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December 17, 2009

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Division of
Biotechnology and
GRAS Notice Review

BY FEDERAL EXPRESS

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

Dear Sirs:

On behalf of our client J.Rettenmaier USA LP, we are hereby submitting the enclosed GRAS Notification for Vitacel ® potato fiber in meat and poultry products. In compliance with 21 C.F.R. 170(b) (proposed), four copies of this Notification are enclosed.

Should you have any questions regarding this Notification, please do not hesitate to contact us.

Sincerely,

(b) (6)

Mark L. Itzkoff

MLI:akp
Enclosures

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December 17, 2009

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 (Rettenmaier) has determined that potato fiber (supplied by Rettenmaier under the trade name Vitacel® Isolated Potato Product)[1] is Generally Recognized As Safe (GRAS) under the conditions of its intended use in food, consistent with Section 201(s) of the *Federal Food, Drug, and Cosmetic Act*. This determination is based on scientific procedures as discussed in the following sections of this Notice. Therefore, the use of potato fiber as detailed below is exempt from the requirement of premarket approval.

Signed,

(b) (6)

12/17/09

Mark L. Itzkoff
Date

Counsel for
J. Rettenmaier USA LP
16369 US Highway 131
Schoolcraft, MI 49087

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Division of Biotechnology and GRAS Notice Review

[1] For the sake of brevity, the potato fiber is referred to herein as simply "Vitacel."

B. Name and Address of Notifier:

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

Telephone: (269) 679 2340
Fax: (269) 679 2364
Email: crath@jrsusa.com

C. Common or usual name of the notified substance:

Potato fiber

D. Conditions of use:

Potato fiber is intended for use as a food ingredient in meat and poultry products (sausage, chicken tenders) at levels consistent with current Good Manufacturing Practice and is self-limiting for technological reasons (as unacceptable taste and texture characteristics result when recommended levels are exceeded). Use of potato fiber improves the texture and stability of the food product. Additionally the moisture binding and retention of the complex polysaccharides from the potato which are independent of external factors such as temperature, pH value or storage time, are synergistically complemented by the temperature-induced water-binding ability of the starch. The intended use of Vitacel® (containing 72% fiber) in meat and poultry products at use levels of up to 3.5% resulted in estimated daily 90th percentile intake of 5.0 g potato fiber/person.

E. Basis for GRAS Determination:

In accordance with 21 CFR 170.30, the Notifier has determined that the intended use of potato fiber is generally recognized as safe (GRAS) based on scientific procedures. A comprehensive search of the scientific literature on potato fiber and related fiber was also utilized for this review. Vitacel® potato fiber contains approximately 72% dietary fiber. It is important to note that of the total dietary fiber, ~62% is cellulose and hemicellulose and ~12% is resistant starch.

Potatoes, including their fiber portion, have been consumed for centuries. Vitacel® is substantially similar, and is in fact identical, to the fiber portion of potatoes. Sufficient qualitative and quantitative scientific evidence, including human and animal data are available to determine safety-in-use for potato fiber. The safety determination of potato fiber is based on human observations and a variety of animal as well as *in vitro* studies on fibers similar to those found in potato further corroborate the human observations.

According to the USDA Nutrient Database for Standard Reference (NDSR), 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 potato fiber (Vitacel®) would contain about 1.8 g and 3.0 g of potato fiber, respectively. As Vitacel® contains 72% fiber, the intake of fiber will be from these foods would be 2.2 g/person/day. Similarly from the intended uses of Vitacel® from chicken tender (serving size 5 pieces, ~85 g) or one patty of poultry serving of 82 g (yield after cooking- 4 oz raw ground turkey) will result in daily intake of 2.2 g fiber.

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 chicken tenders. 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 potato fiber 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® contains 72% fiber, the mean and 90th percentile intake of fiber from the intended uses will be 2.4 and 4.9 g/person/day. For safety assessment purposes the maximum intake of potato fiber is considered as 5 g/person/day. However, the actual intake from the intended uses in sausages or tender chicken is expected to be much lower.

Based on USDA, NDSR, a single serving of baked potato, flesh with skin is 148 g and without skin is 156 g. As potato baked in skin and boiled peeled contains 1.9 and 1.6% potato fiber the resulting potato fiber intake from these foods will be 2.8 and 2.5 g/person/day, respectively. USDA CSFII has published various estimates of potato intake such as French-Fried potatoes, Home-Fried and Hash-Browned Potatoes, Baked Potatoes, Boiled Potatoes and Mashed Potatoes. These data indicate that daily potato intake is over 100 g. The mean and 90th percentile of total white potato consumed in a day is reported as 103 and 210 g, respectively. Considering that potatoes contain 1.9% fiber, the mean and 90th percentile intake of potato fiber will be 2.0 and 4.0 g/person/day. In addition to total white potatoes other sources of potatoes are also consumed and that are likely to add to the potato fiber intake. The available information indicates that the amount of potato fiber consumed from the intended uses of Vitacel® is similar or lower than the intake from potato consumption.

On the basis of scientific procedures[2], J. Rettenmaier USA LP considers the consumption of potato fiber (Vitacel®) as an added food ingredient to be safe at levels up to 5.0 g/day. The estimated daily intake of potato fiber (primarily containing cellulose, hemicellulose and resistant starch) 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) based on human observations where no adverse effects were noted. The estimated daily intake of potato fiber, if ingested daily over a lifetime, is considered safe. Additionally the resulting intake of potato fiber from its intended uses is similar to the intake from its natural presence in potato.

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

Potato fiber, consisting of cellulose, hemicellulose, starch, resistant starch[3].

B. Trade Name:

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

C. Chemical Abstract Registry Number:

None. The product is a naturally occurring fiber.

D. Chemical Formula:

Similar to cooked potato fiber. The empirical formula of cellulose molecule is $(C_6H_{10}O_5)_n$. Starch is a polymer of α-D-glucose and is composed of a mixture of two substances: *amylose*, an essentially linear polysaccharide, and *amylopectin*, a highly branched polysaccharide.

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[2] 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.

[3] The name resistant starch is applied to dietary starch that is not degraded in the stomach and small intestine, but is fermented by microflora in the large intestine.

E. Structure:

Cellulose, the primary constituent of potato fiber is a polysaccharide consisting of a linear chain of several hundred to over ten thousand β-(1→4) linked D-glucose units (Figure 1). The structure of starch amylase moiety is similar to cellulose except that it has α-(1→4) linked D-glucose units. In amylopectin moiety of starch, about one residue in every twenty is also linked by α-(1→6) forming branch-points.

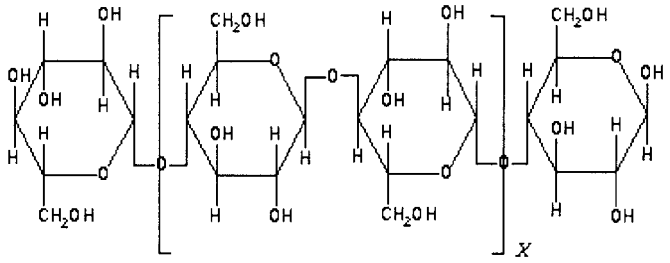

Figure 1. Chemical structure of cellulose

F. Physical Characteristics

Potato fiber (Vitacel®) is a free flowing, off-white to light-tan colored powder, composed primarily of natural insoluble fiber from fresh potato.

G. Typical Composition and Specifications

Typical food grade specifications of potato fiber (Vitacel®) are presented in Table 1. Typical compositional of potato fiber is summarized in Table 2. The compositional analysis suggests that potato fiber primarily contains cellulose, hemicellulose, and resistant starch.

Table 1. Typical specifications for potato fiber

	Specification	Assay method
Description	Tan to off-white powder	Visual
pH value	5 - 7	10% suspension
Moisture	8% Max.	105°C/2 hr
Ash	3% Max.	850°C/4 hr
Bulk density	200-400 g/L	DIN 53-468
Total dietary fiber	~72%	AOAC
Insoluble fiber	~54%	AOAC
Soluble fiber	~6%	AOAC

Table 1. Typical specifications for potato fiber

	Specification	Assay method
Heavy metals		
Lead	0.5 ppm Max	§ 64 LFGB
Arsenic	0.5 ppm Max	§ 64 LFGB
Cadmium	0.5 ppm Max	§ 64 LFGB
Microbiological parameters		
Total plate count	5×10^4 cfu/g (max)	§ 64 LFGB
Yeasts and molds	2×10^2 cfu/g (max)	§ 64 LFGB
Salmonella	Negative/ 25 g	§ 64 LFGB
Clostridium perfringens	100 KbE/g (max)	§ 64 LFGB

Table 2. Typical compositional analysis of potato fiber

Parameter	Level
Total dietary fiber	~72%
Insoluble fiber	~54%
Soluble fiber	~6%
Resistant starch	~12%
Protein (N x 6.25)*	7%
Starch non-resistant*	~16%
Composition of dietary fiber	
Cellulose and hemicellulose	~62%
Resistant starch	~12%

*Typical values

H. Manufacturing process

The process of making Vitacel® is a series of physical processes that renders a free-flowing powder from fresh potatoes. High quality selected potatoes are washed and then ground in water. The water is removed and the suspension is homogenized. The homogenate is dried. The dried extract is further homogenized for uniform consistency by passing through fine sieving. There are no chemical or solvent extractions or treatments involved. The physical processes comprise washing, grinding, dewatering, homogenization and sieving. Once Vitacel® powder has been produced; it is tested to ensure that it meets the standard food grade specifications. The manufacturing process of Vitacel® is outlined in Figure 2. The shelf life of the product is at least 2 years if stored at room temperature in dry conditions. Vitacel® is manufactured according to current Good Manufacturing Practices.

I. Manufacturing process diagram

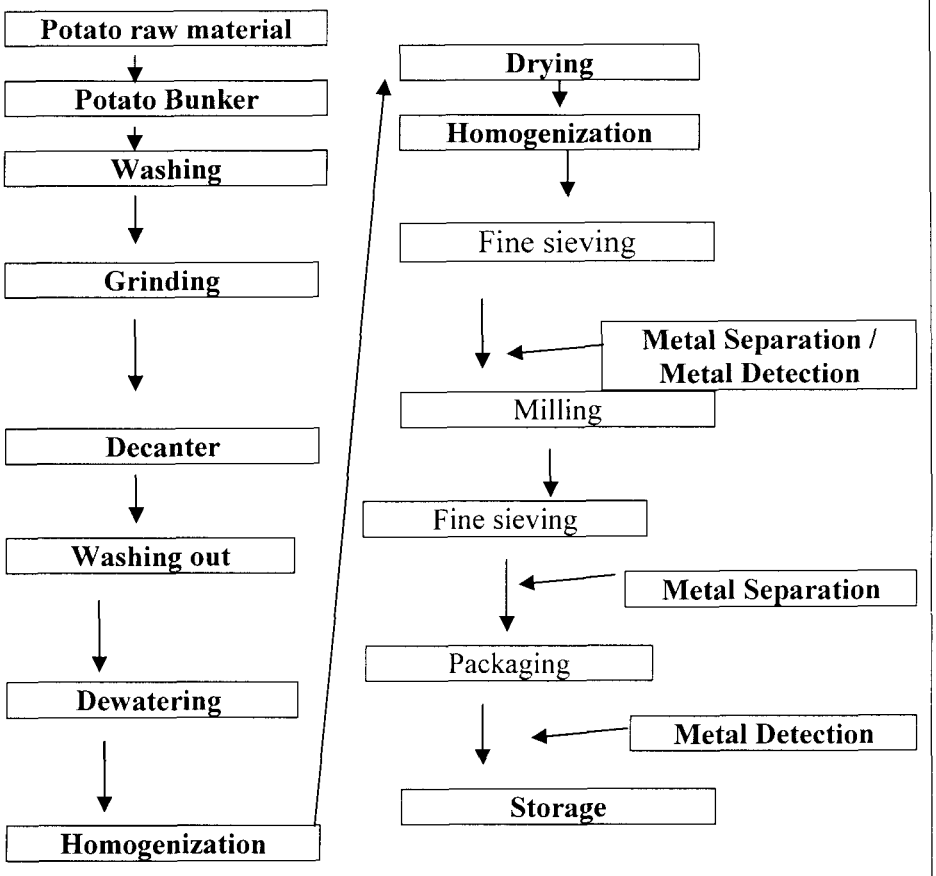

Figure 2. Manufacturing process of potato fiber

J. Intended Technical Effects

Potato fiber is intended for addition to a limited number of conventional foods as a formulation aid (binder) [21 CFR 170.3(o)(14)][4]. Its use is intended at the levels identified in this document for addition to meat (sausage) and poultry products (chicken tender, nuggets). 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.

[4] *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.

III. Summary of the Basis for the Notifier's Determination that Potato Fiber is GRAS

A comprehensive search of the scientific literature for safety and toxicity information on potato fiber and other related fibers was conducted through September 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 potato fiber to Meat products (sausages) and poultry products (chicken tender, nuggets) 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 potato fiber is GRAS, J. Rettenmaier USA LP relied upon the conclusions that neither potato fiber nor any of its constituents pose any toxicological hazards or safety concerns at the intended use levels, as well as on published toxicology 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 Potato Fiber is GRAS for its Intended Use.

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1. INTRODUCTION

A comprehensive search of the scientific literature for safety and toxicity information on potato fiber and other related fibers was conducted through September 2009 by J. Rettenmaier USA LP, to determine the Generally Recognized As Safe (GRAS) status of potato fiber as a formulation aid [21 CFR 170.3(o)(14)][5] in Meat products (sausages) and poultry products (chicken tender, nuggets) at use levels of up to 3.5%.

1.1. Background

From nutritional perspective, potatoes are best known for their carbohydrate content (~26 g in a medium potato). Majority of the carbohydrate in potato is starch. A small but significant portion of this starch is resistant (also called as potato fiber) to digestion by enzymes in the stomach and small intestine, and so reaches the large intestine. Available evidence suggests that this resistant starch has similar physiological properties and health benefits as dietary fiber. Multiple studies on resistant starch show that it provides bulk, increases satiety, improves glucose tolerance and insulin sensitivity, and lowers plasma cholesterol and triglyceride concentrations, and offers protection against colon cancer (Raban et al., 1994; Cummings et al., 1996; Hylla et al., 1998). Additionally, potato fiber is known to improve the texture and stability of the food product. It has been shown that the preparation method affects the amount of resistant starch in potatoes. The amount of resistant starch in potato significantly increases following its cooking and then cooling. Englyst et al. (1992) reported that cooked potato starch contains about 7% resistant starch, which increases to about 13% upon cooling. Potato fiber is also known to improve the texture and stability of food products. Given its beneficial properties, J. Rettenmaier USA LP intends to use potato fiber (Vitacel®) as a formulation aid (binder) in selected food products.

1.2. Description and Specifications

Vitacel®, a natural food ingredient is made through a process developed by J. Rettenmaier USA LP. It is a free flowing, off-white to light-tan colored powder, composed primarily of natural insoluble fiber from fresh potato. Compositional analysis reveals that Vitacel® (potato fiber) primarily contains cellulose, hemicellulose, and resistant starch. Typical food grade specifications and compositional analysis of potato fiber (Vitacel®) from J. Rettenmaier USA LP are presented in Table 1 and 2, respectively. Analytical results of five lots indicate that the product consistently meets these standard specifications (Appendix I).

1.3. Potato fiber

Dietary fiber is defined as the plant polysaccharides and lignins which are resistant to the digestion by digestive enzymes of human. Dietary fiber is not a precise term and opinion varies on its composition. Raw potato dietary fiber ranges from 1-2 g/100 g and part of the fiber may be

[5] *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.

starch that is resistant to hydrolysis enzymes used to remove starch prior to determination of dietary fiber. Formation of resistant starch, also referred as dietary fiber, is know to occur following cooking of potato (Table 3).

Table 3. Carbohydrate and fiber composition of potatoes cooked by different methods*

Cooking method	Total carbohydrate g/100 g	Dietary fiber (crude fiber) g/100 g
Uncooked	18.5	1.7 (0.5)
Boiled in skin (flesh only)	18.5	(0.5)
Boiled peeled	16.8	1.6 (0.6)
Baked in skin (flesh only)	22.9	1.9 (1.2)
Mashed with milk/margarine	15.2	(0.7)
Roasted in shallow fat flesh only	27.2	2.7
French fried chips	36.7	3.3 (1.0)
Chips (crisps)	49.7	11.9 (1.6)

*Adapted from Woolfe, 1987

Extensive studies in recent years have shown that potato fiber or resistant starches have physiological functions similar to those of dietary fiber (Sajilata et al., 2006). Based on the action of digestive enzymes, resistant starch is defined as that fraction of dietary starch, which escapes digestion in the small intestine. It is measured chemically as the difference between total starch obtained from homogenized and chemically treated sample and the sum of rapidly digestible starch and slowly digestible starch, generated from non-homogenized food samples by enzyme digestion. Based on nutritional characteristics (extent of digestibility) resistant starches (RS) are divided in four categories RS_1, RS_2, RS_3 and RS_4 (Table 4). Raw potato contains RS_3 and processing conditions results in the formation of RS_4. From functional point of view in food, RS_3 and RS_4 allow the formation of low-bulk high-fiber products with improved texture, appearance, and mouth feel (such as better organoleptic qualities) (Sajilata et al., 2006).

Table 4. Classification of types of resistant starch (RS)

Type	Description	Food source	Resistance minimized by
RS_1	Physically protected	Whole- or partly milled grains and seeds, legumes	Milling, chewing
RS_2	Ungelatinized resistant granules with type B crystallinity, slowly hydrolyzed by α-amylase	Raw potatoes, green bananas, some legumes, high amylose corn	Food processing and cooking
RS_3	Retrograded starch	Cooked and cooled potatoes, bread, cornflakes, food products with repeated moist heat treatment	Processing conditions

RS_4	Chemically modified starches due to cross-linking with chemical reagents	Foods in which modified starches have been used (for example, breads, cakes)	Less susceptible to digestibility *in vitro*

*Adapted from Sajilata et al., 2006

1.4. Technical effects

Potato fiber (Vitacel®) is intended for addition to a limited number of conventional foods such as Meat and poultry Products as a formulation aid at the levels identified in this document. Use of potato fiber improves the texture and stability of the food product as well as oil/water binding capacity. It is recognized that there are Standard of Identity requirements for some of these foods, and therefore, in these cases, it is not the intent to refer to them by their commonly recognized names.

1.5. Intake from Natural Presence in Food

The U.S. Department of Agriculture collected the food intake data published the intake of different foods (CFSII, 1994-96) (Smiciklas-Wright et al., 2002). This report includes intake of different forms of potato foods such as French-Fried potatoes, Home-Fried and Hash-Browned Potatoes, Baked Potatoes, Boiled Potatoes and Mashed Potatoes. CSFII data indicate that daily potato intake is over 100 g/person/day. For majority of these products quantities consumed per occasion was reported. The mean quantity consumed for these products ranged from 39 g to 188 g, while the 90th percentile quantity consumed ranged from 125 to 397 g. For white potato only daily intake was reported. The daily mean and 90th percentile consumption for white potato was reported as 103 and 210 g/person/day, respectively. Considering that potato contains 1.9% fiber the mean and 90th percentile intake of potato fiber will be 2.0 and 4.0 g/person/day. Additionally there are other forms of potato consumption such as French fries that are not considered in these calculations. The available evidence indicates that the daily intake of potato fiber from potato is similar to that resulting from the intended uses of potato fiber in meat (sausage) and poultry (chicken tender, nuggets) (see Section 1.5.1).

Potatoes are one of the most important world crops and are consumed around the world by humans for centuries without any adverse effects. The consumption of potatoes in Europe is on the average of 200-250 g/day, while the United States average consumption is significantly lower, at 61 g/day (Smiciklas-Wright et al., 2002). The content of fiber in potatoes is approximately 1.5% corresponding to a daily intake of 3.75 and 0.9 g of potato fiber in the Europe and US, respectively. Potatoes have been consumed in amounts up to several hundred grams per day for long periods without ill effect.

1.5.1. Estimated Daily Intake from the Intended Uses

J. Rettenmaier USA LP intends to use potato fiber in sausage at a use level of 3.5%. According to the USDA Nutrient Database for Standard Reference (NDSR), 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 level (3.5%) of potato fiber (Vitacel®) would contain about 1.8 g and 3.0 g of potato fiber, respectively. As Vitacel® contains 72% fiber (primarily cellulose, hemicellulose, resistant starch) the intake of fiber will be 2.2 g/person/day. Additionally, based on USDA surveys (Smiciklas-Wright et al., 2002), the mean and 90th percentile quantities of sausage (pork breakfast) consumption is 44 and 80 g/person/day. The intended use of potato fiber at levels of 3.5% in sausage will result in mean and 90th percentile intake of 1.5 g/person/day and 2.8 g/person/day, respectively. There is no information in the USDA surveys on tender chicken intake but 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 estimation of exposure. The intended use of Vitacel® 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® contains 72% fiber, the mean and 90th percentile intake of fiber from the intended uses will be 2.4 and 4.9 g/person/day. For safety assessment purposes the maximum intake is considered as 5 g/person/day.

2. Safety of Potato Fiber

2.1. Common Knowledge of Safe Use

There is common knowledge of a long history of human consumption of cooked potato, including the fiber portion. Potato is the fourth most important world food crop, surpassed only by wheat, rice, and maize. During the past five centuries, this diverse and adaptable tuber has spread from its original South American heartland in the high Andes to all the continents. Currently, potatoes are grown on an estimated 19.5 x 10^6 hectares around the world. China is the biggest potato producer, and almost a third of all potatoes are harvested in China and India alone. Nutritionally, potatoes are best known for their carbohydrate (starch) content. Potatoes also contain vitamins and minerals that have been identified as vital to human nutrition. Moreover, potatoes are good source of dietary fiber.

Potatoes and its different preparations are listed among the foods containing dietary fiber in the USDA Nutrient Database. In addition to potato, there are several other food sources of dietary fiber such as 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). The available information demonstrates that there is common knowledge of the health benefits associated with the consumption of the fiber, including potato fiber.

The fiber content of a potato is generally considered as equivalent to several whole grain breads, cereals, and pastas. One medium size potato is reported to contain about 3 g of fiber (Anonymous, 2002). Camire et al. (1997) reported that potato peels are a potential source of dietary fiber. These investigators reported that abrasion peeling method used by chip manufacturers' results in more starch and less dietary fiber than the steam peeling procedure used for production of dehydrated potatoes. In another study, Thed and Phillips (1995) reported that microwave-heating and deep-fat frying reduced an appreciable amount of *in vitro* digestible starch and significantly increased both the resistant starch and water-insoluble dietary fiber, while boiling and baking had less effect. It is apparent that some of the starch in cooked potato becomes indigestible, and this resistant starch contributes to the increase in the dietary fiber. Mulinacci et al. (2008) also reported higher levels of resistant starch in microwave treated potatoes than those of their boiled counterparts. In three different varieties of potatoes from Italy, these investigators reported presence of resistant starch in boiled and microwave treated potatoes ranged from 1.76 to 6.31%. Siljestrom and Bjorck (1990) reported that in commercially available autoclaved canned potatoes and reconstituted dry potatoes intended for consumption by infants aged 3 to 8 months contained 1.9 and up to 0.9 g/100 g (dry matter) resistant starch. All this suggest that fiber from potato is commonly consumed from diet and there are no reported adverse effects from its consumption.

2.2. Safety Studies on Potato Fiber

2.2.1. Animal Studies

Le Blay et al. (1999) investigated the effect of prolonged feeding of resistant potato starch (fiber) on butyrate production in rats. In this study, Wistar rats were fed on either a low-fiber diet (basal) or the same diet supplemented with 90 g resistant potato starch/kg for 0.5, 2 and 6 months. The two experimental diets differed only in the proportion of pregelatinized maize starch and raw potato starch (Requette Freres S.A., France). Raw potato starch (fiber) was included in the potato starch diet at the expense of maize starch at a level of about 120 g/kg diet. As raw potato starch contained 765 g resistant starch (determined by the method of Champ et al., 1999), the amount of resistant starch provided by the potato starch was 90 g/kg diet. The approximate resulting intake of potato fiber ranged from 5000 to 7500 mg/kg bw/day. During feeding period, food intake, body weight, transit time, caecal weight content, caecal water, fecal output, dry matter output and water output were measured periodically. From the caecal and colonic content short-chain fatty acid (SCFA) concentrations were determined. Bacterial composition of caecal content was also analyzed.

Feeding of potato fiber did not affect feed intake, final body weights or transit time compared to the basal diet group. Potato fiber augmented caecal weight content by increasing both dry matter and water content. Although the effect on fecal output decreased over time, it was higher with potato fiber. At 0.5 months, none of the bacterial populations enumerated was significantly affected by potato fiber, except for *Streptococcus* sp. Total SCFA concentration increased over time throughout the caecocolonic tract with potato fiber, but was not modified with the basal diet. While propionate concentration was unchanged, butyrate concentration was highly increased by potato fiber at each time period in both the caecum and colon. The amount of butyrate was increased 6-fold in the caecum and proximal colon and 3-fold in the distal colon after 6 months compared with 0.5 months. The results of this show that butyrate production was promoted by long-term ingestion of potato fiber, from the caecum towards the distal colon, which suggests a slow adaptive response of digestive tract to a chronic load of indigestible carbohydrates. The results of this study also show that the long-term ingestion of potato fiber increases caecal short-chain fatty acids (SCFA) concentration and decreases pH, promotes butyrate production and increases fecal output. All of these digestive effects may be considered as beneficial for host health.

Ferguson et al. (2000) examined the effects of replacing normal maize starch in the diet of rats with three preparations of resistant starch (potato starch, high-amylose maize starch, and an alpha-amylase-treated high-amylose maize starch) on the amounts of starch, butyrate, other short-chain fatty acids in the caecum, fecal bulking and transit time. In this study, Wistar rats were provided with control diet or diet containing 35% of the resistant starch (normal, native maize starch from control diet replaced with resistant starch preparation) for 4.5 weeks. The amount of resistant starch received by each group was not provided, however, the investigators stated that based on an *in vitro* method designed to predict the amount of starch that would escape digestion and absorption in the healthy adult small intestine was reported as 16.5 g/100 g in control diet and 65% in potato resistant starch. Feeding of resistant starch diet (all three diets) increased fecal weight and the weight of the caecum but only slightly shortened transit times. Increase in the amount of starch reaching the caecum and short-chain fatty acid production in the caecum was noted. Potato starch enhanced the proportion of butyrate. The investigators noted that there were marked differences among sources of resistant starch, even though these were all classified as RS2. These investigators also suggested that the effects of resistant potato starch are similar to other soluble dietary fiber.

Laerke et al. (2007) investigated the effects of potato fiber (prepared by enzymatic treatment of potato pulp) on central parameters related to risk factors of diabetes mellitus and cardiovascular disease in diabetic prone Goto-Kakizaki (GK) rats. In this study, negative control group received crystalline cellulose. Male GK rats were fed a semisynthetic Western-type diet containing 5% dietary fiber in the form of concentrated potato fiber, insoluble potato fiber, soluble fiber, or cellulose for 4.5 weeks to study weight change and induce diabetic conditions. Subsequently animals underwent slightly restricted feeding for 16 days for the measurement of fecal organic matter digestibility, fecal dry matter, urinary glucose excretion, and fasting blood

glucose. Finally, the rats were euthanized 2 hours postprandial for measurement of postprandial glucose, triacylglycerol and cholesterol levels, and cecal fermentation pattern to assess any relation between digestion processes and hematological risk markers. Feeding of soluble fiber revealed higher fecal organic matter digestibility and led to a significantly larger pool of organic acids with a higher proportion of propionate than the other diets. There was no difference in hematological parameters except for a small but significant reduction in postprandial plasma triacylglycerol concentration of rats fed soluble fiber diet compared to cellulose and concentrated potato fiber fed groups. The investigators concluded that increased fermentation and production of propionate with diet soluble fiber did not reduce plasma cholesterol or glycemic response. These investigators mentioned that the cholesterol response noted in human and hamster following dietary fiber is dependent on the initial level, and a possible reason for the lack of effect noted in their study could be failure to introduce hyperglycemia and hypercholesterolemia in the model.

Rideout et al. (2008) examined the influence of different resistant starch and conventional fibers on nutrient utilization and intestinal fermentation in pigs. In this completely randomized block design study, pigs were fed poultry meal-based diets supplemented with 10% granular resistant corn starch, granular resistant potato starch, retrograded resistant corn starch, guar gum, or cellulose for 36 day. Animals fed basal diet containing normal corn starch served as control. Feeding of resistant starch did not affect feed intake and animals remained healthy. Distal ileal and total tract recoveries were similar among the different resistant starch. Compared to control group, distal ileal starch recovery was higher in pigs consuming the resistant starch diets. Consumption of resistant potato starch reduced total tract calcium digestibility and whole-body retention of calcium and potassium compared with the control group. Similarly, feeding of resistant corn starch also affected total tract calcium digestibility. Consumption of all the resistant starch varieties reduced caecal indole concentrations compared with the control. The investigators concluded that nutrient utilization and intestinal fermentation are differentially affected by the consumption of different resistant starch varieties and types of fibers in pigs. Thermal properties associated with different resistant starch varieties may be useful markers for developing resistant starch varieties with desired functionality.

Lopez et al. (2001) compared the effects of potato resistant starch (potato fiber) and high amylose corn starch on cecal digestion, lipid metabolism and mineral utilization (Ca and Mg) in rats adapted to semipurified diets. Male Wistar rats were fed diets containing 710 g wheat starch/kg diet (control group) alone or 510 g wheat starch/kg diet plus 200 g resistant starch/kg (20% potato fiber or high amylase corn starch) for 21 days. In the article the values for diet are mentioned as per 100 g which should have been 1000 g. Compared with rats fed the control diet, significant caecal hypertrophy (240% after 7 d of the fiber consumption) and short-chain fatty acids accumulation (especially propionic and butyric acids) occurred in both treated groups receiving resistant starch diets. Apparent Ca, Mg, Zn, Fe and Cu absorptions were similarly enhanced by potato fiber and high amylose corn starch (50, 50, 27, 21 and 90%, respectively). Cholesterol absorption was reduced to 14% of intake in rats fed potato fiber and high amylose

corn starch compared with 47% absorption in control rats. Both potato fiber and high amylose corn starch lowered plasma and liver cholesterol and triglycerides. The results of this study suggest that potato fiber and high amylose corn starch have similar effects on intestinal fermentation, mineral utilization and cholesterol metabolism in rats.

2.2.2. Human Studies

Eastwood et al. (1983) measured the effect of a fiber source in the diet on stool bulk. One important property of fiber that influences the ability of fiber to increase stool weight is its water-holding capacity. In this study, initially *in vitro* water-holding capacity was measured using centrifugation, filtration, suction pressure and water flow-rate techniques using fiber concentrates of potato, cereal bran and gum arabic. In the *in vivo* study, seven male volunteers aged 26-44 years were supplemented with potato fiber for 3 weeks. Prior to supplementation the subjects under went a one week control period. Three potato fiber preparations, air dried, roller dried and boiled potato preparations were prepared from potato fiber provided by Nordreco Nestle Ltd. (Bjuv, Sweden). Mean fiber intake during control period was <20 g/day. Dietary supplementation of three preparations of potato fiber (20 g/day) did not affect dietary intake, had no significant effect on stool weight. Potato-fiber supplementation did not affect intestinal transit time, fecal characteristics and serum cholesterol levels. The *in vitro* water-holding capacity of three potato fiber was different as measured by centrifugation and filtration and did not reveal any prediction related to biological efficacy of a fiber. The investigators concluded that the effect of fibers on stool weight is apparently related to the nature of the water-holding properties of fiber rather than absolute water-holding capacity.

Cherbut et al. (1997) investigated the physiological effects of potato fiber and maize fibers in humans. The study comprised two one-month periods with an interval of 21 days. In this randomized, blind, crossover study, 18 healthy subjects (8 male, 10 female; 24-48 years of age) were divided in two groups and each group received 22 g of either potato or maize twice daily providing about 15 g fiber/day during one period and no fiber supplement fiber replaced by sucrose (15 g/day) during other period. Effects on fasting and postprandial blood concentrations of carbohydrate and lipid metabolites as well as on stool output and transit time were measured. Maize fiber resisted fermentation better than potato fiber and had lower digestibility. However, both fibers increased fecal output of dry matter, neutral sugars and water. There was an inverse relationship between stool weight and orofecal transit time, although only maize fiber significantly reduced transit time. Orocaecal transit was lengthened by potato fiber, probably because of its high water binding capacity. Potato fiber ingestion also decreased postprandial plasma levels of total and esterified cholesterol but had no effect on fasting concentrations. The investigators suggested that these fibers would be suitable ingredients in a healthy diet.

Englyst and Cummings (1987) investigated digestion and absorption from the small intestine of starch and nonstarch polysaccharides (potato fiber) from potato cooked and treated in various ways in ileostomy subjects. Five ileostomy subjects (2 males, 3 females) mean age 62 years took part in studies with potato treated in six different ways. Following a 24 hours on a

plant polysaccharide free diet, subjects received test meals (300 g) of potato. Regardless of the treatment, greater than 90% of potato fiber was recovered in ileostomy effluent. Starch from freshly cooked potato was well digested, only 3% being recovered; however, 12% from cooked and cooled potato escaped digestion in the small intestine. Digestibility of starch made resistant to alpha-amylase by cooling improved on reheating. Overall, 9, 18, and 14% of total carbohydrate fed was recovered from freshly cooked, cooled, and reheated potato, respectively. *In vitro* studies with pancreatin also demonstrated incomplete digestion of cooled potato. The results of this study demonstrate that nonstarch polysaccharide escapes breakdown in the small intestine almost completely.

In discussing their results with findings from animal studies, Englyst and Cummings (1987) suggested that their observations are in marked contrast to findings from animal models. Studies of the digestibility of nonstarch polysaccharide from wheat bran, peas, and beet pulp in pigs (often regarded as best model for human) show that only 90, 70, and 62%, respectively, are recovered from the terminal ileum (Graham et al., 1985). The results from Englyst and Cummings (1987) suggest that the stomach and small intestine of the pig, in contrast to man, are heavily contaminated with bacteria capable of fermenting carbohydrates, thus supporting previous observations by Ratcliffe (1985). Similarly, the observations by Englyst and Cummings (1987) also suggest that reduction noted in total tract calcium digestibility and whole-body retention of calcium and potassium in pigs by Rideout (2008) (see Section 2.2.1) may be species specific.

2.2.3. Glycoalkaloid Safety

Potatoes are known to contain glycoalkaloids, as secondary metabolites, that play a role in their defense mechanism against different pathogens such as viruses, bacteria, fungi and insects (Lachman et al., 2001). In potatoes, the commonly found glycoalkaloids are α-solanine and α-chaconine forming as high as 95% of total glycoalkaloids. The other glycoalkaloids found are β- and γ-solanines and chaconines. α- and β-solamarines and aglycones demissidine and 5-β-solanidan-3-a-ol. These glycoalkaloids contribute flavor to potatoes but at higher concentrations cause bitterness and may be toxic to humans (Cantwell, 1996). The highest concentrations of total glycoalkaloids are found in the peel and in the tissue layer just below it. The levels of total glycoalkaloids in consumer varieties of potatoes range from 20 - 150 ppm.

The potato alkaloids exert their toxic effects on the nervous system by inhibiting cholinesterase leading to the accumulation of acetylcholine that is responsible for conducting nerve impulses (Cantwell, 1996). Potato glycoalkaloids also act by general disruption of membranes. Symptoms of solanine toxicity include headache, nausea, fatigue, vomiting, abdominal pain and diarrhea. The glycoalkaloid α-chaconine is considered more toxic than α-solanine. Some individuals consuming potatoes that contained 3-10 mg/100g glycoalkaloids have reported temporary gastrointestinal adverse effects. Majority of the laboratory studies on glycoalkaloids have been conducted in animals. The only comprehensive laboratory experiment on solanine toxicity to humans showed that 2 mg of glycoalkaloid/kg body weight produced

classic symptoms of poisoning. An 80 kg individual consuming 100 g of peels from the potatoes mentioned above with 180 mg solanine/100 g peel would probably experience symptoms of solanine toxicity. For food safety purposes, an upper limit for glycoalkaloid content of 20 mg/100 g of potato is generally accepted. Concentrations of glycoalkaloids are 3 to 10 times greater in the peel than in the flesh. Commonly appreciated are varieties that contain 20 to 130 mg glycoalkaloids/kg fresh weight (Cantwell, 1996). Potatoes with solanine levels greater than 140 mg/kg have a bitter taste (Lachman et al., 2001).The daily per capita intake of glycoalkaloids from potatoes in United Kingdom is estimated to be ~14 mg (Friedman, 2006).

The maximum intake of potato fiber from the intended uses of Vitacel® is estimated as 5 g/person/day. As potato fiber contains 7% protein, the intake of protein will be 0.35 g/person/day. The level of total glycoalkaloids is specified to be less than 150 ppm in the product. Considering that the maximum levels of total glycoalkaloids in the potatoes used in the manufacture of Vitacel® to be 150 ppm, estimated daily intake of 3 g of potato fiber will result in consumption of 0.75 mg of glycoalkaloids. As upper limit of glycoalkaloid of 20 mg/100 g of potato is generally accepted, the resulting intake of 0.75 mg glycoalkaloids from the intended uses of potato fiber is very small and considered as safe. Similarly this intake is also very small compared to the per capita intake of glycoalkaloids (14 mg/day) from potatoes in the United Kingdom. Additionally, because of washing and the dispersion of the homogenates in water at different points in the process, the glycoalkaloid level is likely to be lower than the glycoalkaloid level in the whole potato.

2.2.4. Allerginicity

Given the substantial history of use by significant number of individuals, potatoes are regarded as a safe and non-allergenic food. Rare allergic responses to inhalation of potato dust and skin contact with potato peelings are reported. In people peeling potatoes that are allergic to either birch pollen or latex, raw potatoes have been reported to elicit infrequent allergic responses (Nater and Zwartz 1967; Wahl et al., 1990). It has been suggested that this allergic cross-reactivity is induced because of structural similarities between birch pollen and latex to specific undenatured potato protein(s). In such individuals, cooked potatoes, comprising denatured proteins, are usually well tolerated (Nater and Zwartz 1967, Hannuksela and Lahti, 1977). Available evidence suggests that denaturation of potato protein leads to a decrease in any potential food allergy due to potatoes (Hefle et al., 1996). Given the extraction process employed in the manufacturing of Vitacel®, the potential allergenicity of potato fiber should be the same or less than that of ordinary cooked potatoes.

2.3. Dietary Fiber Adverse Effects

The Institute of Medicine 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 insoluble oat fiber consumption.

3. SUMMARY

Potato is the fourth most important world food crop that has been consumed for centuries. Potato and in turn its fiber enjoys a long history of consumption as a food around the world and in the United States. The fiber content of a potato is generally equivalent to many whole grain breads, pastas, and cereals. One medium size potato is reported to contain about 3 g of fiber. Majority of the carbohydrate in potato is starch of which a small portion is resistant to digestion by enzymes in the stomach and small intestine, and so reaches the large intestine. This resistant starch has similar physiological properties and health benefits as dietary fiber. Potato fiber is also known to improve the texture and stability of the food products. J. Rettenmaier USA LP intends to use Vitacel® (potato fiber) as a formulation aid (binder) in meat (sausage) and poultry products (chicken tender, nuggets). Compositional analysis reveals that Vitacel® (potato fiber) primarily contains cellulose, hemicellulose, and resistant starch. Compared to conventional fiber ingredients, Vitacel® has functional properties that confer important advantages such as texture/structure improvement, high oil/water binding capacity.

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 potato fiber (Vitacel®) in meat and poultry products at levels of 3.5% will result in a 90th percentile daily consumption of 5.0 g of the fiber. Vitacel® or potato fiber contains only components that are present in approximately the same quantity in ordinary cooked potatoes or in cooked, digested potatoes. Ordinary potatoes are therefore the traditional counterpart to the potato fiber and provide a baseline for the toxicological assessment. The components of Vitacel® (primarily cellulose, hemicellulsoe, resistant starch) are part of the daily human diet. Unlike most other fibers (ethyl cellulose, hydroxypropyl cellulose, methyl ethyl cellulose) currently being used in foods, potato fiber (Vitacel®) is made from the edible portion of the fresh commodity.

There is common knowledge of human consumption of cooked potato, including the fiber portion. The USDA Nutrient Database list also includes potatoes and its preparations as foods

containing dietary fiber. The IOM recommended intake levels for total dietary fibers ranges from 21 to 38 g/day, while the current dietary fiber intake of 12-18 g/person in the U.S. is well below recommended levels. The daily reference value for dietary fiber for a 2000 calorie diet is 25 g (21 CFR 101.9(d)). Compared to the recommended daily intake of dietary fiber, the intake of potato fiber of 5 g person/day from the intended uses of Vitacel® is 4-8 times lower. While the intended uses of Vitacel® (potato fiber) may add to the background daily intake of dietary fiber it is unlikely to exceed the currently recommended daily intake of fiber. These estimates are based on levels of consumption that comply with dietary fiber source claims which are considered safe as little to no adverse effects have been observed or reported.

Given the long history of safe dietary uses of potatoes, including its fiber, there is lack of well designed animal or human studies investigating the toxicity or adverse effects of potato fiber. The available animal studies indicate that potato fiber has similar effects to that of other fibers. In rats, long term potato fiber (resistant starch) ingestion increases caecal SCFA, decreases pH, promotes butyrate production, and increases fecal output. The results of available human studies also did not reveal any adverse effects of potato fiber. Both animal and human studies indicate that potato fiber may be beneficial to the host health. The content of resistant starch used in animal and human studies was relatively high compared that of human intake resulting from the intended uses of Vitacel®. The amount of resistant starch in Vitacel® is ~12%.

The totality of available evidence from dietary consumption of potato for centuries, current intake of dietary fiber, and animal and human studies suggest that consumption of potato fiber from the intended uses of Vitacel® at use levels of 3.5% in meat (sausage) and poultry (chicken tender, nuggets) products is safe. On the basis of both scientific procedures[6] corroborated by history of exposure from natural dietary sources, J. Rettenmaier USA LP considers the consumption of potato fiber as an added food ingredient to be safe at daily consumption of up to 5 g/day. Thus the literature studies and available information demonstrate that potato fiber 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.

[6] 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.

4. CONCLUSION

In summary, based on the information provided above and the fact that the constituents of potato fiber are essentially the same as found in potato and are also similar to other dietary fibers, and will be handled metabolically similar to those derived from other sources, it is concluded that scientific experts, generally, would recognize them to be as safe and as acceptable as other dietary fibers. Further, we believe that there are no significant questions regarding the safety of potato fiber that would appear to require additional safety studies. In light of the data and discussion presented above, J. Rettenmaier USA LP respectfully concludes that potato fiber (Vitacel®), meeting the specifications cited above, and when used as a formulation aid (binder) [21 CFR 170.3(o)(14)] in meat products (sausage) and poultry products (chicken tender, nuggets) at levels of 3.5% and when not otherwise precluded by Standards of Identity is GRAS, as demonstrated through scientific procedures.

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6. APPENDIX I

Analytical data from five manufacturing lots

Specifications of potato fiber from five different lots (J. Rettenmaier USA LP, **2009**)

Parameter	**Batch VOG-005**	**Batch VOG-006**	**Batch VOG-004**	**Batch VOG-003**	**Batch VOG-002**
Description	Tan to off-white powder	Tan to off-white powder	Tan to off-white powder	Tan to off-white powder	Tan to off-white powder
pH value	5.5	5.5	5.5	5.5	5.6
Moisture	7.5 %	7.9 %	7.8 %	7.9 %	7.8 %
Ash	2.24 %	2.6 %	2.19 %	1.97 %	2.17 %
Bulk density	307 g/l	321 g/l	304 g/l	304 g/l	305 g/l
Heavy metals					
Lead	Monitoring 2 x / year* (<0.5 ppm)				
Arsenic	Monitoring 2 x / year* (<0.5 ppm)				
Cadmium	Monitoring 2 x / year* (<0.5 ppm)				
Microbiological					
Total plate count	4000 cfu/g	7000 cfu/g	16000 cfu/g	12000 cfu/g	15000 cfu/g
Yeast and molds	30 cfu/g	20 cfu/g	80 cfu/g	110 cfu/g	60 cfu/g
Salmonella	Negative./25 g	Negative/25 g	Negative/25 g	negative/25 g	Negative/25 g
Clostridium perfringens	Monitoring*				

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

SUBMISSION END

AM

West-Barnette, Shayla

From: Mark Itzkoff [mitzkoff@ofwlaw.com]
Sent: Monday, January 25, 2010 3:40 PM
To: West-Barnette, Shayla
Cc: Brett Schwemer
Subject: GRASN 310

Dear Dr. West-Barnett

The purpose of this e-mail is to respond to the question raised during today's conference call regarding GRAS Notice 310 for potato fiber. Specifically, you asked that we confirm the intended use of the potato fiber in meat and poultry products.

We have discussed the Notice with our client, J. Rettenmaier USA LP. They informed us that their original intent was that the GRAS Notice include all meat and poultry applications (whole muscle meat as well as comminuted meat) while the suitability determination would address only the comminuted meat. However, they have now developed applications that utilize the potato fiber in whole meat applications. Thus, while the GRAS Notice remains unchanged, the suitability determination will be amended to cover all meats and poutry. We will submit additional suitability data shortly.

In terms of the GRAS Notice, please note that where the GRAS Notice states a category of food followed by a parenthetical, the foods within the parenthetical are intended only to be examples of the food category, not a list of all foods covered by the Notice.

If you have any further questions, please do not hesitate to contact us.

Sincerely,

Mark Itzkoff

Mark L. Itzkoff
Olsson Frank
202 518-6327

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AM

West-Barnette, Shayla

From: Mark Itzkoff [mitzkoff@ofwlaw.com]
Sent: Thursday, January 28, 2010 2:52 PM
To: West-Barnette, Shayla
Subject: RE: GRASN 310

Dr. West-Barnett,

On behalf of our client, J. Rettenmaier USA, this e-mail hereby confirms that the intended uses of potato fiber in GRAS Notice 310 are in whole and comminuted meat and pultry products. When the Notice includes sausage, chicken tenders or chicken nuggets, these are just examples of the meat and poultry products in which the potato fiber is intended to be used.

If you have any additional questions, please do not hesitate to contact me.

Regards,

Mark Itzkoff

Mark L. Itzkoff
Olsson Frank Weeda
202 518-6327

From: West-Barnette, Shayla [mailto:Shayla.WestBarnette@fda.hhs.gov]
Sent: Thursday, January 28, 2010 2:41 PM
To: Mark Itzkoff
Subject: RE: GRASN 310

Mr. Itzkoff,

Thank you for your response to my previous e-mail message.

Based on your response, it is my understanding that: 1) the original and intended uses of potato fiber are in whole and comminuted meat and poultry products, and 2) that sausage, chicken tenders, and chicken nuggets are merely examples of the meat and poultry products in which potato fiber is intended to be used. Can you confirm this understanding?

Thanks,

Shayla

From: Mark Itzkoff [mailto:mitzkoff@ofwlaw.com]
Sent: Monday, January 25, 2010 3:40 PM
To: West-Barnette, Shayla
Cc: Brett Schwemer
Subject: GRASN 310

Dear Dr. West-Barnett

The purpose of this e-mail is to respond to the question raised during today's conference call regarding GRAS Notice 310 for potato fiber. Specifically, you asked that we confirm the intended use of the potato fiber in meat and poultry products.

We have discussed the Notice with our client, J. Rettenmaier USA LP. They informed us that their original intent was that the GRAS Notice include all meat and poultry applications (whole muscle meat as well as comminuted meat) while the suitability determination would address only the comminuted meat. However, they have now developed applications that utilize the potato fiber in whole meat applications. Thus, while the GRAS Notice remains unchanged, the suitability determination will be amended to cover all meats and poutry. We will submit additional suitability data shortly.

In terms of the GRAS Notice, please note that where the GRAS Notice states a category of food followed by a parenthetical, the foods within the parenthetical are intended only to be examples of the food category, not a list of all foods covered by the Notice.

If you have any further questions, please do not hesitate to contact us.

Sincerely,

Mark Itzkoff

Mark L. Itzkoff
Olsson Frank
202 518-6327

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May 4, 2010

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Division of
Biotechnology and
GRAS Notice Review

BY ELECTRONIC MAIL

Dr. Shayla West-Barnette
Office of Food Additive Safety and Applied Nutrition
The Food and Drug Administration
5100 Paint Branch Parkway
Rockville, MD 20740-3835

Re: GRASN 310

Dear Dr. West-Barnette:

The purpose of this letter is to confirm our recent telephone conversation regarding the intended use for the potato fiber that is the subject of GRASN 310 which we submitted on behalf of J. Rettenmaier USA, LP. Specifically, we hereby amend the intended applications of the Vitacel® potato fiber. Vitacel® potato fiber is intended to be used as an ingredient whole muscle poultry product, comminuted poultry products and comminuted meat products.

If you have any questions regarding this amendment, please do not hesitate to contact us.

Regards,

Mark L. Itzkoff

MLI:jac