GR

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May 21, 2010

RECEIVED
MAY 26 2010
Division of Biotechnology and GRAS Notice Review

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

Re: GRAS Notice for Oat Hull Fiber

Dear Sirs:

On Behalf of our client, JP Rettenmaier USA LP, we are hereby submitting the enclosed GRAS Notice for the use of Oat Hull Fiber as an ingredient in comminuted meat and both whole muscle and comminuted poultry products. In compliance with 21 C.F.R. 170.36(b) (proposed), we are enclosing 3 copies of this Notice.

Should you have any questions regarding this submission, please do not hesitate to contact me.

Sincerely,

(b) (6)

Mark L. Itzkoff

MLI:akp
Enclosure

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May 19, 2010

GRAS NOTIFICATION

I. Claim of GRAS Status

A. Claim of Exemption from the Requirement for Premarket Approval Requirements Pursuant to Proposed 21 CFR § 170.36(c)(1)

J. Rettenmaier USA LP has determined that oat hull fiber (Vitacel® Isolated Oat Product) is Generally Recognized As Safe (GRAS) for use as an ingredient in comminuted meat and in both whole muscle and comminuted poultry products, consistent with Section 201(s) of the *Federal Food, Drug, and Cosmetic Act*. This determination is based on scientific procedures as described in the following sections, under the conditions of its intended use in selected food. Therefore, the use of Isolated Oat Product is exempt from the requirement of premarket approval.

Signed,

(b) (6)

5/19/10

Mark L. Itzkoff Date

Counsel for

J. Rettenmaier USA LP
16369 US 131 Hwy
Schoolcraft, MI 49087
USA

B. Name and Address of Notifier:

Curtis Rath
J. Rettenmaier USA LP
16369 US 131 Hwy
Schoolcraft, MI 49087
USA

Telephone: 269-679-2490
Fax: 269-679-2364
Email: crath@jrsusa.com

C. Common or usual name of the notified substance:

Oat Fiber; Isolated Oat Product

D. Conditions of use:

Isolated Oat Product containing 85% oat fiber is intended for use as a food ingredient in meat (sausage) and poultry (comminuted and whole muscle products) at levels consistent with current Good Manufacturing Practice and is self limiting for technological reasons. Use of Isolated Oat Product improves the texture, controls moisture migration, and improves stability of the food product. The intended use of Vitacel® Isolated Oat Product (containing 85% fiber) in above mentioned food categories is estimated to result in a maximum daily (90th percentile) intake of 5.78 g oat fiber/person.

E. Basis for GRAS Determination:

In accordance with 21 CFR 170.30, the intended use of Isolated Oat Product has been determined to be generally recognized as safe (GRAS) based on scientific procedures. A comprehensive search of the scientific literature on oat hull fiber and other related fiber was also utilized for this review. Oat hulls are a component of whole grain oats that contain a high level of insoluble fiber in the form of celluloses and hemicelluloses. Vitacel® Isolated Oat Product contains approximately 85% dietary fiber.

Oats have been used as human food since ancient times, particularly in Scottish culinary traditions. Oatmeal along with its fiber portion has been consumed for centuries. Available information suggest that in spite of differences in the proportionality of the oat kernel components among the parts of the kernel, the oat kernel components are common throughout various parts of the kernel, including the oat groat, bran, and hull. The similarity of the composition of the oat hull with that of other edible oat tissues (groat and bran) and the safety data of oat groat and bran tissues along with human and animal studies of oat hull fiber supports the safety of oat hull fiber for use as a food ingredient. Sufficient qualitative and quantitative scientific evidence, including human and animal data are available to determine safety-in-use for oat hull fiber. The safety determination of Isolated Oat Product is

based on human observations including clinical experimental studies on oat hull fiber and other similar fibers.

According to the USDA Nutrient Database for Standard Reference (NDSR, 2009), the reference serving sizes for frankfurters or sausages is 55 g, and for meat patties or canned meats is 85 g. Therefore, a serving of these foods containing the maximum intended level (3.5%) of Vitacel® Isolated Oat Product would contain about 1.8 g and 3.0 g of oat hull fiber, respectively. As Vitacel® Oat Product contains 85% fiber, the intake of fiber from these foods would be 1.50 and 2.57 g/person/day. Similarly according to NDSR, (2009) the reference serving sizes for "chicken, breaded and fried, boneless pieces, plain" is 96 g, and for "chicken fillet sandwich, plain" is 182 g. Therefore, a serving of these foods containing the maximum intended level (3.5%) would contain about 3.36 g and 6.37 g of Isolated Oat Product, respectively. As Vitacel® Isolated Oat Product contains 85% fiber, the intake of fiber from these foods would be 2.86 g and 5.41 g/person/day.

Based on USDA Continuing Survey of Food Intakes by Individuals (CSFII) surveys for quantities of foods consumed daily, the mean and 90th percentile quantities of sausage (pork breakfast) consumption is 44 and 80 g/person/day. The CSFII data does not provide the intake of poultry (comminuted and whole muscle products). However, the mean and 90th percentile intake of total chicken and poultry is reported as 96 and 194 g/person/day. As consumers are unlikely to consume meat products and poultry products together, the higher values of total chicken and poultry can be considered for exposure estimates. The intended use of Vitacel® Isolated Oat Product at levels of 3.5% will result in mean and 90th percentile intake of 3.4 and 6.8 g/person/day, respectively. As Vitacel® Oat Product contains 85% fiber, the mean and 90th percentile intake of fiber from the intended uses will be 2.88 and 5.78 g/person/day. For safety assessment purposes the maximum intake of oat hull fiber is considered as 5.78 g/person/day. However, the actual intake from the intended uses in sausages or poultry is expected to be much lower.

Isolated Oat Hulls has recently received "FDA has no Questions" letter for the GRAS notice GRN 000261 (2009). In the notice, oat hull fiber GRAS determination was undertaken through scientific procedures, for use (1) as an ingredient in bread/pizza crust, cookies/crackers/bars, cereal (hot and cold), baby food cereal, and snacks (fried and baked) at levels ranging from 5 percent to 14 percent by weight; (2) as an ingredient in breading and batters applied in coating onto meat and poultry at levels ranging from 2 percent by weight of the total food system (breaded or coated meats) to 5 percent by weight of the dry coating system (breading and batter); and (3) as an extender in meat products at levels ranging from 3 percent to 5 percent. In the notice, oat hull fiber was proposed to be used at a rate of between 2-5 g/50 g serving for a total dietary consumption of 21-28 g/day. Compared to GRN 000261, the estimated daily intake from the current intended use levels of Isolated Oat Product are ~4-fold lower. Additionally, the intended uses of oat hull fiber in the specified food categories are substitutional and lower than those reported in GRN 000261.

On the basis of scientific procedures[1], J. Rettenmaier USA LP considers the consumption of Isolated Oat Product as an added food ingredient to be safe at levels up to 5.78 g/day. The estimated daily intake of Isolated Oat Product from its intended uses is well below the safe or recommended levels of intake of dietary fibers (up to 38 g/day for men and 25 g/day for women) from human observations where no adverse effects were noted. In the GRAS notice (GRN 000261) intake of oat hull fiber at 21-28 g/day was determined as safe. The estimated daily intake of Isolated Oat Product from the intended use levels of Vitacel® Isolated Oat Product, if ingested daily over a lifetime, is considered safe.

F. Availability of Information:

The data and information that form the basis for this GRAS determination will be sent to U.S. Food and Drug Administration (FDA) up on request or will be available for FDA review and copying at reasonable times at the offices of:

Olsson Frank Weeda Terman Bode Matz PC
1400 Sixteenth St., NW
Washington, DC 20036

II. Detailed Information About the Identity of the Notified Substance:

A. Chemical name

Oat hull fiber consisting of: Cellulose (70%), Hemicellulose (25%), and Lignin (max 5%).

B. Trade Name:

The subject of this notification will be marketed as Vitacel® Isolated Oat Product

C. Chemical Abstract Registry Number:

None. The product is a naturally occurring fiber.

D. Chemical Formula:

The empirical formula of cellulose molecule is $(C_6H_{10}O_5)_n$.

[1] 21 CFR §170.3 Definitions. (h) Scientific procedures include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance.

E. Structure:

Cellulose: a polysaccharide consisting of a linear chain of several hundred to over ten thousand β-(1→4) linked D-glucose units (Figure 1).

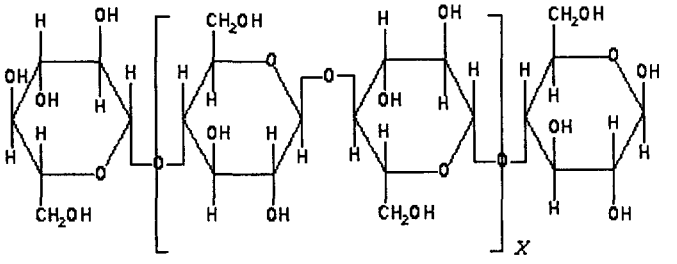

Figure 1. Chemical structure of cellulose

Hemicellulose (25%): is a heteropolymer present in almost all plant cell walls along with cellulose. While cellulose is crystalline, strong, and resistant to hydrolysis, hemicellulose has a random, amorphous structure with little strength. Unlike cellulose, hemicellulose (also a polysaccharide) consists of shorter chains - 500-3000 sugar units as opposed to 7,000 - 15,000 glucose molecules per polymer seen in cellulose. In addition, hemicellulose is a branched polymer, while cellulose is unbranched. Hemicellulose consists of short, highly branched chains of sugars. In contrast to cellulose, which is a polymer of only glucose, a hemicellulose is a polymer of five different sugars.

Lignin (5%): is a complex chemical compound, commonly derived from wood and an integral part of the secondary cell walls of plants.

F. Physical Characteristics

Vitacel® Isolated Oat Product is a bright, dietary fiber produced by a special process from oats.

G. Typical Composition and Specifications

Typical food grade specifications of Vitacel® Isolated Oat Product are presented in Table 1. Complete compositional and nutritional analysis of Isolated Oat Product (mean from three separate batches) is summarized in Table 2. Analytical results of five non-consecutive batches and nutritional composition from three batches is presented in Appendix I and II, respectively.

Table 1. Typical specifications for Vitacel® Isolated Oat Product

	Specification	Assay method
Description	Tan to off-white powder	Visual
pH value	5 - 7	10% suspension
Moisture	8% Max.	105°C/2 hr
Ash	5% Max.	850°C/4 hr
Bulk density	100 – 170 g/L	DIN 53-468
Total dietary fiber	~87%	AOAC 985.29
Insoluble fiber	~84%	AOAC
Soluble fiber	~3 %	AOAC
Heavy metals		
Lead	0.18 ppm Max	§ 64 LFGB
Mercury	0.01 ppm Max	§ 64 LFGB
Arsenic	0.1 ppm Max	§ 64 LFGB
Cadmium	0.05 ppm Max	§ 64 LFGB
Microbiological parameters		
Aerobic plate count	1×10^3 cfu/g (max)	AOAC 17th 990.12
Yeasts and molds	2×10^2 cfu/g (max)	AOAC 17th 997.02
Salmonella	Negative/ 25 g	AOAC 17th BAM 8th

ppm = parts per million

Table 2. Compositional and nutritional analysis of Isolated Oat Product

Parameter	Value
Carbohydrates, Available (%)	3
Carbohydrates, Total (%)	88
Fiber group	
Total dietary fiber (%)	87
Insoluble fiber (%)	84
Soluble fiber (%)	2.6
Sugars (%)	0.0
Protein by Dumas (F=6.25)	1.52
Vitamin C- Total (mg/100 g)	1.5
Sodium (mg/100 g)	90
Calcium (mg/100 g)	78
Iron (mg/100 g)	2.2
Moisture by Forced Air 1 hr (%)	7.2
Fatty acid analysis w/profile (%)	
Total fat (%)	0.25
Saturated fat (%)	0.10
Monounsaturated fat (%)	0.11
Cis-cis polyunsaturated fat (%)	0.53
Trans-fat (%)	0.00
Calories (fiber subtracted)/ 100 g	21
Calories from fat/ 100 g	2

Table 2. Compositional and nutritional analysis of Isolated Oat Product

Parameter	Value
Calories from saturated/ 100 g fat	1

H. Manufacturing process

(b) (4)

I. Manufacturing process diagram

(b) (4)

J. Intended Technical Effects

Isolated Oat Product is intended for addition to a limited number of conventional foods as a formulation aid (binder) [21 CFR 170.3(o)(14)][2]. Due to its neutral and inert character as well as fiber length, Vitacel® oat fiber can be used in foods without sensory interference. Addition of Isolated Oat Product to foods improves the texture, controls moisture migration, and improves stability of the food product. Its use is intended at the levels identified in this document for addition to meat and poultry products. It is recognized that there are Standard of Identity requirements, located in Title 21 of the Code of Federal Regulations, and as such, J. Rettenmaier USA LP does not intend to refer to them by the commonly recognized names.

III. Summary of the Basis for the Notifier's Determination that isolated Oat Product is GRAS

A comprehensive search of the scientific literature for safety and toxicity information on Isolated Oat Product and other related fibers was conducted through November 2009 and was also utilized for this review. Based on a critical evaluation of the pertinent data and information summarized here, J. Rettenmaier USA LP has determined by scientific procedures that the addition of Isolated Oat Product to meat and poultry products when not otherwise precluded by a Standard of Identity meeting the specification cited above and manufactured according to current Good Manufacturing Practice, is Generally Recognized As Safe (GRAS) under the conditions of intended use in selected foods, as specified herein.

In coming to its decision that Isolated Oat Product is GRAS, J. Rettenmaier USA LP relied upon the conclusions that neither Isolated Oat Product nor any of its constituents pose any toxicological hazards or safety concerns at the intended use levels, as well as on published safety studies and other articles relating to the safety of the product. Other qualified and competent scientists, reviewing the same publicly available toxicological and safety information, would reach the same conclusion.

IV. Basis for a Conclusion that Isolated Oat Product is GRAS for its Intended Use

[2] *Formulation aids*: Substances used to promote or produce a desired physical state or texture in food, including carriers, binders, fillers, plasticizers, film-formers, and tableting aids, etc.

TABLE OF CONTENTS

1. Introduction 10

1.1. Background 10

1.2. Description, Manufacturing and Specifications 10

1.3. Intake from Natural Presence in Food 11

1.3.1. Estimated Daily Intake from the Intended Uses 11

2. SAFETY OF ISOLATED OAT PRODUCT 11

2.1. Common Knowledge of Safe Use 11

2.2. Safety Studies of Oat and Other Fibers 13

2.3. Allerginicity 15

2.4. Dietary Fiber Adverse Effects Reported by IOM 16

3. Summary 16

4. Conclusion 17

5. References 18

6. Appendix I 21

1. Introduction

A comprehensive search of the scientific literature for safety and toxicity information on oat fiber, oat hull fiber and other related fibers was conducted through November 2009 by J. Rettenmaier USA LP to determine the Generally Recognized As Safe (GRAS) status of Vitacel® Isolated Oat Product as a formulation aid [21 CFR 170.3(o)(14)][3] in meat (sausages) and poultry products at use levels of up to 3.5%.

1.1. Background

Oat like all other grain varieties belongs to the Poaceae (Gramineae) family. *Avena savita* L (common oat) is the most important among cultivated oats. Oats are a hardy cereal grain that can withstand poor soil conditions in which other crops are unable to thrive. The distinctive flavor of oats is gained from the roasting process after harvesting and cleaning. Following roasting, oats are hulled, however this process does not strip away their bran and germ allowing them to retain a concentrated source of their fiber and nutrients. In foods, oats are used as a grain or cereal. A high daily intake of oat bran and other food sources rich in fiber has been claimed for several health benefits. Whole oats and oat bran are used for several health conditions such as high cholesterol; high blood pressure; diabetes; and digestion problems including diverticulosis, irritable bowel syndrome, inflammatory bowel disease, diarrhea, and constipation. The health benefits of oat products are reported to be primarily due to its fiber content. Majority of these beneficial effects are claimed to be related to the soluble oat fiber. Traditionally the hulls are discarded but in recent years oat hull fiber has been gaining popularity as a source of dietary fiber. Miller et al. (2000) reported that processed oat hull fiber had a high antioxidant activity. As an insoluble dietary fiber with a total dietary fiber content of up to 85%, oat husk fiber combines nutritional-physiological advantages (such as dietary fiber enrichment, calorie and fat reduction, calorific value reduction, etc.) with the technological advantages (such as texture improvement, control of moisture migration, reduced weight loss, etc.) in a perfect way. Given its beneficial properties, J. Rettenmaier & Sons intends to use standardized Vitacel® Isolated Oat Product as a formulation aid (binder) in selected food products.

1.2. Description, Manufacturing and Specifications

Vitacel® Isolated Oat Product is a bright, (fine)-grained dietary fiber concentrate extracted from oat spelt bran. Typical food grade specifications and compositional analysis of Vitacel® Isolated Oat Product from J. Rettenmaier USA LP are presented in Table 1 and 2, respectively. Analytical results of five lots from non-consecutive batches indicate that the product consistently meets these specifications (Appendix I). Vitacel® Isolated Oat Product is manufactured (Figure 2) according to current Good Manufacturing Practices. Rettenmaier USA LP utilizes a HACCP-controlled manufacturing process and rigorously tests its final production batches to verify adherence to quality control specifications.

Vitacel® Oat Isolated Product is gluten-free, phytic acid-free and, GMO-free. The product meets the regulatory prescribed minimum values for pesticide and bioburden (cfu) and these values are extremely low and far below the requirements. The well optimized manufacturing process assures product safety and a longer shelf-life of 5 years when stored under dry conditions.

---

[3] *Formulation aids*: Substances used to promote or produce a desired physical state or texture in food, including carriers, binders, fillers, plasticizers, film-formers, and tableting aids, etc.

1.3. Intake from Natural Presence in Food

The U.S. Department of Agriculture collected the food intake data and published the intake of different foods (CFSII, 1994-96) (Smiciklas-Wright et al., 2002). This report includes intake of oatmeal as cooked cereal, hot cereal, and ready-to-eat cereal. It is likely that in these products oat hull fiber may not be used but some ready-to-eat cereals and other products may contain oat hull fiber. The daily mean and 90th percentile consumption for oatmeal was reported as 267 and 456 g/person/day, respectively. Considering that oatmeal contains 1.7% fiber the mean and 90th percentile intake of fiber from oatmeal will be 4.5 and 7.7 g/person/day. It is likely that majority of this is soluble fiber from oat.

1.3.1. Estimated Daily Intake from the Intended Uses

J. Rettenmaier USA LP intends to use Isolated Oat Product in meat (sausage) and poultry (comminuted and whole muscle products) at a use level of 3.5%. Based on USDA CSFII surveys (Smiciklas-Wright et al., 2002) for quantities of foods consumed daily, the mean and 90th percentile quantities of sausage (pork breakfast) consumption is 44 and 80 g/person/day. The CSFII data does not provide the intake of poultry (comminuted and whole muscle products) but the mean and 90th percentile intake of total chicken and poultry is reported as 96 and 194 g/person/day. It can be assumed that consumers are unlikely to consume meat products and poultry products together. Hence, the higher values of total chicken and poultry can be considered for exposure estimates. The intended use of Vitacel® Isolated Oat Product at levels of 3.5% will result in mean and 90th percentile intake of 3.4 and 6.8 g/person/day, respectively. As Vitacel® Isolated Oat Product contains 85% fiber, the mean and 90th percentile intake of fiber from the intended uses will be 2.88 and 5.78 g/person/day. For safety determination the maximum intake of oat hull fiber is considered as 5.78 g/person/day. However, the actual intake from the intended uses in sausages or tender chicken is expected to be much lower.

2. SAFETY OF ISOLATED OAT PRODUCT

2.1. Common Knowledge of Safe Use

There is common knowledge of a long history of human consumption of oat as a food. The present day oat draws its ancestry from the wild red oat, a plant that originated in Asia. For over two thousand years oats have been cultivated in various parts of the world. In Europe cultivation of oats was widespread, and oats constituted an important commercial crop since they were a dietary staple for the people of many countries including Scotland, Great Britain, Germany and the Scandinavian countries. This staple was brought to North America in the early 17th century by Scottish settlers. At present, the largest commercial producers of oats include the United States, Russian, Germany, Canada, France, Poland, Finland and Australia. Based on recent USDA consumption (per capita) data, Canada ranks the number one consumer oat products followed by Australia and Russia. The USDA national Nutrient Database (NDSR, 2009) has listed 139 food products that contain oat.

Oats are primarily used as livestock feed (EB, 2008). In addition to this, oats are processed for human consumption, especially as breakfast foods. Rolled oats, flattened kernels with the hulls removed, are commonly used for oatmeal. The oat groats kernels with husks removed, but unflattened are used in the preparation of other breakfast foods. The difference between the bran layers and the oat hulls resides

primarily in the occurrence of different tissue components. The textural variability, i.e., inflexible versus flexible configurations of the non-starchy polysaccharides is created by different tissue components

(Marlett, 1993). Although the proportionality of the oat kernel components differs among the parts of the kernel, available information suggest that the oat kernel components are common throughout various parts of the kernel, including the oat groat, bran, and hull. The traditionally recognized palatable "edible" portion of the whole oat contains certain tissues, e.g., strands of celluloses, hemicelluloses and pentosans (xylans in particular) that are unevenly distributed throughout the whole kernel, including the oat groat (dehulled oat). The compositional similarity between oat hull and other edible oat tissues (groat and bran) suggest that safety data of oat groat and bran tissues is applicable to oat hull fiber for use as a food ingredient.

Oat flour is used to make cookies and puddings. Oat grains are high in carbohydrates and contain about 13% protein and 7.5% fat. Oats also contain vitamins and minerals such as calcium, iron, vitamin B1, and nicotinic acid that have been identified as vital to human nutrition. Oat hulls contain a high level of insoluble fiber in the form of cellulose and hemicelluloses. In recent years oat fiber has risen in its popularity as a highly desirable food ingredient in several finished food products such as Oat Fiber enriched bakery goods, Ready-to-Eat cereals, energy bars, reduced and low calorie meal-replacement products, etc. Traditionally, oat hulls have been discarded during processing, but the need for concentrated, insoluble fiber sources for human consumption has resulted in the production of oat hull fiber for human food use. The lack of use of oat hulls in food applications was primarily because of its crystalline texture. The manufacturing process developed by J Rettenmaier USA LP leads to production of Isolated Oat Product that has neutral and inert character and can be used in foods without sensory interference.

Health Canada (2002) has classified oat hull fiber as a novel fiber source that is acceptable for use in grain and bakery products. In its Dietary Guidelines for Americans, the U.S. Department of Health and Human Services (HHS) and USDA (HHS/USDA, 2005) recommends that all adults eat half their grains as whole grains, which includes oats and whole wheat. These guidelines recommend the daily intake of dietary fiber to be 14 grams/1000 calories, which is approximately 20-35 g fiber/day. The food sources of dietary fiber include legumes, nuts, whole grains, bran products, fruits, and non-starchy vegetables. All plant-based foods contain mixtures of soluble and insoluble fiber. There is consistent evidence from clinical trials that fiber-rich diets are associated with significant reductions in cardiovascular disease risk. Given this evidence, the Food and Nutrition Board of the Institute of Medicine established its first recommended intake levels for fiber in 2001 (IOM, 2002). For adults (≤50 years of age), the adequate intake recommendation for total fiber is 38 g/day for men and 25 g/day for women. For adults (≥50 years of age), the recommendation is 30 g/day for men and 21 g/day for women. The daily reference value for dietary fiber is 25 g (for a 2000 calorie diet) [21 CFR 101.9(d)]. Dietary fiber intakes in the U.S. average from 16-18 g/day for men and 12-14 g/day for women, which are well below recommended intake levels (IOM, 2002).

There are numerous scientific studies that investigated the health effects of soluble and insoluble oat fiber. None of these studies reveal any safety concern following consumption of oat fiber containing products (Goldeano and Grossman, 2006; Garcia and McGregor, 1998). In addition to this, a number of over-the-counter laxative products including Metamucil have been marketed for decades without any significant adverse effects. The available information demonstrates that there is common knowledge of the health benefits associated with the consumption of the fiber, including oat products. The available information also

suggests that oats are commonly consumed from diet and there are no reported adverse effects from its consumption as a food.

2.2. Safety Studies of Oat and Other Fibers

Oat hulls are a component of whole grain oats that contain a high level of insoluble fiber in the form of celluloses and hemicelluloses. Oat grain's safety is well-established based on its use as a food. The composition of the oat kernel and its parts, including the bran layers and the hulk are described in several published studies (Marlett, 1993). As oat fiber and oat hulls are considered safe, no standard experimental animal safety studies on oat fiber were found in the published literature. However in several human and animal published studies efficacy of oat hull fiber has been investigated. In some of these reports, as part of the study design adverse events were recorded. Studies to date do not provide evidence of any significant adverse effects related to oat fiber.

In a controlled study, Stephen et al. (1997) investigated the effects oat hull fiber on colonic function and serum lipids. In this study, 10 healthy males, aged 20-37 years consumed for two 3-week periods, a controlled low fiber diet (13.1 g of nonstarch polysaccharide (NSP)/day), and the same diet with 25 g of oat hull fiber/day incorporated into foods, providing 17 g of NSP/day. A significant increase in fecal weight was noted following ingestion of oat hull fiber without any change in transit time or serum lipids. Fermentation of oat hull fiber was studied by analysis of feces for NSP. Excretion of NSP increased from 2.0 g/day to 19.7 g/day, indicating that no degradation occurred. The results of this study indicate that oat hull fiber appears to be resistant to fermentation in the human colon, has no effect on serum lipids, and provides no energy to the body. No subjects reported any adverse gastrointestinal effects following consumption of oat hull fiber, although several reported more constipation on the control diet than on their usual diets.

In an unpublished controlled, randomized, partially blind, crossover study reported in GRN 000261, safety and physiological effects (laxation and glycemic response) of oat hull fiber were investigated. In this study, 8 males and 12 females, aged 22-61 years (average 41.25 years) were given basic white bread with added oat hull fiber and basic cornflake cereal with added oat hull fiber as the test foods for 21 weeks. The test foods were compared against a negative control diet (fiber-unsupplemented cornflakes and fiber unsupplemented white bread) and a positive control diet [American Association of Cereal Chemists (AACC) wheat bran supplemented cornflakes and AACC wheat bran supplemented white bread]. All the fiber-supplemented diets were formulated to add a further 6-7 g fiber to a 50 g portion of cereal or a 60 g slice of white bread. Study subjects were instructed to record any adverse events. These events were minor and consisted of gas, cramps, sore/upset stomach, problems with bowel movements, bloating, headache, heartburn, loose stools/diarrhea. There was no pattern of adverse events on any particular diet, and none of the symptoms lasted more than a day or two. No subjects dropped out or presented any adverse events at dosage levels of 7 g/50 g serving, for a total recommended daily dosage of 20 g of fiber. The results of this study suggest that oat hull fiber is a safe source of dietary fiber.

In a randomized, controlled, single-blind, cross-over study, Weickert et al. (2006) investigated the effects of insoluble cereal fiber intake on whole-body insulin sensitivity. In this study, 17 overweight or obese subjects with normal glucose metabolism consumed nine macronutrient-matched portions of fiber-enriched bread (white bread enriched with 31.2 g insoluble oat fiber/day; 10.4 g insoluble fiber per portion at breakfast, lunch and dinner) or control (white bread) over a time period of 3 days and whole-body insulin sensitivity was assessed by euglycemic-hyperinsulinemic clamp. The oat fiber used in this study Vitacel® OF 101 was provided by Rettenmaier & Sohne, Rosenberg, Germany. The results of this showed a significantly improved

whole-body insulin sensitivity following intake of insoluble dietary fiber for 3 days. No side effects or adverse events were reported by any of the participants.

Both soluble and insoluble fibers are not digested in the human gastrointestinal track. Soluble fiber absorbs water to become a gelatinous, viscous substance and is fermented by bacteria in the digestive tract. Insoluble fiber has bulking action and is not fermented (Anderson et al., 2009). They are therefore not absorbed into the bloodstream. Instead of being used for energy, fiber is excreted from human gastrointestinal track. Insoluble fiber promotes regular bowel movement and prevents constipation. Several published studies have primarily focused on soluble fibers such as oats, psyllium, pectin, and guar gum, and qualitative reviews suggested that these fibers lower total and LDL cholesterol. Vitacel® Isolated Oat Product contains a small amount of (~3%) of soluble fiber. The soluble fiber in oat is primarily composed of beta-glucan. In several studies safety of beta-glucan has also been tested. Overall, apart from some mild and short-lived gastrointestinal side effects such as flatulence and abdominal discomfort, no major gastrointestinal or esophageal obstructions have been reported following beta-glucan ingestion (Beer et al., 1995; Behall et al., 1998; Behall et al., 1997). Gastrointestinal side effects have usually been reported by individuals who shifted abruptly to a high fiber intake from what was typically a low fiber diet. These effects may be reduced by gradually increasing dietary fiber intake. Some of the adverse effects of fiber from IOM (2002) report are described in Section 2.2.

Available evidence does not suggest that increased oat fiber consumption in general is likely to significantly affect mal-absorption of vitamins and minerals (also see Section 2.4). It is known that fat-soluble vitamins are absorbed similar to triacylglycerol. Due to the ability of certain dietary fibers to delay absorption of triacylglycerol, it has been hypothesized that fiber intake may alter absorption of fat-soluble vitamins. Studies of vitamin A absorption indicate that wheat bran consumption may either increase (Rattan et al., 1981) or decrease (Wahal et al., 1986) serum vitamin A levels. As regards effects of consumption of specific fibers on absorption of other fat soluble vitamins limited information is available. The available studies on the effect of fiber on fat-soluble vitamin absorption are inconsistent.

As regards changes in water soluble vitamins, the effect of fiber on absorption of water-soluble vitamins is even less understood compared to fat-soluble vitamins. Available studies suggest that wheat bran has no effect, and psyllium appeared to increase riboflavin absorption at pharmacological doses (Roe et al., 1988). Pectin fiber consumption had no negative effect on the utilization of vitamin B6 (Miller et al., 1980) or urinary ascorbic acid concentration (Keltz et al., 1978).

In addition to vitamins, the effects of various dietary fibers on mineral absorption have also been investigated in some studies. However, the results of these studies are inconsistent. In a controlled study, Spencer et al. (1991) investigated the effect of oat bran muffins on calcium absorption and calcium, phosphorus, magnesium and zinc balance in adult male subjects. After a four-week adaptation period and a 40-day control period, the daily consumption of four oat bran muffins by 11 males did not result in a change in calcium, magnesium and zinc balance, while nitrogen and phosphorus balance improved. Total dietary fiber intake increased from 22.6 g/day in the control period to 43.2 g/day in the oat bran period. The absorption or bioavailability of calcium, phosphorus, magnesium and zinc were not affected by the oat bran fiber intervention. The investigators concluded that there would be no adverse effect on the nutritional status of these minerals if the American population were to increase intakes to reflect an oat bran fiber increase similar to the amounts used in their study.

The available evidence is not sufficient to draw conclusions concerning the effects of particular fiber types (including oat fibers) or fiber mixtures on mineral absorption. Although the possibility that fiber consumption could impair mineral status has been raised, it has been argued persuasively by Gordon *et al.* (1995) that evidence to support this contention is lacking. Overall, there is no compelling evidence that consumption of oat fiber or soluble fibers adversely impair the absorption of vitamins or essential minerals in adequately nourished populations. Furthermore, there is a long history of consumption of fiber-rich foods without any major reports on vitamin-mineral mal-absorption from high fiber intake, therefore it seems unlikely that one would observe any significant effects from the estimated increase in fiber intakes from Oat Isolated Products containing foods.

In addition to the above described human safety-related studies, the effects of feeding oat hull fiber to animals have been studied in pigs (Moser et al., 1982, Moore et al., 1986), rats (Barke and Harrold, 1980), chicks (Thompson and Weber 1981), and cattle (Smith et al., 1980). These studies primarily focused on the effect of oat hull fiber. In one study in rats, Lopez-Guisa et al. (1988) investigated the adverse effects of oat hull products as dietary fiber sources. In these experimental studies, no adverse effects related to the consumption of oat hull fiber were noted. In the study by Smith et al. (1980) that compared oat hulls to maize starch as energy supplements, one yearling heifer became chronically lame. There was no indication that this condition was related to the consumption of oat hull fiber. The available animal studies indicate that the consumption of oat hull fiber is safe.

In the study by Lopez-Guisa et al. (1988), potentials of processed oat hull products as dietary fiber sources in rats were evaluated. In this study, Sprague Dawley rats (9-10/group) were fed purified diets containing 5, 10 and 15% of processed oat hulls, bleached oat hulls or oat hulls coated with starch for 6 weeks. Control diets consisted of 5, 10 or 15% á-cellulose or commercial nonpurified diet. The resulting intake of fiber is estimated as ~2500, 5000 and 7500 mg/kg bw/day. Feeding of oat hull products at the three levels did not affect rat growth. As the concentration of dietary fiber increased, fresh and dry fecal weights increased linearly and were highly correlated with fiber intake. Apparent digestibility of neutral detergent fiber in all diets was low and apparent calcium absorption was not consistently affected by any diet. None of the oat hull diets lowered plasma or hepatic cholesterol levels. Chemical analysis of the oat hull fibers revealed that they were 95% insoluble fiber and high in cellulose and xylans. Light-microscopy histology of kidney, spleen, pancreas, stomach, duodenum, ileum and colon did not reveal any pathological changes. The investigators concluded that processed oat hulls behave physiologically like á-cellulose without any adverse physiopathology effects.

2.3. Allerginicity

Available studies indicate that oat proteins can act as both respiratory and skin allergens in farmers with grain dust allergy and children with atopic dermatitis (Baldo et al., 1980; Pazzaglia et al., 2000; De Paz Arranz et al., 2002; Codreanu et al., 2006; Boussault et al. 2007). However, food allergy from consumption of oat has been debated. Oats were believed to cause adverse effects in individuals with celiac disease. Hence oats were not allowed in the gluten-free diet. In recent years evidence suggest that oats are safe for consumption by most individuals with celiac disease (Rashid et al., 2007). Based on an extensive review of the scientific literature, Health Canada (2007) concluded that the majority of people with celiac disease can tolerate moderate amounts of pure oats, uncontaminated with other cereal grains such as wheat, barley and rye.

Commercially available oats are variably contaminated with gluten-containing grains (Thompson, 2004; 2005). This contamination can occur on the farm, during the growing cycle or during storage, cleaning, transportation or processing (Storsrud et al., 2003).

J. Rettenmaier USA LP acknowledges that Vitacel Oat Fiber Products do not contain any of eight foods (Milk, Egg, Fish, Crustacean shellfish, Tree nuts, Peanuts, Soybeans, Wheat) considered to be major food allergens under the U.S. Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

2.4. Dietary Fiber Adverse Effects Reported by IOM

The Institute of Medicine (IOM) has not established a tolerable upper intake level (UL) for dietary or functional fiber. Some of the fibers such as guar gum, inulin and oligofructose, fructooligosaccharides, polydextrose, resistant starch, and psyllium have been found to cause gastrointestinal distress, including abdominal cramping, bloating, gas, and diarrhea (IOM, 2002). Available evidence also indicates that abrupt increase in the intake of dietary fiber in some people may result in abdominal cramping, bloating or gas. These symptoms can be minimized or avoided by increasing intake of fiber-rich foods gradually and increasing fluid intake to ~2 liters/day. It has been reported that addition of cereal fiber to meals may decrease the absorption of iron, zinc, calcium, and magnesium in the same meal. However, available evidence indicates that phytate present in the cereal fiber rather than the fiber itself may be responsible for the decreased absorption. In general, dietary fiber as part of a balanced diet has not been found to adversely affect the calcium, magnesium, iron, or zinc status of healthy people at recommended intake levels (IOM, 2002).

Further, a number of over-the-counter, retail products with a long and successful track-record of use including but not limited to such well recognized laxative brands as Metamucil, together with popular bakery goods, i.e. low-calorie-high-fiber breads, attest to safety and beneficial health effects of oat fiber consumption.

3. Summary

Oats are a hardy cereal grain that is consumed as a food around the world since ancient times. A high daily intake of oat bran and other food sources rich in fiber has been claimed to possess several health benefits. Oats enjoy a long history of consumption as a food around the world and in the United States. In recent years, oats has become popular as healthy food due to its dietary fiber. Available information from compositional similarity between oat hull fiber and oat groat and bran suggests that safety data of oat groat and bran tissues is applicable to oat hull fiber for safety in use determinations. Traditionally the hulls are discarded. However, in recent years oat hull fiber has been gaining popularity as a source of dietary fiber. Isolated oat fiber is known to improve the texture and stability of the food products. J. Rettenmaier USA LP intends to use Vitacel® Isolated Oat Product as a formulation aid (binder) in meat and poultry products. Compared to conventional fiber ingredients, Vitacel® Isolated Oat Product has functional properties that confer important advantages.

J. Rettenmaier USA LP utilizes a HACCP-controlled manufacturing process and rigorously tests its final production batches to verify adherence to quality control specifications. J. Rettenmaier USA LP estimates that its intended uses of Isolated Oat Product in meat and poultry at maximum use levels of up to 3.5% will result in a total daily consumption of 5.78 g of the fiber. The literature studies and available information

demonstrate that Isolated Oat Product from J. Rettenmaier USA LP offers a source of formulation aid and manufactured under the highest standards of food purity, is safe for its intended uses.

Although dietary fibers are not digested in human gastrointestinal track, they play an important role in promoting regular bowel movement and preventing constipation. The subject of this GRAS assessment offers consumers a safe fiber source manufactured under the highest standards of food purity. Recently, Isolated Oat Hulls GRAS notice (GRN 000261) has received "FDA has no Questions" letter. In the notice, oat hull fiber was proposed to be used at a rate of between 2-5 g/50 g serving for a total dietary consumption of 21-28 g/day. The intake of oat hull fiber at 21-28 g/day was considered safe. Compared

to GRN 000261, the estimated daily intake (5.78 g/person) from the J. Rettenmaier USA LP proposed use levels are ~4-fold lower. The available evidence from human exposure to oat, oat fiber as well as human clinical evidence and animal experimental studies suggests that Isolated Oat Product is safe at levels proposed by J. Rettenmaier USA LP. Therefore, J. Rettenmaier USA LP has established that its Isolated Oat Product use as an ingredient in meat and poultry products is GRAS and, therefore, is exempt from the premarket approval requirements of the FDCA.

4. <u>Conclusion</u>

In summary, based on the information provided above and the compositional similarity between oat hull with other edible oat tissues (groat and bran) that are commonly consumed in diet, it is concluded that Isolated Oat Product to be as safe and as acceptable as other dietary fibers. Further, we believe that there are no significant questions regarding the safety of Isolated Oat Product that would appear to require additional safety studies. In light of the data and discussion presented above, J. Rettenmaier USA LP respectfully concludes that Vitacel® Isolated Oat Product, meeting the specifications cited above, and when used as a as a formulation aid (binder) [21 CFR 170.3(o)(14)] in meat and poultry products at levels of 3.5% and when not otherwise precluded by Standards of Identity is GRAS, as demonstrated through scientific procedures. It is also our opinion that other qualified and competent scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. Therefore, we have also concluded that Isolated Oat Product, when used as described, is GRAS based on scientific procedures.

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6. Appendix I

Analytical data from different manufacturing lots

Results from five different batches (J. Rettenmaier USA LP, 2009)

Parameter	Batch (b)(4)	Batch (b)(4)	Batch (b)(4)	Batch (b)(4)	Batch (b)(4)
Description	White to Off-White	White to Off-White	White to Off-White	White to Off-White	White to Off-White
pH value	6.3	6.3	6.7	6.4	5.9
Moisture	6.00%	6.10%	6.60%	6.70%	6.30%
Ash	2.50%	2.40%	2.10%	2.10%	1.70%
Bulk density	143 g/L	139 g/L	130 g/L	125 g/L	125 g/L
Heavy metals					
Lead	Monitoring 2 x / year*				
Arsenic	Monitoring 2 x / year*				
Cadmium	Monitoring 2 x / year*				
Microbiological					
Total plate count	LT 10 cfu/g	20 cfu/g	860 cfu/g	1000 cfu/g	200 cfu/g
Yeast and molds	LT 10 cfu/g	LT 10 cfu/g	10 cfu/g	LT 10 cfu/g	10 cfu/g
Salmonella	Negative/25 g	Negative/25 g	Negative/25 g	negative/25 g	Negative/25 g
Clostridium perfringens	Monitoring*				

*The monitoring demonstrates that the product complies with the standard specifications.

SUBMISSION END