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GRAS Notice (GRN) No. 525

ORIGINAL SUBMISSION

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June 3, 2014

Office of Food Additive Safety (HFS-255)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: Generally Recognized As Safe ("GRAS") Notification for Pea Fiber

Dear Sir/Madam:

Pursuant to proposed 21 CFR 170.36 (62 FR 18960; April 17, 1997), our client, Fuji Oil Company Limited, Japan, through Amin Talati, LLC as its attorneys, hereby provides notice of a claim that the food ingredient pea fiber described in the enclosed notification document is exempt from the premarket approval requirement of the Federal Food, Drug, and Cosmetic Act because it has been determined to be Generally Recognized As Safe (GRAS), based on scientific procedures.

As required, please find enclosed three copies of the notification. If you have any questions or require additional information, please feel free to contact me by phone at 312.327.3381 or by email at Ashish@AminTalati.com.

Sincerely,

(b) (6)

Ashish Talati, J.D., M.S., RAC

Encl: GRAS Notification for Pea Fiber (3 copies)

RECEIVED
JUN 13 2014
OFFICE OF
FOOD ADDITIVE SAFETY

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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)

Fuji Oil Company Limited (the notifier) has determined that pea fiber concentrate (FIPEA™) derived from beans of *Pisum sativum* L. is Generally Recognized As Safe, 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 as a food ingredient. Therefore, the use of pea fiber concentrate (FIPEA™) is exempt from the requirement of premarket approval.

Signed,

(b) (6) [redacted]

Date 6/2/14

Ashish Talati, J.D., M.S., RAC

Attorney for:

Fuji Oil Company Limited
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JAPAN

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C. Common or Usual Name of the Notified Substance:

The common name of the substance of this notification is pea fiber or soluble pea fiber. The trade name of the substance is FIPEA™.

D. Conditions of Intended Use in Food

Pea fiber concentrate (FIPEA™) containing approximately 65% fiber is intended for use as a food ingredient in Baked goods (bread, cake, noodles), Fruit juices, and Milk (acidified), at use levels up to 0.5 g/serving (reference amounts customarily consumed, 21 CFR 101.12) consistent with current Good Manufacturing Practice and is self limiting for technological reasons. Use of pea fiber improves the texture and controls moisture migration of the food product. The intended use of FIPEA™ derived from pea in above mentioned food categories is estimated to result in a maximum daily (90th percentile) intake of 4.60 g pea fiber concentrate/person. As the product typically contains 65% fiber, the fiber intake will be 2.99 g pea fiber/person/day.

Foods that are intended for infants and toddlers, such as infant formulas or foods formulated for babies or toddlers, and meat and poultry products that come under USDA jurisdiction are excluded from the list of intended food uses of the subject pea fiber.

E. Basis for GRAS Determination:

In accordance with 21 CFR 170.30, the intended use of pea fiber concentrate (FIPEA™) has been determined to be Generally Recognized As Safe (GRAS) based on scientific procedures. The determination is supported by the opinion of the Expert Panel. A comprehensive search of the scientific literature was also utilized for this determination. There exists sufficient qualitative and quantitative scientific evidence, including human and animal data to

determine safety-in-use for pea fiber concentrate (FIPEA™). Peas are an important part of the human diet in several countries and have been consumed since ancient time. Peas are high in protein, fiber, vitamins, minerals and lutein and are considered to be a nutrient rich food. Pea fiber plays a technological role in food. The soluble pea fiber in food can provide mouth feel, viscosity, bulking effects, freezing point depression, and lowering water activity. The totality of available evidence from dietary consumption of peas, current intake of dietary fiber, and animal and human studies suggest that consumption of pea fiber concentrate from the intended uses of FIPEA™ at use levels up to 0.5 g/serving (reference amounts customarily consumed, 21 CFR 101.12) in specified foods is safe. On the basis of scientific procedures[1], Fuji Oil Company Limited (Fuji) considers the consumption of pea fiber concentrate (FIPEA™), as a food ingredient to be safe at levels up to 4.60 g/person/day (2.99 g pea fiber/person/day).

F. Availability of Information:

The data and information that forms the basis for this GRAS determination will be provided to Food and Drug Administration upon request. The primary toxicologist, Dr. Madhusudan G. Soni, responsible for the preparation of this GRAS monograph and who is also a member of the expert panel can be contacted for the data and information that forms the basis for this GRAS determination. The data and information will be available for FDA review and copying at reasonable times at the offices of:

Madhusudan G. Soni, PhD, FACN, FATS
Soni & Associates Inc.
749 46th Square
Vero Beach, FL 32068

Telephone: +1- 772-299-0746;

Email: msoni@soniassociates.net or sonim@bellsouth.net

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

A. Chemical name:

Pea fiber concentrate consisting of >60% dietary fiber

B. Trade Name:

The subject of this notification will be marketed as FIPEA™

C. Chemical Abstract Registry Number:

None; the product is a naturally occurring fiber

D. Physical Characteristics

Yellow to off-white non-fibrous powder without any characteristic taste and odor

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[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. Typical Composition and Specifications

Food grade specifications and compositional analysis of pea fiber concentrate (FIPEA™) are presented in Tables II-E.1 and II-E.2. Analytical data from five manufacturing lots is presented in Appendix I and II.

Table II-E.1. Food Grade Specifications of Pea Fiber (FIPEA™) (Fuji, 2013)*

Parameters	Specification	Assay method
Description	Yellow to off-white powder	Visual
pH value	5.0-6.5	10% suspension
Moisture	6.5% Max.	105°C/5hours
Ash	8.0% Max.	600°C/4.5hours
Bulk Density	400-600 g/L	ISO60
Total dietary fiber	> 60%	AOAC 985.29
Insoluble fiber	< 1%	AOAC
Soluble fiber	> 60%	AOAC
Heavy metal		
Lead	0.05 ppm Max	Atomic absorption spectrometry (AAS)
Mercury	0.01 ppm Max	Cold vapor AAS
Arsenic(as As2O3)	0.1 ppm Max	AAS
Cadmium	0.01 ppm Max	AAS
Microbiological parameters		
Aerobic plate count	3×10^3 cfu/g (max)	TEMPO
Yeasts and molds	1×10^2 cfu/g (max)	TEMPO
Salmonella	Negative	Enrichment Culture Method

*Based on information provided by Fuji. ppm = parts per million; cfu = colony forming units

Table II-E.2. Typical Compositional Analysis of Pea Fiber(FIPEA™)*

Component name	Levels
Total dietary fiber (%)	62-65%*
Insoluble fiber (%)	1%
Soluble fiber (%)	60-64%*
Sugars	25-30%
Protein	3-8%
Sodium	450-800 mg/100 g
Calcium	150-400 mg/100 g

*Based on data from five batches; information provided by Fuji

F. Manufacturing process

Pea fiber concentrate is manufactured according to current good manufacturing practices (cGMP) at Fuji Oil Company Limited (Fuji) facilities located at 1 Sumiyoshi-cho, Izumisano-Shi, Osaka, Japan. The concentrate is an aqueous extract from the fibrous residue of peas that remains after extraction of starch and protein. Pea fiber is efficiently extracted from non-soluble dietary fiber which is widely used as food stuffs. The water soluble extract is refined, sterilized, and then spray dried. A flow diagram of the manufacturing process is shown in Figure F.1.

All raw materials and processing aids used in the manufacture of pea fiber are suitable food-grade materials and/or are used in accordance with applicable U.S. federal regulations for such uses. The manufacturing facility is registered with FDA under the number: 15087013152. Additionally, the facility is ISO certified: ISO9001 1994(1997/09). Furthermore, Fuji has over 60 years of experience in manufacturing several food ingredients and various international quality management systems, including HALAL, Kosher, and GMO-FREE IP certification that assure premium quality of international-grade dietary fiber product that is manufactured from food grade peas.

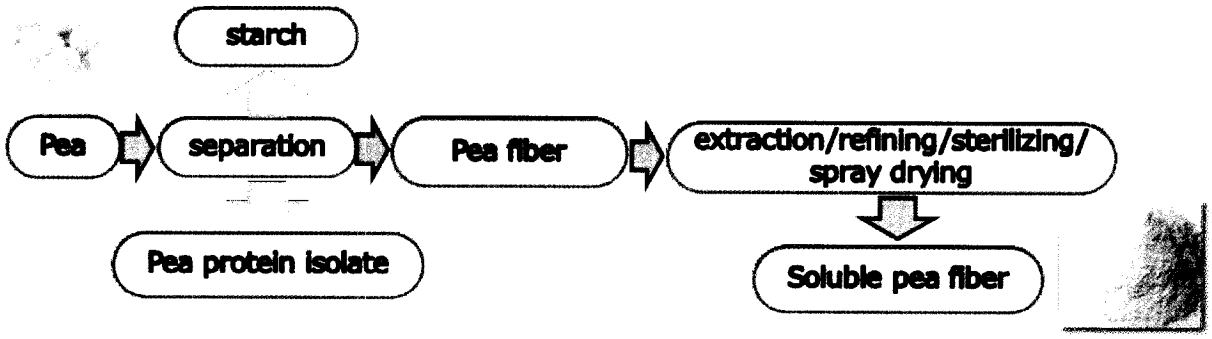

Figure F.1. Manufacturing Process of Pea Fiber Concentrate (FIPEA™)

G. Intended Technical Effects

Addition of pea fiber concentrate 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 Baked goods (bread, cake, noodles), Fruit juices, and Milk (acidified). It is recognized that there are Standard of Identity requirements, located in Title 21 of the Code of Federal Regulations, and as such, Fuji does not intend to refer to them by the commonly recognized names.

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

The determination that pea fiber concentrate is GRAS is based on scientific procedures. A comprehensive search of the scientific literature for safety and toxicity information on fiber particularly derived from pea was conducted through March 2014[2] and was also utilized for this assessment. Based on a critical evaluation of the pertinent data and information summarized here and employing scientific procedures, it is determined that the addition of pea fiber concentrate to the selected foods described in this notice and at use levels of 0.5 g/serving (in accordance with established reference amounts customarily consumed, 21 CFR

[2] The updated database searches performed subsequent to the Expert Panel review of the Pea Fiber GRAS assessment in November 2013 did not reveal any significant findings that will affect the panel conclusion.

101.12) meeting the specification cited above and manufactured according to current Good Manufacturing Practice, is GRAS under the conditions of intended use as specified herein.

In coming to this decision that pea fiber concentrate is GRAS, Fuji relied upon the conclusions that neither pea fiber concentrate nor any of their degradation products 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 Pea Fiber Concentrate is GRAS for its Intended Use.

An independent panel of recognized experts, qualified by their scientific training and relevant national and international experience to evaluate the safety of food and food ingredients, was convened to determine the safety of pea fiber concentrate (FIPEA™). Based on a critical evaluation of the pertinent data and information summarized herein, the Expert Panel members have individually and collectively determined by scientific procedures that the addition of pea fiber concentrate (FIPEA™) in Baked goods (bread, cake, noodles), Fruit juices, and Milk (acidified) at levels up to 0.5 g/serving (reference amounts customarily consumed, 21 CFR 101.12) when not otherwise precluded by a Standard of Identity as described here and resulting in the 90th percentile estimated intake of 4.60 g pea fiber concentrate/person or 2.99 g pea fiber/person/day is GRAS. It is also their opinion that other qualified and competent scientists, reviewing the same publicly available toxicological and safety information, would reach the same conclusion (see attached Expert Panel Statement).

EXPERT PANEL STATEMENT

DETERMINATION OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF

SOLUBLE PEA FIBER

AS A FOOD INGREDIENT

Prepared for:

Fuji Oil Company Limited
1 Sumiyoshi-cho, Izumisano-Shi
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Prepared by:
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749 46th Square
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Panel Members

Robert L. Martin, Ph.D.
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Madhusudan G. Soni, PhD, FACN, FATS

January 2014

EXPERT PANEL STATEMENT
DETERMINATION OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF

SOLUBLE PEA FIBER
AS A FOOD INGREDIENT

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DETERMINATION OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF SOLUBLE PEA FIBER AS A FOOD INGREDIENT

1. INTRODUCTION

The undersigned, an independent panel of recognized experts (hereinafter referred to as the Expert Panel)[1], qualified by their scientific training and relevant national and international experience to evaluate the safety of food and food ingredients, was convened by Soni & Associates Inc. at the request of AminTalati LLC, USA and Fuji Oil Co., Ltd., Japan (Fuji), to determine the Generally Recognized As Safe (GRAS) status of the use of soluble pea fiber (FIPEA™) derived from beans of *Pisum sativum* L. as a source of multifunctional dietary fiber in conventional foods such as Baked goods (bread, cake, noodles), Fruit juices, and Milk (acidified), at use levels up to 0.5 g/serving (reference amounts customarily consumed, 21 CFR 101.12). A comprehensive search of the scientific literature for safety and toxicity information on pea (*Pisum sativum* L.) and its fiber was conducted through November 2013 and made available to the Expert Panel. The Expert Panel independently and critically evaluated materials submitted by Fuji and other information deemed appropriate or necessary. Following an independent, critical evaluation, the Expert Panel conferred on January 09, 2014 and unanimously agreed to the decision described herein.

1.1. Background

Pulses, including peas, have long been important components of the human diet due to their content of starch, protein and other nutrients (Dahl et al., 2012). Dry pea is an important grain legume that is grown around the world on approximately 15 million acres (Lazanyi, 2005). It is primarily used for human consumption and livestock feed. During the Medieval period, peas, along with broad beans and lentils, formed an important part of the diet of the majority of the people in the Middle East, North Africa and Europe (Bianchi and Corbetta, 1976). Peas still continue to be an important part of the diet in several countries. The major pea producing countries are China, India, Canada, Russia, France and the United States (Pavek, 2012). Peas are high in fiber, protein, vitamins (folate and vitamin C), minerals (iron, magnesium, phosphorus and zinc), and lutein. In recent years, several studies have identified potential health benefits of pulses, including peas, beyond meeting basic nutrient requirements (Dahl et al., 2012). Fiber from the seed coat and the cell walls of the pea cotyledon contributes to gastrointestinal function and health, and reduces the digestibility of starch in peas. Pea fiber also plays a technological role in food. The soluble pea fiber can impart effects such as mouth feel, viscosity, bulking in bakery products and confectionary, freezing point depression, and lowering water activity. Given its beneficial properties, Fuji intends to use standardized soluble pea fiber (FIPEA™) as water soluble fiber (dietary fiber), formulation aid (binder) and dispersion aid (stabilizer) in selected food products.

1.2. Description

The subject of this GRAS determination, pea fiber, is a standardized spray dried water

[1]Modeled after that described in section 201(s) of the Federal Food, Drug, and Cosmetic Act, As Amended. See also attachments (curriculum vitae) documenting the expertise of the Panel members.

soluble, polysaccharide extract derived from peas. It is a yellow to off-white non-fibrous powder without any characteristic taste and odor. It will be marketed under the trade name FIPEA™. General descriptive parameters and properties of pea fiber manufactured as FIPEA™ by Fuji are summarized in Table 1.

Table 1. General Descriptive Characteristics of FIPEA™

Parameter	Description (Fuji, 2013)*
Botanical source	*Pisum sativum* L.
Synonym of source	*Pisum arvense* L., *Pisum humile* Boiss. & Noe,
Plant part used	Peas
Synonyms of part used	Garden pea; sweet pea; English pea; filed pea; green pea; spring pea; common pea
Appearance	Powder
Color	Yellow to off-white
Odor	No odor
Taste	Bland
Storage	Store in tightly closed dark containers in a cool dry location.
Shelf life	Two years in the original pack

*Based on information provided by Fuji

The hierarchical classification of *Pisum sativum* L. is presented in Table 2. As described in the USDA Plant Fact Sheet, the pea is a cool-season annual vine that is smooth and has a bluish-green waxy appearance. Vines can be up to 9 ft long, the stem is hollow, leaves are alternate, pinnately compound, and consist of two large leaflike stipules, one to several pairs of oval leaflets, and terminal tendrils. Flowers have five green fused sepals and five white, purple or pink petals of different sizes. The fruit is a closed pod, 1 to 4 inches long that often has a rough inner membrane. Ripe seeds are round, smooth or wrinkled, and can be green, yellow, beige, brown, red-orange, blue-red, dark violet to almost black, or spotted (Pavek, 2012).

Table 2. Classification of *Vigna radiata*

Kingdom	Plantae- Plants
Subkingdom	Tracheobionta- Vascular plants
Superdivision	Spermatophyta- Seed plants
Division	Magnoliophyta- Flowering plants
Class	Dicotyledoneae
Subclass	Rosidae
Order	Fabales
Family	Fabaceae
Genus	*Pisum*
Species	*Pisum sativum* L.

1.3. Typical Specifications and Composition

Food grade specifications of pea fiber (FIPEA™) have been established by Fuji. Typical specifications are presented in Table 3. Typical compositional analysis of pea fiber (FIPEA™) is summarized in Table 4. To demonstrate conformance with the food-grade specifications, Fuji analyzed several batches of pea fiber. Analytical results from five non-consecutive lots (Appendix I, II) suggest that pea fiber (FIPEA™) is consistently

manufactured to meet the standard specifications. The product is standardized to the contents of total dietary fiber of approximately 65%. The product quality is defined by parameters such as moisture, ash, bulk density, pH value and soluble fiber. The saccharide composition of the total dietary fiber part of the pea fiber was as follows: rhamnose = 2.9%, fucose = 1.2%, arabinose = 35.6, xulose = 1.8%, galactose 11.1%, glucose 34.9 and galacturonic acid = 12.5%.

Table 3. Specifications of Pea Fiber (FIPEA™) (Fuji, 2013)*

Parameters	Specification	Assay method
Description	Yellow to off-white powder	Visual
pH value	5.0-6.5	10% suspension
Moisture	6.5% Max.	105°C/5hours
Ash	8.0% Max.	600°C/4.5hours
Bulk Density	400-600 g/L	ISO60
Total dietary fiber	> 60%	AOAC 985.29
Insoluble fiber	< 1%	AOAC
Soluble fiber	> 60%	AOAC
Heavy metals		
Lead	0.05 ppm Max	Atomic absorption spectrometry
Mercury	0.01 ppm Max	Cold vapor atomic absorption spectrometry
Arsenic(as As2O3)	0.1 ppm Max	Atomic absorption spectrometry
Cadmium	0.01 ppm Max	Atomic absorption spectrometry
Microbiological parameters		
Aerobic plate count	3×10^3 cfu/g (max)	TEMPO
Yeasts and molds	1×10^2 cfu/g (max)	TEMPO
Salmonella	Negative	Enrichment Culture Method

*Based on information provided by Fuji. ppm = parts per million; cfu = colony forming units

Table 4. Typical Compositional Analysis of Pea Fiber(FIPEA™)*

Component name	Levels
Total dietary fiber (%)	62-65%
Insoluble fiber (%)	1%
Soluble fiber (%)	60-64%
Sugars	25-30%
Protein	3-8%
Sodium	450-800 mg/100 g
Calcium	150-400 mg/100 g

*Based on information provided by Fuji

000013

1.4. Manufacturing process

Pea fiber (FIPEA™) is manufactured according to current good manufacturing practices (cGMP), as outlined in Figure 1, at Fuji Oil Company facilities located at 1 Sumiyoshi-cho, Izumisano-Shi, Osaka, Japan. FIPEA™ is an aqueous extract from the fibrous residue of peas starch and protein. It is efficiently extracted from non-soluble dietary fiber which is widely used as food stuffs, and subsequently refined, sterilized, and then spray dried. A flow diagram of the manufacturing process is shown in Figure 1.

All raw materials and processing aids used in the manufacture of pea fiber are suitable food-grade materials and/or are used in accordance with applicable U.S. federal regulations for such uses. The manufacturing facility is registered with FDA under the number: 15087013152. Additionally, the facility is ISO certified: ISO9001 1994(1997/09). Furthermore, Fuji has over 60 years of experience in manufacturing several food ingredients and various international quality management systems, including HALAL, Kosher, and GMO-FREE IP certification that assure premium quality of international-grade dietary fiber product that is manufactured from food grade peas.

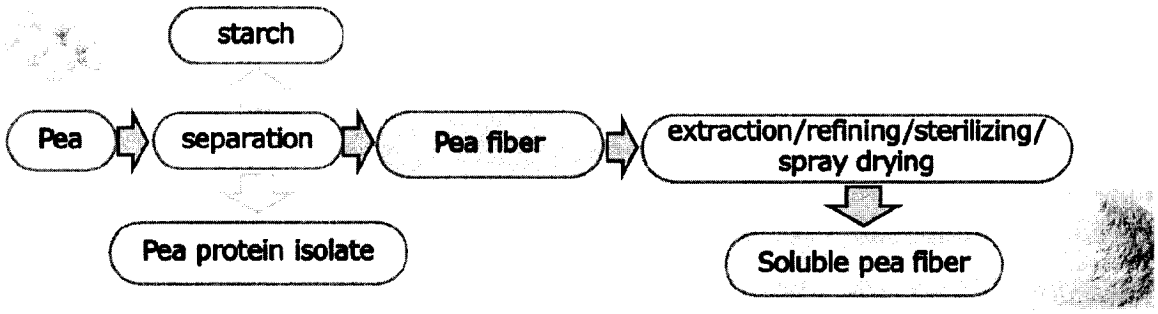

Figure 1. Manufacturing Process of Pea fiber (FIPEA™)

1.5. Regulatory History of Food Fibers and Pea Fiber

Dietary fiber is an important component of a healthful diet. Generally, nutritionists recommend 20 – 35 grams of fiber per day, or 10 – 13 grams per 1,000 kilocalories. In the U.S., the Nutrition Facts panel provides a good reference, stating as a goal 25 grams of dietary fiber for a 2,000 kilocalorie per day diet, or 30 grams of dietary fiber for a 2,500 kilocalorie per day diet. According to the National Center for Health Statistics, consumers average only 14 - 15 grams of fiber intake per day, far below moderate levels of dietary fiber. FDA recognizes the importance of fiber in the diet by requiring that fiber occupy a prominent position on the Nutrition Facts panel on food labels. In addition, FDA has approved several health claims relating fiber intake to lowered risk of heart disease and cancer. In 1997, the FDA approved the health claim on the association of soluble fiber from rolled oats and reduced risk of heart disease (21 CFR 101.81) (62 FR 3584, January 23, 1997). Subsequently, in December 2005, the FDA authorized a health claim for soluble fiber from whole grain barley and barley-containing products and coronary heart disease ("CHD") (21 CFR 101.81).

At present, FDA has not formally defined fiber. However, from a physiological point of view, dietary fiber is the fibrous or gummy non-digestible portion of food that can affect the health of the digestive tract and the output of the bowel. Chemically, fiber is the remnant of plant cell walls, lignin, polysaccharides and similar substances that resist hydrolysis in the human digestive tract. The two sub-classes of fibers are "soluble" and insoluble." These types of fibers are different in chemistry and in physiological effects. About two-thirds to three-fourths of the dietary fiber in a typical diet is insoluble. While there is substantial evidence for the need of soluble fiber in the diet, research is still needed to determine the amount necessary in the typical diet. As a general rule, insoluble fibers contribute to bulk and reduced transit times in the GI tract, while soluble fibers are fermented, and contribute to changes in metabolism. Soluble fibers can slow the digestion and absorption of carbohydrates, preventing wide swings in blood sugar levels. This aids in the control of diabetes. Studies also indicate that soluble fibers interfere with the absorption of bile acids. This causes the liver to remove cholesterol from the blood to replace them. In addition, the increased bulk from insoluble and soluble fibers contributes to a feeling of fullness and, because fiber is low in calories, this may help contribute to weight loss.

The available information from the FDA's GRAS inventory[2] suggest that several fiber ingredients that have been recently developed/produced from other plants or grains are recognized as having GRAS status for designated food uses within the food industry. The fiber ingredients that have received "no questions" letters from the FDA include: Barley Fiber – Cargill Inc., GRN 207; Carrot Fiber – Wm. Bolthouse Farms, GRN 116; Oat Hull Fiber – Grain Millers, Inc., GRN 261; Orange Pulp – Fiberstar citrus fiber, Citri-Fi, GRN 154; Potato Fiber - Rettenmaier & Sohne, Vitacel® GRN 310; Oat Hull Fiber, J. Rettenmaier USA LP, GRN 342; Barley Fiber, Cargill Incorporated, GRN 344; Oat Hull Fiber, Z-Trim Holding Inc, GRN 366; Corn Hull Fiber, Z-Trim Holding Inc, GRN 368; Rice Bran Fiber, CJ America Inc., GRN 373; Rice Hull Fiber, Ribus Inc., GRN 426; Corn Hull Fiber, Z-Trim Holding Inc, GRN 427; and Sugar Beet Fiber, Nordic Sugar A/S, GRN 430. The "no question" letter from FDA to these different types of dietary fiber GRAS notices suggest that the agency is comfortable with the use of dietary fiber.

In addition to FDA GRAS notices, available information from internet searches indicates that several other dietary fiber ingredients are commonly available in the marketplace. These have not been the subject of FDA GRAS notification process. These ingredients include: Pea Fiber – International Fiber Corporation (Justfiber®), Rettenmaier & Sohne (Vitacel®), Canadian Harvest/SunOpta; Apple Fiber - Rettenmaier & Sohne (Vitacel®); Wheat Fiber - International Fiber Corporation (Justfiber®), Rettenmaier & Sohne (Vitacel®); Bamboo fiber - Rettenmaier & Sohne (Vitacel®); Sugar Beet Fiber – International Fiber Corporation (Justfiber®); Cottonseed Fiber - Rettenmaier & Sohne (Vitacel®); Soy Fiber – Canadian Harvest/SunOpta, etc.

Furthermore, FDA has allowed three health claims related to dietary fiber intake and reduced risk of heart disease and cancer: 1) the reduced risk of cancer claim for fiber containing grain products, fruits, and vegetables (21 CFR 101.76); 2) the reduced risk of coronary heart disease (CHD) claim for fruits, vegetables, and grain products that contain fiber, in particular soluble fiber (21 CFR 101.77); and, 3) soluble fiber from certain foods and

[2] Available at: http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing&displayAll=true

risk of coronary heart disease (21 CFR 101.81). To be eligible for using the health claim, a food product must contain at least 2.5 g of total fiber per serving (Reference Amount Customarily Consumed- RACC) of food. Foods providing 2.5 g fiber/serving from rice hull fiber is qualified for at least one health claim (the reduced risk of cancer claim for fiber containing grain products, fruits, and vegetables), if they meet the jelly bean rules (i.e., as part of low sodium and low fat diets).

1.6. Production, Uses and Consumption

Pulses, such as dry beans, peas, lentils, and chickpeas, are the main legume crops used as sources of human food around the world (APA, 2010). In the USA, pulse crops, including peas are cultivated on about 3 million acres with an annual production value in excess of $1 billion. Pulse crops, including peas, currently provide over 12% of the plant protein consumed by humans globally, more than either potatoes or vegetables (FAO, 2009). Generally, pulses, including peas, are considered as a low cost source of dietary fiber, protein and starch. The high nutrient density of peas makes them a valuable food commodity, capable of meeting the dietary needs of the estimated 800-900 million undernourished individuals around the world (Dahl et al., 2012). As per the My Plate Guidelines by USDA consuming at least three cups of dry beans and peas per week is recommended.

In 2009, the World production of peas was reported to be over ten million tons. The major producers of pea are reported as Canada, the Russian Federation, China, the USA and India (Dahl et al., 2012). In an article on trends in pea production, Lazanyi (2005) reported that in developed countries of the European Union, pea production rose yearly by 6-10% during the 1980's. In the 1990's, the European Union produced 4-5 million tonnes of dry peas, of which 3-4 million tons were used for feed and 1 million tons for export. Europe accounts for 50-75% of world pea production. Although peas have been used as a feed for livestock, it is also commonly consumed as food in developing countries for its protein content. This consumption of dry peas as a food is primarily concentrated in developing countries, where grain legumes represent a useful complement to cereal-based diets as a relatively inexpensive source of high quality protein (Lazanyi, 2005). In developing countries, shortage of grain legumes has adverse effects on the nutritional standard of poor people. At the beginning of the 1960's, the consumption of dry pea was 2.2 kg/capita. Based on this information, the daily intake of "pea" is estimated to be 6.03 g/person/day. The available information on composition indicates that dry peas contain approximately 9% soluble fiber (Dahl et al., 2012).

1.7. Intended Use Levels and Food Categories

Fuji intends to use pea fiber (FIPEA™) as a multifunctional dietary fiber in foods such as Baked goods (bread, cake, noodles), Fruit juices, and Milk (acidified), at use levels up to 0.5 g/serving (reference amounts customarily consumed, 21 CFR 101.12). Foods that are intended for infants and toddlers, such as infant formulas or foods formulated for babies or toddlers, and meat and poultry products that come under USDA jurisdiction are excluded from the list of intended food uses of the subject pea fiber. It is recognized that there are Standard of Identity requirements for some of the above specified foods and these foods will not be referred to by their commonly recognized names such as milk, chocolate or yogurt. The proposed use levels of pea fiber (FIPEA™) in the various food categories are summarized in Table 5.

1.7.1. Estimated Daily Intake from the Intended Uses

USDA survey data were used to estimate mean and 90th percentile per capita levels of consumption from the chosen food categories. Based on USDA CSFII surveys (Smiciklas-Wright et al., 2002) for quantities of foods consumed daily, the mean and 90th percentile consumption of pea fiber (FIPEA™) from the proposed uses in Baked goods (bread, cake, noodles), Fruit juices, and Milk (acidified) was determined (Table 5). The CSFII data provides intake of total milk that also includes all milk in ice creams, pudding, yogurt, creams, and processed foods except cheese and margarine. Hence, in Table 5, values for total milk and cheese are included. The intended use of pea fiber (FIPEA™) at levels of 0.5 g *per* serving will result in mean and 90th percentile intake of 2.12 and 4.60 g/person/day (35.3 and 76.6 mg/kg body weight/day for an individual weighing 60 kg), respectively.

Table 5. Intended Use Levels and Estimated Daily Intake of Pea Fiber (FIPEA™) Based on USDA Data[1]

Food category	Consumption of food product (g/day)		Use levels (g/serving)	Use levels (g/kg)	Average serving size (g)	Daily intake by adult (g/person)	
	Mean	90th %				Mean	90th %
Noodles (Pasta)	148	318	0.5	3.57	140	0.53	1.13
Bread[2]	56	104	0.5	10.0	50	0.56	1.04
Total milk (milk, yogurt)	288	671	0.5	2.08	240	0.60	1.40
Fruit & vegetable juices[3]	207	496	0.5	2.08	240	0.43	1.03
					Total (g/person/day)	**2.12**	**4.60**

[1]The daily intake calculations are based on USDA data and mean portion size. [2]For bread all types, total yeast bread is considered; [3]Apple juice intake is considered to represent fruit and vegetable juice intake

2. SAFETY RELATED DATA

2.1. Common Knowledge of Safe Use

There is common knowledge of a long history of human consumption of peas. Peas were one of the earliest food crops. The evidence of wild pea consumption by humans dates back to 9750 BC based on findings from archaeologists exploring the "Spirit Cave" on the border between Burma and Thailand. Cultivation of peas brought stability to once nomadic tribes, and made it possible for peas to be brought by travelers and explorers into the countries of the Mediterranean as well as to the Far East. Pulses, including peas, have long been important components of the human diet due to their content of starch, protein and other nutrients. The field pea (*P. sativum,* L.) was among the first crops cultivated by man. As pea cultivation requires cool weather, historians believe the main center of pea development was middle Asia, including northwest India and Afghanistan. Additional areas of development lie in the Near East, and a third area includes the plateau and mountains of Ethiopia. Wild field peas of related species can still be found in Afghanistan, Iran, and Ethiopia. Peas, more specifically the yellow or green cotyledon varieties known as dry, smooth or field peas, are

grown around the world for human and animal consumption. The US Department of Agriculture "My Plate Guidelines" recommend consuming at least three cups of dry beans and peas per week. Starch and fiber are the major components of peas, 46 and 20% of seed DM, respectively, on average. Peas are reported to contain 14-26% total dietary fiber, of which 10-15% is insoluble fiber and 2-9% is soluble fiber (Dahl et al., 2012). The dietary fiber in peas is found in both the seed (hull) coat (outer fiber), and the cotyledon (inner fiber). The seed coat contains largely water-insoluble polysaccharides, primarily cellulose, whereas the cotyledon fiber consists of polysaccharides having various degrees of solubility, including hemicelluloses and pectins, along with cellulose. Thus, the common consumption of peas and the presence of soluble fiber in it indicate that human beings are routinely exposed to the soluble fiber from peas.

Peas and its different preparations are listed among the foods containing dietary fiber in the USDA Nutrient Database for Standard Reference (NDSR, 2009). This database includes 55 foods that contain peas, including three baby foods, six legumes and legume products, 15 soups, sauces, and gravies, and 31 vegetables and vegetable products. In addition to peas, 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 varying 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 pea fiber.

2.2. Metabolism/Fermentation

Given the prebiotic activity of fiber, in recent years, much of the interest in dietary fiber and its effects in humans have focused on its fermentation in the colon. The available information demonstrates that fermentation of fiber in the colon produces short-chain fatty acids (SCFA) and gases such as carbon dioxide, methane and hydrogen (IOM, 2005). The physiological effects of fiber in humans depend on the extent to which it is fermented. The SCFA produced in the colon are absorbed and each of the primary SCFA produced (acetate, propionate and butyrate) is metabolized differently by the body. Among the SCFAs, butyrate is a preferred energy source for colonocytes and is extensively metabolized by the colon. Propionate is mainly utilized in the liver and has been suggested to be a potential modulator of cholesterol synthesis and a precursor in liponeogenesis. Acetate is largely metabolized by peripheral tissues (i.e., muscle) or bacteria. It has been suggested that unfermented fiber residues and associated water increase fecal mass that may protect against ailments, including colon cancer and diverticulosis (Bourquin et al., 1992). The available information suggest that the colonic effects of poorly fermented fibers depend more on the physical properties (i.e., water-holding capacity) of the fiber itself, whereas the colonic effects of extensively

fermentable fiber sources are related to the end-products of fermentation.

Stark and Madar (1993) investigated the effects of fiber feeding on short-chain fatty acid (SCFA) production in Sprague Dawly rats and in an *in vitro* fermentation model using fecal inoculate from rats adapted to a high fiber diet. Additionally, the effect of fiber intake on endogenous sterol synthesis was also investigated in rats. Male rats were divided into four groups (5/group) and fed a control or 30% fiber diet (cellulose, pectin or pea fiber) for 4 weeks. *In vitro* fermentation was compared with measurements of cecal SCFA content of fiber-adapted rats. Sterol synthesis in isolated hepatocytes was determined in groups of five to seven rats fed 15% dietary fiber for 4 week. In both the *in vitro* and *in vivo* experiments the cellulose was poorly fermented. Pectin fermentation produced high levels of propionate, whereas pea fiber was associated with notable butyrate production. Adaptation to pectin produced seven times more SCFA in rat cecal contents in comparison to a fiber-free diet. Sterol synthesis in hepatocytes of rats fed pectin was significantly greater than in those of control or cellulose-fed rats. Despite significantly higher rates of SCFA production in pectin-fed rats, cholesterol synthesis was not inhibited, suggesting that SCFA are not the cholesterol-lowering factor of highly fermentable fiber sources.

Mirande et al. (2010) investigated fiber degradation, colonization and fermentation, and xylanase activity of two xylanolytic bacteria from the human colon. Both the bacteria *Bacteroides xylanisolvens* XB1A(T) and *Roseburia intestinalis* XB6B4 were cultivated under anaerobic conditions at 37°C in a complex medium containing clarified rumen fluid and 0.5% of complex substrates (oat spelt xylan, wheat or corn bran, pea fiber, cabbage and leek). Both bacteria grew well on fibers from wheat and corn bran, pea, cabbage and leek, and also on purified xylans. *R. intestinalis* colonized the substrates more efficiently as compared to *B. xylanisolvens*. The results of this study indicate that pea fiber can serve as a source material for growth of bacteria from human colon.

In an *in vitro* study to assess fermentation kinetics and end product profiles of 16 dietary fibers for dog foods using canine fecal inoculum, Bosch et al. (2008) reported that citrus pectin and pea fiber showed a similar low Rmax (maximal rate of gas production), but the time at which this occurred was later compared with sugar beet fiber, sugar beet pulp, soy fiber, and wheat middlings. The results also showed that incubation with pea fiber and wheat middlings resulted in the greatest butyrate production. Soy fiber, pea fiber, sugar beet fiber, sugar beet pulp, and wheat middlings were found to be slowly fermentable. The results showed that among different fibers, pea fiber or sugar beet pulp, which were fermented slower, yielded large amounts of butyrate. In another *in vitro* study in dogs, Swanson et al. (2001) reported that pea hulls and tomato pomace produced intermediate concentrations of gas and SCFA. In this study, substrates were fermented *in vitro* for 4, 12, and 24 hours with fecal flora obtained from three healthy dogs.

Mallillin et al. (2007) investigated the dietary fiber and fermentability characteristics of local root crops and legumes, including cowpea, chickpea, green pea and pigeon pea. The dietary fiber from test foods was isolated and fermented *in vitro* using human fecal inoculum simulating conditions in the human colon. The SCFA, e.g., acetate, propionate and butyrate, produced after fiber fermentation, was measured using HPLC. At 24 hours after the inoculation the amount of acetate, propionate and butyrate formed was reported as 1.9, 0.7 and 0.6 mmol/g fiber isolate, respectively. The investigators suggested that SCFA production after *in vitro* fermentation can be estimated using human fecal inoculum and can be used to model

the human colon.

2.3. Animal Safety Studies

Given the history of consumption of peas as a food and the available scientific literature on the effects of peas and its fiber in animals and humans, the safety of pea fiber consumption is not in question since no adverse effects have been reported. Hence, none of the standard basic or screening toxicology studies in laboratory animals are available in the scientific literature for pea fiber. There are a few studies in the literature where peas were fed to animals; however, it is important to note that the focus of these studies was to determine the health effects of feeding pea fiber to animals and not safety endpoints.

Whitlock et al. (2012) compared the effects of feeding uncooked pea fractions (embryo v. seed coat) on glucose homeostasis in glucose-intolerant rats and examined potential mechanisms influencing glucose homeostasis. In this study, Sprague Dawley rats were made glucose intolerant by high-fat feeding, following which diets containing both high-fat (40% of energy from fat, 20% of energy from saturated fat) and pea fractions were fed for 4 weeks. Rats fed diets containing uncooked pea seed coats low (non-colored seed coat; NSC) or high (coloured seed coat; CSC) in proanthocyanidins but not embryos had improved oral glucose tolerance. Feeding of non-colored seed coat also lowered fasting and glucose-stimulated insulin secretion, decreased β-cell mass by 50 % and lowered levels of malondialdehyde. Furthermore, feeding of non-colored seed coat decreased the mucosal thickness of the colon by 25 %, which might affect fiber fermentation and other gut functions. The investigators concluded that pea seed coats are the fraction exerting beneficial effects on glucose tolerance.

Serena et al. (2008) investigated the effect of feeding different types and amounts of dietary fiber (DF) on luminal environment and morphology in the small and large intestine of sows. In this study, three diets, a low-fiber diet (LF) and 2 high-fiber diets (high fiber 1, HF1, and high fiber 2, HF2) were fed to sows. The LF diet (DF, 17%; soluble DF 4.6%) was based on wheat and barley, whereas the 2 high-fiber diets (HF1: DF, 43%; soluble DF, 11.0%; and HF2: DF, 45%; soluble DF, 7.6%) were based on wheat and barley supplemented with different co-products from the vegetable food and agroindustry (HF1 and HF2: sugar beet pulp, potato pulp, and pectin residue; HF2: brewers spent grain, seed residue, and pea hull). The pea hull used in the HF-2 diet was 13.5% as fed basis. The diets were fed for a period of 4 weeks to 12 sows (4 receiving each diet). Thereafter, the sows were killed 4 hours post-feeding, and digesta and tissue samples were collected from various parts of the small and large intestine. The digesta from pigs fed the LF diet provided low levels of fermentable carbohydrates that were depleted in the proximal colon, whereas for pigs fed the 2 high-DF diets, the digesta was depleted of fermentable carbohydrates at more distal locations of the colon. The consequence was an increased retention time, greater DM percentage, decreased amount of material, and a decreased tissue weight after feeding the LF diet compared with the HF diets. The concentration of short-chain fatty acids was consistent with the fermentability of carbohydrates in the large intestine, but there was no effect of the dietary composition on the molar short-chain fatty acid proportions. The diet providing the greatest amount of fermentable carbohydrates (diet HF1, which was high in soluble DF) resulted in significant morphological changes in the colon compared with the LF diet.

In another study, Serena et al. (2009) investigated the absorption and plasma concentration of carbohydrate-derived nutrients [glucose, short-chain fatty acids (SCFA), and

lactate] and the apparent insulin production in sows fed diets containing contrasting types and contents of dietary fiber. In this repeated crossover design study, 6 sows were fed 3 experimental diets, low fiber (177 g of dietary fiber and 44 g of soluble fiber/kg), high soluble fiber (429 g of dietary fiber and 111 g of soluble fiber/kg), and high insoluble fiber (455 g of dietary fiber and 74 g of soluble fiber/kg). Variations in dietary concentration and solubility of dietary fiber were obtained by substituting starch-rich wheat and barley in the low fiber diet with dietary fiber-rich co-products, including pea hulls (primarily for high insoluble fiber). The main carbohydrate component of the low fiber diet was starch and non-starch polysaccharides (cellulose and non-cellulosic polysaccharides) for the two high dietary fiber diets. Consumption of the low fiber diet resulted in increased and rapid glucose absorption at 0 to 4 hours post-feeding. With the high insoluble fiber diet, the glucose absorption pattern was similar but at a decreased rate, whereas it was significantly decreased and delayed with the high soluble fiber diet. These differences were also reflected in the insulin response. The quantitative absorption of SCFA at 0 to 10 hours post-feeding was greater when feeding the high soluble fiber diet compared with the low fiber diet and intermediate when feeding the high insoluble fiber. The results of this study show that feeding the high dietary fiber diets resulted in an increased and more uniform uptake of SCFA compared to feeding the low fiber control. Additionally, the high soluble fiber diet reduced diurnal variation in glucose and insulin concentrations.

2.4. Human Studies

The human studies of pea and pea products are summarized in Table 6. In a randomized cross-over design, Sandstrom et al. (1994) investigated the effect of a pea cell wall fiber preparation with a high content of soluble fiber on fasting and postprandial blood lipids in young healthy volunteers (Table 6). The subjects were fed a low fiber diet and the same diet with added pea fiber, for 2 week each, separated by 2 weeks. The low fiber diet included 33 g pea fiber product/10 MJ (20 g dietary fiber) and was tested in five men and six women (mean age 23 years). No significant differences in fasting concentrations of total cholesterol, LDL cholesterol or HDL cholesterol were observed, whereas total and VLDL triglyceride concentrations were lower when subjects consumed the pea fiber diet compared with the low fiber diet. Postprandial response to pea fiber was studied in eight men. Addition of 12 g pea fiber product/10 MJ to a breakfast meal and 15 g/10 MJ to the following lunch meal resulted in significantly lower total triglyceride, chylomicron triglyceride and insulin concentrations after the lunch meal compared with results following the same meal without pea fiber. No differences were noted in glycemic response. The results of this study showed that dietary fiber lowers fasting and postprandial triglyceride concentrations without any change fasting cholesterol concentrations.

Table 6. Human Clinical studies related to metabolic, cardiovascular and gastrointestinal health outcomes of peas*

Reference	Study type	Study size/ participants	Length of study	Treatment products	Control products	Background diet	Percent change
Gastrointestinal health							
Flogan and Dahl (2010)	Randomized, controlled cross-over clinical study	13 pediatric patients with a history of constipation and/or abdominal pain in the past 12 months	3-week treatment, 3-week placebo period	5 g of inulin, 2 servings of study snacks with 1.4-3.4 g added pea hull fiber	5 g of maltodextrin and 2 servings of study snacks without added fiber	No change to normal background diet (3 d food intake records were taken for each 3-week period)	Pea fiber: 24% increase in bowel movement frequency
Veenstra et al. (2010)	Randomized, controlled cross-over clinical study	21 healthy male patients	28-day treatment period	100g dry weight green peas, Kabuli chickpeas or green Laird green lentil	100 g dry weight potatoes	No change to normal background diet	Green peas: no difference in bowel movement frequency or perceived flatulence, bloating, cramping and intestinal discomfort compared with potatoes or other pulses
Dahl et al. (2003)	Controlled clinical study	114 elderly patients	4-week baseline followed by 6-week treatment period	4 g pea hull fiber added to foods	Foods without added fiber	Daily menu administered by long-term care institution for the elderly	Pea fiber: 7.5% increase in bowel movement frequency
Seewi et al. (1999)	Randomized, controlled clinical study	8 healthy patients	36-h treatment (five meals)	30 g carbohydrate from pea starch dissolved in 500 ml cold tap water	30 g carbohydrate from crude yellow pea flour dissolved in 500 ml cold tap water	No change to normal background diet	Pea starch: 21% decrease in H_2 exhalation and 65% decrease in flatulence
Cardiovascular health							
Trinidad et al. (2010)	Randomized, controlled clinical study	20 patients with moderately elevated cholesterol	Six, 2-week treatment periods, each separated by a	50 g carbohydrate from queen peas, cowpeas, mung beans, pole sitao,	Individuals served as their own controls	No change to normal background diet (foods were recorded during the experimental period)	Pea product: no significant reduction in total or LDL-cholesterol levels

			2-week washout period	chickpeas, groundnuts, pigeon peas or kidney beans			
Sandstrom et al. (1994)	Randomized, controlled cross-over clinical study	8 healthy male patients	2-day treatment period with 2-week washout where patients consumed their habitual diets	7.4 g pea fiber product added to breakfast and 9.3 g pea fiber product added to the following lunch baked into bread	Low-fiber diet matched for energy content and macronutrient distribution	Diet matched for macronutrient distribution: 37% energy from fat, 14% from protein and 49% from carbohydrate	Pea fiber: trend to lower postprandial TAG (P, 0.01); no change in fasting lipid profile
Glycaemic response and insulin resistance							
Marinangeli and Jones (2011)	Randomized, controlled clinical study	23 hypercholesterolaemic overweight patients	28 day followed by 28 day washout periods	50 g carbohydrate from WPF or 50 g FPF	50 g carbohydrate from white wheat flour	NCEP-Step 1 diet, energy intake adjusted based on individual RMR so participants did not gain or lose weight	WPF: 13.5 % reduction in fasting insulin and 25% reduction in insulin resistance (HOMA-IR) FPF: 9.8% reduction in fasting insulin resistance (HOMA-IR)
Marinangeli et al. (2009)	Randomized, controlled cross-over clinical study	22 healthy patients	1 day	50 g carbohydrate from whole yellow pea flour in banana bread (100%), biscotti (100%) and pasta (30%)	50 g carbohydrate from whole wheat flour in banana bread (100%), biscotti (100%), and pasta (100%)	No change to normal background diet	Banana bread: 61.9% reduction in IAUC Biscotti: 55.1% reduction in IAUC Pasta: 43.1% increase in IAUC
Seewi et al. (1999)	Randomized, controlled clinical study	10 healthy patients	1 day	30 g carbohydrate from pea starch dissolved in 500 ml cold tap water	30 g carbohydrate from maize starch preparations dissolved in 500 ml cold	No change to normal background diet	Pea starch: 47% reduction in post-meal glucose, 54% reduction in

					tap water		serum insulin, and 37% reduction in C-peptide responses

* Adapted from Dahl et al. (2012); WPF: Whole pea flour; FPF: fractionated pea flour; NCEP: American Heart Association's National Cholesterol Education Program; HOMA-IR: homeostatic model assessment of insulin resistance; IAUC: incremental area under the curve

In a comparative study, Hamberg et al. (1989b) investigated the effect of wheat bran, sugar beet fiber and pea fiber on starch absorption in healthy subjects. In this study, eight healthy subjects were fed bread made from 100 g wheat flour and were compared with each dietary fiber fed simultaneously. Amounts of starch escaping small-bowel absorption were assessed by comparison of breath H_2 excretion after test meals. Following ingestion of wheat flour bread increases in H_2 excretion was noted in all subjects. Simultaneous ingestion of the bread with wheat bran, or sugar-beet fiber, or pea fiber increased the fraction of unabsorbed starch to 12.5, 12.5, and 12%, respectively. All three fibers decreased mouth-to-caecum transit time. Bread made from 100 g of low gluten wheat flour only escaped small bowel absorption in three subjects with a maximal fraction of 6%.The investigators concluded that the dietary fibers used in this study impaired the absorption of wheat starch and thereby increased the amount of starch-derived carbohydrate available for colonic fermentation.

In another study, Hamberg et al. (1989a) compared the effects of two types of fibers (pea fiber and sugar beet fiber) with wheat bran on postprandial blood glucose and serum insulin responses in normal subjects. In this study, the control meal consisted of 150 g ground beef mixed with 50 g glucose and 20 g lactulose. Addition of 15 g pure pea fiber significantly reduced (by 65%) the area under the incremental blood glucose curve. Although area under the insulin-response curve was reduced by all fibers, the effect was not statistically significantly. Mouth-to-cecum transit time, assessed by the hydrogen breath technique, was decreased by wheat bran and beet fiber but not by pea fiber. The investigators concluded that pea fiber is palatable and may prove beneficial as a fiber supplement for diabetics.

Dubois et al. (1993) evaluated the effects of total dietary fiber on lipid metabolism in humans. In this study, six normolipidaemic males ingested on separate days low-fiber test meal (2.8 g fiber) containing 70 g fat and 756 mg cholesterol, enriched with 10 g fiber in the form of either pea fiber or soybean fiber. Fasting and post-meal blood samples were obtained for 7 hours and chylomicrons were isolated. Addition of fiber did not affect changes in serum glucose, insulin or Apo A1 and Apo B variations as compared to the postprandial response given by the control low-fiber test meal. The serum triglyceride response was not altered by the addition of fibers but the 2-3 hour chylomicron triglyceride rise was noted by soybean fiber. Cholesterolaemia decreased postprandially for 6 hour, and was further lowered in the presence of pea fiber. The results of this study show that dietary fiber present in legumes may alter postprandial lipaemia and lipoproteins in humans to a variable extent. The lack of effect on postprandial triglyceridemia may be related to a higher fat content in relation to the fiber content (70 g fat/10 g fiber) as compared to that in Sandstrom et al. (1994) study, which might have contributed to the different results.

Whelan et al. (2006) compared changes in appetite within healthy subjects consuming

both a standard formula and one supplemented with pea-fiber (10 g/L) and fructo-oligosaccharide (FOS; 5 g/L) as a sole source of nutrition. In this double-blind, cross-over trial, 11 healthy subjects consumed a standard formula or a pea-fiber/FOS formula as a sole source of nutrition for 14 days. All participants showed weight loss during both the pea fiber/FOS period and control period compared to baseline levels, although there was no significant difference in mean weight loss when these two periods were compared. As compared to the standard formula, ingestion of the pea-fiber/FOS formula resulted in higher mean fullness, minimum fullness and minimum satiety. These differences are likely to be due to supplementation with pea-fiber and FOS as there were no differences in macronutrient intake between the formulas. Three of the original 14 subjects dropped out either due to personal reasons or dislike of the formula. No FOS-related dropouts were reported.

Knopp et al. (1999) investigated the blood cholesterol-lowering effects of a dietary supplement of water-soluble and non-water soluble fibers in 125 subjects (18-70 years age) with mild to moderate hypercholesterolemia (defined as low density lipoprotein cholesterol of 3.37 to 4.92 mmol/L and triglycerides of $\leq$ 3.43 mmol/L). The water soluble fibers used in the study were guar gum and pectin while the non-water soluble fibers included soy fiber, pea fiber and corn bran. The subjects were stabilized on a National Cholesterol Education Program Step 1 Diet for at least 9 weeks prior to randomization into the fiber supplement (n = 87) or placebo group(n = 82). The subjects in the fiber group received 20 g/day of the fiber supplement which consisted of 15 g/day of a mixture of guar gum and pectin and 5 g/day of a mixture of soy fiber, pea fiber and corn bran for the next 15 weeks while the other group consumed the placebo. After the 15 weeks of placebo treatment, these subjects received 20 g/day of fiber as well for an additional 36 weeks. The 15-week comparative phase was completed by 102 subjects (52 fiber; 50 placebo). Of these subjects 85 (45 fiber; 40 placebo) elected to continue in the 36-week non-comparative extension phase. During the initial 15 weeks of the study, 6% of the fiber group and 4% of the placebo group withdrew from the study due to treatment-related gastrointestinal side effects. From the subjects who continued after the first 15 weeks, 3% from the fiber group and 7% who were switched from placebo to fiber, withdrew from the study due to gastrointestinal side effects. During the first 15 weeks, 62% of the subjects in the fiber group and 49% of subjects in the placebo group reported side effects which were gastrointestinal in all but one subject per group. The majority of the adverse effects were mild and decreased with increasing duration of fiber supplement consumption. Increased diarrhea, rectal gas and loose stools were noted, as was a decreased incidence of constipation in the fiber group compared to placebo. It should be noted that in this study insoluble pea fiber was used.

2.5. Institute of Medicine Report

In 2005, the Food and Nutrition Board of the Institute of Medicine (IOM) Panel critically reviewed the safety related information on dietary fibers (IOM, 2005). The IOM Panel has not established a tolerable upper intake level (UL) for dietary or functional fiber. Regarding the adverse effects of dietary fibers, it was noted that the fibers, such as guar gum, inulin and oligofructose, fructooligosaccharides, polydextrose, resistant starch, and psyllium, can cause gastrointestinal distress which includes abdominal cramping, bloating, gas, and diarrhea (IOM, 2005). The 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 suggested that addition of cereal fiber to meals can decrease the gastrointestinal absorption of iron, zinc, calcium, and magnesium. However, the 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). The safety of fiber is supported by several over-the-counter retail products that have been consumed successfully for their laxative effects, along with the various dietary uses of fiber in popular bakery goods, i.e., low-calorie-high-fiber breads (IOM, 2005).

2.6. Dietary Fiber and Nutrients

It has been suggested that fiber intake may alter absorption of fat-soluble vitamins. This suggestion is based on the observation that certain dietary fibers delay absorption of triacylglycerol. Studies related to absorption of Vitamin A indicate that wheat bran intake may either increase (Rattan et al., 1981) or decrease (Wahal et al., 1986) serum vitamin A levels. The available information regarding the effects of consumption of specific fibers on absorption of other fat-soluble vitamins is limited and inconsistent. Compared to fat-soluble vitamins, the effect of fiber on absorption of water-soluble vitamins is even less understood. The available evidence suggests that wheat bran has no effect, while psyllium appeared to increase riboflavin absorption at pharmacological doses (Roe et al., 1988). Consumption of pectin fiber had no negative effect on the utilization of vitamin B_6 (Miller et al., 1980) or urinary ascorbic acid concentration (Keltz et al., 1978).

In addition to vitamins, the effects of various dietary fibers have also been investigated on mineral absorption. However, again, the results of these studies are inconsistent. There is a lack of information to draw conclusions on the effects of particular fiber types (including pea fibers) or fiber mixtures on mineral absorption. The possibility that fiber consumption could impair mineral status has been raised. Gordon et al. (1995) has argued persuasively that evidence to support this contention is lacking. In summary, there is no compelling evidence to support the notion that consumption of pea fiber or soluble fibers impairs the absorption of vitamins or essential minerals in well nourished populations. Furthermore, there is a long history of consumption of fiber-rich foods without any major reports on vitamin-mineral mal-absorption from intake of fiber at currently recommended doses. Hence, it seems unlikely that the estimated increase in fiber intake from pea fiber would result in any significant adverse effects.

2.7. Allergenicity

Pea is a cereal grain with proteins that are similar to those in other cereal grains. Individuals allergic to cereal grain products are not allergic to the fiber but to some of the specific proteins found in some cereals. The most common foods causing immunologically mediated reactions include milk, egg, fish, crustaceans, nuts, wheat, soy, peanut, peas and other legumes. Allergenic response to legumes may range from mild skin reactions to life-threatening anaphylactic reactions. Overall, allergenicity due to consumption of legumes in decreasing order may be peanut, soybean, lentil, chickpea, pea, mung bean, and red gram (Verma et al., 2013). Thus far, several allergens from different legumes have been identified and characterized. Most of the identified allergens belong to the storage protein family, profilins, or the pathogenesis-related proteins. Legumes also exhibit the property of

immunological cross-reactivity among themselves and from other sources that also increases the severity of allergenic response to a particular legume.

Legume allergy, mainly to lentils and chickpeas, is the fifth most common cause of food allergy in Spanish children. Ibanez et al. (2003) demonstrated a great degree of cross-reactivity among lentil, chick-pea, pea and peanut by ELISA inhibition (> 50 % max inhibition) in Spanish children. The majority of patients showed symptoms with more than one legume (median 3 legumes). These investigators challenged (open or simple blind) 39 patients with two or more legumes and 32 (82%) reacted to two or more legumes: 43.5% to 3, 25.6% to 2, 13% to 4 legumes. Among these patients, 73% challenged with lentil and pea had positive reaction to both, 69.4% to lentil and chick-pea, 60% to chick-pea and 64.3% to lentil, chick-pea and pea simultaneously. In this study, 82% of the children allergic to legumes had a sensitization to pollen. The investigators suggested that the decision to eliminate one legume from the diet should be based on a positive oral food challenge.

Sanchez-Monge et al. (2009) attempted to identify the main IgE binding components from pea seeds and to study their potential cross-reactivity with lentil vicilin. For this assessment, serum pool or individual sera from 18 patients with pea allergy were used to detect IgE binding proteins from pea seeds by immunodetection and immunoblot inhibition assays. IgE immunodetection of crude pea extracts revealed that convicilin, as well as vicilin and one of its proteolytic fragments (32 kDa), reacted with more than 50% of the individual sera tested. The results of this study show that vicilin and convicilin are potential major allergens found in pea seeds. Additionally, proteolytic fragments from vicilin are also relevant IgE binding pea components.

Wensing et al. (2003) described 3 patients with a history of anaphylaxis to pea who subsequently had symptoms after ingestion of peanut. In this study, peanut-related symptoms were documented according to case history or double-blind, placebo-controlled food challenge results. Skin prick tests were performed, and specific IgE levels were determined for pea and peanut. All patients had a positive skin prick test response and an increased IgE level to pea and peanut. These investigators concluded that clinically relevant cross-reactivity between pea and peanut does occur. The molecular basis for cross reactivity was determined to be vicilin homologues in pea and peanut (Ara h 1).

The available information indicates that pea allergy to pea has been reported and the frequency to pea allergy varies among different populations. Cross-reactivity among lentil, chick-pea, pea and peanut has been reported. Some of the specific proteins in pea are responsible for the allergic reaction. The pea fiber is unlikely to be allergenic. Fuji acknowledges that pea fiber (FIPEA™) 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).

3. SUMMARY AND DICUSSION

Peas are a hardy winter legume grain that has been consumed as a food around the world since ancient times. Peas are high in protein, fiber, vitamins, minerals and lutein and are considered to be a nutrient rich food. Beyond meeting basic nutrient requirements, in recent years, several studies have identified potential health benefits of pulses, including peas. The available evidence indicates that pea fiber contributes to gastrointestinal function and health.

Additionally, pea fiber also plays a technological role in food. The soluble pea fiber in food can provide mouth feel, viscosity, bulking effects, freezing point depression, and lowering water activity. Peas enjoy a long history of consumption as a food around the world and in the United States. The daily intake of soluble fiber from pea consumption can be estimated as 0.54 g/person/day. As fiber present in peas is also consumed along with intake of peas, safety data of consumption of peas as a food is applicable to pea fiber for safety-in-use determinations.

Fuji intends to use a standardized pea fiber (FIPEA™) as a multifunctional food ingredient at use levels up to 0.5 g/serving (reference amounts customarily consumed, 21 CFR 101.12) in baked goods (bread, cake, noodles), fruit juices, and milk (acidified). Pea fiber (FIPEA™) is an aqueous extract from the fibrous residue of peas starch and protein. Pea fiber (FIPEA™) contains 62-65% total dietary fiber, 25-30% sugars and 3-8% protein. The intended use of pea fiber (FIPEA™) by Fuji will result in an estimated daily mean and 90th percentile intake of 2.12 and 4.60 g/person/day (35.3 and 76.6 mg/kg body weight/day for an individual weighing 60 kg), respectively. The available information suggest that several fiber ingredients from other plants or grains are recognized as having GRAS status for designated food uses within the food industry. FDA has allowed three health claims related to dietary fiber intake and reduced risk of heart disease and cancer.

There is common knowledge of human consumption of peas and pea products, including the fiber portion. The USDA Nutrient Database list includes peas 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 pea fiber concentrate of approximately 5.0 g/person/day from the intended uses of FIPEA™ is very low (about 5-fold). While the intended uses of FIPEA™ (pea 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 peas, including its fiber, there is lack of well designed animal or human studies investigating the toxicity or adverse effects of pea fiber. Although dietary fibers are not digested in the 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. The available animal studies indicate that pea fiber has similar effects to that of other fibers. In humans and rats, ingestion of pea fiber increases caecal SCFA and promotes butyrate production. The results of available human studies also did not reveal any adverse effects of pea fiber. Both animal and human studies indicate that pea fiber may be beneficial to the host health. The content of pea fiber used in animal and human studies was relatively high compared that of human intake resulting from the intended uses of FIPEA™.

The totality of available evidence from dietary consumption of peas for centuries, current intake of dietary fiber, and animal and human studies suggest that consumption of pea fiber from the intended uses of FIPEA™ at use levels up to 0.5 g/serving (reference amounts customarily consumed, 21 CFR 101.12) in specified foods is safe. The proposed uses are compatible with current regulations, *i.e.*, pea fiber (FIPEA™) is used as a food ingredients in

baked goods (bread, cake, noodles), fruit juices, and milk (acidified), when not otherwise precluded by a Standard of Identity, and is produced according to current good manufacturing practices (cGMP). On the basis of both scientific procedures[3] corroborated by history of exposure from natural dietary sources, consumption of pea fiber concentrate as an added food ingredient is safe at daily consumption of up to 5.0 g/day.

[3] 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

Based on a critical evaluation of the publicly available data summarized herein, the Expert Panel members whose signatures appear below, have individually and collectively concluded that consumption of pea fiber (FIPEA™) as a food ingredient in selected food products [baked goods (bread, cake, noodles), fruit juices, and milk (acidified)] at levels of up to 0.5 g/serving (reference amounts customarily consumed, 21 CFR 101.12) when not otherwise precluded by a Standard of Identity as described in this monograph and resulting in the 90th percentile estimated intake of 4.6 g/person/day (76.6 mg/kg body weight/day for an individual weighing 60 kg) is safe and GRAS.

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 pea fiber (FIPEA™), when used as described, is GRAS based on scientific procedures.

Signatures

(b) (6)

Robert L. Martin, Ph.D. — Jan. 13, 2014 — Date

(b) (6)

Stanley T. Omaye, Ph.D., D.A.T.S. — 1/9/2014 — Date

(b) (6)

Madhusudan G. Soni, Ph.D., F.A.C.N., F.A.T.S. — Jan. 17, 2014 — Date

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6. APPENDIX I

Specifications and Compositional Analysis of Isolated Pea Product (FIPEA™)

Sample	#79	#85	#97	#108	#119
Parameter	Value	Value	Value	Value	Value
Ash (%)	3.5	3.5	3.5	3.5	3.6
pH value	5.4	5.3	5.3	5.5	5.6
Bulk Density	539 g/L	522 g/L	485 g/L	480 g/L	465 g/L
Fiber group					
Total dietary fiber (%)	65.0	64.4	62.3	64.2	62.1
Insoluble fiber (%)	1.0	1.0	1.0	1.0	1.0
Soluble fiber (%)	64.0	63.4	61.3	63.1	61.1
Sugars (%)	26.0	26.1	28.2	27.9	28.4
Proteins by Dumas (F=6.25)	7.0	6.3	6.2	6.2	6.3
Sodium (mg/100g)	602	615	596	613	594
Calcium (mg/100g)	169	173	168	172	167
Iron (mg/100g)	2.5	2.6	2.5	2.5	2.5
Moisture by Forced Air 1hr (%)	2.8	2.2	2.4	0.8	2.2
Fatty acid analysis w/profile (%)					
Total fat (%)	0.0	0.0	0.0	0.0	0.0
Saturated fat (%)	0.0	0.0	0.0	0.0	0.0
Monounsaturated fat (%)	0.0	0.0	0.0	0.0	0.0
Cis-cis polyunsaturated fat (%)	0.0	0.0	0.0	0.0	0.0
Trans-fat(%)	0.0	0.0	0.0	0.0	0.0
Calories (fiber subtracted)/ 100 g	132	130	138	136	139
Calories from fat/ 100 g	0	0	0	0	0
Calories from saturated/ 100 g fat	0	0	0	0	0
Microbiological parameters					
Aerobic plate count	< 1×10 cfu/g	< 1×10 cfu/g	< 1×10 cfu/g	< 1×10 cfu/g	< 1×10 cfu/g
Yeasts and molds	< 1×10 cfu/g	< 1×10 cfu/g	< 1×10 cfu/g	< 1×10 cfu/g	< 1×10 cfu/g
Salmonella	Negative	Negative	Negative	Negative	Negative

7. APPENDIX II

Additional certificates of analysis for microbiological load and heavy metal levels.

Certificate of Analysis

Aug.22.2013

Sample	Microbiological*1						Arsenic*2 (as As_2O_3)	Lead*2	Cadmium*2	Mercury*3
	Total Plate Count (/g)	Coliforms (/g)	Yeast	Mold	Staphylococci	Salmonella				
#45	< 10	Negative	< 10	< 10	Negative	Negative	Not detected	Not detected	Not detected	Not detected
#50	< 10	Negative	< 10	< 10	Negative	Negative	Not detected	Not detected	Not detected	Not detected
#59	< 10	Negative	< 10	< 10	Negative	Negative	Not detected	Not detected	Not detected	Not detected
#69	< 10	Negative	< 10	< 10	Negative	Negative	Not detected	Not detected	Not detected	Not detected
#75	< 10	Negative	< 10	< 10	Negative	Negative	Not detected	Not detected	Not detected	Not detected

Methods: *1 = Tempo methods; *2 = Atomic absorption spectrometry; *3 = Cold vapor atomic absorption spectrometry

SUBMISSION END

From: Mosley, Sylvester
To: "msoni@soniassociates.net"; Madhu Soni (sonim@bellsouth.net)
Cc: ashish@amintalati.com
Subject: Deficiencies Regarding GRN No. 000525 (Pea Fiber)
Date: Friday, August 15, 2014 9:55:00 AM

Dear Dr. Soni,

The review team for GRN No. 000525 has completed its initial review of Fuji Oil Company Limited's GRAS notice for Pea Fiber. As a result of the review we have a few deficiencies we would request the notifier to address in order for us to move forward with the review of the GRAS notice. The deficiencies are as follows:

- On page 3 of 6 of the GRAS notice the notifier states that the color of the pea fiber is yellow to off-white. Furthermore, pea fiber is intended to be used in food categories (i.e., bread and noodles) where its use might give the impression that egg has been added. Given this, is pea fiber intended to used as a color additive? Please explain.

- On page 1 of 28 of the GRAS notice (Expert Panel Statement), the page is marked confidential. It is our position that the expert panel statement is used to, in part, to get to a consensus for GRAS status of an ingredient for an intended use, as such; the statement should not be confidential. We request a clean copy of this expert panel statement.

- On page 17 of 28 of the GRAS notice the notifier states, "*In 2005, the Food and Nutrition Board of the Institute of Medicine (IOM) Panel critically reviewed the safety related information on dietary fibers (IOM, 2005). The IOM Panel has not established a tolerable upper intake level (UL) for dietary or functional fiber*."
  For the safety argument of pea fiber, an UL is not important. For any food ingredient, an RDA/DRI/AI value indicates a window of safe use level (in order to get benefit). Because the consumption of pea fiber is within the DRI limit suggested by IOM, this information should be integrated into the safety argument of pea fiber consumption. Please consult **Table S-3** of the IOM report (published in the form of a book titled, "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)", paperback 2005, ISBN 978-0-309-08525-0), and provide a narrative in your response, based on the numbers from the Table S-3, as part of the safety argument of pea fiber consumption at the proposed level.

- Is the proposed use of pea fiber additive or substitutional (more likely to be "substitutional" but that is not clearly mentioned)? A substitutional use maintains the exposure within the safe limit.

- In the table describing human studies, study participants are described as "healthy patients" in a number of human studies (Sandstrom et al., 1994, Seewi et al., 1999, Marinangeli et al., 2009, Veenstra et al., 2010). What is a "healthy patient"? Please revise this expression by the expression used in the respective original publications (e.g., "healthy subjects" as in Sandstrom et al., "children with constipation" as in Flogan and Dahl). Check each publication

cited for human studies and describe the study participants accurately.

- Dubois et al. (1993) discussed on page 16 of the notice (under "Human Studies") is missing from the reference. Cite it.

- Please correctly cite the title of Flogan and Dahl (2010).

- Please correctly cite the title of Dahl et al. (2003).

- Correct the Mallilin et al. reference (the year) on page 19 of the PDF (metabolism section).

We request that you respond to these deficiencies within a two-week timeframe (**August 29, 2014**). Please acknowledge receipt of this email. If you have any questions please do hesitate to contact me.

Sincerely,
Sylvester

Sylvester L. Mosley, Ph.D.
Consumer Safety Officer
OFAS Liaison to FSIS/USDA
HHS/FDA/CFSAN/OFAS/DBGNR
5100 Paint Branch Parkway (HFS-255)
College Park, MD 20740-3835
Phone: 240-402-1333
Fax: 301-436-2965

From: Madhu Soni
To: Mosley, Sylvester
Cc: ashish@amintalati.com
Subject: RE: Deficiencies Regarding GRN No. 000525 (Pea Fiber)
Date: Friday, August 22, 2014 9:38:06 AM
Attachments: GRN 525- Pea Fiber GRAS- FDA Query response.pdf

Dear Dr. Mosley,
Please find attached an electronic file providing a point-by-point response to your queries. I hope the information and clarifications, along with some discussion in the attached response addresses your queries. If you have any questions or need additional explanation, please let me know. Thank you for the opportunity to provide this explanation.

Best regards

Madhu

Madhu Soni, *PhD, FACN, FATS*
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From: Mosley, Sylvester [mailto:Sylvester.Mosley@fda.hhs.gov]
Sent: Friday, August 15, 2014 9:55 AM
To: msoni@soniassociates.net; Madhu Soni (sonim@bellsouth.net)
Cc: ashish@amintalati.com
Subject: Deficiencies Regarding GRN No. 000525 (Pea Fiber)

Dear Dr. Soni,

The review team for GRN No. 000525 has completed its initial review of Fuji Oil Company Limited's GRAS notice for Pea Fiber. As a result of the review we have a few deficiencies we would request the notifier to address in order for us to move forward with the review of the GRAS notice. The deficiencies are as follows:

- On page 3 of 6 of the GRAS notice the notifier states that the color of the pea fiber is yellow to off-white. Furthermore, pea fiber is intended to be used in food categories (i.e., bread and noodles) where its use might give the impression that egg has been added. Given this, is pea fiber intended to used as a color additive? Please explain.

- On page 1 of 28 of the GRAS notice (Expert Panel Statement), the page is marked confidential. It is our position that the expert panel statement is used to, in part, to get to a consensus for GRAS status of an ingredient for an intended use, as such; the statement

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  For the safety argument of pea fiber, an UL is not important. For any food ingredient, an RDA/DRI/AI value indicates a window of safe use level (in order to get benefit). Because the consumption of pea fiber is within the DRI limit suggested by IOM, this information should be integrated into the safety argument of pea fiber consumption. Please consult **Table S-3** of the IOM report (published in the form of a book titled, "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)", paperback 2005, ISBN 978-0-309-08525-0), and provide a narrative in your response, based on the numbers from the Table S-3, as part of the safety argument of pea fiber consumption at the proposed level.

- Is the proposed use of pea fiber additive or substitutional (more likely to be "substitutional" but that is not clearly mentioned)? A substitutional use maintains the exposure within the safe limit.

- In the table describing human studies, study participants are described as "healthy patients" in a number of human studies (Sandstrom et al., 1994, Seewi et al., 1999, Marinangeli et al., 2009, Veenstra et al., 2010). What is a "healthy patient"? Please revise this expression by the expression used in the respective original publications (e.g., "healthy subjects" as in Sandstrom et al., "children with constipation" as in Flogan and Dahl). Check each publication cited for human studies and describe the study participants accurately.

- Dubois et al. (1993) discussed on page 16 of the notice (under "Human Studies") is missing from the reference. Cite it.

- Please correctly cite the title of Flogan and Dahl (2010).

- Please correctly cite the title of Dahl et al. (2003).

- Correct the Mallilin et al. reference (the year) on page 19 of the PDF (metabolism section).

We request that you respond to these deficiencies within a two-week timeframe (**August 29, 2014**). Please acknowledge receipt of this email. If you have any questions please do hesitate to contact me.

Sincerely,
Sylvester

Sylvester L. Mosley, Ph.D.
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OFAS Liaison to FSIS/USDA
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Dear Dr. Mosley,

RE: GRN 525 (Pea Fiber)

We are in receipt of your electronic mail dated August 15, 2014, concerning GRN No. 000525 (Pea Fiber GRAS Notice). Below is a point-by-point response to your queries along with some relevant clarifications/discussion.

1. **FDA Query:** On page 3 of 6 of the GRAS notice the notifier states that the color of the pea fiber is yellow to off-white. Furthermore, pea fiber is intended to be used in food categories (i.e., bread and noodles) where its use might give the impression that egg has been added. Given this, is pea fiber intended to used as a color additive? Please explain.

Response: The pea fiber is not intended to be used as a color additive. While the use of pea fiber in the food categories described in GRN 525 may impart a color to the product, the intended use would fall outside the definition of "color additive" for the following reasons: Pea fiber is solely added for its intended technical effects. The fiber in food products improves the texture, controls moisture migration, and improves stability of the food product. The intended uses may constitute an "unimportant color" [21 CFR 70.3(g)] and it does not relate to any use of the ingredient as a color additive [21 CFR 70.3(f)].

2. **FDA Query:** On page 1 of 28 of the GRAS notice (Expert Panel Statement), the page is marked confidential. It is our position that the expert panel statement is used to, in part, to get to a consensus for GRAS status of an ingredient for an intended use, as such; the statement should not be confidential. We request a clean copy of this expert panel statement.

Response: We agree with FDA's position. Please note that by oversight the term "confidential" got included on page 1. We have informed the Panelists and they also agreed to remove the term "confidential." We are enclosing a copy of the revised Page 1 of the Expert Panel statement (see Appendix I).

3. **FDA Query:** On page 17 of 28 of the GRAS notice the notifier states, "*In 2005, the Food and Nutrition Board of the Institute of Medicine (IOM) Panel critically reviewed the safety related information on dietary fibers (IOM, 2005). The IOM Panel has not established a tolerable upper intake level (UL) for dietary or functional fiber*."

For the safety argument of pea fiber, an UL is not important. For any food ingredient, an RDA/DRI/AI value indicates a window of safe use level (in order to get benefit). Because the consumption of pea fiber is within the DRI limit suggested by IOM, this information should be integrated into the safety argument of pea fiber consumption. Please consult **Table S-3** of the IOM report (published in the form of a book titled, "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids

(Macronutrients)", paperback 2005, ISBN 978-0-309-08525-0), and provide a narrative in your response, based on the numbers from the Table S-3, as part of the safety argument of pea fiber consumption at the proposed level.

Response: Thank you for your suggestions. We would like to add the following to the write up on page 17 of 28:

Following an extensive and critical review of the available literature, the Institute of Medicine (IOM, 2005) established Dietary Reference Intake Values (also known as Adequate Intake[1]) for total fiber for different age groups (Life Stage Group). In establishing the adequate intake of total fiber the IOM primarily used following criteria: "Intake level shown to provide the greatest protection against coronary heart disease." For total fiber, the adequate intake is set at 25 and 38 g/day for women and men ages 19 to 50 years, respectively. The adequate intake in different age groups (1 year to > 70 years) ranged from 19 to 38 g/day. These values also indicate that in order to get benefits, the range of fiber intake for different age groups should be 19 to 38 g. These values also indicate a window of safe use levels as compared to current intake or potential intake resulting from new proposed uses. The intended use of pea fiber will result in estimated 90th percentile intake of 4.6 g/day. As compared to the adequate intake, consumption estimate of pea fiber from its intended uses is 4 to 8 fold lower. This also suggests that intended uses of pea fiber as a food ingredient does not present a safety concern.

4. **FDA Query:** Is the proposed use of pea fiber additive or substitutional (more likely to be "substitutional" but that is not clearly mentioned)? A substitutional use maintains the exposure within the safe limit.

Response: This was our oversight. We forgot to mention that the proposed use of pea fiber is substitutional.

5. **FDA Query:** In the table describing human studies, study participants are described as "healthy patients" in a number of human studies (Sandstrom et al., 1994, Seewi et al., 1999, Marinangeli et al., 2009, Veenstra et al., 2010). What is a "healthy patient"? Please revise this expression by the expression used in the respective original publications (e.g., "healthy subjects" as in Sandstrom et al., "children with constipation" as in Flogan and Dahl). Check each publication cited for human studies and describe the study participants accurately.

Response: Thank you for bringing this to our attention. Although the Table was adopted from a publication by Dahl et al. (2012), we agree that accurate description of the study participants is important. We have revised the table describing human studies (Table 6 of the GRAS notice); please see Appendix II included with this response.

[1] Adequate Intake (AI): the recommended average daily intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate—used when an RDA cannot be determined.

6. FDA Query: Dubois et al. (1993) discussed on page 16 of the notice (under "Human Studies") is missing from the reference. Cite it.

Response: Sorry for our oversight. The missing citation that needs to be included in the reference list is as follows:

Dubois, C., Cara, L., Armand, M., Borel, P., Senft, M., Portugal, H., Pauli, A.M., Bernard, P.M., Lafont, H., Lairon, D., 1993. Effects of pea and soybean fibre on postprandial lipaemia and lipoproteins in healthy adults. Eur. J. Clin. Nutr. 47(7):508-520.

7. FDA Query: Please correctly cite the title of Flogan and Dahl (2010)

Response: Thank you for bringing this to our attention. The correct citation is as follows:

Flogan, C., Dahl, W.J., 2010. Effects of fiber-fortified foods on children with constipation potential improved stool frequency and decreased energy intake. ICAN: Infant, Child, & Adolescent Nutr. 2(5): 312-317.

8. FDA Query: Please correctly cite the title of Dahl et al. (2003)

Response: Thank you for bringing this to our attention. The correct citation is as follows:

Dahl, W.J., Whiting, S.J., Healey, A.D., Zello, G.A., Hildebrandt, S.L., 2003. Increased stool frequency occurs when finely processed pea hull fiber is added to usual foods consumed by elderly residents in long-term care. J. Am. Diet. Assoc. 103 (9):1199-1202.

9. FDA Query: Correct the Mallilin et al. reference (the year) on page 19 of the PDF (metabolism section)

Response: Thank you for bringing this to our attention. The correct year on page 19 of the PDF for Mallilin et al. reference should be 2008.

We hope the above information and clarification addresses your queries. If you have any questions or need additional explanation, please let me know.

Thank you for the opportunity to provide this explanation to your questions.

Best regards

Madhu Soni, PhD

Appendix I:

Revised Page 1 of the Expert Panel statement

EXPERT PANEL STATEMENT

DETERMINATION OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF

SOLUBLE PEA FIBER

AS A FOOD INGREDIENT

Prepared for:

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January 2014

Appendix II

Revised table describing human studies

Table 6. Human Clinical studies related to metabolic, cardiovascular and gastrointestinal health outcomes of peas*

Reference	Study type	Study size/ participants	Length of study	Treatment products	Control products	Background diet	Percent change
Gastrointestinal health							
Flogan and Dahl (2010)	Randomized, controlled cross-over clinical study	13 children with a history of constipation and/or abdominal pain in the past 12 months	3-week treatment, 3-week placebo period	5 g of inulin, 2 servings of study snacks with 1.4-3.4 g added pea hull fiber	5 g of maltodextrin and 2 servings of study snacks without added fiber	No change to normal background diet (3 d food intake records were taken for each 3-week period)	Pea fiber: 24% increase in bowel movement frequency
Veenstra et al. (2010)	Randomized, controlled cross-over clinical study	20 healthy adult males	28-day treatment period	100 g dry weight green peas, Kabuli chickpeas or green Laird green lentil	100 g dry weight potatoes	No change to normal background diet	Green peas: no difference in bowel movement frequency or perceived flatulence, bloating, cramping and intestinal discomfort compared with potatoes or other pulses
Dahl et al. (2003)	Controlled clinical study	114 elderly institutionalized residents	4-week baseline followed by 6-week treatment period	4 g pea hull fiber added to foods	Foods without added fiber	Daily menu administered by long-term care institution for the elderly	Pea fiber: 7.5% increase in bowel movement frequency
Seewi et al. (1999)	Randomized, controlled clinical study	8 healthy non-obese subjects (4 women and 4 men)	36-h treatment (five meals)	30 g carbohydrate from pea starch dissolved in 500 ml cold tap water	30 g carbohydrate from crude yellow pea flour dissolved in 500 ml cold tap water	No change to normal background diet	Pea starch: 21% decrease in H_2 exhalation and 65% decrease in flatulence
Cardiovascular health							
Trinidad et al.	Randomized,	20 subjects with	Six, 2-week	50 g carbohydrate	Individuals served as	No change to normal	Pea product: no

(2010)	controlled clinical study	moderately elevated serum cholesterol	treatment periods, each separated by a 2-week washout period	from queen peas, cowpeas, mung beans, pole sitao, chickpeas, groundnuts, pigeon peas or kidney beans	their own controls	background diet (foods were recorded during the experimental period)	significant reduction in total or LDL-cholesterol levels
Sandstrom et al. (1994)	Randomized, controlled cross-over clinical study	"Eight male volunteers" with a measurable response in plasma triglyceride concentration of ≥1 mmol/L above fasting concentrations 3 h after a fat load of 200 mL of cream (80 g of fat)	2-day treatment period with 2-week washout where patients consumed their habitual diets	7.4 g pea fiber product added to breakfast and 9.3 g pea fiber product added to the following lunch baked into bread	Low-fiber diet matched for energy content and macronutrient distribution	Diet matched for macronutrient distribution: 37% energy from fat, 14% from protein and 49% from carbohydrate	Pea fiber: trend to lower postprandial TAG (P, 0.01); no change in fasting lipid profile
Glycaemic response and insulin resistance							
Marinangeli and Jones (2011)	Randomized, controlled clinical study	23 hypercholesterolaemic overweight men and women	28 day followed by 28 day washout periods	50 g carbohydrate from WPF or 50 g FPF	50 g carbohydrate from white wheat flour	NCEP-Step 1 diet, energy intake adjusted based on individual RMR so participants did not gain or lose weight	WPF: 13.5 % reduction in fasting insulin and 25% reduction in insulin resistance (HOMA-IR) FPF: 9.8% reduction in fasting insulin resistance (HOMA-IR)
Marinangeli et al. (2009)	Randomized, controlled cross-over clinical study	22 healthy subjects (15 women and 7 men)	1 day (single meal)	50 g carbohydrate from whole yellow pea flour in banana bread (100%), biscotti (100%) and	50 g carbohydrate from whole wheat flour in banana bread (100%), biscotti (100%), and pasta	No change to normal background diet	Banana bread: 61.9% reduction in IAUC Biscotti: 55.1% reduction in IAUC Pasta:

				pasta (30%)	(100%)		43.1% increase in IAUC
Seewi et al. (1999)	Randomized, controlled clinical study	10 healthy non-obese subjects (3 women and 7 men)	1 day (single meal)	30 g carbohydrate from pea starch dissolved in 500 ml cold tap water	30 g carbohydrate from maize starch preparations dissolved in 500 ml cold tap water	No change to normal background diet	Pea starch: 47% reduction in post-meal glucose, 54% reduction in serum insulin, and 37% reduction in C-peptide responses

* Adapted from Dahl et al. (2012); WPF: Whole pea flour; FPF: fractionated pea flour; NCEP: American Heart Association's National Cholesterol Education Program; HOMA-IR: homeostatic model assessment of insulin resistance; IAUC: incremental area under the curve