oat Beta-Fiber

APPENDIX

Appendix 1: Product Information for Oat Beta Glucan Products

Tate and Lyle:

- Product Data Sheet: PromOat® Beta Glucan
- PromOat® Beta Glucan – "The natural, heart-healthy, functional oat ingredient" - provides more detailed information about these effects. Numerous references provide supporting technical information.
- PromOat® Beta Glucan – "Give your food and beverages the goodness of oats" – provides general information on the use of oat beta-glucan in a variety of foods.

TATE & LYLE

PromOat
Beta Glucan

PRODUCT DATA SHEET: PromOat® Beta Glucan

Description: PromOat® Beta Glucan is a natural soluble dietary fibre ingredient from oat grain, rich in {1-3, 1-4} beta glucan

Appearance: Fine, cream coloured powder

Origin: 100% Swedish oat grain which is non-GMO
Avena sativa, SW Kerstin variety

Label declaration recommendation: oat beta glucan/ oat bran soluble fibre/ oat fibre/ oat soluble fibre

Supply specification	Value	Typical	Method
Beta glucan (on dry matter)	> 33%	34-36%	AOAC method 995.16
Dry matter	> 93%	94-95%	

Nutritional Data (Values per 100g PromOat®, expressed on dry matter)

Energy	315 kcal or 1319 kJ
Fat	0.5 g
of which saturates	<0.1 g
Carbohydrate (oat maltodextrins)	56 g
of which Sugars	<0.5 g
Fibre (oat beta glucan)	35 g
Protein (N* 6,25)	4 g
Salt	<70mg
Sodium	<25mg

Microbiological data	Value	Method
Total plate count 30° cfu/g	<1000	NMKL Nr 86, 1999
Enterobacteriaceae cfu/g	<10	NMKL Nr 144, 2000
S. aureus cfu/g	<20	NMKL Nr 66, 3 edt. 1999 modified
Yeasts cfu/g	<100	IDF 94B: 1990 modified
Moulds cfu/g	<100	IDF 94B: 1990 modified
Salmonella	negative / 25g	NMKL nr 71, 5 edt. modified
E. coli cfu/g	negative	NMKL nr 125 3 edt. 1996

PromOat® Beta Glucan generates pH 6-7 when dissolved or mixed in water (1%)

Packaging: 15kg plastic lined paper sack.
Bag labelling includes batch code, label declaration and best before date

Pallets: Euro pallets which hold 24 x 15kg bags of PromOat® = 360kg in total

Storage and handling: store in a clean, dry, well-ventilated warehouse at ambient temperature and humidity, away from odorous materials

Best before: 24 months after production date

oat.info@tateandlyle.com

TATE & LYLE

Simply the Goodness of Oats

PromOat®
Beta Glucan

The natural, heart-healthy, functional oat ingredient

PromOat® Beta Glucan, a unique soluble fibre ingredient from oats, gives your products access to the positive effects recognized for oats, including promotion of healthy cholesterol levels and healthy digestion, and a reduced glycaemic response.

Cholesterol management

Use PromOat® Beta Glucan in foods positioned for their beneficial effects on heart health. High blood cholesterol is a risk factor in the development of coronary heart disease. Many clinical trials over the years have shown than oat beta glucan helps to lower blood cholesterol, and thereafter help maintain healthy blood cholesterol concentrations.

In Europe, EFSA and the European Commission have granted the following health claim for oat beta glucan: Oat beta glucan has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.

Blood Glucose management

Use PromOat® Beta Glucan in foods intended to help maintain healthy blood glucose levels. Oat beta glucan has a low glycaemic response. In addition, research indicates that oat beta glucan, when consumed with meals, may help maintain healthy blood glucose levels after the meal.

In Europe, EFSA and the European Commission have granted the following health claim for oat beta glucan: Consumption of beta glucans from oats as part of a meal contributes to a reduction of the blood glucose rise after that meal.

Oat Beta Glucan can help in many ways:

- Reduces blood cholesterol
- Reduces glycaemic response
- Helps promote digestive/intestinal health
- Supplies fibre which may help promote satiety
- Helps rebalance recipe fat and calorie content due to fat mimicking properties

Talk to us about health claim opportunities and conditions of use in your country.

promoat@ateandlyle.com

TATE & LYLE

Simply the Goodness of Oats

Give your food and beverages the goodness of oats

PromOat® Beta Glucan is a gently-produced, natural component of wholegrain Swedish oats with the associated health benefits of oats.

And here's more good news: this unique beta glucan soluble fibre is clean on taste and neutral on colour, and makes a versatile functional ingredient for foods and drinks.

PromOat® Beta Glucan

Versatile PromOat® is ideal to use in:

- Biscuits and cakes
- Bread
- Cereals and bars
- Sauces and dressings
- Shakes
- Smoothies
- Soups
- Supplements

...and more

PromOat® offers unique functional benefits:

Clean taste, neutral colour, no graininess

PromOat® Beta Glucan is produced as a creamy white, neutral-tasting powder that integrates easily into your recipes.

Soluble

Soluble and clean-tasting PromOat® is ideal in beverages where it can also contribute mouthfeel and smoothness.

Stabilizer and viscosity modifier

PromOat® has strong water-binding and emulsifying properties. It thickens and stabilizes creamy emulsions, creating a smooth texture and indulgent creamy mouthfeel in reduced-fat products.

Improved shelf-life for your products

PromOat® not only adds body to reduced fat muffins or cakes, it also improves shelf life due to improved moisture management.

Easy to use, easy to handle

PromOat® Beta Glucan integrates easily in manufacturing conditions. PromOat® is acid and heat stable, enabling its use in a wide variety of industrial processes.

PromOat® offers attractive labelling options:

Health Claims in many countries including the EU

With a beta glucan content as high as 35%, PromOat® Beta Glucan makes it easy to achieve the daily dosages required for health claims.

Natural, Clean Label Ingredient

PromOat® Beta Glucan can be used in your naturally positioned and 'clean label' products. To make PromOat® we use high quality, locally sourced non-GM Swedish oats, and we don't add any chemicals during processing. In the EU, PromOat® is labelled as 'oat beta glucan' or 'oat bran fibre'.

'High Fibre' or 'Source of Fibre' claims

With PromOat® you can boost your products' fibre content, and more easily achieve front-of-pack claims for fibre nutrition.

Reduced Fat and Calories

PromOat® can help create calorie-reduced recipes for indulgent products. Its unique moisture binding and texturizing properties allow PromOat® to be used to replace some of the fat in recipes without affecting the great taste of the products.

May be suitable for gluten-free products

PromOat® Beta Glucan can help you create gluten-free products, so you can offer consumers more choice. Possibilities for gluten-free positioning are dependent on the recipe and the level of use.

Contact us for more information or a PromOat® sample:
promoat@tateandlyle.com





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APPENDIX

Appendix 2: Stepwise Process for Manufacture of PromOat® Oat Beta Glucan

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Petition to Add to the National List 7 CFR 205.606: Oat Beta-Fiber

APPENDIX

Appendix 3: GRAS Determination of Oat Beta Glucan for Use in Food

Submitted by: Tate & Lyle, September 5, 2014

GRAS Determination of Oat Beta-Glucan for Use in Food

SUBMITTED BY:

Tate & Lyle
5450 Prairie Stone Parkway
Hoffman Estates, IL 60192

SUBMITTED TO:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
HFS-200
5100 Paint Branch Parkway
College Park MD 20740-3835

CONTACT FOR TECHNICAL OR OTHER INFORMATION

Donald F. Schmitt, MPH
ToxStrategies, Inc.
739 Thornapple Drive
Naperville, IL 60540

September 5, 2014

Table of Contents

List of Acronyms

ADME	absorption, distribution, metabolism, and excretion
AUC	area under the curve
BMI	body mass index
bw	body weight
B-G	beta-glucan
C	centigrade
cGMP	current Good Manufacturing Practice
CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations
CHD	coronary heart disease
CI	confidence interval
COA	certificate of analysis
CT	computed topography
CVD	cardiovascular disease
dL	deciliter
DNA	deoxyribonucleic acid
DRV	dietary reference value
EFSA	European Food Safety Authority
EU	European Union
FDA	Food and Drug Administration
g	gram
GI	gastrointestinal
GLP	Good Laboratory Practice
GMO	genetically modified organism
GMP	Good Manufacturing Practice
GRAS	Generally Recognized as Safe
GRNs	Generally Recognized as Safe Notifications
h	hour
HDL	high-density lipoprotein
IgG	immunoglobulin G
IgM	immunoglobulin M
IOM	Institute of Medicine
IP	intraperitoneal
IU	International Units
IV	intravenous
JHCI	United Kingdom Joint Health Claims Initiative
kDa	kilodalton
kg	kilogram
L	liter
LDL	low-density lipoprotein
mg	milligram
mL	milliliter
mmol	millimole
MoAb	monoclonal antibody

PO	per oral
SCFA	short-chain fatty acid
TEF	thermic effect of food
TGL/TAG	triglyceride/triacylglycerol
ug	microgram
US	United States
VLDL	very low-density lipoprotein
WMD	weight mean difference

1.0. GRAS Exemption Claim

A. Name and Address of Notifier

Tate & Lyle, through its agent ToxStrategies, Inc., hereby notifies the Food and Drug Administration that the use of the identified oat β-glucan product described below and which meets the specifications described herein is exempt from pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act because Tate & Lyle has determined that such use is generally recognized as safe (GRAS) through scientific procedures.

_____ _____

Donald F. Schmitt, M.P.H. Date
Senior Managing Scientist
ToxStrategies, Inc.
Agent for Tate & Lyle

B. Name of GRAS Substance

The name of the substance that is the subject of this GRAS determination is PromOat® Beta-Glucan, a β-glucan from oat bran.

C. Intended Use in Food

Oat-derived β-glucans are intended for use as a source of dietary fiber for general addition to all foods except infant formula and meat and poultry products. It will be added to the same foods at per serving levels as identified in the oat and barley β-glucan GRAS Notification submissions to the U.S. FDA (all received "no objection letters", GRNs 207, 344, and 437). The amount used will not exceed the amount reasonably required to accomplish its intended technical effect.

D. Basis for GRAS Determination

This Assessment documents the evidence of the safety and the "Generally Recognized As Safe" (GRAS) status of the proposed uses of Tate & Lyle's oat-derived β-glucan product (PromOat®). It consists of an evaluation of the safety and the GRAS status of the proposed uses of this ingredient, and the conclusion by a panel of experts (Expert Panel) qualified by scientific training and experience to evaluate the safety of substances added to food that the proposed uses of Tate& Lyle's β-glucan ingredient are safe and GRAS as determined by scientific procedures.

Tate & Lyle's GRAS determination for the intended use of oat-derived β-glucan is based on scientific procedures as described under 21 CFR § 170.30(b). The intended use of the oat β-glucan preparation has been determined to be safe, and Generally Recognized as

Safe (GRAS) and the safety of intake exposure under the proposed conditions of use is based on knowledge and information that is both publicly available and widely accepted by experts qualified by scientific training and experience to evaluate the safety of substances in food. The publicly available safety data combined with the widely disseminated knowledge concerning the chemistry of β-glucan from various sources such as oats, barley, and yeast combined with the long history of approval/use of such ingredients provide a sufficient basis for an assessment of the safety of oat-derived β-glucan for the uses proposed herein.

To date, the FDA has issued "no questions" letters in response to five Generally Recognized As Safe (GRAS) Notifications (GRNs) on β-glucan preparations from various sources (FDA, 2006, 2008a, 2010, 2011, 2013). In addition to containing reviews of the published safety information, the GRNs included expert panel reports that reviewed and discussed in detail the metabolism, toxicology, and human health and safety data for β-glucan. Based on these GRAS notifications, FDA currently permits the use of β-glucan preparations from a variety of sources at the use-levels indicated in the notifications.

As noted in the GRNs cited above, there is a long history of safe use of oats and products derived from oats such as oat β-glucan concentrates. Other natural sources of β-glucan concentrates such as barley have been safely consumed for decades. In addition, β-glucan is not absorbed to any significant degree because of its large molecular size. While there is a noted lack of published safety studies of oat β-glucan concentrates, the safety section herein describes numerous animal and human safety studies of barley β-glucan which is similar to oat β-glucan, as both contain polysaccharides of unbranched, linear, mixed-linkage (1-3)(1-4)-β-D-glucan. These studies support the safe use of oat β-glucan for the proposed uses.

The focus of this GRAS self-determination is for an identical general food use of oat-derived β-glucan (excluding infant formula, medical foods, and meat and poultry) as current barley- and oat-derived β-glucan products as described in GRN 207, 344, and 437 (FDA, 2006; FDA, 2011; FDA, 2013). Cargill, in GRAS Notification 344, estimated the combined average intake of barley betafiber by consumers from all uses of barley hetafiber (i.e., general food use and meat and poultry) would be 12.4 g/person/day (8.7 g β-glucan/person/day). The 90th percentile intake was estimated to be 23.5 g/person/day (16.5 g β-glucan/person/day). Cargill stated that barley betafiber would be added to food at levels of 4.3 g/serving, resulting in approximately 3 g of β- glucan/serving. Given the lower level of β-glucan (approximately 35%) in Tate & Lyle's PromOat® product, the estimated intake of β-glucan from the proposed uses of Tate & Lyle's product will be lower by approximately 50% (i.e., 4.35 and 8.25 g β-glucan/person/day for the mean and 90th percentile, respectively). While Tate & Lyle's PromOat® product could be added at a higher per serving level, the use of oat β-glucan in this manner is considered to be self-limiting for technological reasons such as product texture and/or flavor profile. In addition, since use in meat and poultry is not being considered as part of this GRAS Notification, the resulting estimated intake will be less than the current GRAS oat- and barley-derived β glucan products that were the subject of GRN Nos. 207, 344, and 437.

In summary, the proposed uses of PromOat® will not result in an increase in the overall consumption of β-glucan, but simply provide an alternative source of β-glucan for use in food.

Numerous studies have been conducted and published in support of the evaluation of the safety of barley β-glucan, including *in vitro* and *in vivo* animal studies as well as clinical studies in humans. While there is a lack of published preclinical safety studies on oat β-glucan, products containing oat β-glucan concentrates have been employed in numerous clinical trials. Other than mild, transient gastrointestinal (GI) effects such as flatulence and abdominal discomfort, no significant adverse effects were noted. It should be noted that these GI effects commonly occur following a shift from a low- to high-fiber diet. Evaluation of the possible effects of oats, cereal fiber and/or β-glucan on mineral absorption and allergenicity have also been considered by the U.S. FDA and the European Food Safety Authority (EFSA) and found not to present a significant safety concern as consumed as part of the normal diet.

Determination of the safety and GRAS status of this oat-derived β-glucan preparation described above for direct addition to food under its intended conditions of use was made through deliberation of an Expert Panel consisting of Michael Carakostas, DVM, Ph.D., Carol A. Knight, Ph.D., and Stanley M. Tarka, Jr., Ph.D, who reviewed a dossier prepared by ToxStrategies as well as other information available to them. These individuals are qualified by scientific training and experience to evaluate the safety of food and food ingredients. They individually and collectively critically evaluated published data and information pertinent to the safety of oat-derived β-glucan, and unanimously concluded that the intended use of oat β-glucan in food, produced consistent with cGMP and meeting appropriate specifications, as delineated ahove is "generally recognized as safe" ("GRAS") based on scientific procedures.

E. Availability of Information

The data and information that serve as the basis of this GRAS determination, as well any information that has become available since the GRAS determination, will be sent to the FDA upon request, or are available for the FDA's review and copying at reasonable times from ToxStrategies, Inc., Naperville, IL.

2.0 Description of Substance

A. Identity

Oat β-glucan (beta-glucan) is a natural soluble dietary fiber ingredient derived from oat grain and is rich in {1-3, 1-4} β-glucan.

B. Common Name

Oat β-glucan.

C. Formal/Chemical Names

The chemical names and synonyms for oat β-glucan include the following:

- β-D-glucan
- (1-3),(1-4)- β-D-glucan
- β-D-glucosylglucan

The Chemical Abstracts Service (CAS) Registry Number for β-D-glucans of any origin is 9041-22-9 (i.e., barley, oat, mushroom and yeast). The CAS number for the mixed-linkage (1-3),(1-4)- β-D-glucan is 55965-23-6.

D. Trade Names

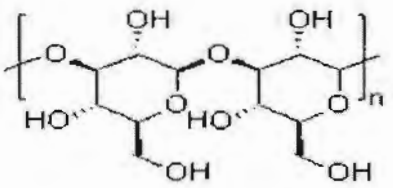
The trade name of Tate & Lyle's oat β-glucan is PromOat® or PromOat® Beta Glucan.

E. Chemical/Structural Formulas

Oat β-glucan consists of polysaccharides of unbranched, linear, mixed-linkage (1-3),(1-4)- β-D-glucans. Oat and barley derived β-glucans contain approximately 70% (1-4) linkages and 30% (1-3) linkages (Woodward and Fincher, 1983; Saulnier et al., 1994; FDA, 2011; FDA, 2012). Typically, blocks of three or four (1-4)-linked β-glucosyl units are connected by (1-3) linkages. Oat-derived β-glucan appears to consist of higher tetrasaccharide and fewer trisaccharide building blocks and may have a higher molecular weight than β-glucan from barley. Furthermore, wheat-derived β-glucan contains an even greater amount of trisaccharides compared to barley-derived β-glucan. In other words, the composition of β-glucans from oat, barley, and wheat form a continuum (FDA 2011, 2012). However, the respective differences are rather small and are unlikely to produce physiological differences (FDA, 2011; FDA, 2012).

The molecular formula for β-D-glucan is $(C_6H_{10}O_5)n$ and the molecular structure can be

found below.



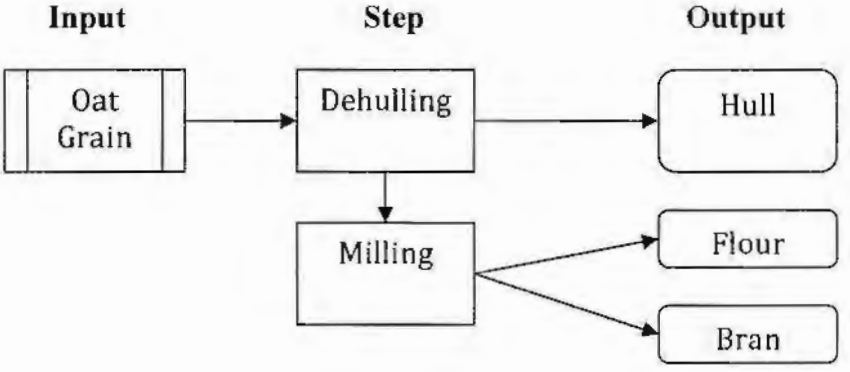
The molecular weight of the oat β-glucan present in commercially available processed food preparations ranges from about 100 kDa to 2000 kDa (EFSA, 2010). The finished product weight-average molecular weight of PromOat® is 2,000 kDa.

F. Manufacturing Process

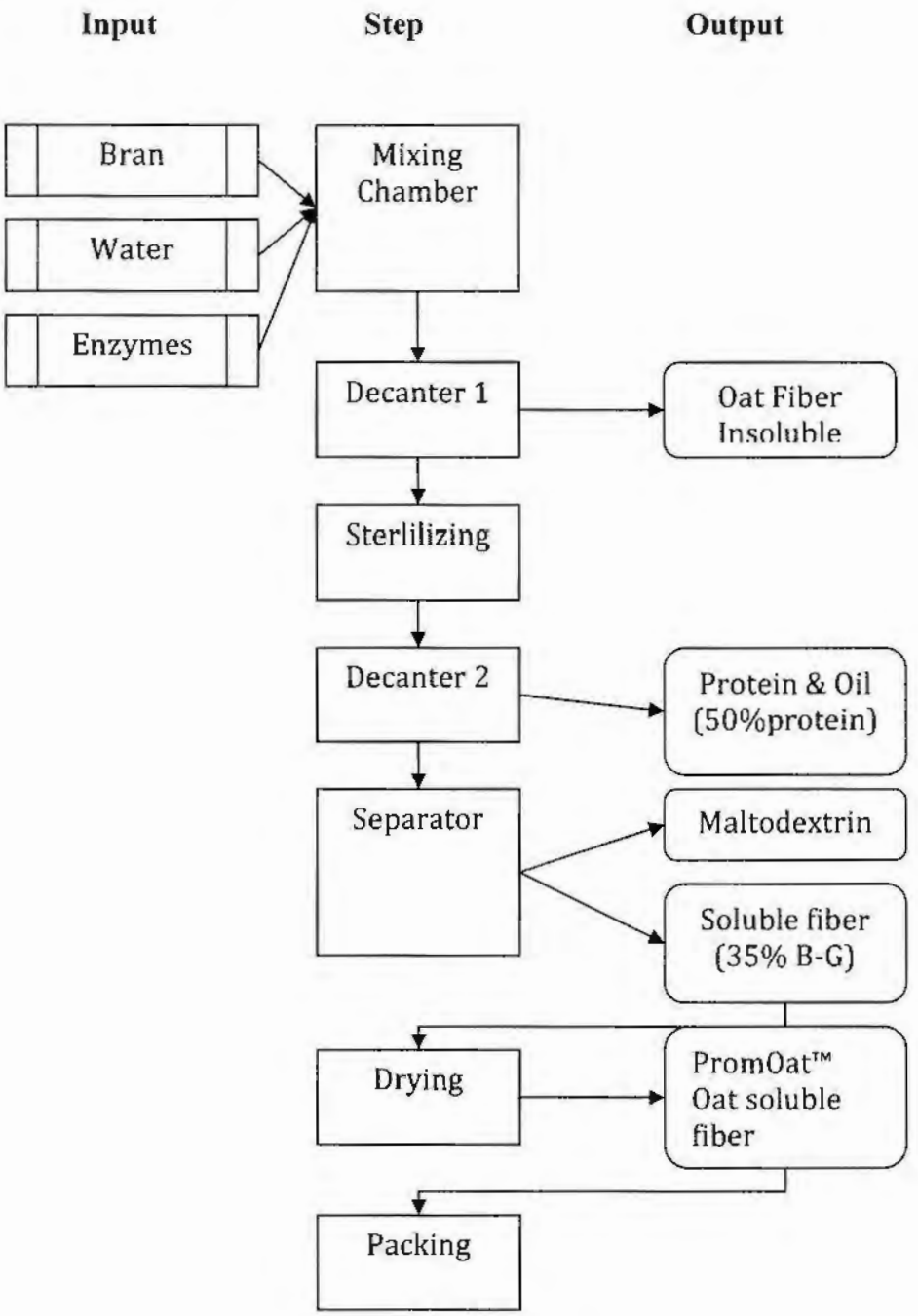
Tate & Lyle's PromOat® product that is the subject of this GRAS self-determination is manufactured in a two-step process. It is manufactured following current Good Manufacturing Practice (cGMP) for food (21 CFR Part 110). The first-step is a dry mill process in which the oat grain is dehulled (husk and most of endosperm separated) and milled to specifications. The final output of the dry milling process is oat bran, which is employed in the second processing step, a wet process. In the wet fractionation process, the oat bran is mixed with water and food use-approved enzymes from non-GMOs (genetically modified organisms) at specified temperatures. The mixture is passed through physical separation procedures and sterilized. The process output is insoluble fiber, protein, oat oil, maltodextrin (approved in 21 CFR §184.1444), and oat soluble fiber rich in β-glucan. The maltodextrin and oat soluble fiber (35% β-glucan) components comprise the PromOat® product (see Step 2 below).

A flow diagram of Tate & Lyle's manufacturing process can be found below.

Step 1. Dry Process



Step 2. Wet Process



Reagents/processing aids used in the manufacture of oat β-glucan are limited to water and the enzyme alpha-amylase which is commonly used in food ingredient manufacturing processes. No chemical processing aids are employed in Tate & Lyle's manufacturing process. The alpha-amylase enzyme preparation employed in the process is GRAS per

21 CFR §184.1012, complies with Food Chemical Codex specifications, and is used at levels not to exceed current good manufacturing practice.

G. Product Specifications

Food grade specifications for Tate & Lyle's oat β-glucan (PromOat®) are presented in Table 1. The typical β-glucan content of PromOat® is 33-36% on a dry matter basis. PromOat® is a fine, cream-colored powder. Analytical results from three non-consecutive lots are provided in Appendix A. A comparison of three non-consecutive lots of β-glucan to the specifications below can be found in Table 2.

Table 1. Specifications for Oat Beta-Glucan (PromOat®)

Parameter (Assay Method)	Specification
Physical Characteristics	
Appearance (Visual)	Fine, cream colored powder
Moisture (IDF Standard 4A 1982)	Typically, 4-6% on a dry basis
β-D-glucan (AOAC 995.16)	33-36%, on a dry basis
Heavy Metals*	
Lead (NMKL No 161 1998)	≤ 0.1 ppm
Arsenic (NMKL No 161 1998)	≤ 0.1 ppm
Cadmium (NMKL No 161 1998)	≤ 0.1 ppm
Mercury (NMKL No 161 1998)	≤ 0.1 ppm
Microbiological Analyses	
Total plate count (NMKL No 86 1999)	<1000 cfu/g
Enterobacteriaceae (NMKL No 144 2000)	<10 cfu/g
Staphylococcus aureus (NMKL No 66, 3 ed, 1999 modified)	<20 cfu/g
Yeasts (IDF 94B; 1990 modified)	<100 cfu/g
Molds (IDF 94B; 1990 modified)	<100 cfu/g
Salmonella (NMKL No 71, 5 ed, modified)	Negative/25g
E.coli (NMKL No 125, 3 ed, 1996)	Negative

* It should be noted that heavy metals levels are not routinely reported on COAs (see Appendix A), but are documented in routinely conducted analytical reports which are also included in Appendix A.

Table 2. Analytical Results for 3 Lots of Oat Beta-Glucan (PromOat®)

Specification		Lot No. 1326	Lot No. 1344	Lot No. 1411
β-D-glucan	33-36%, on a dry basis	34.0	35.0	34.0
Moisture	4-6%, on a dry basis	5.3	5.7	6.0
Heavy Metals*				
Lead	≤ 0.1 ppm	<0.020	<0.020	<0.020
Arsenic	≤ 0.1 ppm	<0.010	<0.010	<0.010
Cadmium	≤ 0.1 ppm	<0.050	<0.050	<0.050
Mercury	≤ 0.1 ppm	<0.020	<0.020	<0.020
Microbiological Analyses				
Total plate count	<1000 cfu/g	<500	<600	<100
Enterobacteriaceae	<10 cfu/g	<10	<10	<10
Staphylococcus aureus	<20 cfu/g	<20	<20	<20
Yeasts	<100 cfu/g	<60	<20	<20
Molds	<100 cfu/g	<80	<80	<20
Salmonella	Negative/25g	Neg/25g	Neg/25g	Neg/25g
E.coli	Negative	Negative	Negative	Negative

* Heavy metals levels are not routinely reported on COAs (see Appendix A), but are documented in routinely conducted analytical reports which are also included in Appendix A.

Typical compositional and nutritional analyses of Tate & Lyle's PromOat® product containing 33-36% β-glucan are presented in Table 3.

Table 3. Nutritional Analyses of PromOat®

Nutrient	Amount
Calories (kcal)	315
Protein (g/100g)	4.0
Total fat (g/100g)	0.5
Saturated fat (g/100g)	<0.1
Carbohydrate (oat maltodextrins) (g/100g)	56
Total Dietary Fiber (g/100g)	36-38

Soluble Fiber (g/100g)	35
Sugars (g/100g)	<0.5
Iron (mg/kg)	3.2
Sodium (mg/100g)	<25 mg
Cholesterol (mg/100g)	<1.0
Calcium (mg/kg)	90
Vitamin A Retinol (IU/100g)	<50
Vitamin C (mg/100g)	<1.0

The analytical (chemical and microbiological) results for oat β-glucan summarized in the above tables and included in the COAs and Technical Data Sheets in Appendices A and B confirm that the finished product meets the analytical specifications, demonstrates that the PromOat® manufacturing process results in a consistently reproducible product, and confirms the lack of impurities/contaminants (e.g., heavy metals, pesticides, microbiological toxins).

H. Stability Data for Oat β-Glucan

Tate & Lyle's oat β-glucan product PromOat® meets the above analytical specifications. Stability testing of PromOat® has been conducted at room temperature, 0°C, and 40°C for up to 18 months. After an 18-month storage period under a variety of storage conditions, PromOat® was found to be stable in terms of protein content, dry matter, β-glucan content, molecular weight, pH, appearance, color, smell, taste, volumetric weight (density), and microbiological parameters. Stability test results can be found in Appendix C.

3.0 History of Use/Regulatory Approval of Oat β-Glucan

There is common knowledge of a long history of human consumption of oats. Oats have been cultivated around the world for more than 2000 years. The U.S., Germany, Russia, Canada, France, Finland, Poland, and Australia are the largest producers of oats (FDA, 2012). Numerous food products containing oats are currently marketed in the U.S. and around the world. Oat fiber has become a desirable ingredient for addition to a variety of food products as a source of dietary fiber.

Epidemiological studies and clinical trials have consistently revealed that fiber-rich diets are associated with significant reductions in cardiovascular disease risk. While there is no established dietary reference value (DRV) for soluble fiber, the amount of soluble fiber in a typical mixed diet is one-fourth to one-third of the total dietary fiber intake (ADA, 2008; FDA, 2102).

Dietary Guidelines for Americans (HHS/USDA, 2005) recommend that adults eat half their grains as whole grains, which include oats and wheat. Adequate intake recommendations for adults (≤ 50 years of age) are 38g total dietary fiber/day for men and 25g total dietary fiber/day for women (IOM, 2005). For adults greater than 50 years of age, IOM recommends 30 g/day and 21 g/day for men and women, respectively. The guidelines also note that most Americans need to increase their intake of dietary fiber (USD/DHHS, 2005). The daily reference value for dietary fiber is 25 g for a 2000 calorie diet per 21 CFR § 101.9(d).

Oat β-glucan is found in the cell walls of oat kernels. Beside oats, β-glucan is consumed from other cereals and edible plants such as barley, rye, and wheat. Oat-derived β-glucan concentrates (e.g., Oatrim with a β glucan content of up to 10% and OatVantage™ with 54% β-glucan) are marketed in the United States and have GRAS status (FDA, 2011; FDA, 2013). Quaker Oats self-determined the GRAS status of Oatrim in 1992 (FDA, 2011). As described in GRAS Notification No. 437 (FDA, 2012), the GRAS status of Oatrim was supported by several factors including: 1) Oatrim's similarity to oat starch and maltodextrin (food ingredients with a known safety use profile), 2) the enzymatic manufacturing process was analogous to the biological digestion of starch by humans, and 3) short-term toxicity studies and safety evaluations of Oatrim's constituents did not reveal any areas of concern (FDA, 2011; Garuda, 2012). OatVantage™ has similarly been on the market for 10+ years and no safety concerns have been reported.

The U.S. FDA and European Food Safety Authority (EFSA) have reviewed the association of soluble fiber from oats and the reduced risk of heart disease (21 CFR § 101.81) (62 FR 3584, January 23, 1997) and/or the maintenance of normal blood cholesterol concentrations (EFSA 2010). As described in Garuda's GRN No. 437 (Garuda, 2012), in October 2002, in response to a petition jointly filed by the Quaker Oats Co. and Rhodia, Inc., FDA (2002) amended the 1997 health claim for soluble fiber from rolled oats to add an additional eligible source of whole oat β-glucan soluble fiber, the soluble fraction of α-amylase-hydrolyzed oat bran or whole oat flour with a β-glucan soluble fiber content at levels up to 10%. The agency concluded, based on the publicly available scientific evidence that---in addition to rolled oats, oat bran, and whole oat flour—the soluble fraction of α-amylase-hydrolyzed oat bran or whole oat flour with a β-glucan content up to 10% and not less than that of the starting material is an appropriate source of β-glucan soluble fiber for the health claim. Regarding safety, the petitioners determined their product to be GRAS, and the basis of the safety determination for their products (containing up to 25% β-glucan) was the similarity to other existing cereal adjuncts, such as pre-cooked flours, pre-cooked bran, and starches. Following its review, FDA concluded that the petitioners satisfied the preliminary requirement of 21 CFR § 101.14(b)(3)(ii) to demonstrate to FDA's satisfaction that the use of Oatrim, as described previously, is safe and lawful as a food ingredient at levels necessary to justify the health claim (FDA 2011).

The FDA has also authorized a health claim for soluble fiber from whole grain barley and barley-containing products and coronary heart disease ("CHD") (21 CFR § 101.81)

(FDA, 2005). In August 2008, FDA published a final regulation authorizing barley betafiber as an eligible source of soluble fiber for this health claim (FDA, 2008b). Barley soluble fiber-containing foods must provide at least 0.75 g of β-glucan soluble fiber per serving of the food. In 2008, the agency published a final regulation on the health claim regulation entitled "Soluble fiber from certain foods and risk of coronary heart disease (CHD)" to add barley betafiber as an additional eligible source of β-glucan soluble fiber. In support of the safety of barley-derived β-glucan (≥70%), the petitioner determined that its product was GRAS for the proposed uses. FDA also received two GRAS notices, GRN 207 and 344 (FDA 2006; 2011) on this subject and issued letters stating that the agency had "no questions" about the GRAS determination under the intended conditions of use.

EFSA also authorized a health claim regarding the maintenance of normal blood cholesterol concentrations for soluble cereal fibers, particularly β-glucan from oats (EFSA, 2010). In an opinion on the scientific substantiation of a health claim related to oat β-glucan and lowering of blood LDL and total cholesterol, the EFSA Panel concluded that a cause and effect relationship has been established between the consumption of oat β-glucan and lowering of blood LDL-cholesterol concentrations. For support of the health claim, the Panel recommended that foods should provide at least 3 g of oat β-glucan/day. In a previous health claim approval, EFSA (2009) also agreed to the following claim for β-glucan: maintenance of normal blood cholesterol concentrations and maintenance or achievement of a normal body weight.

To date, FDA has reviewed two GRAS Notifications of β-glucan from barley (FDA, 2006; FDA, 2011) and one from oats (FDA, 2013). Extensive published information and data on β-glucan were submitted. All of the GRAS notifications received "no questions" letters from the FDA. Tate & Lyle considers the information and study data described in these cited notifications as directly applicable to this notification. Furthermore, β-glucan derived from oats or barley contains polysaccharides of unbranched, linear, mixed-linkage (1-3), (1-4)-β-D-glucan, and from a physiological perspective, there is virtually no difference. Thus, from a safety perspective, the available studies of barley β-glucan and the studies described in GRNs 207, 344, and 437 are applicable to the safety assessment of oat β-glucan. No recent studies raising any new safety concerns have appeared in the published literature subsequent to these evaluations, particularly the most recent GRAS notice GRN 437.

4.0 Intended Use and Estimated Intake (EDI)

Estimated intake

The focus of this GRAS self-determination is for an identical general food use of oat-derived β-glucan (excluding infant formula, medical foods, and meat and poultry) to the current barley- and oat-derived β-glucan products as described in GRN 207, 344, and 437 respectively (FDA, 2006; FDA, 2011; FDA, 2013). Cargill, in GRAS Notification 344, estimated the combined average intake of barley betafiber by consumers from all uses of

barley betafiber (i.e., general food use, and meat and poultry) would be 12.4 g/person/day (8.7 g β-glucan/person/day). The 90th percentile intake was estimated to be 23.5 g/person/day (16.5 g β-glucan/person/day). Cargill stated that barley betafiber would be added to food at levels of 4.3 g/serving, resulting in approximately 3 g of β-glucan/serving. Given the lower level of β-glucan (approximately 35%) in Tate & Lyle's PromOat® product, the estimated intake of β-glucan from the proposed uses of Tate & Lyle's product will be lower by approximately 50% (i.e., 4.35 and 8.25 g β-glucan/person/day for the mean and 90th percentile, respectively). In addition, since use in infant formula, medical foods, and meat and poultry is not being considered as part of this GRAS Notification, the resulting estimated intake will be less than the current GRAS oat- and barley-derived β glucan products that were the subject of GRN Nos. 207, 344, and 437. In summary, the proposed uses of PromOat® will not result in an increase in the overall consumption of β-glucan, but simply provide an alternative source of β-glucan for use in food. Therefore, cumulative intake analysis is not considered necessary.

Self-limiting use

While Tate & Lyle's PromOat® product could be added at a higher per serving level, the use of oat β-glucan in this manner is considered to be self-limiting for technological reasons such as product texture and/or flavor profile.

5.0 Safety

A. Introduction

Tate & Lyle currently markets oat β-glucan (PromOat®) outside of the U.S. Both EFSA and the U.S. FDA have reviewed the safety of oat β-glucan and other cereal β-glucan sources, such as barley, and found their use to be safe based upon the available animal, *in vitro*, and human safety data. The published data, as well as reviews conducted by regulatory agencies, support the conclusion that β-glucan, and in particular oat-derived β-glucan, is safe for use as a human food ingredient.

B. Safety Data

Beta-glucan from a variety of sources including barley and oats has been the subject of numerous published scientific evaluations and regulatory reviews (e.g., FDA, 2006, 2008a, 2010, 2011, 2013; EFSA, 2011). These data and regulatory submissions form the basis of the safety summary presented below and are considered directly applicable to this GRAS notification. The available animal and human metabolism and safety/toxicity information indicate that β-glucan from all sources will be similarly metabolized/handled by the body following consumption.

A summary of the most relevant studies on β-glucan metabolism and toxicity along with clinical and epidemiological studies is presented below.

1. Absorption, Distribution, Metabolism, and Excretion (ADME)

Oat β-glucan is a dietary fiber and is resistant to digestion by mammalian enzymes, passing into the large intestine mostly intact once ingested (IOM, 2005). While the fermentation quality of dietary fibers range widely in the large intestine, soluble fiber, such as β-glucan, is highly fermentable by bacteria in the colon to carbon dioxide, methane, hydrogen, and short-chain fatty acids (SCFAs) (IOM, 2005). Several studies in animals and humans characterizing the degradation of β-glucan in the gastrointestinal tract are reported below.

Animal studies

Berggren et al. (1993) examined cecal SCFA content, cecal pH, fermentability, and dry matter digestibility in Wistar rats fed diets containing different nondigestible components including barley β-glucan. The authors reported that β-glucan was highly fermentable (>90%) and resulted in one of the largest pool sizes of short-chain fatty acids. β-glucan (as well as oat bran) diets were associated with low dry matter digestibility (~93%) compared to the other diets. Knudsen et al. (1993) studied the effect of oat β-glucan on digestion and metabolism of polysaccharides in ileum-cannulated pigs (n=4/group) using diets containing 22-76 g/kg oat β-glucan. Digestibility of β-glucan was 17-31% in the ileum and 100% in the feces.

Dongowski et al. (2002) demonstrated very high fermentability of β-glucan in male rats. Animals were fed a control diet for 1 week followed by 1 of 4 barley diets (groups A-D) or the control diet for 6 weeks (n=10/group; 5 groups total). The control diet contained 0.03% β-glucan and 0.45% resistant starch, and the 4 test diets contained various amounts of β-glucan (~4-6%) and resistant starch (~4-12%). β-glucan was detected in stomach and small intestine contents, at much lower concentrations in the cecum and colon contents, but not in the feces, indicating complete fermentation. Rats on barley test diets also had significantly higher concentrations of SCFAs in feces compared to controls.

Human studies

Robertson et al. (1997a) evaluated the effect of barley-based flapjacks (5.6 g β-glucan, of which 1.6 g was soluble) on the ileal contents of ileostomy patients. Ileal contents recovered after 12 hours contained 3.64 g β-glucan, approximately 65% of what was consumed. The ileal β-glucan was approximately 60% soluble, an increase from the test meal (~28%), indicating that solubility increased with passage through the small intestine. The authors indicated that this was likely due to digestive activities of proteolytic enzymes on the barley product, which was further supported by tests *in vitro*. Additionally, the authors reported that the proportion of lower molecular weight β-glucans was likely increased in the ileal contents. Robertson et al. (1997b) conducted a similar study, with findings consistent with Robertson et al. (1997a), showing that "unextractable" β-glucans in barley can be solubilized in the upper gut and serve as a source of dietary fiber.

Sundberg et al. (1996) likewise showed that there is a depolymerization of β-glucan as it transits through the upper gastrointestinal tract. In this study, 9 ileostomy patients received 4 different diets, in random order, which differed only in the type of bread: oat bread, oat bread with β-glucanase ("enzymatic oat"), barley bread, or wheat bread corresponding to β-glucan intakes of approximately 12.5, 4, 12.9, or 1.1 g, respectively. In the oat, enzymatic oat, and barley breads, about 50% of β-glucan was soluble. In those consuming oat or barley breads, 81-87% of β-glucan intake was excreted in ileal samples whereas individuals eating enzymatic oat and wheat breads had excretions of 58 and 36%, respectively. The peak molecular weight of the β-glucan excreted from individuals consuming the oat bread was notably lower than the β-glucan in the original oat bread indicating that depolymerization was taking place. However, the authors also noted that degradation was known to occur in the ileostomy bags, and so care should be taken when interpreting these results.

Hughes et al. (2008) evaluated the fermentation of barley and oat β-glucans by human fecal microbiota *in vitro*. Three barley-derived β-glucan fractions (average molecular weights of 243, 172, and 137 kDa) and two oat-derived β-glucan fractions (average molecular weights of 230 and 150 kDa) were added to human fecal samples in pH-controlled anaerobic batch culture fermenters and SCFAs and lactic acid were measured. The mean SCFA ratio for all β-glucan treatments at 24 hours was 51:32:17 acetate: propionate: butyrate, which the authors reported to be propionate-rich. In general, beta-glucans displayed no apparent prebiotic potential.

2. Toxicological Studies

Animal Studies

Short-term studies

Dongowski et al. (2002) evaluated the physiologic effects of diets containing barley extrudates (containing β-glucan and resistant starches) in the intestines of male rats. Animals were fed a control diet for 1 week followed by 1 of 4 barley diets (groups A-D) or the control diet for 6 weeks (n=10/group; 5 groups total). The control diet contained 0.03% β-glucan and 0.45% resistant starch, and the 4 test diets contained various amounts of β-glucan (~4-6%) and resistant starch (~4-12%). The authors reported that all diets were well accepted by the rats and there were no treatment-related changes in appearance or behavior. However, colon and cecum weight were significantly greater in rats on test diets, which the authors attributed to the β-glucan content.

Delaney et al. (2003a) evaluated the toxicity of a water-extracted, β-glucan-enriched, soluble barley fiber (barley betafiber) in a 28-day feeding study in Wistar rats conducted according under Good Laboratory Practice (GLP) and according to OECD Guideline 407. Animals (n=5/group/sex) were given 1, 5, or 10% barley betafiber (0.7, 3.5, or 7% β-glucan) in a modified rodent diet as a replacement for pregelatinized potato starch (digestible carbohydrate), or a starch control diet for 28 days. Mean β-glucan intakes were determined to be 0.55, 2.9, and 5.6 g/kg-bw/day. All rats survived until scheduled

necropsy, and no treatment-related adverse effects were noted in general condition or behavior, growth, feed and water consumption, feed conversion efficiency, red blood cell or clotting potential parameters, clinical chemistry parameters, or organ weights. There were no abnormalities seen at necropsy or histopathology. Although clinical chemistry parameters (plasma urea, total protein, albumin, chloride, and calcium) exhibited slight changes, they were within the limits of historical controls and were not considered adverse. There was a dose-related increase in weight of full and empty cecum; however, this effect is typically seen in rodents on high fermentable, poorly digestible carbohydrate diets and is not considered toxicologically relevant. Increased total white blood cell counts were observed in males, which the authors attributed to increased peripheral lymphocytes as an indicator of β-glucan's immune modulating activity. This effect was not dose-dependent and only occurred in males at the low- and mid-dose levels. The authors concluded that daily consumption of concentrated amounts of barley β-glucan under the conditions of their study was not associated with signs of toxicity in Wistar rats.

Delaney et al. (2003b) conducted a similar study in CD-1 mice, a rodent species frequently used to evaluate inflammatory responses, to further investigate the potential for the immunological changes observed in rats to determine if any of these constitute an adverse effect. The study was conducted under GLP and according to a slightly modified OECD Guideline 407. Animals (n=12/group/sex) were given 1, 5, or 10% barley betafiber (0.7, 3.5, or 7 % β-glucan) in a commercial rodent diet as a replacement for pregelatinized potato starch (digestible carbohydrate), or a starch control diet for 28 days. Mean β-glucan intakes were determined to be 1.8, 9.3, or 19.0 g/kg-bw/day and 2.4, 11.6, or 23.6 g/kg-bw/day in males and females, respectively. Following 28 days, half the animals in each group were sacrificed for evaluation of clinical chemistry, hematology, and organ pathology, and the remaining mice were placed on the control diet for a 14-day recovery period. An additional (naïve) group (n=24/sex) consumed only the control diet and was used for hematological analysis given that the effect of multiple blood draws under the conditions of this study on hematology parameters was not known. Six mice from the naïve group/sex were sacrificed on days 0, 14, 27, and 41. Blood was collected from all animals prior to study initiation (day -2), from 6 animals/group/sex on days 14 and 27, and from the remaining recovery animals on days 27 and 41. No treatment-related adverse effects were seen in any sex or dose group at any time point. No treatment-related histopathologic changes were seen in primary immune organs or peritoneal immune organs. The authors concluded that daily consumption of concentrated amounts of barley β-glucan under the conditions of the study was not associated with treatment-related adverse effects in CD-1 mice, and further, that concentrated barley β-glucan is not likely to result in adverse immunological or inflammatory effects.

More recently, Jonker et al. (2010) conducted a 28-day oral toxicity study in Wistar rats using a high (75.6%) purity barley β-glucan (Glucagel™). The study was conducted according to OECD Guideline 407 and EC Guideline B.7. Animals (n=5/group/sex) were given 0 (control[1]), 1, 5, or 10% Glucagel™ in a modified rodent diet as a replacement for

[1] The control diet did not contain Glucagel™, but contained approximately 0.8% β-glucan from the basal diet.

pregelatinized potato starch (digestible carbohydrate), or a starch control diet for 28 days. Mean β-glucan intakes were 0.62, 3.0, or 5.8 g/kg-bw/day and 0.60, 3.1, or 5.9 g/kg-bw/day in males and females, respectively (based on 75.6% β-glucan in Glucagel™). Results were generally consistent with the 28-day study in rats conducted by Delaney et al. (2003a); the treatment was well-tolerated, and there were no adverse effects on general condition and appearance, neurobehavioral observations, growth, feed or water consumption, ophthalmoscopy, hematology, clinical chemistry, urinalysis, organ weights, or pathological findings. Cecal enlargement occurred in mid- and high-dose males, which the authors described as a non-specific, physiological response following ingestion of non-digestible carbohydrate and therefore was not toxicologically relevant. Lower plasma total cholesterol and phospholipids were noted in high-dose males. The authors stated that β-glucan has known cholesterol-lowering effects in animals and plasma lipids were within the normal range, and were therefore not considered toxicologically relevant. Also considered to be toxicologically insignificant, high-dose males had a slightly increased mean plasma urea result. All other test results for renal function were statistically and biologically unremarkable. Unlike the findings of Delaney et al. (2003a), increased circulating lymphocytes were not observed in the present study. The authors concluded that consumption of up to 10% Glucagel™ (5.8-5.9 g/kg-bw/day β-glucan) for 28 days was not associated with toxicity in Wistar rats.

Genotoxicity

Delaney et al. (2004) evaluated the genotoxicity of β-glucan (barley betafiber) in a standard *in vivo* bone marrow micronucleus assay in mice conducted under GLP and according to OECD Guideline 474. Male CD-1 mice (n=10/dose) were gavaged with barley betafiber in corn oil at doses of 74, 222, 666, or 2,000 mg/kg-bw. Half of the animals were sacrificed after 24 hours, the remaining after 48 hours. No clinical signs of toxicity were observed, so only the animals in the high dose group were evaluated and compared to negative and positive controls. No statistical increases in micronucleated polychromatic or normochromatic erythrocytes were observed. The authors concluded that barley betafiber was not clastogenic under the conditions of the study.

Several studies have evaluated the anti-genotoxic effects of β-glucans. Tohamy et al. (2003) evaluated the protective role of barley β-glucan against chromosomal aberrations in bone marrow and spermatogonial cells induced by anti-cancer drugs in CD-1 mice. β-glucan (100 mg/kg-bw) was administered i.p. to mice 24 hours prior to anti-cancer drug (cyclophosphamide, adriamycin, or cisplatin). Animals were sacrificed 24 hours following administration of the anti-cancer drug. Pretreatment with β-glucan significantly reduced the frequency of structural chromosomal aberrations induced by the three anti-cancer drugs in bone marrow and spermatogonial cells. The authors concluded that their results suggest that β-glucan plays a role in reducing the genotoxicity associated with chemotherapeutic drugs.

Angeli et al. (2006) investigated the clastogenic/anti-clastogenic potential of barley β-glucan in a chromosomal aberration assay using cells proficient or deficient in phase I and II enzymes (rat hepatoma HTC or Chinese ovarian CHO-k1 cells, respectively). Cells were incubated with β-glucan (2.5, 5, or 10 ug/L) and DNA damaging agents

(methylmethane sulfonates, 2-aminoanthracene, and arabinoside-3-phosphate) for 12 or 24 hours. No clastogenic effects were observed, and protective effects of β-glucan were evident even at the lowest dose tested. Similarly, Oliveira et al. (2006) evaluated the mutagenic activity of barley β-glucan (5, 10, or 20 ug/L) in a micronucleus assay in HTC or CHO-k1 cells. Only the highest dose (20 ug/L) showed mutagenic activity, which was seen in both cell lines. Antimutagenicity experiments were also conducted using methylmethane sulfonates and 2-aminoanthracene, with various types of β-glucan treatments at the same concentrations (pre-treatment, simultaneous treatment, or post-treatment). The authors reported that barley β-glucan showed desmutagenic and bioantimutagenic activities at varying doses, depending on the timing of treatment and the cell line.

Angeli et al. (2009) assessed the genotoxicity of barley β-glucan in a Comet assay in HepG2 cells. Cells were incubated with β-glucan (1, 5, 25, 100, or 200 µg/ml) for 24 hours. Cytotoxicity was observed at 200 µg/mL, and genotoxicity was observed in the 100 µg/mL dose group. The researchers also evaluated the protective effect of 1, 5, or 25 µg/mL β-glucan (administered pre-treatment, simultaneously, or post-treatment) on benzo(a)pyrene induced genotoxicity. Simultaneous treatment showed the greatest protective effect on genotoxicity, which was significant at 5 and 25 µg/L, but not at 1 µg/L. Cytotoxicity was significantly reduced at all concentrations tested. The authors reported that β-glucan possessed antimutagenic activity (mainly desmutagenic, but also bioantimutagenic).

3. Human Studies on Beta-Glucan

In 1997, FDA authorized the use of label health claims on the association between soluble fiber from whole oats and a reduced risk of coronary heart disease. The Federal Register Notice acknowledges the beneficial contribution from β-glucan (FDA, 1997):

> *Based on its review of evidence submitted with comments to the proposal, as well as of the evidence described in the proposal, the agency has concluded that the type of soluble fiber found in whole oats, i.e., beta (β)-glucan soluble fiber, is primarily responsible for the association between consumption of whole oats, including oat bran, rolled oats, and whole oat flour, and an observed lowering of blood cholesterol levels... (I)ntakes of β-glucan soluble fiber at or above 3 g per day were more effective in lowering serum lipids than lower intake levels.*

Published safety studies of oat β-glucan concentrates are lacking, however published clinical trials exist evaluating oat β-glucan in various types of food (e.g., beverages, breads, cereal, muffins) (Garuda GRN 437, 2012). Human studies evaluating oat-derived β-glucan and its effects are discussed herein, and a number of studies of barley- and wheat-derived β-glucan are also included.

In a recent article, Daou and Zhang (2012) reviewed advances in the beneficial health effects of oat β-glucan. Oat β-glucan has been shown to decrease total and low-density lipoprotein (LDL) cholesterol, improve high-density lipoprotein (HDL) cholesterol and

blood lipid profiles, attenuate postprandial glycemic and insulinemic responses in blood and help maintain body weight. By activating monocytes/macrophages and increasing the amounts of killer T-cells, NK cells and immunoglobulin, oat β-glucan can stimulate the immune system, which can improve the body's resistance to infectious and parasitic diseases as well as cancer.

Studies of the Cholesterol-Lowering Effect of Beta-Glucan

Soluble or viscous fibers, such as oat bran, have been shown to decrease serum cholesterol and low-density lipoprotein (LDL) cholesterol in humans. Oat bran has been shown to decrease high-density lipoprotein (HDL) cholesterol, but the difference is not significant (Anderson and Hanna, 1999).

Othman and coworkers (2011) evaluated recent studies to determine if recent investigations support previous conclusions by the FDA and United Kingdom Joint Health Claims Initiative (JHCI) that β-glucan soluble fiber from oats can decrease plasma cholesterol levels and the risk of heart disease. The authors found in their review that studies conducted during the past 13 years support the conclusion that oat β-glucan intake of at least 3 g/day may reduce plasma total- and LDL-cholesterol levels by 5-10% in both hypercholesterolemic and normocholesterolemic participants, with an average decrease of 5-7%. The authors concluded that scientific agreement continues to support a strong relationship between oat β-glucan and cholesterol levels, with newer information being consistent with earlier conclusions drawn by the FDA and JHCI.

In a 6-week randomized controlled trial using 87 men and women with mildly elevated cholesterol levels, Charlton and coworkers (2012) evaluated whether 1.5 g/d β-glucan consumed as ready-to-eat oat flakes was as effective in reducing blood cholesterol as 3.0 g/d β-glucan from oat porridge. Participants were assigned to 1 of 3 diet arms (25% energy protein; 45% energy carbohydrate; 30% energy fat): minimal β-glucan (control), 1.5 or 3.0 g β-glucan. Total cholesterol was significantly decreased in all groups (-7.8%, -7.2 % and -5.5% in the high, low and control groups, respectively), as was LDL (-8·4%, -8.5 % and -5.5 % in the high, low and control groups, respectively); however between-group differences were insignificant. The authors concluded that oat β-glucan intakes of 1.5 g/d were as effective as 3 g/d at lowering blood cholesterol.

In their meta-analysis of the literature and of unpublished trials on the cholesterol lowering effects of oat products, Ripsin et al. (1992) indicated that the addition of oat products to a diet yields a modest reduction in blood cholesterol level. For the 10 studies meeting the inclusion criteria, a summary effect size for change in blood total cholesterol level of -5.9 mg/dL (95% CI, -8.4 to -3.3 mg/dL) was calculated. The summary effect size for studies using wheat control groups was -4.4 mg/dL (95% CI, -8.3 to -0.38 mg/dL). The greatest reductions in blood cholesterol were seen in trials where participants had initially higher blood cholesterol levels (≥229 mg/dL). The authors concluded that their analysis provides strong support for the hypothesis that approx. 3 g/day soluble fiber from oat products can lower the total cholesterol level by 5-6 mg/dL. β-glucan concentrations were not specified.

Behall et al. (1997) conducted a crossover study to assess whether moderate amounts of oat fiber extract (concentrated β-glucan), often used as a fat replacer, would reduce plasma lipid concentrations and if it could be added to a typical diet. Twenty-three subjects (7 men, 16 women) with mildly elevated blood cholesterol consumed oat fiber extracts containing high (10%) or low (1%) β-glucan for 5 weeks after consuming a maintenance diet for one week. Total- and LDL-cholesterol were significantly lower after the oat fiber extract diets. However, compared to the maintenance diet, triglyceride levels, VLDL, HDL and HDL2 cholesterol did not significantly change. The authors concluded that modest amounts of oat extract in the diet produced significant reductions of cholesterol. Further, a significant dose response occurred between β-glucan and total cholesterol levels.

In a controlled, single-blind, randomized, cross-over trial, Beer et al. (1995) studied the effect of oat β-glucan on serum lipid concentrations in 14 healthy, hypercholesterolemic young men. Participants were assigned to a test group diet (oat gum instant whip, 9 g/day β-glucan) or a control group (placebo instant whip) for 14 days. After completion of the first diet, subjects switched to the alternate diet. Dietary intakes of the two groups were similar. The results indicated no significant effect of the oat gum on triglyceride, total- or LDL-cholesterol levels. HDL-cholesterol was significantly higher during consumption of the test diet. The authors concluded that in healthy young men oat gum's cholesterol-lowering ability is weak. Further, the authors concluded that the impact of oat bran products on cholesterol levels cannot be estimated by the β-glucan content, but instead by measuring the viscosity and solubility of the β-glucan.

Biorklund et al. (2005) performed a side-by-side comparison of the effects of beverages enriched with 5 or 10 g β-glucan from oats or barley on insulin and postprandial glucose concentrations and serum lipoproteins. The study was an 8-week single-blind, dose-controlled study using 5 parallel groups of 100 men and women with mildly elevated blood cholesterol levels. The study was conducted identically at two locations (the Netherlands and Sweden) and 89 persons (45 women, 44 men) completed the study. During an initial 3-week period, all participants consumed a control beverage containing rice starch. For the following 5-week period, 1 group consumed the control beverage and 4 groups consumed a beverage containing 5 or 10 g β-glucan from barley or oats. All participants consumed their own habitual diets. Blood samples were collected during weeks 0, 2, 3, 7 and 8 and analyzed for glucose, insulin, serum lipids and lipoproteins. Consumption of 5 g β-glucan from oats significantly lowered postprandial concentrations of glucose (30 min), insulin (30 min) and total cholesterol (7.4%). Consumption of 10 g β-glucan from oats did not significantly impact serum lipids, nor did consumption of the barley-derived β-glucan. The authors concluded that daily consumption of 5 g of oat β-glucan in a beverage improved glucose and lipid metabolism, while β-glucan from barley in the beverage matrix did not. It was noted that a dose–response effect of 5 g compared with 10 g of β-glucan was not shown in this study. Therefore, they concluded the level of β-glucan in a food product does not necessarily inform its effect on serum cholesterol concentrations.

In a study using men and women with mildly elevated blood cholesterol, Behall et al. (2004) investigated whether barley consumption reduced CVD risk factors on a similar scale with that of other sources of soluble fiber. In the study, 7 men (43±5 years), 9 postmenopausal women (50±3 years) and 9 premenopausal women (47±4 years) consumed American Heart Association Step 1 diets for 17 weeks. After an initial 2-week period, whole-grain foods containing barley β-glucan (0, 3, or 6 g/day) were included in the Step 1 diets for 5 weeks in a Latin square design. Subjects acted as their own controls, and fasting blood samples were collected 2 times/week. Triacylglycerol and HDL levels did not differ with the 3 amounts of dietary β-glucan. Total cholesterol was significantly lower with the diet at the 3 and 6 g/day β-glucan amount than with no β-glucan; the effect was most pronounced in the postmenopausal women and the men. The authors concluded that dietary changes including higher β-glucan intake, increased consumption of whole grains including barley, and decreased fat intake can reduce risk factors for CVD.

Shimizu and co-workers (2008) conducted a study in 44 hypercholesterolemic Japanese men evaluating whether consumption of a diet in which rice was replaced by high β-glucan barley would decrease LDL and total cholesterol, as well as the visceral fat area. In this double-blinded, randomized, placebo-controlled intervention study, participants (age 30-60 years) were randomly assigned to groups consuming either a 50:50 mixture of rice and pearl barley containing 7 g/day β-glucan or rice alone (control) for 12 weeks. Recruited participants regularly consumed pearled rice as a staple food source in more than 2 of 3 daily meals. Subjects consumed the diets, which were nearly identical in calories, for the entire 12 week period. Blood samples were taken and CT scans were performed before the study and every four weeks throughout the trial. Thirty-nine men completed the study. Barley intake was shown to significantly reduce LDL (153.4±16.4 vs 147.7±27.7 mg/dL) and total cholesterol (234.8±21.7 vs 223.8±33.9 mg/dL), as well as BMI, waist circumference and visceral fat. The authors concluded that consumption of pearl barley with a high β-glucan content reduces total- and LDL- cholesterol, as well as the visceral fat area.

In a 4-week crossover-designed experiment, 21 men with mildly elevated blood cholesterol (5.4-7.0 mmol/L), age 30-59 years, consumed comparable wheat and barley foods for 4 weeks (McIntosh et al., 1991). The authors examined the influence of two sources of dietary fiber on blood glucose and lipid concentrations. Wheat contained the largely insoluble cellulose and hemicellulose fiber (as a source of dietary fiber), while barley contained β-glucan. Both groups showed a significant increase in total dietary fiber, from a previous intake of 21-38 g/d. When compared to wheat, barley consumption was associated with a significant decrease in LDL-cholesterol (7%) and plasma total cholesterol (6%); significant changes did not occur in glucose and triglyceride concentrations. The authors concluded that barley dietary fiber is more effective than wheat dietary fiber at lowering blood cholesterol, particularly LDL-cholesterol, in men with high cholesterol levels.

Bourdon and co-workers (1999) studied the response of glucose, insulin, lipid, and cholecystokinin to 2 test meals containing β-glucan in 11 healthy American men (28.6 ± 2.0 years). One of the two meals was low in fiber (5.0 g) and the other had a high fiber

content (15.7 g). Two additional low-fiber (control) meals contained pasta prepared from wheat flour; the main one was a commercial preparation, and an additional one was prepared in-house. The high-fiber meals contained pasta made by replacing 40% of the wheat with 1 of 2 types of barley flour: flour enriched in β-glucan during processing or barley naturally high in β-glucan (Prowashonupana). Both types of high fiber meals contained approximately 5 g β-glucan. Each participant consumed each of the 3 test meals (two high-fiber, one commercial low-fiber), on 3 different days, 1–3 weeks apart in a randomized, crossover design. Five participants also consumed the noncommercial low-fiber control meal. Blood samples were taken at intervals from 30 to 360 min after the meal began. While both insulin and plasma glucose concentrations increased significantly after all meals, the insulin response was decreased following the meals containing barley. Cholecystokinin remained elevated for a longer time period after the barley-containing meals compared to the low-fiber meal. Four hours after the barley-containing meals, cholesterol concentrations fell below the fasting concentrations and were significantly lower than levels following consumption of the low-fiber meal. Cholesterol concentrations were not significantly altered after consumption of the low-fiber meal. The authors concluded that consumption of the barley-containing meals appeared to stimulate reverse cholesterol transport, which may be associated with barley's cholesterol-lowering effect. Also, carbohydrate was more slowly absorbed from the 2 high-fiber meals than the low-fiber meal.

Talati and coworkers (2009) performed a systematic literature review (through January 2008) to assess the association between consumption of β-glucan from barley and alterations in plasma lipids in hypercholesterolemic and healthy men and women. Barley studies were included if they were randomized, controlled trials that reported efficacy data for at least one lipid endpoint. Parallel and crossover trials were eligible; however, crossover studies required at least a 4-week washout period. The authors identified 8 trials (n = 391 participants) of 4-12 weeks in length, which evaluated barley's lipid-reducing effects and met the appropriate criteria. The β-glucan dose reported in the various studies was 3-10 g/day, with a median dose of 7 g/day. The β-glucan was present in various forms (e.g., barley bran flour, barley-containing beverages, pearled barley, barley concentrates). Barley consumption was found to significantly decrease triglycerides (weighted mean difference [WMD], –11.83 mg/dL; 95% CI, –20.12 to –3.55 mg/dL), total cholesterol (WMD, –13.38 mg/dL; 95% CI, –18.46 to –8.31 mg/dL), and LDL-cholesterol (WMD, –10.02 mg/dL; 95% CI, –14.03 to –6.00 mg/dL), but did not significantly affect HDL-cholesterol. The observed reduction in total- and LDL-cholesterol is consistent with a similar published meta-analysis of β-glucan derived from oats. Since barley and oats have similar β-glucan content (3.5%-5.9% of dry matter), this is reasonable. The authors concluded that β-glucan from barley appears to beneficially impact triglycerides, total- and LDL-cholesterol, but does not affect HDL-cholesterol. They further recommended that larger clinical trials be conducted to better evaluate the potential for a dose-response relationship with barley β-glucan. It was stated, "*Health practitioners should feel comfortable recommending barley β-glucan to their patients to help reduce total cholesterol and LDL cholesterol concentrations as recommended by the National Cholesterol Education Program guidelines.*"

Unlike the majority of the literature, Keogh and co-workers (2003) did not find an impact on blood cholesterol following β-glucan consumption. The authors conducted a randomized crossover intervention trial to determine whether consumption of a highly β-glucan enriched barley (75% by wt) would result in a clinically significant decrease in CVD risk in men with mildly elevated blood cholesterol (mean 4.0 ± 0.6 mmol LDL cholesterol/L). In this study, 18 men (38.8±10.1 years of age) were recruited on the basis of no history of CVD, mildly elevated LDL-cholesterol (>3.5 mmol/L), and no current treatment for hyperlipidemia. Participants were randomly assigned in this 2 x 4-wk, single-blind study to either the treatment arm [8.1–11.9 g /day β-glucan (scaled to body weight)] or the control arm (equally active dose of 6.5–9.2 g/day glucose). An oral-glucose-tolerance test was conducted on days 0 and 29; fasted blood samples were collected on days 0, 1, 7, 14, 21, 28, and 29. Following a 4-week washout period, the dietary regimens were crossed over. There was no significant change in total-, HDL-, or LDL- cholesterol, or in postprandial or fasting glucose when measured between treatments. The authors concluded that there was no evidence of a significant improvement in CVD risk, and the effect of β-glucan enriched barley on the lipid profile varied substantially between subjects. The authors hypothesized that the lack of observed effect may result from structural changes in β-glucan due to storage, freezing, or baking of the product during the intervention period, or from commercial processing of the barley into a highly enriched β-glucan product.

Studies of the Modulation of Blood Glucose and Insulin by Beta-Glucan

Tiwari and Cummins (2011) conducted a meta-analysis on epidemiologic studies to evaluate the relationship between oat and barley β-glucan consumption on blood glucose, cholesterol and triglyceride/triacylglycerol (TGL/TAG) levels. The authors identified 30 research articles (some with multiple dose levels) yielding 126 clinical studies. After β-glucan consumption, the overall analysis showed a significant change in blood glucose level (-2.58 mmol/L, 95% CI -3.22 to -1.84) with high heterogeneity between and across studies. There was a significant inverse relation in LDL-cholesterol (-0.66 mmol/L, 95% CI -0.96 to -0.36), total cholesterol (-0.60 mmol/L, 95% CI -0.85 to -0.34), and TGL/TAG (-0.04 mmol/L, 95% CI -0.15 to 0.07). However, an increase in HDL-cholesterol was noted (0.03 mmol/L, 95% CI -0.06 to 0.13). Dose-response modeling indicated that 3 g/day consumption of β-glucan derived from oats or barley was sufficient to decrease total cholesterol. The authors considered β-glucan's effect on blood glucose to be inconclusive, with high heterogeneity, and recommended additional clinical research studies with longer periods of intervention.

Using 32 healthy volunteers with normal body mass indices, Granfeldt and coworkers (2008) evaluated the effect of an extruded muesli product, which was based on oat bran rich in β-glucan, on post-meal glycemia and insulinemia. The study was performed in 2 series: Series 1 (19 subjects) test breakfast meals included 3 g β-glucan; Series 2 (13 subjects) test breakfast meals included 4 g β-glucan. Muesli was served in yogurt together with white bread. While 3 g β-glucan produced no significant impact on glycemic response (compared to a control meal without β-glucan and muesli), 4 g β-glucan significantly reduced both glucose and insulin responses. The authors concluded that 4 g

of oat-derived β-glucan appears to be a critical level for a significant decrease in insulin and glucose responses in healthy persons.

Using a Latin square design, Hallfrisch et al. (2003) conducted a study comparing insulin, glucose and glucagon responses following consumption of high-soluble β-glucan compounds from oats and barley. Eleven men and 11 women, 35–57 years, participated in the study. After consuming a prescribed diet for 3 days, on the third day of 5 periods, participants consumed 1 g/kg of carbohydrate as glucose or 0.66 g/kg pudding (mainly sucrose) and 0.33 g/kg as oat bran, oat or barley extract (Nu-trimX) or barley flour in a random design. Compared to the glucose solution, glucose responses to oats, barley, both extracts, and areas under the curve were significantly decreased. The barley extract had the lowest insulin response. The authors stated that both oat and barley extracts retain the beneficial effects from the parent grains. While both oats and barley can help control plasma glucose response, high-soluble fiber barley is more effective than standard oats.

Liljeberg et al. (1996) performed a study with 9 healthy subjects (6 women and 3 men, 24-46 years). The purpose of the investigation was to evaluate the insulinemic and glycemic responses to porridge and bread products consisting of a barley genotype containing a high amount of β-glucan (Prowashonupana). The Prowashonupana contained 18 g/100 g dry weight β-glucan, which is approximately 4-fold higher than the levels in common barley or oats. In random order at 1-week intervals, at breakfast, subjects consumed products (porridge, bread or flatbread) made from oats, common barley or the barley containing high β-glucan levels. All high fiber barley products produced significantly lower postprandial insulin and glycemic responses than did the white bread reference (insulin and glycemic indices were 42-72%, and 57-72%, respectively). The most pronounced effect occurred for the flatbread made with 80% high-fiber barley flour. In contrast, common barley and oat porridges induced insulin and glucose responses similar to the reference bread, indicating that naturally occurring dietary fiber in these whole-meal flours has no effect on glucose tolerance. The authors concluded that pleasant tasting, "lente" products can be prepared from barley containing a high concentration of soluble dietary fiber. As the glycemic index of these products compares favorably with that of products made from common cereals, they could be used in diets for patients who are predisposed to metabolic disease, as well as those with hyperlipidemia and diabetes.

Nilsson et al. (2008b) evaluated the impact of 8 cereal-based bread evening meals (containing 50 g available starch), varying in content of indigestible carbohydrates and glycemic index, on glucose tolerance and related indices following a subsequent standardized breakfast. Study participants were 17 healthy volunteers (6 women and 11 men, 22-32 years of age) with normal BMI (22.5±2.1 kg/m^2); one male and one female did not complete the study. The participants consumed the test meals approximately once per week in random order. One of the meals contained bread from a barley variety with elevated β-glucan levels (14% dry basis, mutant 13, Svalöf Weibull); the other test meals contained various types of wheat or barley. At breakfast, blood samples were collected for 15- and 3-minute intervals over 3 hours for measurement of blood glucose, serum insulin, and other clinical parameters, and satiety was subjectively rated after breakfast.

At the subsequent breakfast, glucose tolerance was improved after consuming evening meals with barley kernel-based bread (including the β-glucan-rich genotype) or white wheat flour bread enriched with resistant starch and barley fiber, compared to non-enriched white wheat bread. At breakfast, glucose response and colonic fermentation were inversely correlated (r = -0.25). Breath hydrogen (marker of colonic fermentation) correlated inversely with gastric emptying rate (r = -0.23) and positively with satiety (r = 0.27). The authors stated that the high β-glucan bread produced a low and prolonged net increment in blood glucose and a higher feeling of satiety, likely due to lowered gastric emptying rate. The authors concluded that the constitution of indigestible carbohydrates in the evening meal may impact glycemic excursions and related metabolic risk variables at breakfast through a mechanism involving colonic fermentation. These results provide evidence of a link between gut microbial metabolism and key factors involved in insulin resistance.

In a randomized crossover study of 17 normoglycemic, obese women at increased risk for insulin resistance, Kim et al. (2009) investigated the linearity of reduced glucose and insulin responses after consumption of whole grains containing soluble fiber. After consuming controlled diets for 2 days, the participants (51.6±2.1 years, BMI 33.2±0.8) consumed 5 hot breakfast cereal test meals containing barley and/or wheat containing varying amounts of β-glucan (0, 2.5, 5, 7.5 and 10 g). Each test day was separated by a washout period of 7 days. Blood samples were collected before and 30, 60, 120 and 180 min after test meal consumption. Consumption of 10 g β-glucan delayed the rate of glucose response and significantly decreased peak glucose response at 30 min. β-glucan content did not impact the area under the curve for 2-hour postprandial glycemic response. However, both area under the curve and peak insulin responses were significantly affected by β-glucan concentration in an inverse linear relationship. The authors concluded that in obese women who are at risk for insulin resistance, acute consumption of 10 g β-glucan can induce beneficial effects on postprandial insulin responses. The authors hypothesized that this effect may be mediated by changes in gut hormones.

Keogh and coworkers (2007) conducted a randomized-single-blinded crossover study of 14 lean, healthy women (28.6±8.3 years, BMI 22.8±2.3 kg/m^2) to investigate the impact of barley flour vs. white wheat flour on the subsequent food intake, thermic effect of food (TEF), and metabolic indices. The barley (barley cultivar, Hordeum Vulgare var Himalaya 292) or wheat flour was incorporated into breakfast and lunch. β-glucan concentrations varied between 3.2 and 4.0 g/serving for the barley items and were 0.5 g/serving for all wheat items. Each test day was separated by a 7-day washout period. Blood samples were collected 6 hours after breakfast, then at 30, 60, 120 and 180 min after beginning lunch. The results showed that *ad libitum* food intake over the next 10 hours was decreased by 23% following the wheat-containing meals compared to the barley-containing meals. TEF was 5% for both test lunches. Mean area under the curve (AUC) of insulin following consumption of the wheat-containing meals was 32% greater than the barley-containing meals (78.1±35.3 vs 52.8±24.7 mmol/L/h). AUC for glycemic response for wheat-containing meals was 22% higher than for the barley-containing meals (4.68±1.67 mmol/L/h, 3.67±1.91 mmol/L/h). The authors concluded that meals

containing increased amylose and soluble fiber did not reduce spontaneous food intake, but rather were associated with higher energy intakes, despite lowering glucose and insulin levels.

Studies of Immune-Modulating Effects of Beta-Glucan

Rieder and Samuelsen (2012) state that β-glucans are known for having immune-modulating properties and have been shown to protect against viral, bacterial, and parasitic infections in mice. The authors cite a number of studies in mice discussing immunological effects of oat β-glucans; effects include increased resistance to herpes virus infection, increased cytokine secretion spleen cells and macrophages, increased resistance to *Eimeria vermiformis* and *Stapyhlococcus aureus* infection, and increase in respiratory burst activity of neutrophils. Other effects include diminished spread of lung tumor metastasis, NF-κB activation of intestinal epithelial cells and leukocytes. However, human studies of oat β-glucan exposure did not cause any changes in various immunological parameters, including leukocyte activity, reported upper respiratory tract infections, cytokine production, or C-reactive protein level (Rieder and Samuelsen, 2012).

Since *in vitro* β-glucan can increase tumor cytotoxicity via iC3b receptors on leukocytes, Cheung and Modak (2002) studied whether (1→3),(1→4)-D-β-glucan could synergize with anti-GD2 monoclonal antibody (MoAb) 3F8 (mouse IgG3) in treating human neuroblastoma xenografts. In the study, nude, athymic mice with neuroblastoma xenografts were treated daily with β-glucan, i.p. or p.o. administration. The treatments occurred with or without i.v. MoAb administration twice a week, for 22–29 days. Body weights and serial tumor volumes were measured. The results showed that an antitumor effect was seen at ≥40 μg of β-glucan dose, i.v. or p.o., in all human neuroblastoma lines. β-glucan with 3F8 yielded near-complete disease stabilization/tumor regression, while β-glucan or 3F8 alone did not significantly impact tumor growth. While <3% of controls remained progression free, 18% percent of the mice with LAN-1 cell line and 47% of those NMB7 cell line did not show progression. No toxicities were observed in animals treated with either β-glucan alone or 3F8 plus β-glucan (4–4,000 μg/dose). It is hypothesized that β-glucan plus complement activation may increase B-cell response to tumor cells, or innate immunity may be involved following β-glucan leukocyte activation. The authors concluded that p.o. β-glucan synergized with antitumor IgM and IgG MoAb in this *in vivo* study. Since β-glucan was well tolerated and inexpensive, it could be potentially valuable in chemotherapy (Cheung and Modak, 2002).

Additional Protective Effects of Beta-Glucan

Nilsson et al. (2008) administered 40 g β-glucan-enriched oat bran per day, in 4 slices of bread to 25 healthy subjects (age 24± 1.3 years) for 12 weeks. The objective of the study was to determine how the colonic concentration of carboxylic acids in healthy subjects is influenced by dietary supplementation with oat bran. Carboxylic acids, particularly butyric acid, are believed to counteract colonic diseases, such as colon cancer and ulcerative colitis. Oat bran increased the fecal carboxylic acid levels after 8 weeks, which

also indicated an increased concentration in the distal colon. Fecal concentrations of butyric, acetic, isobutyric, isovaleric and propionic acids were significantly higher after 8 weeks on the oat bran diet as compared with initial values, but lactic acid concentrations were lower. After 12 weeks, isobutyric, acetic and propionic acid concentrations were still higher and lactic acid levels were lower. Inter-individual variation was high, whereas intra-individual variation was low. The authors concluded that oat bran may have the potential to protect against colonic diseases.

Tolerance Studies in Human Volunteers

As discussed above, in multiple studies evaluating the potential benefits of β-glucan products, human volunteers have consumed these products under controlled conditions. Toxic effects did not occur in any of the studies. In 2 recent meta-analyses (Tiwari and Cummins, 2011; Othman et al., 2011), and 1 earlier one (Ripsin et al., 1992), safety concerns were not reported following consumption of oat β-glucan.

In an 11-week controlled crossover study by Hallfrisch and Behall (1997), 17 women and 7 men (37-61 years) consumed diets in which the fat content of foods was reduced by Oatrim addition. The Oatrim contained either a low (1%) or high (10%) level of soluble β-glucan. While a significantly longer adaptation period and gastrointestinal symptoms (5 vs. 13 days) were more often reported for the meals containing the higher β-glucan level, the effects were not serious enough for any of the subjects to withdraw or refuse to consume any of the foods. In healthy men with elevated blood cholesterol levels, Beer et al. (1995) reported that the participants experienced mild, transient GI effects after consumption of 9 g/day oat β-glucan in oat gum instant whip. In their study investigating whether barley consumption reduced CVD risk factors on a similar scale with that of other sources of soluble fiber, Behall et al. (2004) administered American Heart Association Step 1 diets for 17 weeks with whole-grain foods containing barley β-glucan (0, 3, or 6 g/day). Persons on the high β-glucan diet indicated they were experiencing bloating and flatulence.

Interaction with Nutrient Absorption

Due to their soluble fiber content, oats are known for retarding absorption of nutrients and their effects on satiety, as well as a deterrent for various GI disorders. Oat β-glucan lowers the rate of glucose absorption and delays intestinal absorption of carbohydrates, all beneficial effects (Daou and Zhang, 2012).

Cargill (2010) stated that β-glucan does not complex with metal ions, therefore it is not anticipated to impair absorption of essential minerals in tbe small intestine. Upon review of the literature, Cargill (2010) concluded that dietary fiber, at recommended intake levels, does not adversely affect vitamin and mineral absorption of the average consumer. According to the American Dietetic Association (ADA, 2008):

> *Potential negative effects of excessive dietary fiber include reduced absorption of vitamins, minerals, proteins, and energy. It is unlikely that healthy adults who consume dietary fiber in amounts within the recommended ranges will have problems*

with nutrient absorption; however, high dietary fiber intakes may not be appropriate for children and older adults because so little research has been conducted in these populations.

Allergenicity

Children with atopic dermatitis and farmers with allergies to grain dust may experience allergic reactions to oat proteins. These proteins can act as skin and respiratory allergens (Boussault et al., 2007; Garuda 2012).

Allergy manifestation resulting from consumption of oats and oat products has been debated. It has been alleged that oats may cause adverse effects in individuals with celiac disease. As a result, use of oats in gluten-free diets was not allowed. Evidence from more recent reports indicates that oats are safe for consumption by most individuals with celiac disease (Rashid et al., 2007). Health Canada (2007) critically reviewed the scientific literature and concluded that the majority of people with celiac disease can tolerate moderate amounts of pure oats that are uncontaminated with other cereal grains such as wheat, barley and rye. It is recognized that commercially available oats are variably contaminated with gluten-containing grains that can occur on the farms, during the growing cycle or during storage, cleaning, transportation or processing.

The Canadian Celiac Association stated that in past years, oats were not allowed in a gluten-free diet and were considered to be averse to persons with celiac disease. However, based on recent data, pure oats, uncontaminated with other gluten-containing grains, if consumed in limited amounts, are safe for most of those with celiac disease. For children, up to 25 g/day (1/4 cup) and for adults, up to 70 g/day (1/2 to 3/4 cup) is a safe consumption rate (Rashid et al., 2007). With the current labeling of gluten-free foods, these are helpful guidelines for consumers with celiac disease to use as a reference. Health Canada supports the position that oats can be part of a gluten-free diet, indicating that persons with celiac disease can tolerate some amounts of pure oats (uncontaminated with other cereal grains such as wheat, barley and rye). In fact, pure oats may be beneficial to persons with celiac disease, as its palatability may increase patients' compliance with a gluten-free diet (Health Canada, 2007).

Oat consumption by celiac disease patients is not widely recommended in the U.S. due to concerns of potential contamination of commercial oats (Kupper, 2005; American Celiac Society, 2014). According to the National Foundation for Celiac Awareness (NFCA, 2014), although oats do not contain gluten, a small percentage of persons with celiac disease react to pure, uncontaminated oats. Further, most mills that process oats also manufacture grains which contain gluten, making cross contamination likely. However, up to 50 g/day of dry, gluten-free oats is considered safe (NFCA, 2014).

The potential allergenicity of β-glucan in itself was researched in the available literature, but no relevant information was located. Natural sources of β-glucan concentrates, such as barley, have been safely consumed for decades. β-glucan is not listed among FDA's list of the 8 major food allergens (FDA, 2010). The lack of available information and

absence from FDA's list leads to the conclusion that allergic reactions to β-glucan itself are not of concern.

C. Safety Data Summary

There is common knowledge of a long history of human consumption of oats. Oats have been cultivated around the world for more than 2000 years. The U.S., Germany, Russia, Canada, France, Finland, Poland, and Australia are the largest producers of oats (FDA, 2012). Numerous food products containing oats are currently marketed in the U.S. and around world. Oat fiber has become a desirable ingredient for addition to a variety of food products as a source of dietary fiber.

Oat β-glucan is found in the cell walls of oat kernels. Beside oats, β-glucan is consumed from other cereals and edible plants such as barley, rye, and wheat. Oat-derived β-glucan concentrates (e.g., Oatrim with a β glucan content of up to 10% and OatVantage™ with 54% β-glucan) are marketed in the United States and have GRAS status (FDA, 2011; FDA, 2012). Quaker Oats self-determined the GRAS status of Oatrim in 1992 (FDA, 2011). As described in GRAS Notification No. 437 (FDA, 2012), the GRAS status of Oatrim was supported by several factors including: 1) Oatrim's similarity to oat starch and maltodextrin (food ingredients with a known safety use profile), 2) the enzymatic manufacturing process was analogous to the biological digestion of starch by humans, and 3) short-term toxicity studies and safety evaluations of Oatrim's constituents did not reveal any areas of concern (FDA, 2011; FDA, 2012). OatVantage™ (54% β-glucan content) has similarly been on the market for 10+ years and no safety concerns have been reported.

Numerous studies have been conducted and published in support of the evaluation of the safety of barley β-glucan, including *in vitro* and *in vivo* animal studies as well as clinical studies in humans. While there is a lack of published preclinical safety studies on oat β-glucan, products containing oat β-glucan concentrates have been employed in numerous clinical trials. Other than mild, transient gastrointestinal (GI) effects such as flatulence and abdominal discomfort, no significant adverse effects were noted. It should be noted that these GI effects commonly occur following a shift from a low- to high-fiber diet (IOM, 2005). Updated literature searches covering the period of 2010 – present have revealed no recent studies that report safety concerns.

Epidemiological studies and clinical trials have consistently revealed that fiber-rich diets are associated with significant reductions in cardiovascular disease risk and other health benefits. The intended uses of PromOat® have the potential to increase the dietary fiber intakes among the US population. The Institute of Medicine (2005) reviewed the possible effect of cereal fiber on mineral absorption (e.g., iron, zinc, calcium, magnesium) and determined that dietary fiber, as part of a balanced diet, has not been found to adversely affect mineral status in healthy people at recommended intake levels.

Children with atopic dermatitis and farmers with allergies to grain dust may experience allergic reactions to oat proteins. These proteins can act as skin and respiratory allergens (Boussault et al., 2007; Garuda, 2012).

Allergy manifestation resulting from consumption of oats and oat products has been the subject of debate. It has been alleged that oats may cause adverse effects in individuals with celiac disease. As a result, use of oats in a gluten-free diets was not allowed. Evidence from more recent reports indicates that oats are safe for consumption by most individuals with celiac disease (Rashid et al., 2007).

For instance, Health Canada (2007) critically reviewed the scientific literature and concluded that the majority of people with celiac disease can tolerate moderate amounts of pure oats that are uncontaminated with other cereal grains such as wheat, barley and rye. The Canadian Celiac Association stated that in past years, oats were not allowed in a gluten-free diet and were considered to be averse to persons with celiac disease. However, based on recent data, pure oats, uncontaminated with other gluten-containing grains, if consumed in limited amounts, are safe for most of those with celiac disease. Health Canada supported this position, indicating that persons with celiac disease can tolerate some amounts of pure oats (uncontaminated with other cereal grains such as wheat, barley and rye). In fact, pure oats may be beneficial to persons with celiac disease, as its palatability may increase patients' compliance with a gluten-free diet (Health Canada, 2007).

The potential allergenicity of β-glucan itself was researched in the available literature, but no relevant information was located. Natural sources of β-glucan concentrates, such as barley, have been safely consumed for decades. β-glucan is not listed among FDA's list of the 8 major food allergens (FDA, 2010). The lack of available information and absence from FDA's allergen list leads to the conclusion that allergic reactions to β-glucan itself are not of concern.

6.0 Basis for the GRAS Determination

A. Introduction

The regulatory framework for determining whether a substance can be considered generally recognized as safe (GRAS) in accordance with section 201(s) (21 U.S.C. § 321(s)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et. Seq.) ("the Act"), is set forth at 21 CFR 170.30, which states:

> General recognition of safety may be based only on the view of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.
>
> General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies, which may be corroborated by unpublished studies and other data and information.

These criteria are applied in the analysis below to determine whether the use of an oat-derived β-glucan for use in food for human consumption is GRAS based upon scientific procedures. All data used in this GRAS determination are publicly available and generally known, and therefore meet the "general recognition" standard under the FD&C Act.

B. Safety Determination

The subject of this GRAS determination is the use of oat-derived β-glucan for use as a source of dietary fiber for general addition to all foods except infant formula and meat and poultry products. There is a long history of the safe use of oats and products derived from oats such as oat β-glucan concentrates. Furthermore, other natural sources of β-glucan concentrates, such as barley, have been safely consumed for decades. While there is a noted lack of published safety studies of oat β-glucan concentrates, the safety section describes numerous animal and human safety studies of barley β-glucan which is similar to oat β-glucan, as both contain polysaccharides of unbranched, linear, mixed-linkage (1-3)(1-4)-β-D-glucan.

The focus of this GRAS self-determination is for an identical general food use of oat-

derived β-glucan (excluding infant formula and meat and poultry) as current barley- and oat-derived β-glucan products as described in GRN 207, 344, and 437 (FDA, 2006; FDA, 2011; FDA, 2013). Cargill, in GRAS Notification 344, estimated the combined average intake of barley betafiber by consumers from all uses of barley betafiber (i.e., general food use and meat and poultry) would be 12.4 g/person/day (8.7 g β-glucan/person/day). The 90th percentile intake was estimated to be 23.5 g/person/day (16.5 g β-glucan/person/day). Cargill stated that barley betafiber would be added to food at levels of 4.3 g/serving, resulting in approximately 3 g of β- glucan/serving. Given the lower level of β-glucan (approximately 35%) in Tate & Lyle's PromOat® product, the estimated intake of β-glucan from the proposed uses of Tate & Lyle's product will be lower by approximately 50% (i.e., 4.35 and 8.25 g β-glucan/person/day for the mean and 90th percentile, respectively). While Tate & Lyle's PromOat® product could be added at a higher per serving level, the use of oat β-glucan in this manner is considered to be self-limiting for technological reasons such as product texture and/or flavor profile. In addition, since use in infant formula, medical foods, and meat and poultry are not being considered as part of this GRAS Notification, the resulting estimated intake will be less than the current GRAS oat- and barley-derived β glucan products that were the subject of GRN Nos. 207, 344, and 437. In summary, the proposed uses of PromOat® will not result in an increase in the overall consumption of β-glucan, hut simply provide an alternative source of β-glucan for use in food.

Numerous studies have been conducted and published in support of the evaluation of the safety of barley β-glucan, including *in vitro* and *in vivo* animal studies as well as clinical studies in humans. While there is a lack of published preclinical safety studies on oat β-glucan, products containing oat β-glucan concentrates have been employed in numerous clinical trials. Other than mild, transient gastrointestinal (GI) effects such as flatulence and abdominal discomfort, no significant adverse effects were noted. It should be noted that these GI effects commonly occur following a shift from a low- to high-fiber diet. Evaluation of the possible effects of oats, cereal fiber and/or β-glucan on mineral absorption and allergenicity have also been considered by U.S. FDA and EFSA and found not to present a significant safety concern as consumed as part of the normal diet.

C. General Recognition of the Safety of Oat-Beta-Glucan

The intended use of oat β-glucan has been determined to be safe through scientific procedures as set forth in 21 CFR§170.3(b), thus satisfying the so-called "technical" element of the GRAS determination.

The oat β-glucan that is the subject of this notification (PromOat® Beta Glucan) is produced from the starting material oat bran. The oat β-glucan product is manufactured consistent with current Good Manufacturing Practice (cGMP) for food (21 CFR Part 110). The raw materials used in the manufacturing process are food grade and/or approved for use as processing aids in food. No chemical processing aids are employed in the manufacturing process. The oat β-glucan product containing approximately 35% β-glucan has been characterized and meets the food grade specifications found in Table 1.

There is common knowledge of a long history of human consumption of oats. Oats have been cultivated around the world for more than 2000 years. The U.S., Germany, Russia, Canada, France, Finland, Poland, and Australia are the largest producers of oats (Garuda, 2012). Numerous food products containing oats are currently marketed in the U.S. and around world. Oat fiber has become a desirable ingredient for addition to a variety of food products as a source of dietary fiber.

Epidemiological studies and clinical trials have consistently revealed that fiber-rich diets are associated with significant reductions in cardiovascular disease risk. While there is no established dietary reference value (DRV) for soluble fiber, the amount of soluble fiber in a typical mixed diet is one-fourth to one-third of the total dietary fiber intake (ADA, 2002; FDA, 2102). The intended uses of PromOat® (oat-derived β-glucan) will provide an alternative to other dietary sources of β-glucan as part of the total dietary fiber intakes among the U.S. population.

Oat β-glucan is found in the cell walls of oat kernels. Besides oats, β-glucan is consumed from other cereals and edible plants such as barley, rye, and wheat. Oat-derived β-glucan concentrates (e.g., Oatrim with a β glucan content of up to 10% and OatVantage™ with 54% β-glucan) are marketed in the United States and have GRAS status (FDA, 2011; FDA, 2012).

To date, FDA has reviewed two GRAS Notifications of β-glucan from barley (FDA, 2006; FDA, 2011) and one from oats (FDA, 2013). Extensive published information and data on β-glucan were submitted. All of the GRAS notifications received "no questions" letters from the FDA. Tate & Lyle considers the information and study data described in these cited notifications as directly applicable to this notification. Furthermore, β-glucan derived from oats or barley contains polysaccharides of unbranched, linear, mixed-linkage (1-3), (1-4)-β-D-glucan, and from a physiological perspective there is virtually no difference. Thus, from a safety perspective, the available studies of barley β-glucan and the studies described in GRNs 207, 344, and 437 are applicable to the safety assessment of oat β-glucan. No recent studies raising any new safety concerns have appeared in the published literature subsequent to these evaluations, particularly the most recent GRAS notice GRN 437.

Given that oat β-glucan meets the proposed specifications for the use of β-glucan as a food ingredient for human consumption, the safe use of oat β-glucan is justified by scientific procedures. In addition, the publicly available scientific literature is sufficient to support the safety and GRAS status of the proposed oat β-glucan product.

Numerous studies have been conducted and published in support of the evaluation of the safety of β-glucan, including *in vitro* and *in vivo* animal studies as well as clinical studies in humans and are described herein. Therefore, since this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

Determination of the safety and GRAS status of oat β-glucan that is the subject of this self-determination has been made through the deliberations of an Expert Panel convened by Tate & Lyle and comprised of Michael Carakostas, DVM, Ph.D., Carol A. Knight, Ph.D., and Stanley M. Tarka, Jr., Ph.D. These individuals are qualified by scientific training and experience to evaluate the safety of substances intended to be added to foods. They have critically reviewed and evaluated the publicly available information summarized in this document and have individually and collectively concluded that oat-derived β-glucan, produced consistent with Good Manufacturing Practice and meeting the specifications described herein, is safe under its intended conditions of use. The Panel further unanimously concludes that these uses of oat β-glucan are GRAS based on scientific procedures, and that other experts qualified to assess the safety of foods and food additives would concur with these conclusions. The Panel's GRAS opinion is included as Exhibit 1 to this document.

It is also Tate & Lyle's opinion that other qualified scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. Tate & Lyle has concluded that oat β-glucan is GRAS under the intended conditions of use on the basis of scientific procedures; and therefore, it is excluded from the definition of a food additive and may be marketed and sold for its intended purpose in the U.S. without the promulgation of a food additive regulation under Title 21 of the CFR.

Tate & Lyle is not aware of any information that would be inconsistent with a finding that the proposed use of oat β-glucan in food for human consumption meeting appropriate specifications and used according to Good Manufacturing Practice, is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

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8.0 Appendices

Appendix A. Certificates of Analysis – Characterization

TATE & LYLE

CERTIFICATE OF ANALYSIS

Product:	**100 015 PromOat Betaglucan**
Batch no:	**1326**
Prod. Date:	**24-06-2013**
Best before:	**23-06-2015**

Chemical analysis	**Result**	**Unit**
Average value		
Beta Glucan	34	%
Dry matter	94.7	%

Bacteriological analysis

Total plate count	<500	cfu/g
Enterobacteriaceae	<10	cfu/g
Staff. Aureus	<20	cfu/g
Yeast	<60	cfu/g
Moulds	<80	cfu/g
Salmonella	Neg/25g.	
E-coli	Negative	

Tate&Lyle Sweden AB
03-09-2014

Ingbritt Johansson
Quality Manager

TATE & LYLE

CERTIFICATE OF ANALYSIS

Product:	**100 015 PromOat Betaglucan**
Batch no:	**1344**
Prod. Date:	**30-10-2014**
Best before:	**29-10-2015**

Chemical analysis	Result	Unit
Average value		
Beta Glucan	35	%
Dry matter	94.3	%
Bacteriological analysis		
Total plate count	<600	cfu/g
Enterobacteriaceae	<10	cfu/g
Staff. Aureus	<20	cfu/g
Yeast	<20	cfu/g
Moulds	<80	cfu/g
Salmonella	Neg/25g.	
E-coli	Negative	

Tate&Lyle Sweden AB
03-09-2014

Ingbritt Johansson
Quality Manager

TATE & LYLE

CERTIFICATE OF ANALYSIS

Product:	**100 015 PromOat Betaglucan**
Batch no:	**1411**
Prod. Date:	**11-03-2014**
Best before:	**10-03-2016**

Chemical analysis	Result	Unit
Average value		
Beta Glucan	34	%
Dry matter	94	%
Bacteriological analysis		
Total plate count	<100	cfu/g
Enterobacteriaceae	<10	cfu/g
Staff. Aureus	<20	cfu/g
Yeast	<20	cfu/g
Moulds	<20	cfu/g
Salmonella	Neg/25g.	
E-coli	Negative	

Tate&Lyle Sweden AB
03-09-2014

Ingbritt Johansson
Quality Manager

eurofins

Rapport utfärdad av ackrediterat laboratorium

Report issued by Accredited Laboratory

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Tlf: +46 10 490 5310

Tate&Lyle Sweden AB
Ingbritt Johansson
Älvåsvägen 1
610 20 KIMSTAD

AR-14-LW-018537-01

EUSELI-00064747

Client code:. LW9901581

ANALYTICAL REPORT

Sample code:	525-2014-04280095
Client Sample:	PromOat 1411
Received:	2014-04-28
Report finished:	2014-05-06
Start of analysis:	2014-04-28

	Analysis	Result	MRL	Unit	Uncert.	Method	Lab
LW00V	Fat acc. Soxtec	0.33		g/100 g	± 30%		EUSELI
SL412	Sodium (Na)	250		mg/kg	± 25%	NMKL No 139 1991 mod	EUSELI2
SL408	Calcium (Ca)	91		mg/kg	± 10%	NMKL No 139 1991 mod	EUSELI2
SL411	Magnesium (Mg)	370		mg/kg	± 10%	NMKL No 139 1991 mod	EUSELI2
SL413	Iron (Fe)	< 2.0		mg/kg	± 30%	NMKL No 139 1991 mod	EUSELI2
SL410	Potassium (K)	7400		mg/kg	± 15%	NMKL No 139 1991 mod	EUSELI2
SL409	Phosphorus (P)	2800		mg/kg	± 10%	NMKL No 139 1991 mod	EUSELI2
SL415	Zinc (Zn)	1.5		mg/kg	± 20%	NMKL No 139 1991 mod	EUSELI2
SL405	Aluminium (Al)	< 5.0		mg/kg	± 30%	NMKL No 161 1998 mod	EUSELI2
SL403	Lead (Pb)	< 0.020		mg/kg	± 20%	NMKL No 161 1998 mod	EUSELI2
SL404	Cadmium (Cd)	< 0.010		mg/kg	± 20%	NMKL No 161 1998 mod	EUSELI2
SL402	Arsenic (As)	<0.050		mg/kg	± 35%	NMKL No 161 1998 mod	EUSELI2
SL399	Mercury (Hg)	< 0.020		mg/kg	± 30%	EN 16277:2012	EUSELI2
JJ006	Aflatoxin B1	<0.1		µg/kg		internal method based on EN 14123	EUHAWE3
JJ006	Aflatoxin B2	<0.1		µg/kg		internal method based on EN 14123	EUHAWE3
JJ006	Aflatoxin G1	<0.1		µg/kg		internal method based on EN 14123	EUHAWE3
JJ006	Aflatoxin G2	<0.1		µg/kg		internal method based on EN 14123	EUHAWE3
LW020	Ochratoxin	0.14		µg/kg	± 30%	NMKL 143	EUSELI
LW03Z	Deoxynivalenol (Vomitoxin)	58		µg/kg	± 25%	In house method (210)	EUSELI

Uncert: Measurement uncertainty

Symbol description: AR-004 v21

- : (Not part of the accreditation)

Performing laboratory if nothing else is stated: Eurofins Food & Agro (Lidköping)

LW03X	HT-2 Toxin	<10	µg/kg	± 30%	In house method (210)	*EUSELI*
LW03Y	T-2 Toxin	<10	µg/kg	± 30%	In house method (210)	*EUSELI*
LW041	Zearalenone (ZON)	<10	µg/kg	± 35%	In house method (210)	*EUSELI*
MJ011	Starch and sugar	42	g/100 g		Internal method	*EUNOTR2*
SLB89	Sulphur total (S)	1600	mg/kg	± 20%	NMKL No 161 1998 mod	*EUSELI2*

LP130 No pesticide residue detected (SLV K1-f4-m016 1).

Per-Olov Södergren, ASM

This test report has been created electronically and has been verified and authorised.

Test was performed by

EUHAWE3	Eurofins WEJ Contaminants GmbH (Hamburg)
EUNOTR2	Eurofins Food & Agro Testing Norway AS (Skansen), Trondheim
EUSELI	Eurofins Food & Agro Testing Sweden AB, Lidköping
EUSELI2	Eurofins Environment Sweden, Lidköping

Uncert: Measurement uncertainty

Symbol description:

AR-004 Y21

+ : (Not part of the accreditation)

Performing laboratory if nothing else is stated: Eurofins Food & Agro (Lidköping)

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Rapport utfärdad av ackrediterat laboratorium

Report issued by Accredited Laboratory

Eurofins Food & Agro Testing Sweden AB
Box 887
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Tlf: +46 10 490 8310

Tate&Lyle Sweden AB
Ingbritt Johansson
Älvåsvägen 1
610 20 KIMSTAD

AR-13-LW-028445-01

EUSELI-00046392

Client code: LW9901581

ANALYTICAL REPORT

Sample code:	**525-2013-07170148**
Client Sample:	Soluble Oat Fibre. Batch: 1326
Received:	2013-07-17
Report finished:	2013-07-30
Start of analysis	2013-07-22

	Analysis	Result:	MRL	Unit	Uncert.	Method	Lab
LW00V	Fat acc. Soxtec	0.42		g/100 g	± 30%		EUSELI
SL412	Sodium (Na)	280		mg/kg	± 25%	NMKL No 139 1991 mod	EUSELI2
SL408	Calcium (Ca)	83		mg/kg	± 10%	NMKL No 139 1991 mod	EUSELI2
SL411	Magnesium (Mg)	380		mg/kg	± 10%	NMKL No 139 1991 mod	EUSELI2
SL413	Iron (Fe)	3.2		mg/kg	± 30%	NMKL No 139 1991 mod	EUSELI2
SL409	Phosphorus (P)	3100		mg/kg	± 10%	NMKL No 139 1991 mod	EUSELI2
SL405	Aluminium (Al)	<5.0		mg/kg	± 30%	NMKL No 161 1998 mod	EUSELI2
SL403	Lead (Pb)	<0.020		mg/kg	± 20%	NMKL No 161 1998 mod	EUSELI2
SL404	Cadmium (Cd)	<0.010		mg/kg	± 20%	NMKL No 161 1998 mod	EUSELI2
SL402	Arsenic (As)	<0.050		mg/kg	± 35%	NMKL No 161 1998 mod	EUSELI2
SL399	Mercury (Hg)	< 0.020		mg/kg	± 30%	EN 16277:2012	EUSELI2
JJ006	Aflatoxin B1	<0.1		µg/kg		internal method based on EN 14123	EUHAWE3
JJ006	Aflatoxin B2	<0.1		µg/kg		internal method based on EN 14123	EUHAWE3
JJ006	Aflatoxin G1	<0.1		µg/kg		internal method based on EN 14123	EUHAWE3
JJ006	Aflatoxin G2	<0.1		µg/kg		internal method based on EN 14123	EUHAWE3
LW020	Ochratoxin	<0.10		µg/kg	± 30%	NMKL 143	EUSELI
LW03Z	Deoxynivalenol (Vomitoxin)	200		µg/kg	± 25%	In house method (210)	EUSELI
LW03X	HT-2 Toxin	<10		µg/kg	± 30%	In house method (210)	EUSELI
LW03Y	T-2 toxin	<10		µg/kg	± 30%	In house method (210)	EUSELI
LW041	Zearalenone (ZON)	<10		µg/kg	± 25%	In house method (210)	EUSELI

Uncert. Measurement uncertainty

Symbol description

AR-004 v21

* (Not part of the accreditation)

Performing laboratory if nothing else is stated: Eurofins Food & Agro (Lidköping)

eurofins

AR-13-LW-028445-01

EUSELI-00046392

LP130	Dimethylaminosulphotoluidide (DMST)	0.014		mg/kg		SLV K1-f4-m016.1	EUSELI
LP130	Diphenylamine	0.014	0.05	mg/kg		SLV K1-f4-m016.1	EUSELI
MJ011	Starch and sugar	[illegible]		g/100 g		AOAC 996.12	EUNOTR2
SLB89	Sulphur total (S)	1400		mg/kg	± 20%	NMKL No 161 1998 mod	EUSELI2

LP130: No other pesticide residues detected (SLV K1-f4-m016.1).

Sample conclusion:

Pesticide residues have a measurement uncertainty at an interval of 30-60%.

Ulrica Svensson, ASM

This test report has been created electronically and has been verified and authorised.

Test was performed by

EUHAWE3	Eurofins WEJ Contaminants GmbH (Hamburg)
EUNOTR2	Eurofins Food & Agro Testing Norway AS (Skansen), Trondheim
EUSELI	Eurofins Food & Agro Testing Sweden AB, Lidköping
EUSELI2	Eurofins Environment Sweden, Lidköping

Uncert: Measurement uncertainty

Symbol description

AR-004 v21

* (Not part of the accreditation)

Performing laboratory if nothing else is stated: Eurofins Food & Agro (Lidköping)

eurofins

Rapport utfärdad av ackrediterat laboratorium

Report issued by Accredited Laboratory

Eurofins Food & Agro Testing Sweden AB
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Tlf. +46 10 490 8310

Tate&Lyle Sweden AB
Ingbritt Johansson
Älvåsvägen 1
610 20 KIMSTAD

AR-13-LW-047866-01
EUSELI-00054839
Client code: LW9901581

ANALYTICAL REPORT

Sample code:	525-2013-12030224
Client Sample:	Soluble Oat Fibre, Batch 1344-1
Received:	2013-12-03
Report finished:	2014-01-02
Start of analysis	2013-12-04

	Analysis	Result	MRL	Unit	Uncert.	Method	Lab
LW50V	Fat acc. Soxlet	0.71		g/100 g	± 10%		EUSELI2
SL412	Sodium (Na)	21		mg/100 g	± 25%	NMKL No 139 1991 mod	EUSELI2
SL406	Calcium (Ca)	8.0		mg/100 g	± 10%	NMKL No 139 1991 mod	EUSELI2
SL411	Magnesium (Mg)	36		mg/100 g	± 10%	NMKL No 139 1991 mod	EUSELI2
SL413	Iron (Fe)	0.20		mg/100 g	± 20%	NMKL No 139 1991 mod	EUSELI2
SL410	Potassium (K)	700		mg/100 g	± 15%	NMKL No 139 1991 mod	EUSELI2
SL409	Phosphorus (P)	300		mg/100 g	± 10%	NMKL No 139 1991 mod	EUSELI2
SL415	Zinc (Zn)	0.22		mg/100 g	± 20%	NMKL No 139 1991 mod	EUSELI2
SL405	Aluminium (Al)	<5.0		mg/kg	± 30%	NMKL No 161 1998 mod	EUSELI2
SL403	Lead (Pb)	< 0.020		mg/kg	± 20%	NMKL No 161 1998 mod	EUSELI2
SL404	Cadmium (Cd)	< 0.010		mg/kg	± 20%	NMKL No 161 1998 mod	EUSELI2
SL402	Arsenic (As)	< 0.050		mg/kg	± 35%	NMKL No 161 1998 mod	EUSELI2
SL399	Mercury (Hg)	< 0.020		mg/kg	± 30%	EN 16277:2012	EUSELI2
JJ006	Aflatoxin B1	<0.1		µg/kg		internal method based on EN 14123	EUHAWE3
JJ006	Aflatoxin B2	<0.1		µg/kg		internal method based on EN 14123	EUHAWE3
JJ006	Aflatoxin G1	<0.1		µg/kg		internal method based on EN 14123	EUHAWE3
JJ006	Aflatoxin G2	<0.1		µg/kg		internal method based on EN 14123	EUHAWE3
LW020	Ochratoxin	<0.10		µg/kg	± 30%	NMKL 143	EUSELI
LW032	Deoxynivalenol (Vomitoxin)	52		µg/kg	± 25%	In house method (210)	EUSELI

Uncert.: Measurement uncertainty

Symbol description:
* (Not part of the accreditation)

AR-004 v21

Performing laboratory if nothing else is stated: Eurofins Food & Agro Sweden AB.

eurofins

AR-13-LW-047866-01

EUSELI-00054839

LW03X	HT 2 Toxin	<10	µg/kg	± 30%	In house method (210)	EUSELI
LW0JY	T 2 Toxin	<10	µg/kg	± 30%	In house method (210)	EUSELI
LW041	Zearalenone (ZON)	<10	µg/kg	± 35%	In house method (210)	EUSELI
NJ011	Starch and sugar	44	%		AOAC 996.12	EUNOTH2
SLB89	Sulphur total (S)	140	mg/100 g	± 20%	NMKL No 161 1998 mod	EUSEL/2

LP130: No pesticide residue detected (SLV K144-m816.1).

Report comments:

Pesticide residues have a measurement uncertainty, at an interval of 30-60%.

Per-Olov Södergren, ASM

This test report has been created electronically and has been verified and authorised.

Test was performed by

EUHAWE3	Eurofins WEJ Contaminants GmbH (Hamburg)
EUNOTR2	Eurofins Food & Agro Testing Norway AS (Skansen), Trondheim
EUSELI	Eurofins Food & Agro Testing Sweden AB, Linköping
EUSELI2	Eurofins Environment Sweden, Linköping

Uncert. Measurement uncertainty

Symbo beskrivn AR-304 v21

* = Not part of the accreditation

Performing laboratory, if nothing else is stated: Eurofins Food & Agro, (accred.)

This report may not be reproduced except in full, without written approval of the laboratory. The results relate only to the sample analysed.

Appendix B. Technical Product/Data Sheets

PromOat™

TECHNICAL DATA SHEET: PromOat™ BETA GLUCAN

Description: PromOat™ Beta Glucan is a natural soluble dietary fibre ingredient from oat grain, rich in (1-3, 1-4) beta glucan

Appearance: Fine, cream coloured powder

Origin: 100% Swedish oat grain which is non-GMO
Avena sativa, SW Kerstin variety

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY/UNDERTAKING

Product identity / name	**PromOat™ Beta Glucan**
Product use	Food ingredient / food preparations
Product make-up	Oat kernel extract: Beta glucan soluble fibres and amylodextrins from oat bran
Company	Tate & Lyle Oat Ingredients Älvåsvägen 1 SE 610 20 Kimstad Sweden
Tel no	+ 46 11 25 36 30
Email	oat.info@tateandlyle.com

2. COMPOSITION / INFORMATION ON INGREDIENTS

PromOat™ Beta Glucan is a fraction of milled whole oat grain, derived from the bran, which is gently processed using an alpha-amylase enzyme and physical separation in down-stream processing, and is particularly rich in the soluble fibre component, beta glucan. The product also contains dextrins (amylodextrins) and gluco-oligosaccharides from the oat grain. Insoluble fibre, proteins and oils present in the original oat bran fraction are removed from the product by centrifugation. PromOat™ Beta Glucan is supplied as a drum dried powder.

3. PHYSICAL AND CHEMICAL DATA

PromOat™ Beta Glucan is a fraction of oat bran.

Dietary Fibre Soluble ß glucan	33-36%
Total Dietary Fibre	36-38%
Carbohydrate (dextrin)	54-57%
Protein	<4.5%
Mineral ash	1-3%
Fat	0.5-1%

Supplied with a typical moisture content of 4-6%

Appearance: Fine, cream coloured powder

Density (g/cm^3): circa 0.25

Water solubility: good to moderate

TATE & LYLE

PromOat
Beta Glucan

PRODUCT DATA SHEET: PromOat® Beta Glucan

Description: PromOat® Beta Glucan is a natural soluble dietary fibre ingredient from oat grain, rich in (1-3, 1-4) beta glucan

Appearance: Fine, cream coloured powder

Origin: 100% Swedish oat grain which is non-GMO
Avena sativa, SW Kerstin variety

Label declaration recommendation: oat beta glucan/ oat bran soluble fibre/ oat fibre/ oat soluble fibre

Supply specification	Value	Typical	Method
Beta glucan (on dry matter)	> 33%	34-36%	AOAC method 995.16
Dry matter	> 93%	94-95%	

Nutritional Data (Values per 100g PromOat®, expressed on dry matter)

Energy	315 kcal or 1319 kJ
Fat	0.5 g
of which saturates	<0.1 g
Carbohydrate (oat maltodextrins)	56 g
of which Sugars	<0.5 g
Fibre (oat beta glucan)	35 g
Protein (N* 6.25)	4 g
Salt	<70mg
Sodium	<25mg

Microbiological data	Value	Method
Total plate count 30° cfu/g	<1000	NMKL Nr 86, 1999
Enterobactenaceae cfu/g	<10	NMKL Nr 144, 2000
S. aureus cfu/g	<20	NMKL Nr 66, 3 edt. 1999 modified
Yeasts cfu/g	<100	IDF 94B: 1990 modified
Moulds cfu/g	<100	IDF 94B: 1990 modified
Salmonella	negative / 25g	NMKL nr 71, 5 edt. modified
E. coli cfu/g	negative	NMKL nr 125 3 edt. 1996

PromOat® Beta Glucan generates pH 6-7 when dissolved or mixed in water (1%)

Packaging: 15kg plastic lined paper sack.
Bag labelling includes batch code, label declaration and best before date

Pallets: Euro pallets which hold 24 x 15kg bags of PromOat® = 360kg in total

Storage and handling: store in a clean, dry, well-ventilated warehouse at ambient temperature and humidity, away from odorous materials

Best before: 24 months after production date

Tate & Lyle Oat Ingredients, Arvidsvagen 1, 610 20 Katrineholm, Sweden | +46 11 203030 oat.info@tateandlyle.com

Appendix C. Stability Test Results

Analysis	Start R	3 mos. R	3 mos. V	3 mos. F		6 mos. R	6 mos. V	6 mos. F		9 mos. R	9 mos. V	9 mos. F
Peroxide number mekv/kg	x	x	x	x		x	x	x		x	x	x
Free fatty acids g/100g	x	x	x	x		x	x	x		x	x	x
Protein content* g/100g	3.9	3.9	3.9	3.8		3.7	3.9	4		3.9	3.9	3.9
Dry matter g/100g	95.5	95.3	96	95.5		95.5	96.3	95.6		94.8	95.8	95.5
Beta-glucan g/100g	34.3	34.6	35.3	34.7		34.3	35	35.7		33.6	34.7	33
Mol. wt. milj.Dalton	2.3	2.2	2.1	2.1		2.2	2.1	2.1		2.1	2.2	1.9
pH 10% solution	5.9	5.9	6	6		5.9	6.1	6.1		5.9	6	6.1
Appearance	OK	OK	OK	OK		OK	OK	OK		OK	OK	OK
Color	OK	OK	OK	OK		OK	OK	OK		OK	OK	OK
Smell	OK	OK	OK	OK		OK	OK	OK		OK	OK	OK
Taste	OK	OK	OK	OK		OK	OK	OK		OK	OK	OK
Vol. wt. kg/l										0.56/0.59	0.56/0.59	0.55/0.58
Total count cfu/g	200	50	50	<50		250	<50	100		<50	<50	<50
Total thermophilic count cfu/g	50	<50	<50	<50		50	150	<50		<50	<50	<50
Enterobact. cfu/g	<10	<10	<10	<10		<10	<10	<10		<10	<10	<10
Bacillus.cereus cfu/g	<20	<20	<50	<20		<20	<20	<20		<20	<20	<20
Staph. aureus cfu/g	<20	<20	<50	<20		<20	<20	<20		<20	<20	<20
Yeast cfu/g	<20	<20	<20	<20		<20	<20	<20		<20	<20	<20
Molds cfu/g	<20	20	20	<20		<20	<20	<20		<20	<20	<20
E. coli cfu/g	x	x	x	x		x	x	x		x	x	x

* R - room temperature; V - 40°C; F - freezer (0°C)

Analysis	12 mos. R	12 mos. V	12 mos. F		18 mos. R	18 mos. V	18 mos. F
Peroxide number mekv/kg	x	x	x		x	x	x
Free fatty acids g/100g	x	x	x		x	x	x
Protein content* g/100g	3.9	3.9	3.9				
Dry matter g/100g	94.4	95.3	95.7		94.5	96.2	95.5
Beta-glucan g/100g	35.1	35.2	33.8		33.3	35.3	34.2
Mol. wt. milj.Dalton							
pH 10% solution	5.9	6.1	6.1				
Appearance	OK	OK	OK		OK	OK	OK
Color	OK	OK	OK		OK	OK	OK
Smell	OK	OK	OK		OK	NA	OK
Taste	OK	OK	OK		OK	OK	OK
Vol. wt. kg/l	0.56/0.58	0.56/0.57	0.54/0.59		0.54/0.56	0.55/0.58	0.54/0.56
Total count cfu/g	<50	50	<50		<50	<50	50
Total thermophilic count cfu/g	50	<50	<50		100	<50	<50
Enterobact. cfu/g	<10	<10	<10		<10	<10	<10
Bacillus. cereus cfu/g	<20	<20	<20		<20	<20	<20
Staph. aureus cfu/g	<20	<20	<20		<20	<20	<20
Yeast cfu/g	<20	<20	<20		<20	<20	<20
Molds cfu/g	<20	<20	<20		<20	<20	<20
E. coli cfu/g	x	x	x		x	x	x

- R - room temperature; V - 40°C; F - freezer (0°)

Exhibit I. Report of the Expert Panel

CBI Deleted Copy

Petition to Add to the National List 7 CFR 205.606: Oat Beta-Fiber

APPENDIX

Appendix 4: Tate & Lyle Oat Ingredients
Launches in the Market with PromOat® Oat Beta Glucan

TATE & LYLE

Tate & Lyle Oat Ingredients

Launches in the Market with Beta-Glucan

PromOat®
Beta Glucan

Migros - Yogurt Switzerland

With 1g of beta-glucan per portion (225g)

	100g containing	**1 cup** (225g) contains
Energy	410kJ (98kcal)	221kcal
Protein	6g	14g
Carbohydrate	14g	32g
of which sugars	7g	16g
Fat	1.2g	2.7g
of which saturates	0.4g	0.9g
Fibre	3.5g	8g
of which oat beta-glucan	0.4g	1g
Sodium	0.07g	0.16g
Cooking salt	<0.1g	0.2g

TATE & LYLE

Blevita Hafer Honig: Spelled Cookies with Oatmeal and Honey Flavor Switzerland

With 1g of beta-glucan per portion (36g)

	100g containing	**1 Portion** (36g) contains
Energy	1650kJ (392kcal)	141kcal
Protein	13g	4.5g
Carbohydrate	57g	21g
of which sugars	4.5g	1.5g
Fat	10g	3.5g
of which saturates	1g	<0.5g
Fibre	11g	4g
of which oat beta-glucan	2.8g	1g
Sodium	0.58g	0.21g
Cooking salt	1.3g	0.5g

TATE & LYLE

Sponser Pro Mass Gainer - Dietary Supplement Switzerland

With 1g of beta-glucan per portion (60g)

ARÔMES/CONDITIONNEMENT

Chocolat	Boîte de 1200 g
Vanilla	Boîte de 1200 g, 2000 g

VALEUR NUTRITIVES

VALEUR NUTRITIVE	PER 100 G POUDRE		1 PORTION (60 G)	
energie kJ (kcal)		1680 (396)		1007 (238)
proteine		30 g		18 g
glucides		61 g		37 g
dont				
- sucrose		17 g		10 g
- glucose		7.1 g		4.3 g
- fructose		0 g		0 g
- lactose		0.4 g		0.2 g
lipides		3.0 g		1.8 g
- dont acides gras saturés		2.8 g		1.7 g
- dont triglycérides moyen		1.5 g		0.9 g
fibres alimentaires		2.6 g		1.6 g
- dont bêta-glucanes		1.7 g		1.0 g
sodium		0.28 g		0.17 g
VITAMINES		**%AJR***		**%AJR***
E	4.0 mg	33%	2.4 mg	20%
C	27 mg	34%	16 mg	20%
B1	0.3 mg	27%	0.2 mg	18%
B2	0.5 mg	36%	0.3 mg	21%
niacine	5.3 mg	33%	3.2 mg	20%
B6	0.5 mg	36%	0.3 mg	21%
acide folique	67 µg	34%	40 µg	20%
B12	0.8 µg	32%	0.5 µg	20%
biotine	17 µg	34%	10 µg	20%
acide pantothénique	2.0 mg	33%	1.2 mg	20%
SELS MINÉRAUX		**%AJR**		**%AJR***
calcium	400 mg	50%	240 mg	30%
magnésium	60 mg	16%	36 mg	10%
phosphore	280 mg	40%	168 mg	24%
chrome	34 µg	85%	20 µg	50%
créatine		2.5 g		1.5 g

*apport journalier recommandé

TATE & LYLE

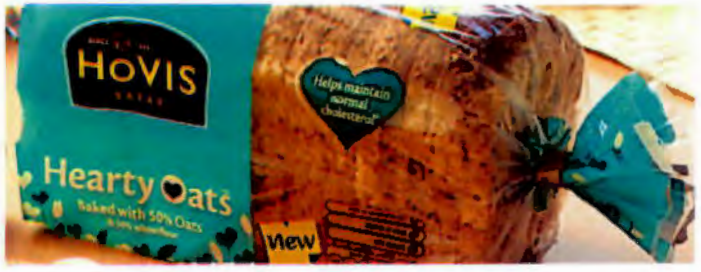
BetaBalance - Sachet Supplement UK

PromOat
Beta Glucan

With 1g of beta-glucan per portion (6g)

TATE & LYLE

Hovis Hearty Oats – Bread UK



With 1g of beta-glucan per portion (2 slices - 88g)

	Per slice (44g)	Per portion 2 slices (88g)
Energy	460 kJ 109 kcal	920kJ 218kcal
Fat	1.9g	3.8g
of which saturates	0.4g	0.8g
Carbohydrate	16.4g	32.8g
of which sugars	1.2g	2.4g
Fibre	2.5g	5g
Protein	5.4g	10.8g
Salt	0.42g	0.84g
Beta-glucan	**0.5g**	**1g**

Migros, Farmer Croc – Cereal Switzerland

With 1g of beta-glucan per portion (45g)

	100g containing	**1 Portion** (45g) contains
Energy	1710kJ (460kcal)	183kcal
Protein	8g	3.5g
Carbohydrate	65g	29g
of which sugars	24g	11g
Fat	10g	4.5g
of which saturates	3.5g	1.5g
Fibre	12g	5g
of which oat beta-glucan	2.5g	1g
Sodium	0.18g	0.08g
Cooking salt	0.5g	0.2g

Col Cuore, Galbusera – Biscuits Italy

INGREDIENTI
Farina di **frumento** integrale 40%, fiocchi di **avena** 25%, zucchero di canna grezzo 17%, olio di mais 14%, fibre di cereali (**orzo, avena**) ricche in betaglucani 5%, sciroppo di glucosio-fruttosio, agenti lievitanti (carbonato acido di sodio, carbonato acido di ammonio), sale marino integrale 0,5%.
Può contenere tracce di uova, latte, nocciole e altra frutta a guscio.

Codice EAN: 8002190001913
Peso: 300 grammi (48 biscotti)

With 1g of beta-glucan per portion (50g)

	Per 100g	Per portion 8 biscuits (50g)
Energy	1872 kJ 447 kcal	936 kJ kcal 223 kcal
Fat	16.5g	8.3g
of which saturates	2.5g	1.3g
Carbohydrate	61.2g	30.6g
of which sugars	22.5g	11.3g
Fibre	10g	5g
Protein	8.3g	4.2g
Sodium	0.4g	0.2g
Beta-glucan	2g	1g

Marks & Spencer - Juice UK

With 0.75g of beta-glucan per portion (300ml)

	Per 100ml	Per portion (300ml)
Energy	280 kJ 65kcal	840 kJ 195kcal
Fat	0.9g	2.7g
of which saturates	0.5g	1.5g
Carbohydrate	13.8g	41.4g
of which sugars	11.8g	35.4g
Fibre	0.7g	2.1g
Protein	0.4g	1.2g
Sodium	0.01g	0.03g
Beta-glucan	**0.25g**	**0.75g**

Vetta – Pasta Australia

With 1g of beta-glucan per portion (100g)

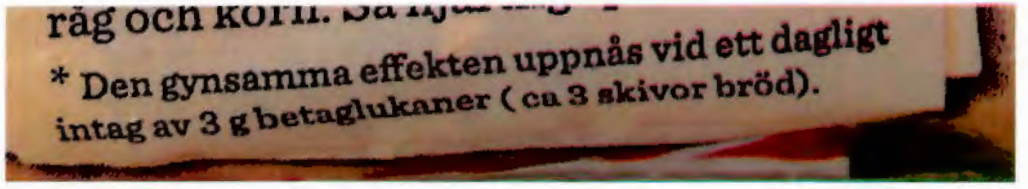
NUTRITION INFORMATION†
SERVINGS PER PACKAGE: 3.75 SERVING SIZE: 100g

	AVE QTY PER SERVING	% DAILY INTAKE PER SERVING*	AVE QTY PER 100g
ENERGY	1500kJ (359kcal)	17%	1500kJ (359kcal)
PROTEIN	12.5g	25%	12.5g
FAT – TOTAL	1.5g	2%	1.5g
– SATURATED	0.3g	1%	0.3g
DIETARY FIBRE	4.6g	15%	4.6g
– SOLUBLE	3.0g	-	3.0g
– BETA GLUCAN	1.0g	-	1.0g
CARBOHYDRATE	70.5g	23%	70.5g
– SUGARS	3.4g	4%	3.4g
SODIUM	25mg	1.1%	25mg

†INFORMATION RELATES TO UNCOOKED PASTA
*% DAILY INTAKES ARE BASED ON AN AVERAGE ADULT DIET OF 8700kJ. YOUR DAILY INTAKES MAY BE HIGHER OR LOWER DEPENDING ON YOUR ENERGY NEEDS.

Östras – Bread Sweden

Claimed to provide 1g of beta-glucan per slice



	Per 100g
Energy	1020 kJ 240kcal
Fat	1.5g
of which saturates	0.2g
Carbohydrate	46g
of which sugars	4g
Fibre	5.5g
Protein	9g
Sodium	0.32g

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Petition to Add to the National List 7 CFR 205.606: Oat Beta-Fiber

APPENDIX

Appendix 5: Material Safety Data Sheet (MSDS) for PromOat® Oat Beta-Glucan

MATERIAL SAFETY DATA SHEET (MSDS): PromOat™ BETA GLUCAN

1. IDENTIFICATION OF THE SUBSTANCE AND COMPANY

Product identity / name	**PromOat™ Beta Glucan**
Product use	Food, beverage and nutritional supplements ingredient
Product make-up	Oat kernel extract: Beta glucan soluble fibres and amylodextrins from oat bran
Company	Tate & Lyle Oat Ingredients Älvåsvägen 1 SE 610 20 Kimstad Sweden
Tel no	+ 46 11 25 36 30
Email	oat.info@tateandlyle.com

2. COMPOSITION / INFORMATION ON INGREDIENTS

PromOat™ Beta Glucan is a fraction of milled whole oat grain, derived from the bran, which is gently processed using enzymes and physical separation in down-stream processing, and is particularly rich in the soluble fibre component, beta glucan. The product also contains dextrins (amylodextrins) and gluco-oligosaccharides. Insoluble fibre, proteins and oils present in the original oat bran fraction are removed from the product by centrifugation. PromOat™ Beta Glucan is supplied as a powder.

3. PHYSICAL AND CHEMICAL DATA

PromOat™ Beta Glucan is derived from milled whole oat grains.

Dietary Fibre (Soluble ß-glucan)	33-36%
Total Dietary Fibre	36-38%
Carbohydrate (oat maltodextrins)	54-57%
Protein	<4.5%
Mineral ash	1-3%
Fat	0.5-1%

Supplied with a typical moisture content of 4-6%

Appearance: Fine, cream coloured powder
Melting point: Not Applicable (decomposes before melting)
Boiling point: Not applicable
Vapour density: Not applicable
Vapour pressure: Not applicable
Density (g/cm^3): circa 0.25
Flash point: Not applicable
Explosion limits: Avoid flames/sparks or equipment where sparks are generated
Auto ignition temperature: Not given
Water solubility: good

4. HAZARDS IDENTIFICATION

None identified

5. FIRST-AID MEASURES

INHALATION:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

INGESTION:
PromOat™ beta glucan is designed for human consumption and is not known to cause any adverse effects. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, or belt waistband.

SKIN CONTACT
Wash with soap and water.

EYE CONTACT
Wash with running water, holding eyelids open, or use an eye fountain. In the unlikely event of any discomfort, or continuing discomfort, seek medical attention.

6. FIRE-FIGHTING MEASURES

The product is in the form of a powder and may be flammable at high temperatures.

SMALL FIRE: Use DRY chemical powder.

LARGE FIRE: Use water spray, fog or foam. Do not use water jet. Combustion of any dry residues releases CO2

7. ACCIDENTAL RELEASE MEASURES

SPILLAGE: Sweep up. Avoid formation of dust cloud.

WASTE DISPOSAL: Dispose of in accordance with national and regional regulations. PromOat™ Beta Glucan is entirely biodegradable.

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

8. HANDLING AND STORAGE

STORAGE: Store in cool dry place away from heat and oxidizing agents.
No other special precautions needed.

USAGE PRECAUTIONS: Avoid spillage and direct skin and eye contact. Safety goggles should be worn when dealing with large volumes. No particular hand protection is required.

STORAGE CLASS: Unspecified storage

9. EXPOSURE CONTROL / PERSONAL PROTECTION

COMMENTS: No exposure limits noted for the ingredient
Those very few people who have a specific allergy to oat grain should consult a doctor before working with PromOat™.

PROTECTIVE EQUIPMENT: Good laboratory practice.

RESPIRATORY EQUIPMENT
None needed or recommended

HAND PROTECTION
Good GLP: Use waterproof protective gloves made from, eg pvc, polyethylene, neoprene

EYE PROTECTION
Good GLP: Use of approved safety glasses or goggles is recommended only when eye exposure is probable

OTHER PROTECTION
None needed

HYGIENE MEASURES
Always wash at the end of each working shift, before eating, smoking or using toilet facilities

10. STABILITY AND REACTIVITY

The product is stable under normal conditions of temperature and pressure.
Combustible as PromOat™ is a carbohydrate-rich powder.
Try to avoid formation of a PromOat™ Beta Glucan dust cloud. Regard as equivalent to starch in this respect.

Avoid contact with extremely strong oxidizing agents.

No dangerous reactions are known or reasonably foreseen.

11. HEALTH HAZARDS / TOXICOLOGY

ACUTE EFFECTS: None

CHRONIC EFFECTS: None

TOXICITY DATA: None given

No known toxicity.
Not absorbed through the skin.

Inhalation of excessive dust may transiently irritate the nose, throat and respiratory tract. Eye contact with dust may cause mild and transient irritation. Ingestion of quantities sufficient to produce any adverse effects whatsoever is not plausible in an industrial or manufacturing situation.

Skin contact is not known to be hazardous.

Oat bran soluble fibre and carbohydrates have no known carcinogenicity and are not classified as a reproductive toxin by any authoritative body or regulatory agency.

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Petition to Add to the National List 7 CFR 205.606: Oat Beta-Fiber

APPENDIX

Appendix 6: USDA NHANES Nutrient Intakes from Food, 2009 – 2010.

Data Source:

What We Eat in America, NHANES 2009 – 2010, page 1 (fiber data highlighted by author)
http://www.ars.usda.gov/SP2UserFiles/Place/80400530/pdf/0910/Table_1_NIN_GEN_09.pdf

Table 1. Nutrient Intakes from Food: Mean Amounts Consumed per Individual[1], by Gender and Age, in the United States, 2009-2010

Gender and age (years)	Sample size	Food energy kcal (SE)	Protein g (SE)	Carbohydrate g (SE)	Total sugars g (SE)	Dietary fiber g (SE)	Total fat g (SE)	Saturated fat g (SE)	Mono-unsaturated fat g (SE)	Poly-unsaturated fat g (SE)
Males:										
2 - 5	452	1553 (25.6)	55.7 (1.24)	216 (3.4)	111 (1.9)	12.1 (0.25)	54.4 (1.74)	19.6 (0.76)	19.0 (0.61)	10.8 (0.38)
6 - 11	588	1922 (32.6)	68.3 (1.40)	259 (4.5)	126 (1.9)	13.6 (0.24)	70.3 (1.56)	24.7 (0.70)	24.8 (0.56)	14.5 (0.41)
12 - 19	672	2539 (72.8)	95.2 (3.14)	335 (11.0)	161 (5.1)	16.4 (0.70)	91.9 (3.25)	31.3 (1.37)	32.7 (1.25)	19.4 (0.65)
20 - 29	450	2626 (79.4)	101.0 (3.75)	320 (9.7)	146 (6.2)	17.2 (0.80)	93.0 (3.49)	30.7 (1.10)	33.5 (1.36)	20.3 (0.97)
30 - 39	455	2736 (44.9)	106.4 (3.47)	327 (7.6)	143 (6.7)	19.7 (0.86)	97.6 (2.33)	31.5 (1.10)	35.9 (0.83)	21.2 (0.57)
40 - 49	481	2730 (73.2)	107.9 (3.04)	320 (7.8)	141 (4.3)	20.3 (0.98)	103.1 (4.32)	34.2 (1.67)	37.9 (1.60)	21.5 (0.82)
50 - 59	470	2482 (55.3)	99.8 (3.13)	279 (8.9)	122 (7.0)	18.9 (0.82)	96.6 (2.92)	32.3 (1.29)	34.6 (0.98)	21.0 (0.66)
60 - 69	449	2206 (40.0)	89.3 (1.68)	254 (4.7)	108 (4.1)	18.2 (0.49)	84.5 (2.07)	27.2 (0.80)	31.0 (0.90)	18.6 (0.66)
70 and over	484	1907 (41.1)	74.4 (1.79)	232 (5.1)	104 (3.8)	17.1 (0.58)	72.4 (1.73)	23.0 (0.64)	27.0 (0.69)	16.1 (0.55)
20 and over	2789	2512 (30.7)	98.9 (1.37)	296 (3.5)	131 (2.4)	18.7 (0.39)	93.3 (1.71)	30.6 (0.71)	34.0 (0.57)	20.2 (0.39)
Females:										
2 - 5	409	1520 (36.7)	55.6 (1.49)	206 (5.2)	108 (3.3)	11.3 (0.41)	54.9 (1.72)	20.6 (0.91)	18.8 (0.61)	10.5 (0.52)
6 - 11	566	1812 (24.5)	63.2 (1.35)	252 (4.9)	120 (2.5)	14.5 (0.46)	63.9 (0.97)	22.1 (0.45)	22.5 (0.39)	13.5 (0.33)
12 - 19	593	1821 (43.9)	64.0 (1.48)	242 (6.6)	117 (4.4)	12.6 (0.35)	67.9 (1.72)	23.1 (0.63)	23.6 (0.64)	15.2 (0.63)
20 - 29	524	1949 (54.7)	70.1 (1.90)	250 (7.0)	120 (4.6)	13.6 (0.40)	70.8 (2.70)	23.6 (1.08)	25.0 (0.96)	15.7 (0.58)
30 - 39	499	1831 (31.5)	69.6 (1.68)	232 (3.4)	104 (3.2)	16.6 (0.63)	67.8 (1.95)	22.2 (0.61)	24.3 (0.74)	15.1 (0.57)
40 - 49	555	1794 (59.2)	69.0 (2.04)	228 (8.3)	105 (5.0)	15.1 (0.70)	65.3 (2.14)	21.2 (0.70)	22.9 (0.73)	15.3 (0.65)
50 - 59	429	1759 (38.4)	69.6 (1.99)	219 (5.6)	100 (3.4)	17.0 (0.57)	66.0 (1.84)	21.0 (0.78)	23.6 (0.69)	15.4 (0.46)
60 - 69	453	1717 (35.4)	66.8 (1.55)	209 (4.6)	96 (3.3)	15.6 (0.38)	66.7 (2.21)	21.9 (0.85)	23.8 (0.82)	15.1 (0.61)
70 and over	513	1535 (34.4)	60.1 (1.51)	196 (4.1)	89 (2.2)	15.2 (0.39)	57.8 (1.42)	19.0 (0.48)	20.2 (0.55)	13.5 (0.38)
20 and over	2973	1778 (15.0)	68.0 (0.68)	224 (2.1)	103 (1.0)	15.5 (0.21)	66.0 (0.59)	21.6 (0.22)	23.4 (0.18)	15.1 (0.22)
Males and females:										
2 and over	9042	2081 (12.9)	79.5 (0.70)	259 (1.7)	119 (1.1)	16.2 (0.20)	76.8 (0.75)	25.5 (0.30)	27.5 (0.24)	16.8 (0.23)

DATA SOURCE: *What We Eat in America*, NHANES 2009-2010, individuals 2 years and over (excluding breast-fed children), day 1 dietary intake data, weighted.

Symbol Legend

* Indicates an estimate that may be less statistically reliable than estimates that are not flagged. The rules for flagging estimated means are as follows:

Mean: An estimated mean is flagged when based on a sample size of less than 30 times the variance inflation factor (VIF), where the VIF represents a broadly calculated average design effect, or when the relative standard error is greater than 30 percent. The VIF used in this table is 2.04.

Footnotes

[1] Sample weights designed for dietary analysis were used to allow estimates representative of the U. S. population for the years of collection.

[2] Salt adjustment is not applied to *What We Eat in America*, NHANES 2009-2010 and all subsequent surveys. Estimates of sodium intake include salt added in cooking and food preparation as assumed in the nutrient profiles for foods in FNDDS 5.0. Details available at: www.ars.usda.gov/ba/bhnrc/fsrg.

[3] Alcohol estimates are shown only for 20 years and over age groups. Although the data are collected for all individuals, estimates are not presented due to extreme variability and/or inadequate sample size.

Abbreviations

SE = standard error; RAE = retinol activity equivalents; DFE = dietary folate equivalents. SFA = saturated fatty acid; MFA = monounsaturated fatty acid; PFA = polyunsaturated fatty acid.

Notes Applicable to All Tables in Series: *What We Eat in America*, NHANES 2009-2010

The statistics in this table are estimated from Day 1 dietary recall interviews conducted in the *What We Eat in America*, National Health and Nutrition Examination Survey (NHANES) 2009-2010. The 24-hour dietary recalls were conducted in-person, by trained interviewers, using the USDA 5-step Automated Multiple-Pass Method. Food intakes were coded and nutrient values were determined using the USDA Food and Nutrient Database for Dietary Studies 5.0 www.ars.usda.gov/ba/bhnrc/fsrg which is based on nutrient values in the USDA National Nutrient Database for Standard Reference, Release 24 (Agricultural Research Service, Nutrient Data Laboratory, 2011).

Intakes of nutrients and other dietary components are based on the consumption of food and beverages, including water, and do not include intake from supplements or medications.

The table includes data from individuals 2 years and over. Breast-fed children were excluded because breast milk was not quantified in dietary recall interviews.

Suggested Citation

U.S. Department of Agriculture, Agricultural Research Service. 2012. Nutrient Intakes from Food: Mean Amounts Consumed per Individual, by Gender and Age, *What We Eat in America*, NHANES 2009-2010. Available: www.ars.usda.gov/ba/bhnrc/fsrg

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Petition to Add to the National List 7 CFR 205.606: Oat Beta-Fiber

APPENDIX

Appendix 7: 21 CFR 101.81 Health claims: Soluble fiber from certain foods and risk of coronary heart disease (CHD)

[Code of Federal Regulations]
[Title 21, Volume 2]
[Revised as of April 1, 2013]
CITE: 21CFR101.81]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION

PART 101 -- FOOD LABELING[9]

Subpart E--Specific Requirements for Health Claims

Sec. 101.81 Health claims: Soluble fiber from certain foods and risk of coronary heart disease (CHD).

(a) *Relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and the risk of CHD.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease (CHD) is one of the most common and serious forms of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total cholesterol and low density lipoprotein (LDL)-cholesterol levels are associated with increased risk of developing coronary heart disease. High CHD rates occur among people with high total cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk total cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of CHD.

(2) Populations with a low incidence of CHD tend to have relatively low blood total cholesterol and LDL-cholesterol levels. These populations also tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in fiber-containing fruits, vegetables, and grain products, such as whole oat products.

(3) Scientific evidence demonstrates that diets low in saturated fat and cholesterol may reduce the risk of CHD. Other evidence demonstrates that the addition of soluble fiber from certain foods to a diet that is low in saturated fat and cholesterol may also help to reduce the risk of CHD.

(b) *Significance of the relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and the risk of CHD.* (1) CHD is a major public health concern in the United States. It accounts for more deaths than any other disease or group of diseases. Early management of risk factors for CHD is a major public health goal that can assist in reducing risk of CHD. High blood total and LDL-cholesterol are major modifiable risk factors in the development of CHD.

(2) Intakes of saturated fat exceed recommended levels in the diets of many people in the United States. One of the major public health recommendations relative to CHD risk is to consume less than 10 percent of calories from saturated fat and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 milligrams (mg) or less per day. Scientific evidence demonstrates that diets low in saturated fat and cholesterol are associated with lower blood total- and LDL-cholesterol levels. Soluble fiber from certain foods, when included in a low saturated fat and cholesterol diet, also helps to lower blood total- and LDL-cholesterol levels.

(c) *Requirements.* (1) All requirements set forth in 101.14 shall be met. The label and labeling of foods containing psyllium husk shall be consistent with the provisions of 101.17 (f).

(2) *Specific requirements* --(i) *Nature of the claim.* A health claim associating diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods with

reduced risk of heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(iii) of this section, provided that:

(A) The claim states that diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods "may" or "might" reduce the risk of heart disease.

(B) In specifying the disease, the claim uses the following terms: "heart disease" or "coronary heart disease";

(C) In specifying the substance, the claim uses the term "soluble fiber" qualified by the name of the eligible source of soluble fiber (provided in paragraph (c)(2)(ii)) of this section. Additionally, the claim may use the name of the food product that contains the eligible source of soluble fiber;

(D) In specifying the fat component, the claim uses the terms "saturated fat" and "cholesterol";

(E) The claim does not attribute any degree of risk reduction for CHD to diets that are low in saturated fat and cholesterol and that include soluble fiber from the eligible food sources from paragraph (c)(2)(ii) of this section; and

(F) The claim does not imply that consumption of diets that are low in saturated fat and cholesterol and that include soluble fiber from the eligible food sources from paragraph (c)(2)(ii) of this section is the only recognized means of achieving a reduced risk of CHD.

(G) The claim specifies the daily dietary intake of the soluble fiber source that is necessary to reduce the risk of coronary heart disease and the contribution one serving of the product makes to the specified daily dietary intake level. Daily dietary intake levels of soluble fiber sources listed in paragraph (c)(2)(ii) of this section that have been associated with reduced risk coronary heart disease are:

(*1*) 3 g or more per day of [beta]-glucan soluble fiber from either whole oats or barley, or a combination of whole oats and barley.

(*2*) 7 g or more per day of soluble fiber from psyllium seed husk.

(ii) *Nature of the substance--Eligible sources of soluble fiber.* (A) Beta ([beta]) glucan soluble fiber from the whole oat and barley sources listed below. [beta]-glucan soluble fiber will be determined by method No. 992.28 from the "Official Methods of Analysis of the AOAC INTERNATIONAL," 16th ed. (1995), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html* ;

(*1*) *Oat bran.* Oat bran is produced by grinding clean oat groats or rolled oats and separating the resulting oat flour by suitable means into fractions such that the oat bran fraction is not more than 50 percent of the original starting material and provides at least 5.5 percent (dry weight basis (dwb)) [beta]-glucan soluble fiber and a total dietary fiber content of 16 percent (dwb), and such that at least one-third of the total dietary fiber is soluble fiber;

(*2*) *Rolled oats.* Rolled oats, also known as oatmeal, produced from 100 percent dehulled, clean oat groats by steaming, cutting, rolling, and flaking, and provides at least 4 percent (dwb) of [beta]-glucan soluble fiber and a total dietary fiber content of at least 10 percent.

(*3*) *Whole oat flour.* Whole oat flour is produced from 100 percent dehulled, clean oat groats by steaming and grinding, such that there is no significant loss of oat bran in the final product, and provides at least 4 percent (dwb) of [beta]-glucan soluble fiber and a total dietary fiber content of at least 10 percent (dwb).

(*4*) *Oatrim.* The soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour, also known as oatrim. Oatrim is produced from either oat bran as defined in paragraph (c)(2)(ii)(A)(*1*) of this section or whole oat flour as defined in paragraph (c)(2)(ii)(A)(*3*) of this section by solubilization of the starch in the starting material with an alpha-amylase hydrolysis process, and then removal by centrifugation of the insoluble components consisting of a high portion of protein, lipid, insoluble dietary fiber, and the majority of the flavor and color components of the starting material. Oatrim shall have a beta-glucan soluble fiber content up to 10 percent (dwb) and not less than that of the starting material (dwb).

(*5*) *Whole grain barley and dry milled barley* . Dehulled and hull-less whole grain barley with a [beta]-glucan soluble fiber content of at least 4 percent (dwb) and a total dietary

fiber content of at least 10 percent (dwb). Dry milled barley grain products include barley bran, barley flakes, barley grits, pearl barley, barley flour, barley meal, and sieved barley meal that are produced from clean, sound dehulled or hull-less barley grain using standard dry milling techniques, which may include steaming or tempering, and that contain at least 4 percent (dwb) of (beta)-glucan soluble fiber and at least 8 percent (dwb) of total dietary fiber, except barley bran and sieved barley meal for which the minimum (beta)-glucan soluble fiber content is 5.5 percent (dwb) and minimum total dietary fiber content is 15 percent (dwb). Dehulled barley, hull-less barley, barley bran, barley flakes, barley grits, pearl barley, and barley flour are as defined in the Barley Glossary (AACC Method 55-99), published in Approved Methods of the American Association of Cereal Chemists, 10th ed. (2000), pp. 1 and 2, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Association of Cereal Chemists, Inc., 3340 Pilot Knob Rd., St. Paul, Minnesota, 55121, or may be examined at the Center for Food Safety and Applied Nutrition Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:*http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html* . Barley meal is unsifted, ground barley grain not subjected to any processing to separate the bran, germ, and endosperm. Sieved barley meal is an endosperm cell wall-enriched fraction of ground barley separated from meal by sieving or by air classification.

(*6*) *Barley betafiber* . Barley betafiber is 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.

(B)(*1*) Psyllium husk from the dried seed coat (epidermis) of the seed of*Plantago* (*P.*) ovata, known as blond psyllium or Indian psyllium,*P. indica*, or*P. psyllium*. To qualify for this claim, psyllium seed husk, also known as psyllium husk, shall have a purity of no less than 95 percent, such that it contains 3 percent or less protein, 4.5 percent or less of light extraneous matter, and 0.5 percent or less of heavy extraneous matter, but in no case may the combined extraneous matter exceed 4.9 percent, as determined by U.S. Pharmacopeia (USP) methods described in USP's "The National Formulary," USP 23, NF 18, p. 1341, (1995), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:*http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html* ;

(*2*) FDA will determine the amount of soluble fiber that is provided by psyllium husk by using a modification of the Association of Official Analytical Chemists' International (AOAC's) method for soluble dietary fiber (991.43) described by Lee et al., "Determination of Soluble and Insoluble Dietary Fiber in Psyllium-containing Cereal Products,"*Journal of the AOAC International*, 78 (No. 3):724-729, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:*http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html* ;

(iii)*Nature of the food eligible to bear the claim.* (A) The food product shall include:

(*1*) One or more of the whole oat or barley foods from paragraphs (c)(2)(iii)(A)(*1*), (*2*), (*3*), and (*5*) of this section, and the whole oat or barley foods shall contain at least 0.75 gram (g) of soluble fiber per reference amount customarily consumed of the food product; or

(*2*) The food containing the oatrim from paragraph (c)(2)(ii)(A)(*4*) of this section or the barley betafiber from paragraph (c)(2)(ii)(A)(*6*) of this section shall contain at least 0.75 g of beta-glucan soluble fiber per reference amount customarily consumed of the food product; or

(3) Psyllium husk that complies with paragraph (c)(2)(ii)(B) of this section, and the psyllium food shall contain at least 1.7 g of soluble fiber per reference amount customarily consumed of the food product;

(B) The amount of soluble fiber shall be declared in the nutrition label, consistent with 101.9(c)(6)(i)(A).

(C) The food shall meet the nutrient content requirement in 101.62 for a "low saturated fat" and " ow cholesterol" food; and

(D) The food shall meet the nutrient content requirement in 101.62(b)(2) for a "low fat" food, unless the food exceeds this requirement due to fat content derived from whole oat sources listed in paragraph (c)(2)(ii)(A) of this section.

(d)*Optional information.* (1) The claim may state that the development of heart disease depends on many factors and may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of CHD; elevated blood total and LDL-cholesterol; excess body weight; high blood pressure; cigarette smoking; diabetes; and physical inactivity. The claim may also provide additional information about the benefits of exercise and management of body weight to help lower the risk of heart disease;

(2) The claim may state that the relationship between intake of diets that are low in saturated fat and cholesterol and that include soluble fiber from the eligible food sources from paragraph (c)(2)(ii) of this section and reduced risk of heart disease is through the intermediate link of "blood cholesterol" or "blood total- and LDL-cholesterol;"

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and coronary heart disease and the significance of the relationship;

(4) The claim may specify the name of the eligible soluble fiber;

(5) The claim may state that a diet low in saturated fat and cholesterol that includes soluble fiber from whole oats or barley is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO);

(6) The claim may state that individuals with elevated blood total- and LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total- and LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment;

(7) The claim may include information on the number of people in the United States who have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, GPO.

(e)*Model health claim.* The following model health claims may be used in food labeling to describe the relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and reduced risk of heart disease:

(1) Soluble fiber from foods such as [name of soluble fiber source from paragraph (c)(2)(ii) of this section and, if desired, the name of food product], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies ____ grams of the [grams of soluble fiber specified in paragraph (c)(2)(i)(G) of this section] soluble fiber from [name of the soluble fiber source from paragraph (c)(2)(ii) of this section] necessary per day to have this effect.

(2) Diets low in saturated fat and cholesterol that include [____ grams of soluble fiber specified in paragraph (c)(2)(i)(G) of this section] of soluble fiber per day from [name of soluble fiber source from paragraph (c)(2)(ii) of this section and, if desired, the name of the food product] may reduce the risk of heart disease. One serving of [name of food] provides ____ grams of this soluble fiber.

[61 FR 2600, Jan. 23, 1997, as amended at 62 FR 15344, Mar. 31, 1997; 63 FR 8119, Feb. 18, 1998; 66 FR 06674, Dec. 27, 2001; 67 FR 61782, Oct. 1, 2002; 68 FR 15355, Mar. 31, 2003; 70 FR 40880, July 15, 2005; 70 FR 76162, Dec. 23, 2005; 73 FR 9947, Feb. 25, 2008; 73 FR 23953, May 1, 2008]

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Petition to Add to the National List 7 CFR 205.606: Oat Beta-Fiber

APPENDIX

Appendix 8: Beta-Glucan: Health Benefits and Product Applications (Tate & Lyle)

TATE & LYLE

Beta-Glucan: Health Benefits and Product Applications

Innovating to Meet Nutrition, Health, and Wellness Needs Every Day

PromOat® Beta Glucan

Scan for more information.

To learn more about Tate & Lyle ingredients and innovation, please visit www.foodnutritionknowledge.info, www.tateandlyle.com, and www.promoat.com.

PromOat®
Beta Glucan

- Research indicates that diets higher in fibre are associated with improved health and reduced risk of certain diseases
- Oat beta-glucan is a viscous, soluble fibre that can help maintain healthy blood cholesterol and blood glucose levels as well as support gastrointestinal health and assist in weight management
- Despite the fact that many consumers say that they are making efforts to consume diets high in dietary fibre, current fibre intakes remain below recommendations
- Tate & Lyle's PromOat® Beta Glucan is a great example of an ingredient that manufacturers can use in the development of new and innovative products that may promote health while helping to meet the population's dietary fibre needs

Fibre types and health benefits

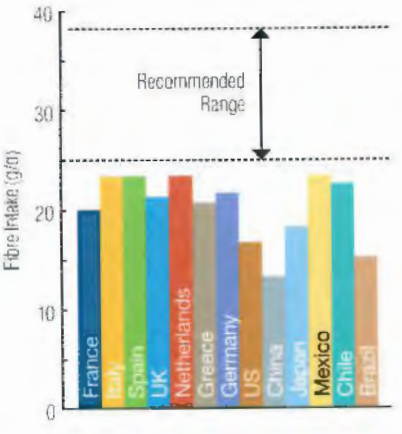
Decades of research indicate that diets higher in fibre are associated with reduced risks for heart disease and diabetes[1,2] as well as improved gut health and digestion[2]; however, average intakes remain well below the currently recommended amounts[1-3]. With fibre intakes low across global populations, there is potential for long-term public health implications[1-3].

Dietary fibres are nondigestible carbohydrates in the diet that, when consumed, pass through the small intestine into the large intestine where they may be partially or completely fermented by colonic microbiota[2]. There are several varieties of dietary fibre, and each type provides specific health benefits; thus, it is recommended that individuals consume fibre from multiple sources. Fibres can be soluble or insoluble in water as well as viscous or nonviscous. Viscous soluble fibres, including oat beta-glucan, are the only fibres that have been shown to lower cholesterol[4]. Research studies have demonstrated that increasing soluble fibre intake by 5-10 g/day can reduce LDL cholesterol by 5%[5]. For greater LDL cholesterol reductions, the Therapeutic Lifestyle Changes (TLC) diet recommends soluble fibre intakes up to 25 g/day[4]. Considering that most individuals habitually consume less than 25 grams of fibre per day in total[6-12], methods to increase soluble fibre intake are needed.

Tate & Lyle's PromOat® Beta Glucan is a viscous soluble fibre made from non-genetically modified (non-GM) Swedish oats that can be added to foods and beverages to promote healthy cholesterol levels while increasing dietary fibre intake. Clinical studies have demonstrated additional health benefits associated with oat beta-glucan intake, such as maintaining health blood glucose levels, supporting gastrointestinal health, and assisting with weight management.

Figure 1

Adult fibre intakes by country[6-12]



Dietary fibre gap: Intakes vs. recommendations

Most dietary fibre recommendations for adults call for intakes ranging from 25-38 g/day depending on country-specific guidelines[2,7]. The World Health Organization (WHO) suggests worldwide recommendations of 25 g/day[7]. Figure 1 notes a wide range of fibre intakes across various countries against the recommended range for consumption[6-12]. In the United States (US), for most age and gender groups, less than 5% meet the dietary recommendations for fibre[13] despite consistent messaging to the public to increase dietary fibre intake. In the United Kingdom (UK), only 13% of women and 28% of men meet dietary fibre recommendations[12].

Data indicate that consumers believe fibre is important to health and that they recognize the lack of fibre in their diets[14], yet closing the fibre intake gap has not been easy, as many diets continue to lack adequate servings of fruits, vegetables, whole grains, and fibre-fortified foods. Recent innovations are making it easier for food manufacturers to fortify their products to help boost fibre content and close this intake gap. An abundance of research continues to demonstrate that fibres added to foods provide similar benefits as "intact" fibres inherent in whole foods.

Fibre Innovation for Health

Benefits

Oat beta-glucan has been tested by a number of independent researchers to demonstrate its physiological health benefits. The following are some highlights of the research on the health benefits of oat beta-glucan:

- **Promotes heart health by lowering blood cholesterol levels[16-20]**
- **Supports healthy blood glucose levels by eliciting a lower glycaemic response[21-23]**
- **Well tolerated and may support a healthy gut by producing short-chain fatty acids[24-26]**
- **May assist with weight management through calorie and fat reduction in foods and promotion of satiety[27-29]**

Fibre Innovation

While traditional sources of fibre like whole grains, fruits, and vegetables should be encouraged, fibres added to foods are also important contributors to dietary fibre intakes. Dietary fibres that are either extracted or synthesized nondigestible carbohydrates and have beneficial physiologic effects in humans are now available on the market; the US Institute of Medicine refers to these as functional fibres[2]. Fibres such as these are useful in developing products that have exceptional taste and appeal to the consumer while offering the same health benefits as fibres that are intact and naturally occurring in fruits, vegetables, and grains. Adding even small amounts of fibre to foods traditionally low in dietary fibre, resulting in amounts as low as 2.5-5.0 g/serving, could help individuals meet their fibre requirements without exceeding calorie needs[19].

PromOat® Beta Glucan is an example of a versatile functional fibre ingredient produced by Tate & Lyle and currently used in foods and beverages in North America, Europe, and Asia as a potential solution to increase fibre intake without sacrificing taste, texture, or enjoyment. Total daily intakes of beta-glucan as low as 3.0-4.0 g/day have been shown to promote health through maintenance of healthy blood cholesterol and blood glucose levels while helping to meet daily recommended fibre needs[19,20].

Characterization of PromOat® Beta Glucan

Beta-glucans from oats and barley are polysaccharides of linear, mixed linkage (1,3), (1,4)-beta-D-glucans. PromOat® Beta Glucan is concentrated beta-glucan derived from non-GM, Swedish oats, produced by a chemical-free, aqueous, enzymatic process. The final product is a fine, cream-colored powder with a caloric value of 3.2 kcal/g of ingredient. PromOat® Beta Glucan is a source of 35% oat soluble beta-glucan fibre by weight and contains small amounts of carbohydrate and protein; fat content is negligible (Table 1).

Oat beta-glucans from different sources can have a wide range of molecular weights, as processing conditions affect the final product. PromOat® Beta Glucan has a high molecular weight similar to native oat beta-glucan. The high molecular weight makes PromOat® Beta Glucan highly viscous. Many health benefits associated with oat beta-glucan are attributed to viscosity that increases with molecular weight[19,23,30].

PromOat® Beta Glucan has strong water-binding and emulsifying properties. It thickens and stabilizes emulsions, creating a smooth texture and creamy mouth feel in reduced-fat products. This ingredient can also lengthen the shelf life of food products due to improved moisture management, and it is acid- and heat-stable, which allows for easy integration into many food and beverage products.

Table 1

Nutritional content of PromOat® Beta Glucan[a]

	PromOat® Beta Glucan
Energy[b]	315 kcal or 1319 kj
Total fat	0.5 g
Saturated fat	< 0.1 g
Carbohydrate	56 g
Fibre (beta-glucan)[c]	35 g
Sugars	< 0.5 g
Protein	4 g
Sodium	< 25 mg

[a] Values per 100 g on a dry weight basis.
[b] Determined by calculation using 2 kcal/g for the soluble fibre portion. When using 4 kcal/g for the soluble fibre portion, the calculated calorie value is 385 kcal.
[c] Typical range: 34-36 g; minimum: 33 g.

Fibre Innovation for Health

Supports healthy blood cholesterol

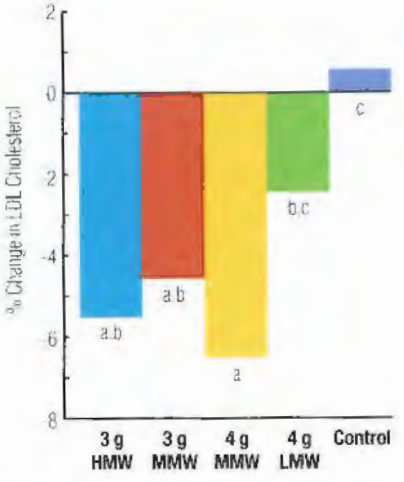
In 2012, the World Health Organization (WHO) reported that coronary heart disease (CHD) was the leading cause of mortality, resulting in 7.6 million deaths worldwide[31]. It is well established that reducing blood cholesterol reduces the risk of CHD, and the US National Cholesterol Education Program (NCEP)* estimates that each 1% reduction in LDL cholesterol reduces the risk of heart disease by 1-2%[5]. Several clinical studies have demonstrated that increasing intake of viscous soluble fibres like beta-glucan can effectively reduce LDL and total cholesterol. Three meta-analyses have summarized nearly 50 randomized controlled trials including 1,780 normo- and hypercholesterolaemic subjects completed between 1985 to 2007[16,17,32]. Overall, the data suggest that 3 g/day of beta-glucan can lower LDL cholesterol by 3-5% and total cholesterol by 2-4%[16,17,32]. This may result in a reduction in heart disease by 3-10%, with the greatest reductions occurring in those with higher starting cholesterol levels[16]. Additionally, the physicochemical properties of beta-glucans can impact the efficacy in lowering cholesterol. Oat beta-glucans with high molecular weight and solubility used at high concentrations are thought to be more viscous in the small intestine. This increased viscosity may reduce reabsorption of bile acids and increase the synthesis of new bile acids from cholesterol, thus reducing circulating LDL concentrations[33].

In weighing the totality of the evidence, the European Food Safety Authority (EFSA) issued a positive opinion for the ability of oat beta-glucans to lower blood cholesterol and reduce the risk of cardiovascular disease[16]. Several countries allow health claims or functional claims for beta-glucan and heart health/ cholesterol reduction. The claims are based on a daily consumption of 3 g beta-glucan, which in most cases can be divided among three to four servings of foods.

Even the most recent studies continue to support the findings that oat beta-glucan may promote the reduction of blood cholesterol. For example, Queenan et al. demonstrated that 6 g/day of oat beta-glucan significantly reduced LDL cholesterol in those with elevated cholesterol compared to a control[18]. Further, Wolever et al. demonstrated that both oat beta-glucan dose and molecular weight are critical in cholesterol lowering[19]. In this study, 3 g/day of a high molecular weight and 3 g/day and 4 g/day of a medium molecular weight oat beta-glucan significantly reduced LDL cholesterol compared to a wheat fibre control (Figure 2)[19]. PromOat® Beta Glucan is a high molecular weight beta-glucan.

Figure 2

Reduction in LDL cholesterol following four weeks of oat beta-glucan consumption[19]



Treatment groups with different letters are significantly different (P<0.05)
HMW = High molecular weight
MMW = Medium molecular weight
LMW=Low molecular weight

Favorable blood glucose and insulin response

The impact of oat beta-glucan on blood glucose and insulin responses has also been studied extensively over the past few decades. In 2011, EFSA determined that a cause and effect relationship has been established between the consumption of beta-glucans (from both oat and barley sources) and a reduction of postprandial glycaemic responses[21]. Their conclusion was based off of six key clinical trials that consistently demonstrated 'an effect of oat and barley beta-glucans in decreasing postprandial glycaemic responses, without disproportionately increasing postprandial insulinaemic responses, at doses of at least 4 g per 30 g of available carbohydrates[21].' Further, EFSA determined that the mechanism by which beta-glucans lower blood glucose has been well established[21]. Beta-glucans increase the viscosity of the meal bolus, thereby reducing the interaction between food and digestive enzymes in the stomach, delaying gastric emptying, and reducing absorption of glucose[21,22,33-36]. Because viscosity plays a large role in reducing blood glucose and insulin responses, differences in physicochemical properties of beta-glucans, such as molecular weight, may impact the magnitude of the effect.

*A program managed by the US National Institute of Health.

A recent review by Tosh concluded that the EFSA recommendation of including 4 g of beta-glucan per 30 g available carbohydrate may be too restrictive[27]. A total of 34 studies with 119 treatments including both oat and barley beta-glucan were included in this review. These studies were controlled, randomized, blinded, crossover, or parallel in design and included information on available carbohydrate dose, beta-glucan dose, and postprandial blood glucose response. Data were combined for oat and barley products as average reductions in area under the curve (AUC) for glycaemic response were not significantly different. Tosh found that glycaemic response was more strongly related to beta-glucan dose than the ratio of beta-glucan to available carbohydrate in processed foods. Including at least 4 g beta-glucan per ~30-80 g of available carbohydrate should significantly reduce postprandial glycaemic response[27].

Studies published after these reviews continue to provide evidence that beta-glucan can reduce postprandial glycaemic response and that the physicochemical properties of the beta-glucan consumed may impact the magnitude of the results. For example, Kwong et al. demonstrated that at a dose of 4 g, a high molecular weight, high viscosity beta-glucan was more effective at attenuating peak blood glucose rise than a low molecular weight, lower viscosity beta-glucan[28]. PromOat® Beta Glucan is a high molecular weight beta-glucan.

Weight management

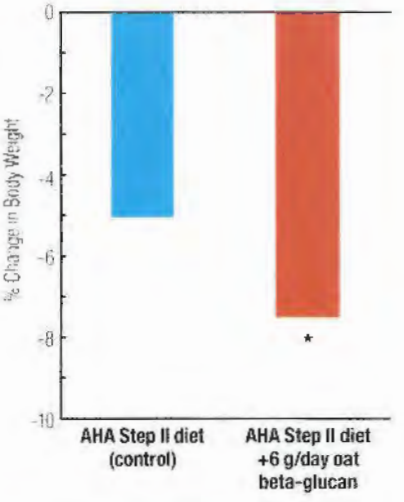
PromOat® Beta Glucan may help support weight management through enabling fat and calorie reduction in food formulations. Intake of beta-glucan may also promote satiety and/or reduced energy intake at a subsequent meal. For example, Beck et al.[27,28] observed that subjective satiety ratings significantly increased with an oat beta-glucan dose as low as 2.2 g and that appetite suppressant hormones cholecystokinin (CCK) and plasma peptide YY (PYY) were significantly increased in a dose-dependent manner when evaluating 0 g (control), 2.2 g, 3.8 g, and 5.5 g of beta-glucan for part or all of the study population. Energy intake at a subsequent meal was also reduced in subjects who consumed the highest dose of beta-glucan compared to the control. Although these energy intake results did not reach statistical significance, the absolute difference was greater than 400 kJ (~95 kcal) in a single meal, which is clinically relevant as it could equate to a 0.4 kg (0.9 lb) weight loss monthly if maintained[28].

Chronic studies provide a better indication of the long-term effects of oat beta-glucan on satiety and weight management. In a randomized, controlled, parallel-group study of an oat-derived beta-glucan extract, thirty-eight overweight men consumed the TLC/Step II diet** for eight weeks and bread with 6 g of beta-glucan or a whole wheat bread control[29]. The two breads were equivalent in energy, protein, fat, and carbohydrate, and energy intakes between the groups were similar overall. Both body weight and body mass index (BMI) were reduced by 7.5% in the oat beta-glucan group and 4.9% in the control group, resulting in a statistically significant difference between the two groups (Figure 3)[29].

While additional studies are needed, this emerging evidence suggests that oat beta-glucan may support weight management efforts through increased satiety, changes in satiety hormones, and reduced calorie intake.

Figure 3

Reduction in body weight after 6 g/day oat beta-glucan for eight weeks[29]



***Significant difference compared to control (P<0.002)**

** The TLC/Step II diet is recommend by the US NCEP and the American Heart Association for individuals with elevated blood cholesterol. The diet is reduced in fat, saturated fat, and cholesterol compared to a typical western diet.

Fibre Innovation for Health

Promotes GI health

Resists digestion and is fermented in the gut

Oat beta-glucan contains a mixture of β (1-3) and β (1-4) glucosidic linkages that reduce the digestibility of this ingredient[36-39]. Undigested beta-glucan serves as a valuable substrate for fermentation by colonic bacteria, leading to the production of the short chain fatty acids (SCFA) propionate, butyrate, and acetate. In vitro studies demonstrate that significantly greater production of butyrate occurs with fermentation of beta-glucan compared to inulin[24], FOS, psyllium, and corn arabinoxylan[25]. Increasing butyrate is desirable as it is the main energy source for colonocytes and has demonstrated anti-inflammatory and anticarcinogenic properties[40-41]. Propionate production was also enhanced in these studies[24,25], which may be beneficial due to links between this SCFA and satiety as well as inhibition of cholesterol synthesis[41,42]. Fermentation of oat beta-glucan has also been demonstrated in rats. Over a six week period, faecal pH was reduced and SCFA concentrations were increased in rats fed oat beta-glucan. Additionally, ammonia levels, β-glucuronidase activity, and azoreductase activity were reduced, suggesting that consumption of oat beta-glucan may reduce the concentration of toxic compounds in the colon[26]. Compared to many other fibres, the fermentation of oat beta-glucan is delayed, which may further promote colonic health by enhancing production of beneficial SCFA in the distal colon where toxic compounds from protein digestion are created and the majority of colon cancer lesions are seen[10,25,43], however, additional research is needed.

Good digestive tolerance

The majority of studies investigating the various health benefits of oat beta-glucan have been completed without reports of gastrointestinal disturbances. Oat beta-glucan is a well tolerated soluble fibre.

Use of PromOat® Beta Glucan in foods and beverages

PromOat® Beta Glucan can be used in a wide variety of foods and beverages including cereals, baked goods, soups, sauces, salad dressings, dips, smoothies, fruit juices, and sports drinks. Its contribution to the product's overall fibre would be included in the fibre listing on the nutrition information panel for food. Depending upon the recipe, usage level, and local regulations, products containing PromOat® Beta Glucan may be labelled as gluten-free*.

Current fibre intakes are very low among US adults, at about one-half of the US daily fibre recommendation of 25-38 g/day for women and men[2,44]. In other nations[3], average fibre intakes also fall well below recommended intakes. Diets high in fibre have been associated with lower risk of heart disease and improved blood glucose control while also supporting digestive health and laxation and aiding in weight management[45,46].

Consumption of foods and beverages made with PromOat® Beta Glucan can help close the fibre intake gap and may help to reduce calorie and fat intake. PromOat® Beta Glucan is well tolerated, and research suggests that it supports healthy cholesterol and blood glucose levels, may promote gastrointestinal health, and may help consumers maintain a healthy body weight.

To learn more about PromOat® Beta Glucan please visit www.promoat.com

* Labelling and claims may vary by country. Customers are advised to consult their own regulatory experts to determine appropriate labelling and claims for their products.

Innovating to Meet Nutrition, Health, and Wellness Needs Every Day

Nutrition professionals opportunity to educate consumers

Despite the fact that many consumers say that they are making efforts to consume diets high in dietary fibre and that they review labels for dietary fibre content when purchasing products, current fibre intakes remain low[14]. This has long-term implications for public health related to risk of coronary heart disease, stroke, hypertension, certain gastrointestinal disorders, obesity, and the continuum of metabolic dysfunctions including prediabetes and type 2 diabetes[1,4,7]. According to a 2014 food and health survey of US consumers by the International Food Information Council, 53% of individuals stated that they are trying to consume more dietary fibre[14]. Nutrition professionals can help to move consumers toward the goal of increasing fibre intake with education on benefits and sources of dietary fibre as consumers desire to make dietary changes.

Conclusions

While individuals should increase their consumption of dietary fibre from sources such as beans and peas, other vegetables, fruits, and whole grains[1], the incorporation of added fibre like PromOat® Beta Glucan into foods as part of a well-balanced diet can help individuals meet their recommended fibre intakes without exceeding their calorie needs. As a gently processed, high molecular weight, neutral tasting beta-glucan, Tate & Lyle's PromOat® Beta Glucan is uniquely positioned to be an ingredient that food manufacturers can use in the development of new and innovative products to meet the population's fibre needs and provide health benefits, including maintenance of healthy blood cholesterol and blood glucose, supporting gastrointestinal health, and potentially supporting weight management.

A commitment to innovation

Tate & Lyle, a global leader in wellness innovation, is committed to delivering innovative ingredients that can be incorporated into great-tasting foods to help consumers meet their nutrition, health, and wellness needs every day. That is because Tate & Lyle invests heavily in innovation and research and in developing ingredients that can be incorporated into a wide variety of great-tasting food and beverage solutions. Teams of food and nutrition scientists are continuously innovating, researching, and testing ingredients that will meet current and future health and nutrition needs.

At the same time, Tate & Lyle has a robust market research program designed to provide the necessary insights on consumer preferences around the world. The research program allows Tate & Lyle to customize its offerings and provide tailor-made solutions in local and regional markets.

Better-for-you ingredients for health and wellness

In response to global public health efforts calling for people to reduce calories and sodium and increase fibre intakes, Tate & Lyle offers a number of novel ingredient solutions that meet these needs.

Tate & Lyle's global Commercial and Food Innovation Center, Hoffman Estates, Illinois, USA

To learn more about Tate & Lyle ingredients and innovation as well as health benefits and relevant research, please visit www.foodnutritionknowledge.info and www.tateandlyle.com

TATE & LYLE

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Petition to Add to the National List 7 CFR 205.606: Oat Beta-Fiber

APPENDIX

Appendix 9A:

Oat Bran Concentrate Petition for Inclusion on the National List of Allowed Substances

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Petition for Inclusion on the National List of Allowed Substances

Vantage

OatVantage™
Oat Bran Concentrate

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October 10, 2007

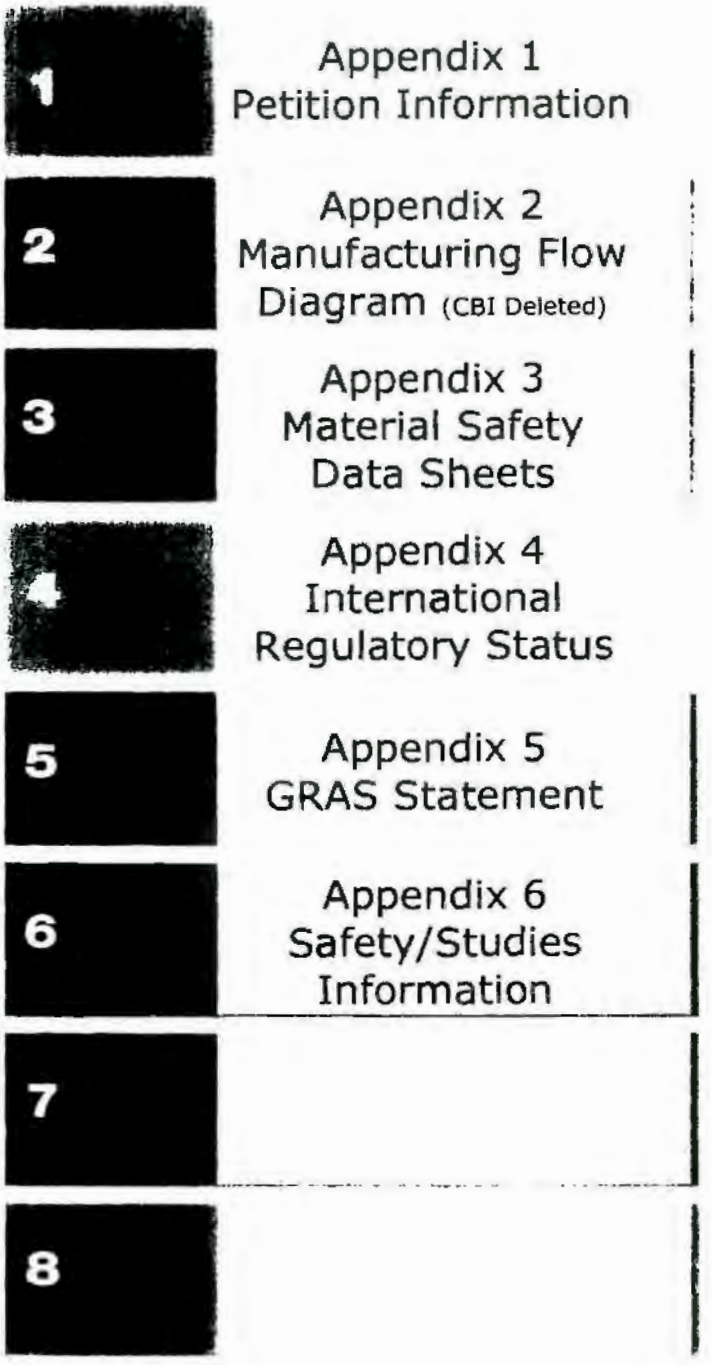
Program Manager, USDA/AMS/TM/NOP
Room 4008-So., Ag Stop 0268
1400 Independence Ave., SW.
Washington, DC 20250
Phone: 202-720-3532
Fax: 202-205-7808

Dear Program Manager:

Please find enclosed duplicate copies of GTC Nutrition's petition to have OatVantage™, oat bran concentrate included on the National List of Allowed Substances in Organic Production. If you have any questions or need additional information please contact me directly.

Sincerely,

Luke R. Kazmierski
Quality Assurance and Regulatory Affairs Specialist
GTC Nutrition
Phone: 303-216-2489
E-mail: lkazmierski@gtcnutrition.com


1
Appendix 1
Petition Information
2
Appendix 2
Manufacturing Flow
Diagram (CBI Deleted)
3
Appendix 3
Material Safety
Data Sheets
4
Appendix 4
International
Regulatory Status
5
Appendix 5
GRAS Statement
6
Appendix 6
Safety/Studies
Information
7
8

Item A:

Category: §205.606 Agricultural (nonorganic) nonsynthetic substances allowed in or on processed products labelled as "organic" or "made with organic (specified ingredients)."

Item B:

1. Common name of substance:
OatVantage™ (Oat Bran Concentrate), oat bran derived from oats, *Avena sativa*

2. Manufacturer's information:
GTC Nutrition
5840 Expressway
Missoula, MT 59808

3. Intended or current use:
Ingredient in food products

4. Handling activity:
OatVantage is normally added to other dry ingredients or liquids.

5. Source and manufacturing procedures:
The raw material is a naturally occurring oat bran derived from whole oats. The oat bran is milled to a concentrated form using a patented aqueous process. Please see attached flow chart (see Appendix 2).

6. Summary of previous regulatory reviews:
Oat bran has been approved by several regulatory bodies regarding health claims (see Appendix 4).

7. Information regarding regulatory registrations:
Oat bran is a well known food ingredient and Generally Recognized as Safe per 21 CFR 170.30(d) (see Appendix 5)

8. CAS number:
None

9. Chemical properties and mode of action

A) The substance, oat bran, is derived from whole oats and does not chemically react with other substances (see MSDS, Appendix 3).
B) There is no toxicity or environmental persistence as this is a naturally occurring oat bran source produced from whole oats.
C) This type of product has no significant effect on the human environment due to it being a naturally occurring oat bran source.
D) Effects on human health are attached (see Appendix 6). Generally the product is used for the improvement of human heart health.
E) Oat bran has no effect on soil organisms, crops or livestock.

10. Safety information:
MSDS attached (see Appendix 3)
GRAS Statement (see Appendix 5)

11. Research reviews provided:
The research reviews provided pertain to health benefits (see Appendix 6).

12. Petition justification statement:
The product falls under the category §205.606 Agricultural (nonorganic) nonsynthetic substances allowed in or on processed products labelled as "organic" or "made with organic (specified ingredients)." There are currently no organic equivalents of the product available. The product is not synthetic, it is a naturally occurring oat bran source produced from whole oats. Therefore OatVantage should be included on the National List, as it provides a valuable source of beta-glucan. OatVantage is easily incorporated into a wide range of foods, snacks, beverages and dietetic foods and leads to interesting documented health benefits at low inclusion levels.

13. Commercial confidential information statement:
The process flow chart for the manufacturing of OatVantage is considered confidential business information (CBI). This diagram is located in Appendix 2.

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: May 2008	Substance: Oat Bran Concentrate

Committee: Crops ☐ Livestock ☐ Handling X **Petition is for:** Inclusion of Oat Bran Concentrate on the National List § 205.606

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) — **Criteria Satisfied? (see B below)**

1.	Impact on Humans and Environment	Yes	X	No ☐	N/A	☐
2.	Essential & Availability Criteria	Yes	X	No ☐	N/A	☐
3.	Compatibility & Consistency	Yes	☐	No ☐	N/A	X
4.	Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes	☐	No X	N/A	☐

B. Substance Fails Criteria Category: 4 Comments: The petition did not provide information demonstrating that this material cannot be obtained organically in the appropriate form, quantity, or quality.

C. Proposed Annotation (if any): _____

_____

Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____

D. Recommended Committee Action & Vote (State Actual Motion): For Inclusion of Oat Bran Concentrate on the National List § 205.606

Motion by: Steve DeMuri *Seconded:* Joe Smillie *Yes:* 0 *No:* 6 *Absent:* 0 *Abstain:* 0

Crops		Agricultural	X	Allowed[1]		
Livestock		Non-Synthetic		Prohibited[2]		
Handling	X	Synthetic		Rejected[3]	X	
No restriction		Commercially Un-Available as Organic[1]		Deferred[4]		

1) Substance as "allowed" on 205._____with _____ voted to be added National List to § Annotation (if any)

_____

2) Substance to be added as "prohibited" on National List to § 205._____with Annotation (if any) _____

_____

Describe why a prohibited substance: _____

_____

3) Substance was rejected by vote for amending National List to § 205. 606 Describe why material was rejected: Material was rejected because the petition did not demonstrate why organic oat bran, which is widely available, cannot be processed into the needed form.

4) Substance was recommended to be deferred because _____

_____ If follow-up needed, who will follow up _____

E. Approved by Committee Chair to transmit to NOSB:

Julie Weisman — **Committee Chair**

April 2, 2008 — **Date**

NOSB Evaluation Criteria for Substances added to the National List

Category 1. Adverse impacts on humans or the environment? Substance - Oat Bran Concentrate

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		X		Per the attached MSDS appendix 3.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		Same as above
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Same as above
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		None listed in the petition, ingredient specification, or MSDS.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		This is an agricultural product, and petitioner claims it is inert.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		Substance is an agricultural product, is GRAS, and is intended as an ingredient of food products.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		Same as above
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		None per the MSDS.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		Same as above
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		Substance is an agricultural product, is GRAS, and is intended as an ingredient of food products.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		Substance is an agricultural product, is GRAS, and is intended as an ingredient of food products.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			Statement attached to the petition (Appendix 5), indicates it is GRAS under 21 CFR 170.30(d).
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		None listed in the MSDS attached to the petition.

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production? Substance - Oat Bran Concentrate

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]		X		The manufacturing process flow diagram is CBI deleted from the petition, but petitioner states the oat bran is milled to a concentrated form using a patented "aqueous" process.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		X		See above
3. Is the substance created by naturally occurring biological processes? [6502 (21)]			X	This is an agricultural product
4. Is there a natural source of the substance? [§205.600 b.1]			X	This is an agricultural product
5. Is there an organic substitute? [§205.600 b.1]			X	Material is being petitioned for inclusion on §205.606; see category 4 below.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	This is an agricultural product
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			X	This is an agricultural product
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			This is an agricultural product being petitioned for inclusion on §205.606.
9. Is there any alternative substances? [§6518 m.6]			X	
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]			X	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 3. Is the substance compatible with organic production practices? Substance - Oat Bran Concentrate

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			X	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]			X	
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]		X		Substance is a food ingredient intended for human heart health improvement.
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		X		
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;		X		
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?		X		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

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Petition to Add to the National List 7 CFR 205.606: Oat Beta-Fiber

APPENDIX

Appendix 9B:

NOSB Committee Recommendation: Oat Bran Concentrate, May 2008

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NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: May 2008	Substance: Oat Bran Concentrate

Committee: Crops ☐ Livestock ☐ Handling X Petition is for: Inclusion of Oat Bran Concentrate on the National List § 205.606

A. Evaluation Criteria (Applicability noted for each category; Documentation attached)

		Criteria Satisfied? (see B below)		
1.	Impact on Humans and Environment	Yes X	No ☐	N/A ☐
2.	Essential & Availability Criteria	Yes X	No ☐	N/A ☐
3.	Compatibility & Consistency	Yes ☐	No ☐	N/A X
4.	Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes ☐	No X	N/A ☐

B. Substance Fails Criteria Category: 4 Comments: The petition did not provide information demonstrating that this material cannot be obtained organically in the appropriate form, quantity, or quality.

C. Proposed Annotation (if any): _____

_____

Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____

D. Recommended Committee Action & Vote (State Actual Motion): For Inclusion of Oat Bran Concentrate on the National List § 205.606

Motion by: Steve DeMuri *Seconded:* Joe Smillie *Yes:* 0 *No:* 6 *Absent:* 0 *Abstain:* 0

Crops		Agricultural	X	Allowed[1]	
Livestock		Non-Synthetic		Prohibited[2]	
Handling	X	Synthetic		Rejected[3]	X
No restriction		Commercially Un-Available as Organic[1]		Deferred[4]	

1) Substance as "allowed" on 205._____with _____ voted to be added National List to § Annotation (if any)

_____

2) Substance to be added as "prohibited" on National List to § 205._____with Annotation (if any) _____

_____

Describe why a prohibited substance: _____

_____

3) Substance was rejected by vote for amending National List to § 205. 606 Describe why material was rejected: Material was rejected because the petition did not demonstrate why organic oat bran, which is widely available, cannot be processed into the needed form.

4) Substance was recommended to be deferred because _____

_____ If follow-up needed, who will follow up _____

E. Approved by Committee Chair to transmit to NOSB:

Julie Weisman
Committee Chair

April 2, 2008
Date

NOSB Evaluation Criteria for Substances added to the National List

Category 1. Adverse impacts on humans or the environment? Substance - Oat Bran Concentrate

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		X		Per the attached MSDS appendix 3.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		Same as above
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Same as above
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		None listed in the petition, ingredient specification, or MSDS.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		This is an agricultural product, and petitioner claims it is inert.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		Substance is an agricultural product, is GRAS, and is intended as an ingredient of food products.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		Same as above
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		None per the MSDS.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		Same as above
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		Substance is an agricultural product, is GRAS, and is intended as an ingredient of food products.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		Substance is an agricultural product, is GRAS, and is intended as an ingredient of food products.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			Statement attached to the petition (Appendix 5), indicates it is GRAS under 21 CFR 170.30(d).
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		None listed in the MSDS attached to the petition.

[1] If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production? Substance - Oat Bran Concentrate

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]		X		The manufacturing process flow diagram is CBI deleted from the petition, but petitioner states the oat bran is milled to a concentrated form using a patented "aqueous" process.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		X		See above
3. Is the substance created by naturally occurring biological processes? [6502 (21)]			X	This is an agricultural product
4. Is there a natural source of the substance? [§205.600 b.1]			X	This is an agricultural product
5. Is there an organic substitute? [§205.600 b.1]			X	Material is being petitioned for inclusion on §205.606; see category 4 below.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	This is an agricultural product
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			X	This is an agricultural product
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			This is an agricultural product being petitioned for inclusion on §205.606.
9. Is there any alternative substances? [§6518 m.6]			X	
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]			X	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 3. Is the substance compatible with organic production practices? Substance - Oat Bran Concentrate

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			X	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]			X	
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]		X		Substance is a food ingredient intended for human heart health improvement.
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		X		
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;		X		
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?		X		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)] **- Oat Bran Concentrate**

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?		X		Petition did not provide sufficient comparative information explaining why the non-organic form of the material is necessary for use in organic handling
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?		X		No information was provided in the petition demonstrating the unavailability of raw organic oat bran for further processing, nor of the absence of processors to manufacture the oat bran concentrate. An internet search by the evaluator, and phone calls to several suppliers by the evaluator, indicated that organic oat bran is commercially available.
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?		X		No information provided.
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?		X		No information provided.
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following: a. Regions of production (including factors such as climate and number of regions);		X		No information provided.
b. Number of suppliers and amount produced;		X		No information provided.
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;		X		No information provided.
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		X		No information provided.
e. Are there other issues which may present a challenge to a consistent supply?		X		No information provided.