#788

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May 28, 2018

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety (HFS-200)
5100 Campus Drive
College Park, MD 20740

Subject: GRAS Notification for Pea Protein

Dear Sir/Madam:

In accordance with 21 CFR part 170, subpart E, Yantai Oriental Protein Tech Co., Ltd. (Yantai), through Soni & Associates Inc. as its agent, hereby submits the enclosed notice of a claim that the food ingredient pea protein (>80%) 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.

Given the compositional and manufacturing process differences, we believe that pea protein manufactured by Yantai is different compared to the pea protein products that have already been reviewed by FDA under other GRAS notices.

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 772-299-0746 or by email at sonim@bellsouth.net .

Sincerely,

Madhu G. Soni, Ph.D.

EVALUATION OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF PEA PROTEIN

Submitted to:
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
HFS-200
5001 Campus Drive
College Park, MD 20740-3835
USA

Submitted by::
Yantai Oriental Protein Tech Co., Ltd.
Jincheng Road, Zhaoyuan 265400
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Panel Members

Robert L. Martin, Ph.D.
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Madhusudan G. Soni, Ph.D., F.A.C.N., F.A.T.S.

May, 2018

EVALUATION OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF PEA PROTEIN

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EVALUATION OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF PEA PROTEIN

1. Part I- SIGNED STATEMENT AND CERTIFICATION

1.1. Basis of Conclusion:

This GRAS conclusion for use of pea protein (>80%) as a food ingredient has been reached in accordance with requirements described in 21 CFR 170.220, subpart E.

1.2. Name and Address of Organization:

Yantai Oriental Protein Tech Co., Ltd.
#668 Jincheng Road,
Zhaoyuan City
CHINA 265400

1.3. Name of Substance:

The name of the substance of this GRAS assessment is pea protein. The tradename is GINCORY.

1.4. Intended Conditions of use of Pea Protein:

Yantai Oriental Protein Tech Co., Ltd. (Yantai) intends to use pea protein (containing >80% protein) derived from *Pisum sativum* L. seed-pods (peas) as a food ingredient, formulation aid [21 CFR 170.3(o)(14)][1], nutrient supplements [21 CFR 170.3(o)(20)][2], stabilizers and thickeners [21 CFR 170.3(o)(28)][3] and texturizer [21 CFR 170.3(o)(32)][4] in conventional foods such as Baked Goods and Baking Mixes; Beverages and Beverage Bases; Breakfast Cereals; Dairy Product Analogs; Fats and Oils; Grain Products and Pastas; Milk Products; Plant Protein Products; Processed Fruits and Fruit Juices; Processed Vegetables and Vegetable Juices; Soups and Soup Mixes at levels ranging from 0.96 to 34.3%. It is recognized that there are Standard of Identity requirements for some of these specified foods and these foods will not be referred by their commonly recognized names.

1.5. Statutory Basis for GRAS Conclusion:

This GRAS conclusion is based on scientific procedures in accordance with 21 CFR 170.30(a) and 170.30(b).

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[1]*Formulation aids*: Substances used to promote or produce a desired physical state or texture in food, including carriers, binders, fillers, plasticizers, film-formers, and tableting aids, etc.
[2]*Nutrient supplements*: Substances which are necessary for the body's nutritional and metabolic processes.
[3]*Stabilizers and thickeners* : Substances used to produce viscous solutions or dispersions, to impart body, improve consistency, or stabilize emulsions, including suspending and bodying agents, setting agents, jellying agents, and bulking agents, etc.
[4]*Texturizers*: Substances which affect the appearance or feel of the food.

1.6. Exemption from Premarket Approval Requirements:

Yantai has concluded that pea protein (containing >80% protein) is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on our conclusion that pea protein (containing >80% protein), meeting the specifications cited herein, and when used as a formulation aid, nutrient supplements, stabilizers and thickeners, and texturizer is GRAS and is therefore exempt from the premarket approval requirements.

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 protein (containing >80% protein), when used as described in this dossier, is GRAS based on scientific procedures.

1.7. Availability of data and information:

The data and information that are the basis for this GRAS conclusion will be made available to FDA upon request by contacting Ms. Dora Xu or Dr. Soni at the below addresses. The data and information will be made available to FDA in a form in accordance with that requested under 21 CFR 170.225(c)(7)(ii)(A) or 21 CFR 170.225(c)(7)(ii)(B).

Ms. Dora Xu
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Or

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Soni & Associates Inc.,
749 46th Square,
Vero Beach FL, 32968

Phone: (772) 299-0746;
E-mail: sonim@bellsouth.net

1.8. Data exempt from Disclosure:

Parts 2 through Part 7 of this GRAS notification does not contain data or information that is exempt from disclosure under the Freedom of Information Act. There is no privileged or confidential information such as trade secrets and/or commercial or financial information in this document. Therefore. All of the information contained in this dossier can be made publicly available.

1.9. Certification:

Yantai, certifies that to the best of its knowledge, this GRAS conclusion is based on a complete, representative, and balanced dossier that includes all relevant information, available and obtainable by Yantai, including any favorable or unfavorable information, and pertinent to the evaluation of the safety and GRAS status of the use of pea protein. Yantai accepts responsibility for the GRAS conclusion that has been made for pea protein as described in this dossier.

1.10. Name, position/title of responsible person who signs dossier and signature:

Ms. Dora Xu
Import and Export Manager
Yantai Oriental Protein Tech Co., Ltd.
#668 Jincheng Road,
Zhaoyuan City
CHINA 265400

Tel: +86-535-8072189
Mobile: +86-155-8959-1169
Email: doraxu@orientalprotein.com

Signature: (b) (6)

1.11. FSIS/USDA – Use in Meat and/or Poultry:

Yantai does not intend to add pea protein to any meat and/or poultry products that come under USDA jurisdiction. Therefore, 21 CFR 170.270 does not apply.

2. Part II-IDENTITY AND TECHNICAL INFORMATION

2.1. Description

The subject of this GRAS assessment, standardized pea protein, is derived from high quality non-GMO *Pisum sativum* L. seed-pods (peas). The preparation is a concentrate prepared by water extraction to yield a protein rich (>80% protein) fraction by the processes of isolation. Pea protein is a light cream colored powder with a bland odor and a characteristic taste. General descriptive characteristics and properties of pea protein manufactured by Yantai are presented in Table 1.

Table 1. General Descriptive Characteristics of Pea Protein

Parameter	Description (Yantai, 2017)*
Botanical source	*Pisum sativum* L.
Source synonyms	*Pisum arvense* L., *Pisum humile* Boiss. & Noe,
Plant part used	Peas; seeds
Synonyms of part used	Golden pea; Yellow pea; Bush pea; False lupine
Product Appearance	Powder
Color	Light cream
Odor	Bland
Taste	Characteristic
Storage	Store in a well closed, air tight container, protected from light and moisture, in a dry and cool place
Shelf life	Two years

*Based on information provided by Yantai (2017)

The taxonomic classification of the source material, *Pisum sativum* L., is summarized in Table 2. As described in the USDA Plant Fact Sheet[5], the pea is a cool-season annual vine that is smooth and has a bluish-green waxy appearance. Vines can be up to nine feet long; the stem is hollow; and, the leaves are alternate, pinnately compound, and consist of two large leaf-like 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). A picture of split yellow peas is shown in Figure 1.

Table 2. Taxonomic Classification of *Pisum sativum* L.

Rank	Scientific Name – Common Name
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.

[5] Available at: https://plants.usda.gov/core/profile?symbol=pisa6

Figure 1. Typical Picture of Split Yellow Peas

2.2. Specifications and Identity

Yantai has established the food-grade specifications for pea protein. These specifications are presented in Table 3. The protein content of the final product is >80%. The other components consist of fat, fiber, carbohydrates and moisture (H_2O).The product identity and quality is standardized by parameters such as the content of protein, crude fiber, moisture, ash, fat, and pH. The product specification also includes microorganism load and heavy metals levels. In order to demonstrate conformance with the food-grade specifications, Yantai has provided batch analysis data from five non-consecutive batches of pea protein. This data, presented in Appendix I, support the consistent manufacturing process. In the batch analysis data provided in Appendix I, the values for Aflatoxin (G1+G2+B1+B2) are given as "/" and it was not clear. However, in order to confirm the aflatoxin levels are below 5 μg/kg, three batches were analyzed and the reports are provided as Appendix II. Yantai recognizes that lot-to-lot variations occur, depending upon a variety of factors. However, the final product will comply with the standard specifications set forth in Table 3.

Table 3. Food Grade Specifications of Pea Protein*

Parameter	Values	Assay method
Protein (dry basis)	≥ 80%	AOAC 981.10
pH	6.5-8.5	Q/DFS0002S
Total Fat	≤ 10%	AOAC 945.18
Dietary Fiber	≤ 1.5%	AOAC 991.43
Moisture	≤ 10%	AOAC 925.09
Ash	≤ 8%	AOAC 942.05
Total Carbohydrate	≤ 3%	Nutrition Labeling and Education Act
Particle size	100 mesh	Sieve method
Heavy metals		
Lead	< 0.1 ppm	EN ISO17294-2
Arsenic	< 0.1 ppm	EN ISO17294-2
Cadmium	< 0.3 ppm	EN ISO17294-2
Mercury	< 0.02 ppm	EN ISO17294-2
Microbiological assays		
Total plate count	< 30000 cfu/g	AOAC 990.12
Total Coliforms	< 10 cfu/g	AOAC 991.14
Yeast and Mold	< 100 cfu/g	AOAC 997.02
Pathogenic bacteria	No detected	GB 4789.4
Salmonella	Absent /10 g	AOAC 2003.09
Escherichia coli	Absent /1 g	AOAC 991.14
Staphylococcus aureus	Absent /1 g	ISO21657:2004
Other Contaminants		
Aflatoxin (G1+G2+B1+B2)	<5 µg/kg	GB/T 18979
Pesticides	Complies	BS EN 15662:2008

*Based on information provided by Yantai (2017)

2.3. Manufacturing Process

The standardized pea protein is produced from yellow peas (*Pisum sativum* L.) according to current Good Manufacturing Practices (cGMP) at Yantai Oriental Protein Tech Co., Ltd. facility located in Shandong, China (Mainland). The production facility is ISO certified (9001:2008) and follows the HACCP protocols. Additionally, the facility has passed certifications such as CIQ registered, FDA registered under number 13488197390, KOSHER and HALAL, and has a QS Quality Safety Food Manufacturing Permit.

In brief, the manufacturing process of pea protein involves selection of high quality dry peas from the suppliers. The peas obtained are cleaned and subjected to dehulling of the grains followed by grinding. The grinded pea powder is mixed with water resulting in the liquid mixture of protein and starch that is subjected to homogenization. Base precipitation and acid neutralization are used to dissolve the protein out from the mixture fluid. This mixture is subjected to centrifugation to separate the starch. The protein concentrate is isolated. This is followed by further centrifugation to concentrate the protein. The protein concentrate is subjected to flash evaporation and drying by using spray dryers to obtain the final dry product. The protein thus obtained is tested and packaged. The preparation procedure assures a consistent

and high-quality product. During manufacturing, no solvents other than water are used; the concentrate is an aqueous preparation derived from peas. The processing aids such as acid and base used are food grade and in compliance with the current regulation for such agents for food production. The production process is provided in Figure 2.

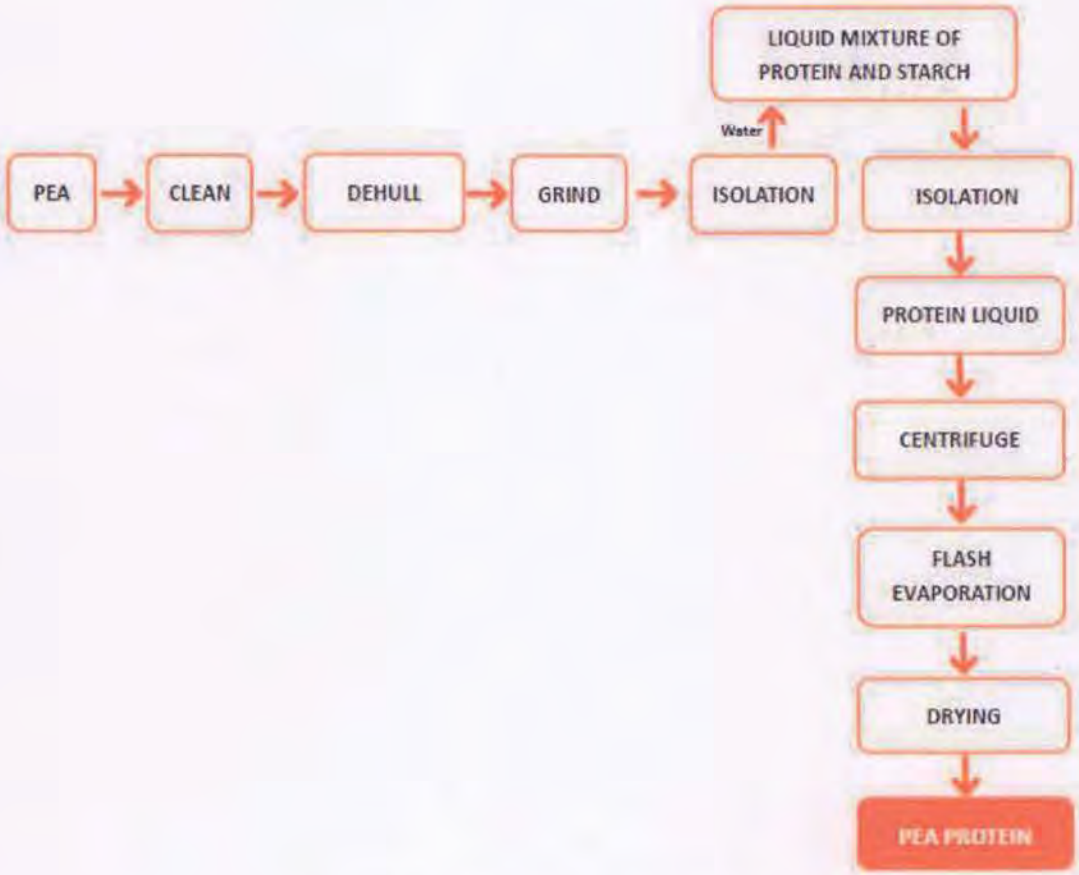

Figure 2. Manufacturing Process of Pea Protein

2.4. Compositional and Nutritional Analysis

Yellow peas offer many nutritional benefits, including being rich in dietary protein and fiber. The nutritional composition of pea protein (80% protein) is provided in Table 4. As per the USDA definition, this form of protein is classified as concentrate. In Table 4, the nutritional composition of pea protein, the subject of this GRAS assessment, is also compared with unprocessed peas (green seeds, split, mature seeds, raw).

Table 4. Comparison of Nutritional Composition of Peas and Pea Protein

Nutrient	Content per 100 g	
	Pisum sativum[1]	Pea Protein
Protein (g)	23.82	81.4
Total Fat (g)	1.16	9.6
Saturated Fat (g)	0.161	1.9
Cholesterol (mg)	0	0
Total Carbohydrates	63.34	2.5
Total Dietary Fiber (g)	25.5	1.6
Sugars (g)	8.00	0.6
Sodium (mg)	15	0.886
Potassium	0.823	0.0978
Calcium (mg)	37	17.9
Iron (mg)	4.82	32.6
Vitamin D (µg)	7	0
Total Calories (Kcal)	352	422

1. Source: United States Department of Agriculture, 2013. National Nutrient Database for Standard Reference, Nutrient data for 16085, Peas, split, mature seeds, raw. Release 28. http://ndb.nal.usda.gov/ndb/foods/show/4823?fgcd=&manu=&lfacet=&format=&count=&max=35&offset=&sort=&qlookup=16085

2.4.1. Amino Acid Profile

The amino acid profile of the subject of this GRAS, pea protein (≥80% protein), is presented in Table 5. The amino acid profile in Table 5 includes all amino acids such as essential, conditionally essential, and non-essential, and is compared with the source material (peas) amino acid. The information in Table 5 suggest that the amino acid profile of pea protein is similar to the amino acid composition of other peas, except for some minor variations in a few amino acids. The comparative amino acid profile with unprocessed peas (source material) suggest that the manufacturing process is unlikely to significantly affect the levels of the amino acids in the final product. It is recognized that pea protein is an incomplete protein. However, it is expected that pea protein will not be the sole source of protein in the diet. Therefore, other complementary proteins in the diet will compensate for the amino acids that are low in pea protein[6]. Ref.:

[6] Available at: https://www.accessdata.fda.gov/scripts/interactivenutritionfactslabel/factsheets/protein.pdf.

Table 5. Comparison of Amino Acid Profile of Peas and Pea Protein

Amino Acids	Peas		Pea Protein
	g/100g[1]	% of Total Amino Acid[1]	% of Total Amino Acid
Essential amino acids			
Phenylalanine	1.132	4.82	4.09
Valine	1.159	4.94	3.80
Threonine	0.872	3.72	3.30
Tryptophan	0.275	1.17	0.68
Methionine	0.251	1.07	0.79
Isoleucine	1.014	4.32	3.73
Leucine	1.760	7.50	6.59
Lysine	1.772	7.55	5.88
Histidine	0.597	2.54	1.97
Conditionally Essential amino acids			
Arginine	2.188	9.33	6.26
Cysteine	0.373	1.59	0.99
Glycine	1.092	4.65	3.09
Glutamic	4.196	17.88	12.33
Proline	1.014	4.32	3.95
Serine	1.080	4.60	3.70
Tyrosine	0.711	3.03	3.11
Other amino acids			
Aspartic Acid	2.896	12.34	9.08
Alanine	1.080	4.60	3.32
Total Amino Acids	23.462	100	76.69

1. Source: United States Department of Agriculture. National Nutrient Database for Standard Reference, Nutrient data for 16085, Peas, split, mature seeds, raw. Release 26. 2013.

3. Part III- DIETARY EXPOSURE

3.1. Intended Technical Effects and Food Categories

Yantai intends to use pea protein for the following technical effects as defined in 21 CFR 170.3(o) formulation aid (14), nutrient supplement (20), stabilizers and thickeners (28) and texturizers (31). Pea protein will be used as a substitute for, and/or in conjunction with, soy protein and whey protein in conventional food products. The targeted foods include snacks and cereals, high protein foods, gluten-free foods (pasta, baking), sports foods (mix, bars), and other conventional food products needing protein-source properties. The effects of pea protein in these foods include, promotion of ease of dry flow, masking of off-flavors, texturing of meat analogues, retention of oils and gelation, increase of water-solubility, and source of nutrients. The intended use levels and food categories are presented Table 6. It is recognized that there are Standard of Identity requirements for some of the foods and these foods will not be referred by their commonly recognized names such as milk, chocolate or yogurt. 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 protein.

3.1.1. Intended Uses and Estimated Intake

Pea protein by Yantai is intended for use in the same foods, and at identical use levels, mentioned in the GRN 608. There are no new food uses proposed by Yantai for pea protein. The substance mentioned in GRN 608 (Axiom Foods, 2015) has been reported to contain ≥80% pea protein, which is the same as the subject of this GRAS assessment. Pea protein will be added to Baked Goods and Baking Mixes; Beverages and Beverage Bases; Breakfast Cereals; Dairy Product Analogs; Fats and Oils; Grain Products and Pastas; Milk Products; Plant Protein Products; Processed Fruits and Fruit Juices; Processed Vegetables and Vegetable Juices; Soups and Soup Mixes at levels ranging from 0.96 to 34.3%. The use levels are based on the purity criteria of 80% protein concentrate.

As indicated above, pea protein is intended for use in the same foods, and at identical levels of addition, as notified by Axiom Foods in GRN 608. The proposed uses and use levels of pea protein are presented in Table 6. The intended use of pea protein in the same foods and at the same levels as those in GRN 608 is not expected to noticeably affect the intake of pea protein in the overall diet of the public from introduction into the market by another supplier who will have to compete in essentially the same markets and foods. In GRN 608 (Axiom Foods, 2015), estimates for the intake of pea protein were determined using the U.S. National Center for Health Statistics' (NCHS) National Health and Nutrition Examination Surveys (NHANES) 2011-2012.

Table 6. Summary of the Individual Proposed Food-Uses and Use-Levels of Pea Protein*

Food Category	Food-Uses	Proposed Use Level of Pea Protein (%)[1]
Baked Goods and Baking Mixes	Breads	4.8
	Rolls	4.8
	Bagels	4.4
	English Muffins	4.4
Beverages and Beverage Bases	Non-Milk Based Meal Replacements	1.04
Breakfast Cereals	Ready-to-Eat Breakfast Cereals	4.4 - 16
Dairy Product Analogs	Soy/Imitation Milks	1.04
Fats and Oils	Margarine[2]	17.12
	Salad Dressings	8
Grain Products and Pastas	Health Bars and Grain-Based Bars Containing Fruit and Vegetable[3]	20
Milk Products	Flavored Milk Drinks	1.04
	Milk-Based Meal Replacements	1.04
	Yogurt (Regular and Frozen)[2]	1.1 - 2.0
Plant Protein Products	Meat Alternatives	1 - 34.3
Processed Fruits and Fruit Juices	Fruit Juice[2]	1.04
	Fruit Nectars	1.04
	Fruit-Flavored Drinks	1.04
	Fruit Smoothies	20
Processed Vegetables and Vegetable Juices	Vegetable/Tomato Juice Including Vegetable Smoothies[4]	20
Soups and Soup Mixes	Prepared Soups, Dry Soup Mixes, and Condensed Soups	0.96

*Adapted from GRN 608 (Axiom Foods, 2015); [1] Use levels are calculated based on the purity criteria of 80% protein; [2] These food-uses represent non-standardized food products; however, in order to obtain a conservative intake estimate, surrogate codes for the standardized food products were chosen; [3] It should be noted that there were no food codes identified for grain-based bars containing vegetable. However, for this assessment, it is assumed that the estimated consumption of grain-based bars containing fruit would also reflect the intake of grain-based bars containing vegetable; [4] There were no food codes identified for vegetable smoothies within the NHANES dataset; however, the intake estimate for vegetable-based juices is expected to be representative of the intake from both vegetable-based juices and vegetable smoothies. It was assumed that a consumer of vegetable-based juices would drink a vegetable smoothie in replacement of a vegetable-based juice.

The intake analysis (Table 7) revealed that approximately 98% of the total U.S. population was identified as potential consumers of pea protein from the proposed food uses (Axiom Foods, 2015). The estimated mean and 90th percentile all-user intakes of pea protein was determined as 10.3 g/person/day (181 mg/kg bw/day) and 17.3 g/person/day (388 mg/kg bw/day),

respectively. As described in GRN 608, among the individual population groups, male adults were determined to have the greatest mean and 90th percentile all-user intakes of pea protein on an absolute basis, at 11.2 and 20.5 g/person/day, respectively. A summary of dietary intake calculations from the intended food categories is presented in Table 7. For safety assessment purposes the highest 90th percentile intake of 20.5 g/person/day, noted in male adults, was considered. Similar to that as described in GRN 608, Yantai also intends to market pea protein as a directly consumed supplemental protein at levels ranging from 5 to 15 g/serving when used as a protein supplement in sports nutrition or meal replacement applications, where consumers prepare their own beverages. These products can be used by consumers two times per day for lower protein use levels and one time per day for higher use levels. Thus, the maximum intake of pea protein from its proposed uses in sports nutrition will be 30 g/person/day.

Table 7. Summary of the Estimated Daily Intake of Pea Protein from Proposed Food-Uses*

Population Group	Age Group (Years)	All-Person Consumption (g/day)		All-Users Consumption (g/day)			
		Mean	90th Percentile	% Users	n	Mean	90th Percentile
Infants	0 to 3	5.9	12.4	83.2	683	7.1	13.4
Children	4 to 11	9.4	14.8	99.9	1,347	9.4	14.8
Female Teenagers	12 to 19	10.5	16.5	98.8	526	10.6	16.5
Male Teenagers	12 to 19	11.8	18.7	98.5	508	12.0	19.7
Female Adults	20 and up	9.7	16.1	99.8	2,204	9.7	16.1
Male Adults	20 and up	11.1	20.3	98.8	2,067	11.2	20.5
Total Population	**All Ages**	**10.1**	**17.2**	**98.4**	**7,335**	**10.3**	**17.3**

*Adapted from GRN 608 (Axiom Foods, 2015)

3.2. Current Exposure to Peas

In the U.S., peas are also a commonly consumed food. The USDA considers peas under the general food product category, legumes. Other examples of legumes include beans, peas, lentils and peanut. The USDA National Nutrient Database categorized peas under a general food group that includes several products such as Legumes and Legume Products (6), Soups, Sauces, and Gravies (15), Vegetables and Vegetable Products (31), and Baby Foods (3). The USDA database has listed 55 food products that contain peas (United States Department of Agriculture, 2013). The Reference Amount Customarily Consumed (RACC) for peas is 85 g/serving (Food and Drug Administration, 2013). This figure was promulgated by the FDA based on data on consumption of peas reported in the 1987-88 Nationwide Food Consumption Survey and the 1989-90 and 1990-91 Continuing Surveys of Food Intakes by Individuals, and it represents an average intake of peas by Americans at a single serving. Multiple servings during the day or larger-than-average servings result in a daily intake of peas well in excess of the 85 g average single serving. The FDA recommends that the 90th percentile of intake can normally be approximated by doubling the mean (FDA, 2006). This suggests that a reasonable estimate of the 90th percentile daily intake of peas is 170 g.

Peas have been reported to contain approximately 24.55% protein, the intake of protein from the consumption of peas at the 90th percentile in the US is estimated to be 41.7 g/person/day. The 90th percentile intake of pea protein from the intended uses of pea protein in different food categories of 17.3 g/person/day or from the maximum intake of pea protein from its uses in sports nutrition of 30 g/person/day is lower than the 90th percentile daily intake of pea protein resulting from the dietary consumption of peas, indicating that the intended or recommended levels of use and resulting intake are safe for human consumption.

Smiciklas-Wright et al. (2002) reported the mean and 90th percentile total for dried beans and peas consumption in the U.S. for all individuals to be 96 and 197 g/person/day, respectively. This data does not separate beans from peas and it is likely that, for some individuals, the entire consumption of this food category may come from peas. As peas contain approximately 24.55% protein, the intake of protein from consumption of peas at the mean and 90th percentile in the U.S. is estimated to be 23.57 and 48.36 g/person/day, respectively. The 90th percentile intake of pea protein from the intended uses of the pea protein in different food categories of 17.3 g/person/day or from the maximum intake of pea protein from its uses in sports nutrition of 30 g/person/day is lower than the daily intake of pea protein resulting from the consumption of peas (dried bean and peas). It is likely that to some extent the proposed uses of pea protein may add to the existing background intake of protein from peas. The intended use of pea protein is unlikely to add significantly to the existing intake of protein from peas or from other sources, as the use of pea protein as a macro-ingredient will likely replace the intake of other similar foods and not in addition to the other food products.

4. Part IV- SELF LIMITING LEVELS OF USE

Excessive amounts of pea protein is unlikely to be added to food products because of the unpleasant taste at high levels. Protein in food is considered as a macro component of the diet. Use of protein at high levels will lead to products becoming bitter and unpalatable. Additionally, given the water binding properties of protein ingredients, excessive use levels can make the food product dry, gummy and difficult to manufacture. The projected use levels are supported by the current protein levels in marketed products. Additionally, the cost of the product will also prohibit the excessive use.

5. Part V- EXPERIENCE BASED ON COMMON USE IN FOODS BEFORE 1958

The statutory basis for the conclusion of GRAS status of pea protein in this document is not based on common use in foods before 1958. The GRAS assessment is based on scientific procedures. As described below, the source material for pea protein, peas have been commonly used in foods prior to 1958. Notwithstanding this, it is reasonable to conclude that, humans are exposed to pea protein from consumption of peas, suggesting that it was present in foods prior to 1958.

6. Part VI- NARRATIVE

6.1. Traditional and Current Safe Uses of Peas

There is common knowledge of dietary intake of peas by human beings for centuries. Peas were one of the earliest food crops. The history of food uses of legumes is intertwined with that of human civilization. The available evidence suggest safe consumption of peas as a staple by humans for centuries. Based on findings from archaeologists exploring the "Spirit Cave" on the border between Burma and Thailand, the evidence of consumption of wild peas by humans' dates back to 9750 BC. Peas are one of the oldest cultivated crops in the world. In Neolithic sites in China dating as far back as 7000 to 6000 BC domesticated peas were found (Simoons, 1991). 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 protein, starch 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 include the Near East and the plateau and mountains of Ethiopia.

Wild field peas of related species can still be found in Afghanistan, Iran, and Ethiopia. Peas, particularly yellow or green cotyledon varieties known as dry, smooth or field peas, are grown around the world for human and animal consumption. Peas (*P. sativum*), or field peas, originated in southwest Asia and are now grown in temperate areas (Aykroyd and Doughty, 1982). Cultivated peas have been classified into garden peas (*P. sativum* sp. hortense) identified by the wrinkled nature of their seed and cotyledon, and field peas (*P. sativum* sp. arvense) commonly known as dry peas. Among the different varieties of dry peas grown throughout the world, two main varieties are the dry green cotyledon and the dry yellow cotyledon. Split peas are simply dry peas (green, yellow, or red) that have been split.

During times when meat was not available, legumes became an important staple by providing essential supplementing protein, as well as key vitamins and minerals. Protein was the major reason for the development of pulses, especially in Europe. It remains an important dietary component of many millions of people around the world, often combined with a cereal crop to provide energy. Pulses are considered to be a very important group of plant food stuffs in developing countries as a cheap source of protein when animal protein is scarce. A significant part of the human population relies on legumes, including peas, as staple food for subsistence, particularly in combination with cereals.

At present, the leading pea-producing countries around the world include Canada, Russia, China, USA and India (Dahl et al., 2012), with more than 10 million tons of peas being produced annually worldwide. Eaten fresh or dry, peas are a major diet staple throughout the world. Dry peas are a valued source of vegetable protein. Peas provide a cost-effective and convenient source of protein, complex carbohydrates, vitamins and minerals (Dahl et al., 2012). In keeping with the increasingly popular use of vegetable proteins as functional ingredients in the food industry, dry peas have proven especially sought after due to their wide acceptance as part of the human diet.

In the USA, pulse crops, including peas, are cultivated on about 3 million acres with an annual production value in excess of $1 billion. Currently, these crops provide over 12% of the

plant protein consumed by humans globally, more than either potatoes or vegetables (Food and Agricultural Organization, 2009). Generally, pulses, including peas, are considered as a low cost source of dietary protein, fiber 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). The USDA's My Plate Guidelines for food intake recommends consuming at least three cups of dry beans and peas per week.

In an article on trends in pea production, Lazanyi (2005) reported yearly rise of pea production during the 1980's by 6-10% in developed countries of the European Union. In the 1990's, the European Union produced 4-5 million tons 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.

In summary, the available information described above, and in Section 3.2, suggests that there is common knowledge that human beings are regularly exposed to peas and the protein present in it, without any safety concerns. The available information also suggests that intake of pea protein from its proposed uses is lower than the background intake from the consumption of peas.

6.2. Nutritional Role and Safety

Similar to other legumes, peas provide protein, complex carbohydrates, vitamins and minerals to millions of people and animals worldwide. Approximately half of the protein in the human diet is derived from cereals. However, cereals are a poor source of the amino acid lysine. Hence, other protein sources are required to enrich the human diet (Coyne et al., 2005). Lysine-rich legumes (including peas) make for an excellent complimentary protein source to cereals. The available information suggest that the rate of digestive utilization of protein in peas is high, similar to that found for fava beans and much higher than that of lentils, chickpeas, and beans (Urbano et al., 2003).

6.2.1. Comparison with Other Proteins

Dietary sources of protein for humans include both animals and plants. The animal protein sources include meats, dairy products, fish and eggs, while the plant proteins are grains, legumes and nuts. Given the differences in protein sources, the nutrient profile of pea protein, the subject of this present GRAS assessment, is compared with other similar proteins such as whey, casein and soy protein in Table 8. The values provided in Table 8 are compared for each serving of the protein. The data presented in Table 8 shows that, as regards nutritional profile, pea protein is substantially equivalent to other commonly marketed proteins. As per regulation for whey (21 CFR 184.1979), reduced lactose whey (184.1979a), reduced minerals whey 184.1979b, and whey protein concentrate (184.1979c) are direct food substances Affirmed as GRAS. Similarly, as per 21 CFR 184.1553, peptones, a variable mixture of polypeptides, oligopeptides, and amino acids produced by partial hydrolysis of casein as well as from soy protein isolate is GRAS. Additionally, whey protein isolate and dairy product solids that has been subject of GRN

37 received no question letter from the FDA. Thus, pea protein, the subject of this present GRAS assessment, is similar to other commonly used and approved proteins.

Table 8. Nutrient Profile Comparison of Pea Protein and Other Commonly used Proteins

Parameters	Pea Protein	Optimum Whey[1]	Cellucor Whey[2]	Optimum Casein[3]	Muscle Pharm Whey[4]	Weight Loss Lab. Whey[5]	Optimum Soy[6]
Serving size (g)	35	39	33	34	38	40	31.5
Protein (g)	28.5	30	25	24	38	20	25
Total Fat (g)	3.4	1	1.5	1	1.5	2	1.5
Saturated Fat (g)	0.7	0.5	0.5	0.5	1	1	0
Cholesterol (mg)	0	5	35	15	75	55	0
Total Carbohydrates (g)	0.87	2	3	3	7	15	2
Dietary Fiber (g)	0.56	NA	1	1	1	8	NA
Sugars (g)	0.21	1	1	1	3	5	0
Sodium (mg)	310	190	130	280	159	95	330
Total Calories	148	140	120	120	150	160	120
Calories from Fat	27	10	10	10	20	15	15

[1] Nutrient Values based on Optimum, Platinum Hydrowhey (Advanced Hydrolyzed Whey Protein), Cookies and Cream. Available at: http://www.optimumnutrition.com; [2] Nutrient Values based on Cellucor, COR-Performance Whey, Molten Chocolate. Available at: http://www.cellucor.com; [3] Nutrient Values based on Optimum, Gold Standard 100% Casein, Chocolate Supreme. Available at: http://www.optimumnutrition.com; [4] Nutrient Values based on MusclePharm, Combat Powder, Smores. Available at: http://www.musclepharm.com; [5] Nutrient Values based on Weight Loss Laboratories, Ultimate Nutrition Raw Whey Protein, Combat Powder, Smores. Available at: http://www.alibaba.com/product-tp/141985615/Ultimate_Nutrition_Raw_Whey_Protein.html; [6] Nutrient Values based on Optimum, 100% Soy Protein, Dutch Chocolate. Available at: http://www.optimumnutrition.com. Adapted from GRN 608.

6.2.2. Amino Acid Profile Comparison

The similarity and differences between protein from pea and other currently marketed protein products such as whey, soy products and pea protein from GRN 608 are compared with the subject of this GRAS pea protein in Table 9. The comparison data from Table 9 shows that the amino acid profile of pea protein is substantially equivalent to other commonly marketed high-protein concentration products. As pea and soybeans are legumes, there are some similarities in the amino acid profile of their proteins. Similar to soy protein, pea protein has a low content of methionine and a high content of arginine as compared to whey protein. Additionally, in pea and soybean proteins the ratio of arginine: lysine is higher as compared to casein.

Tomoskozi et al. (2001) investigated the chemical composition, amino acid content, and functional properties of pea protein concentrate, comparing results with soy and lupin protein product parameters. It was found that the solubility of pea protein isolates is similar to other legume proteins, such as soy, and that pea protein isolate provided an advantageous amino acid composition and acceptable functional properties. The study concluded that "pea protein

concentrate and isolate can be successfully used in bakery products for enrichment in protein and improvement of biological value."

Table 9. Amino Acid Profile Comparison of Pea Protein with Other Proteins

Amino Acids	*Pisum sativum* % of total amino acids (AA)	Present GRAS pea protein % of total AA	GRN 608 pea protein % of total AA	Whey[1] % of total AA	Soy[2] % of total AA
Alanine	4.60	3.32	3.60	4.82	4.07
Arginine	9.33	6.26	7.07	3.16	7.57
Aspartic Acid	12.34	9.08	9.79	12.26	11.58
Cysteine	1.59	0.99	0.84	2.28	1.25
Glutamic Acid	17.88	12.33	14.01	15.41	19.80
Glycine	4.65	3.09	3.44	2.00	4.09
Histidine	2.54	1.97	2.06	2.41	2.61
Isoleucine[3,4]	4.32	3.76	4.06	6.41	4.83
Leucine[3,4]	7.50	6.59	7.08	11.60	7.70
Lysine[3]	7.55	5.88	6.15	9.83	6.04
Methionine[3]	1.07	0.79	0.90	2.35	1.28
Phenylalanine[3]	4.82	4.09	4.54	3.56	5.21
Proline	4.32	3.95	3.62	6.28	5.63
Serine	4.60	3.70	4.32	6.24	5.21
Threonine[3]	3.72	3.00	3.11	8.44	3.56
Tryptophan[3]	1.17	0.68	0.87	1.80	1.27
Tyrosine	3.03	3.11	3.20	3.26	3.66
Valine[3,4]	4.94	3.80	4.39	6.09	4.65

[1] Cribb PJ. U.S. Whey Proteins in Sports Nutrition 2005. Whey Protein Concentrate 80% Available: http://usdec.files.cms-plus.com/Publications/WheySportsNutrition_English.pdf; [2] United States Department of Agriculture. National Nutrient Database for Standard Reference Release 26, Nutrient data for 16122, Soy protein isolate. Available: http://ndb.nal.usda.gov/ndb/foods/show/4842?qlookup=16122&fg=&format=&man=&lfacet=&max=25&new=1; [3] Essential Amino Acid; [4] Branched Chain Amino Acid

6.2.3. Requirements of Protein-RDA

Protein is an important macronutrient that is required in the daily diet. The Recommended Dietary Allowance (RDA) for protein is a modest 0.8 g protein/kg bw/day. For an individual weighing 60 kg, this will be 48 g/person/day which is sufficient to meet basic nutritional requirements. Using USDA Continuing Survey of Food Intakes by Individuals (CSFII) 1994-1996, 1998, the Institute of Medicine (IOM, 2005) estimated the background dietary intakes of protein for the U.S. population. Depending on age group, the mean and 90th percentile protein intake for adults ranged from 56 to 104 g/day and from 76 to 142 g/day, respectively.

Lack of sufficient dietary intake of protein has been associated with adverse effects in human health and development. For infants, aged 0 to 6 months, adequate intake (AI) of protein was set at 1.52 g/kg bw/day. In the absence of sufficient information, the IOM concluded that the Tolerable Upper Intake Levels (UL) for total protein or individual amino acids cannot be established. In a review article, Bilsborough (2006) suggested that the maximum daily protein intake of approximately 176 g for an 80 kg individual on a 2867 kcal/day diet is safe.

6.3. FDA Evaluation of GRAS Notice on Pea Protein

In 2015, the FDA received a GRAS notice on pea protein submitted by Axiom Foods. In this GRAS notice, Axiom Foods (2015) informed the FDA that the use of pea protein is GRAS, through scientific procedures, for use as an ingredient, formulation aid and texturizer in baked goods and baking mixes, beverages and beverage bases, breakfast cereals, dairy product analogs, fats and oils, grain products and pastas, milk products, plant protein products, processed fruits and fruit juices, processed vegetables and vegetable juices, soups and soup mixes at levels ranging from 0.96 to 34.3% and as a source of protein in sports and meal replacement beverages at a level of 15 to 25 g/serving. Pea protein was described as light beige, free-flowing powder that is isolated from yellow peas (*P. sativum* L). The typical composition and specifications for pea protein were described. The product consisted of protein (≥80%), fat (≤8%), carbohydrates (≤10%), ash (≤6%), and moisture (≤10%). The notifier stated that for manufacturing of pea protein, raw yellow peas are sifted, dehulled, and milled. The milled peas are then mixed with water and centrifuged to separate the protein and starch fractions. The protein fraction is concentrated by additional centrifugation. The protein concentrate is then washed and dried to obtain the final product. The mean and 90th percentile estimated daily intake of pea protein from the proposed uses was determined as 10.3 and 17.3 g/person/day (equivalent to 181 and 388 mg/kg bw/day), respectively. Additionally, the dietary exposure to individuals, consuming sports or meal replacement beverage containing pea protein, was reported to be 30 g/person/day. For comparison, the background dietary intake of protein from the consumption of peas, at the mean and 90th percentile was estimated as 20.9 and 41.7 g/person/day, respectively.

In the GRAS notification, the notifier extensively summarized and discussed the available published studies supporting the safety of pea protein and other similar products. The safety of pea protein was supported by the consumption of peas in human and animal diets, as well as various studies conducted with pea protein. The notifier cited a published genotoxicity study that demonstrated a pea protein isolate with similar composition to pea protein, was nonmutagenic and nongenotoxic. Axiom Foods (2015) also cited a published toxicity study in which rats were fed pea protein isolate in the diet for 90 days. No compound-related adverse effects were reported at up to 100,000 ppm (equivalent to 8,726 mg/kg bw/day for male rats and 9,965 mg/kg bw/day for female rats). Additionally, the notifier discussed published studies where pea protein concentrate, isolate, or hydrolysate was fed to animals and humans to assess possible health effects. No adverse effects are reported in these studies. Axiom Foods (2015) stated that allergenicity to pea along with cross-reactivity to other allergens have been reported. These reactions are rare, and pea protein concentrate does not contain any of the eight allergens that are considered to be major food allergens under the United States Food Allergen Labelling and Consumer Protection Act of 2004 (FALCPA). Based on the totality of the data and information described above, the notifier concluded that pea protein concentrate is GRAS under the intended conditions of use. In a response letter to the notifier on May 27, 2016, the FDA stated that the agency has 'no questions" regarding the conclusion that pea protein concentrate is GRAS under the intended conditions of use (FDA, 2016).

6.4. Safety Studies of Pea and its Protein

6.4.1. Metabolism

In a study with seven adult volunteers (4 males and 3 females with mean body weight 64 kg, ranging from 46 to 77 kg), Gausseres et al. (1997) evaluated postprandial absorption of pea

protein as well as exogenous nitrogen retention in humans. In this study, the gastrointestinal absorption of pea protein following ingestion of 21.45 g (195 mMol N) of [^{15}N]-labeled pea protein [each meal contained 75 g pea flour (195 mMol N)] was studied. Total absorption was estimated at 89.4 ± 1.1%, resulting in 19.2 g being absorbed in the 8-hour postprandial period at a rate of 2.4 g/hour. This absorption was correlated with a significant increase in [^{15}N]-enrichment in the plasma amino acids and in the nitrogen incorporated into the body urea pool for 1 h following pea ingestion. At 24 h after pea ingestion, the enrichment remained significantly higher than the basal values in these pools. The recovery of total urinary exogenous nitrogen after 22 h was 31.1 +/- 9.3 mmol N. Moreover, the kinetics of [^{15}N]-labeled pea amino acids deamination reached a plateau of 39 mmol. Under these conditions, pea nitrogen retention represented 78% of the absorbed dietary nitrogen in healthy humans. The results of this study demonstrate the good true nitrogen digestibility and retention of pea protein in humans.

Mariotti et al. (2001) investigated the bioavailability and metabolic utilization of pea albumins and globulins in healthy human subjects consuming their usual diets. In this study, volunteers ingested a mixed meal of 30 g of raw purified pea protein either as [^{15}N]-globulins (G, n = 9; 6 men and 3 women) or as a mix of [^{15}N]-globulins and [^{15}N]-albumins (GA, n = 7; 4 men and 3 women) in their natural proportions (22:8). The postprandial sampling was done hourly for eight hours following ingestion of protein meal. The pea albumin fraction significantly lowered the real ileal digestibility of pea protein, did not promote acute intestinal losses of endogenous nitrogen and did not significantly improve the postprandial biological value of pea protein, despite the fact that it corrected the globulin deficiency in sulfur amino acids. The ileal digestibility was 94.0 ± 2.5% and 89.9 ± 4.0% for the globulins, and globulins plus albumins meals respectively yielding amino acid absorption rates of approximately 3.5 g/hour and 3.4 g/hour. The authors concluded that both globulins as well as mixture of globulin and albumin are of good nutritional value for humans and show that cysteine-rich albumins have a far more modest effect on the efficiency of postprandial dietary protein utilization than would be expected from the amino acid scores. The investigators also noted that, when given selectively to healthy humans, pea proteins exhibit a good nutritional value, similar to that of soy protein.

6.4.1.1. Human Clinical Studies

In an open-label, randomized, exploratory study in 44 healthy overweight subjects with cardio-metabolic syndrome (CMS) risk factors, Dahlberg et al. (2017) investigated the safety and tolerability of a proprietary lifestyle modification program without (DIET) and with (PROG) targeted dietary supplementation, including phytosterols, antioxidants, probiotics, fish oil, bebeerine, and soy, pea, and whey proteins over a period of 13 weeks. The subjects in the PROG diet received protein shake containing soy pea or whey protein. The subjects within the study were allowed to choose between commercially available soy, whey, or pea proteins with scoop size normalized to deliver 20 g of protein. The daily intake of pea protein was reported as 12 g/day. Estimates of the relative soy, pea, and whey protein consumption during the study were made from returned product canisters. Soy protein shakes were most popular and represented 50% of the consumed snakes followed by pea protein at 30% and whey protein at 20%. Key metrics were recorded at baseline and weeks 9 and 13. For the DIET and PROG groups, compliance was 85% and 86%, respectively, with no adverse events related to the diet or supplements. Although data were not reported, the investigators stated that complete blood counts and metabolic profiles covering baseline, week 9, and week 13 were normal. Twelve

subjects discontinued participation before week 9 for reasons unrelated to the study. The results of this study show that intake of pea protein at a daily dose of 12 g/day was well tolerated.

Kristensen et al. (2016) compared the acute meal-induced appetite sensations of meals based on vegetable protein sources (beans/peas) with animal protein sources (veal/pork). In this randomized, double-blind, placebo controlled, three-way, cross-over meal test study, 43 healthy, normal-weight, young men participated. The meals [all 3.5 MJ, 28 energy-% (E%) fat] were either high protein (39 g/100g) based on veal and pork meat, HP-Meat (19 E% protein, 53 E% carbohydrate, 6 g fiber/100 g); high protein (38 g/100 g) based on legumes (beans and peas), HP-Legume (19 E% protein, 53 E% carbohydrate, 25 g fiber/100 g); or low-protein (18 g/100 g) based on legumes, LP-Legume (9 E% protein, 62 E% carbohydrate, 10 g fiber/100 g). Subjective appetite sensations were recorded at baseline and every half hour using visual analog scales until the *ad libitum* meal three hours after the test meal. HP-Legume induced lower composite appetite score, hunger, prospective food consumption, and higher fullness compared to HP-Meat and LP-Legume. Furthermore, satiety was higher after HP-Legume than HP-Meat. The investigators concluded that vegetable-based meals (beans/peas) influenced appetite sensations favorably compared to animal based meals (pork/veal) with similar energy and protein content, but lower fiber content. Vegetable-based meal with low protein content was as satiating and palatable as an animal-based meal with high protein content.

Babault et al. (2015) studied the effect of oral supplementation with pea protein vs. whey protein and placebo on biceps brachii muscle thickness and strength following a 12-week resistance training program. In this double-blind, randomized, placebo-controlled trial, 161 male volunteers (age 18-35 years) were divided into three groups: pea protein (n=53), whey protein (n=54) or placebo (n=54) group. The subjects underwent 12 weeks of resistance training on upper limb muscles. During the 12-week training period all subjects received 25 g of the proteins or placebo twice a day (50 g/day). Tests were performed on biceps muscles three times, and supplementation compliance or adverse effects were recorded. A significant time effect for biceps brachii muscle thickness was noted that was significantly greater in the pea protein group as compared to placebo whereas there was no difference between whey and the two other conditions. Muscle strength also increased with time but without any statistical difference between groups. Of the 161 subjects who took protein products, three presented an adverse event in the whey group (7.4%), four in the placebo group (7.4%) and one in the pea group (1.9%). Except for two digestive disorders (diarrhea) in the placebo group, the adverse effects were all musculotendinous or back pains related to their usual daily activity throughout the study. All symptoms disappeared spontaneously except for an elbow tendinopathy in the whey group which persisted at the end of the trial but any association with the product intake was ruled out. As no adverse effects of pea protein at intake levels of 50 g/day for 12 weeks were noted, the results of this study support safety of pea protein concentrate. In this study, the general (background) food intake was not monitored over the experimental procedure but participants were instructed to maintain their diet habits throughout the experimental protocol. This indicates that the pea protein intake in this study was in addition to the background intake of any exposure to peas from diet. The findings from this study support the safety of proposed uses of pea protein, the subject of the present GRAS.

In another randomized, double-blind, parallel clinical trial, Teunissen-Beekman et al. (2012) studied the effects of increased protein intake at two levels (about 25% compared with about 15% of energy intake that isoenergetically replaces carbohydrate intake) for four weeks to

lower blood pressure of male and female subjects during office and daytime as compared with increased carbohydrate intake. In this study, consumption of 3×20 g protein/day (20% pea, 20% soy, 30% egg, and 30% milk-protein isolate) with 3×20 g maltodextrin/day was compared. In this study, protein or maltodextrin were isoenergetically substituted for a sugar-sweetened drink. Primary outcomes were office and daytime blood pressure. In this study, a total of 99 male and female subjects (20-70 years old; BMI 25-35 kg/m^2) with untreated elevated BP (BP ≥130/85 and <160/100 mm Hg) were randomized. Ninety-four subjects, 51 subjects in the maltodextrin group and 43 subjects in the protein group, completing the study were included in the analyses. In the protein group, the office systolic blood pressure (SBP) and diastolic blood pressure (DBP) were 4.9±1.7 mm Hg and 2.7±1.3 mm Hg lower, respectively. Daytime SBP was 4.6±1.7 mm Hg lower in the protein group, whereas daytime DBP did not differ between groups. Urinary sodium excretion was higher in the maltodextrin group. Five participants in the protein group dropped out during the intervention. Two participants stopped because of immediate adverse effects after consumption of the supplement (one subjects experienced nausea, and one subject experienced a lightly swollen face, abdomen, and thighs). Two participants were excluded after randomization because they started with antihypertensive medication, and one subject stopped for personal reasons that were not related to the intervention. The investigators concluded that increased protein intake, at the expense of maltodextrin, lowers blood pressure in overweight adults with upper-range pre-hypertension and grade 1 hypertension.

In addition to the above described Teunissen-Beekman et al. (2012) study, in two separate recent studies, Teunissen-Beekman et al. (2015) investigated the effects of dietary proteins and carbohydrates on markers of endothelial dysfunction (ED) and low-grade inflammation (LGI) in overweight/obese individuals with untreated elevated blood pressure. In the first study, 52 subjects consumed a protein mix or maltodextrin (3×20 g/day) for four weeks. The protein mix consisted of 20% pea protein, 20% soy protein, 30% egg-white protein, 30% milk protein isolates. Fasting levels and 12 hour postprandial responses of markers of ED (soluble intercellular adhesion molecule 1 (sICAM), soluble vascular cell adhesion molecule 1 (sVCAM), soluble endothelial selectin and von Willebrand factor) and markers of LGI (serum amyloid A, C-reactive protein and sICAM) were evaluated before and after intervention. In the second study, 4 hour postprandial responses of ED and LGI markers in 42 participants was compared after ingestion of pea protein, milk protein and egg-white protein at a dose level of 0.6 g/kg. In addition, postprandial responses after maltodextrin intake were compared with a protein mix and sucrose. In the first study, significantly lower fasting ED Z-scores and sICAM after four weeks on the high-protein diet were noted. The postprandial studies found no clear differences of ED and LGI between test meals. However, postprandial sVCAM decreased more after the protein mix compared with maltodextrin in both studies. The investigators concluded that dietary protein is beneficial for fasting ED, but not for fasting LGI, after four weeks of supplementation. On the basis of Z-scores, postprandial ED and LGI were not differentially affected by protein sources or carbohydrates. In this publication, no safety related parameters or adverse effects were reported by the authors.

Abou-Samra et al. (2011) investigated the effect of different proteins, including pea protein, on satiation and short-term satiety in two separate randomized single-blind cross-over studies. In the first study, the effects of a preload containing 20 g of casein, whey, pea protein, egg albumin or maltodextrin vs. water control on food intake 30 min later in 32 male volunteers (25±4 years, BMI 24±0.4 kg/m^2) was studied. The results of this study revealed that food intake was significantly lower only after casein and pea protein compared to water control. Caloric

compensation was 110, 103, 62, 56 and 51% after casein, pea protein, whey, albumin and maltodextrin, respectively. Feelings of satiety were significantly higher after casein and pea protein compared to other preloads. Blood glucose response to the meal was significantly lower when whey protein was consumed as a preload compared to other groups. In the second study, the effect of 20 g of casein, pea protein or whey vs. water control on satiation in 32 male volunteers (25±0.6 years, BMI 24 ± 0.5 kg/m^2) was investigated. No difference between preloads on ad libitum intake was noted. No adverse effects were reported.

Li et al. (2011) investigated the blood pressure lowering effect of a pea protein hydrolysate that contained <3 kDa peptides, isolated by membrane ultrafiltration from the thermolysin digest of pea protein isolate in hypertensive human subjects. The focus of the study was to investigate the blood pressure lowering effect of a pea protein hydrolysate, containing <3 kDa peptides and isolated by membrane ultrafiltration from the thermolysin digest of pea protein, using rat models (with disease), as well as hypertensive human subjects. The study was carried out in in 7 volunteers (4 females and 3 males, ages 30-55 years, 145-185 lb) with systolic blood pressure ranging from 125 to 170 mm Hg. There were 3 treatments as follows: placebo (50 mL of orange juice), 1.5 and 3 g of pea protein hydrolysate per day divided into 3 doses of 0.5 or 1 g each and taken at breakfast, lunch and dinner. In this 3-week randomized, double blind, placebo-controlled crossover human intervention trial, administration of pea protein hydrolysate (1.5 g/day of the peptides consumed with orange juice as a delivered vehicle) to seven volunteers (4 females and 3 males, ages 30-55 years, 145-185 lb.; with systolic blood pressure ranging from 125 to 170 mm Hg) resulted in a significant reductions (over placebo) in SBP of 5 and 6 mmHg in the second and third weeks, respectively. The findings from this study suggest that pea protein hydrolysate reduces blood pressure in hypertensive human subjects. No safety related clinical chemistry or hematological parameters were investigated. The investigators did mention that during the three-week duration of this experiment, none of the participants reported any adverse side effects. These investigators also studied the effects of pea protein hydrolysate in rats. As compared to the protein fraction used in the study by Li et al. (2011), in peas, there are two major protein fractions: globulins (salt soluble) and albumins (water soluble) that have much higher molecular weights.

The use of pea protein in infant formula has been suggested as an alternative to soybean formula in countries where soybean is not a native crop, or when soybean protein cannot be used due to allergic reactions or intolerances. Davidsson et al. (2001) studied the iron (Fe) absorption from experimental infant formulas based on pea protein isolate in healthy non-anemic women (n=20; 10/study; mean age 22 years; weight 55 kg). The effects of phytic acid and ascorbic acid on iron absorption were studied. Fe absorption from experimental infant formulas based on pea-protein isolate was measured in women. Phytic acid has negative effects on Fe absorption while ascorbic acid has a positive effect on Fe absorption. The stable-isotope technique was used to analyze the effects, and the results indicated that pea protein had improved Fe absorption effects compared to the soy protein.

6.4.1.2. Subchronic Toxicity Study

In a sub-chronic toxicity study designed as per OECD Test Guidelines, Aouatif et al. (2013a) investigated the effects of pea protein isolate in Wistar rats. In this dose-response study conducted as per OECD Guidelines, male and female rats were fed diet containing pea protein isolate (Nutralys) at levels of 0 ppm, 25,000 ppm (low), 50,000 ppm (intermediate) and 100,000 ppm (high) for 90 days. The pea protein isolate (Nutralys) used in this study was manufactured

and supplied by Roquette Freres, France. The isolate is a high quality white powder source food grade with 85% pea protein content, extracted in water. For this study, rats were randomly divided in to six groups (10/sex/group) namely G1 (control), G2 (Low dose- 2.5%), G3 (Intermediate dose- 5%), G4 (High dose- 10%), G5 (Satellite control) and G6 (Satellite high dose- 10%) group. At end of 90 days, the satellites groups were given only diet without the test item for an additional 28 days to evaluate any possible withdrawal effects.

Exposure to dietary pea protein isolate did not reveal any treatment-related adverse effects in rats as their clinical signs, body weights, feed consumption, water consumption, hematological, blood biochemical and urinalysis were comparable with concurrent control animals. Further, organ weights, gross and histological examinations did not reveal any systemic toxicity induced by pea protein consumption. Some statistical changes, such as eosinophil in male rats and prothrombin in females of low dose rats; significant decrease in platelets and neutrophils and increase in lymphocyte counts observed in female rats of the high dose group; triglyceride levels in all the three treated groups of female rats; absolute weight of the testes of male rats in the low dose group; and, absolute weight of the spleen of female rats in the high dose group, were noted. These hematological and biochemical changes were statistically significant; however, these changes were not dose related. Overall, pea protein isolate did not alter liver or kidney function or have an adverse effect on the hemopoietic system. Further, histological and gross examinations of organs did not reveal abnormal findings. The changes noted in the satellite group were not considered as treatment related (Aouatif et al., 2013a).

Based on the findings of this 90-day feeding toxicity study in Wistar rats, Aouatif et al. (2013a) considered the highest dose tested of 100,000 ppm of pea protein in diet, equivalent to 8726 for male and 9965 for female mg/kg bw/day as the no-observed-adverse-effect-level (NOAEL). The pea protein isolate (85%) used in the Aouatif et al. (2013a) study is substantially equivalent to the pea protein concentrate (80% minimum), the subject of present GRAS assessment. The highest safe dose noted in the Aouatif et al. (2013a) study is 17 to 20 fold higher as compared to the highest dose of 30 g/person/day of pea protein. The results of this study support the safety of pea protein. The pea protein in the Aouatif et al. (2013a) study is hydrolyzed using enzymes, whereas pea protein by Yantai is mechanically separated using a centrifuge. The findings from this study support the safety of proposed uses of pea protein concentrate.

6.4.1.3. Genotoxicity

In a series of genotoxicity assays conducted as per OECD guidelines, Aouatif et al. (2013b) investigated the potential genotoxic effects of pea protein isolate (NUTRALYS) in Ames assay, *in vitro* chromosomal aberration test, and *in vivo* micronucleus test. In the Ames assay, pea protein isolate (85%) at concentrations of 312.5, 625, 1250, 2500, and 5000 µg/plate was tested using five tester strains of *Salmonella typhimurium* (TA100, TA102, TA1535, TA98, and TA1537) in the presence and absence of metabolic activation (S9). Under the experimental conditions employed, pea protein was non-mutagenic in the Ames reverse mutation assay. In the *in vitro* chromosomal aberration test, using cultured human peripheral blood lymphocytes, pea protein at concentrations of 125, 250, and 500 µg/mL was evaluated for its potentials to induce structural and numerical aberrations. The findings from this study suggest that pea protein isolate did not induce genotoxic responses in human lymphocytes.

In the *in vivo* mouse micronucleus assay by Aouatif et al. (2013b), a limit test was performed in which male and female CD1 mice received a single and two-day treatments (24 hours apart) with pea protein isolate at the highest dose of 2000 mg/kg bw. No evident increase in the frequencies of micro-nucleated polychromatic erythrocytes (MN-PCE) was observed in the dose group compared to that of the concurrent vehicle control groups in all time points of euthanasia. The results of this study suggest that pea protein isolate was non-genotoxic in single- and two-day treatments. In summary, pea protein isolate is non-mutagenic and non-genotoxic, at conditions utilized under the Ames assay, *in vitro* chromosomal aberration test, and the *in vivo* bone marrow micronucleus test (Aouatif et al., 2013a). The observations from this study employing 85% pea protein concentrate are applicable to the subject of present GRAS assessment.

6.4.1.4. Other Safety-Related Studies

Li et al. (2011) also investigated the blood pressure lowering effects of pea protein isolate in hypertensive rats. Oral administration of the pea protein hydrolysate to spontaneously hypertensive rats (SHR) at doses of 100 and 200 mg/kg bw led to a lowering of hourly systolic blood pressure (SBP), with a maximum reduction of 19 mm Hg at four hours. In contrast, orally administered unhydrolyzed pea protein hydrolysate had no blood pressure reducing effect in SHR, suggesting that thermolysin hydrolysis may have been responsible for releasing bioactive peptides from the native protein. Oral administration of the pea protein hydrolysate to the Han:SPRD-cy rat (a model of chronic kidney disease) over an 8-week period led to 29 and 25 mmHg reductions in SBP and diastolic blood pressure, respectively. The pea protein hydrolysate-fed rats had lower plasma levels of angiotensin II, the major vasopressor involved in development of hypertension, but there was no effect on plasma activity or renal mRNA levels of ACE. However, renal expression of renin mRNA levels was reduced by approximately 50% in the pea protein hydrolysate -fed rats, suggesting that reduced renin may be responsible for the reduced levels of angiotensin II. In the long term study in rats with kidney disease, the investigators also mentioned that during the 8-week period, there were no differences in feed consumption (average 25-30 g/day) and growth rate (325-340 g at week 8) of rats in the control and pea protein hydrolysate-fed groups. The information on rat feed consumption was not provided in the publication. No other safety related parameters were mentioned.

In an *in vitro* study, Li and Aluko (2010) studied the inhibitory activities of multifunctional peptides from pea protein isolate against Calmodulin-dependent phosphodiesterase (CaMPDE), renin, and angiotensin I-converting enzyme (ACE). Results showed that pea protein isolate peptides do exhibit inhibitory activities against ACE, renin, and CaMPDE, indicating an improved health response, and suggesting the peptides "may be used as potential ingredients to formulate multifunctional food products and nutraceuticals".

In order to ensure compliance with international food safety legislation, the Canadian Grain Commission undertook a baseline study of various trace elements in Canadian peas. For this, Gawalko et al. (2009) compared the levels of toxic trace elements in field peas from Canada with the international (CODEX) maximum limits for these trace element. In this study, a total of 295 field pea samples from 35 regional varieties from the years 2004-2006 were analyzed. The results revealed mean total cadmium content of 0.023 mg/kg, arsenic and lead mean values of 0.050 mg/kg and total mean mercury level of <0.002 mg/kg. All measured values were below the maximum residue levels (MRLs) established by the Food and Agriculture Association (FAO)

and the World Health Organization (WHO). The results of this study suggest that Canadian field peas are in compliance with CODEX standards (Gawalko et al., 2009).

In a study in mice, Ndiaye et al. (2012) investigated the anti-oxidant, anti-inflammatory and immune-modulating characteristics of enzymatic pea protein hydrolysate from yellow field pea seeds. The pea protein hydrolysate showed inhibition of nitric oxide production by activated macrophages up to 20%, TNF-α up to 35% and IL-6 up to 80%, and when administered orally in mice, enhanced phagocytic activity of their peritoneal macrophages and stimulated the gut mucosa immune response.

6.4.1.5. Allergenicity

Pea is a cereal grain with proteins that are similar to those in other cereal grains. Individuals allergic to cereal grain products are allergic to some of the specific proteins found in some cereals. Peas are part of a family of plants called legumes, which also include alfalfa, clover, beans, lentils, mesquite, carob, soybeans, peanuts, tamarind, and wisteria. 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). The most common foods causing immunologically-mediated reactions include milk, eggs, fish, crustaceans, nuts, wheat, soy, peanuts, peas and other legumes. 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.

Legumes have been reported to be a cause of food allergies, and especially well-known is the peanut allergy. Peanut allergies affect approximately 0.6% to 1.3% of the U.S. population (Food Allergy Research and Education, 2014). Peanut and soybeans are the major legume allergies known in the United States, United Kingdom, and Japan, while lentils, chickpeas and pea allergies are more common in the Mediterranean area and India (Sanchez-Monge et al., 2004). Pea proteins are mainly storage protein comprised of albumins and globulins. Albumins and globulins separate into two major fractions; the 7S vicilin and convicilin fraction, and an 11S fraction made up mostly of legumin (Casey et al., 1985). Legume allergies are most often caused by these storage proteins (albumins, globulins, prolamins) (University of Nebraska - Lincoln, 2014). Food allergies can be identified scientifically by determining the effect on IgE antibodies. IgE antibody synthesis is stimulated by cytokines such as Interleukin 4 (IL-4), IL-5, and IL-13, which are produced by Type II T-Helper Cell (T_H2).

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 reactions 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.

Selected legume proteins (soybean, lentil, pea, bean) have shown Immunoglobulin E (IgE) mediated cross-reactivity, which could be caused by the inability of IgE specific antibodies to distinguish between the proteins of different sources, which have very similar tertiary structure and amino acid sequences (Dziuba et al., 2014). 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 three 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 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 available information indicates that, although people with peanut allergies may also be sensitive to peas, allergy to peas is actually quite rare and the frequency to pea allergy varies among different populations. Yantai acknowledges that pea protein does not contain any of the 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).

6.4.1.6. Safety of Mycotoxin

Mycotoxins are secondary metabolites produced by microfungi that are capable of causing disease and death in humans and other animals (Bennett and Klich, 2003). It is well recognized that even small amounts can have a detrimental effect on the immune system and metabolism, thus posing a continuous threat to human and animal health. In spite of several uncertainties such as toxicological and survey analytical data as well as insufficient methods of mycotoxin analysis, different countries have enforced different thresholds to limit the passage of mycotoxins along the food chain. At high doses and over long periods, aflatoxin is known to cause acute and chronic liver injury and liver cancer. Aflatoxins are considered unavoidable contaminants in the U.S. food supply, especially in corn and peanuts, and levels are regulated by the FDA. The FDA has established action levels for poisonous or deleterious substances in

human food and animal feed[7]. The action levels and tolerances are established based on the unavoidability of the poisonous or deleterious substances and do not represent permissible levels of contamination where it is avoidable. The FDA established action levels for aflatoxins present in human food that include 0.5 ppb (aflatoxin M1) for milk and 20 ppb for foods such as peanuts and peanut products, brazil and pistachio nuts.

Recently, Chen et al. (2016) summarized the limits of aflatoxins, ochratoxin A, and citrinin set by the CODEX Alimentarius Commission, European Commission, USA and Japan in different food commodities. These investigators reported the levels of mycotoxins from 712 food samples in Taiwan and 96.8% were found in compliance with Taiwan government regulation of 15 ppb for aflatoxin and 10 ppb for other food products. The National Grain and Feed Association described FDA Regulatory Guidance for Mycotoxins[8]. This document stated that FDA currently has not established regulatory limits for mycotoxins found in specific food or feed, although it has stated its intent to eventually establish such limits for aflatoxin. The document summarizes the above described aflatoxin limits. An FDA advisory level for vomitoxin in finished wheat products for human consumption is 1 ppm. FDA guidance levels for fumonisin (FB1, FB2, FB3) for corn and corn products intended for human food range from 2 to 4 ppm.

In pea protein, the subject of present GRAS assessment, the aflatoxins (B1+B2+G1+G2 sum of the four) levels from five lots were measured. To further confirm these levels, recently Yantai also measured aflatoxins from three additional lots. The details of the recent analysis are provided in Appendix II. The aflatoxin profile as analyzed by GB/T 18979 method was non-detectable for the individual and sum of Aflatoxins B1, B2, G1, G2 at a detection limit of < 5 µg/kg. The low (undetectable) levels of aflatoxins in pea protein is below the FDA established action levels of 20 ppb for foods in general and thus is considered as safe.

6.5. GRAS Panel Review, Summary and Discussion

Yantai Oriental Protein Tech Co., Ltd. (Yantai) convened an independent panel of recognized experts (hereinafter referred to as the Expert Panel)[9], qualified by their scientific training and relevant national and international experience to evaluate the safety of food and food ingredients, to evaluate the Generally Recognized As Safe (GRAS) status of pea protein (>80% protein) derived from *Pisum sativum* L. seed-pods (peas) as a food ingredient, formulation aid and texturizer, in conventional foods such as Baked Goods and Baking Mixes; Beverages and Beverage Bases; Breakfast Cereals; Dairy Product Analogs; Fats and Oils; Grain Products and Pastas; Milk Products; Plant Protein Products; Processed Fruits and Fruit Juices; Processed Vegetables and Vegetable Juices; and, Soups and Soup Mixes at levels ranging from 0.96 to 34.3%. A comprehensive search of the scientific literature for safety and toxicity information on pea and its protein was conducted through February 2018 and made available to the Expert Panel. The Expert Panel independently and critically evaluated materials submitted by Yantai and other information deemed appropriate or necessary. Following an independent, critical evaluation, the Expert Panel conferred on May 18, 2018 and unanimously agreed to the decision described herein.

[7] Available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ChemicalContaminantsMetalsNaturalToxinsPesticides/ucm077969.htm

[8] Available at: www.ngfa.org

[9] 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.

Yantai ensured that all reasonable efforts were made to identify and select a balanced Expert Panel with expertise in food safety, toxicology, and nutrition. Efforts were also placed on identifying conflicts of interest or relevant "appearance issues" that could potentially bias the outcome of the deliberations of the Expert Panel and no such conflicts of interest or "appearance issues" were identified. The Expert Panel received a reasonable honorarium as compensation for their time; the honoraria provided to the Expert Panel were not contingent upon the outcome of their deliberations.

Peas are one of the oldest cultivated crops in the world and an important source of protein for humans and animals alike. It is a hardy winter legume grain that has been consumed as a food around the world since ancient times. Peas are an excellent source of the amino acid lysine and protein (approximately 25%). In addition to nutritional properties, pea protein has several functional effects in foods, such as promotion of ease of dry flow, ability to mask off-flavors, improves texture, increases water-solubility, etc. Given its common consumption as a food, peas are generally regarded as safe. The USDA Nutrient Database list includes peas and its preparations as foods. Based on USDA data on food consumption, the mean and 90th percentile estimated daily intake of peas is 96 and 197 g/person/day, respectively. As peas contains about 25% protein, the protein intake from pea consumption will be 23.57 and 48.36 g pea protein/person/day, respectively. The available information demonstrates common knowledge of the human consumption of peas and thus its protein. As regards daily protein intake from all sources, the Institute of Medicine (IOM, 2005) has established the recommended daily intake of protein of 0.8 g/kg bw for an adult. The IOM has also reported that the mean adult protein intake ranges from 56 - 104 g/day, depending on age group. At the 90th percentile, adult protein intakes ranged from 76 g/day to 142 g/day.

Yantai intends to use pea protein (80%) as a multifunctional food ingredient. The processes by which pea protein is derived from raw field peas are purely mechanical such as sifting, centrifugation, drying, and sieving. These processes do not result in chemical alteration of the peas. The pea protein is manufactured as per current GMP from yellow peas by base precipitation, acid neutralization and isolation of protein. The pea protein has been well characterized for its nutritional composition and characteristics. The nutritional constituents and amino acid profile comparison of pea protein with other protein concentrates such as whey, casein and soy, revealed substantial similarity. Whey protein concentrate has been recognized as GRAS by the FDA. Additionally, peptones produced by partial hydrolysis of casein as well as from soy protein isolate are also recognized as GRAS. Additionally, whey protein isolate and dairy product solids has been the subject of GRAS (GRN 37) that received no question letter from the FDA. Furthermore recently in 2015, pea protein concentrate has been the subject of a GRAS notice (GRN 608) to FDA that also received 'no question' letter from the FDA.

The proposed uses of pea protein by Yantai includes Baked Goods and Baking Mixes; Beverages and Beverage Bases; Breakfast Cereals; Dairy Product Analogs; Fats and Oils; Grain Products and Pastas; Milk Products; Plant Protein Products; Processed Fruits and Fruit Juices; Processed Vegetables and Vegetable Juices; Soups and Soup Mixes at levels ranging 0.96 to 34.3%. The proposed use of pea protein will result in daily maximum intake (90th percentile) of 20.5 g/person/day. This proposed intake is pea protein is over 2-fold lower compared to the 90th percentile intake of protein (48.36 g/person/day, respectively) from the consumption of peas as a staple. Yantai also intends to use pea protein in sports nutrition. In this case, pea protein powder will be provided to consumers, such as athletes, for mixing in beverages (5 to 15 g/serving) that

would be used in sports nutrition or as meal replacements. The consumer may consume such beverages once daily. Using conservative FDA methodology, the maximum dietary exposure from these uses will be 30 g/person/day. This value from the proposed uses of pea protein in sports nutrition is about 1.5 fold lower as compared to the 90th percentile intake of protein from the consumption of peas as a staple. As compared to the IOM established daily protein intake that ranges from 76 g/day to 142 g/day, the resulting intake of pea protein from its uses in different food categories as well as in sports nutrition is much less.

There is sufficient qualitative and quantitative scientific, as well as history of use evidence to determine the safety-in-use of the pea protein in the above mentioned food applications. Similar to other dietary protein, pea protein is digested in the human gastrointestinal tract. The comparison of pea protein proximate as well as amino acid profile with other commonly consumed proteins such as whey, soy, casein, other pea protein, suggest that pea protein, the subject of this GRAS assessment determination, is substantially equivalent to other commonly used proteins. In human clinical studies, supplementation with pea protein at levels up to 50 g/day for 12 weeks did not reveal any adverse effects. In a subchronic toxicity study conducted as per OECD guidelines, the NOAEL of pea protein isolate (80% protein) in male and female rats was determined as 8,726 and 9,965 mg/kg bw/day. This safe dose is 17 to 20 fold higher as compared to the highest dose of 30 g/person/day of pea protein. The results of available animal and human studies did not indicate any potential for adverse effects of pea protein. The pea protein is unlikely to cause allergic reaction.

Recently, in response to a GRAS notice (GRN 608), the FDA did not question the safety of pea protein concentrate for the specified food uses identical to this present GRAS assessment. The subject of this present GRAS assessment is substantially equivalent to the pea protein concentrate that has been the subject of the FDA GRAS notified substance. The use of a substantially equivalent preparation of the pea protein that is the subject of this GRAS assessment and the one that has been the subject of FDA notifications suggests that the differences between pea protein products would be limited to minor variations in the amino acid profile, and to differences in the residual levels of other components. These observations also suggest that the safety information on pea protein products can be interchangeable.

The totality of the available evidence from dietary consumption of peas for centuries, the current intake of peas as a staple, the substantial equivalence of pea protein produced by Yantai with other substantially equivalent marketed GRAS protein concentrates or isolates, and available safety studies in animals and humans described in this document, suggest that consumption of pea protein concentrate from the intended uses at use levels ranging 0.96 to 34.3% in specified foods is safe. On the basis of scientific procedures corroborated by exposure from natural dietary sources, consumption of pea protein, as an added food ingredient to the food supply, or its use as a nutritional supplement, is safe at daily consumption levels up to 30 g/person/day. The proposed uses are compatible with current regulations, *i.e.*, the pea protein is used as a food ingredient in Baked Goods and Baking Mixes; Beverages and Beverage Bases; Breakfast Cereals; Dairy Product Analogs; Fats and Oils; Grain Products and Pastas; Milk Products; Plant Protein Products; Processed Fruits and Fruit Juices; Processed Vegetables and Vegetable Juices; Soups and Soup Mixes, when not otherwise precluded by a Standard of Identity, and is produced according to current good manufacturing practices (cGMP).

6.6. 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 protein as a food ingredient in selected food products such as Baked Goods and Baking Mixes; Beverages and Beverage Bases; Breakfast Cereals; Dairy Product Analogs; Fats and Oils; Grain Products and Pastas; Milk Products; Plant Protein Products; Processed Fruits and Fruit Juices; Processed Vegetables and Vegetable Juices; and, Soups and Soup Mixes at levels ranging 0.96 to 34.3%, when not otherwise precluded by a Standard of Identity as described in this monograph and resulting in the maximum daily intake of up to 30 g/person is safe.

It is also our opinion that other qualified and competent scientists reviewing the same publicly available toxicological and safety information, further corroborated by history of safe use, would reach the same conclusion. Therefore, the Panelists also concluded that pea protein, when used as described, is GRAS based on scientific procedures.

Signatures

(b) (6)

Robert L. Martin, Ph.D. — May 17, 2018 — Date

(b) (6)

John A. Thomas, Ph.D., F.A.T.S., F.A.C.T. — May 24, 2018 — Date

(b) (6)

Madhusudan G. Soni, Ph.D., F.A.C.N., F.A.T.S. — May 28, 2018 — Date

Advisor to Expert Panel

7. Part VII- SUPPORTING DATA AND INFORMATION

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8. APPENDIX I

Analytical data from five non-consecutive manufacturing lots of Pea Protein

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668 Jincheng Rd., Zhaoyuan City, Shandong Province, China.

CERTIFICATE OF ANALYSIS

NO: DFPG0605.1-I

Sample Analyzed	Pea Protein 80%	Produce Date	May 16, 2017
Date of Analysis	May 17, 2017	Date of Expiration	May 15, 2019
BATCH NO	20170516-2	Date of Dispatch	/
Packaging	20kg		

Item	Testing Method	Standard	Result
Protein(dry basis) (NX6.25), %	AOAC 981.10	≥80	81.2
Moisture, %	AOAC 925.09	≤10	5.9
Ash, %	AOAC 942.05	≤8	3.9
Pb, mg/kg	EN ISO 17294-2	≤0.1	<0.01
As, mg/kg	EN ISO 17294-2	≤0.1	<0.1
Cd, mg/kg	EN ISO 17294-2	≤0.3	0.18
Hg, mg/kg	EN ISO 17294-2	≤0.02	<0.02
PH	Q/DFS0001S-2015	6.5~8.5	7.2
TPC, cfu/g	AOAC 990.12	≤10000	$6.2*10^3$
Total Coliform, cfu/g	AOAC 990.14	≤90	<10
E-Coli, cfu/g	AOAC 990.14	ND	ND
Yeasts and Molds, cfu/g	BAM Ch.18	≤100	10
Salmonella, cfu/375g	AOAC2003.09	ND	ND
Gluten, mg/kg	R7001	<20	<5
Soy Allergen, mg/kg	R7102	<20	6.3
Aflatoxin (G1+G2+B1+B2), μg/kg	GB/T 18979	/	<5
S aureus, cfu/g	ISO21657:2004	ND	ND

Assesor signature: WU MEIYAN Inspector signature:CHENG GANG

YAN TAI ORIENTAL PROTEIN TECH CO., LTD

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CERTIFICATE OF ANALYSIS

NO: DFPG0605.2-I

Sample Analyzed	Pea Protein 80%	Produce Date	May 11, 2017
Date of Analysis	May 12, 2017	Date of Expiration	May 10, 2019
BATCH NO	20170511-2	Date of Dispatch	/
Packaging	20kg		

Item	Testing Method	Standard	Result
Protein(dry basis) (NX6.25), %	AOAC 981.10	≥80	81.3
Moisture, %	AOAC 925.09	≤10	6.5
Ash, %	AOAC 942.05	≤8	4.3
PH	Q/DFS0001S-2015	6.5~8.5	7.4
Pb, mg/kg	EN ISO 17294-2	≤0.1	<0.01
As, mg/kg	EN ISO 17294-2	≤0.1	<0.1
Cd, mg/kg	EN ISO 17294-2	≤0.3	0.18
Hg, mg/kg	EN ISO 17294-2	≤0.02	<0.02
TPC, cfu/g	AOAC 990.12	≤10000	$8.1*10^3$
Total Coliform, cfu/g	AOAC 991.14	≤90	<10
E-Coli, cfu/g	AOAC 990.14	ND	ND
Yeasts and Molds, cfu/g	BAM Ch.18	≤100	10
Salmonella, cfu/375g	AOAC2003.09	ND	ND
Gluten, mg/kg	R7001	<20	<5
Soy Allergen, mg/kg	R7102	<20	7.2
Aflatoxin (G1+G2+B1+B2), μg/kg	GB/T 18979	/	<5
S aureus, cfu/g	ISO21657:2004	ND	ND

Assesor signature: WU MEIYAN Inspector signature:CHENG GANG

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CERTIFICATE OF ANALYSIS

NO: DFPG0605.3-I

Sample Analyzed	Pea Protein 80%	Produce Date	May 19, 2017
Date of Analysis	May 20, 2017	Date of Expiration	May 18, 2019
BATCH NO	20170519-2	Date of Dispatch	/
Packaging	20kg		

Item	Testing Method	Standard	Result
Protein(dry basis) (NX6.25), %	AOAC 981.10	≥80	81.5
Moisture, %	AOAC 925.09	≤10	6.6
Ash, %	AOAC 942.05	≤8	4.2
PH	Q/DFS0001S-2015	6.5~8.5	7.3
Pb, mg/kg	EN ISO 17294-2	≤0.1	<0.01
As, mg/kg	EN ISO 17294-2	≤0.1	<0.1
Cd, mg/kg	EN ISO 17294-2	≤0.3	0.18
Hg, mg/kg	EN ISO 17294-2	≤0.02	<0.02
Total Coliform, cfu/g	AOAC 991.14	≤90	<10
TPC, cfu/g	AOAC 990.12	≤10000	$5*10^3$
E-Coli, cfu/g	AOAC 990.14	ND	ND
Yeasts and Molds, cfu/g	BAM Ch.18	≤100	10
Salmonella, cfu/375g	AOAC2003.09	ND	ND
Gluten, mg/kg	R7001	<20	<5
Soy Allergen, mg/kg	R7102	<20	5.7
Aflatoxin (G1+G2+B1+B2), μg/kg	GB/T 18979	/	<5
S aureus, cfu/g	ISO21657:2004	ND	ND

Assesor signature: WU MEIYAN **Inspector signature:**CHENG GANG

YAN TAI ORIENTAL PROTEIN TECH CO., LTD

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CERTIFICATE OF ANALYSIS

NO: DFPG0404.3-II

Sample Analyzed	Pea Protein 80%	Produce Date	March 09, 2018
Date of Analysis	March 10, 2018	Date of Expiration	March 08, 2020
BATCH NO	20180309-3	Date of Dispatch	April 04, 2018
Packaging	2kg	Model	PPI80

Item	Testing Method	Standard	Result
Protein(dry basis) (NX6.25), %	AOAC 981.10	≥80	84.7
Moisture, %	AOAC 925.09	≤10	6.4
Ash, %	AOAC 942.05	≤8	4.6
PH	Q/DFS0001S-2017	6.5~8.5	7.1
Pb, mg/kg	EN ISO 17249-2	≤0.1	<0.1
As, mg/kg	EN ISO 17249-2	≤0.1	<0.1
Cd, mg/kg	EN ISO 17249-2	≤0.3	<0.3
Hg, mg/kg	EN ISO 17249-2	≤0.02	<0.02
TPC, cfu/g	AOAC 990.12	≤10000	$5.3*10^3$
Total Coliform, cfu/g	AOAC 991.14	≤10	<10
E.Coli, cfu/g	AOAC 991.14	ND	ND
Yeast and Mold , cfu/g	BAM Ch.18	<100	<10
Salmonella, cfu/375g	AOAC2003.09	ND	ND
Gluten , mg/kg	R7001	<20	<5
Soy Allergen, mg/kg	8410	<20	<2.5
Aflatoxin (G1+G2+B1+B2), μg/kg	GB/T 18979	/	<5
S aureus, cfu/g	ISO21657:2004	ND	ND

Assesor signature: WU MEIYAN Inspector signature:CHENG GANG

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CERTIFICATE OF ANALYSIS

NO: DFPG0605.5-I

Sample Analyzed	Pea Protein 80%	Produce Date	May 29, 2017
Date of Analysis	May 30, 2017	Date of Expiration	May 28, 2019
BATCH NO	20170529-1	Date of Dispatch	/
Packaging	20kg		

Item	Testing Method	Standard	Result
Protein(dry basis) (NX6.25), %	AOAC 981.10	≥80	81.3
Moisture, %	AOAC 925.09	≤10	6.3
Ash, %	AOAC 942.05	≤8	4.0
PH	Q/DFS0001S-2015	6.5~8.5	7.4
Pb, mg/kg	EN ISO 17294-2	≤0.1	<0.01
As, mg/kg	EN ISO 17294-2	≤0.1	<0.1
Cd, mg/kg	EN ISO 17294-2	≤0.3	0.18
Hg, mg/kg	EN ISO 17294-2	≤0.02	<0.02
TPC, cfu/g	AOAC 990.12	≤ 30000	$4*10^3$
Total Coliform, cfu/g	AOAC 991.14	≤10	<10
E-Coli, cfu/g	AOAC 990.14	ND	ND
Yeasts and Molds, cfu/g	BAM Ch.18	<100	10
Salmonella, cfu/375g	AOAC2003.09	ND	ND
Gluten, mg/kg	R7001	<20	<5
Soy Allergen, mg/kg	R7102	<20	9.1
Aflatoxin (G1+G2+B1+B2), μg/kg	GB/T 18979	/	<5
S aureus, cfu/g	ISO21657:2004	ND	ND

Assesor signature: WU MEIYAN Inspector signature: CHENG GANG

YAN TAI ORIENTAL PROTEIN TECH CO., LTD

9. APEPNDIX II

Additional Data on Afflatoxin Analysis from three batches

中国认可
国际互认
检测
TESTING
CNAS L0604

Test Report **Report No: QDAFF171015836-3** **Date: Oct 24 2017**

Client name:	YAN TAI ORIENTAL PROTEIN TECH CO.,LTD
Client address:	668Jincheng R.d Zhaoyuan City Shandong P.V.China
Sample name:	pea protein 80
Sample Batch No.:	20171011
Product Date:	/
Manufacturer:	/

Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

SGS Sample No.:	QDAFF171015836-3
SGS reference No.:	TAOFD1705008501
Date of sample received:	Oct 18 2017
Testing period:	Oct 18 2017 ~ Oct 24 2017

TEST(S) REQUESTED:
Selected test(s) as requested by applicant

TEST RESULT(S):
Please refer to the next page(s)

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, and for clients internal use only, not to the society has the proof function. This document cannot be used for publicity, without prior approval of the SGS.

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SGS Authorized Signature

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SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101 t 400-691-0488 f (86-532) 83884538 www.sgsgroup.com.cn

TEST RESULT(S):

Test item(s)	Unit(s)	Test method(s)	Test result(s)	Method detection limit(s)
Pb	mg/kg	GB 5009.12-2017 I	Not detected	0.05
As	mg/kg	GB 5009.11-2014 I	Not detected	0.01
Hg	mg/kg	GB 5009.17-2014 I	Not detected	0.01
Cd	mg/kg	GB 5009.15-2014	0.042	0.005
Aflatoxin B_1	μg/kg	GB 5009.22-2016 III	Not detected	0.3
Aflatoxin B_2	μg/kg	GB 5009.22-2016 III	Not detected	0.2
Aflatoxin G_1	μg/kg	GB 5009.22-2016 III	Not detected	0.3
Aflatoxin G_2	μg/kg	GB 5009.22-2016 III	Not detected	0.2
Aflatoxin (B_1 +B_2 + G_1+G_2)	μg/kg	GB 5009.22-2016 III	Not detected	1

SAMPLE DESCRIPTION: Sample in bag

*** End of Report***

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SGS

CMA 2015150662V

中国认可
国际互认
检测
TESTING
CNAS L0604

Test Report

QDF18-009263-01

Date: 12 Apr 2018

Client Name: YAN TAI ORIENTAL PROTEIN TECH CO.,LTD
Client Address: 668Jincheng R.d Zhaoyuan City Shandong P.V.China

Sample Name:	Pea Protein 80
Sample Batch No.:	20180420
Production Date:	/
Manufacturer:	/

Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

SGS Reference No. :	TAOFD1801431701
Date of Sample Received :	08 Apr 2018
Testing Period :	08 Apr 2018 - 12 Apr 2018
Test Requested :	Selected test(s) as requested by client.
Test Method :	Please refer to next page(s).
Test Result(s) :	Please refer to next page(s).

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.

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PREPARED BY CHECKED BY APPROVED BY

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.

Test Report

QDF18-009263-01

Date: 12 Apr 2018

Sample Description :

Specimen No.	SGS Sample ID	Description
1	QDF18-009263.001	sample in bag

Chemical test

Test Result(s) :

Test Item(s)	Unit	Test Method(s)	Test Result(s) 001	MDL
Aflatoxin B_1	μg/kg	GB 5009.22-2016 III	ND	0.3
Aflatoxin B_2	μg/kg	GB 5009.22-2016 III	ND	0.2
Aflatoxin G_1	μg/kg	GB 5009.22-2016 III	ND	0.3
Aflatoxin G_2	μg/kg	GB 5009.22-2016 III	ND	0.2
Aflatoxin (B_1+B_2+G_1+G_2)	μg/kg	GB 5009.22-2016 III	ND	1

Remark:
1.ND = Not Detected (< MDL)
2.MDL = Method Detection Limit

*** End ***

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SGS

Test Report **Report No: QDAFF170201907-3.1** **Date: Feb 27 2017**

Client name:	YAN TAI ORIENTAL PROTEIN TECH CO.,LTD
Client address:	668Jincheng R.d Zhaoyuan City Shandong P.V.China
Sample name:	pea protein 80
Sample Batch No.:	20170215
Product Date:	/
Manufacturer:	/

Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

SGS Sample No.:	QDAFF170201907-3
SGS reference No.:	TAOFD1700590101
Date of sample received:	Feb 21 2017
Testing period:	Feb 21 2017 – Feb 27 2017

TEST(S) REQUESTED:
Selected test(s) as requested by applicant

TEST RESULT(S):

Test item(s)	unit(s)	Test method(s)	Test result(s)	Method detection limit(s)
Aflatoxin G_2	μg/kg	GB/T 18979-2003	Not detected	0.30
Aflatoxin G_1	μg/kg	GB/T 18979-2003	Not detected	0.20
Aflatoxin B_2	μg/kg	GB/T 18979-2003	Not detected	0.30
Aflatoxin B_1	μg/kg	GB/T 18979-2003	Not detected	0.20
Aflatoxin (G_2+G_1+ B_2+B_1)	μg/kg	GB/T 18979-2003	Not detected	1

SAMPLE DESCRIPTION: Sample in bag

The results shown in this test report refer only to the sample(s) tested, and for clients internal use only. This document cannot be used for publicity, without prior approval of the SGS.

(b) (6)

SGS Authorized Signature

*** End of Report***

QDAF

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中国·青岛·高科技工业园株洲路143号通标中心 邮编: 266101 t (86-532) 8388 4638 e sgs.china@sgs.com

69 pages of Curriculum Vitae removed in accordance with the Privacy Act of 1974.

From: Madhu Soni
To: Morissette, Rachel
Subject: RE: missing information for GRN 000788
Date: Monday, August 06, 2018 11:25:48 AM
Attachments: image007.png
Expert Panel CVs for pea protein GRAS GRN 788.pdf

Dear Dr. Morissette,
Sorry for the oversight, please find attached GRAS Panel CVs as mentioned in our Pea Protein GRAS notice (GRN 000788). If you have any questions, please let me know

Best regards

Madhu

Madhu G. Soni, *PhD, FACN, FATS*
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From: Morissette, Rachel [mailto:Rachel.Morissette@fda.hhs.gov]
Sent: Monday, August 6, 2018 9:43 AM
To: Madhu Soni <sonim@bellsouth.net>
Subject: missing information for GRN 000788

Dear Dr. Soni,

The CV information for the GRAS panel in GRN 000788 is referenced in Footnote 9, but no attachments containing the CVs were provided with the submitted notice. Can you please provide these missing attachments to me via email at your earliest convenience?

Best regards,

Rachel

Rachel Morissette, Ph.D.
Consumer Safety Officer

Center for Food Safety and Applied Nutrition
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