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July 16, 2018

Via FedEx & CD-ROM

Dr. Susan Carlson
Director, Division of Biotechnology and GRAS
Notice Review
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: GRAS Notification for Ingredion and Shandong Jianyuan Pea Protein

Dear Dr. Carlson:

We respectfully submit the attached GRAS Notification on behalf of our client, Ingredion Incorporated (Ingredion Inc.), and their supplier, Shandong Jianyuan Bioengineering Company Limited (Shandong Jianyuan Bioengineering Co. Ltd.) for pea protein to be used as a protein substitute, formulation aid, nutrient supplement, stabilizer, thickener, and texturizer in conventional food products including meat and poultry products, as well as in sports nutrition and meal replacement applications as a source of protein. The pea protein contains ≥80% protein and will be used at levels that will not increase the consumer's overall exposure to protein. More detailed information regarding product identification, intended use levels, and the manufacturing and safety of the ingredient is set forth in the attached GRAS Notification.

Ingredion Inc. and Shandong Jianyuan Bioengineering Co. Ltd. have determined that their pea protein is GRAS based on scientific procedures in accordance with 21 C.F.R. § 170.30(b) and in conformance with the guidance issued by the Food and Drug Administration (FDA) under 21 C.F.R. § 170.36, 81 Fed. Reg. 54960 (Aug. 17, 2016). Therefore, the use of the pea protein as described in this GRAS Notification is exempt from the requirement of premarket approval as set forth in the Federal Food, Drug, and Cosmetic Act.

The analytical data, published studies, and information that are the basis for this GRAS Notification are available for FDA review and copying at reasonable times at Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001, or will be sent to FDA upon request.

We look forward to the Agency's review of this submission and would be happy to provide Agency officials with any information they may need to complete their assessment. Thank you for your attention to this matter.

Sincerely,

(b) (6)

Evangelia C. Pelonis

4839-1611-1719, v. 2

GRAS Notice for Pea Protein

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

Submitted by: Keller and Heckman LLP
1001 G Street, NW
Suite 500W
Washington, DC 20001

On behalf of our client

Ingredion Incorporated
5 Westbrook Corporate Center
Westchester, Illinois 60154
United States

and their supplier

Shandong Jianyuan Bioengineering Company Limited
No. 100, Shengtai Road, Development Zone, Zhaoyuan City,
Yantai City, Shandong Province
China

July 16, 2018

GRAS NOTICE FOR PEA PROTEIN

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Part 1 – Signed statements and certification

(1) Applicability of 21 C.F.R. part 170, subpart E

We submit this generally recognized as safe (GRAS) notice in accordance with proposed 21 C.F.R. part 170, subpart E consisting of sections 170.203 through 170.285.

(2) Name and address of the notifier

Ingredion Incorporated
5 Westbrook Corporate Center
Westchester, Illinois 60154
USA
Tel: +18007130208
www.ingredion.com

Shandong Jianyuan Bioengineering Company Limited
No. 100, Shengtai Road, Zhaoyuan City,
Yantai, Shandong Province
CHINA
Tel : +865358139216
Fax: +865358216095
www.jianyuangroup.com

All communications on this matter are to be sent to Counsel for Ingredion Inc.

Evangelia C. Pelonis
Keller and Heckman LLP
1001 G Street, NW
Suite 500W
Washington DC 20005
Tel: 202-434-4106
Fax: 202-434-4646
Email: pelonis@khlaw.com

(3) Name of the notified substance

Pea Protein

(4) Applicable conditions of use of the notified substance

Pea protein produced from *Pisum sativum L.* seed-pods (peas) is intended for use as an ingredient that is a source of protein, formulation aid, nutrient supplement, stabilizer/thickeners and

texturizer in various foods including meat and poultry products. The pea protein will be used at levels that will not increase the consumer's overall exposure to protein.

Ingredion Inc. and Shandong Jianyuan Bioengineering Co. Ltd. intend to use pea protein for the following technical effects, as defined in 21 C.F.R. §170.3(o): (1) formulation aid, (2) nutrient supplement, (3) stabilizer and thickener, and (4) texturizers. Specifically, the effects of pea protein in these foods include fat and water binding, emulsifying, gelation, and source of protein. Foods intended for infants are excluded from the list of intended food uses.

(5) Basis for the GRAS determination

Keller and Heckman LLP, on behalf of Ingredion Incorporation (Ingredion Inc.) hereby notifies the Agency of its determination that Pea Protein (>80% protein) is Generally Recognized as Safe (GRAS), consistent with Section 201(s) of the Federal Food, Drug, and Cosmetic Act. This GRAS conclusion is based on scientific procedures in accordance with 21 C.F.R. §170.30(a) and (b), and conforms to the guidance issued by the Food and Drug Administration (FDA) under 21 C.F.R. §170.36, 81 Fed. Reg. 54960 (Aug. 17, 2016). The GRAS determination has also been evaluated by experts qualified by scientific training and experience to assess the safety of Pea Protein under the conditions of its intended use in food.

(6) Exclusion from premarket approval

Ingredion Inc. and Shandong Jianyuan Bioengineering Co. Ltd. have concluded that their pea protein is GRAS and not subject to the premarket approval requirements of the Federal Food,

Drug, and Cosmetic Act. Pea protein meets the required specifications when used as a formulation aid, nutrient supplements, stabilizers and thickeners, and texturizer.

(7) Availability of data and information

The information for this GRAS conclusion including analytical data, published studies, and information that are the basis for this GRAS determination are available to FDA upon request as required by 21 C.F.R. § 170.225(c)(7)(ii)(A) or (B) by contacting Keller and Heckman LLP at the below address.

Evangelia C. Pelonis
Keller and Heckman LLP
1001 G Street, NW
Suite 500W
Washington DC 20005
Tel: 202-434-4106
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(8) Applicability of FOIA exemptions

Ingredion Inc. and Shandong Jianyuan Bioengineering Co. Ltd. are not claiming any information in Parts 2 through 7 of this document as trade secret, confidential or financial information that is privileged or confidential. Thus, all information and data in this submission are not exempt from the Freedom of Information Act (FOIA), 5 U.S.C. Section 552.

(9) FSIS/USDA – Use in Meat and Poultry Products

Ingredion Inc. and Shandong Jianyuan Bioengineering Co. Ltd. intend to add pea protein to meat and poultry products that come under U.S. Department of Agriculture (USDA) jurisdiction (21

C.F.R. § 170.270) and authorize FDA to send USDA any portion of this filing, which does not include any discussion of trade secrets.

(11) Certification

We certify on behalf of our client Ingredion Inc. and their supplier Shandong Jianyuan Bioengineering Co. Ltd. that this GRAS conclusion is based on representative data from Ingredion Inc. and Shandong Jianyuan Bioengineering Co. Ltd. required for the safety and GRAS status of the use of pea protein. To the best our knowledge based on the information provided by Ingredion Inc. and Shandong Jianyuan Bioengineering Co. Ltd., this GRAS Notice (GRN) is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to us and pertinent to the evaluation of safety and GRAS status of the use of the substance.

Signed:

(b) (6)

7/16/18

Evangelia C. Pelonis
Partner
Keller and Heckman LLP

Date: July 16, 2018

Part 2 – Identity, method of manufacture, specifications, and physical or technical effect

(1) Identity of the notified substance

Pea protein is a light cream to off-white colored powder with a neutral to bland taste, clean to no off-odor. General descriptive characteristics and properties of pea protein manufactured by Shandong Jianyuan Bioengineering Co. Ltd. are presented in **Table 1**.

(a) General characteristics

Table 1: General Descriptive Characteristics of Ingredion and Shandong Jianyuan Pea Protein

Parameter	**Description**
Botanical source	*Pisum sativum L.*
Source synonyms	*Pisum arvense L., Pisum humile Boiss. & Noe*
Parts of plant used	Peas; seeds
Synonym of part used	Golden pea; Yellow pea; Bush pea; False lupine
Product appearance	Powder
Color	Light yellow or milky white
Odor	No off odor
Taste	No off taste
Storage	Store in a cool dry place away from strong odor or volatile materials
Shelf life	24 months

(b) Amino acid analyses

The typical amino acid profile of pea protein (≥80% protein) and its source material (peas) is presented in **Table 2**. The information suggests that the amino acid profile of pea protein is similar to the amino acid composition of peas. The amino acid data of pea protein provided in the table is based on a composite of three lots. The comparative amino acid profile of pea

protein with unprocessed peas (source material) suggests that the manufacturing process is unlikely to significantly affect the levels of the amino acids in the final product.

Table 2: Comparison of Amino Acids of Pea and Ingredion and Shandong Jianyuan Pea Protein

Nutrient		**Pisum sativum (peas)***		**Pea protein**	
		g/100g	**% amino acid**	**% amino acid/100g pea protein "as is"**	**% amino acid/100g pea protein "Dry Basis"**
Histidine	%	0.597	2.54	1.93	2.06
Isoleucine	%	1.014	4.32	3.90	4.17
Leucine	%	1.760	7.50	6.53	6.98
Lysine	%	1.772	7.55	6.11	6.53
Methionine	%	0.251	1.07	0.78	0.83
Cysteine	%	0.373	1.59	0.54	0.58
Phenylalanine	%	1.132	4.82	4.18	4.47
Tyrosine	%	0.711	3.03	2.91	3.11
Threonine	%	0.872	3.72	2.84	3.03
Tryptophan	%	0.275	1.17	0.79	0.84
Valine	%	1.159	4.94	4.15	4.43
Glycine	%	1.092	4.65	3.13	3.34
Arginine	%	2.188	9.33	6.84	7.31
Proline	%	1.014	4.32	3.45	3.69
Aspartic acid	%	2.896	12.34	9.19	9.82
Glutamic acid	%	4.196	17.88	13.91	14.86
Alanine	%	1.080	4.60	3.45	3.69
Serine	%	1.040	4.60	3.99	4.26
Total amino acids	%	23.462	**100**	78.62	**84.00**

* Source: United States Department of Agriculture. National Nutrient Database for Standard Reference, Nutrient data for 1608S, Peas, split, mature seeds, raw. Release 26. 2013.

(2) Taxonomic classification

The taxonomic classification of *Pisum sativum L*. is summarized in **Table 3**.

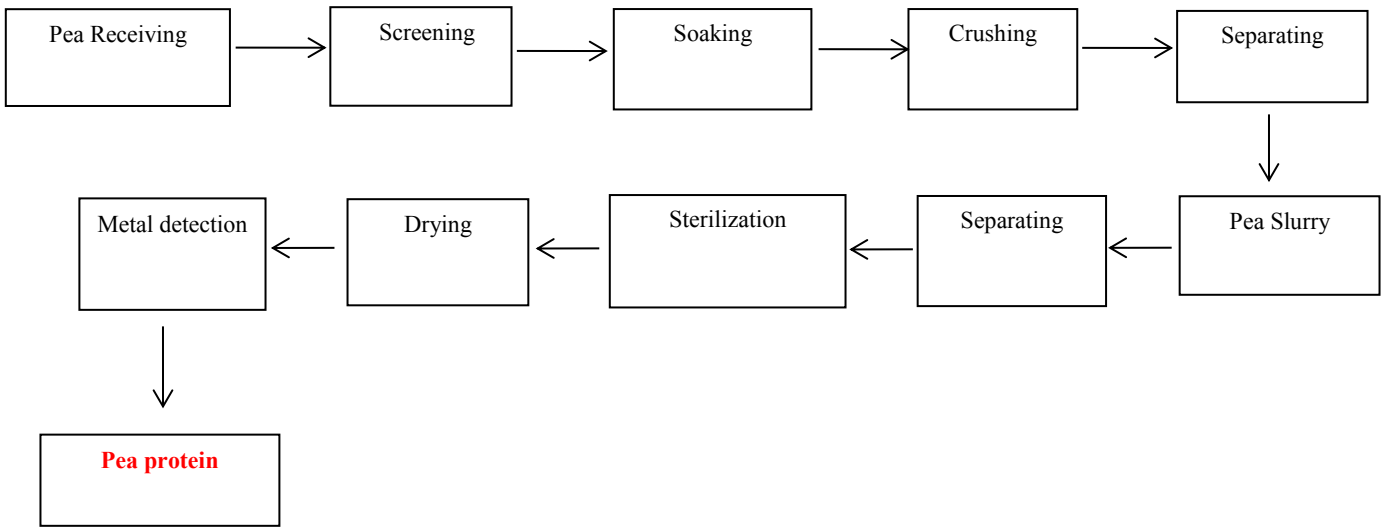
Table 3: Classification of *Pisum sativum L.*

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.*

(3) Description of the method of manufacture

The manufacturing process of pea protein begins with the yellow pea (*Pisum sativum L.*) and is produced without the use of organic solvents. The flow chart for manufacturing of pea protein is shown below.

Figure 1. Manufacturing Process of Ingredion and Shandong Jianyuan Pea Protein



Shandong Jianyuan Bioengineering Co. Ltd.'s Quality Assurance department reviews the raw material Certificate of Analysis (COA) of the peas to ensure that they meet the specifications as stated on the supplier specification sheet. All ingredients used in the production of pea protein are approved based on external third-party testing lab analysis. Any lot that does not meet the specification as stated on the specification sheet is rejected.

Upon receipt, peas are first screened for foreign material and then soaked in water. The soaked peas are then crushed and the crushed material is pumped into centrifuge decanters. The pea fiber and pea starch are removed and the remaining protein curd is pumped into a neutralization tank for further processing. Food grade sodium hydroxide is added to the protein curd to adjust pH to 7.0 ~ 8.0. Following neutralization, the protein curd is pumped into automatic high temperature steam sterilizing equipment for sterilization. After sterilization, the protein curd is dried by air spray drying and packed into appropriate containers.

The pea protein is produced in facilities that adhere to good manufacturing practices (GMPs) for the production of food pursuant to Subpart B in 21 C.F.R. Part 117 and otherwise adhere to all FDA food safety requirements. Further, all processing aids used in the production of the pea protein are food grade and have an appropriate food regulatory status in the U.S.

(4) Specifications and Identity

Rich in dietary protein and fiber, yellow peas offer many nutritional benefits. The nutritional composition of pea protein (80% protein) is provided in **Table 4,** where the nutritional composition of pea protein is also compared to the nutritional profile of raw or unprocessed peas.

Table 4: Nutritional Composition of Ingredion and Shandong Jianyuan Pea Protein

Nutrient	Unit	Raw Pea - Pisum sativum*	Pea protein
Calories	Kcal/100g	352	407
Protein	g/100g	23.82	80
Total fat	g/100g	1.16	8.8
Saturated fat	g/100g	0.161	2.3
Cholesterol	g/100g	0	ND
Carbohydrate	g/100g	63.34	3.7
Sugars	g/100g	8.00	< 0.5
Dietary fiber	g/100g	25.5	3.5
Sodium	mg/100g	15	1127
Calcium	mg/100g	37	127
Iron	mg/100g	4.82	22.2

* Source: United States Department of Agriculture. National Nutrient Database for Standard Reference, Nutrient data for 16085, Peas, split, mature seeds, raw. Release 28.

Shandong Jianyuan Bioengineering Co. Ltd. has established specifications for their pea protein and are summarized in **Table 5**, including protein, crude fiber, moisture, ash, fat, pH, microbial load, and heavy metals. Ingredion Inc. has provided analyses from three non-consecutive lots of pea protein indicating a consistent manufacturing process as shown **Table 6**.

Table 5: Ingredion and Shandong Jianyuan Pea Protein Specifications

Property	Unit	Method	Specification
Chemical and Physical Properties			
Moisture	%	AOAC: 950.46	≤ 8.0
Protein (dry basis)	%	AOAC: 992.15; AACC: 46-30	≥ 80.0
Ash	%	AOAC: 923.03	≤ 6.0
pH (10%w/w solution)	-	Internal Method	7.0 -8.0
Particle size	%	Thru U.S.S # 80 (177 microns)	≤ 95.0
Heavy Metals			
Arsenic	ppm	AOAC 993.14	≤ 0.2
Cadmium	ppm	AOAC 993.14	≤ 0.2
Lead	ppm	AOAC 993.14	≤ 0.5

Mercury	ppm	AOAC 993.14	≤ 0.2
Microbiological Analysis			
Aerobic Plate Count	cfu/g	AOAC 966.23	≤ 10,000
Coliforms	cfu/g	AOAC 991.14	≤ 10
E. coli	cfu/g	AOAC 991.14	Negative
Salmonella	cfu/25 g	AOAC 2004.03	Negative
Yeast	cfu/g	FDA-BAM, 7th ed.	≤ 100
Mold	cfu/g	FDA-BAM, 7th ed.	≤ 100

Table 6: Analyses of Three Non-Consecutive Lots of Ingredion and Shandong Jianyuan Pea Protein

Property	Unit	Method	Specification	Lot # 20171710	Lot # 170925	Lot # 170926
Chemical and Physical Properties						
Moisture	%	AOAC: 950.46	≤ 8.0	7.51	7.074	7.156
Protein (dry basis)	%	Calculated	≥ 80.0	81.2	82.1	82.5
Ash	%	AOAC: 923.03	≤ 6.0	4.54	4.843	4.847
pH (10%w/w solution)	–	Internal Method	7.0 -8.0	7.35	7.57	7.55
Particle size	%	Thru U.S.S # 80 (177 microns)	≤ 95.0	92.98%	93.93%	94.17%
Heavy Metals						
Arsenic	ppm	AOAC 993.14	≤ 0.2	0.0174	0.0111	0.0117
Cadmium	ppm	AOAC 993.14	≤ 0.2	0.0192	0.0337	0.0349
Lead	ppm	AOAC 993.14	≤ 0.5	0.0349	0.0446	0.0475
Mercury	ppm	AOAC 993.14	≤ 0.2	<0.005	<0.006	<0.007
Microbiological Analysis						
Aerobic Plate Count	cfu/g	AOAC 966.23	≤ 10,000	20	50	840
Coliforms	cfu/g	AOAC 991.14	≤ 10	<10	<10	<10

E.Coli	cfu/g	AOAC 991.14	Negative	<10	<10	<10
Salmonella	cfu/25 g	AOAC 2004.03	Negative	Negative	Negative	Negative
Yeast	cfu/g	FDA-BAM, 7th ed.	≤ 100	<10	<10	<10
Mold	cfu/g	FDA-BAM, 7th ed.	≤ 100	<10	30	<10

Ingredion Inc. and Shandong Jianyuan Bioengineering Co. Ltd. routinely monitor for the following values: protein (as is), total carbohydrates, total fat, dietary fiber, density, soy protein and gluten. Total carbohydrates, total fat, and dietary fiber are tested twice per year. The results of three non-consecutive batch analyses are provided below.

Table 7. Typical Characteristics of Ingredion and Shandong Jianyuan Pea Protein

Property	Unit	Method	Specification	Lot # (b) (6)	Lot #	Lot #
Chemical and Physical Properties						
Protein (As is)	%	AOAC: 992.15; AACC: 46-30	–	75.1	76.3	76.6
Total Carbohydrates	%	Calculated	–	3.9	3	3
Total Fat	%	AOAC: 996.06	–	8.97	8.78	8.37
Dietary Fiber	%	AOAC: 991.43	–	0.5	< 0.1	< 0.1
Density	kg/L	Internal Method	–	0.393	0.432	0.425
Allergens						
Soy	ppm	Veratox for Soy Allergen: Quantitative Test	–	3.9	<2.5	<2.5

Gluten	ppm	AOAC 2012.01	–	<5.0	<5.0	<5.0

(5) Contaminants

Ingredion Inc. and Shandong Jianyuan Bioengineering Co. Ltd. monitor the pea protein ingredient for the following potential contaminants two times per year: melamine and cyanuric acid, mycotoxins (aflatoxin B1, B2, G1, G2, ochratoxin A, and zearalenone), and pesticide residues. The results of three batch analyses are provided below in Table 7 and indicate that the pea protein does not contain any of these contaminants at levels of concern.

Table 8. Contaminant Analysis

Property	Unit	Method	Specification	Lot # (b) (6)	Lot #	Lot #
Melamine/Cyanuric Acid						
Melamine	ppb	LC/MS	–	<10.0	<10.0	<10.0
Cyanuric Acid	ppb		–	<100	<100	<100
Mycotoxins						
Aflatoxin B1	ppb	Stable Isotope dilution assay for the accurate determination of mycotoxins in maize by UHPLC-MS/MS	-	<0.300	<0.300	<0.300
Aflatoxin B2	ppb		-	<0.300	<0.300	<0.300
Aflatoxin G1	ppb		-	<0.300	<0.300	<0.300
Aflatoxin G2	ppb		-	<0.300	<0.300	<0.300
Ochratoxin A	ppb		-	<1.00	3.45	3.78
Zearalenone	ppb		-	<16.7	<16.7	<16.7
Pesticide Residue Analysis						
Pesticides (300+ compounds)	-	AOAC 2007.01	-	Below LOQ	Below LOQ	Below LOQ

Part 3 – Dietary exposure

(1) Estimate of Dietary Exposure

This pea protein will be used as a substitute for, and/or in conjunction with, other proteins (such as soy protein, whey protein and animal derived protein) in conventional food products. The pea protein will also be used in sports nutrition and meal replacement applications as a source of protein at levels ranging from 5 to 15 grams per serving at one or two servings per day for a maximum of 30 grams per person per day.

The pea protein will be added to food products as a protein substitute and therefore will not contribute any additional exposure to protein for consumers. We do not realistically expect that the actual consumption of foods containing pea protein products would result in a daily consumption of greater than the Daily Reference Value (DRV) of 50 g/day for protein for adults and children 4 or more years of age. In addition, the Institute of Medicine (IOM) used the Continuing Survey of Food Intakes by Individuals (CSFII) 1994-1996, 1998 to estimate the background dietary intakes of protein for the US population.[1] The mean adult protein intake ranged from 56-104 g/day, depending on the age group. At the 90th percentile, adult protein intakes ranged from 76 g/day to 142 g/day. Thus, the IOM has established a Recommended Dietary Allowance (RDA) for protein of 56 g/day for adult males and 46 g/day for adult females.

Insufficient dietary protein intake has been associated with adverse effects in human health and development. In 2005, IOM set a Recommended Dietary Allowance (RDA) value for protein of

[1] *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat_ Fatty Acids, Cholesterol, Protein and Amino Acids*, INSTITUTE OF MEDICINE (2005), http://www.nal.usda.gov/fnic/DRI/DRI_Energy/energy_full_report.pdf.

0.8 g/kg body weight/day in adult males and females. One study estimated the protein intake by using data from the NHANES release from 2003 to 2004 and the results show that the protein intake averaged 55±14 g/d in young children, increased to a high of about 91±22 g/d in adults aged 19–30 y, and then decreased to around 66±17 g/d in older adults (71+years).[2] Median intakes for the groups were 53, 89, and 63 g/d, respectively. Other sources offered a suggested safe maximum daily protein intake of approximately 176 grams for an 80 kg individual on a 2867 kcal/day diet.[3]

Pea protein will be used as a food ingredient, formulation aid, nutrient supplement, stabilizer/thickeners and texturizer in various food products including meat and poultry products. As discussed above, the pea protein will be substituting for other sources of protein and will not result in significant increase of protein intake. Most of the population's intake of protein is, and will remain, in the form of unprocessed foods, including meat, poultry, fish and legumes. We do not realistically expect that the actual consumption of foods containing pea protein would result in a daily consumption of greater than the DRV, RDA or the average intakes for protein. In addition, pea protein as a directly consumed protein in sports nutrition or meal replacement applications will not have an impact on the overall protein intake since it is used to substitute the protein from other sources, i.e., animals or whey. Most of the population's intake of protein is, and will remain, in the form of unprocessed foods, including meat, poultry, fish and legumes.

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[2] V.L. Fulgoni III, Current protein intake in America: analysis of the National Health and Nutrition Examination Survey, 2003–2004. Am J Clin Nutr 2008;87(suppl):1554S–7S.

[3] S.A. Bilsborough, *A Review of Issues of Dietary Protein Intake in Humans*, 16 INT'L J. OF SPORT NUTRITION AND EXERCISE METABOLISM 2, 129-152 (2006).

In accordance with the Federal Meat Inspection Act and the Poultry Products Inspection Act, the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) is responsible for determining the efficacy and suitability of food ingredients intended for use in meat and poultry products. The intended uses of pea protein include use as a binder and/or processing aid in meat and poultry products. Suitability as a binder is determined by FSIS on a case-by-case basis by considering the proposed use of the substance and the specific meat or poultry product categories to which the ingredient is added. Attached in **Appendix I** and **Appendix II** are reports of the effectiveness of pea protein when used as a moisture retaining agent in comminuted meat products (hot dogs) and whole muscle products (turkey breast). The intended use of pea protein also includes the use as an egg replacement. The effects of the addition of pea protein to replace egg in products is for binding and stabilizing benefits, especially as an agent to assist with whipping.

(2) Current Exposure to Peas

The USDA considers peas under the general food product category of "legumes," which include beans, peas, lentils, and peanuts. 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. Based on the above information, and as peas have been reported to contain approximately 24.55% protein,[4] 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.

[4] FOOD AND DRUG ADMIN., *Agency Response Letter GRAS Notice No. GRN 000608 (Pea Protein Concentrate)*, (May 27, 2016), https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm511 732.htm.

Part 4 – Self-limiting levels of use

Pea protein has self-limiting levels of use due to the high water-retention capacity of the products. When used above the self-limiting levels there are undesirable sensory attributes. Excessive amounts of pea protein are unlikely because of the unpleasant taste (*i.e.*, bitterness) and texture (*i.e.*, dry, gummy, manufacturing difficulty) at high levels. 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.

Part 5 – Experience based on common use in food 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 determination is based on scientific procedures. However, as described below, the pea protein source material, peas, has been commonly used in foods prior to 1958.

Part 6 – Narrative

(1) Introduction

The conclusion that pea protein is GRAS under the conditions of its intended use in specific conventional food and beverage products is based on (1) the composition and manufacturing process of the pea protein, (2) the intended uses that result in safe dietary exposure, and (3) the safety information on pea and pea protein.

(2) Existing Clearances for Pea Protein

Pea protein has been recognized as GRAS by FDA for use as an ingredient, formulation aid, and texturizer in baked goods, 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%.

Further, unhydrolyzed and hydrolyzed pea protein has been recognized as GRAS by FDA for use as an ingredient in bakery products, snack foods, beverages (including nutritional beverages), soups, dairy products, dry instant milk shake mixes and protein drinks, instant powdered nutritional beverages, processed meat products, vegetarian food products/meat analogues, and meal replacement/nutritional bars at levels ranging from 2-90% of the finished food.

Effective GRAS notices pertaining to pea and pea protein are described in **Table 9** below.

Table 9. GRAS Notices for Pea Ingredients

Year	Clearance
2016	GRN 608, Pea protein concentrate; For use as an ingredient in conventional foods; FDA has no questions
2016	GRN 581, Unhydrolyzed and hydrolyzed pea protein; FDA has no questions
2014	GRN 525, Pea fiber; For use as an ingredient in conventional foods; FDA has no questions
2006	GRN 182, Pea protein isolate; For use as a filling agent in wine making; FDA has no questions

(3) Safety of Pea

Peas, Pisum Sativum, have a long history of safe human consumption as food around the world. The pea culture was found in Neolithic sites dating as far back as 7000 to 6000 BC in China, Jarmo (Iraq), Syria, Turkey, and Jordan; and peas were cultivated in the Egyptian delta area by 4800-4400 BC.[5,6,7] The yellow pea cultivar of Pisum Sativum is popular in Europe and traditionally sold after dehulling as dried "split peas", and made into soups or purées. The green variety, or garden pea, was common in the American colonies by 1600.[8] Different cultivars have approximately the same overall composition, subject to the varietal influences of climate, season and soil quality. Peas provide a cost-effective and convenient source of protein, complex carbohydrates, vitamins and minerals. At present, Canada, Russia, China, USA and India are the leading pea-producing countries, with more than 10 million tons of peas being produced annually worldwide.[9]

5 F.J. Simoons, FOOD IN CHINA: A CULTURAL AND HISTORICAL INQUIRY (1991).

6 *A Brief History of Peas*, BEST COOKING PULSES, http://www.bestcookingpulses.com/history.php.

7 D. Zohary & M. Hopf, DOMESTICATION OF PLANTS IN THE OLD WORLD 105-107 (3rd ed. 2000).

8 Food Resource, College of Public Health and Human Sciences, Oregon State University.

9 W.J. Dahl, L.M. Foster, & R.T. Tyler, *Review of the health benefits of peas*, BRITISH JOURNAL OF NUTRITION, 108 (Suppl. 1), S3-S10 (2012).

Based on the long history of common use, peas are generally regarded as safe up to the level at which they are commonly consumed. The USDA database has listed 56 food products that contain peas, including baby foods, legumes and legume products, soups, sauces, and gravies, and vegetables and vegetable products.[10] The Reference Amount Customarily Consumed (RACC) for peas is 85 g/serving, which represents an average intake of peas by Americans at a single serving.[11] Taking the FDA's recommendation that the 90th percentile of intake is normally be approximated by doubling the mean, the 90th percentile daily intake of peas would be 170 g. As peas contain approximately 24.55% protein, the intake of protein from the consumption of peas at the mean and 90th percentile in the US is estimated to be 20.9 and 41.7 g/person/day.

(4) Safety of Pea Protein

(a) Metabolism of Pea Protein

Mariotti et. al. (2001)[12] examined the bioavailability and metabolic utilization of pea albumins and globulins when given selectively to healthy humans consuming their usual diets. In this study, human volunteers ingested a mixed meal of 30 g of raw purified pea protein either as [15N]-globulins (G, n = 9; 6 men and 3 women) or as a mix of [15N]-globulins and [15N]-

10 U.S. DEP'T OF AGRIC., *National Nutrient Database for Standard Reference* (2013), http://ndb.nal.usda.gov/ndb/foods.

11 FOOD AND DRUG ADMIN., Code of Federal Regulations, Title 21 (Apr. 1, 2013), http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.12.

12 F. Mariotti, M.E. Pueyo, D. Tomé, S. Bérot, R. Benamouzig, S. Mahé, *The influence of the albumin fraction on the bioavailability and postprandial utilization of pea protein given selectively to humans*, 131 J. OF NUTRITION 6, 1706-1713 (2001).

albumins (GA, n = 7; 4 men and 3 women) in their natural proportions (22:8). Following ingestion of protein meal, the postprandial sampling was done hourly for 8 hours. Dietary and endogenous nitrogen fluxes at the terminal ileum were assessed using a tube perfusion technique with an isotopic dilution method. Systemic dietary amino acid availability and the retention of dietary amino acids were determined using 15N enrichment in plasma amino acids and deamination products in blood and urine for 8 hours postprandially. The results showed that 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. It was also noted that when given selectively to healthy humans, pea proteins exhibit a good nutritional value, similar to that of soy protein.

Gausserés et. al. (1997)[13] evaluated the gastrointestinal absorption of pea protein in seven healthy adults (4 males and 3 females with mean mass of 64 kg, ranging from 46 to 77 kg) following ingestion of 21.45 g (195 mMol N) of [15N]-labeled pea protein. Each meal contained

[13] N. Gausserés, S. Mahé, R. Benamouzig, C. Luengo, F. Ferriere, J. Rautureau, D. Tomé, *[15N]-Iabeled pea flour nitrogen exhibits good ileal digestibility and postprandial retention in humans*, 127 J. OF NUTRITION 6, 1160-1165 (1997).

75 g pea flour (195 mMol N). Ileal effluents were collected for 8 h at 30-min intervals using a nasointestinal intubation technique. Urine and plasma samples were collected for 24 h. The [15N]-enrichment was determined in the intestinal samples, in the plasma amino acids and urea as well as in the urinary urea and ammonia fractions. The true gastroileal absorption of pea protein was 89.4 +/- 1.1%. This absorption was correlated with a significant increase ($P < 0.05$) in [15N]-enrichment in the plasma amino acids and in the nitrogen incorporated into the body urea pool for 1 h following pea ingestion. The enrichment remained significantly higher than the basal values in these pools 24 h after pea ingestion. The recovery of total urinary exogenous nitrogen after 22 h was 31.1 +/- 9.3 mmol N. Moreover, the kinetics of [15N]-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 authors concluded that the results demonstrate the good true nitrogen digestibility and retention of pea protein in humans.

Gausserés et. al. (1996)[14] determined the gastro-ileal behavior of pea protein in humans. Twelve healthy volunteers were intubated with an intestinal tube located either in the jejunum (n 5) or in the ileum (n 7). After fasting overnight, they ingested 195 mmol N of [15N]pea. Intestinal samples were collected for 6 h in the jejunum and for 8 h in the ileum. Before meal ingestion the basal liquid flow rate (ml/min) was 2.01 (SD 0.31) in the jejunum and 2.02 (SD 0.33) in the ileum. After meal ingestion the liquid phase of the meal peaked in the 40-60 min period in the jejunum and in the 150-180 min period in the ileum. The jejuno-ileal transit time of the liquid

[14] N. Gausserés, S. Mahé, R. Benamouzig, C. Luengo, H. Drouet, J. Rautureau, D. Tomé, *The gastro-ileal digestion of 15N-labelled pea nitrogen in adult humans*, 76 BRITISH J. OF NUTRITION 1, 75-85 (Jul. 1996).

phase of the meal was 102 min. The basal flow rate of endogenous N (mmol N/min) was 0.22 (SD 0.15) in the jejunum and 0.16 (SD 0.10) in the ileum. The endogenous N flow rate peaked significantly ($P < 0.05$) in the jejunum in the 40-60 min period whereas no stimulation of endogenous N could be detected in the ileum after meal ingestion. A significantly increased ($P < 0.05$) concentration of exogenous N was detected in the jejunum during the 20-320 min period and during the 90-480 min period in the ileum. The overall true gastro-ileal absorption of pea N was 89.4 (SD 1.1)% with 69 (SD 14)% absorbed between the stomach and the proximal jejunum and 20.4% between the proximal jejunum and the terminal ileum. The percentage of ethanol-insoluble fraction (PN) in the exogenous N at the terminal ileum increased significantly ($P < 0.05$) to 75% after 360 min. These results suggest that heat-treated pea protein has a digestibility close to that of animal protein.

In summary, the metabolic studies show good true nitrogen digestibility and good nutritional value of pea protein, close to that of animal or soy protein.

(b) Toxicological Studies on Pea Protein

Aouatif et. al. (2013)[15] determined that the LD50 of NUTRALYS®, pea protein isolated from dry pea, is more than 2000 mg/kg bw/day in Wistar rats and CD1 Mice The genotoxic potential of NUTRALYS® was evaluated by using a battery of genotoxicity tests (AMES test, in vitro chromosomal aberration test, and in vivo micronucleus test) employing OECD guidelines under GLP conditions.[16] For Ames assay, pea protein isolate (85%) at concentrations of 312.5, 625,

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[15] C. Aouatif, P. Looten, M. Srinivassan, A. Srinivas, *Acute Oral Toxicity of Pea Protein Isolate (Nutralys®) in Wistar Rats and Cd1 Mouse*, 103 THE J. OF TOXICOLOGY AND HEALTH PHOTON 180-184 (2013).

[16] C. Aouatif, P. Looten, M.S. Parvathi, S.R. Ganesh, & V. Paranthaman, *Genotoxilogical Evaluation of NUTRALYS® Pea Protein Isolate*, ISRN TOXICOLOGY 1-6 (2013).

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). The results showed that pea protein did not show positive responses in strains detecting point and frame shift mutations. Under the experimental conditions, pea protein was non-mutagenic in the Ames reverse mutation assay. In the in vitro chromosomal aberration assay, pea protein at concentrations of 125, 250, and 500 µg/ml was evaluated for its capacity to induce structural and numerical aberrations in cultured human peripheral blood lymphocytes. The results showed that pea protein did not induce chromosome aberrations in the presence and absence of metabolic activation in human lymphocytes. For the in vivo mouse micronucleus assay, 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 body weight. The results showed that pea protein did not induce significant increases of micronucleated immature (polychromatic) erythrocytes in bone marrow of test animals. It was concluded that pea protein isolate is non-mutagenic and non-genotoxic.

NUTRALYS® was also tested in a 90-day subchronic oral toxicity study in Wistar rats.[17] Rats of both sex were fed with dietary levels of low (25000 ppm or 2.5%), intermediate (50000 ppm or 5%) and high (100000 ppm or 10%) pea protein isolate for 90 days. No treatment related toxicological changes were observed. Clinical signs, body weights, food and water consumption, hematological, blood biochemical and urinalysis were comparable for the treated and control animals. Further, organ weights, gross and histological examination did not reveal any systemic

[17] C. Aouatif, P. Looten, M. Srinivasan, A. Srinivas, Yogeshkumar V. Murkunde, *Subchronic toxicological effects of pea protein isolate (Nutralys®) on wistar rats: A ninety-day dietary*, 103 THE J. OF TOXICOLOGY AND HEALTH PHOTON 225-233 (2013).

toxicity induced by pea protein consumption. The authors concluded that the NOAEL of pea protein isolate for male and female rats were 10% of the diet (equivalent to 8726 mg/kg bw/day for male rats and 9965 mg/kg bw/day for female rats).

In addition, Overduin et. al. (2015)[18] characterized pea-protein-induced physiological signals relevant to satiety in vitro via gastric digestion kinetics and in vivo by monitoring post-meal gastrointestinal hormonal responses in rats. Under in vitro simulated gastric conditions, the digestion of NUTRALYS® pea protein was compared to that of two dairy proteins, slow-digestible casein and fast-digestible whey. In vivo, blood glucose and gastrointestinal hormonal (insulin, ghrelin, cholecystokinin [CCK], glucagon-like peptide 1 [GLP-1], and peptide YY [PYY]) responses were monitored in nine male Wistar rats following isocaloric (11 kcal) meals containing 35 energy% of either NUTRALYS® pea protein, whey protein, or carbohydrate (non-protein). The results indicate that pea protein transiently aggregates in the stomach and has an intermediately fast intestinal bioavailability in between that of whey and casein. In addition, pea-protein- and dairy protein-containing meals were comparably efficacious in triggering gastrointestinal satiety signals. No adverse effects were reported in this study.

In summary, genotoxicity studies show that pea protein isolate is not genotoxic. The oral LD50 of pea protein is more than 2000 mg/kg bw/day in rats and mice. A 90-day oral toxicity study in rats with pea protein did not reveal any adverse effect and the NOAEL for pea protein isolate is

[18] J. Overduin, L. Guérin-Deremaux, D. Wils, & T.T. Lambers, *NUTRALYS(®) pea protein: characterization of in vitro gastric digestion and in vivo gastrointestinal peptide responses relevant to satiety*, 59 FOOD & NUTRITION RESEARCH 25622 (2015).

determined to be 10% of the diet (equivalent to 8726 mg/kg bw/day for male rats and 9965 mg/kg bw/day for female rats), the high dose tested.

(c) Animal Efficacy Studies on Pea and Pea Protein

Stein et. al. (2006)[19] conducted an experiment to test the hypothesis that field peas may replace soybean meal in diets fed to growing and finishing pigs without negatively influencing pig performance, carcass quality, or pork palatability. Forty-eight pigs were allotted to 1 of 3 treatments with 2 pigs per pen. There were 8 replications per treatment, 4 with barrows and 4 with gilts. The treatments were control, medium field peas, and maximum field peas. Pigs were fed grower diets for 35 d, early finisher diets for 35 d, and late finisher diets for 45 d. Pigs receiving the control treatment were fed corn-soybean meal diets. All diets fed to pigs receiving the medium field peas treatment contained 36% field peas and varying amounts of corn; soybean meal was also included in the grower and the early finisher diets fed to pigs on this treatment. In contrast, no soybean meal was included in diets fed to pigs on the maximum field peas treatment, and field peas were included at concentrations of 66, 48, and 36% in the grower, early finisher, and late finisher diets, respectively. Pig performance was monitored within each phase and for the entire experimental period. At the conclusion of the experiment, carcass composition, carcass quality, and the palatability of pork chops and pork patties were measured. Results showed that there were no significant effects of dietary treatments on the parameters measured and no adverse effect were reported. The authors concluded that field peas may replace all of the soybean meal in diets fed to growing and finishing pigs without negatively influencing pig

[19] H. H. Stein, A.K. Everts, K.K. Sweeter, D.N. Peters, R.J. Maddock, D.M. Wulf, C. Pedersen, *The influence of dietary field peas (Pisum sativum L.) on pig performance, carcass quality, and the palatability of pork*, 84 J. ANIMAL SCI. 11, 3110-3117 (2006).

performance, carcass composition, carcass quality, or pork palatability. Similar results were obtained from several other studies in pigs.[20,21,22]

Pea protein has been successfully substituted for soybean protein in diets fed to cows and cattle.[23] Cows fed for six months on a diet containing up to 100% of their protein from field peas produced milk in equivalent quantity and quality as those on soy protein diets.[24] Corazzin et al. (2017) evaluated the effect of dietary substitution of soybean with pea (Pisum sativum L.) on carcass characteristics and meat quality in young bulls. Twenty-four young bulls of Rendena breed were randomly assigned to two diet treatments differing in protein supplement (soybean (SB) or field pea (FP) 1.52 – 3.13 kg dry matter/day). Carcass characteristics and meat chemical composition, color, cooking loss and Warner–Bratzler shear force did not differ between groups. In descriptive sensory analysis, trained judges were not able to differentiate meats from SB and FP, which also had similar overall liking expressed by consumers. The results of this study indicate that FP can replace SB in the diet of dual purpose young bulls with only a minor influence on fatty acid composition and no effect on carcass characteristics and meat quality. No adverse effects were reported in this study.

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[20] H. H. Stein, G. Benzoni, R.A. Bohlke, D.N. Peters, *Assessment of the feeding value of South Dakota-grown field peas (Pisum sativum L.) for growing pigs*, 82 J. ANIMAL SCI. 9, 2568-2578 (2004).

[21] F. Grosjean and F. Gatel, *Peas for pigs*, 7 PIG NEWS INF. 443–448 (1986).

[22] D. J. Newman, E. K. Harris, A. N. Lepper, E. P. Berg, & H. H. Stein, *Effects of pea chips on pig performance, carcass quality and composition, and palatability of pork*, 89 J. ANIMAL SCI. 3132-3139 (2011).

[23] D. Galméus, *Peas as feed for dairy cows*, DEP'T OF ANIMAL NUTRITION AND MGMT., Swedish University of Agricultural Sciences (2012).

[24] R.R. Corbett, *Peas as a protein and energy source for ruminants*, ALBERTA AGRIC. FOOD AND RURAL DEV. (1997), http://www.wcds.ca/proc/1997/ch18-97.htm.

In summary, pea and pea protein have been included in the feed to livestock without adverse effects. Studies in livestock show that pea can replace soy bean in the feed.

(d) Human Studies on Pea and Pea Protein

Babault et al. (2015) compared the impact of an oral supplementation with vegetable Pea protein (NUTRALYS®) vs. Whey protein and Placebo on biceps brachii muscle thickness and strength after a 12-week resistance training program.[25] One hundred and sixty-one males, aged 18 to 35 years were enrolled in the study and underwent 12 weeks of resistance training on upper limb muscles. According to randomization, they were included in the Pea protein (n = 53), Whey protein (n = 54) or Placebo (n = 54) group. All took 25 g of the proteins or placebo twice a day during the 12-week training period. Tests were performed on biceps muscles at inclusion (D0), mid (D42) and post training (D84). Muscle thickness was evaluated using ultrasonography, and strength was measured on an isokinetic dynamometer. Results showed a significant time effect for biceps brachii muscle thickness for the pea protein group compared to placebo whereas there was no difference between whey and the other two conditions. Muscle strength increased with time with no statistical difference between groups. Of the 161 subjects who took the products, three from the whey group, 4 from the placebo group and one from the pea group reported some adverse events which were back pains related to their usual activities. It was concluded that pea proteins could be used as an alternative to Whey-based dietary products. As there were no

[25] N. Babault, C. Paizis, G. Deley, L. Guerin-Deremaux, M. Saniez, C. Lefranc-Millot, F.A. Allaet, *Pea proteins oral supplementation promotes muscle thickness gains during resistance training: a double-blind, randomized, Placebo-controlled clinical trial vs. Whey protein*, 12 J. INT. SOC. SPORTS NUTRITION 1, 3 (2015).

adverse effects of pea protein at an intake level of 50g/day for 12 weeks, this study supports the safety of pea protein.

Teunissen-Beekman et al. (2012, 2014, 2015)[26] [27] [28] investigated the effects of increased protein intake on blood pressure (BP) and endothelial function by including pea protein in the dietary of participants for 4 weeks. Beneficial results were reported and no adverse effects were noted in these studies.

Abou-Samra et al. (2011)[29] studied the effects 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 of casein containing 20 g of casein, whey, pea protein, albumin, or maltodextrin vs. water control on food intake 30 min later in 32 male volunteers was studied. The results of this study revealed that food intake was significantly lower only after casein and pea protein compared to water control. Feeling of satiety was significantly higher after casein and pea protein compared to other preloads. In the second study, the effect of 20 g

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[26] K.F. Teunissen-Beekman, J. Dopheide, J.M. Geleijnse, S.J. Bakker, E.J. Brink, P.W. de Leeuw, M.A. van Baak, *Protein supplementation lowers blood pressure in overweight adults: effect of dietary proteins on blood pressure (PROPRES), a randomized trial*, 95 AM. J CLINICAL NUTRITION 4, 966-71 (Apr. 2012).

[27] K.F. Teunissen-Beekman, J. Dopheide, J.M. Geleijnse, S.J. Bakker, E.J. Brink, P.W. de Leeuw, J. Serroyen, M.A. van Baak, *Differential effects of proteins and carbohydrates on postprandial blood pressure-related responses*, 112 BRITISH J. OF NUTRITION 4, 600-08 (Aug. 28, 2014).

[28] K.F. Teunissen-Beekman, J. Dopheide, J.M. Geleijnse, S.J. Bakker, E.J. Brink, P.W. de Leeuw, C.G. Schalkwijk, M.A. van Baak, *Dietary proteins improve endothelial function under fasting conditions but not in the postprandial state, with no effects on markets of low-grade inflammation*, 114 BRITISH J. OF NUTRITION 11, 1819-28 (Dec. 14, 2015).

[29] R. Abou-Samra, L. Keersmaekers, D. Brienza, R. Mukherjee and K. Macé, *Effect of different protein sources on satiation and short-term satiety when consumed as a starter*, 10 NUTRITION J. 139 (2011).

of casein pea protein or whey vs. water control on satiation in 32 male volunteers was investigated. The result of this study showed no difference between preloads on ad libitum intake. It was concluded that casein and pea proteins show a promising effect on lowering short-term food intake. No adverse effects were reported.

Nielsen et. al. (2018)[30] investigated how a meal based on vegetable protein (fava beans/split peas) affected ad libitum energy intake and appetite sensations, compared to macronutrient-balanced, iso-caloric meals based on animal protein (veal/pork or eggs). Thirty-five healthy men were enrolled in this acute cross-over study and tested for four days. On each test day, participants were presented with one of four test meals (~3550 kilojoules (kJ) 19% of energy from protein), (1) patties with beans served with mashed split peas; (2) patties with minced pork/veal and pea fiber served with fiber-supplemented mashed potatoes; (3) patties with eggs and pea fiber served with fiber-supplemented mashed potatoes; and (4) patties with eggs served with non-fiber-supplemented mashed potatoes. Subjective appetite sensations were recorded at baseline and every half hour until the ad libitum meal three hours later. There were no differences in ad libitum energy intake across test meals. Further, no differences were found across meals for hunger, satiety, fullness, prospective food consumption, or composite appetite score. Iso-caloric, macronutrient-balanced, fiber-matched meals based on vegetable protein (fava beans/split peas) or animal protein (veal/pork or eggs) had similar effects on ad libitum energy intake and appetite sensations. No adverse effects were noted in the study.

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[30] L.V. Nielsen, M.D. Kristensen, L. Klingenberg, C. Ritz, A. Belza, A. Astrup, & A. Raben, *Protein from Meat or Vegetable Sources in Meals Matched for Fiber Content has Similar Effects on Subjective Appetite Sensations and Energy Intake—A Randomized Acute Cross-Over Meal Test Study*, 10 NUTRIENTS 96 (2018).

Kristensen et. al. (2016)[31] examined whether meals based on vegetable protein sources (beans/peas) are comparable to meals based on animal protein sources (veal/pork) regarding meal-induced appetite sensations. A total of 43 healthy, normal-weight, young men completed this randomized, double-blind, placebo-controlled, three-way, cross-over meal test. The meals (all 3.5 MJ, 28 energy-% (E%) fat) were either high protein based on veal and pork meat, HP-Meat (19 E% protein, 53 E% carbohydrate, 6 g fiber/100 g); high protein based on legumes (beans and peas), HP-Legume (19 E% protein, 53 E% carbohydrate, 25 g fiber/100 g); or low-protein 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 3 h after the test meal. The results indicate 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. Interestingly, a vegetable-based meal with low protein content was as satiating and palatable as an animal-based meal with high protein content. No adverse effects were reported in this study.

In summary, human studies indicate beneficial results of pea and pea protein in the diet and no adverse effects are noted.

(e) Allergenicity

Peas are not one of the "big eight allergens" (milk, egg, peanut, tree nut, seafood, shellfish, soy and wheat), which collectively account for approximately 90% of all food-borne allergies.

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[31] M.D. Kristensen, N.T. Bendsen, S.M. Christensen, A. Astrup, & A. Raben, *Meals based on vegetable protein sources (beans and peas) are more satiating than meals based on animal protein sources (veal and pork)—A randomized cross-over meal test study*, 60 FOOD & NUTRITION RESEARCH 32634 (2016).

Individuals allergic to peas is a rare occurrence. There are only few studies estimating the incidence of pea allergy in populations. Most of the available literature refers to cross-reactivity.

A Finnish study based on allergy was conducted on 802 children aged from 1 to 6 years. Three percent of the children showed a positive reaction to pea in the 1-3 year-group and only 0.5% in the 6 year-group, which is lower than the most common food allergens identified in this study including citrus fruit, tomato, eggs, strawberry, and fish.[32]

The prevalence of adverse reactions to food as well as the prevalence of food allergy in Icelandic and Swedish 18-month-old children was investigated. Positive reactions to pea were reported in only five Icelander children out of 324 participated. None of the 328 Swedish children involved in the study experienced any adverse effects.[33]

In a group of 69 study patients (1-21 years old) with legume hypersensitivity, 87% showed positive prick skin tests to peanut, 43% to soybean, 41% to lima bean (on 32 patients), 26% to pea, and 22% to green bean (on 41 patients). However, after oral challenge, 45% showed positive reactions to peanut, 15% to soybean, and only 3% to pea. There were no positive challenge reactions to green bean or lima bean.[34]

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[32] M. Kajosaari, *Food allergy in Finnish children aged 1 to 6 years*, ACTA. PAEDIATR. SCAND. 71, 815-819 (1982); see also I. Kristjansson, B. Ardal, J.S. Jonsson, J.A. Sigurdsson, M. Foldevi, & B. Bjorksten, *Adverse reactions to food and food allergy in young children in Iceland and Sweden*, SCAND. J. PRIM. HEALTH CARE 17, 30-34 (1999).

[33] I. Kristjansson, B. Ardal, J.S. Jonsson, J.A. Sigurdsson, M. Foldevi, & B. Bjorksten, *Adverse reactions to food and food allergy in young children in Iceland and Sweden*, SCAND. J. PRIM. HEALTH CARE 17, 30-34 (1999).

[34] J. Bernhisel-Broadbent & H.A. Sampson, *Cross-allergenicity in the legume botanical family in children with food hypersensitivity*, J. ALLERGY CLINICAL IMMUNOL. 83, 435-440 (1989).

The low prevalence of pea allergy, does not affect the GRAS conclusion. Further, the ingredient will be adequately labeled to inform pea allergic consumers as to its presence in the food.

(5) Discussion and Conclusion

In recent years, proteins of plant origin are gaining interest as an alternative to animal-derived proteins for health and environmental reasons. Pea protein powder can be substitute protein from other sources to a variety of food categories. Pea protein has several functional effects, such as a flow agent, ability to mask off flavors, improve texture, increase water holding capacity, and solubility. The process by which pea protein is produced from raw field peas is a purely mechanical process – soaking, crushing, separating, drying which does not result in chemical alteration of peas. The pea protein is manufactured under good manufacturing practices (GMP).

The FDA has established a Daily Reference Value (DRV) of 50 g/day for protein for adults and children 4 or more years of age. The Institute of Medicine (IOM) used the Continuing Survey of Food Intakes by Individuals (CSFII) 1994-1996, 1998 to estimate the background dietary intakes of protein for the US population.[35] The mean adult protein intake ranged from 56-104 g/day, depending on the age group. At the 90th percentile, adult protein intakes ranged from 76 g/day to 142 g/day. Insufficient dietary protein intake has been associated with adverse effects in human health and development. In 2005, IOM set a Recommended Dietary Allowance (RDA) value for protein of 0.8 g/kg body weight/day in adult males and females. Fulgoni V. estimated

[35] *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat_ Fatty Acids, Cholesterol, Protein and Amino Acids*, INSTITUTE OF MEDICINE (2005), http://www.nal.usda.gov/fnic/DRI/DRI_Energy/energy_full_report.pdf.

the protein intake by using data from the NHANES release from 2003 to 2004 and the results show that the protein intake averaged 55±14 g/d in young children, increased to a high of about 91±22 g/d in adults aged 19–30 y, and then decreased to around 66±17 g/d in older adults (71+years).[36] Median intakes for the groups were 53, 89, and 63 g/d, respectively. Other sources offered a suggested safe maximum daily protein intake of approximately 176 grams for an 80 kg individual on a 2867 kcal/day diet.[37]

Substituting with pea protein in the conventional foods will not result in significant increase of protein intake, therefore, it is deemed safe. We do not realistically expect that the actual consumption of foods containing pea protein would result in a daily consumption of greater than the DRV, RDA or the average intakes for protein. In addition, pea protein as a directly consumed protein in sports nutrition or meal replacement applications will not have an impact on the overall protein intake since it is used to substitute the protein from other sources, i.e., animals or whey. Most of the population's intake of protein is, and will remain, in the form of unprocessed foods, including meat, poultry, fish and legumes.

Based on a critical evaluation and analysis of the information and literature available on pea protein summarized above, it is concluded that there is reasonable certainty that pea protein is safe under the intended conditions of use and is also Generally Recognized as Safe (GRAS), by scientific procedures.

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[36] V.L. Fulgoni III, Current protein intake in America: analysis of the National Health and Nutrition Examination Survey, 2003–2004. Am J Clin Nutr 2008;87(suppl):1554S–7S.

[37] S.A. Bilsborough, *A Review of Issues of Dietary Protein Intake in Humans*, 16 INT'L J. OF SPORT NUTRITION AND EXERCISE METABOLISM 2, 129-152 (2006).

Part 7 – List of supporting data and information

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APPENDIX I

Technical Report

Use of pea protein as a functional ingredient in comminuted meat products

for

Jianyuan Bioengineering Company Limited

by

PHD Technologies LLC
3234 Bayberry Road
Ames, IA 50014

January, 2017

Use of pea protein as a functional ingredient in comminuted meat products

Objectives

The objectives of this study were to evaluate the quality characteristics of hot dogs containing 0%-3% pea protein.

Materials and Methods

Fresh beef 80's (with 20% fat) and beef 50's (with 50% fat) were obtained from Amend Packing Company, 410 SE 18th St, Des Moines, IA. Pea protein, pea fiber and pea starch was obtained from Jianyuan Bioengineering Company Ltd. (Shengtai Road, Zhaoyuan City,Shandong, China). Four treatments were formulated as shown in Table 1. Mechanically deboned chicken was chopped in a bowl chopper (Kramer and Grebe model VSM65, GmbH & Co. KG, Wallau/Lahn, Germany) with salt, sodium phosphate, sodium nitrite, sodium erythorbate and half the water to 4.4°C (40°F), then pork fat with trace lean, water, pea protein and the other dry ingredients were added. Chopping was continued until the batter reached 12°C (53.6°F). Meat batters were then stuffed (Model RS 1000/65, Risco Brevetti, Zane-vi-Italy) into 22 mm diameter cellulose casings (Devro Teepak Summerville, SC) and smoked in an Alkar single truck smokehouse (Alkar, Lodi, WI) to an internal temperature of 71°C (162°F) using the smokehouse process shown in Table 2. After cooking, frankfurters were chilled using a cold shower for 30 min. They were then stored in a cooler at 2°C (35.6°F) for 24 h., peeled and vacuum packaged (AG800, Sepp Haggenmuller KG, West Germany) in high oxygen barrier pouches (Cryovac Sealed Air Corp., Duncan, SC) and kept in a cooler at 2°C (35.6°F) for subsequent evaluation.

Evaluations

Cooked yield

For each individual treatment, product cooked yield was calculated by dividing the chilled product weight 24 h. after it came out of the smokehouse by the uncooked product weight (cooked product weight/uncooked product weight x100). Cooked yield, therefore, represented product weight losses that occurred primarily during thermal processing and chilling.

Purge

Purge was measured every 2 weeks up to 8 weeks after manufacturing of the hot dogs. For each treatment, packages containing approximately 190 g of hot dogs were weighed before opening the package. The samples were then removed from the bag, and dried off with a paper towel and weighed. Purge was calculated as a percentage of the initial weight [(bag & product weight)-(bag

weight)-(product weight)/(bag & product weight)-(bag weight)]. Two packages from each treatment were used for purge measurement during each testing period.

Instrumental texture evaluation

Texture was measured using a TA-XT2 Stable Microsystems Texture Analyzer equipped with a ½" diameter round probe. The product was heated inside the package by dipping the package in 90°C water for 10 min. (to eating temperature) before texture was measured. Texture was measured on 10 cross sectional pieces cut to 20 mm. The texture measurements were done by compressing cross sectional pieces to 30% of the height.

Instrumental color evaluation

Instrumental color determinations were made on the interior of the hot dogs sliced longitudinally by using a Hunter Lab DP - 9000 equipped with a D25 A Optical Sensor (Hunter Assoc. Laboratory Inc., Reston, VA). Standardization was done by using the white and black standard plate. Measurements were taken directly on the surface of several hot dogs cut longitudinally. Samples were measured for "L", "a" and "b" values. Mean value of a sample was obtained from 5 readings.

Results and Discussion

Table 1: Hot dog formulation

Hot dogs were formulated with increasing amounts of pea protein ranging from 0% to 3.0%. The usage level of all other ingredient was held constant across all treatments.

	Control	1% Pea Protein	2% Pea Protein	3% Pea Protein
Chicken MDM (20 down)	60.45%	60.45%	60.45%	60.45%
Pork trimmings with a trace of lean	14.00%	14.00%	14.00%	14.00%
Beef 50s	0.01%	0.01%	0.01%	0.01%
Water	15.50%	15.50%	15.50%	15.50%
Corn syrup	4.00%	4.00%	4.00%	4.00%
Modified food starch	2.00%	2.00%	2.00%	2.00%
Salt	2.00%	2.00%	2.00%	2.00%
Flavorings (spice) w phosphate and erythorbate	1.00%	1.00%	1.00%	1.00%
Nitrite	0.01%	0.01%	0.01%	0.01%
Potassium lactate	0.95%	0.95%	0.95%	0.95%
Sodium diacetate	0.08%	0.08%	0.08%	0.08%
Test ingredient	0.00%	1.00%	2.00%	3.00%
Total	100.00%	101.00%	102.00%	103.00%

Table 2: Hot dog cook cycle

Step #	Step Type	Step Time	DB F.	WB F.	rH	IT F.	pH	Main Blower	Exhaust Fan	Humidity	Dampers	Shower On	Shower Off	Smk Gen Preheat time	Liq Smk On	Liq Smk Dwell	Idle After Step
1	Cook	00:05	110	100	70%	---	0.00	8	Off	Steam	Auto	---	---	---	---	---	Off
2	Cook	01:30	120	0	0%	---	0.00	8	On	Steam	Auto	---	---	---	---	---	Off
3	Smoke Cook	00:30	130	0	0%	---	0.00	10	Off	Steam	Closed	---	---	---	---	---	Off
4	Smoke Cook	00:30	150	125	48%	---	0.00	10	Off	Steam	Closed	---	---	---	---	---	Off
5	Cook	00:15	165	140	51%	---	0.00	8	Off	Steam	Auto	---	---	---	---	---	Off
6	Cook	00:01	175	165	78%	162	0.00	8	Off	Steam	Auto	---	---	---	---	---	Off
7	Cold Shower	00:30	50	0	0%	---	0.00	0	Off	Off	Auto	---	---	---	---	---	Off

The cook cycle utilized natural smoke followed by increased humidity and finished off with a cold shower.

Table 3: Cooked yield

	Cooked Yield
Control	89.87%
1% Pea Protein	91.39%
2% Pea Protein	93.54%
3% Pea Protein	94.04%

Table 4: Purge

	Week 2 Purge	Week Purge	Week 6 Purge	Week 8 Purge
Control	2.40	2.33	1.93	1.96
1% Pea Protein	1.98	1.78	1.70	1.63
2% Pea Protein	1.32	1.36	1.36	1.15
3% Pea Protein	1.16	1.20	1.16	1.12

Table 5: Texture

	Hardness
Control	452.76
1% Pea Protein	420.55
2% Pea Protein	460.00
3% Pea Protein	480.16

Table 6: Interior color

	Interior Color		
	L	a	b
Control	67.04	10.38	13.52
1% Pea Protein	69.15	9.77	13.77
2% Pea Protein	68.75	9.89	13.86
3% Pea Protein	69.06	9.89	13.86

Conclusions

1. The cook yield for hot dogs containing pea protein was significantly higher compared to the control. As the level of pea protein was increased in the formulation, the cook yields increased.

2. After weeks 8 weeks of refrigerated storage, the purge was significantly lower when pea protein was used in the formulation at 1% or higher. The highest level of pea protein showed the lowest purge over 8 weeks of storage.

3. Hardness values were significantly higher for treatments containing pea protein at a usage level of 2% or higher compared to the control. The firmness of the hot dogs increased as the level of pea protein in the formulation increased.

4. Interior color values were not significantly different from the control for treatments with 1%, 2% and 3% of pea protein.

5. Pea protein from Jianyuan Foods is a functional ingredient that can increase cook yield, reduce purge and improve texture without significantly changing the quality attributes in comminuted meat products.

APPENDIX II

Technical Report

Use of pea protein as a functional ingredient in turkey breast

for

Jianyuan Bioengineering Company Limited

by

PHD Technologies LLC

3234 Bayberry Road
Ames, IA 50014

January, 2017

Use of pea protein as a functional ingredient in injected turkey breast

Objectives

The objectives of this study were to evaluate the quality characteristics of 20% injected turkey breast containing 0%-1% pea protein.

Materials and Methods

Fresh turkey breast was obtained from a commercial processing plant in Iowa (West Liberty Foods, West Liberty, IA). Pea protein was obtained from Jianyuan Bioengineering Company Limited (Shengtai Road, Zhaoyuan City,Shandong, China). Three treatments were formulated as shown in Table 1. Brines were prepared by dissolving sodium phosphate followed by salt, dextrose and pea protein in 1°C (33.8°F) water with ice. Turkey breasts were injected to 20% of the green weight with the brine solution, then vacuum tumbled (Globus Laboratories Inc. South Hackensack, N.J., U.S.A) continuously for 2 hours. After refrigeration overnight, turkey breasts were hand macerated, then stuffed head to tail into a cook-in bag. The stuffed turkey breast were thermally processed in an Alkar single truck smokehouse (Alkar, Lodi, WI) to an internal temperature of 70°C (158°F). After cooking, the product was cold showered for 30 min. The cooked product was stored overnight in a cooler at 4°C (39.2°F). The turkey breast were sliced into 0.75mm-thick or 25mm-thick slices by using a Hobart slicer (Model 1712 Hobart Manufacturing Co., Troy, Ohio, U.S.A.), placed in high oxygen barrier pouches (Cryovac Sealed Air Corp., Duncan, SC), vacuum sealed at 1kaPA by using a Multivac MG-2 packaging machine (Sepp Haegenmuller KG) and kept in a cooler at 2°C (35.6°F) for subsequent evaluation.

Evaluations

Cooked loss

For each individual treatment, product cooked loss was calculated by dividing the chilled product weight 24 h. after it came out of the smokehouse by the uncooked product weight (cooked product weight/uncooked product weight x100). Cooked yield, therefore, represented product weight losses that occurred primarily during thermal processing and chilling of the product.

Purge

Purge was measured every 2 weeks up to 8 weeks after manufacturing of the turkey breast. For each treatment, individually packaged 0.75mm-thick turkey breast slices were weighed, and the initial weight was recorded. The samples were then removed from the bag and dried with a paper towel and weighed again (final weight). Purge was calculated as a percentage of the initial weight [(bag &

product weight)-(bag weight)-(product weight)/(bag & product weight)-(bag weight)]. Two packages from each treatment were used for purge measurement during each testing period.

Instrumental texture evaluation

Texture was measured on the surface of the 25mm-thick ham slices using a TA-XT2 Stable Microsystems Texture Analyzer equipped with a ½" diameter round probe. Texture was measured on the surface of 10 turkey breast samples per treatment. The texture measurements were done by compressing the turkey breast slices to 30% of the height. Peak load was measured in grams/cm^3.

Instrumental color evaluation

Instrumental color determinations were made on the surface of the sliced turkey breast by using a Hunter Lab DP - 9000 equipped with a D25 A Optical Sensor (Hunter Assoc. Laboratory Inc., Reston, VA). Standardization was done by using the white and black standard plate. Measurements were taken directly on the surface of the sliced product in 5 different locations. Samples were measured for "L", "a" and "b" values. Mean value of a sample was obtained from 5 readings.

Results and Discussion

Table 1: Brine formulation

Brine Formulation	0.6		
Ingredient	*Control*	*0.5% Pea Protein*	*1% Pea Protein*
	%	*%*	*%*
Water	83.13	80.97	78.80
Salt	8.65	8.65	8.65
Dextrose	6.50	6.50	6.50
Sodium phosphate	1.72	1.72	1.72
Pea Protein	0.00	2.17	4.34
Total	100.00	100.00	100.00

Finished Product Formulation			
Ingredient	*Control*	*0.5% Pea Protein*	*1% Pea Protein*
	%	*%*	*%*
Turkey breast	83.33	83.33	83.33
Water	13.86	13.49	13.13
Salt	1.44	1.44	1.44
Dextrose	1.08	1.08	1.08
Sodium phosphate	0.29	0.29	0.29
Pea Protein	**0.00**	**0.36**	**0.72**
Total	100.00	100.00	100.00

Turkey breast were formulated with increasing amounts of pea protein, pea fiber and pea starch ranging from 0% to 1%.

Table 2: Cook loss

	Average Cook Loss (%)
Control	22.65
0.5% Pea Protein	13.12
1% Pea Protein	8.33

Cook loss for all treatments based on the starting meat weight after brine addition ranged from 8.33 – 22.65%. The measured weight loss occurred primarily during thermal processing and chilling. Addition of 0.5% pea protein, pea fiber and pea starch and higher resulted in lower cook loss compared to the control. 1% pea protein had the lowest cook loss, 1% pea protein had the next lowest cook loss.

Table 3: Purge

	Week 2	Week 4	Week 6	Week 8
Control	7.27	8.63	7.98	7.63
0.5% Pea Protein	5.05	5.05	5.36	6.19
1% Pea Protein	3.26	4.06	3.96	5.55

An objective method of measuring free water is purge measurement. The higher the purge, greater is the free water content. As the level of pea protein increased, the amount of purge decreased. The highest purge values were seen in the control and the lowest was seen in the treatment with 1% pea protein over 8 weeks of refrigerated storage.

Table 4: Texture

	Hardness g/cm3
Control	1552.98
0.5% Pea Protein	1743.23
1% Pea Protein	2141.24

The result of the instrumental texture analysis shows that there was increased firmness in the turkey breast as the level of pea protein in the formulation increased. The control had the lowest Peak Force values while the highest Peak Force values were seen in the treatment containing 1% pea protein.

Table 5: Interior color

	L	a	b
Control	70.46	8.77	9.66
0.5% Pea Protein	66.96	9.51	9.35
1% Pea Protein	66.89	9.42	10.09

The L values were lower in treatments with pea protein compared to the control.

Conclusions

1. The cook loss for turkey breast containing pea protein was significantly lower compared to the control. The cook loss decreased as the level of pea protein in the formulation increased.
2. After 8 weeks of refrigerated storage, the purge was significantly lower when pea protein was used at 0.5% and above compared to the control.
3. Hardness values were significantly higher for treatments containing 1% of pea protein compared to the control. The firmness of the turkey breast increased as the level of pea protein in the formulation increased to 1%.
4. Interior color values for pea protein resulted in lower L values compared to the control.
5. Pea protein from Jianyuan Bioengineering Company Limited are functional ingredients that can decrease cook loss, reduce purge and improve texture without significantly changing the quality attributes in whole muscle meat products.

From: Pelonis, Evangelia C.
To: Bonnette, Richard
Subject: GRAS Notice 803 - Pea Protein
Date: Tuesday, March 05, 2019 2:17:39 PM

Dear Mr. Bonnette,

This email follows up on our discussion regarding GRAS Notice 803 for Pea Protein. Page 8 of the GRAS Notice states that "Food grade sodium hydroxide is added to the protein curd to adjust pH to 7.0 ~ 8.0." We are requesting that FDA consider the use of any safe and suitable pH adjusting agents in its review of the GRAS Notice.

Best regards,
Eve Pelonis

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