Trinity Consultants SafeBridge® Regulatory & Life Sciences Group

December 20, 2022 via UPS

Susan J. Carlson, Ph.D., Director
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740-3835

Re: Replacement GRAS Notification for Pea Protein Fermented by Shiitake Mycelia

Dear Dr. Carlson,

In accordance with 21 CFR §170, Subpart E - Generally Recognized as Safe (GRAS) Notice, I am submitting, as the agent of the Notifier, MycoTechnology, Inc., a **replacement** GRAS Notification regarding the conclusion of GRAS status for the use of pea protein fermented by shiitake mycelia, as a food ingredient, formulation aid and texturizer in foods where protein is used for nutritional purposes and in foods needing protein-source properties. MycoTechnology does not intend to add FPP to infant formula or to meat and poultry applications that come under USDA jurisdiction.

Enclosed is one electronic copy of the Notification on CD. This file is intended to **replace** the Notification for pea protein fermented by shiitake mycelia that was previously submitted on behalf of MycoTechnology, Inc. via WebTrader on May 27, 2022.

Please contact me with any questions.

Best regards,

G. Craig Llewellyn, Ph.D.
Principal Toxicologist and Scientific Director

GCL/mor

Enclosure

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GRAS Notice for Pea Protein Fermented by Shiitake Mycelia

Prepared for:
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive College Park, MD
20740 USA

Date:
December 16, 2022

GRAS Notice for Pea Protein Fermented by Shiitake Mycelia

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GRAS Notice for Pea Protein Fermented by Shiitake Mycelia

Part 1: §170.225 Signed Statements and Certification

In accordance with 21 CFR §170 Subpart E consisting of §170.203 through 170.285, MycoTechnology, Inc. hereby informs the United States (U.S.) Food and Drug Administration (FDA) that pea protein fermented by shiitake mycelia, is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on MycoTechnology's view that the notified substance is Generally Recognized as Safe (GRAS) under the conditions of its intended use described in Section 1.4 below. This conclusion is largely based on the fact that this product as produced by the notifier is substantially similar to pea and rice protein fermented by shiitake mycelia, which is manufactured by the notifier (GRAS No. 848), using the same strain and through an equivalent manufacturing process, but with pea as the primary protein raw material.

In addition, as a responsible official of MycoTechnology, the undersigned hereby certifies that all data and information presented in this Notice represents a complete, representative, and balanced submission, and considered all unfavorable as well as favorable information known to MycoTechnology and pertinent to the evaluation of the safety and GRAS status of the pea protein ingredient for use as a food ingredient, as described herein.

Signed,

12/16/2022

Dan Zhao, MS
Manager, Global Regulatory Strategy
MycoTechnology, Inc.
dzhao@mycoiq.com

1.1 GRAS Notice Submission

MycoTechnology, Inc. submits this GRAS Notification in accordance with the requirements of Title 21 of the Code of Federal Regulations (CFR) Part 170, Subpart E.

1.2 Name and Address of Notifier

MycoTechnology, Inc.
18250 E 40th Ave Suite 50
Aurora, CO
80011 USA

1.3 Common or Usual Name of Notified Substance

The common name is **pea protein fermented by shiitake mycelia**
The trade name of this product is FermentIQ™

1.4 Conditions of Use

Pea protein fermented by shiitake mycelia, which is FermentIQ™ pea protein (FPP), containing approximately 77% protein, is intended for use as a food ingredient, formulation aid and texturizer in foods where protein is used for nutritional purposes and in foods needing protein-source properties such as promotion of ease of dry flow, masking of off-flavors, texturing of meat analogues, increased water holding capacity and gelation, and increased water-solubility. In addition, it can be texturized by high pressure/temperature extrusion to add mouth feel to food products. Intended food categories include baked goods and bakery mixes, beverages and beverage bases, breakfast cereals, coffee and tea, dairy product analogues, grain products and pastas, milk products, nut and nut products, plant protein products, snack foods, soups and soup mixes. The proposed ingredient will be used as a substitute for and/or in conjunction with other sources of protein in conventional food products. MycoTechnology does not intend to add FPP to infant formula or to meat and poultry applications that come under USDA jurisdiction.

The U.S. FDA has raised no questions on the use of pea and rice protein fermented by shiitake mycelia (GRN 848) under intended conditions of use. FPP is comparable to the pea/rice blend fermented by shiitake mycelia described in GRN 848 and currently recognized as a GRAS food ingredient, but with pea protein as the primary protein raw material.

1.5 Statutory Basis for GRAS Status

Pursuant to 21 CFR Part, the proposed use of pea protein fermented by shiitake mycelia manufactured by MycoTechnology, Inc. has been concluded to have GRAS status, on the basis of scientific procedures.

The GRAS determination is based on information generally available in the public domain pertaining to the safety of commonly consumed plant proteins and the method of production using shiitake mycelia, and on the consensus among a panel of experts who are qualified by scientific training and experience to evaluate the safety of pea protein fermentation by shiitake mycelia as a food ingredient [see Appendix A, titled “GRAS Panel Statement on the Generally Recognized as Safe (GRAS) Conclusion for the Proposed Uses of Pea Protein Fermented by Shiitake Mycelia”].

1.6 Premarket Exempt Status

Pea protein fermented by shiitake mycelia (FPP) is not subject to the premarket approval requirements of the Federal Food, Drug and Cosmetic Act (FFDCA) based on the conclusion that the

notified substance is GRAS under the conditions of intended use.

1.7 Availability of Information

The data and information that serve as the basis for this GRAS Notification will be made available to the U.S. FDA for review and copying upon request during business hours at the offices of:

MycoTechnology, Inc.
18250 E 40th Ave Suite 50
Aurora, CO
80011 USA

MycoTechnology will supply additional data and information should the FDA have any questions regarding this notification during or after the Agency's review of the Notice.

1.8 Freedom of Information Act, 5 U.S.C. 552

It is MycoTechnology's view that all data and information presented in Parts 2 through 7 of this Notice do not contain any trade secret, commercial, or financial information that is privileged or confidential, and therefore none of the data and information presented herein are exempt from the Freedom of Information Act, 5 U.S.C. 552.

Part 2. §170.230 Identity, Method of Manufacture, Specifications, and Physical or Technical Effect

2.1 Identity

2.1.1 Common or Usual Name

Pea protein fermented by shiitake mycelia

2.1.2 Synonyms

FermentIQ™; FermentIQ™ Pea Protein; FPP

2.1.3 Chemical and Physical Characteristics

The subject of this GRAS Notice is pea protein fermented by shiitake mycelia (FPP). Fermentation with shiitake mycelia is performed to improve organoleptic quality and functionality properties of the input pea protein raw material; however, the input pea protein is not substantially modified by the fermentation process. FPP contains ≥77% protein on a dry weight basis (DWB). The shiitake mycelia biomass in the final product is <0.1%.

2.2 Method of Manufacturing

The manufacturing of pea protein fermented by shiitake mycelia (FPP) involves successive fermentations of a primary culture of shiitake mycelia to build up an amount of a pure shiitake mycelial biomass, followed by a main fermentation step where the built-up shiitake mycelia biomass is combined with sterile input pea protein material and allowed to ferment for up to 40 hours. At the end of the fermentation, the contents of the fermentation tank are concentrated and spray dried. The resultant material is called pea protein fermented by shiitake mycelia. All input materials into the manufacturing process are safe and suitable for the described use in food ingredient production. The main fermentation step allows the shiitake mycelia biomass developed from the initial fermentations to improve the organoleptic qualities (as measured by human sensory testing; described at Section 2.5.4) of the input pea protein raw material. The input pea protein raw material is not substantially modified (see Section 2.5.3). A comprehensive safety assessment for the shiitake mycelia is presented in Part 6.

2.2.1 Raw Materials and Processing Aids

All raw materials, processing aids, and equipment used to manufacture pea protein fermented by shiitake mycelia (FPP) are food-grade ingredients[1] permitted by US regulation or have GRAS status.

[1] Compliant with the specifications set forth in the Food Chemicals Codex or equivalent international food or pharmacopeia standard (*e.g.,* JECFA, CODEX, United States Pharmacopeia, European Pharmacopoeia).

2.2.1.1 Pea protein raw material

The pea protein raw material used to produce FPP is obtained from commercial suppliers and meets specifications and quality criteria defined by MycoTechnology (see Table 2.2.1.1-1). The pea protein is a free-flowing, cream colored powder with a protein content of not less than 80% (dry basis). The pea protein is obtained from the mechanically milled and wet fractionated portion of de-hulled yellow peas (*Pisum sativum*). Supporting documentation is on file with MycoTechnology.

Table 2.2.1.1-1. Pea Protein Raw Material Specification

Parameter	Specification	Test Method
Appearance	Light yellow	Visual against standard
Odor	Inherent pea odor	Sensory
Protein, % dry weight (DW) basis	≥80%	AOAC 990.03 AOAC 992.15
Aerobic Plate Count	≤10,000 cfu/g	AOAC 990.12 (Petrifilm)
Yeast	≤100 cfu/g	AOAC 997.02
Mold	≤100 cfu/g	AOAC 997.02
Coliforms	≤10 cfu/g	AOAC 991.14
E. coli SSP	≤10 cfu/g	AOAC 991.14
Salmonella SSP	Negative/25g	AOAC 2004.03 AOAC-RI 121501
Mercury	<1 ppm	ICP-MS
Cadmium	<0.5 ppm	ICP-MS
Arsenic	<1 ppm	ICP-MS
Lead	<1 ppm	ICP-MS
Mycotoxins	<5 ppb	HPLC AOAC 991.31 (Mod)

2.2.1.2 Shiitake Mushroom Mycelia

The strain of shiitake used to produce FPP was originally obtained from Pennsylvania State University (https://plantpath.psu.edu/about/facilities/mushroom/cultures-spawn; ID No. WC 1008). The strain was genotyped by a third-party lab and the cultures were identified as *Lentinula edodes* (100% match) by internal transcribed spacer sequencing data (ITS; 28SDNA; MycoTechnology, unpublished data). Based on the ITS results, it was concluded that the microorganism used in the manufacturing process to produce FPP is *L. edodes*. Under conditions of use in aqueous culture, *L. edodes* grows as a vegetative form (Tsifileva et al, 2005; Aminuddin et al, 2013; Aminuddin et al, 2007). This vegetative form is identified herein as 'shiitake mycelia'. Based on this information, MycoTechnology, Inc. concludes that the organism used in the manufacturing process of FPP is the vegetative form of *L Edodes* or shiitake mycelia.

A safety assessment of shiitake mycelia is presented in Part 6 and is fully discussed in GRN 848.

2.2.1.3 Additional Raw Materials and Processing Aids

All remaining raw materials and processing aids used to produce FPP, including carrot powder, mango puree, rice protein, maltodextrin, and a commercial anti-foam preparation are considered safe and suitable.

Maltodextrin ($(C_6H_{10}O_5)n$, CAS Reg. No. 9050-36-6) is a non-sweet nutritive saccharide polymer that consists of D-glucose units linked by [alpha]-1-4 bonds and has a dextrose equivalent (D.E.) of less than 20. It is prepared by partial hydrolysis of corn starch, potato starch, or rice starch with safe and suitable acids and enzymes, meeting specifications in Food Chemicals Codex, 3d ed., 3d supp. (1992), p. 125. Maltodextrin as used in FPP is listed in 21 CFR 184.1444 as affirmed GRAS and is consistent with current Good Manufacturing Practice (cGMP, 21 CFR 184.1444). The carrot powder and mango puree used in the production of FPP (to support the fermentation process as sources of carbohydrates and micronutrients for mycelium growth) are composed of 100% organic carrots and organic mango respectively. The antifoam agent used in the production of FPP is made with ingredients that are compliant with 21 CFR 173.340 Defoaming agents. A small amount (<0.5% in finished product dry mass) of rice protein, previously recognized as GRAS for use in food (e.g. GRN 609), is also used to support the fermentation process. With the exception of mango puree, these ingredients are also described in GRN 848.

2.2.2 Manufacturing Process

Pea protein fermented by shiitake mycelia (FPP) is manufactured consistent with current Good Manufacturing Practices (cGMP) as defined in 21 CFR §117 at a facility with an established Hazard Analysis and Critical Control Points (HACCP) plan. Supporting documentation is on file with MycoTechnology.

The manufacturing is initiated by starting the growth of pure cultures of shiitake mycelia on agar plates developed from a confirmed shiitake spawn culture stored at -80°C. The identity of shiitake spawn is discussed in Section 2.2.1.2. The grown cultures on agar plates are used to initiate liquid cultures of shiitake mycelia in shake flasks. For the shake flask cultures, the media is an approximately 2% slurry of pea protein concentrate, rice protein concentrate, supplemented with maltodextrin, mango puree, carrot powder and antifoam agent. Prior to culture inoculation, the media is sterilized by heat treatment and the inoculation with shiitake mycelia is carried out using sterile procedure. The inoculated shake flasks are incubated until the shiitake mycelia has achieved the desired level of growth in the shake flasks. The entirety of the volume of the shake flasks is then transferred into the first of three “seed development” bioreactors to continue to build shiitake mycelia biomass, as described in the following paragraphs.

The shiitake mycelia biomass-building process is continued in the “seed development” bioreactor process using three separate fermentations in three progressively larger bioreactors. The three successive fermentations (“Fermentation 1”, “Fermentation 2,” and “Fermentation 3”) are carried out in these progressively larger bioreactors. Prior to inoculation, all bioreactor media is sterilized at 121°C for 90 minutes and cooled down using air and water circulation on the vessel’s cooling jacket, and all inoculations are carried out with sterile procedure to maintain a pure shiitake mycelia culture.

After inoculation of the first bioreactor (Fermentation 1) with the shake flask cultures, the cultures are allowed to grow for 24 to 48 hours. During all fermentations, purity of the culture and growth of the shiitake mycelia are confirmed via microscopy. At the conclusion of Fermentation 1, the entirety of the volume of the bioreactor is transferred into the second bioreactor, together with fresh media to fill to volume, to initiate Fermentation 2. Fermentation 2 is carried out for 24 to 48 hours. At the conclusion of Fermentation 2, the entirety of the volume of the second bioreactor is then transferred into the third bioreactor together with fresh media to fill to volume, to begin Fermentation 3. Fermentation 3 is carried out for 24 to 48 hours. At the conclusion of Fermentation 3, the shiitake mycelia biomass has reached a biomass level of approximately 2 g/mL. Log phase of

the shiitake mycelia is maintained between shake flasks and the seed fermentations by use of similar media, temperature, and agitation. The growth of the shiitake biomass is confirmed by pH monitoring. Change in pH is a lead indicator of growth of shiitake mycelia (Aminuddin et al., 2013).

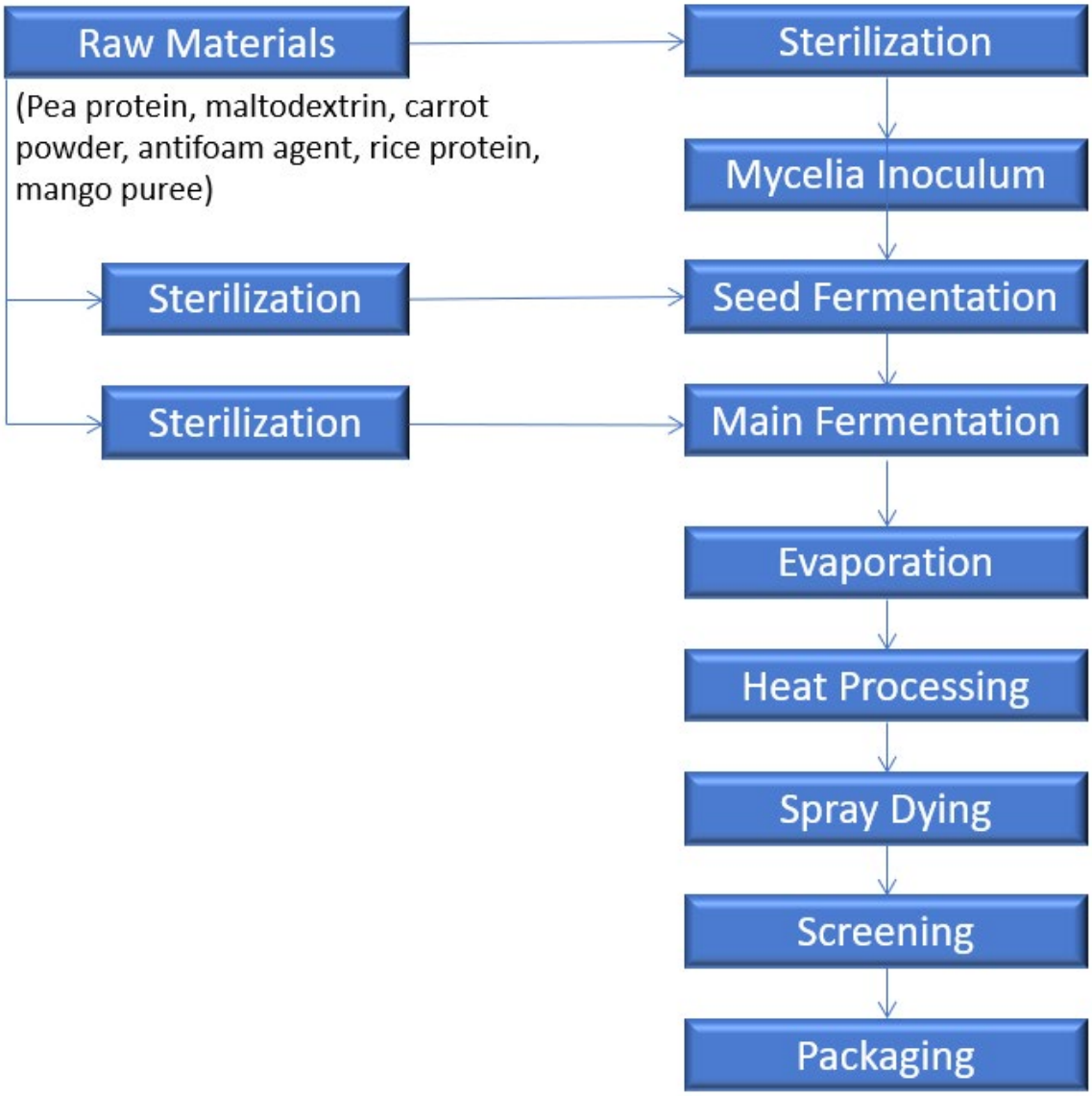
In the final fermentation stage of the manufacturing process (called herein "main fermentation") for FPP, the entirety of the volume from Fermentation 3 is inoculated into the main fermenter, for an input volume of 4% of the volume of the main fermenter. The remainder of the input is the main fermentation media. The difference between the main fermentation media and the media used for the seed fermentation is that the main fermentation media component is pea protein at significantly higher concentrations (i.e. 95% total protein concentrates) than found in the seed fermentation media. Prior to inoculation, all media is sterilized at 121°C for 90 minutes, and all inoculations are carried out with sterile procedure. The main fermentation process is completed in up to 40 hours.

It is known from the literature that a significant change in media will induce a lag phase in an aqueous shiitake culture; specifically, the literature shows that after inoculation of shiitake mycelia into liquid media, a period of 6 to 10 days of culture time is required before appreciable increase is observed in mycelial biomass (Cavallazzi et al., 2005). The main fermentation phase is carried out for no longer than 40 hours under conditions known to induce lag phase in shiitake mycelia. The pH of the main fermentation does not change, indicating no mycelial growth is occurring. MycoTechnology, Inc. therefore concludes that the shiitake mycelia culture enters lag phase upon inoculation into the main fermentation and remains in lag phase throughout the duration of the main fermentation.

The manufacturing process is continued by heat processing and spray-drying steps at the conclusion of the main fermentation. The fermentation process is terminated by heat treatment (~ 65°C for 60 minutes), followed by an evaporator/concentration step. Then the product is heated to 80°C for 1 minute as safety control, followed by spray drying. The spray dried powder is the manufacturing process final output. As discussed below, the input pea protein raw material is not substantially modified after fermentation (see Section 2.5.3).

The flow chart for the manufacture of FPP is provided in Figure 2.2.2-1 and is consistent with the process described in GRN 848 for pea and rice protein fermented by shiitake mycelia.

Figure 2.2.2-1. Process Flow Chart



2.3 Product Specifications and Batch Analysis

2.3.1 Product Specifications

Appropriate food-grade specifications have been established for pea protein fermented by shiitake mycelia (FPP) (Table 2.3.1-1). All cited analytical methods are validated for their intended purpose.

Table 2.3.1-1. Product Specifications for FPP

Parameter	Specification	Test Method
Protein, % dry weight (DW) basis	≥77 (DW)	AOAC 990.03 AOAC 992.15
Ash	≤10%	AOAC 942.05
Moisture	≤6%	AOAC 925.09 AOAC 985.14
Total Fat	≤10%	AOAC 996.06 mod
Carbohydrate (by calculation)	≤15%	FDA CFR 21 - Calculated
pH	>5.5	AOAC 943.02 AOAC 981.12
Aerobic Plate Count	<10,000 cfu/g	AOAC 990.12 Petrifilm AOAC 966.23
Yeast	<100 cfu/g	AOAC 997.02 Petrifilm BAM Ch 18
Mold	<100 cfu/g	AOAC 997.02 Petrifilm BAM Ch 18
Coliforms	<10 cfu/g	AOAC 991.14 Petrifilm
E Coli SSP.	<10 cfu/g	AOAC 991.14 Petrifilm
Salmonella SSP.	Negative/25g	AOAC 2004.03 AOAC-RI 121504
Listeria monocytogenes	Negative/25g	AOAC 2004.02 AOAC-RI 061703
Aflatoxin B1	<5 ppb	AOAC 999.07 Mod
Aflatoxin B2	<5 ppb	AOAC 999.07 Mod
Aflatoxin G1	<5 ppb	AOAC 999.07 Mod
Aflatoxin G2	<5 ppb	AOAC 999.07 Mod
Aflatoxin Total	<5 ppb	AOAC 999.07 Mod
Arsenic	<0.1 ppm	AOAC 2011.19 AOAC 993.14 Mod
Cadmium	<0.1 ppm	AOAC 2011.19 AOAC 993.14 Mod
Lead	<0.1 ppm	AOAC 2011.19 AOAC 993.14 Mod
Mercury	<0.1 ppm	AOAC 2011.19 AOAC 993.14 Mod

2.3.2 Batch Analysis

Analysis of 3 non-consecutive batches of FPP produced by fermentation with shiitake mycelia demonstrates the manufacturing process produces a consistent product that meets the established product specifications. Summaries of the batch analysis for each pea protein product is presented in Table 2.3.2-1.

Table 2.3.2-1. Analytical Data from 3 Non-Consecutive Batches of FPP

Parameter	Specification	Batch ID: Lot 101355	Batch ID: Lot 101646B	Batch ID: Lot 101602B
Protein, % dry weight (DW) basis	≥77	78.32	78.45	78.68
Ash (%)	≤10%	5.03	5.30	5.67
Moisture (%)	≤6%	2.4	4.4	2.7
Total Fat (%)	≤10%	9.11	9.51	9.18
Carbohydrate by calculation (%)	≤15%	7.02	5.79	5.89
pH	>5.5	6.37	6.61	6.59
Aerobic Plate Count (cfu/g)	<10,000	1,500	<10	<10
Yeast (cfu/g)	<100	<10	<10	<10
Mold (cfu/g)	<100	<10	<10	20
Coliforms (cfu/g)	<10	<10	<10	<10
E Coli SSP (cfu/g)	<10	<10	<10	<10
Salmonella SSP	Negative/25g	Negative/25g	Negative/25g	Negative/25g
Listeria monocytogenes	Negative/25g	Negative/25g	Negative/25g	Negative/25g
Aflatoxin B1 (ppb)	<5	<5	<5	<5
Aflatoxin B2 (ppb)	<5	<5	<5	<5
Aflatoxin G1 (ppb)	<5	<5	<5	<5
Aflatoxin G2 (ppb)	<5	<5	<5	<5
Aflatoxin Total (ppb)	<5	<5	<5	<5
Arsenic (ppm)	<0.1	<0.010	0.0182	0.0157
Cadmium (ppm)	<0.1	0.0392	0.0375	0.0376
Lead (ppm)	<0.1	0.0121	0.012	0.0144
Mercury (ppm)	<0.1	<0.005	<0.005	<0.005

2.3.3 Stability

The FPP product should be stored in a cool, dry location, and in the original sealed package away from odorous material. The protein content of this product is stable under accelerated conditions. The FPP product has a shelf life of 24 months from date of manufacture.

2.4 Technical Effect of Pea Protein Fermented by Shiitake Mycelia (FPP)

FPP is intended to be used as a substitute for, and/or in conjunction with, pea protein, rice protein and other protein sources in conventional food products. FPP also has beneficial functional properties in food/beverage systems: ease of dry flow, masking of off-flavors, texturing of meat analogues, increasing water holding capacity and gelation, and increase of water-solubility as compared to conventional products. Intended food categories include baked goods and baking mixes, beverages and beverage bases, breakfast cereals, coffee and tea, dairy product analogues, grain products and pastas, milk products, nut and nut products, plant protein products, snack foods, soups and soup mixes.

2.5 GRAS Material Characterization

2.5.1 Physical Characteristics of FPP

Appearance: Powder

Color: Light cream

Aroma: Low aroma

Taste: Clean taste

2.5.2 Composition of FPP

The FPP product is comprised of primarily protein (≥77%; based on 95% total pea protein raw material input), fat, carbohydrates and up to 5% adjunct material (e.g., remainder of fermentation media components such as carrot powder and maltodextrin (refer to Section 2.2.1)). A minimal amount of protein (<0.05%) may also be contributed by the shiitake mycelium (based on <0.1% shiitake biomass in the final FPP product). Nutritional and compositional data and amino acid profile for FPP is presented in 2.5.2-1.

Table 2.5.2-1. Nutritional and Compositional Data for FPP

Parameter	Results		
Batch ID	**101355**	**101646B**	**101602B**
Protein (% DW)[1]	78.32	78.45	78.68
Protein (% as is)[2]	76.44	75	76.56
Moisture and Volatiles (%)	2.4	4.4	2.7
Ash (%)	5.03	5.3	5.67
Total fat as Triglycerides (%)	9.11	9.51	9.18
Carbohydrates (%) Calculated	7.02	5.79	5.89
Fiber (%)	6.8	6	6.9
Sucrose (%)	0.62	0.65	0.68
Total sugars (%)	1.11	1.13	1.19
Amino Acid (%)	78.23	74.39	75.31
Tryptophan (%)	0.71	0.72	0.74
Cystine (%)	0.6	0.88	0.65
Methionine (%)	0.86	1.18	0.82
Alanine (%)	3.52	3.23	3.29
Arginine (%)	6.53	6.33	6.47
Aspartic Acid (%)	9.25	8.54	8.7
Glutamic Acid (%)	13.34	13.01	13.26
Glycine (%)	3.28	3.03	3.1
Histidine (%)	1.9	1.86	1.9
Isoleucine (%)	3.79	3.58	3.65
Leucine (%)	6.84	6.35	6.48
Phenylalanine (%)	4.31	3.98	4.08
Proline (%)	3.4	3.18	3.23
Serine (%)	4.1	3.78	3.88
Threonine (%)	2.98	2.67	2.74
Lysine (%)	5.77	5.48	5.61
Tyrosine (%)	2.94	2.7	2.76
Valine (%)	4.11	3.89	3.95

[1]% Protein (DW) = $\frac{\text{\% Protein (As Sampled)}}{\text{(100 - \% Moisture)}} \times 100$

[2]Protein content calculated using a nitrogen to protein conversion factor of 6.25.

2.5.3 Similarity of FPP to input pea protein starting material

A comparison of the amino acid profiles of pea protein and FPP are provided in Table 2.5.3-1. The overall typical amino acid profile of FPP generally aligns with the amino acid values of pea protein.

Table 2.5.3-1. Amino Acid Profile Comparison of FPP with Pea Protein

Amino Acids	Pea Protein Raw Material*	FPP Finish Product*
Alanine %	3.36	3.35
Arginine %	6.94	6.44
Aspartic Acid %	9.14	8.83
Glutamic Acid %	13.48	13.20
Glycine %	3.18	3.14
Histidine %	2.00	1.89
Isoleucine %	3.88	3.67
Leucine %	6.71	6.56
Phenylalanine %	4.29	4.12
Proline %	3.41	3.27
Serine %	3.84	3.92
Threonine %	2.83	2.80
Lysine %	6.00	5.62
Tyrosine %	2.94	2.80
Valine%	4.15	3.98
Cystine %	0.68	0.71
Methionine %	0.84	0.95
Tryptophan %	0.83	0.72
Total Amino Acid%	78.50	75.98

*Data presented in this column is average amino acid value from 3 lots of unfermented pea protein and 3 lots of FPP.

The total amino acid content (%) of FPP remained substantially unchanged (≤ 3% difference) from the raw material. Individual amino acid values are slightly lower in FPP (< 0.5% differences) probably due to the dilution of FPP product with about 5% of other materials such as, carrot powder and maltodextrin. In summary, the composition of the input pea protein material remains largely unchanged after fermentation with shiitake mycelia.

2.5.4 Proposed Mechanism for Improvement to Organoleptic Properties of Input Pea Protein

Vegetable-derived protein isolates and concentrates possess objectionable flavor compounds that can arise from oxidative deterioration of unsaturated fatty esters in protein-bound lipids (Rackis et al., 1979). Schindler identified several volatile organic compounds (VOC) in pea protein extracts which impart undesirable organoleptic qualities impacting their acceptance by consumers (Schindler et al., 2012; Table 1). In many cases, the VOCs associated with undesirable organoleptic qualities are below limits of detection (LOD) or limits of quantification (LOQ) by contemporary analytical techniques (Rackis

et al., 1979; Sessa and Rackis, 1977; Buttery et al., 1988). On the other hand, human sensory (taste and smell) testing can be reliably used to detect the presence of these VOCs at levels undetectable by contemporary analytical techniques (Yoshikawa et al., 1965).

Consistent with the literature discussed above, MycoTechnology, Inc.'s analysis of organoleptic qualities (by human sensory analysis) of the input pea protein used to produce FPP found undesirable levels of green pea, yellow pea/beany, chalky, and cardboard notes in the input pea protein (MycoTechnology; unpublished data on file). Sensory studies on FPP compared to unfermented pea protein standard show that FPP has improved organoleptic qualities (i.e. flavor, taste, and aroma attributes reported by trained descriptive panelists) as compared to the unfermented pea protein standard. These results indicate that the manufacturing process described in section 2.2 remediates the undesirable organoleptic qualities associated with the control pea protein starting material including 30% reduction in aroma intensity, green pea flavor reduced by 53% and yellow pea/beany flavor reduced by 41% (MycoTechnology; unpublished data on file).

Consistent with the discussion provided in GRN 848, the improvement in organoleptic qualities of FPP during the fermentation process described in section 2.2 may be due to the secretion of enzymes by the shiitake mycelia during the main fermentation step which act to modify certain VOCs known to impart unpleasant organoleptic qualities of pea protein concentrates. As discussed above (see Section § 2.2.2), MycoTechnology concluded that shiitake mycelia are in lag phase during the main fermentation step, but the literature shows that even during lag phase, shiitake mycelia remain metabolically active, due to adaptation of the organism to a change in media (Cavallazzi, 2005). Shiitake mycelia are known to secrete a number of fungal enzymes, such as pectinases; cellulases; amylases; laccases; laminarinases; and xylanases (Mata et al., 2016). In particular, it is known that Shiitake mycelia constitutively express laccases (Matjuskova et al., 2017), and expression of laccases in shiitake mycelia may be upregulated or stimulated by the presence of lignin-derived phenols and or polymeric lignin materials (Matjuskova et al., 2017; Agrawal et al., 2018). Copper-containing laccases have the ability to oxidize a wide range of aromatic and non-aromatic compounds which includes substituted phenols, some inorganic ions, and a variety of non-phenolic compounds (Agrawal et al., 2018). Laccase is currently used in the food industry for a variety of functional applications including improvement of food sensory parameters (Osma et al., 2010). For example, Schroeder et al. (2008) demonstrated that laccase treatment of apple juice degraded the levels of certain phenolic compounds, guaiacol and 2,6-dibromophenol, responsible for off-flavors in apple juice. Other mechanisms such as physical trapping of volatiles and thermal reactions during the sterilization and drying of the protein blends may also contribute to the changes in olfactory character (Clark et al., 2022).

From its critical evaluation of the available information summarized above, MycoTechnology concludes that confirmed improvements to the organoleptic qualities of FPP relative to the protein input are likely due to the action of secreted enzymes (e.g. laccase) from shiitake mycelia to modify molecules that confer unpleasant organoleptic qualities to pea protein concentrates.

2.5.5 Absence of Viable Shiitake Mycelia in FPP

The main fermentation phase for FPP is carried out under conditions known to induce lag phase in shiitake mycelia (Cavallazzi et al., 2005). Since the pH of the main fermentation does not change, it may be concluded that no mycelial growth is occurring. Thus, MycoTechnology concludes that the shiitake

mycelia culture enters lag phase upon inoculation into the main fermentation and remains in lag phase throughout the duration of the main fermentation. The fermentation process concludes with a thermal deactivation step at about 65 °C for 60 minutes which would kill any remaining live shiitake mycelia.

MycoTechnology confirmed this by conducting an experiment to demonstrate the presence and viability of shiitake mycelia present in FPP. A sample was obtained from the stock 15 kg bags (commercial product size). A total of 4 independent FPP batches were tested in triplicate. For each batch, one gram of FPP was analyzed by plating in two different shiitake solid growing media (plates); for each medium 3 technical replicates were used. Sterile water was used to ensure the quality and sterility of the plates. Blended shiitake mycelium was added as a positive control to ensure that mycelium would grow on the selected media. The samples were incubated at 26 °C in the dark for seven days.

The results presented below demonstrate the absence of fungal/mycelia growth in any of the sample plates at the end of the 7-day incubation period. Fungal/mycelia growth was reported in the positive control plates that contained shiitake mycelium as expected. Results for all samples are shown in Table 2.5.5-1. The report for this study is found in Appendix B.

Table 2.5.5-1. Shiitake Mycelia Growth Results

Sample Lot	MYPGA+AKS Replicate 1	MYPGA+AKS Replicate 2	MYPGA+AKS Replicate 3	PDA Replicate 1	PDA Replicate 2	PDA Replicate 3
101646	ND	ND	ND	ND	ND	ND
101355	ND	ND	ND	ND	ND	ND
101602	ND	ND	ND	ND	ND	ND
101905	ND	ND	ND	ND	ND	ND
Negative Control (Sterile H_2O)	ND	ND	ND	ND	ND	ND
Positive Control Blended shiitake flask	D	D	D	D	D	D

*ND- No mycelial growth detected.
D- Mycelial growth detected.

Part 3: §170.235 Dietary Exposure

3.1 FPP Application Usage Estimates

The proposed uses of MycoTechnology, Inc.'s pea protein fermented by shiitake mycelia (FPP) as a food ingredient in multiple food categories are summarized in Table 3.1-1 below.

Table 3.1-1. Application of Usage Estimates

Food Category	Use Level (%)
Baked Goods and Baking Mixes	5 -15
Beverages and Beverage Bases	40
Breakfast Cereals	15
Coffee and Tea	10
Dairy Product Analogues	10 - 25
Grain Products and Pastas	20
Milk Products	15
Nut and Nut Products	10
Plant Protein Products	12 - 30
Snack Foods	4
Soups and Soup Mixes	5

3.2 FPP Daily Consumption Calculation

FPP is intended to be used as a substitute for, and/or in conjunction with, pea protein, rice protein and other protein sources in conventional food products. Target product categories include food products needing protein-source properties such as promotion of ease of dry flow, masking of off-flavors, texturing of meat analogues, increasing water holding capacity and gelation, and increase of water-solubility. MycoTechnology concludes that the intended uses of FPP will not result in an increase in the overall consumption of protein.

3.2.1 FPP Estimated Daily Intake

Estimates for the intake of FPP were based on its proposed food uses and use levels (Table 3.1-1, above) in conjunction with food consumption data included in the U.S. National Center for Health Statistics' National Health and Nutrition Examination Surveys (NHANES) 2015-2016 or 2017-2018. Calculations for the mean and 90th percentile *per capita* and consumer-only intakes were performed for all proposed food uses of FPP and the percentage of consumers was determined. The per person (g/day) and per kilogram body weight (g/kg bw/day) intakes were reported for the total population and various population groups as presented below in Tables 3.2.1-1 and 3.2.1-2. The complete report for the intake assessment of FPP is included in Appendix C.

Among the total population (ages 2 years and older), the mean and 90th percentile consumer-only intakes of FPP were 22 and 54 g/person/day, respectively. Among the individual population groups, male adults were determined to have the greatest mean and 90th percentile consumer-only intakes of FPP on an absolute basis, at 25 and 60 g/person/day, respectively, while children ages 2 to 5 years had the lowest mean and 90th percentile consumer-only intakes of 12 and 27 g/person/day, respectively.

Table 3.2.1-1. Summary of the Estimated Daily Intake of FPP from Proposed Food Uses in the U.S. by Population Group (2017-2018 NHANES Data)

Population Group	Age Group (Years)	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Children	2 to 5	12	27	99.8	468	12	27
Children	6 to 11	15	31	99.0	672	15	31
Female Teenagers	12 to 19	20	43	97.8	432	21	43
Male Teenagers	12 to 19	19	41	97.8	429	19	41
Female Adults	≥20	22	56	96.5	2,076	23	56
Male Adults	≥20	24	59	96.8	1,888	25	60
Total Population	≥2	21	53	97.1	5,965	22	54

n = sample size; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

On a body weight basis, the total population (ages 2 years and older) mean and 90th percentile consumer-only intakes of FPP were determined to be 0.34 and 0.79 g/kg body weight/day, respectively. Among the individual population groups, children ages 2 to 5 years were identified as having the highest mean and 90th percentile consumer-only intakes of any population group, of 0.75 and 1.48 g/kg body weight/day, respectively. Male adults had the lowest mean consumer-only intake of 0.29 g/kg body weight/day, while male teenagers had the lowest 90th percentile consumer-only intake of 0.70 g/kg body weight/day, respectively.

Table 3.2.1-2. Summary of the Estimated Daily Per Kilogram Body Weight Intake of FPP from Proposed Food Uses in the U.S. by Population Group (2017-2018 NHANES Data)

Population Group	Age Group (Years)	*Per Capita* Intake (g/kg bw/day)		Consumer-Only Intake (g/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Children	2 to 5	0.75	1.48	99.8	460	0.75	1.48
Children	6 to 11	0.46	0.89	99.0	670	0.46	0.91
Female Teenagers	12 to 19	0.34	0.73	97.8	425	0.35	0.73
Male Teenagers	12 to 19	0.29	0.70	97.8	426	0.30	0.70
Female Adults	≥20	0.30	0.76	96.5	2,058	0.31	0.77
Male Adults	≥20	0.28	0.71	96.8	1,873	0.29	0.72
Total Population	≥2	0.33	0.79	97.1	5,912	0.34	0.79

bw = body weight; n = sample size; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

To allow comparisons to current dietary reference intakes for protein, the estimated total intake of protein from FPP consumption (g/person/day) from all proposed food uses was calculated assuming a

maximum protein content of approximately 79% in FPP (Table 3.2.1-3). Among the total population (ages 2 years and older), the mean and 90th percentile consumer-only intakes of protein from FPP were determined to be 17 and 43 g/person/day, respectively. Of the individual population groups, male adults were determined to have the greatest mean and 90th percentile consumer-only intakes of protein on an absolute basis, at 20 and 48 g/person/day, respectively, while children ages 2 to 5 years had the lowest mean and 90th percentile consumer-only intakes of 10 and 22 g/person/day, respectively.

Table 3.2.1-3. Summary of the Estimated Daily Intake of FPP as Protein[a] from Proposed Food Uses in the U.S. by Population Group (2017-2018 NHANES Data)

Population Group	Age Group (Years)	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Children	2 to 5	10	22	99.8	468	10	22
Children	6 to 11	12	24	99.0	672	12	24
Female Teenagers	12 to 19	16	34	97.8	432	16	34
Male Teenagers	12 to 19	15	33	97.8	429	15	33
Female Adults	≥20	17	44	96.5	2,076	18	45
Male Adults	≥20	19	47	96.8	1,888	20	48
Total Population	≥2	17	42	97.1	5,965	17	43

n = sample size; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.
[a] Calculation: (Estimated Daily Intake of FermentIQ ™ Pea Protein)*(Maximum protein content, 79.31%)

Based on the above information, the conservative 90th percentile estimate of the daily consumption of FPP from proposed food categories is 54 g/person/day for the total population (2 years and older). Assuming a maximum protein content of approximately 79% for the FPP ingredient, the conservative 90th percentile estimate of the daily consumption of protein from FPP in these categories is approximately 43 g/day for the total population (2 years and older).

3.2.2 Comparison of FPP Estimated Daily Intake to Background Intake Levels for Protein

The Institute of Medicine (IOM) Recommended Dietary Allowance (RDA) for protein varies from approximately 10 g/day (for infants) to 71 g/day (for pregnant and lactating women), with the RDA for adult females and males as 46 and 56 g/day, respectively (IOM, 2005). The FDA daily reference value (DRV) for protein is 50 g/day for adults and children 4 or more years of age and 13 g/day for children 1 through 3 years of age (FDA, 2016). As noted in GRNs 803 and 851 for pea protein, background dietary intake of protein by adults at the 90th percentile was estimated to range from 76 to 142 g/day using data from the Continuing Survey of Food Intakes by Individuals (CSFII) 1994-1996, 1998 (IOM, 2005). Average protein intake for the U.S. population using food consumption data from the National Health and Nutrition Examination Survey (NHANES 2011-2012) was estimated to be in the range of 80-103 g/day in men and 58.8-75.5 g/day in women (GRN 683 [FDA, 2017]). Additionally, as discussed in GRN 608 (pea protein concentrate [FDA, 2016a]), the Reference Amount Customarily Consumed (RACC) for peas is 85 g/serving (21 CFR 101.12), with the 90th percentile daily intake estimated to be approximately doubled the RACC (FDA, 2006), i.e. 170 g/day. Since peas contain ~24% protein (GRN 608; USDA NNDSF, 2018a), it can be determined that the amount of protein that would be provided by peas is 20.4 g protein per serving (mean), and 40.8 g protein per day (90th percentile). Based on the intake estimates

for FPP presented above, the estimated 90th percentile intake of protein from FPP from all proposed uses is lower than or within the range of these recommended and/or background intake levels of protein in the diet. Since FPP is intended as a source of protein that will substitute for other proteins in the diet, this ingredient will not result in an overall increase in the consumption of protein in the diet. As discussed in GRN 575 for oat protein (p. 000026-27) and the associated FDA Response Letter (FDA, 2015), it is reasonable to expect that most of the U.S. population's intake of protein is expected to remain in the form of unprocessed foods including meat, poultry, fish, and legumes. The mean protein intake from FPP consumption is similar to or below current FDA and IOM recommendations for protein in the diet further supporting a conclusion of safety.

3.3 Dietary Exposure to Shiitake Mycelia via Consumption of FPP at Estimated Consumption Levels

As discussed above in section 3.2, for the Total Population All-Users Consumption dietary exposure of FPP from all proposed food categories is estimated to be 54 g/day at the 90th percentile of consumption, and 22 g/day at the mean level of consumption.

The level of shiitake mycelia present in the FPP is determined as follows: MycoTechnology, Inc. has confirmed that the shiitake mycelia, when added as input into the main fermentation step, enters lag phase upon inoculation (see Method of Manufacture section 2.2). Lack of additional biomass accumulation of the shiitake mycelia during the main fermentation is confirmed by microscopy and pH monitoring. The input shiitake mycelia in the final fermentation step is <0.1 wt.%. Therefore, MycoTechnology concludes that the relative amount of shiitake mycelia in the FPP matches the relative amount of the input shiitake mycelia, which is <0.1 wt.%.

At <0.1% w/w shiitake mycelia in FPP, for an estimated Total Population All-Users Consumption at the worst-case 90th percentile level of estimated daily consumption of FPP of 54 g, MycoTechnology, Inc. concludes that the corresponding level of shiitake mycelia dietary exposure is 54 mg per person per day. At <0.1% w/w shiitake mycelia in FPP, for an estimated Total Population All-Users Consumption mean level of estimated daily consumption of FPP per person of 22 g, MycoTechnology, Inc. concludes that the corresponding level of shiitake mycelia dietary exposure is 22 mg per person per day. At a mean body weight of 60 kg this would result in an intake of approximately 0.9 mg/kg bodyweight/day at the 90th percentile level of estimated daily consumption of FPP or 0.4 mg/kg bodyweight/day at the mean level of estimated daily consumption for the Total Population.

The safety assessment of the consumption of shiitake mycelia at estimated dietary exposures in FPP is presented below in section 6.2.4.

3.4 Dietary Exposure Conclusions

The FPP product will be used as source of protein in a number of food products. Most of the population's protein intake is derived from, and will continue to be derived from, unprocessed foods, including meat, poultry, fish, and legumes. FPP will be added to products as a competitive protein alternative ingredient on the market in a similar manner to other products on the market such as pea and rice protein. Thus, the addition of FPP ingredients will simply serve as a replacement for these other competitive protein sources and will not increase overall consumer exposure to protein. In addition, considering the current FDA and IOM recommendations for protein in the diet, even overly exaggerated

protein intake estimates from current proposed uses of FPP would not pose any human safety concern.

As discussed below in section 6.2.4, consumption of shiitake mycelia at estimated dietary exposures in FPP is also considered to be safe.

Part 4: §170.240 Self Limiting Levels of Use

The use of the pea protein fermented by shiitake mycelia (FPP) as a food ingredient is limited by the level that can technically be added to a given food without jeopardizing its quality and consumer acceptability. The self-limiting level of use is independent of safety (toxicity, allergenic, etc.) concerns.

Part 5: §170.245 Experience Based on Common Use in Food Before 1958

The statutory basis for the GRAS conclusion for pea protein fermented by shiitake mycelia (FPP) is based on scientific procedures; therefore, information regarding experience based on common use of the notified substance in food prior to 1958 is not applicable. The historical consumption of the GRAS material raw ingredient (pea) and fermentation organism (shiitake mushroom) is discussed below in §170.250 Part 6 (GRAS Narrative) as supporting information.

Part 6: §170.250 GRAS Narrative and Safety Rationale

FPP is composed of pea protein fermented with *L. edodes* (shiitake) mycelium. Based on its method of the manufacture (section 2.2) and demonstrated confirmation that the input raw materials are not substantially modified following fermentation (section 2.5.3), the safety of FPP can be established through the safety of the ingredients used to produce it. FPP is substantially similar to pea and rice protein fermented by shiitake mycelia (GRN 848), using the same strain and through an equivalent manufacturing process, with pea protein as the primary protein raw material.

6.1 Safety of FPP Raw Materials

The safety of pea protein raw material was reviewed in GRN 848 (pea and rice protein fermented by shiitake mycelia). The GRAS status of pea protein has been reviewed by FDA (581, 608, 788, 803, 804, 851, and 948) without any questions. Other raw materials used in the process to manufacture FPP such as maltodextrin, carrot powder, rice protein and mango puree, have been commonly consumed prior to 1958 or previously recognized as GRAS and thus meet the standard for generally recognized as safe ingredients. The antifoam used in the production of FPP is made from vegetable oil, which is a safe food processing aid. Antifoam agent is considered a secondary direct food additive according to the Code of Federal Regulations, Title 21, and is compliant with 21 CFR 173.340. These raw materials are substantially degraded or removed during the production process and residues are either not expected or at the lowest possible quantities having no function in the final product.

6.2 Safety of *L. edodes* (Shiitake) Mycelia Fermentation Organism

The strain of shiitake (*L. edodes*) used to produce FPP was originally obtained from Pennsylvania State University and grown in aqueous culture as the vegetative form (shiitake mycelia). The relative amount of inactive shiitake mycelia in FPP is estimated at <0.1%. Based on the weight-of-evidence evaluation described below, including bridging to the safety and historical consumption of the fruiting bodies of shiitake mushrooms (*L. edodes)*, MycoTechnology concludes that the use of *L. edodes* (shiitake) mycelia in the fermentation of FPP is safe.

6.2.1 Historical Consumption of L. edodes (Shiitake Mushroom)

The fruiting bodies of *L. edodes*, also known as shiitake, are a commonly consumed food. As a source of diverse secondary metabolites, fungi have a long history of use in both culinary and medicinal applications (VanderMolen et al., 2017). The shiitake mushroom is the second most widely produced mushroom in the world (Bisen et al., 2010). The world mushroom industry markets more than 2 million tons of mushrooms per year and is still expanding (Nakamura, 1992).

Mushrooms have nutritional value since they contain protein (~2.26 % protein), providing essential amino acids, and fiber (Finimundy, 2014). Edible mushrooms are a high nutritional quality food and have been used as an alternative to dietary protein in countries with high malnutrition rates (Finimundy, 2014, Canadian Nutrient File for Shiitake Mushroom, Food code 6904). The chemical and nutritional characteristics of mushrooms vary in function after harvest, and processing (Finimundy, 2014).

In a review of the nutritional compounds found in *L. edodes,* Finimundy (2014) reported that the dietary fiber present in *L. edodes* consists of soluble and insoluble fractions. Water-soluble β-glucans and

proteins are found in the soluble fraction. In the non-soluble fraction, polyuronide (acidic polysaccharide), hemicellulose, β-glucan chains with hemicellulose, lignin, and chitin are found. *L. edodes* provides a nutritionally significant content of vitamins B_1, B_2, B_{12}, C, D, and E. The aroma components include alcohols, ketones, sulfides, alkanes, and fatty acids. The main constituents which are volatile include matsutakeol (1-octen-3-ol) and ethyl, n-amyl ketone (Finimundy, 2014). The characteristic aroma of shiitake was identified as 1,2,3,5,6-Pentathiepane (Finimundy, 2014). *L. edodes* mycelium are composed of glycoproteins containing glucose, galactose, xylose, arabinose, mannose, and fructose (Coates, 2010).

6.2.2 Similarity of Shiitake Mushroom and Shiitake Mycelia Composition

The life cycle of mushrooms starts with a spore which produces a primary mycelium. When the mycelium originating from two spores mates, a secondary mycelium is produced. This mycelium continues to grow vegetatively. When vegetative mycelium has matured, its cells are capable of a phenomenal rate of reproduction which culminates in the development of the mushroom fruitbody. The fruitbody represents the last functional change in the mushroom life cycle and it is tertiary mycelium. The entire mushroom is composed of compressed mycelia (Stamets & Chilton, 1983). The shiitake mushroom is largely made up of bundles of mycelia composing the pileus (cap) and stalk, and having only a small portion of tissue, located underside of the mushroom cap that differentiates into gills (lamella) to produce spores (basidiospores) for reproduction of the shiitake organism. Thus, shiitake mushroom itself, aside from gill tissue on undersides of caps producing spores, is, physically indistinguishable from its parent mycelia (Stamets & Chilton, 1983; Liu et al., 2016). From this information, MycoTechnology, Inc. concludes that the shiitake mycelia and shiitake mushroom compositions are physically very similar, and the safety demonstrated for shiitake mushroom is directly applicable to shiitake mycelia.

Van der Molen et al. (2017) (discussed further below in § 6.3.3) reported on a comparison of 1:1 methanol-chloroform (MeOH-$CHCl_3$) extracts of culinary mushrooms and identified similarity of 98% in the composition of shiitake mycelia culture to grocery store shiitake mushrooms using ultrahigh-performance liquid chromatography-photodiode array-evaporative light scattering-high resolution mass spectrometry (UHPLCPDA-ELS-HRMS) analysis, confirming that the mycelium were not substantially different from the fruiting bodies used as food. The polarity of 1:1 MeOH-$CHCl_3$ is such that most organic soluble molecules are extracted efficiently. Total unevaluated peak area was 2%. In another approach, shiitake fungal raw material (i.e. mycelia) extract was subjected to a targeted UHPLC-PDA-HRMS/MS protocol that screened for the presence of cytotoxins and mycotoxins from a database of over 300 fungal secondary metabolites (El-Elimat et al., 2013 as reported in Van der Molen et al., 2017). The shiitake fungal raw material extract yielded matches for fungal metabolites from this database based on retention time, UV data, HRMS data, and MS/MS data. The cytotoxic metabolite ergosterol peroxide was detected in the shiitake fungal raw material extract, and in the store-bought culinary shitake mushroom extract. MycoTechnology, Inc. concludes that the shiitake mycelia and shiitake mushroom compositions are virtually identical and the safety demonstrated for shiitake mushroom is directly applicable to shiitake mycelia.

Song et al. (2018) reported on the differential expression of 11,675 total genes known to shiitake and identified that 9,595 of these are not differentially expressed between mycelia and fruit body. There is an approximately an 82% identity in expression activity between shiitake mycelia and shiitake fruiting body tissue. While Song et al. (2018) reported that gene expression levels differ, the authors attribute the differential expression to overexpression of genes in the mature fruiting body stage (the mushroom)

related to “DNA replication, recombination, repair, chromatin structure, and the associated dynamics” and the transcripts from the fruiting body are “significantly enriched in ‘replication and repair’ and ‘transcription’ pathways for premeiotic replication, karyogamy, or meiosis.” The differential expression reported by Song et al. (2018) appears to be primarily related to the reproductive activity related to shiitake fruiting in the fruiting body, which does not occur for the shiitake mycelia. MycoTechnology, Inc. therefore concludes that the differences in gene expression between shiitake mycelia and mature fruiting body tissues of the shiitake mushroom are of little to no consequence to the safety of consumption of shiitake mycelia.

6.2.3 Absence of Fungal Toxins in FPP

Cultivation of shiitake mycelia in solid culture to produce shiitake mushrooms as culinary mushrooms for use in food is a well-known practice (Van der Molen et al., 2017). Shiitake culture is grown in solid-state as mycelial tissue (“spawn”) usually on grain or wood chips. After running out of nutrient substrate, the mycelial tissue fruits mushrooms (basidiocarps) which produce spores (basidiospores) (Przybylowicz & Donoghue, 1988). Neither shiitake mushrooms nor shiitake mycelia are known to produce mycotoxins during the growth of the mycelia or during the fruiting phase (production of mushrooms) (Han et al., 2014).

Shiitake mycelia may also be grown in aqueous culture. In aqueous culture, shiitake mycelia are not known to produce mushrooms, instead propagating as mycelia only (Tsivileva et al., 2005; Aminuddin et al., 2013; Aminuddin et al., 2007). During growth of shiitake mycelia in aqueous culture, no known mycotoxins were produced (Van der Molen et al., 2017; EFSA, 2010). An exhaustive literature search also failed to identify any scientific report in which *L. edodes* or closely related fungal species (*Schizophyllum commune*, *Gymnopus luxurians)* have been associated with the production of mycotoxins or other toxic compounds. Inspection of the *L. edodes* genome identified a total of 32 metabolite gene clusters, none of them seem to be involved in the production of known fungal toxins (Chen et al., 2011).

As described in GRN 848, an analysis of organic compounds was performed on pea and rice protein fermented by shiitake mycelia compared with a sham fermentation control (pea and rice protein subjected to identical processing as FermentIQ™ protein but lacking a shiitake mycelia inoculation step) using LCMS-APCI-QTOF (MycoTechnology; unpublished data on file). This analysis did not identify the presence of any fungal toxins, corroborating the findings of the literature search discussed above. The pea and rice protein fermented by shiitake mycelia was further evaluated via comparison to National Biotechnology Center for Information (NCBI)’s databases “NCBI Fungi” and “NCBI green plant” (MycoTechnology; unpublished data on file). The results showed that less than 1% of the sample matched the identity of a fungal protein according to the database, and no toxic fungal proteins were identified.

From this information, MycoTechnology, Inc. concluded that shiitake mycelia grown under the conditions described under the manufacturing conditions as described in section 2.2 is not expected to produce mycotoxins or toxic metabolites during the production of FPP.

6.2.4 Safety of Consumption of Shitake Mycelia

6.2.4.1 Safety of Consumption of Shiitake Mycelia at Estimated Dietary Exposures in FPP (Van der Molen et al (2017))

The estimated dietary exposure to shiitake mycelia from consumption of FPP at conservatively estimated mean and 90th percentile levels are 22 mg/person/day and 54 mg/person/day, respectively (see section 3.3). The safety of this exposure level for shiitake mycelia was evaluated using a weight-of-evidence approach as described by Van der Molen et al. (2017) for the safety assessment of mushrooms in dietary supplements by combining analytical data with *in silico* toxicology evaluation.

Van der Molen et al. (2017) assessed the safety of seven fungal raw materials including shiitake (*L. edodes*) consisting primarily of mycelium. Consumption of shiitake mycelia in dietary supplements at a maximum dose of 1,500 mg and a median dose of 50 mg was evaluated by a decision tree driven weight-of-evidence approach consisting of five key principles as outlined below. MycoTechnology has also addressed these five key principles in its weight-of-evidence approach to the safety assessment of the shiitake mycelia used to produce FPP.

1) Identification by sequencing the nuclear ribosomal internal transcribed spacer (ITS) region (commonly referred to as ITS barcoding)
    - Van der Molen et al. (2017) verified, by ITS barcoding, that an obtained fungal raw material analyzed was shiitake mycelia
    - MycoTechnology similarly verified, by ITS barcoding, that the microorganism used in the manufacturing process to produce FPP is *L. edodes* which is grown in aqueous culture as the vegetative form *(*mycelia) (see section 2.2.1.2)
2) Screening an extract of each fungal raw material against a database of known fungal metabolites
    - Van der Molen et al. (2017) screened the shiitake mycelia 1:1 MeOH-CHCl3 extract against a database of 300 known cytotoxic metabolites. Table 9 of Van der Molen et al. (2017) confirms that shiitake mycelia in commerce produced no unique detectable toxins.
    - MycoTechnology similarly confirmed that no unique fungal toxins were detected in FPP (see Section 6.2.3 below).
3) Similarity of the shiitake mycelia extract to culinary mushroom extracts
    - Van der Molen et al. (2017) performed UHPLC-PDA-ELS-HRMS analysis to assign individual peaks for the shiitake mycelia extract a percent similarity or difference to grocery store-bought shiitake culinary mushroom. Van der Molen et al. (2017) showed that there was a 98% similarity of shiitake mycelia to grocery store-bought shiitake mushrooms, per UHPLCPDA-ELS-HRMS analysis (2% unevaluated) and that the shiitake mycelia is "[c]hemically very similar to food." (see Van der Molen et al., 2017; Table 9).
    - As described above (Section 6.2.2), MycoTechnology concludes that the shiitake mycelia used to produce FPP is substantially equivalent to shiitake culinary mushrooms (fruiting body).
4) Review of the toxicological and chemical literature for each fungus
    - Van der Molen et al. (2017) performed a literature review of the current toxicological and chemical literature for shiitake mushrooms. The authors concluded that shiitake has a long history of use as food (fruiting body) and numerous toxicological studies were available showing minimal toxicity.
    - MycoTechnology also performed a review of the available literature regarding the safety of shiitake mycelia (see section 6.2.4.2, below). MycoTechnology concluded that the

available literature supports the safety of shiitake mycelia for use in the production of FPP.

5) Evaluation of data establishing presence in-market.
    - Van der Molen et al. (2017) reviewed in-market data using the Dietary Supplements Labels Database (DSLD) maintained by the National Institutes of Health (NIH) for a total of 223 shiitake products with the most common ingredients being "shiitake" (98 products) and "shiitake Mushroom" (43 products). Most products did not report the dose of the ingredient, instead listing only the dose of a proprietary blend in which shiitake was included (assumed to be shiitake mycelia since commercial fungal raw materials predominantly consist of mycelia because of its rapid growth characteristics compared to the mushroom / fruiting body). The maximum dose was 1500 mg, and the median dose was 50 mg.
    - MycoTechnology concluded that the current market use of shiitake mycelia in the form of a dietary supplement supports the safety of shiitake mycelia at a lower range of exposure levels in FPP (i.e. mean and 90th percentile levels are 22 mg/person/day and 54 mg/person/day, respectively). In contrast to shiitake mycelia dietary exposure in the form of a dietary supplement, in FPP the shiitake mycelia is dispersed, i.e. it is intermixed with all other components (primarily pea protein). In both cases, the dietary exposure results from a heat-treated and killed shiitake mycelia.

Based on the above analysis, Van der Molen et al. (2017) concluded that:

> "Shiitake and Maitake are commonly eaten as foods, and shiitake, at least, has a wealth of available toxicological data supporting its safe use. The apparent prevalence in the marketplace, the lack of reported adverse events, as determined by the literature review and the very high degree of similarity between their mycelial growths (the raw materials investigated) and the culinary fruiting bodies to which they were compared give confidence that these materials are safe for consumption at doses consistent with dietary intakes of culinary mushrooms."

MycoTechnology, using the weight-of-evidence safety assessment approach of Van der Molen et al. (2017) concluded that a dietary exposure to shiitake mycelia of 50 mg to 1,500 mg (assumed daily) is safe, considering the existing history of use and available toxicological data indicating no greater risk than culinary mushrooms (Van der Molen et al., 2017). Of note, approximately 700 branded shiitake mushrooms products are available in the US market indicating widespread culinary use and consumption (USDA, 2022). Using the approach described by Van der Molen et al. (2017), including ITS barcoding results, demonstrated absence of fungal toxins, confirmed similarity of shiitake mycelia to culinary mushrooms, a review of toxicology and clinical safety literature, and comparison to in-market use of dietary supplements containing shiitake ingredients, MycoTechnology, Inc. also concluded that the dietary exposure to shiitake mycelia in FPP at lower exposure levels is safe.

6.2.4.2 Safety Assessment of L. edodes (Shiitake) Mycelia

In order to assess the safety of oral intake of *L. edodes* mycelia used to produce FPP, a comprehensive search of the scientific literature through March 2022 was conducted using the U.S. National Library of Medicine (NLM) PubMed and TOXLINE databases. Search terms to identify relevant literature on the mycelia included "lentinula edodes" / "shiitake mushroom" AND "mycelium" / "mycelia". Search terms to identify relevant literature on the fruiting body included "lentinula edodes" / "shiitake mushroom" and the additional keywords (PubMed search only) "safety" / "toxicity" / "carcinogenicity" / "genotoxicity" / "adverse effect" / "tolerability"/ "consumption" / "allergen" / "allergy". Relevant literature regarding the safety of dietary consumption of shiitake mycelia is discussed below. Compared to the literature review summarized in GRN 848 (search performed in January 2019), the recent search identified one publication reporting a lack of reproductive or embryofetal developmental effects following oral dosing of *L. edodes* powder (Camargo et al., 2020; summarized below), and several publications reporting human case reports of flagellate dermatitis from shiitake mushroom consumption (references cited below) which is considered very unlikely to occur with FPP consumption due to heat treatment steps during the manufacturing process and low dietary exposure to shiitake mycelia in FPP. Therefore, the previous conclusions regarding the safety of *L. edodes* mycelia (as outlined in GRN 848) remain valid and support the current GRAS conclusion for FPP.

Yoshioka et al. (2010) assessed the safety of an aqueous suspension of a powdered extract of *L. edodes* mycelia (L.E.M.) when administered to male and female Wistar rats (10 animals/sex/group) via gavage at 2,000 mg/kg bodyweight/day (single dose level evaluated) for 28 days. The study was performed according to OECD testing guideline 407. Cultured *L. edodes* mycelia together with the solid medium were extracted with hot water (temperature not reported) and the L.E.M. extract was prepared by filtration, concentration, sterilization and lyophilization of the raw extract. Although an L.E.M. extract does not contain insoluble portions of shiitake mycelia cells, and is therefore not identical in composition to the shiitake mycelia present in FPP, both the L.E.M. extract and shiitake mycelia present in FPP will contain the same water-soluble (presumably bioavailable) components. Thus, the Yoshioka et al. (2010) L.E.M. extract repeated-dose toxicity data are relevant to the safety assessment of shiitake mycelia present in FPP.

Yoshioka et al. (2010) did not report any unscheduled deaths or clinical signs suggesting toxicity. Body weight and food consumption were slightly decreased () compared to the control groups, particularly for males. The lower body weights were statistically significant at Day 14 through 28 for males and Day 7 through 11 for females. Lower food consumption was statistically significant at Day 0 through 21 for males and not statistically significant for females. At the study termination, male body weights were only 8% less than control groups (associated with slightly [not statistically significant] decreased food consumption) and female body weights were only 5% less than control groups. These minor differences were not considered adverse. None of the hematological parameters were statistically significantly different from respective controls after the 28-day dosing phase. Serum biochemistry revealed very few statistically significantly different parameters compared to respective controls, including increased phosphorus in both sexes; however, all values were reported as being within the laboratory's normal reference ranges. Although females had slightly increased organ weights relative to bodyweight (thyroid gland, kidneys, adrenals, uterus/ovaries) as did males (thyroid gland, adrenals), these differences were minor and without histopathological correlates. There were no pathological alterations in any examined tissues or organs. The no observed adverse effect level (NOAEL) of L.E.M. extract determined in this study was 2,000 mg/kg/day, the only dose tested. This rat NOAEL is the

equivalent to a dietary exposure of 120 g of L.E.M. extract per day for a 60 kg human. As discussed above in section 3.3, the worst-case estimated dietary exposure of shiitake mycelia from FPP consumption for proposed uses, at the 90th percentile is 54 mg per day (or 0.9 mg/kg bw/day). Therefore, a more than 2222-fold difference exists between the estimated dietary consumption of shiitake mycelia in FPP and L.E.M. extract tested in Yoshioka et al. (2010). MycoTechnology, Inc. concludes that this 28-day oral repeated-dose study with Wistar rats provides an adequate Margin of Safety for FPP at the estimated levels of consumption.

Yoshioka et al. (2009) evaluated the safety of foods containing an extract of cultured *L. edodes* mycelia (L.E.M.) in healthy adult volunteers. The publication is in Japanese with a limited English abstract, so details of the methods and results are difficult to discern. Yoshioka et al. (2009) evaluated a lyophilized hot water extract of *L. edodes* mycelia (LEM) material administered to subjects in granular food. Although an L.E.M. extract will not contain insoluble portions of shiitake mycelia cells and is therefore not identical in composition to the shiitake mycelia present in FPP, both the L.E.M. extract and shiitake mycelia present in FPP will contain the same water-soluble components. Thus L.E.M. extract clinical data is useful to evaluate the safety of FPP. Eleven healthy subjects (8 males and 3 females, ages 33.4 ± 9.4 years) consumed the test foods containing 5,400 mg L.E.M. extract per day for 4 weeks. No adverse effects were reported, except for mild gastrointestinal symptoms such as soft stool in one subject who had a "hypersensitive" intestine. The authors concluded that food containing L.E.M. extract is safe for healthy adults at up to 5,400 mg per day. As discussed above in section 3.3, the estimated dietary exposure of shiitake mycelia from FPP consumption at the 90th percentile of intake is 54 mg/day. This dietary intake would be about 100-fold less than the dietary exposure to L.E.M. extract administrated daily for 4 weeks in Yoshioka et al. (2009). From this information, MycoTechnology, Inc. concludes that the Yoshioka et al. (2009) study provides an adequate Margin of Safety for shiitake mycelia present in FPP.

Additional human clinical studies addressing the safety of shiitake mycelial extract are summarized in Table 6.2.5-1. Although these studies were performed to assess the possible therapeutic effects of shiitake mycelial extract on quality of life and immune function, no adverse events from treatment with shiitake mycelial extract were reported. Therefore, these studies support a conclusion of safety for shiitake mycelia present in FPP. The worst-case theoretical estimate of dietary exposure to shiitake mycelia from FPP consumption (i.e. 54 mg/day at the 90th percentile of intake) is more than 33-fold lower than the doses of L. edodes mycelia extract (L.E.M.) that were evaluated for effects on immune function (i.e. 1800 mg/day [Okuno, 2011; Nagashima et al., 2013 & 2017; Suzuki, 2013], and the heat treatment steps during the manufacturing process of FPP protein are expected to render any immunomodulatory compounds inactive. Therefore, MycoTechnology, Inc. concludes that the putative or potential bioactive constituents of *L. edodes* are not a safety concern under the intended conditions of use of FPP.

Table 6.2.4.2-1. Shiitake Mushroom Mycelia, Safety Evidence from Human Studies

Study Title (reference)	Study Design	Study Details	Results & Conclusions
Consuming *L. edodes* (Shiitake) Mushrooms Daily Improves Human Immunity (Dai, 2015)	A randomized dietary intervention study; to determine whether consumption of whole, dried *L. edodes* (shiitake) mushrooms could improve human immune function.	Fifty-two healthy males and females (21-41 years), participated in a 4 weeks parallel group study, consuming either 5 or 10 g of shiitake mushrooms daily.	Conclusion: Dosage was well tolerated. Safety and adverse events were not reported in the study.
Safety of orally administered *L. edodes* mycelia extract for patients undergoing cancer chemotherapy: a pilot study. (Yamaguchi, 2011)	Observational study to investigate safety of *L. edodes* on quality of life (QOL) and the immune response in patients undergoing cancer chemotherapy.	Seven patients were studied in total. The patients were undergoing post-operative adjuvant chemotherapy for breast cancer (n = 3) or gastrointestinal cancer (n = 2), or were receiving chemotherapy to prevent recurrence of gastrointestinal cancer (n = 2). The first course of treatment was chemotherapy alone and the second was chemotherapy plus concomitant administration of *L. edodes* extract. Outcome measures: Adverse events and changes in the QOL score were evaluated during the study period.	Conclusion: Treatment with *L. edodes* extract with chemotherapy is safe and no adverse events were attributable to *L. edodes* extract.
Oral Administration of *L. edodes* Mycelia Extract for Breast Cancer Patients Undergoing Postoperative Hormone Therapy. (Suzuki, 2013)	This was a 12-week, single-arm, open-label study. All subjects first entered a 4-week observation period, followed by an 8-week period of oral *L. edodes* extract	This study investigated the influence of *L. edodes* on the quality of life (QOL) and immune response in breast cancer patients undergoing postoperative adjuvant hormone therapy.	Conclusion: No subjects reported any serious adverse events. Safety of oral administration of *L. edodes* Mycelia Extract was supported by this study.

Study Title (reference)	Study Design	Study Details	Results & Conclusions
	ingestion at 1800 mg daily. Preparation: *L. edodes* mycelia were cultivated in a solid medium composed of sugar-cane bagasse and defatted rice bran. Medium containing the mycelia was incubated in hot water, and then the soluble fraction was dried and used as *L. edodes* extract.	Twenty patients* were studied in total. They received only hormone therapy in the first 4 weeks followed by hormone therapy and *L. edodes* (1800 mg/day) during the next 8 weeks. *As subjects are breast cancer patients, this suggests strongly that all subjects are female.	
Efficacy of Orally Administered *L. edodes* Mycelia Extract for Advanced Gastrointestinal Cancer Patients Undergoing Cancer Chemotherapy: a Pilot Study. (Okuno, 2011).	This study was conducted as an 8-week single-group open label study. During the study period, each subject took two courses of chemotherapy. *L. edodes* extract was orally ingested during the second course at a dose of 1800 mg/day for 4 weeks. Preparation: *L. edodes* mycelia were cultivated in a solid medium composed of sugar-cane bagasse and defatted rice bran. Medium containing the mycelia was incubated in hot water, and then the soluble fraction was dried and used as LEM	This study investigated the influence of *L. edodes* mycelia extract (LEM), an oral immunomodulator, on immune function and adverse events from chemotherapy. Subjects comprised 1 gastric (male) and 7 colorectal (5 females, 2 males) cancer patients. Ages ranged from 52 to 71. The first course of treatment was chemotherapy alone and the second was chemotherapy plus concomitant administration of LEM. Adverse events and interferon (IFN)-γ production by CD4+ T, CD8+ T and CD56+ NK/NKT cells were evaluated at the end of each course.	Conclusion: Concomitant use of *L. edodes* Mycelia Extract with chemotherapy can decrease the incidence of adverse effects from cancer chemotherapy among patients with advanced cancer. Safety of *L. edodes* is supported by this study.

Study Title (reference)	**Study Design**	**Study Details**	**Results & Conclusions**
Dietary supplementation with rice bran fermented with *Lentinus edodes* increases interferon-γ activity without causing adverse effects: a randomized, double-blind, placebo-controlled, parallel-group study. (Choi, 2014)	A randomized, double-blind, placebo-controlled, and parallel-group investigated the hypothesis that dietary supplementation with rice bran fermented with *Lentinus edodes* (rice bran exo-biopolymer, RBEP), a substance known to contain arabinoxylan, enhances natural killer (NK) cell activity and modulates cytokine production in healthy adults.	Dosage: 80 healthy (non-pregnant/lactating adults, aged 25-70 years old comprised of 31 females and 49 males) participants were randomly assigned to take six capsules per day of either 3g RBEP or 3g placebo for 8 weeks.	Conclusion: This well designed RCT demonstrates the safety of rice bran fermented with *Lentinus edodes*. No adverse events were reported.
Evaluation of host quality of life and immune function in breast cancer patients treated with combination of adjuvant chemotherapy and oral administration of *L. edodes* mycelia extract (Nagashima et al., 2013)	Ten breast cancer patients with nodal metastases receiving surgery were enrolled in this study. This was an open-label trial with a single group. Subjects were treated with two courses of FEC75 chemotherapy for 3 weeks as one course. The first course comprised FEC75 chemotherapy alone, whereas the second course used LEM in combination with FEC.	Dosage: *L. edodes* mycelia extract (LEM; 1800 mg/day by mouth) was administered for 21 days during the second course.	The authors concluded that concomitant use of *L. edodes* mycelia extract with FEC75 therapy can maintain host QOL and immune function, and offer important implications for an application of LEM as a useful oral adjuvant to anthracycline-based chemotherapies. No adverse events associated with LEM treatment were reported.

Study Title (reference)	Study Design	Study Details	Results & Conclusions
L. edodes mycelia extract plus adjuvant chemotherapy for breast cancer patients: Results of a randomized study on host quality of life and immune function improvement. (Nagashima et al., 2017)	A randomized double-blind study was conducted to evaluate the effectiveness of *L. edodes* mycelia extract (LEM), which is an oral biological response modifier (BRM) medicine for cancer patients as such an adjuvant. A total of 47 breast cancer patients who were scheduled to receive postoperative adjuvant anthracycline-based chemotherapy were enrolled in the study.	Dosage: *L. edodes* mycelia extract (LEM; 1800 mg/day by mouth) was ingested daily over two 3-week courses, for a total of 6 weeks	The authors concluded that LEM appears to be a useful oral adjuvant for patients receiving anthracycline-based chemotherapy. No adverse events associated with LEM treatment were reported.

6.2.4.3 Safety of Fruiting Bodies (Mushrooms) at Estimated Levels of Consumption of FPP

The fruiting bodies of *L. edodes*, also known as shiitake mushroom, are a common food, particularly in Asia. Shiitake mushroom is the second most popular edible mushroom in the global market (Bisen et al., 2010). Relevant literature regarding the safety of dietary consumption of shiitake mushroom (fruiting body) is discussed below.

Pregnant Wistar rats (6/group) were gavaged daily with *L. edodes* powder (100 mg/kg bw/day) before implantation from gestation days 1 to 19 days or after implantation from gestation days 9 to 19 (testing guideline not reported). A control group received daily gavage doses of 0.9% saline. On gestation day 20, cesarean sections were performed, blood was collected and hematological parameters (hemoglobin, hematocrit, white and red blood cells and platelets) were analyzed. Additionally, albumin, calcium, creatine kinase, alkaline phosphatase, transferases, creatinine, urea, triglycerides, cholesterol, lipase, glucose, and insulin were assessed in serum. Organs were collected and weighed, and the fetuses were analyzed morphologically by body measurements. There were no changes in maternal weight, biochemical and hematological parameters, organ weight, or reproductive capacity (as assessed by preimplantation loss percentage, postimplantation loss percentage, offspring vitality percentage, fetus weight, placenta weight, placental index, and ovary weight), and no morphological changes in the fetuses' body measurements (Camargo et al., 2020).

Frizo et al. (2014) reported on the effects of reconstituted shiitake mushroom powder consumption in a rat developmental toxicity study at daily gavage doses of 400 mg/kg and 800 mg/kg (0.53 g β-glucan per 100 g mushroom) from the 1st to the 20th day of gestation (testing guideline not reported). Saline was administered to the control group. Only an abstract is available so additional details of the methods and quantitative results cannot be discerned. The fetuses were removed on the 21st day of gestation by caesarean section. Maternal kidney and liver toxicity were assessed and oxidative stress was determined by measurement of glutathione (GSH). The corpora lutea, implantations, resorptions, live and dead fetuses were counted. The placentae and fetuses were weighed. External and visceral morphological examinations of fetuses were performed following fixation with Boudin solution. Skeletal evaluations were performed following diaphonization and staining with alizarin red-S. Although there was an absence of maternal toxicity, the glutathione (GSH) plasma ratio was reduced at 400 and 800 mg/kg/day, suggesting antioxidant properties of shiitake mushroom at the relatively high dose levels used in this study. No changes were reported in urea plasma ratio *[sic]*, creatinine, aspartate aminotransferase (AST), and alanine aminotransferase (ALT). There was an increase in post implantation loss, reduced body weight and external measurements of fetuses. However, no visceral or skeletal abnormalities of the fetuses were reported. The estimated dietary exposure of shiitake mycelia in FPP is 54 mg/day at the 90th percentile of intake, corresponding to 0.9 mg/kg/day level of consumption at a mean body weight of 60 kg. The shiitake mushroom dietary exposure in this study is more than 444-fold higher than that from FPP. From this study, MycoTechnology, Inc. concludes that the level of dietary exposure to shiitake mycelia in FPP is significantly less than the dietary exposure levels of shiitake mushroom powder reported to show developmental toxicity in fetal rats following *in utero* exposure for 20 days, providing an adequate Margin of Safety.

Mus musculus NIH/S mice (n = 6/group) received to 0, 3, 6, or 9 g dry Lentinus edodes/kg body weight/day (fresh mushroom equivalents 19.4, 41.9, and 61.4 g/kg bw/day) as a dietary admixture (1.8%, 3.6% or 5.4% of feed) for 5 days (Nieminen et al., 2009). These were high doses, i.e. with human equivalent doses of fresh shitake mushrooms for a 60 kg person being 1164, 2514, and 3684 g/day. Food and water consumption, plasma clinical chemistry and liver and muscle histopathology were evaluated.

Although there were statistically significant decreases of HDL/total cholesterol (mid- and high-dose groups), and increases of total protein (low-, mid- and high-dose groups), creatinine kinase (high-dose group) and total bilirubin (low-, mid- and high-dose groups) following 5 days of consumption in the diet, no adverse histopathological findings were reported. The worst-case estimated dietary exposure of 54 mg per day (0.9 mg/kg body weight/day) to shiitake mycelia (section 3.3) from consumption of FPP is approximately 3333 times less than the low-dose level of dry shiitake mushroom (i.e. 3 g/kg body weight/day) showing minimal toxicity in mice in the Nieminen et al. (2009) study, providing an adequate Margin of Safety.

Four groups (6/group) of male Wistar rats received dry and powdered *L. edodes* (shiitake mushroom) reconstituted in water at daily gavage doses of 100, 400, or 800 mg/kg for 30 days. Reductions in hemoglobin concentration and leukocytes were reported at 400 and 800 mg/kg compared to controls; only the leukocyte differences were dose-dependent. The authors concluded that the NOAEL of *L. edodes* determined in this study was 100 mg/kg. The human equivalent dose of *L. edodes* for a 60 kg person would be 6000 mg/day; therefore, the worst-case estimated dietary exposure of 54 mg per day (0.9 mg/kg body weight/day) to shiitake mycelia (section 3.3) from consumption of FPP is more than 111 times less than the safe daily intake level of *L. edodes* identified in this study.
(Grotto et al., 2016).

Levy et al. (1998) reported the effects of ingestion of shiitake mushroom powder on eosinophilia, changes in eosinophil-active cytokines and eosinophil proteins in blood and stool, or gastrointestinal symptoms. In this study, 10 normal persons (9 males and 1 female; average age 40.6 years; range, 31 to 63 years) were studied. Exclusion criteria were a history of allergy to mushrooms, disease associated with significant eosinophilia, and gastrointestinal disease. Additional exclusion criteria included baseline blood eosinophil counts greater than 500/mm^3, abnormal serum IgE levels, use of prescription medication (except oral contraceptives), and pregnancy. Four (4) g shiitake mushroom powder (open label) was ingested daily by each subject for 10 weeks (trial 1), and the same protocol was repeated in these subjects after 3 to 6 months (trial 2). The investigators defined responders as subjects having peak eosinophil counts four or more times their average baseline counts. Each trial had four responders, and trial 2 had one new and three repeat responders. Responders had increased blood eosinophils, serum major basic protein, stool eosinophil-derived neurotoxin, and factors that enhanced eosinophil viability. Anti-shiitake IgE was not detected, but anti-shiitake IgG was increased in two responders. Gastrointestinal symptoms coincided with eosinophilia in two subjects. Gastrointestinal symptoms and eosinophilia resolved after discontinuing shiitake ingestion. The authors stated that eosinophilic response to shiitake does not appear to be a typical allergic reaction because of the inability to detect anti-shiitake IgE and by the delayed and gradual time-course of the response. However, the response is likely immune-mediated because it is associated with cytokines that enhance eosinophil viability and elevations in anti-shiitake IgG in two of the five responders.

During a 10-week clinical study of the cholesterol-lowering effect of 4 g/day shiitake mushroom powder ingestion (Unpublished Personal Communication, D. Jacobson, J. O. Hill, University of Colorado, 1994 summarized by Levy et al., 1998), 17 of 49 subjects (no demographic details provided) in the treatment arm withdrew from the trial because of either rash (seven subjects) or abdominal discomfort (10 subjects). Two subjects had marked peripheral blood eosinophilia at the time they stopped ingesting mushrooms. However, their eosinophilia resolved after discontinuation of mushrooms.

Although the results in these clinical trials reported by Levy et al. (1998) show transient effects for consumption of shiitake mushroom powder at 4 g per day for 10 weeks, this intake level is at least 74-fold higher than the 90th percentile daily estimated intake of 54 mg of shiitake mycelium from FPP

dietary consumption (§ 3.3). Therefore, MycoTechnology, Inc. concludes that similar adverse effects from FPP consumption are highly unlikely.

Nguyen et al. (2017) reported on the results of their review of published studies on the clinical features of shiitake dermatitis. They identified 50 total reported patient cases (38 males, 12 females; mean age: 44.58 years) of this "rare" cutaneous reaction and noted that "the majority" of cases resulted after consumption of raw mushrooms (93% of cases were associated with raw, lightly or undercooked mushrooms; Table 2). They further note that shiitake dermatitis "is self-limiting, resolving in approximately 12.5 d without treatment." Additional case reports of flagellate dermatitis after ingestion of shiitake mushrooms were reported by Balasuriya and Goel (2021), Browning et al. (2021), Gomez et al. (2021), Albuscheit et al. (2020), Heer et al. (2020), Mills and Walker (2020), Mulhall et al. (2020), and Ribeiro et al., (2019). Nguyen et al. (2017) postulated that a heat-labile beta-glucan in the cell walls of shiitake mushrooms (lentinan) may be responsible for the clinical dermatitis. Corazza et al., 2015 (cited in Nguyen et al., 2017) reported a presumed association between lentinan exposure and dermatitis by demonstrating a cutaneous response to the consumption of shiitake mushrooms cooked at 100 °C but not to those cooked at 150 °C. Since lentinan would be expected to degrade at 150 °C, heat processing of shiitake mycelia would seem likely to minimize shiitake dermatitis from FPP. As noted in section 2.2, the FPP manufacturing process is concluded with thermal deactivation (65°C for 60 minutes) and heat treatment (80°C for 1 minute) before spray drying step (air inlet 250 °C; powder outlet 75 °C), which should be sufficient to denature and deactivate lentinan. MycoTechnology, Inc. concludes that the rare cutaneous shiitake dermatitis effect is very unlikely to occur with FPP consumption due to heat treatment steps during the manufacturing process, as well as due to the low dietary exposure to shiitake mycelia in FPP (54 mg per day at the 90th percentile of intake).

Additional human clinical studies reporting shiitake dermatitis are summarized in Table 6.2.4.3-1. MycoTechnology, Inc. concludes that the rare cutaneous shiitake dermatitis effect is very unlikely to occur with FPP consumption due to heat treatment steps during the manufacturing process, as well as due to the low dietary exposure to shiitake mycelia in FPP (54 mg per day at the 90th percentile of intake).

Miyaji et al. (2004) reported on the *in vitro* genotoxic and antigenotoxic effects of aqueous extracts of shiitake mushroom using the Comet assay with Hep-2 cells at high concentrations (0.5, 1.0, and 1.5 mg/ml) and three temperatures (4°, 22° and 60°C). They reported a "low level" of genotoxic activity at all aqueous extract test concentrations prepared at 22 ± 2 and 60°C and two concentrations (1.0 and 1.5 mg/mL) of extract prepared at 4 °C using the *in vitro* Comet assay. Since cytotoxicity data was not reported for this test and the validation status of the performing laboratory is unknown, the results of this study are of limited reliability. The International Workshop on Genotoxicity Testing (IWGT) has repeatedly concluded that cytotoxicity could be a confounder of Comet assay results, adding that Comet assay results are more reliable if obtained in laboratories with demonstrated proficiency (IWGT, 2015). It should also be noted that a standardized and validated regulatory testing guideline for the *in vitro* Comet assay is not available and the OECD guideline for the *in vivo* mammalian alkaline comet assay did not exist until recently (i.e. OECD Testing Guideline 489; Adopted 29 July 2016). Therefore, Miyaji et al. (2004) predated a standardized and validated Comet assay protocol. Furthermore, the Comet assay is not among the standard battery of *in vitro* tests for genetic toxicity assessment of food ingredients or pharmaceuticals recommended by regulatory authorities (e.g. ICH S2(R1), 2011; EFSA, 2012; FDA, 2007).

The same investigators have reported the possible "antigenotoxicity" effects of shiitake mushroom extracts via modulation of micronuclei induction after treatment with alkylating agents *in vitro* or *in vivo*

(de Lima et al., 2001; Miyaji et al., 2006). These studies are of limited relevance to the current safety assessment.

In an Ames test performed prior to standardized testing guidelines or Good Laboratory Practice (GLP) regulations, a crude ethanol extract of *L. edodes* was reported to have mutagenic activity on tester strains TA100 and TA1535, which are sensitive to base-pair substitutions (von Wright et al., 1982). As neither statistical analysis nor cytotoxicity data were reported, the results of this study are limited Additionally, the crude ethanol extract used as the test article is not representative of t.he *L. edodes* mycelia used in the production of FPP. Based on this information, MycoTechnology, Inc. concludes that a genotoxic hazard is not likely to occur upon exposure to shiitake mycelia in FPP.

In its Scientific Opinion on the safety of "Lentinus edodes extract" (Lentinex®) as a Novel Food ingredient, the EFSA Panel on Dietetic Products, Nutrition and Allergies concluded that "owing to the fermentative production of the novel food ingredient [Lentinex®] from the mycelium and the final application of a heat-induced sterilization step, adverse effects reported after the consumption of the fruiting body of the shiitake mushroom are not considered relevant" (EFSA, 2010). MycoTechnology, Inc. similarly concludes that any adverse effects reported after the consumption of the fruiting body of the shiitake mushroom are not likely to occur upon exposure to low amounts (<0.1%) of heat-inactivated shiitake mycelia in FPP.

Table 6.2.4.3-1. Human Clinical Evidence of Shiitake Mushroom Dermatitis

Study Title (reference)	Study Design	Study Details	Results & Conclusions
Shiitake *(Lentinus edodes*) dermatitis (Nakamura, 1992).	Retrospective study (from 1974 to 1991) to examine 51 patients with shiitake dermatitis due to the intake of half-baked raw shiitake.	Shiitake dermatitis in 41 men and 10 women (15-76 years) was analyzed retrospectively. Dosage: varies and not reported.	All patients (n=51) had truncal involvement of shiitake dermatitis. Extremities, neck, face and head were involved in decreasing order of frequency. No patients had digestive or nervous system symptoms, nor were the mucous membranes affected. Conclusion: Shiitake dermatitis can be avoided by eating sufficiently boiled raw shiitake.
Flagellate dermatitis after consumption of shiitake Mushrooms. (Czarnecka et al, 2014).	Case report, investigated Flagellate dermatitis occurrence in patients who had eaten shiitake mushrooms.	A 55-year-old German patient (male) was diagnosed with Flagellate dermatitis after eating shiitake mushroom at a restaurant. Dosage: not reported.	Examination revealed severely-itching parallel, striped whiplash-like infiltrated erythema with severe itching on the trunk and upper extremities. In addition, there were papulovesicles on urticarial erythemas on the shoulders. Conclusion: Flagellate dermatitis could be avoided by eating adequately cooked shiitake mushrooms.
Flagellate mushroom (shiitake) dermatitis and photosensitivity. (Hanada, 1998).	Case report, investigated Flagellate skin lesions in a patient after eating the mushroom *Lentinus edodes.*	A 44-year-old man was diagnosed with Flagellate dermatitis after eating shiitake mushroom.	This patient was diagnosed with flagellate skin lesions on his trunk after eating *L. edodes*. The patient also developed photosensitive lesions on skin exposed to sunlight . Analysis of the case histories of 94 Japanese

Study Title (reference)	Study Design	Study Details	Results & Conclusions
			patients with shiitake dermatitis revealed that 44 (47%) cases developed dermatitis on the skin exposed to sunlight. Conclusion: Despite the high consumption of Shiitake mushrooms, the incidence of severe allergic reactions appears to be very low.
Systemic allergic contact dermatitis due to consumption of raw shiitake mushroom. (Kopp, 2009).	Case report, investigated the effect of raw shiitake mushroom (*Lentinus edodes*) on contact dermatitis.	A 52-year-old man who developed a generalized pruritic papulovesicular eruption 2 weeks after daily consumption of uncooked shiitake mushrooms. Prick-to-prick and scratch tests with uncooked mushrooms resulted in an eczematous reaction at 24 h that peaked at 72 h and persisted for 1 week.	This patient had systemic allergic contact dermatitis due to consumption of raw shiitake mushroom. Conclusion: Shiitake dermatitis could be avoided by eating adequately cooked or processed shiitake mushrooms.
Eosinophilia and gastrointestinal symptoms after ingestion of shiitake mushrooms. (Levy, 1998)	An open label, observational study; investigated whether ingestion of shiitake mushroom powder (freeze dried powder) induces eosinophilia or symptoms.	Dosage: Each capsule contained 250 mg of shiitake mushroom powder (freeze dried). 10 Subjects (9 men and 1 woman*, with an average age of 40.6 years, range of 31 – 63 years) ingested 4 grams (16 capsules = 4 medium sized mushrooms) of freeze dried shiitake powder daily for up to 10 weeks (trial 1) or 3 to 6 months (trial 2). *The woman was of child-bearing age and she was requested to use contraception to prevent pregnancy during the study.	Conclusion: At 4g per day of raw shiitake mushrooms some abdominal cramping and eosinophilia were reported.

6.2.5 Safety of Fungal Enzymes

The use of fungal enzymes to modify and improve food products is well established in the food industry. *Aspergillus*, a genus of filamentous fungus closely related to the filamentous fungus genus *Lentinula*, has been identified as a source of a number of enzymes used in industrial food processing applications, several of which are recognized as GRAS for use in food (Soares et al., 2012; FDA 2018a; FDA, 2018b). *L. edodes* is also known to secrete a number of these fungal enzymes with GRAS status, such as pectinase, cellulase, amylase, laminarinase (beta-glucanase), and xylanase (Mata et al., 2016; Soares et al., 2012). In particular, it is known that shiitake mycelia constitutively express laccases, and expression of laccases in shiitake mycelia may be upregulated or stimulated by the presence of lignin-derived phenols and/or polymeric lignin materials (Matjuškova et al., 2017). MycoTechnology concludes that there are no safety concerns associated with these enzymes commonly used for food processing that may be present during the manufacturing process for FPP.

Testing by MycoTechnology has confirmed the secretion of endogenous laccase during the manufacturing process for pea and rice protein fermented by shiitake mycelia, which is attributed to the improved organoleptic properties (via oxidation of volatile taste and aroma compounds) of the input pea and rice protein raw materials (see GRN 848). However, the manufacturing conditions used for concentration and spray-drying steps of the manufacturing process as described in section 2.2 are consistent with conditions that are known to denature and deactivate enzymes (i.e. the fermentation process is terminated at 65°C for 60 minutes followed by an evaporator/concentration step; a heat treatment step is carried out at 80°C for 1 minute, followed by spray drying (air inlet 250 °C; powder outlet 75 °C)). In GRN 848, testing for residual laccase enzyme activity in pea and rice protein fermented by shiitake mycelia after termination of fermentation was performed according to published methodology[2] and no residual laccase enzyme activity was detected (MycoTechnology; unpublished data on file). The production process for FPP is identical to pea and rice protein fermented by shiitake mycelia (less the input of rice protein as a primary raw material), therefore the result is applicable for FPP. From this information, MycoTechnology, Inc. concluded that any enzymes secreted by the shiitake mycelia during the manufacturing process are inactivated in the finished FPP product.

6.3 Allergenicity Assessment for FPP

MycoTechnology Inc. uses an allergen control program to ensure that the facility has evaluated processes and the premises to mitigate with proper use, storage and labeling any risk of allergen related food safety incidents. MycoTechnology Inc. also maintains a complete HACCP program including personnel training as it relates to allergens in its facility.

Although at least 170 foods have been reported to cause allergic reactions, there are only nine major food allergens – milk, egg, peanut, tree nuts, wheat, soy, sesame, fish and crustacean shellfish are responsible for most of the serious food allergy reactions in the US (FARE, n.d.; FDA CFSAN, 2022). It is estimated that up to 32 million Americans have food allergies, including 5.6 million children under the age of 18 (FARE, n.d.). Each year in the U.S., it is estimated that anaphylaxis to food results in 30,000 emergency room visits, 2,000 hospitalizations, and 150 deaths (USDA, 2019).

[2] https://www.sigmaaldrich.com/technical-documents/protocols/biology/enzymatic-assay-of-laccase.html

MycoTechnology, Inc. acknowledges that FPP does not contain any of the nine food allergens (milk, egg, fish, crustacean shellfish, tree nuts, peanuts, soybeans, wheat, sesame) considered to be major food allergens under the U.S. Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). On April 23, 2021, the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act was signed into law, declaring sesame as the 9th major food allergen recognized by the United States. For a more extensive review of potential allergens which may be present in FPP please refer to Table 6.3-1

FPP is primarily composed of pea protein. The following discussion is limited to the potential allergenicity of pea protein.

Peas are part of a family of plants called legumes, which also include alfalfa, clover, beans, lentils, mesquite, carob, soybeans, peanuts, tamarind, and wisteria (Grains & Legumes Nutrition Council, 2017). Allergenic response to legumes may range from mild skin reactions to life-threatening anaphylactic reactions (Verma, 2013). Legumes have been reported to be a cause of food allergies, especially peanut allergy (Sicherer, 1999). Peanuts and soybeans are the major legume allergies 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, 2004). Peanut and/or Tree Nut allergy affects approximately 1.1% of the general population, or about 3 million Americans (Sicherer, 1999). Legume cross-reactivity varies by region - while extensive cross-reactivity among lentil, chickpea and pea were reported in the Mediterranean area, only minimal cross-reactivity among legumes (mainly reported between peanut and soy) have been reported in North America (Abrams, 2015). The available information for allergenicity of pea proteins indicates that persons with peanut allergies may be sensitive to peas; however, allergic reactions to peas appear to be rare and may fluctuate among different populations. For example, Lavine and Ben-Shorshan (2019) described a Canadian pediatric case series in which 6 children presented with allergic reactions to foods that were confirmed to contain pea ingredients. Of the 6 patients, 4 had confirmed peanut allergy with either known clinical reactivity or with strongly reactive skin tests; 2 were able to eat peanuts and tree nuts freely. Pea protein allergy has not been extensively studied although the prevalence of allergy to pea protein in adults was reported to be identical to the prevalence of soy allergy according to FDA Food Safety Surveys (Messina and Venter, 2020). A search of the literature did not locate any additional information related to the prevalence of pea protein allergy in children. Additionally, it is expected that boiling or roasting decreases the IgE-binding capacity for legume allergens (Lavine and Ben-Shorshan, 2019); therefore, the heat treatment steps during the processing of FPP are also expected to decrease the potential for allergenicity of this ingredient.

The low anticipated allergenicity concern with pea protein in FPP can be mitigated by the listing of the common name of this product on a label, which is pea protein fermented by shiitake mycelia. Appropriate labelling by use of the common name of FPP does not hinder the safety and GRAS status that is the subject of this notification.

Table 6.3-1. Absence of Allergens in FPP

Component	Present in the product	Present in other products produced on the same line	Present in the same plant
1. Barley, Rye, Oats	NO	NO	NO
2. Celery (not including seeds)	NO	NO	NO
3. Corn	NO	NO	NO
4. Egg or egg product	NO	NO	NO
5. Fish	NO	NO	NO
6. Mille & Mille by-product	NO	NO	NO
7. Monosodium Glutamate (MSG)	NO	NO	NO
8. Peanuts or peanut products	NO	NO	NO
9. Seeds (Poppy, Sunflower, Cottonseed)	NO	NO	NO
10. Sesame Seeds	NO	NO	NO
11. Shell Fish & Crustaceans	NO	NO	NO
12. Soybean Oil (excluding refined soy oil)	NO	NO	NO
13. Soybean (not including oil)	NO	NO	NO
14. Sulphites (enter maximum ppm)	NO	NO	NO
15. Tree Nuts	NO	NO	NO
16. Wheat or wheat products	NO	NO	NO
17. Gluten <l O ppm	NO	NO	NO
18. Yellow 5 (Tartrazine)	NO	NO	NO
19. Animal Fat	NO	NO	NO
20. Grains containing gluten	NO	NO	NO
21. Mustard	NO	NO	NO
22. Lupin	NO	NO	NO
23. Lactose	NO	NO	NO

6.4 Safety Narrative Summary

Pea protein fermented by shiitake mycelia (FPP) is a product manufactured with fermentation technology composed of proven safe food ingredients with a long history of common use and regulatory acceptance in the worldwide food supply. MycoTechnology Inc. has determined the Generally Recognized as Safe (GRAS) status of FPP based on the following:

- FPP is manufactured within a British Retail Consortium (BRC) inspected facility under current Good Manufacturing Practices (cGMPs) and meets appropriate food grade specifications.
- The identity of FPP has been clearly defined and confirmed through scientific data and information.
- Pea protein, the main constituent of FPP, has been consumed for centuries through the consumption of peas and through the consumption of the protein products as affirmed GRAS (GRNs 581, 608, 788, 803, 804,851, and 948).
- All ingredients included in FPP, including shiitake mycelia, are concluded to be safe for use in food at inclusion levels and food categories proposed.
- No FPP raw materials are listed as major allergens according to Food Allergen Labeling and Consumer Protection Act of 2004 and Food Allergy Safety, Treatment, Education, and Research (FASTER) Act that expands the definition of major food allergen to include sesame.
- The fermentation organism used to produce FPP, *L. edodes* (shiitake mushroom), is commonly consumed as food and there are no identified hazards associated with the use of shiitake mycelia described herein.
- Following fermentation, the absence of live shiitake mycelia or fungal enzymes in the final FPP is achieved through multiple heat treatment steps and thermal deactivation.
- An estimated daily intake of FPP from intended uses was conservatively calculated for the U.S. population. In summary, the worst-case mean and 90th percentile intake of FPP for “all users” is estimated to be 22 g/person/day and 54 g/person/day, respectively.
- FPP will substitute for other protein sources in the diet, and thus will not increase the overall consumption of protein in the diet.
- The exaggerated, highly unrealistic protein consumption estimates from FPP at the 90th percentile of intake would not pose any human safety concern.
- The mean, but still exaggerated estimate of protein intake from FPP consumption is similar to or below current FDA and IOM recommendations for protein in the diet further supporting a conclusion of safety.
- The weight of evidence from reliable published toxicological and human clinical studies using the same or closely-related (e.g. Shitake mycelial extracts, reconstituted powdered shiitake mushroom) test materials as those components included in FPP support a conclusion that no adverse health effects are expected at dietary intake levels which are proposed for FPP.

6.5 Conclusion of the GRAS Panel

At the request of MycoTechnology, Inc., a panel of experts, (the "GRAS Panel"), qualified by their scientific training and relevant national and international experience to evaluate the safety of food ingredients, independently and collectively critically evaluated the information summarized in this GRAS dossier on the safety of the proposed uses of pea protein fermented by shiitake mycelia (FPP). The GRAS Panel also considered other published data and information deemed appropriate. The GRAS Panel consisted of Michael W. Pariza, Ph.D. (Chair), Joseph Borzelleca, Ph.D., and Madhusudan Soni, Ph.D.

Following its independent and collective critical evaluation of the available information, the GRAS Panel convened by telephone, summarized its findings, and unanimously concluded that the proposed uses of MycoTechnology's pea protein fermented by shiitake mycelia, produced consistent with current Good Manufacturing Practice (cGMP) and meeting the food ingredient specifications described herein, are safe and GRAS based on scientific procedures.

The GRAS Panel opined that other qualified experts would concur with these conclusions.

The signed opinion of the GRAS Panel is provided as Appendix A.

Part 7: §170.255 List of Supporting Data and Information

All the references used in this GRAS including animal and human studies are generally available and listed below.

2018_06_01_Penn_State_Mushroom_Culture_List.pdf | Powered by Box. Retrieved November 27, 2018, from https://psu.app.box.com/v/mushroom-spawn-cultures

Abrams, E. (2015). Allergy to cooked, but not raw, peas: A case series and review. *Allergy Asthma Clinical Immunology* 11(1):10

Agrawal, K., Chaturvedi, V., & Verma, P. (2018). Fungal laccase discovered but yet undiscovered. *Bioresources and Bioprocessing 5*(1). https://doi.org/10.1186/s40643-018-0190-z

Albuscheit, N., Riedemann, H., Aljehani, W.G., & Yazdi, A.S. (2020). Shiitake dermatitis: a type IV allergic hypersensitivity reaction to raw mushrooms. *Eur J Dermatol*. 30(3):316-317.

Aminuddin, H., Khan, A. M., & Madzlan, K. (2013). Effects of pH on mycelial growth and amino acid composition of *Lentinula edodes* in submerged cultures. *J. Trop. Agric. and Fd. Sc.* 41(1):63–70.

Aminuddin, H., Khan, A. M., Abidin, H., Madzlan, K., Suri, R., & Kamal, M. K. (2007). Optimization of submerged culture for the production of *Lentinula edodes* mycelia biomass and amino acid composition by different temperatures. *J. Trop. Agric. and Fd. Sc*. 35(1):131–138.

Balasuriya, A., Goel, A. (2021). Shiitake flagellate dermatitis (toxicoderma): A case report. *Natl Med J India* 34(3):161-162.

Bisen, P. S., Baghel, R. K., Sanodiya, B. S., Thakur, G. S., & Prasad, G. B. K. S. (2010). Lentinus edodes: A macrofungus with pharmacological activities. *Current Medicinal Chemistry*, *17*(22):2419–2430. https://doi.org/10.2174/092986710791698495

Browning, R.J., Fathi, R., Smith, M.A., & Alkousakis, T. (2021). Flagellate shiitake mushroom reaction with histologic features of acute generalized exanthematous pustulosis.
Cutis. 108(3):E8-E10.

Buttery, R.G., Turnbaugh, J.G., & Ling, L. C. (1988). Contribution of volatiles to rice aroma. *Journal of Agricultural and Food Chemistry 36*(5):1006–1009. https://doi.org/10.1021/jf00083a025

Clark, A.J., Soni, B.K., Sharkey, B., Acree, T., Lavin, E., Bailey, H.M., Stein, H.H., Han, A., Elie, M., & Nadal, M. (2022). Shiitake mycelium fermentation improves digestibility, nutritional value, flavor and functionality of plant proteins. *LWT - Food Science and Technology* 156:113065.

Camargo, I.F., Caetano, E.L.A., Pickler, T.B., Gerenutti, M., & Grotto, D. (2020). Shiitake culinary-medicinal mushroom, Lentinus edodes (Agaricomycetes): Absence of changes in maternal reproductive performance and embryofetal development in vivo. *Int J Med Mushrooms* 22(8):781-791.

Canadian Nutrient File, Food Code 6904, (Mushroom) https://food-nutrition.canada.ca/cnf-fce/serving-portion.do?id=6904

Cavallazzi, J.R.P., Kasuya, C.M., & Soares, M.A. (2005). Screening of inducers for laccase production by *Lentinula edodes* in liquid medium. *Brazilian Journal of Microbiology*, *36*(4):383-387. https://doi.org/10.1590/S1517-83822005000400015

Chen, S.N., Nan, F.H., Chen, S., Wu, J.F., Lu, C.L., & Soni, M.G. (2011). Safety assessment of mushroom β-glucan: subchronic toxicity in rodents and mutagenicity studies. *Food Chem Toxicol*. 49(11):2890-8.

Choi, J., Paik, D.J., Kwon, D.Y., & Park, Y. (2014). Dietary supplementation with rice bran fermented with *Lentinus edodes* increases interferon-γ activity without causing adverse effects: a randomized, double-blind, placebo-controlled, parallel-group study. *Nutrition Journal* 13:35.

Coates, P.M. (2010). *Encyclopedia of dietary supplements*. New York: Informa Healthcare.

Czarnecka, A.B., Kreft, B., & Marsch, W.C. (2014). Flagellate dermatitis after consumption of Shiitake mushrooms. *Postepy Dermatol Alergol*. 31(3):187-90.

Dai, X., Stanilka, J.M., Rowe, C.A., Esteves, E.A., Nieves, C., Spaiser, S.J., Christman, M.C., Langkamp-Henken, B., & Percival, S.S. (2015). Consuming *Lentinula edodes* (shiitake) mushrooms daily improves human immunity: a randomized dietary intervention in healthy young adults. *J Am Coll Nutr*, 34(6):478-87.

de Lima, P.L., Delmanto, R.D., Sugui, M.M., da Eira, A.F., Salvadori, D.M., Speit, G., Ribeiro, L.R. (2001). Letinula edodes (Berk.) Pegler (Shiitake) modulates genotoxic and mutagenic effects induced by alkylating agents in vivo. *Mutat Res*. 496(1-2):23-32.

EFSA (European Food Safety Authority). (2012). Guidance for submission for food additive evaluations. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). *EFSA Journal* 10(7):2760. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2760

EFSA (European Food Safety Authority). (2010). Scientific Opinion on the safety of "Lentinus edodes extract" (Lentinex®) as a Novel Food ingredient. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). *EFSA Journal* 8(7):1685.

FARE (Food Allergy Research and Education) (n.d.). Facts and Statistics. Retrieved November 23, 2017, from https://www.foodallergy.org/resources/facts-and-statistics

FDA CFSAN (FDA Center for Food Safety and Applied Nutrition). (2022). Consumers - Food Allergies: What You Need to Know. Page Last Updated: 02/17/2022: https://www.fda.gov/food/buy-store-serve-safe-food/food-allergies-what-you-need-know

FDA (U.S. Food and Drug Administration). (2006). *Guidance for Industry: Estimating Dietary Intake of Substances in Food.* Retrieved from U.S. Food and Drug Administration. https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm074725.htm

FDA (U.S. Food and Drug Administration). (2007). Toxicological Principles for the Safety Assessment of Food Ingredients. *Redbook 2000*. Chapter IV.C.1. Short-Term Tests for Genetic Toxicity. https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm078321.htm

FDA (U.S. Food and Drug Administration). (2016). Nutrition labeling of food. U.S. Code of Federal Regulations, Title 21, Section 101.9. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=101.9

FDA (U.S. Food and Drug Administration). (2015). *GRN No. 575* . Retrieved from GRAS Notices: https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=575&sort=GRN_No&order=DESC&startrow=1&type=basic&search=575

FDA (U.S. Food & Drug Administration). (2016, January 25). *GRN No. 581* . Retrieved from GRAS Notices: https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=581

FDA (U.S. Food & Drug Administration). (2016, June 6). *GRN No. 609.* Retrieved from GRAS Notices: https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=609

FDA (U.S. Food & Drug Administration). (2016, May 27). *GRN No. 608.* Retrieved from GRAS Notices: https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=608

FDA (U.S. Food and Drug Administration). (2015, May 10). *GRN No. 683* . Retrieved from GRAS Notices: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=683&sort=GRN_No&order=DESC&startrow=1&type=basic&search=683

FDA (U.S. Food & Drug Administration). (2018, October 12). *GRN No. 788.* Retrieved from GRAS Notices: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=788&sort=GRN_No&order=DESC&startrow=1&type=basic&search=pea%20protein

FDA (U.S. Food & Drug Administration). (2019, November 8). *GRN No. 804.* Retrieved from GRAS Notices: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=804&sort=GRN_No&order=DESC&startrow=1&type=basic&search=pea%20protein

FDA (U.S. Food & Drug Administration). (2020, April 15). *GRN No. 851.* Retrieved from GRAS Notices: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=851&sort=GRN_No&order=DESC&startrow=1&type=basic&search=pea%20protein

FDA (U.S. Food & Drug Administration). (2021, September 9). *GRN No. 948.* Retrieved from GRAS Notices: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=948&sort=GRN_No&order=DESC&startrow=1&type=basic&search=948

FDA (U.S. Food and Drug Administration). (2018a). Enzyme Preparations Used in Food (Partial List). Page Last Updated: 01/04/2018. https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/EnzymePreparations/default.htm

FDA (U.S. Food and Drug Administration). (2018b). FDA GRAS Notice Inventory. Page Last Updated: 09/26/2018.
https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm

Finimundy, T. (2014). A review on general nutritional compounds and pharmacological properties of the *Lentinula edodes* mushroom. *Food and Nutrition Sciences* 5:1095-1105.

Food Allergen Labeling and Consumer Protection Act of 2004. 21 USC 301.

Frizo, Í., Pickler, T. B., Grotto, D., & Gerenutti, M. (2014). Alterations in the reproductive performance of the female rats and fetotoxicity of *Lentinula edodes* (Shiitake). *Reproductive Toxicology* 48:25. https://doi.org/10.1016/j.reprotox.2014.07.034

Gomez, J., Sharma, K., Huho, A., & Gregory, N. (2021). A case of shiitake dermatitis in the United States. Oxf Med Case Reports. 2021(8):omab071.

Grains & Legumes Nutrition Council. (2017). *Types of Legumes*. Retrieved from Grains & Legumes Nutrition Council: http://www.glnc.org.au/legumes/types-of-legumes/

Grotto, D., Bueno, D.C., Ramos, G.K., da Costa, S.R., Spim, S.R., and Gerenutti, M. (2016). Assessment of the safety of the shiitake culinary-medicinal mushroom, Lentinus edodes (Agaricomycetes), in rats: biochemical, hematological, and antioxidative parameters. *Int J Med Mushrooms* 18(10):861-870.

Han, Z., Feng, Z., Shi, W., Zhao, Z., Wu, Y., & Wu, A. (2014). A quick, easy, cheap, effective, rugged, and safe sample pretreatment and liquid chromatography with tandem mass spectrometry method for the simultaneous quantification of 33 mycotoxins in Lentinula edodes. *Journal of Separation Science* 37(15):1957–1966. https://doi.org/10.1002/jssc.201400329

Hanada, K. & Hashimoto, I. (1998). Flagellate mushroom (Shiitake) dermatitis and photosensitivity. *Dermatology* 197:255-257.

Heer, R.S., Patel, N.B., Mandal, A.K.J., Lewis, F., & Missouris, C.G. (2020). Not a fungi to be with: Shiitake mushroom flagellate dermatitis. *Am J Emerg Med*. 38(2):412.e1-412.e2.

ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use). (2011). ICH Harmonised Tripartite Guideline Guidance on Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use; S2(R1). Current Step 4 version dated 9 November 2011.
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Safety/S2_R1/Step4/S2R1_Step4.pdf

IOM (Institute of Medicine). (2005). Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids. Washington, DC: The National Academies Press. https://doi.org/10.17226/10490.

Kopp, T., Mastan, P., Mothes, N., Tzaneva, S., Stingl, G., & Tanew, A. (2009). Systemic allergic contact dermatitis due to consumption of raw shiitake mushroom. *Clinical and Experimental Dermatology*, 34:e910-913.

Lavine, E., Ben-Shoshan, M. (2019). Anaphylaxis to hidden pea protein: A Canadian pediatric case series. J Allergy Clin Immunol Pract. 7(6):2070-2071.

Levy, A.M., Kita, H., Phillips, S.F., Schkade, P.A., Dyer, P.D., Gleich, G.J., & Dubravec, V.A. (1998). Eosinophilia and gastrointestinal symptoms after ingestion of shiitake mushrooms. *Journal of Allergy and Clinical Immunology*, 101:613-620.

Liu, S.-R., Zhang, W.-R., Chen, A.-P., & Kuang, Y.-B. (2016). Investigating the effect of tissue size on mycelial growth of seven mushroom species by using a novel device for precise tissue isolation. *Indian Journal of Microbiology* 56(4):516–521. https://doi.org/10.1007/s12088-016-0615-3

Mata, G., Salmones, D., & Pérez-Merlo, R. (2016). Hydrolytic enzyme activities in Shiitake mushroom (Lentinula edodes) strains cultivated on coffee pulp. *Revista Argentina de Microbiología 48*(3):191–195. https://doi.org/10.1016/j.ram.2016.05.008

Matjuškova, N., Okmane, L., Zaļā, D., Rozenfelde, L., Puķe, M., Krūma, I., Vederņikovs, N. & Rapoport, A. (2017). Effect of lignin-containing media on growth of medicinal mushroom lentinula edodes. *Proceedings of the Latvian Academy of Sciences. Section B. Natural, Exact, and Applied Sciences 71*(1–2):38–42. https://doi.org/10.1515/prolas-2017-0007

Messina, M., Venter, C. (2020). Recent surveys on food allergy prevalence. *Nutrition Today* 55(1):22-29.

Mills, H., Walker, S.L. (2020). Shiitake Mushroom Dermatitis in a Returning Traveler. *Am J Trop Med Hyg*. 102(2):483.

Miyaji, C., Jordão, B., Ribeiro, L., Eira, A., & Cólus, I. (2004). Genotoxicity and antigenotoxicity assessment of Shiitake (*Lentinula edodes* (Berkeley) Pegler) using the Comet assay. *Genetics and Molecular Biology*, *27*(1):108–114. https://doi.org/10.1590/S1415-47572004000100018

Miyaji, C.K., Poersch, A., Ribeiro, L.R., Eira, A.F., & Cólus, I.M. (2006). Shiitake (*Lentinula edodes* (Berkeley) Pegler) extracts as a modulator of micronuclei induced in HEp-2 cells. *Toxicol In Vitro*. 20(8):1555-9.

Mulhall, J., Elseth, A., Perdue, J., Pomerantz, H., Brown, B., & Frasca, D. (2020). Flagellate dermatitis after ingestion of shiitake mushrooms in a healthy female living in the Southeastern United States. J Emerg Med. 59(1):e13-e15.

Nagashima, Y., Maeda, N., Yamamoto, S., Yoshino, S., & Oka, M. (2013). Evaluation of host quality of life and immune function in breast cancer patients treated with combination of adjuvant chemotherapy and oral administration of *Lentinula edodes* mycelia extract. *Onco Targets Ther*. 6:853-9.

Nagashima, Y., Yoshino, S., Yamamoto, S., Maeda, N., Azumi, T., Komoike, Y., Okuno, K., Iwasa, T., Tsurutani, J., Nakagawa, K., Masaaki, O., & Hiroaki, N. (2017). *Lentinula edodes* mycelia extract plus adjuvant chemotherapy for breast cancer patients: Results of a randomized study on host quality of life and immune function improvement. *Mol Clin Oncol.* 7(3):359-366.

Nakamura T. (1992). Shiitake (*Lentinus edodes*) dermatitis. *Contact Dermatitis* 27:65-70.

Nguyen, A.H., Gonzaga, M.I., Lim, V.M., Adler, M.J., Mitkov, M.V., & Cappel, M.A. (2017). Clinical features of Shiitake dermatitis: a systematic review. *International Journal of Dermatology 56*(6):610–616. https://doi.org/10.1111/ijd.13433

Nieminen, P., Kärjä, V., & Mustonen, A.M. (2009). Myo- and hepatotoxic effects of cultivated mushrooms in mice. Food Chem Toxicol. 47(1):70-74.

Okuno, K. & Uno, K. (2011). Efficacy of orally administered *Lentinula edodes* mycelia extract for advanced gastrointestinal cancer patients undergoing cancer chemotherapy: a pilot study. *Asian Pacific Journal of Cancer Prevention* 12:1671-16764.

Osma, J.F., Toca-Herrera, J.L., & Rodríguez-Couto, S. (2010). Uses of laccases in the food industry. *Enzyme Research*, vol. 2010, Article ID 918761, pp. 1–8. https://doi.org/10.4061/2010/918761

Przybylowicz, P., & Donoghue, J. (1988). *Shiitake growers handbook: the art and science of mushroom cultivation*. Dubuque, Iowa: Kendall/Hunt Pub. Co.

Rackis, J.J., Sessa, D.J., & Honig, D.H. (1979). Flavor problems of vegetable food proteins. *Journal of the American Oil Chemists' Society*, *56*(3Part2):262–271. https://doi.org/10.1007/BF02671470

Ribeiro, C.S., Sodré, C.T., & Ramos-E-Silva, M. (2019). Flagellate dermatitis by shiitake mushroom. *Case Rep Dermatol*. 11(2):220-225.

Sanchez-Monge, L.-T. G.-E. (2004). Vicilin and convicilin are potential major allergens from pea. *Clin Exp Allergy* 34(11):1747-1753.

Schindler, S., Zelena, K., Krings, U., Bez, J., Eisner, P., & Berger, R. G. (2012). Improvement of the aroma of pea (*Pisum sativum*) protein extracts by lactic acid fermentation. *Food Biotechnology 26*(1):58–74. https://doi.org/10.1080/08905436.2011.645939

Schroeder, M., Pöllinger-Zierler, B., Aichernig, N., Siegmund, B., & Guebitz, G. M. (2008). Enzymatic removal of off-flavors from apple juice. *Journal of Agricultural and Food Chemistry 56*(7):2485–2489. https://doi.org/10.1021/jf073303m

Sessa, D.J. & Rackis, J.J. (1977). Lipid-derived flavors of legume protein products. *Journal of the American Oil Chemists' Society* 54(10):468-473.

Shiitake Mycelia Extract-V. Label Information of the Dietary Supplement Label Database (DSLD). (2012) (2012) Retrieved November 27, 2018, from https://www.dsld.nlm.nih.gov/dsld/docs/9753.pdf

Sicherer SH, M.-F. A. (1999). Prevalence of peanut and tree nut allergy in the US determined by a random digit dial telephone survey. *J Allergy Clin Immunol* 103(4):559-562.

Soares, I., Távora, Z., Barcelos, R. P., & Baroni, S. (2012). Microorganism-Produced Enzymes in the Food Industry. In: Scientific, Health and Social Aspects of the Food Industry. Valdez, B. (Ed.). https://doi.org/10.5772/31256

Song, H.-Y., Kim, D.-H., & Kim, J.-M. (2018). Comparative transcriptome analysis of dikaryotic mycelia and mature fruiting bodies in the edible mushroom Lentinula edodes. *Scientific Reports 8*(1):8983. https://doi.org/10.1038/s41598-018-27318-z

Stamets, P., & Chilton, J. S. (1983). *The mushroom cultivator: a practical guide to growing mushrooms at home*. Olympia, Wash. : Seattle, Wa: Agarikon Press ; Western distribution by Homestead Book Co.

Suzuki, N. et al. (2013). Efficacy of oral administration of Lentinula eododes mycelia extract for breast cancer patients undergoing postoperative hormone therapy. *Asian Pacific Journal Cancer Prevention* 14(6):3469-72.

Tsivilev, O.M., Pankratov, A.N., Nikitina, V.E., & Garibova, L.V. (2005). Effect of media components on the mycelial film formation in submerged culture of Lentinus edodes (Shiitake). *Food Technology and Biotechnology* 43(3):227–234.

USDA (United States Department of Agriculture). (2019). AskUSDA. https://ask.usda.gov/s/article/How-many-Americans-have-food-allergies

USDA (United States Department of Agriculture). (2018). National Nutrient Database for Standard Reference Legacy Release, April 2018. 16085, Peas, green, split, mature seeds, raw. USDA Agricultural Research Service. https://ndb.nal.usda.gov/ndb/search/list?home=true

USDA (United States Department of Agriculture). (1998). *Food and Nutrient Intakes by Children 1994-96, 1998 - USDA ARS.* Retrieved from Agricultural Resarch Service: https://www.google.ca/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&ved=0ahUKEwj6jZfCztbVAhWLxYMKHbDrAgoQFggxMAI&url=https%3A%2F%2Fwww.ars.usda.gov%2FARSUserFiles%2F80400530%2Fpdf%2Fscs_all.pdf&usg=AFQjCNFTvThLTw4P7oidy2gAOKHJUPUj2w

USDA (United States Department of Agriculture). (2022). FoodData Central. https://fdc.nal.usda.gov/fdc-app.html#/?query=shiitake

Van der Molen, K. M., Little, J. G., Sica, V. P., El-Elimat, T., Raja, H. A., Oberlies, N. H., & Mahony, C. (2017). Safety assessment of mushrooms in dietary supplements by combining analytical data with in silico toxicology evaluation. *Food and Chemical Toxicology 103*:133–147. https://doi.org/10.1016/j.fct.2017.03.005

Verma, A.K., Kumar, S., Das, M. & Dwivedi, P.D. (2013). A comprehensive review of legume allergy. *Clinical Review Allergy Immunology* 45(1):30-46.

von Wright, A., Knuutinen, J., Lindroth, S., Pellinen, M., Widén, K.G., Seppä, E.L. (1982). The mutagenicity of some edible mushrooms in the Ames test. *Food Chem Toxicol.* 20(3):265-7.

Yamaguchi, Y., Miyahara, E., & Hihara, J. (2011). Efficacy and safety of orally administered *Lentinula edodes* mycelia extract for patients undergoing cancer chemotherapy: a pilot study. *Am J Chin Med*. 39(3):451-459.

Yoshikawa, K., Libbey, L. M., Cobb, W. Y., & Day, E. A. (1965). 1-Pyrroline: The odor component of Strecker-degraded proline and ornithine. *Journal of Food Science 30*(6):991–994. https://doi.org/10.1111/j.1365-2621.1965.tb01875.x

Yoshioka, Y., Tamesada, M., & Nagayama, A. (2009). The safety of excessive intake of the food containing extract of cultured *Lentinula edodes* Mycelia (L.E.M.) in healthy adult volunteers. *Japanese Journal of Complementary and Alternative Medicine* 6(1):9-15.

Yoshioka, Y., Tamesada, M., & Tomi, H. (2010). A repeated dose 28-day oral toxicity study of extract from cultured *Lentinula edodes* mycelia in Wistar rats. *J Toxicol Sci.* 35(5):785-91.

Appendix A GRAS Panel Consensus Statement

GRAS Panel Statement on the Generally Recognized As Safe (GRAS) Conclusion for the Proposed Uses of Pea Protein Fermented by Shiitake Mycelia

May 24, 2022

MycoTechnology, Inc. intends to market pea protein fermented by shiitake mycelia (i.e. FermentIQ™ pea protein, FPP) as a protein source, formulation aid and texturizer in conventional foods. A panel of independent experts (the "GRAS Panel"), qualified by their scientific training and relevant national and international experience to evaluate the safety of food ingredients, was convened to conduct an independent, critical and comprehensive evaluation of the available technical and safety information on FPP, and to determine if the proposed use of FPP as a nutritional food ingredient is safe and suitable and can be considered Generally Recognized As Safe (GRAS) based on scientific procedures in accordance with 21CFR§170.30(a) and (b). The GRAS Panel consisted of Professor Michael W. Pariza, Ph.D., chair, Madhusudan Soni, Ph.D., and Professor Joseph F. Borzelleca, Ph.D.

A technical dossier, "*GRAS Notice for Pea Protein Fermented by Shiitake Mycelia*" (issued 29 April 2022; revised 19 May 2022), was prepared on behalf of MycoTechnology, Inc. and made available to the GRAS Panel. This dossier contains data and information on the characterization, method of manufacture, product specifications, composition and stability, analytical testing, proposed levels of use, consumer exposure estimates, and safety assessment of FPP raw materials (including pea protein as the primary protein raw material, shiitake mushroom mycelia as the fermentation organism, and other safe and suitable raw materials and processing aids). This dossier further describes that FPP is substantially similar to pea and rice protein fermented by shiitake mycelia (GRN 848), using the same strain and through an equivalent manufacturing process, with pea protein as the primary protein raw material. The GRAS Panel, independently and collectively, critically evaluated this document and other published information deemed appropriate, and convened by telephone on 11 May 2022.

Following their critical evaluation, the GRAS Panel unanimously concluded that the proposed use of pea protein fermented by shiitake mycelia (FPP) as a nutritional food ingredient, manufactured consistent with current Good Manufacturing Practice (cGMP) and meeting appropriate food-grade specifications as described in technical dossier, is safe and suitable and GRAS based on scientific procedures. The GRAS Panel unanimously opined that other qualified scientists reviewing the same body of information would concur with these conclusions.

Conclusion

We, the independent qualified members of the GRAS Panel, have individually and collectively critically evaluated the data and information summarized in the technical dossier, "*GRAS Notice for Pea Protein Fermented by Shiitake Mycelia*" and other published data and information that we deemed pertinent to the safety of the proposed use of pea protein fermented by shiitake mycelia. We unanimously conclude that the proposed use of pea protein fermented by shiitake mycelia as a nutritional food ingredient, produced consistent with current Good Manufacturing Practice (cGMP) and meeting appropriate food grade specifications, is safe and suitable and Generally Recognized As Safe (GRAS) based on scientific procedures.

It is our opinion that other qualified experts would concur with these conclusions.

[redacted]

Michael W. Pariza, Ph.D., Chair
Professor Emeritus, University of Wisconsin

24 May 2022
Date

[redacted]

Joseph F. Borzelleca, Ph.D.
Professor Emeritus, Virginia Commonwealth School of Medicine

24 May 2022
Date

[redacted]

Madhusudan Soni, Ph.D.
President, Soni & Associates, Inc.

May 24, 2022
Date

Appendix B Measurement of Viable Mycelium in FPP

Measurement of Viable Mycelium in FermentIQ™ Protein Powder PEA

FINAL REPORT

Objective

To demonstrate there is no viable *Lentinula edodes* mycelium in final FermentIQ Protein Powder PEA (FPP).

Summary

The purpose of this test is to ensure that the commercialized product does not contain viable shiitake mycelium. FPP was obtained from the stock 15 kg bags (commercial product size). A total of 4 independent FPP lots were tested in triplicates. For each lot, one gram of sample was analyzed by plating in two different shiitake solid growing media (plates); for each medium 3 technical replicates were considered. Sterile water was also used to ensure the quality and sterility of the plates. Blended shiitake mycelium was added as a positive control to ensure that mycelium would grow on the selected media.

Test Material

All the tested samples are listed in Table 1. Samples included 4 lots of FPP commercial final product. A negative control (1ml of sterile water inoculated in each medium plate) was included to show sterility of the medium plates. To ensure that the 2 different media (PDA and YMPGA+AKS) and cultivation conditions enable growth of any possible viable shiitake mycelium remaining in the product, a positive control consisting of blended shiitake mycelium was plated in clean PDA and MYPG plates. All samples were tested in triplicate by plating 1g of the corresponding sample onto Potato Dextrose Agar (PDA) and Malt Yeast Peptone Glucose Agar (MYPG+AKS) media (Table 2 and 3, respectively). To avoid bacterial contamination in the very nutrient rich MYPG+AKS plates, an antibiotic solution was added (See table 3). These included ampicillin disodium salt (100mg/ml), kanamycin (50mg/ml), and spectinomycin (50mg/ml). All samples tested were divided into three samples/lot or control making a total of 18 samples for the entire assay.

Table 1. Description of samples

Test Products	Lot Numbers	Sample size (g)	Number of Replicates Tested
FermentIQ Protein Powder PEA	101646	1	3
FermentIQ Protein Powder PEA	101355	1	3
FermentIQ Protein Powder PEA	101602	1	3
FermentIQ Protein Powder PEA	101905	1	3
Negative Control	Sterile H_2O	1	3
Positive Control	Blended shiitake mycelium flask	1	3

Table 2. Composition of PDA medium.

Ingredient	Chemical Formula	Amount/L	Final Concentration
Potato Infusion Powder	Not applicable	4.0 g	0.4% (w/v)
D-Glucose	C6H12O6	20.0 g	2.0% (w/v)
Potassium Phosphate Monobasic	KH2PO4	3.0 g	0.3% (w/v)
Magnesium Sulfate Heptahydrate	MgSO4·7H2O	1.0 g	0.1% (w/v)
Agar	Not applicable	15.0 g	1.5% (w/v)
Water	H2O	Bring to volume 1 L	

Table 3. Composition of MYPG+AKS medium.

Ingredient	Chemical Formula	Amount/L	Final Concentration
Malt Extract	Not applicable	10.0 g	1.0% (w/v)
Yeast Extract	Not applicable	4.0 g	0.4% (w/v)
Peptone	Not applicable	1.0 g	0.1% (w/v)
D-Glucose	$C_6H_{12}O_6$	4.0 g	0.4% (w/v)
Agar	Not applicable	15.0 g	1.5% (w/v)
Ampicillin Disodium Salt	Not applicable	0.1 g	0.01% (w/v)
Kanamycin	Not applicable	0.05 g	0.005% (w/v)
Spectinomycin	Not applicable	0.05 g	0.005% (w/v)
Water	H2O	Bring to volume 1 L	

Methods:

Incubation: One gram of each sample was loaded onto prelabeled 15 x 100mm MYPG (define) and PDA plates and distributed evenly (FDA BAM). Samples were incubated in a 26°C incubator, in the dark and left undisturbed for 7 days.

Plate counting: Mycelia growth will present as small white colonies atop of the agar. This can be used to quantify any viable mycelium or contamination left in the commercialized final product.

Results:

Results showed that there was no fungal/mycelia growth in any of the sample plates at the end of the 7-day incubation period. There were no colonies counted. Fungal/mycelia growth was observed in the positive control plates that contained shiitake mycelium as expected. Results for all samples are shown in Table 4.

Table 4. Growth Results

Sample Lot	MYPGA+AKS Replicate 1	MYPGA+AKS Replicate 2	MYPGA+AKS Replicate 3	PDA Replicate 1	PDA Replicate 2	PDA Replicate 3
101646	ND	ND	ND	ND	ND	ND
101355	ND	ND	ND	ND	ND	ND
101602	ND	ND	ND	ND	ND	ND
101905	ND	ND	ND	ND	ND	ND
Negative Control (Sterile H_2O)	ND	ND	ND	ND	ND	ND
Positive Control Blended shiitake flask	D	D	D	D	D	D

*ND- No mycelial growth detected.
D- Mycelial growth detected.

Megan McMaster, MSc. Laboratory Manager
Name of investigator: Title

[redacted]

03/07/2022
Date

Reference:
FDA BAM Chapter 18, Yeasts, Molds, and Mycotoxins

Appendix C Intake Assessment for FPP

ESTIMATED DAILY INTAKE OF FERMENTIQ PEA PROTEIN THE U.S. POPULATION FROM PROPOSED FOOD USES (2017-2018 NHANES)

MycoTechnology, Inc.
18250 E 40th Avenue
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USA 80011

DATE:
24 March 2022

Estimated Daily Intake of FermentIQ Pea Protein by the U.S. Population from Proposed Food Uses (2017-2018 NHANES)

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Estimated Daily Intake of FermentIQ Pea Protein by the U.S. Population from Proposed Food Uses (2017-2018 NHANES)

1.0 INTRODUCTION

FermentIQ Pea Protein is proposed for use in the United States (U.S.) in foods, such as baked goods and baking mixes, beverages and beverage bases, breakfast cereals, coffee and tea, dairy product analogues, grain products, milk products, nut and nut products, plant protein products, snack foods, and soups and soup mixes.

Estimates for the intake of FermentIQ Pea Protein were based on the proposed food uses and use levels for FermentIQ Pea Protein in conjunction with food consumption data included in the U.S. National Center for Health Statistics' National Health and Nutrition Examination Surveys (NHANES) 2017-2018. Calculations for the mean and 90th percentile *per capita* and consumer-only intakes were performed for all proposed food uses of FermentIQ Pea Protein and the percentage of consumers was determined. Similar calculations were used to estimate the intake of FermentIQ Pea Protein resulting from each individual proposed food use, including the calculations of percent consumers. In both cases, the per person and per kilogram body weight intakes were reported for the following population groups:

- Children, ages 2 to 5 years;
- Children, ages 6 to 11 years;
- Female teenagers, ages 12 to 19 years;
- Male teenagers, ages 12 to 19 years;
- Female adults, ages 20 years and older;
- Male adults, ages 20 years and older; and
- Total population (ages 2 years and older, and both gender groups combined).

2.0 FOOD CONSUMPTION SURVEY DATA

2.1 Survey Description

NHANES for the years 2017-2018 are available for public use (USDA, 2021a,b; CDC, 2022a,b). NHANES are conducted as continuous, annual surveys, and they are released in 2-year cycles. During each year of the ongoing NHANES program, individuals from the U.S. are sampled from up to 30 different study locations in a complex multi-stage probability design intended to ensure the data are a nationally representative sample of the U.S. population.

NHANES 2017-2018 dietary survey data were collected from individuals and households *via* 24-hour dietary recalls administered on 2 non-consecutive days (Day 1 and Day 2) throughout all 4 seasons of the year. Day 1 data were collected in-person, and Day 2 data were collected by telephone in the following 3 to 10 days, on different days of the week, to achieve the desired degree of statistical independence. The data were collected by first selecting primary sampling units (PSUs), which were counties throughout the U.S., of which 30 PSUs are visited per year. Smaller contiguous counties were combined to attain a minimum population size. These PSUs were segmented, and households were chosen within each segment. One or more participants within a household were interviewed. For NHANES 2017-2018, 16,211 individuals were selected for the sample, 9,254 were interviewed (51.9%), and 8,704 were examined (48.8%).

In addition to collecting information on the types and quantities of foods being consumed, NHANES 2017-2018 collected socio-economic, physiological, and demographic information from individual participants in the survey, such as sex, age, body weight, and other variables (such as height and race-ethnicity) that may be useful in characterizing consumption. The inclusion of this information allows for further assessment of food intake based on consumption by specific population groups of interest within the total population. The primary sample design for NHANES 2017-2018 includes an oversample of non-Hispanic Asian persons, Hispanic persons, non-Hispanic black persons, non-Hispanic white and "other" older persons (≥80 years), and non-Hispanic low-income white and "others" persons (≤185% of the Department of Health and Human Services poverty guidelines); however, sample weights were incorporated to allow estimates from these subgroups to be combined to obtain national estimates that reflect the relative proportions of these groups in the population as a whole (USDA, 2021a,b; CDC, 2022a,b).

2.2 Statistical Methods

For the intake assessment, consumption data from individual dietary records, detailing food items ingested by each survey participant, were collated by computer and used to generate estimates for the intake of FermentIQ Pea Protein by the U.S. population[1]. Estimates for the daily intake of FermentIQ Pea Protein represent projected 2-day averages for each individual from Day 1 and Day 2 of NHANES 2017-2018 (*i.e.*, a value was established for each person). From these average amounts, a distribution was established from which the mean and percentile intake estimates for the cohort of interest were determined, which incorporated survey weights in order to provide representative intakes for the entire U.S. population. "*Per capita*" intake refers to the estimated intake of FermentIQ Pea Protein averaged over all individuals surveyed, regardless of whether they consumed food products in which FermentIQ Pea Protein is proposed for use, and therefore includes individuals with "zero" intakes (*i.e.*, including individuals who reported no intake of food products containing FermentIQ Pea Protein during the 2 survey days). "Consumer-only" intake refers to the estimated intake of FermentIQ Pea Protein by only those individuals who reported consuming food products of interest on either Day 1 or Day 2 of the survey.

Mean and 90th percentile intake estimates based on sample sizes of less than 30 and 80, respectively, may not be considered statistically reliable due to the limited sampling size (CDC, 2013). As such, the reliability of estimates for the intake of FermentIQ Pea Protein based on consumption estimates derived from individual population groups of a limited sample size should be interpreted with caution. These values are marked with an asterisk in the relevant data tables.

3.0 FOOD USAGE DATA

The proposed food uses and use levels for FermentIQ Pea Protein employed in the current intake analysis are summarized in Table 3-1. Food codes representative of each proposed food use were chosen from the NHANES 2017-2018 (CDC, 2022b). Food codes were grouped in food use categories according to Title 21, Section §170.3 of the *Code of Federal Regulations* (U.S. FDA, 2021). If necessary, product-specific adjustment factors were developed for composite foods/mixtures based on data provided in the Food and Nutrient Database for Dietary Studies (USDA ARS, 2021a,b) or the Food Commodity Intake Database (U.S. EPA & USDA, 2022). All food codes included in the current intake assessment are listed in Appendix C.

[1] Statistical analysis and data management were conducted in DaDiet Software (Dazult Ltd., 2018). DaDiet Software is a web-based software tool that allows accurate estimate of exposure to nutrients and to substances added to foods, including contaminants, food additives and novel ingredients. The main input components are concentration (use level) data and food consumption data. Data sets are combined in the software to provide accurate and efficient exposure assessments.

Table 3-1 Summary of the Individual Proposed Food Uses and Use Levels for FermentIQ Pea Protein in the U.S.

Food Category (21 CFR §170.3) (U.S. FDA, 2021)	Food Uses[a]	FermentIQ Pea Protein Use Levels (%)	FermentIQ Pea Protein, on Protein Basis[b] (g protein/100 g of food as consumed)
Baked Goods and Baking Mixes	Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	5	4.0
	Crackers	5	4.0
	Biscuits; Cookies	10	7.9
	French Toast, Pancakes, and Waffles	10	7.9
	Bread (high protein)	15	11.9
Beverages and Beverage Bases	Non-Milk Meal Replacements and Protein Drinks	40	31.7
Breakfast Cereals	Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	15	11.9
	Ready-To-Eat Cereals	15	11.9
Coffee and Tea	Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	10	7.9
	Ready-To-Drink Tea Beverages; Instant Tea	10	7.9
Dairy Product Analogues	Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	10	7.9
	Cream Cheese Substitute[d]	12	9.5
	Non-Dairy Frozen Desserts	10	7.9
	Non-Dairy Dips (includes imitation sour cream)	10	7.9
	Non-Dairy Yogurt	25	19.8
	Imitation Cheese	25	19.8
Grain Products and Pastas	Cereal Bars, Nutritional Bars, and Meal Replacement Bars	20	15.9
Milk Products	Milk-Based Meal Replacements and Protein Drinks	15	11.9
Nut and Nut Products	Nut Butters and Spread	10	7.9
Plant Protein Products	Meat Analogs and Substitutes	30	23.8
	Butter and Spread Alternative	12	9.5
Snack Foods	Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	4	3.2
Soups and Soup Mixes	Soups and Soup Mixes	5	4.0

CFR = *Code of Federal Regulations*; U.S. = United States.

[a] FermentIQ Pea Protein is intended for use in unstandardized products when standards of identity, as established under 21 CFR §130 to 169, do not permit its addition.

[b] Calculation: (FermentIQ Pea Protein use level)*(Maximum protein content, 79.31%).

[c] Includes ready-to-drink and powdered forms.

[d] Food codes for were not available; therefore, food codes for the conventional product were used as surrogates.

4.0 FOOD SURVEY RESULTS

Estimates for the total daily intakes of FermentIQ Pea Protein from proposed food uses are provided in Section 4.1. Estimates for the daily intake of protein from FermentIQ Pea Protein are summarized in

Section 4.2. Estimates for the daily intake of FermentIQ Pea Protein from individual proposed food uses in the U.S. are summarized in Section 4.3 and presented in Tables A-1 to A-7 and B-1 to B-7 of Appendices A and B, respectively.

The percentage of consumers was high among all age groups evaluated in the current intake assessment; more than 96.5% of the population groups consisted of consumers of food products in which FermentIQ Pea Protein is currently proposed for use (Table 4.1-1). Children ages 2 to 5 years had the greatest proportion of consumers at 99.8%. The consumer-only estimates are more relevant to risk assessments as they represent exposures in the target population; consequently, only the consumer-only intake results are discussed in detail herein.

4.1 Estimated Daily Intake of FermentIQ Pea Protein from All Proposed Food Uses in the U.S.

Table 4.1-1 summarizes the estimated total intake of FermentIQ Pea Protein (g/person/day) from all proposed food uses in the U.S. population groups. Table 4.1-2 presents this data on a per kilogram body weight basis (g/kg body weight/day).

Among the total population (ages 2 years and older), the mean and 90th percentile consumer-only intakes of FermentIQ Pea Protein were determined to be 22 and 54 g/person/day, respectively. Of the individual population groups, male adults were determined to have the greatest mean and 90th percentile consumer-only intakes of FermentIQ Pea Protein on an absolute basis, at 25 and 60 g/person/day, respectively, while children ages 2 to 5 years had the lowest mean and 90th percentile consumer-only intakes of 12 and 27 g/person/day, respectively (Table 4.1-1).

Table 4.1-1 Summary of the Estimated Daily Intake of FermentIQ Pea Protein from Proposed Food Uses in the U.S. by Population Group (2017-2018 NHANES Data)

Population Group	Age Group (Years)	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Children	2 to 5	12	27	99.8	468	12	27
Children	6 to 11	15	31	99.0	672	15	31
Female Teenagers	12 to 19	20	43	97.8	432	21	43
Male Teenagers	12 to 19	19	41	97.8	429	19	41
Female Adults	20 and older	22	56	96.5	2,076	23	56
Male Adults	20 and older	24	59	96.8	1,888	25	60
Total Population	2 and older	21	53	97.1	5,965	22	54

n = sample size; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

On a body weight basis, the total population (ages 2 years and older) mean and 90th percentile consumer-only intakes of FermentIQ Pea Protein were determined to be 0.34 and 0.79 g/kg body weight/day, respectively. Among the individual population groups, children ages 2 to 5 years were identified as having the highest mean and 90th percentile consumer-only intakes of any population group, of 0.75 and 1.48 g/kg body weight/day, respectively. Male adults had the lowest mean consumer-only intake of 0.29 g/kg body weight/day, while male teenagers had the lowest 90th percentile consumer-only intake of 0.70 g/kg body weight/day, respectively (Table 4.1-2).

Table 4.1-2 Summary of the Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Proposed Food Uses in the U.S. by Population Group (2017-2018 NHANES Data)

Population Group	Age Group (Years)	*Per Capita* Intake (g/kg bw/day)		Consumer-Only Intake (g/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Children	2 to 5	0.75	1.48	99.8	460	0.75	1.48
Children	6 to 11	0.46	0.89	99.0	670	0.46	0.91
Female Teenagers	12 to 19	0.34	0.73	97.8	425	0.35	0.73
Male Teenagers	12 to 19	0.29	0.70	97.8	426	0.30	0.70
Female Adults	20 and older	0.30	0.76	96.5	2,058	0.31	0.77
Male Adults	20 and older	0.28	0.71	96.8	1,873	0.29	0.72
Total Population	2 and older	0.33	0.79	97.1	5,912	0.34	0.79

bw = body weight; n = sample size; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

4.2 Estimated Daily Intake of Protein from FermentIQ Pea Protein from All Proposed Food Uses in the U.S.

Table 4.2-1 summarizes the estimated total intake of protein from FermentIQ Pea Protein (g/person/day) from all proposed food uses in the U.S. population groups. Table 4.2-2 presents this data on a per kilogram body weight basis (g/kg body weight/day). Protein intakes were calculated using the estimated intakes of FermentIQ Pea Protein and assuming a maximum protein content of 79.31% for the ingredient.

Among the total population (ages 2 years and older), the mean and 90th percentile consumer-only intakes of protein from FermentIQ Pea Protein were determined to be 17 and 43 g/person/day, respectively. Of the individual population groups, male adults were determined to have the greatest mean and 90th percentile consumer-only intakes of protein on an absolute basis, at 20 and 48 g/person/day, respectively, while children ages 2 to 5 years had the lowest mean and 90th percentile consumer-only intakes of 10 and 22 g/person/day, respectively (Table 4.1-1).

Table 4.2-1 Summary of the Estimated Daily Intake of FermentIQ Pea Protein as Protein[a] from Proposed Food Uses in the U.S. by Population Group (2017-2018 NHANES Data)

Population Group	Age Group (Years)	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Children	2 to 5	10	22	99.8	468	10	22
Children	6 to 11	12	24	99.0	672	12	24
Female Teenagers	12 to 19	16	34	97.8	432	16	34
Male Teenagers	12 to 19	15	33	97.8	429	15	33
Female Adults	20 and older	17	44	96.5	2,076	18	45

Table 4.2-1 Summary of the Estimated Daily Intake of FermentIQ Pea Protein as Protein[a] from Proposed Food Uses in the U.S. by Population Group (2017-2018 NHANES Data)

Population Group	Age Group (Years)	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Male Adults	20 and older	19	47	96.8	1,888	20	48
Total Population	2 and older	17	42	97.1	5,965	17	43

n = sample size; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.
[a] Calculation: (Estimated daily intake of FermentIQ Pea Protein)*(Maximum protein content, 79.31%).

On a body weight basis, the total population (ages 2 years and older) mean and 90th percentile consumer-only intakes of protein from FermentIQ Pea Protein were determined to be 0.27 and 0.63 g/kg body weight/day, respectively. Among the individual population groups, children ages 2 to 5 years were identified as having the highest mean and 90th percentile consumer-only intakes of any population group, of 0.59 and 1.18 g/kg body weight/day, respectively. Male adults had the lowest mean consumer-only intake of 0.23 g/kg body weight/day, while male teenagers had the lowest 90th percentile consumer-only intake of 0.55 g/kg body weight/day, respectively (Table 4.2-2).

Table 4.2-2 Summary of the Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein as Protein[a] from Proposed Food Uses in the U.S. by Population Group (2017-2018 NHANES Data)

Population Group	Age Group (Years)	*Per Capita* Intake (g/kg bw/day)		Consumer-Only Intake (g/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Children	2 to 5	0.59	1.18	99.8	460	0.59	1.18
Children	6 to 11	0.36	0.71	99.0	670	0.37	0.72
Female Teenagers	12 to 19	0.27	0.58	97.8	425	0.27	0.58
Male Teenagers	12 to 19	0.23	0.55	97.8	426	0.24	0.55
Female Adults	20 and older	0.24	0.60	96.5	2,058	0.25	0.61
Male Adults	20 and older	0.22	0.56	96.8	1,873	0.23	0.57
Total Population	2 and older	0.26	0.62	97.1	5,912	0.27	0.63

bw = body weight; n = sample size; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.
[a] Calculation: (Estimated daily intake of FermentIQ Pea Protein)*(Maximum protein content, 79.31%).

4.3 Estimated Daily Intake of FermentIQ Protein from Individual Proposed Food Uses in the U.S.

Estimates for the mean and 90th percentile daily intakes of FermentIQ Pea Protein from each individual food category are summarized in Tables A-1 to A-7 and B-1 to B-7 on a g/day and g/kg body weight/day basis, respectively. The total U.S. population (ages 2 years and older) was identified as being significant consumers of “snack foods” (47 to 66% consumers), “biscuits and cookies” (34 to 58% consumers), “ready-to-eat breakfast cereals” (26 to 58% consumers), “crackers” (17 to 42% consumers), and “bagels, English muffins, cornbread, corn muffins, and tortillas” (31 to 40% consumers).

In terms of contribution to total mean intake of FermentIQ Pea Protein, “tea drinks” (which contributed 8 to 23% to total mean intakes) and “hot breakfast cereals” (which contributed 6 to 22% to total mean intakes) were the 2 main sources of intake across all population groups. High protein bread, cream cheese substitutes, non-dairy frozen desserts, non-dairy yogurt, imitation cheese, and butter and spread alternatives all individually contributed ≤1% to total mean FermentIQ Pea Protein intakes across all population groups (see Tables A-1 to A-7 and/or B-1 to B-7 for further details).

5.0 SUMMARY AND CONCLUSIONS

Consumption data and information pertaining to the individual proposed food uses of FermentIQ Pea Protein were used to estimate the *per capita* and consumer-only intakes of FermentIQ Pea Protein for specific demographic groups and for the total U.S. population. There were a number of assumptions included in the assessment which render exposure estimates that may be considered suitably conservative. For example, it has been assumed in both exposure assessments that all food products within a food category contain FermentIQ Pea Protein at the maximum specified level of use. In reality, the levels added to specific foods will vary depending on the nature of the food product and it is unlikely that FermentIQ Pea Protein will have 100% market penetration in all identified food categories.

In summary, on a consumer-only basis, the resulting mean and 90th percentile intakes of FermentIQ Pea Protein by the total U.S. population (ages 2 years and older) from all proposed food uses, were estimated to be 22 g/person/day (0.34 g/kg body weight/day) and 54 g/person/day (0.79 g/kg body weight/day), respectively. Among the individual population groups, the highest mean and 90th percentile consumer-only intakes of FermentIQ Pea Protein were determined to be 25 g/person/day (0.29 g/kg body weight/day) and 60 g/person/day (0.72 g/kg body weight/day), respectively, as identified among male adults. Children ages 2 to 5 years had the lowest mean and 90th percentile consumer-only intakes of 12 g/person/day and 27 g/person/day, respectively; however, when intakes were expressed on a body weight basis, children ages 2 to 5 years had the highest mean and 90th percentile consumer-only intakes of 0.75 and 1.48 g/kg body weight/day.

Consumer-only protein intakes from FermentIQ Pea Protein among the total population were determined to be 17 g/person/day (0.27 g/kg body weight/day) and 43 g/person/day (0.63 g/kg body weight/day) at the mean and 90th percentile, respectively. Among the individual population groups, male adults were determined to have the greatest mean and 90th percentile consumer-only intakes of 20 g/person/day (0.23 g/kg body weight/day) and 48 g/person/day (0.57 g/kg body weight/day), respectively. On a body weight basis, children ages 2 to 5 years were identified as having the highest mean and 90th percentile consumer-only intakes of protein of 0.59 and 1.18 g/kg body weight/day, respectively.

6.0 REFERENCES

CDC (2013). *National Health and Nutrition Examination Survey: Analytic Guidelines, 1999–2010*. (Vital and Health Statistics. Series 2, Number 161). Hyattsville (MD): Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS). Available at: https://www.cdc.gov/nchs/data/series/sr_02/sr02_161.pdf [Last accessed October 30, 2016].

CDC (2022a). *National Health and Nutrition Examination Survey (NHANES): 2017-2018*. Hyattsville (MD): Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS). Available at: https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx?BeginYear=2017 [page last reviewed: March 17, 2022].

CDC (2022b). *National Health and Nutrition Examination Survey (NHANES): 2017-2018 – Dietary Data*. Hyattsville (MD): Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS). Available at: https://wwwn.cdc.gov/nchs/nhanes/Search/DataPage.aspx?Component=Dietary&CycleBeginYear=2017 [page last reviewed: March 17, 20221].

Dazult Ltd. (2018). *DaDiet - The Dietary Intake Evaluation Tool [Software]*. (Version 17.04). Straffan, Ireland: Dazult Ltd. Available online: http://dadiet.daanalysis.com.

U.S. EPA & USDA (2022). Commodity consumption calculator. In: *Food Commodity Intake Database: What We Eat in America [2005-2010]*. [FCID]. Washington (DC): U.S. Environmental Protection Agency (U.S. EPA), Office of Pesticide Programs/ Beltsville (MD): United States Department of Agriculture (USDA). Available at: http://fcid.foodrisk.org/ ; http://fcid.foodrisk.org/dbc/ ; http://fcid.foodrisk.org/percentiles [© University of Maryland 2012 – 2022].

U.S. FDA (2021). Part 170—Food additives. Section §170.3—Definitions. In: *U.S. Code of Federal Regulations (CFR). Title 21: Food and Drugs* (Food and Drug Administration). Washington (DC): U.S. Government Printing Office (GPO). Available at: https://www.govinfo.gov/app/collection/cfr/.

USDA (2021a). *What We Eat in America: National Health and Nutrition Examination Survey (NHANES): 2017-2018.* Riverdale (MD): U.S. Department of Agriculture (USDA). Available at: https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/wweianhanes-overview/#release [last modified: 1/29/2021].

USDA (2021b). *What We Eat in America: National Health and Nutrition Examination Survey (NHANES): 2017-2018: Documentation and Data Sets*. Beltsville (MD): U.S. Department of Agriculture (USDA). Available at: https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/wweia-documentation-and-data-sets/ [last modified: 1/29/2021].

USDA ARS (2021a). *USDA Food and Nutrient Database for Dietary Studies 2017-2018 [FNDDS]*. Beltsville (MD): U.S. Department of Agriculture (USDA), Agricultural Research Service (ARS), Food Surveys Research Group. Available at: https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/fndds/ [last modified: 1/7/2021].

USDA ARS (2021b). *USDA Food and Nutrient Database for Dietary Studies 2017-2018 [FNDDS]: Documentation and Databases*. Beltsville (MD): U.S. Department of Agriculture (USDA), Agricultural Research Service (ARS), Food Surveys Research Group. Available at: https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/fndds-download-databases/ [last modified: 1/7/2021].

APPENDIX A
Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Different Population Groups within the U.S. (2017-2018 NHANES Data)

Table A-1 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Children Ages 2 to 5 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***12***	***27***	***99.8***	***468***	***12***	***27***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	4.8	1	2	31.0	133	2	4
Crackers	3.3	<1	2	42.3	201	1	2
Biscuits; Cookies	9.4	1	4	44.8	213	3	6
French Toast, Pancakes, and Waffles	9.2	1	4	27.7	118	4	8
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	0.3	<1*	na	0.4	1	8*	8*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	22.5	3	11	14.6	81	19	36
Ready-to-Eat Cereals	14.1	2	5	58.4	275	3	6
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	0.1	<1*	na	0.3	2	5*	5*
Ready-to-Drink Tea beverages; Instant Tea	8.0	1*	na	5.7	21	17*	33*
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	5.1	1*	na	6.5	26	10*	17*
Cream Cheese Substitute[d]	0.3	<1*	na	3.3	21	1*	2*
Non-Dairy Frozen Desserts	0	0	0	0	0	0	0
Non-Dairy Dips (includes imitation sour cream)	1.2	<1*	na	4.2	13	3*	6*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.1	<1*	na	0.3	1	4*	4*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	5.0	1	2*	14.2	59	4	9*
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	2.6	<1*	na	2.0	10	16*	23*
Nut and Nut Products							
Nut Butters and Spread	3.4	<1	2	25.7	122	2	3
Plant Protein Products							
Meat Analogs and Substitutes	0.5	<1*	na	1.3	6	5*	16*
Butter and Spread Alternative	0.2	<1*	na	7.6	26	<1*	1*

Table A-1 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Children Ages 2 to 5 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	4.0	1	1	62.2	300	1	2
Soups and Soup Mixes							
Soups and Soup Mixes	5.9	1	3*	13.9	72	5	9*

n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table A-2 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Children Ages 6 to 11 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***15***	***31***	***99.0***	***672***	***15***	***31***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	5.9	1	3	34.0	223	3	6
Crackers	2.4	<1	1	30.7	189	1	2
Biscuits; Cookies	12.9	2	5	58.3	346	3	6
French Toast, Pancakes, and Waffles	10.7	2	6	25.9	157	6	12
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	0.4	<1*	na	0.4	1	17*	17*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	6.0	1	na	5.4	46	16	24*
Ready-to-Eat Cereals	17.9	3	7	56.9	404	5	9
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	1.6	<1*	na	1.6	9	14*	31*
Ready-to-Drink Tea beverages; Instant Tea	11.5	2	na	8.6	55	20	39*
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	3.9	1*	na	4.7	25	12*	25*
Cream Cheese Substitute[d]	0.7	<1*	na	5.3	25	2*	4*
Non-Dairy Frozen Desserts	0	0	0	0	0	0	0
Non-Dairy Dips (includes imitation sour cream)	1.0	<1*	na	2.6	13	6*	9*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	<0.1	<1*	na	0.2	1	4*	4*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	5.0	1	4*	16.1	75	5	9*
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	2.7	<1*	na	1.5	9	28*	45*
Nut and Nut Products							
Nut Butters and Spread	2.7	<1	2	23.6	120	2	3
Plant Protein Products							
Meat Analogs and Substitutes	0.3	<1*	na	1.4	9	3*	6*
Butter and Spread Alternative	0.4	<1	na	8.6	51	1	2*

Table A-2 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Children Ages 6 to 11 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	5.3	1	2	66.2	446	1	2
Soups and Soup Mixes							
Soups and Soup Mixes	8.7	1	5	15.0	102	9	13

n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table A-3 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Female Teenagers Ages 12 to 19 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***20***	***43***	***97.8***	***432***	***21***	***43***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	5.0	1	3	36.4	148	3	5
Crackers	1.4	<1	1	22.1	82	1	3
Biscuits; Cookies	6.3	1	3	41.9	165	3	6
French Toast, Pancakes, and Waffles	5.5	1	5*	15.9	61	7	14*
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	3.3	1*	na	0.2	1	353*	353*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	6.2	1	na	6.1	40	20	36*
Ready-to-Eat Cereals	10.3	2	7	36.9	155	6	12
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	7.9	2*	na	6.5	24	24*	35*
Ready-to-Drink Tea beverages; Instant Tea	23.0	5	19*	19.7	62	24	45*
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	8.0	2	2*	13.2	46	12	25*
Cream Cheese Substitute[d]	0.8	<1*	na	8.7	26	2*	4*
Non-Dairy Frozen Desserts	0	0	0	0	0	0	0
Non-Dairy Dips (includes imitation sour cream)	0.7	<1*	na	4.3	12	3*	7*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.1	<1*	na	1.2	1	1*	1*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.6	1	4*	15.4	51	5	8*
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	5.6	1*	na	4.7	10	24*	28*
Nut and Nut Products							
Nut Butters and Spread	1.4	<1	1*	12.6	38	2	4*
Plant Protein Products							
Meat Analogs and Substitutes	0.1	<1*	na	1.1	5	2*	1*
Butter and Spread Alternative	0.3	<1*	na	7.1	20	1*	1*

Table A-3 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Female Teenagers Ages 12 to 19 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	2.9	1	2	56.7	276	1	2
Soups and Soup Mixes							
Soups and Soup Mixes	7.5	2	7	16.1	88	9	17

n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table A-4 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Male Teenagers Ages 12 to 19 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***19***	***41***	***97.8***	***429***	***19***	***41***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	7.1	1	4	38.1	152	3	7
Crackers	1.3	<1	1*	16.6	50	1	3*
Biscuits; Cookies	6.6	1	3	34.7	164	4	8
French Toast, Pancakes, and Waffles	7.0	1	5*	14.7	61	9	21*
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	0.3	<1*	na	<0.1	1	151*	151*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	7.3	1*	na	5.1	22	27*	71*
Ready-to-Eat Cereals	14.1	3	9	41.3	178	6	12
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	3.9	1*	na	3.9	17	19*	26*
Ready-to-Drink Tea beverages; Instant Tea	20.1	4	12*	12.6	53	30	52*
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	3.0	1*	na	6.9	29	8*	12*
Cream Cheese Substitute[d]	0.6	<1*	na	5.3	17	2*	3*
Non-Dairy Frozen Desserts	0	0	0	0	0	0	0
Non-Dairy Dips (includes imitation sour cream)	0.5	<1*	na	2.5	7	4*	6*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	<0.1	<1*	na	0.1	1	3*	3*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.2	1	2*	10.3	46	6	12*
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	12.0	2*	na	6.3	21	36*	53*
Nut and Nut Products							
Nut Butters and Spread	1.3	<1	<1*	10.6	43	2	3*
Plant Protein Products							
Meat Analogs and Substitutes	0	0	0	0	0	0	0
Butter and Spread Alternative	0.1	<1*	na	4.0	13	1*	1*

Table A-4 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Male Teenagers Ages 12 to 19 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	3.8	1	2	52.6	239	1	2
Soups and Soup Mixes							
Soups and Soup Mixes	7.8	1	6*	13.0	66	11	21*

n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table A-5 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Female Adults Ages 20 Years and Older within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***22***	***56***	***96.5***	***2,076***	***23***	***56***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	4.4	1	3	36.5	786	3	5
Crackers	0.8	<1	1	23.6	482	1	2
Biscuits; Cookies	5.1	1	4	35.0	745	3	7
French Toast, Pancakes, and Waffles	3.0	1	2	11.0	218	6	11
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	3.1	1*	na	1.2	11	56*	101*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	14.5	3	14	14.4	394	22	42
Ready-to-Eat Cereals	6.5	1	5	26.2	525	5	10
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	9.2	2	na	9.4	159	21	31
Ready-to-Drink Tea beverages; Instant Tea	19.1	4	13	12.2	249	35	72
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	8.1	2	5	32.8	722	5	14
Cream Cheese Substitute[d]	0.5	<1	na	6.5	109	2	3
Non-Dairy Frozen Desserts	0.2	<1*	na	0.4	2	11*	14*
Non-Dairy Dips (includes imitation sour cream)	1.3	<1	na	7.4	120	4	7
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.1	<1*	na	0.4	4	6*	7*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.3	1	3	11.6	177	6	11
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	8.2	2	na	5.5	100	33	63
Nut and Nut Products							
Nut Butters and Spread	0.9	<1	1	12.9	250	1	2
Plant Protein Products							
Meat Analogs and Substitutes	1.6	<1	na	2.8	61	13	34*
Butter and Spread Alternative	0.4	<1	<1	11.2	227	1	2

Table A-5 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Female Adults Ages 20 Years and Older within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	2.1	<1	1	48.7	990	1	2
Soups and Soup Mixes							
Soups and Soup Mixes	7.6	2	7	15.5	400	11	20

n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table A-6 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Male Adults Ages 20 Years and Older within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***24***	***59***	***96.8***	***1,888***	***25***	***60***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	5.7	1	4	39.5	714	3	7
Crackers	1.0	<1	1	21.2	363	1	2
Biscuits; Cookies	6.7	2	5	34.1	707	5	9
French Toast, Pancakes, and Waffles	2.5	1	na	8.7	171	7	13
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	0.1	<1*	na	<0.1	1	101*	101*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	14.6	4	14	12.9	303	27	51
Ready-to-Eat Cereals	7.1	2	7	26.0	508	7	13
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	5.7	1	na	5.4	89	25	49
Ready-to-Drink Tea beverages; Instant Tea	21.8	5	18	13.3	244	39	99
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	5.7	1	3	24.0	513	6	14
Cream Cheese Substitute[d]	0.3	<1	na	4.1	52	2	3*
Non-Dairy Frozen Desserts	<0.1	<1*	na	0.4	2	3*	3*
Non-Dairy Dips (includes imitation sour cream)	1.2	<1	na	5.3	76	5	12*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	<0.1	<1*	na	0.2	3	4*	4*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.2	1	3	11.6	143	7	14
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	10.0	2	na	5.9	94	40	62
Nut and Nut Products							
Nut Butters and Spread	1.4	<1	2	13.0	230	3	4
Plant Protein Products							
Meat Analogs and Substitutes	0.6	<1	na	1.8	33	8	14*
Butter and Spread Alternative	0.3	<1	na	7.8	210	1	2

Table A-6 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Male Adults Ages 20 Years and Older within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	2.5	1	2	46.6	864	1	3
Soups and Soup Mixes							
Soups and Soup Mixes	9.6	2	9	16.1	321	14	24

n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table A-7 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by the U.S. Population Ages 2 Years and Older (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***21***	***53***	***97.1***	***5,965***	***22***	***54***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	5.2	1	4	37.2	2,156	3	6
Crackers	1.1	<1	1	23.8	1,367	1	2
Biscuits; Cookies	6.4	1	5	37.4	2,340	4	7
French Toast, Pancakes, and Waffles	3.7	1	3	12.7	786	6	11
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	1.5	<1*	na	0.5	16	58*	101*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	13.6	3	10	12.2	886	24	45
Ready-to-Eat Cereals	8.2	2	6	31.6	2,045	6	10
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	6.8	1	na	6.4	300	22	37
Ready-to-Drink Tea beverages; Instant Tea	19.7	4	12	12.4	684	34	73
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	6.5	1	3	23.6	1,361	6	15
Cream Cheese Substitute[d]	0.4	<1	na	5.4	250	2	4
Non-Dairy Frozen Desserts	0.1	<1*	na	0.3	4	7*	12*
Non-Dairy Dips (includes imitation sour cream)	1.2	<1	na	5.7	241	4	9
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.1	<1*	na	0.3	11	4*	7*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.4	1	3	12.2	551	6	11
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	8.6	2	na	5.2	244	35	62
Nut and Nut Products							
Nut Butters and Spread	1.3	<1	1	14.3	803	2	3
Plant Protein Products							
Meat Analogs and Substitutes	0.9	<1	na	2.0	114	10	25
Butter and Spread Alternative	0.3	<1	na	8.9	547	1	2

Table A-7 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by the U.S. Population Ages 2 Years and Older (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	2.6	1	2	50.7	3,115	1	2
Soups and Soup Mixes							
Soups and Soup Mixes	8.5	2	8	15.5	1,049	12	22

n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

APPENDIX B

Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Different Population Groups within the U.S. (2017-2018 NHANES Data)

Table B-1 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Children Ages 2 to 5 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***0.75***	***1.48***	***99.8***	***460***	***0.75***	***1.48***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	4.7	0.04	0.13	30.9	131	0.12	0.23
Crackers	3.3	0.02	0.08	43.0	201	0.06	0.13
Biscuits; Cookies	9.5	0.07	0.21	44.8	210	0.16	0.36
French Toast, Pancakes, and Waffles	9.2	0.07	0.23	27.9	117	0.25	0.41
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	0.3	<0.01*	na	0.4	1	0.64*	0.64*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	22.9	0.17	0.65*	14.4	79	1.19	2.20*
Ready-to-Eat Cereals	14.2	0.11	0.29	58.3	271	0.18	0.34
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	0.1	<0.01*	na	0.3	2	0.27*	0.31*
Ready-to-Drink Tea beverages; Instant Tea	7.1	0.05*	na	5.8	21	0.91*	1.77*
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	5.2	0.04*	na	6.6	25	0.59*	1.14*
Cream Cheese Substitute[d]	0.3	<0.01*	na	3.3	21	0.06*	0.10*
Non-Dairy Frozen Desserts	0	0	0	0	0	0	0
Non-Dairy Dips (includes imitation sour cream)	1.3	0.01*	na	4.3	13	0.22*	0.43*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.1	<0.01*	na	0.3	1	0.30*	0.30*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	4.7	0.04	0.16*	14.4	59	0.24	0.37*
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	2.6	0.02*	na	2.1	10	0.95*	1.63*
Nut and Nut Products							
Nut Butters and Spread	3.6	0.03	0.10	26.0	121	0.10	0.20
Plant Protein Products							
Meat Analogs and Substitutes	0.6	<0.01*	na	1.3	6	0.34*	1.20*
Butter and Spread Alternative	0.2	<0.01*	na	7.8	26	0.02*	0.03*

Table B-1 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Children Ages 2 to 5 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	4.0	0.03	0.08	62.3	295	0.05	0.10
Soups and Soup Mixes							
Soups and Soup Mixes	5.8	0.04	0.19*	13.8	69	0.32	0.61*

bw = body weight; n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table B-2 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Children Ages 6 to 11 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***0.46***	***0.89***	***99.0***	***670***	***0.46***	***0.91***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	5.5	0.03	0.09	34.0	222	0.07	0.14
Crackers	2.4	0.01	0.04	30.8	189	0.04	0.08
Biscuits; Cookies	13.1	0.06	0.17	58.3	345	0.10	0.22
French Toast, Pancakes, and Waffles	11.6	0.05	0.19	25.9	157	0.21	0.43
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	0.6	<0.01*	na	0.4	1	0.69*	0.69*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	6.0	0.03	na	5.4	46	0.51	0.84*
Ready-to-Eat Cereals	18.1	0.08	0.23	56.9	403	0.15	0.29
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	1.3	0.01*	na	1.7	9	0.35*	0.72*
Ready-to-Drink Tea beverages; Instant Tea	10.2	0.05	na	8.6	55	0.54	0.95*
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	4.0	0.02*	na	4.7	25	0.39*	0.93*
Cream Cheese Substitute[d]	0.7	<0.01*	na	5.3	25	0.06*	0.14*
Non-Dairy Frozen Desserts	0	0	0	0	0	0	0
Non-Dairy Dips (includes imitation sour cream)	1.1	0.01*	na	2.6	13	0.20*	0.34*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.1	<0.01*	na	0.2	1	0.16*	0.16*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	5.0	0.02	0.11*	16.1	75	0.14	0.30*
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	2.5	0.01*	na	1.5	9	0.78*	1.10*
Nut and Nut Products							
Nut Butters and Spread	3.0	0.01	0.05	23.6	120	0.06	0.14
Plant Protein Products							
Meat Analogs and Substitutes	0.3	<0.01*	na	1.4	9	0.09*	0.17*
Butter and Spread Alternative	0.4	<0.01	na	8.7	51	0.02	0.06*

Table B-2 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Children Ages 6 to 11 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	5.3	0.02	0.06	66.2	444	0.04	0.07
Soups and Soup Mixes							
Soups and Soup Mixes	8.8	0.04	0.15	15.0	101	0.27	0.45

bw = body weight; n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table B-3 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Female Teenagers Ages 12 to 19 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***0.34***	***0.73***	***97.8***	***425***	***0.35***	***0.73***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	4.9	0.02	0.06	36.2	145	0.05	0.09
Crackers	1.4	<0.01	0.02	22.4	81	0.02	0.05
Biscuits; Cookies	6.5	0.02	0.06	41.9	163	0.05	0.14
French Toast, Pancakes, and Waffles	5.7	0.02	0.08*	16.2	61	0.12	0.20*
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	3.1	0.01*	na	0.2	1	5.49*	5.49*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	5.1	0.02	na	5.8	38	0.30	0.50*
Ready-to-Eat Cereals	10.1	0.03	0.11	36.5	152	0.09	0.19
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	7.3	0.02*	na	6.6	24	0.37*	0.51*
Ready-to-Drink Tea beverages; Instant Tea	23.3	0.08	0.31*	20.0	62	0.39	0.75*
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	7.6	0.03	0.03*	13.1	45	0.20	0.39*
Cream Cheese Substitute[d]	0.8	<0.01*	na	8.8	26	0.03*	0.06*
Non-Dairy Frozen Desserts	0	0	0	0	0	0	0
Non-Dairy Dips (includes imitation sour cream)	0.6	<0.01*	na	4.0	11	0.05*	0.11*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.1	<0.01*	na	1.2	1	0.02*	0.02*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.9	0.01	0.06*	15.6	51	0.09	0.18*
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	7.2	0.02*	na	4.7	10	0.52*	0.56*
Nut and Nut Products							
Nut Butters and Spread	1.4	<0.01	0.02*	12.8	38	0.04	0.07*
Plant Protein Products							
Meat Analogs and Substitutes	0.1	<0.01*	na	1.2	5	0.04*	0.01*
Butter and Spread Alternative	0.3	<0.01*	na	7.1	19	0.01*	0.02*

Table B-3 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Female Teenagers Ages 12 to 19 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	2.9	0.01	0.03	56.7	271	0.02	0.04
Soups and Soup Mixes							
Soups and Soup Mixes	7.8	0.03	0.11	16.2	87	0.16	0.28

bw = body weight; n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table B-4 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Male Teenagers Ages 12 to 19 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***0.29***	***0.70***	***97.8***	***426***	***0.30***	***0.70***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	6.7	0.02	0.06	38.0	151	0.05	0.13
Crackers	1.6	<0.01	0.01*	16.5	49	0.03	0.07*
Biscuits; Cookies	7.5	0.02	0.06	34.3	162	0.06	0.14
French Toast, Pancakes, and Waffles	7.4	0.02	0.07*	14.8	61	0.15	0.36*
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	0.2	<0.01*	na	<0.1	1	2.03*	2.03*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	7.1	0.02*	na	4.9	21	0.43*	1.07*
Ready-to-Eat Cereals	14.2	0.04	0.14	41.4	177	0.10	0.17
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	3.7	0.01*	na	3.9	17	0.27*	0.34*
Ready-to-Drink Tea beverages; Instant Tea	19.3	0.06	0.18*	12.4	52	0.46	0.87*
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	3.1	0.01*	na	6.9	29	0.13*	0.21*
Cream Cheese Substitute[d]	0.7	<0.01*	na	5.3	17	0.04*	0.07*
Non-Dairy Frozen Desserts	0	0	0	0	0	0	0
Non-Dairy Dips (includes imitation sour cream)	0.4	<0.01*	na	2.5	7	0.05*	0.07*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	<0.1	<0.01*	na	0.1	1	0.03*	0.03*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.1	0.01	0.02*	10.3	46	0.09	0.21*
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	11.1	0.03*	na	6.3	21	0.51*	0.80*
Nut and Nut Products							
Nut Butters and Spread	1.5	<0.01	0.01*	10.7	43	0.04	0.06*
Plant Protein Products							
Meat Analogs and Substitutes	0	0	0	0	0	0	0
Butter and Spread Alternative	0.1	<0.01*	na	3.8	12	0.01*	0.01*

Table B-4 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Male Teenagers Ages 12 to 19 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	4.0	0.01	0.03	52.6	237	0.02	0.05
Soups and Soup Mixes							
Soups and Soup Mixes	8.4	0.02	0.10*	12.8	65	0.19	0.35*

bw = body weight; n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table B-5 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Female Adults Ages 20 Years and Older within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***0.30***	***0.76***	***96.5***	***2,058***	***0.31***	***0.77***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	4.3	0.01	0.04	36.5	781	0.04	0.07
Crackers	0.8	<0.01	0.01	23.7	476	0.01	0.02
Biscuits; Cookies	5.0	0.02	0.05	35.0	738	0.04	0.09
French Toast, Pancakes, and Waffles	2.9	0.01	0.02	11.0	217	0.08	0.14
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	3.2	0.01*	na	1.2	11	0.81*	1.45*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	15.2	0.05	0.17	14.4	389	0.32	0.67
Ready-to-Eat Cereals	6.5	0.02	0.07	26.3	519	0.08	0.15
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	8.9	0.03	na	9.4	156	0.29	0.49
Ready-to-Drink Tea beverages; Instant Tea	17.8	0.05	0.15	12.2	249	0.44	0.94
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	8.3	0.03	0.07	32.7	715	0.08	0.21
Cream Cheese Substitute[d]	0.5	<0.01	na	6.5	108	0.02	0.04
Non-Dairy Frozen Desserts	0.2	<0.01*	na	0.4	2	0.14*	0.16*
Non-Dairy Dips (includes imitation sour cream)	1.3	<0.01	na	7.4	119	0.05	0.11
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.2	<0.01*	na	0.4	4	0.11*	0.13*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.5	0.01	0.03	11.6	177	0.09	0.17
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	8.9	0.03	na	5.5	100	0.49	0.75
Nut and Nut Products							
Nut Butters and Spread	0.9	<0.01	0.01	12.9	246	0.02	0.04
Plant Protein Products							
Meat Analogs and Substitutes	1.6	<0.01	na	2.8	61	0.18	0.62*
Butter and Spread Alternative	0.4	<0.01	<0.01	11.1	223	0.01	0.02

Table B-5 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Female Adults Ages 20 Years and Older within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	2.0	0.01	0.02	48.8	983	0.01	0.03
Soups and Soup Mixes							
Soups and Soup Mixes	7.6	0.02	0.10	15.5	395	0.15	0.28

bw = body weight; n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table B-6 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Male Adults Ages 20 Years and Older within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***0.28***	***0.71***	***96.8***	***1,873***	***0.29***	***0.72***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	5.7	0.02	0.05	39.6	709	0.04	0.08
Crackers	1.0	<0.01	0.01	21.2	359	0.01	0.02
Biscuits; Cookies	6.6	0.02	0.06	34.1	703	0.05	0.11
French Toast, Pancakes, and Waffles	2.6	0.01	na	8.7	171	0.08	0.16
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	0.1	<0.01*	na	<0.1	1	0.90*	0.90*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	14.9	0.04	0.15	12.9	301	0.32	0.59
Ready-to-Eat Cereals	7.2	0.02	0.08	26.0	504	0.08	0.14
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	6.6	0.02	na	5.4	89	0.34	0.65
Ready-to-Drink Tea beverages; Instant Tea	20.8	0.06	0.19	13.3	240	0.44	0.91
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	5.7	0.02	0.04	24.0	510	0.07	0.18
Cream Cheese Substitute[d]	0.3	<0.01	na	4.1	51	0.02	0.03*
Non-Dairy Frozen Desserts	<0.1	<0.01*	na	0.4	2	0.03*	0.03*
Non-Dairy Dips (includes imitation sour cream)	1.2	<0.01	na	5.3	76	0.06	0.13*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	<0.1	<0.01*	na	0.2	3	0.04*	0.04*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.2	0.01	0.03	11.6	142	0.08	0.16
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	9.8	0.03	na	5.9	93	0.46	0.79
Nut and Nut Products							
Nut Butters and Spread	1.3	<0.01	0.02	13.0	225	0.03	0.05
Plant Protein Products							
Meat Analogs and Substitutes	0.6	<0.01	na	1.8	33	0.09	0.17*
Butter and Spread Alternative	0.3	<0.01	na	7.8	208	0.01	0.03

Table B-6 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Male Adults Ages 20 Years and Older within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	2.4	0.01	0.02	46.7	859	0.01	0.03
Soups and Soup Mixes							
Soups and Soup Mixes	9.7	0.03	0.10	16.2	320	0.17	0.34

bw = body weight; n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table B-7 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by the U.S. Population Ages 2 Years and Older (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***0.33***	***0.79***	***97.1***	***5,912***	***0.34***	***0.79***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	5.1	0.02	0.05	37.2	2,139	0.05	0.09
Crackers	1.4	<0.01	0.01	23.9	1,355	0.02	0.04
Biscuits; Cookies	7.1	0.02	0.07	37.4	2,321	0.06	0.13
French Toast, Pancakes, and Waffles	4.9	0.02	0.05	12.7	784	0.13	0.26
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	1.5	<0.01*	na	0.5	16	0.89*	1.46*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	14.1	0.05	0.15	12.2	874	0.38	0.76
Ready-to-Eat Cereals	9.5	0.03	0.11	31.6	2,026	0.10	0.21
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	6.0	0.02	na	6.4	297	0.31	0.53
Ready-to-Drink Tea beverages; Instant Tea	17.0	0.06	0.17	12.4	679	0.45	0.94
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	6.4	0.02	0.04	23.5	1,349	0.09	0.24
Cream Cheese Substitute[d]	0.4	<0.01	na	5.4	248	0.03	0.06
Non-Dairy Frozen Desserts	0.1	<0.01*	na	0.3	4	0.09*	0.15*
Non-Dairy Dips (includes imitation sour cream)	1.2	<0.01	na	5.7	239	0.07	0.13
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.1	<0.01*	na	0.3	11	0.09*	0.14*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.7	0.01	0.04	12.2	550	0.10	0.20
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	7.8	0.03	na	5.2	243	0.49	0.81
Nut and Nut Products							
Nut Butters and Spread	1.6	0.01	0.02	14.3	793	0.04	0.07
Plant Protein Products							
Meat Analogs and Substitutes	0.9	<0.01	na	2.0	114	0.14	0.34
Butter and Spread Alternative	0.3	<0.01	na	8.9	539	0.01	0.03

Table B-7 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by the U.S. Population Ages 2 Years and Older (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	2.9	0.01	0.03	50.7	3,089	0.02	0.04
Soups and Soup Mixes							
Soups and Soup Mixes	8.2	0.03	0.10	15.5	1,037	0.18	0.35

bw = body weight; n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

APPENDIX C
Representative Food Codes for Proposed Food Uses of FermentIQ Pea Protein in the U.S. (2017-2018 NHANES Data)

Representative Food Codes for Proposed Food Uses of FermentIQ Pea Protein in the U.S. (2017-2018 NHANES Data)

Baked Goods and Baking Mixes

Bagels and English Muffins, Cornbread, Corn Muffins, or Tortillas
[FermentIQ Pea Protein] = 5 g/100 g

51180010	Bagel
51180030	Bagel, with raisins
51180080	Bagel, with fruit other than raisins
51186010	Muffin, English
51186100	Muffin, English, with raisins
51186130	Muffin, English, cheese
51186160	Muffin, English, with fruit other than raisins
51187000	Melba toast
51300100	Bagel, whole grain white
51301700	Bagel, wheat
51301750	Bagel, whole wheat
51301800	Bagel, wheat, with raisins
51301805	Bagel, whole wheat, with raisins
51301820	Bagel, wheat, with fruit and nuts
51301900	Bagel, wheat bran
51302500	Muffin, English, wheat bran
51302520	Muffin, English, wheat bran, with raisins
51303010	Muffin, English, wheat or cracked wheat
51303030	Muffin, English, whole wheat
51303050	Muffin, English, wheat or cracked wheat, with raisins
51303070	Muffin, English, whole wheat, with raisins
51303100	Muffin, English, whole grain white
51401200	Muffin, English, rye
51404500	Bagel, pumpernickel
51404550	Muffin, English, pumpernickel
51501080	Bagel, oat bran
51503000	Muffin, English, oat bran
51503040	Muffin, English, oat bran, with raisins
51630000	Bagel, multigrain
51630100	Bagel, multigrain, with raisins
51630200	Muffin, English, multigrain
52101040	Crumpet
52201000	Cornbread, prepared from mix
52204000	Cornbread stuffing
52206010	Cornbread muffin, stick, round
52207010	Corn flour patty or tart, fried

52208010 Corn pone, baked
52208020 Corn pone, fried
52208760 Gordita/sope shell, plain, no filling
52209010 Hush puppy
52211010 Johnnycake
52213010 Spoonbread
52215000 Tortilla, NFS
52215100 Tortilla, corn
52215200 Tortilla, flour
52215260 Tortilla, whole wheat
52215300 Taco shell, corn
52215350 Taco shell, flour
52220110 Arepa Dominicana

Mixed foods containing bagels and English muffins, cornbread, corn muffins, or tortillas
Adjusted for baked good content of 5.1 to 79.0%
[FermentIQ Pea Protein] = 0.26 to 3.95 g/100 g

32202010 Egg, cheese, and ham on English muffin
32202025 Egg, cheese and ham on bagel
32202030 Egg, cheese, and sausage on English muffin
32202045 Egg, cheese, and steak on bagel
32202080 Egg, cheese, and bacon on English muffin
32202085 Egg, cheese and bacon on bagel
32202120 Egg, cheese and sausage on bagel
58100000 Burrito, taco, or quesadilla with egg
58100005 Burrito, taco, or quesadilla with egg and potato
58100010 Burrito, taco, or quesadilla with egg and breakfast meat
58100013 Burrito, taco, or quesadilla with egg and breakfast meat, from fast food
58100015 Burrito, taco, or quesadilla with egg, potato, and breakfast meat
58100017 Burrito, taco, or quesadilla with egg, potato, and breakfast meat, from fast food
58100020 Burrito, taco, or quesadilla with egg, beans, and breakfast meat
58100100 Burrito with meat
58100120 Burrito with meat and beans
58100125 Burrito with meat and beans, from fast food
58100135 Burrito with meat and sour cream
58100140 Burrito with meat, beans, and sour cream
58100145 Burrito with meat, beans, and sour cream, from fast food
58100160 Burrito with meat, beans, and rice
58100165 Burrito with meat, beans, rice, and sour cream
58100200 Burrito with chicken
58100220 Burrito with chicken and beans
58100235 Burrito with chicken and sour cream
58100245 Burrito with chicken, beans, and sour cream

58100255 Burrito with chicken, beans, and rice
58100260 Burrito with chicken, beans, rice, and sour cream
58100300 Burrito with beans and rice, meatless
58100320 Burrito with beans, meatless
58100325 Burrito with beans, meatless, from fast food
58100330 Burrito with beans, rice, and sour cream, meatless
58100360 Chilaquiles, tortilla casserole with salsa, cheese, and egg
58100370 Chilaquiles, tortilla casserole with salsa and cheese, no egg
58100500 Enchilada, no sauce
58100520 Enchilada with meat and beans, red-chile or enchilada sauce
58100525 Enchilada with meat and beans, green-chile or enchilada sauce
58100530 Enchilada with meat, red-chile or enchilada sauce
58100535 Enchilada with meat, green-chile or enchilada sauce
58100620 Enchilada with chicken and beans, red-chile or enchilada sauce
58100625 Enchilada with chicken and beans, green-chile or enchilada sauce
58100630 Enchilada with chicken, red-chile or enchilada sauce
58100635 Enchilada with chicken, green-chile or enchilada sauce
58100720 Enchilada with beans, meatless, red-chile or enchilada sauce
58100725 Enchilada with beans, green-chile or enchilada sauce
58100800 Enchilada, just cheese, meatless, no beans, red-chile or enchilada sauce
58100805 Enchilada, just cheese, meatless, no beans, green-chile or enchilada sauce
58101320 Taco or tostada with meat
58101323 Taco or tostada with meat, from fast food
58101325 Taco or tostada with meat and sour cream
58101345 Soft taco with meat
58101347 Soft taco with meat, from fast food
58101350 Soft taco with meat and sour cream
58101357 Soft taco with meat and sour cream, from fast food
58101450 Soft taco with chicken
58101457 Soft taco with chicken, from fast food
58101460 Soft taco with chicken and sour cream
58101520 Taco or tostada with chicken
58101525 Taco or tostada with chicken and sour cream
58101540 Taco or tostada with fish
58101555 Soft taco with fish
58101610 Soft taco with beans
58101615 Soft taco with beans and sour cream
58101620 Soft taco with meat and beans
58101625 Soft taco with chicken and beans
58101630 Soft taco with meat, beans, and sour cream
58101635 Soft taco with chicken, beans, and sour cream
58101720 Taco or tostada with beans
58101725 Taco or tostada with beans and sour cream
58101730 Taco or tostada with meat and beans

58101733 Taco or tostada with meat and beans, from fast food
58101735 Taco or tostada with chicken and beans
58101745 Taco or tostada with meat, beans, and sour cream
58101750 Taco or tostada with chicken, beans, and sour cream
58101800 Ground beef with tomato sauce and taco seasonings on a cornbread crust
58101930 Taco or tostada salad with meat
58101935 Taco or tostada salad with chicken
58101940 Taco or tostada salad, meatless
58101945 Taco or tostada salad with meat and sour cream
58101950 Taco or tostada salad with chicken and sour cream
58101955 Taco or tostada salad, meatless with sour cream
58103120 Tamale with meat
58103130 Tamale with chicken
58103210 Tamale, meatless, with sauce, Puerto Rican or Caribbean style
58103250 Tamale, plain, meatless, no sauce, Mexican style
58103310 Tamale casserole with meat
58104260 Gordita, sope, or chalupa with beans
58104270 Gordita, sope, or chalupa with beans and sour cream
58104280 Gordita, sope, or chalupa with meat and sour cream
58104290 Gordita, sope, or chalupa with meat
58104320 Gordita, sope, or chalupa with chicken and sour cream
58104340 Gordita, sope, or chalupa with chicken
58104500 Chimichanga with meat
58104520 Chimichanga, meatless
58104530 Chimichanga with chicken
58104535 Chimichanga with meat and sour cream
58104540 Chimichanga, meatless, with sour cream
58104550 Chimichanga with chicken and sour cream
58104710 Quesadilla, just cheese, meatless
58104720 Quesadilla, just cheese, from fast food
58104730 Quesadilla with meat
58104740 Quesadilla with chicken
58104745 Quesadilla with chicken, from fast food
58104750 Quesadilla with vegetables
58104760 Quesadilla with vegetables and meat
58104770 Quesadilla with vegetables and chicken
58104800 Taquito or flauta with cheese
58104820 Taquito or flauta with meat
58104825 Taquito or flauta with meat and cheese
58104830 Taquito or flauta with chicken
58104835 Taquito or flauta with chicken and cheese
58104900 Taquito or flauta with egg
58104905 Taquito or flauta with egg and breakfast meat
58105000 Fajita with chicken and vegetables

58105050 Fajita with meat and vegetables
58105075 Fajita with vegetables
58105100 Pupusa, cheese-filled
58105105 Pupusa, bean-filled
58105110 Pupusa, meat-filled
58115110 Tamale casserole, Puerto Rican style
58115150 Tamal in a leaf, Puerto Rican style
58115210 Taco with crab meat, Puerto Rican style
58128110 Chicken cornbread
58200250 Wrap sandwich, filled with vegetables
58306010 Beef enchilada dinner, NFS, frozen meal
58306020 Beef enchilada, chili gravy, rice, refried beans, frozen meal
58306070 Cheese enchilada, frozen meal

Crackers

[FermentIQ Pea Protein] = 5 g/100 g

54001000 Crackers, NFS
54102010 Graham crackers
54102015 Graham crackers (Teddy Grahams)
54102020 Graham crackers, chocolate covered
54102050 Crackers, oatmeal
54102060 Crackers, Cuban
54102100 Graham crackers, reduced fat
54102200 Graham crackers, sandwich, with filling
54103000 Crackers, breakfast biscuit
54200100 Crackers, butter, reduced sodium
54201010 Crackers, matzo, reduced sodium
54202020 Crackers, saltine, reduced sodium
54204020 Crackers, wheat, reduced sodium
54204030 Crackers, woven wheat, reduced sodium
54301010 Crackers, butter, plain
54301020 Crackers, butter, flavored
54301030 Crackers, butter (Ritz)
54301100 Crackers, butter, reduced fat
54304000 Crackers, cheese
54304005 Crackers, cheese (Cheez-It)
54304020 Crackers, cheese (Goldfish)
54304100 Crackers, cheese, reduced fat
54304110 Crackers, cheese, reduced sodium
54304150 Crackers, cheese, whole grain
54305010 Crackers, crispbread
54305020 Crackers, flatbread
54307000 Crackers, matzo

54308000 Crackers, milk
54313000 Crackers, oyster
54318000 Chips, rice
54318500 Rice cake
54319000 Crackers, rice
54319005 Crackers, rice and nuts
54319020 Popcorn cake
54319500 Rice paper
54325000 Crackers, saltine
54325010 Crackers, saltine, reduced fat
54325060 Crackers, saltine, multigrain
54326000 Crackers, multigrain
54328000 Crackers, sandwich
54328100 Crackers, sandwich, peanut butter filled
54328105 Crackers, sandwich, peanut butter filled (Ritz)
54328110 Crackers, sandwich, reduced fat, peanut butter filled
54328120 Crackers, whole grain, sandwich, peanut butter filled
54328200 Crackers, sandwich, cheese filled
54328210 Crackers, sandwich, cheese filled (Ritz)
54336000 Crackers, water
54336100 Crackers, wonton
54337010 Crackers, woven wheat
54337020 Crackers, woven wheat, plain (Triscuit)
54337030 Crackers, woven wheat, flavored (Triscuit)
54337060 Crackers, woven wheat, reduced fat
54338000 Crackers, wheat
54338010 Crackers, wheat, plain (Wheat Thins)
54338020 Crackers, wheat, flavored (Wheat Thins)
54338100 Crackers, wheat, reduced fat
54339000 Crackers, corn
54340100 Crackers, gluten free, plain
54340110 Crackers, gluten free, flavored

Biscuits, Cookies
[FermentIQ Pea Protein] = 10 g/100 g

52101000 Biscuit, NFS
52102040 Biscuit, from refrigerated dough
52103000 Biscuit, from fast food / restaurant
52104040 Biscuit, wheat
52104100 Biscuit, cheese
52104200 Biscuit with fruit
52105100 Scone
52105200 Scone, with fruit

53200100 Cookie, batter or dough, raw
53201000 Cookie, NFS
53202000 Cookie, almond
53203000 Cookie, applesauce
53203500 Cookie, biscotti
53204000 Cookie, brownie, NS as to icing
53204010 Cookie, brownie, without icing
53204100 Cookie, brownie, with icing or filling
53204840 Cookie, brownie, reduced fat, NS as to icing
53204860 Cookie, brownie, fat free, NS as to icing
53205250 Cookie, butterscotch, brownie
53205260 Cookie, bar, with chocolate
53206000 Cookie, chocolate chip
53206020 Cookie, chocolate chip, made from home recipe or purchased at a bakery
53206030 Cookie, chocolate chip, reduced fat
53206100 Cookie, chocolate chip sandwich
53206500 Cookie, chocolate, made with rice cereal
53206550 Cookie, chocolate, made with oatmeal and coconut, no bake
53207000 Cookie, chocolate or fudge
53207020 Cookie, chocolate or fudge, reduced fat
53207050 Cookie, chocolate, with chocolate filling or coating, fat free
53208000 Cookie, marshmallow, chocolate-covered
53208200 Cookie, marshmallow pie, chocolate covered
53209005 Cookie, chocolate, with icing or coating
53209010 Cookie, sugar wafer, chocolate-covered
53209015 Cookie, chocolate sandwich
53209020 Cookie, chocolate sandwich, reduced fat
53209100 Cookie, chocolate, sandwich, with extra filling
53209500 Cookie, chocolate and vanilla sandwich
53210000 Cookie, chocolate wafer
53210900 Cookie, graham cracker with chocolate and marshmallow
53211000 Cookie bar, with chocolate, nuts, and graham crackers
53215500 Cookie, coconut
53220000 Cookie, fruit-filled bar
53220010 Cookie, fruit-filled bar, fat free
53220030 Cookie, fig bar
53220040 Cookie, fig bar, fat free
53222010 Cookie, fortune
53222020 Cookie, cone shell, ice cream type, wafer or cake
53223000 Cookie, gingersnaps
53223100 Cookie, granola
53224000 Cookie, ladyfinger
53224250 Cookie, lemon bar
53225000 Cookie, macaroon

53226000 Cookie, marshmallow, with coconut
53226500 Cookie, marshmallow, with rice cereal, no bake
53226550 Cookie, marshmallow, with rice cereal and chocolate chips
53226600 Cookie, marshmallow and peanut butter, with oat cereal, no bake
53228000 Cookie, meringue
53230000 Cookie, molasses
53231000 Cookie, Lebkuchen
53231400 Cookie, multigrain, high fiber
53233000 Cookie, oatmeal
53233010 Cookie, oatmeal, with raisins
53233040 Cookie, oatmeal, reduced fat, NS as to raisins
53233050 Cookie, oatmeal sandwich, with creme filling
53233060 Cookie, oatmeal, with chocolate chips
53233080 Cookie, oatmeal sandwich, with peanut butter and jelly filling
53233100 Cookie, oatmeal, with chocolate and peanut butter, no bake
53234000 Cookie, peanut butter
53234100 Cookie, peanut butter, with chocolate
53234250 Cookie, peanut butter with rice cereal, no bake
53235000 Cookie, peanut butter sandwich
53235500 Cookie, with peanut butter filling, chocolate-coated
53235600 Cookie, Pfeffernusse
53236000 Cookie, Pizzelle
53236100 Cookie, pumpkin
53237000 Cookie, raisin
53237010 Cookie, raisin sandwich, cream-filled
53237500 Cookie, rum ball, no bake
53238000 Cookie, sandwich-type, not chocolate or vanilla
53239000 Cookie, shortbread
53239010 Cookie, shortbread, reduced fat
53239050 Cookie, shortbread, with icing or filling
53239100 Pocky
53240000 Cookie, animal
53240010 Cookie, animal, with frosting or icing
53241500 Cookie, butter or sugar
53241510 Marie biscuit
53241600 Cookie, butter or sugar, with fruit and/or nuts
53242000 Cookie, sugar wafer
53242500 Cookie, toffee bar
53243000 Cookie, vanilla sandwich
53243010 Cookie, vanilla sandwich, extra filling
53243050 Cookie, vanilla sandwich, reduced fat
53244010 Cookie, butter or sugar, with chocolate icing or filling
53244020 Cookie, butter or sugar, with icing or filling other than chocolate
53246000 Cookie, tea, Japanese

53247000 Cookie, vanilla wafer
53247050 Cookie, vanilla wafer, reduced fat
53247500 Cookie, vanilla with caramel, coconut, and chocolate coating
53251100 Cookie, rugelach
53260030 Cookie, chocolate chip, sugar free
53260200 Cookie, oatmeal, sugar free
53260300 Cookie, sandwich, sugar free
53260400 Cookie, sugar or plain, sugar free
53260500 Cookie, sugar wafer, sugar free
53260600 Cookie, peanut butter, sugar free
53261000 Cookie, gluten free
53270100 Cookies, Puerto Rican style

Mixed foods containing biscuits or cookies
Adjusted for biscuit or cookie content of 33.16 to 87.20%
[FermentIQ Pea Protein] = 3.32 to 8.72 g/100 g

27515080 Steak sandwich, plain, on biscuit
27520170 Bacon on biscuit
27520250 Ham on biscuit
27540145 Chicken fillet biscuit, from fast food
27560650 Sausage on biscuit
27560705 Sausage balls, made with biscuit mix and cheese
32202020 Egg, cheese, and ham on biscuit
32202050 Egg, cheese, and sausage on biscuit
32202060 Egg and sausage on biscuit
32202070 Egg, cheese, and bacon on biscuit
32202090 Egg and bacon on biscuit
32202110 Egg and ham on biscuit
32202130 Egg and steak on biscuit
32202200 Egg and cheese on biscuit

French Toast, Pancakes, and Waffles
[FermentIQ Pea Protein] = 10 g/100 g

53344300 Dessert pizza
53400200 Blintz, cheese-filled
53400300 Blintz, fruit-filled
53430000 Crepe, NS as to filling
53430100 Crepe, chocolate filled
53430200 Crepe, fruit filled
55100005 Pancakes, NFS
55100010 Pancakes, plain, from frozen
55100015 Pancakes, plain, reduced fat, from fozen
55100020 Pancakes, with fruit, from frozen

55100025	Pancakes, with chocolate, from frozen
55100030	Pancakes, whole grain, from frozen
55100035	Pancakes, whole grain, reduced fat, from frozen
55100040	Pancakes, gluten free, from frozen
55100050	Pancakes, plain, from fast food / restaurant
55100055	Pancakes, with fruit, from fast food / restaurant
55100060	Pancakes, with chocolate, from fast food / restaurant
55100065	Pancakes, whole grain, from fast food / restaurant
55100070	Pancakes, whole grain and nuts, from fast food / restaurant
55100080	Pancakes, from school, NFS
55101000	Pancakes, plain
55101015	Pancakes, plain, reduced fat
55103000	Pancakes, with fruit
55103020	Pancakes, pumpkin
55103100	Pancakes, with chocolate
55105000	Pancakes, buckwheat
55105100	Pancakes, cornmeal
55105200	Pancakes, whole grain
55105205	Pancakes, whole grain, reduced fat
55106000	Pancakes, gluten free
55200010	Waffle, NFS
55200020	Waffle, plain, from frozen
55200030	Waffle, plain, reduced fat, from frozen
55200040	Waffle, fruit, from frozen
55200050	Waffle, chocolate, from frozen
55200060	Waffle, whole grain, from frozen
55200070	Waffle, whole grain, reduced fat, from frozen
55200080	Waffle, whole grain, fruit, from frozen
55200090	Waffle, gluten free, from frozen
55200100	Waffle, plain, from fast food / restaurant
55200110	Waffle, chocolate, from fast food / restaurant
55200120	Waffle, fruit, from fast food / restaurant
55200130	Waffle, whole grain, from fast food / restaurant
55200200	Waffle, from school, NFS
55201000	Waffle, plain
55203000	Waffle, fruit
55203600	Waffle, chocolate
55203700	Waffle, cinnamon
55204000	Waffle, cornmeal
55205000	Waffle, whole grain
55208000	Waffle, gluten free
55211050	Waffle, plain, reduced fat
55212000	Waffle, whole grain, reduced fat
55300010	French toast, NFS

55300020 French toast, plain, from frozen
55300030 French toast, whole grain, from frozen
55300040 French toast, gluten free, from frozen
55300050 French toast, plain, from fast food / restaurant
55300055 French toast, whole grain, from fast food / restaurant
55300060 French toast, from school, NFS
55301000 French toast, plain
55301010 French toast, plain, reduced fat
55301015 French toast, whole grain
55301020 French toast, whole grain, reduced fat
55301025 French toast, gluten free
55301030 French toast sticks, NFS
55301031 French toast sticks, plain, from frozen
55301040 French toast sticks, plain, from fast food / restaurant
55301048 French toast sticks, from school, NFS
55301050 French toast sticks, plain
55301055 French toast sticks, whole grain
55310100 Fried bread, Puerto Rican style
55400010 Crepe, NFS
55401000 Crepe, plain
55501000 Chinese pancake
55610300 Dumpling, plain
55701000 Cake made with glutinous rice
55702000 Cake or pancake made with rice flour and/or dried beans
55702100 Dosa (Indian), plain
55703000 Cake made with glutinous rice and dried beans
58128000 Biscuit with gravy
58174100 Dosa (Indian), with filling
58310210 Sausage and french toast, frozen meal
58310310 Pancakes and sausage, frozen meal

Bread (high protein)
[FermentIQ Pea Protein] = 15 g/100 g

51123010 Bread, high protein
51123020 Bread, high protein, toasted

Beverages and Beverage Bases

Non-Milk Meal Replacements and Protein Drinks
[FermentIQ Pea Protein] = 40 g/100 g

95120050 Nutritional drink or shake, liquid, soy-based

Foods adjusted for being present in dried form (not reconstituted)
Reconstitution factor of 7

95201300	Nutritional powder mix (EAS Soy Protein Powder)
95230010	Nutritional powder mix, protein, soy based, NFS

Breakfast Cereals

Hot Breakfast Cereals
[FermentIQ Pea Protein] = 15 g/100 g

56200300	Cereal, cooked, NFS
56200390	Barley, NS as to fat
56200400	Barley, no added fat
56200410	Barley, fat added
56200490	Buckwheat groats, NS as to fat
56200500	Buckwheat groats, no added fat
56200510	Buckwheat groats, fat added
56200990	Grits, NS as to regular, quick, or instant, NS as to fat
56201000	Grits, NS as to regular, quick, or instant, no added fat
56201040	Grits, NS as to regular, quick, or instant, fat added
56201050	Grits, regular or quick, made with water, NS as to fat
56201051	Grits, regular or quick, made with water, no added fat
56201052	Grits, regular or quick, made with water, fat added
56201055	Grits, regular or quick, made with milk, NS as to fat
56201056	Grits, regular or quick, made with milk, no added fat
56201057	Grits, regular or quick, made with milk, fat added
56201065	Grits, regular or quick, made with non-dairy milk, NS as to fat
56201066	Grits, regular or quick, made with non-dairy milk, no added fat
56201067	Grits, regular or quick, made with non-dairy milk, fat added
56201090	Grits, with cheese, NS as to fat
56201091	Grits, with cheese, no added fat
56201092	Grits, with cheese, fat added
56201210	Grits, instant, made with water, no added fat
56201220	Grits, instant, made with water, fat added
56201230	Grits, instant, made with water, NS as to fat
56201340	Grits, instant, made with milk, fat added
56201342	Grits, instant, made with milk, no added fat
56201344	Grits, instant, made with milk, NS as to fat
56201350	Grits, instant, made with non-dairy milk, NS as to fat
56201355	Grits, instant, made with non-dairy milk, no added fat
56201360	Grits, instant, made with non-dairy milk, fat added
56201515	Cornmeal mush, NS as to fat
56201516	Cornmeal mush, no added fat
56201517	Cornmeal mush, fat added

56201540	Cornmeal, Puerto Rican Style
56201550	Cornmeal dumpling
56201600	Masa harina, cooked
56201990	Millet, NS as to fat
56202000	Millet, no added fat
56202100	Millet, fat added
56202900	Oatmeal, from fast food, plain
56202905	Oatmeal, from fast food, maple flavored
56202910	Oatmeal, from fast food, fruit flavored
56202920	Oatmeal, from fast food, other flavors
56202960	Oatmeal, NS as to regular, quick, or instant, NS as to fat
56203000	Oatmeal, NS as to regular, quick, or instant, no added fat
56203040	Oatmeal, NS as to regular, quick, or instant, fat added
56203055	Oatmeal, regular or quick, made with water, NS as to fat
56203056	Oatmeal, regular or quick, made with water, no added fat
56203057	Oatmeal, regular or quick, made with water, fat added
56203065	Oatmeal, regular or quick, made with milk, NS as to fat
56203066	Oatmeal, regular or quick, made with milk, no added fat
56203067	Oatmeal, regular or quick, made with milk, fat added
56203075	Oatmeal, regular or quick, made with non-dairy milk, NS as to fat
56203076	Oatmeal, regular or quick, made with non-dairy milk, no added fat
56203077	Oatmeal, regular or quick, made with non-dairy milk, fat added
56203085	Oatmeal, instant, plain, made with water, NS as to fat
56203086	Oatmeal, instant, plain, made with water, no added fat
56203087	Oatmeal, instant, plain, made with water, fat added
56203095	Oatmeal, instant, plain, made with milk, NS as to fat
56203096	Oatmeal, instant, plain, made with milk, no added fat
56203097	Oatmeal, instant, plain, made with milk, fat added
56203105	Oatmeal, instant, plain, made with non-dairy milk, NS as to fat
56203106	Oatmeal, instant, plain, made with non-dairy milk, no added fat
56203107	Oatmeal, instant, plain, made with non-dairy milk, fat added
56203125	Oatmeal, instant, maple flavored, NS as to fat
56203130	Oatmeal, instant, maple flavored, no added fat
56203135	Oatmeal, instant, maple flavored, fat added
56203150	Oatmeal, instant, fruit flavored, NS as to fat
56203155	Oatmeal, instant, fruit flavored, no added fat
56203160	Oatmeal, instant, fruit flavored, fat added
56203170	Oatmeal, instant, other flavors, NS as to fat
56203175	Oatmeal, instant, other flavors, no added fat
56203180	Oatmeal, instant, other flavors, fat added
56203500	Oatmeal, reduced sugar, plain, NS as to fat
56203510	Oatmeal, reduced sugar, plain, no added fat
56203520	Oatmeal, reduced sugar, plain, fat added
56203540	Oatmeal, made with milk and sugar, Puerto Rican style

56203550	Oatmeal, reduced sugar, flavored, NS as to fat
56203555	Oatmeal, reduced sugar, flavored, no added fat
56203560	Oatmeal, reduced sugar, flavored, fat added
56203600	Oatmeal, multigrain, NS as to fat
56203610	Oatmeal, multigrain, no added fat
56203620	Oatmeal, multigrain, fat added
56205050	Rice, cream of, cooked, no added fat
56205080	Rice, creamed, made with milk and sugar, Puerto Rican style
56205090	Rice, cream of, cooked, fat added
56205092	Rice, cream of, cooked, NS as to fat
56205094	Rice, cream of, cooked, made with milk
56205101	Congee
56206990	Cream of wheat, NS as to regular, quick, or instant, NS as to fat
56207000	Cream of wheat, NS as to regular, quick, or instant, no added fat
56207005	Cream of wheat, NS as to regular, quick, or instant, fat added
56207015	Cream of wheat, regular or quick, made with water, NS as to fat
56207016	Cream of wheat, regular or quick, made with water, no added fat
56207017	Cream of wheat, regular or quick, made with water, fat added
56207021	Cream of wheat, regular or quick, made with milk, NS as to fat
56207022	Cream of wheat, regular or quick, made with milk, no added fat
56207023	Cream of wheat, regular or quick, made with milk, fat added
56207025	Cream of wheat, regular or quick, made with non-dairy milk, NS as to fat
56207026	Cream of wheat, regular or quick, made with non-dairy milk, no added fat
56207027	Cream of wheat, regular or quick, made with non-dairy milk, fat added
56207030	Cream of wheat, instant, made with water, no added fat
56207050	Wheat, cream of, cooked, made with milk and sugar, Puerto Rican style
56207060	Cream of wheat, instant, made with water, fat added
56207070	Cream of wheat, instant, made with water, NS as to fat
56207094	Cream of wheat, instant, made with milk, fat added
56207095	Cream of wheat, instant, made with milk, no added fat
56207096	Cream of wheat, instant, made with milk, NS as to fat
56207101	Cream of wheat, instant, made with non-dairy milk, NS as to fat
56207102	Cream of wheat, instant, made with non-dairy milk, no added fat
56207103	Cream of wheat, instant, made with non-dairy milk, fat added
56207190	Whole wheat cereal, cooked, NS as to fat
56207200	Whole wheat cereal, cooked, no added fat
56207210	Whole wheat cereal, cooked, fat added
56207370	Wheat cereal, chocolate flavored, cooked
56208500	Oat bran cereal, cooked, no added fat
56208510	Oat bran cereal, cooked, fat added
56208520	Oat bran cereal, cooked, NS as to fat
56209000	Cream of rye
57601100	Wheat bran, unprocessed
57602100	Oats, raw

57602500 Oat bran, uncooked
58157300 Congee, with meat, poultry, and/or seafood
58157310 Congee, with meat, poultry, and/or seafood, and vegetables
58157320 Congee, with vegetables
58174000 Upma, Indian breakfast dish

Ready-to-Eat Cereals

[FermentIQ Pea Protein] = 15 g/100 g

57000100 Cereal, oat, NFS
57100100 Cereal, ready-to-eat, NFS
57101000 Cereal (Kellogg's All-Bran)
57103000 Cereal (Post Alpha-Bits)
57103100 Cereal (General Mills Cheerios Apple Cinnamon)
57104000 Cereal (Kellogg's Apple Jacks)
57106050 Cereal (Post Great Grains Banana Nut Crunch)
57106060 Cereal (General Mills Cheerios Banana Nut)
57106260 Cereal (General Mills Cheerios Berry Burst)
57117000 Cereal (Quaker Cap'n Crunch)
57117500 Cereal (Quaker Christmas Crunch)
57119000 Cereal (Quaker Cap'n Crunch's Crunchberries)
57120000 Cereal (Quaker Cap'n Crunch's Peanut Butter Crunch)
57123000 Cereal (General Mills Cheerios)
57124030 Cereal (General Mills Chex Chocolate)
57124050 Cereal (General Mills Chex Cinnamon)
57124100 Cereal (General Mills Cheerios Chocolate)
57124200 Cereal, chocolate flavored, frosted, puffed corn
57124300 Cereal (General Mills Lucky Charms Chocolate)
57125000 Cereal (General Mills Cinnamon Toast Crunch)
57125010 Cereal (General Mills 25% Less Sugar Cinnamon Toast Crunch)
57125900 Cereal (General Mills Honey Nut Clusters)
57126000 Cereal (Kellogg's Cocoa Krispies)
57127000 Cereal (Post Cocoa Pebbles)
57128000 Cereal (General Mills Cocoa Puffs)
57130000 Cereal (General Mills Cookie Crisp)
57132000 Cereal (General Mills Chex Corn)
57134000 Cereal, corn flakes
57135000 Cereal (Kellogg's Corn Flakes)
57137000 Cereal, corn puffs
57139000 Cereal (General Mills Count Chocula)
57143000 Cereal (Kellogg's Cracklin' Oat Bran)
57143500 Cereal (Post Great Grains, Cranberry Almond Crunch)
57148000 Cereal (Kellogg's Crispix)
57151000 Cereal, crispy rice

57206700 Cereal (General Mills Fiber One)
57206710 Cereal (General Mills Fiber One Honey Clusters)
57206715 Cereal (General Mills Fiber One Raisin Bran Clusters)
57207000 Cereal, bran flakes
57208000 Cereal (Kellogg's All-Bran Complete Wheat Flakes)
57209000 Cereal (Post Bran Flakes)
57211000 Cereal (General Mills Frankenberry)
57213000 Cereal (Kellogg's Froot Loops)
57213010 Cereal (Kellogg's Froot Loops Marshmallow)
57213850 Cereal (General Mills Cheerios Frosted)
57214000 Cereal (Kellogg's Frosted Mini-Wheats)
57216000 Cereal, frosted rice
57221700 Cereal, fruit rings
57221810 Cereal (General Mills Cheerios Fruity)
57223000 Cereal (Post Fruity Pebbles)
57224000 Cereal (General Mills Golden Grahams)
57227000 Cereal, granola
57228000 Granola, homemade
57229000 Cereal (Kellogg's Low Fat Granola)
57230000 Cereal (Post Grape-Nuts)
57231200 Cereal (Post Great Grains Raisins, Dates, and Pecans)
57237100 Cereal (Post Honey Bunches of Oats Honey Roasted)
57237200 Cereal (Post Honey Bunches of Oats with Vanilla Bunches)
57237300 Cereal (Post Honey Bunches of Oats with Almonds)
57238000 Cereal (Post Honeycomb)
57240100 Cereal (General Mills Chex Honey Nut)
57241000 Cereal (General Mills Cheerios Honey Nut)
57241200 Cereal (Post Shredded Wheat Honey Nut)
57243000 Cereal (Kellogg's Honey Smacks)
57301500 Cereal (Kashi 7 Whole Grain Puffs)
57301505 Cereal (Kashi Autumn Wheat)
57301510 Cereal (Kashi GOLEAN)
57301511 Cereal (Kashi GOLEAN Crunch)
57301512 Cereal (Kashi GOLEAN Crunch Honey Almond Flax)
57301530 Cereal (Kashi Heart to Heart Honey Toasted Oat)
57303100 Cereal (General Mills Kix)
57303105 Cereal (General Mills Honey Kix)
57303200 Cereal (Kellogg's Krave)
57304100 Cereal (Quaker Life)
57305100 Cereal (General Mills Lucky Charms)
57305150 Cereal, frosted oat cereal with marshmallows
57305160 Cereal (Malt-O-Meal Blueberry Muffin Tops)
57305165 Cereal (Malt-O-Meal Cinnamon Toasters)
57305170 Cereal (Malt-O-Meal Coco-Roos)

57305174 Cereal (Malt-O-Meal Colossal Crunch)
57305175 Cereal (Malt-O-Meal Cocoa Dyno-Bites)
57305180 Cereal (Malt-O-Meal Corn Bursts)
57305210 Cereal (Malt-O-Meal Frosted Flakes)
57305300 Cereal (Malt-O-Meal Fruity Dyno-Bites)
57305400 Cereal (Malt-O-Meal Honey Graham Squares)
57305500 Cereal (Malt-O-Meal Honey Nut Toasty O's)
57305600 Cereal (Malt-O-Meal Marshmallow Mateys)
57306500 Cereal (Malt-O-Meal Golden Puffs)
57306700 Cereal (Malt-O-Meal Toasted Oat Cereal)
57306800 Cereal (Malt-O-Meal Tootie Fruities)
57308190 Cereal, muesli
57308400 Cereal (General Mills Cheerios Multigrain)
57309100 Cereal (Nature Valley Granola)
57316380 Cereal (General Mills Cheerios Oat Cluster Crunch)
57316385 Cereal (General Mills Cheerios Protein)
57316450 Cereal (General Mills Oatmeal Crisp with Almonds)
57316710 Cereal (Quaker Honey Graham Oh's)
57320500 Cereal (Quaker Granola with Oats, Honey, and Raisins)
57321900 Cereal (Nature's Path Organic Flax Plus)
57326000 Cereal (Barbara's Puffins)
57327450 Cereal (Quaker Toasted Oat Bran)
57327500 Cereal (Quaker Oatmeal Squares)
57329000 Cereal, raisin bran
57330000 Cereal (Kellogg's Raisin Bran)
57330010 Cereal (Kellogg's Raisin Bran Crunch)
57331000 Cereal (Post Raisin Bran)
57332100 Cereal (General Mills Raisin Nut Bran)
57335550 Cereal (General Mills Reese's Puffs)
57336000 Cereal (General Mills Chex Rice)
57337000 Cereal, rice flakes
57339000 Cereal (Kellogg's Rice Krispies)
57339500 Cereal (Kellogg's Rice Krispies Treats Cereal)
57340000 Cereal, puffed rice
57341200 Cereal (Kellogg's Smart Start Strong)
57341300 Cereal (Kellogg's Smorz)
57344000 Cereal (Kellogg's Special K)
57344001 Cereal (Kellogg's Special K Blueberry)
57344005 Cereal (Kellogg's Special K Chocolatey Delight)
57344010 Cereal (Kellogg's Special K Red Berries)
57344015 Cereal (Kellogg's Special K Fruit & Yogurt)
57344020 Cereal (Kellogg's Special K Vanilla Almond)
57344025 Cereal (Kellogg's Special K Cinnamon Pecan)
57347000 Cereal (Kellogg's Corn Pops)

57348000 Cereal, frosted corn flakes
57349000 Cereal (Kellogg's Frosted Flakes)
57355000 Cereal (Post Golden Crisp)
57401100 Cereal, toasted oat
57407100 Cereal (General Mills Trix)
57408100 Cereal (Uncle Sam)
57411000 Cereal (General Mills Chex Wheat)
57412000 Wheat germ, plain
57416000 Cereal, puffed wheat, plain
57416010 Cereal, puffed wheat, sweetened
57417000 Cereal (Post Shredded Wheat)
57418000 Cereal (General Mills Wheaties)

Coffee and Tea

Specialty Coffee Drinks (lattes, cappuccinos, mochas)
[FermentIQ Pea Protein] = 10 g/100 g

92101600 Coffee, Turkish
92101610 Coffee, espresso
92101630 Coffee, espresso, decaffeinated
92101800 Coffee, Cuban
92101810 Coffee, macchiato
92101820 Coffee, macchiato, sweetened
92101850 Coffee, cafe con leche
92101851 Coffee, cafe con leche, decaffeinated
92101900 Coffee, Latte
92101901 Coffee, Latte, nonfat
92101903 Coffee, Latte, with non-dairy milk
92101904 Coffee, Latte, flavored
92101905 Coffee, Latte, nonfat, flavored
92101906 Coffee, Latte, with non-dairy milk, flavored
92101910 Coffee, Latte, decaffeinated
92101911 Coffee, Latte, decaffeinated, nonfat
92101913 Coffee, Latte, decaffeinated, with non-dairy milk
92101917 Coffee, Latte, decaffeinated, flavored
92101918 Coffee, Latte, decaffeinated, nonfat, flavored
92101919 Coffee, Latte, decaffeinated, with non-dairy milk, flavored
92101920 Frozen coffee drink
92101921 Frozen coffee drink, nonfat
92101923 Frozen coffee drink, with non-dairy milk
92101925 Frozen coffee drink, with whipped cream
92101926 Frozen coffee drink, nonfat, with whipped cream
92101928 Frozen coffee drink, with non-dairy milk and whipped cream

92101930 Frozen coffee drink, decaffeinated
92101931 Frozen coffee drink, decaffeinated, nonfat
92101933 Frozen coffee drink, decaffeinated, with non-dairy milk
92101935 Frozen coffee drink, decaffeinated, with whipped cream
92101936 Frozen coffee drink, decaffeinated, nonfat, with whipped cream
92101938 Frozen coffee drink, decaffeinated, with non-dairy milk and whipped cream
92101950 Coffee, Cafe Mocha
92101955 Coffee, Cafe Mocha, nonfat
92101960 Coffee, Cafe Mocha, with non-dairy milk
92101965 Coffee, Cafe Mocha, decaffeinated
92101970 Coffee, Cafe Mocha, decaffeinated, nonfat
92101975 Coffee, Cafe Mocha, decaffeinated, with non-dairy milk
92102000 Frozen mocha coffee drink
92102010 Frozen mocha coffee drink, nonfat
92102020 Frozen mocha coffee drink, with non-dairy milk
92102030 Frozen mocha coffee drink, with whipped cream
92102040 Frozen mocha coffee drink, nonfat, with whipped cream
92102050 Frozen mocha coffee drink, with non-dairy milk and whipped cream
92102060 Frozen mocha coffee drink, decaffeinated
92102070 Frozen mocha coffee drink, decaffeinated, nonfat
92102080 Frozen mocha coffee drink, decaffeinated, with non-dairy milk
92102090 Frozen mocha coffee drink, decaffeinated, with whipped cream
92102100 Frozen mocha coffee drink, decaffeinated, nonfat, with whipped cream
92102110 Frozen mocha coffee drink, decaffeinated, with non-dairy milk and whipped cream
92102500 Coffee, Iced Latte
92102501 Coffee, Iced Latte, nonfat
92102502 Coffee, Iced Latte, with non-dairy milk
92102503 Coffee, Iced Latte, flavored
92102504 Coffee, Iced Latte, nonfat, flavored
92102505 Coffee, Iced Latte, with non-dairy milk, flavored
92102510 Coffee, Iced Latte, decaffeinated
92102511 Coffee, Iced Latte, decaffeinated, nonfat
92102512 Coffee, Iced Latte, decaffeinated, with non-dairy milk
92102513 Coffee, Iced Latte, decaffeinated, flavored
92102514 Coffee, Iced Latte, decaffeinated, nonfat, flavored
92102515 Coffee, Iced Latte, decaffeinated, with non-dairy milk, flavored
92102600 Coffee, Iced Cafe Mocha
92102601 Coffee, Iced Cafe Mocha, nonfat
92102602 Coffee, Iced Cafe Mocha, with non-dairy milk
92102610 Coffee, Iced Cafe Mocha, decaffeinated
92102611 Coffee, Iced Cafe Mocha, decaffeinated, nonfat
92102612 Coffee, Iced Cafe Mocha, decaffeinated, with non-dairy milk
92152000 Coffee and chicory, brewed
92152010 Coffee and chicory, brewed, decaffeinated

92161000 Coffee, Cappuccino
92161001 Coffee, Cappuccino, nonfat
92161002 Coffee, Cappuccino, with non-dairy milk
92162000 Coffee, Cappuccino, decaffeinated
92162001 Coffee, Cappuccino, decaffeinated, nonfat
92162002 Coffee, Cappuccino, decaffeinated, with non-dairy milk
92171000 Coffee, bottled/canned
92171010 Coffee, bottled/canned, light

Ready-to-Drink Tea Beverages; Instant Tea
[FermentIQ Pea Protein] = 10 g/100 g

92305010 Tea, iced, instant, black, unsweetened
92305040 Tea, iced, instant, black, pre-sweetened with sugar
92305050 Tea, iced, instant, black, decaffeinated, pre-sweetened with sugar
92305090 Tea, iced, instant, black, pre-sweetened with low calorie sweetener
92305110 Tea, iced, instant, black, decaffeinated, pre-sweetened with low calorie sweetener
92305180 Tea, iced, instant, black, decaffeinated, unsweetened
92305900 Tea, iced, instant, green, unsweetened
92305910 Tea, iced, instant, green, pre-sweetened with sugar
92305920 Tea, iced, instant, green, pre-sweetened with low calorie sweetener
92307500 Iced Tea / Lemonade juice drink
92307510 Iced Tea / Lemonade juice drink, light
92307520 Iced Tea / Lemonade juice drink, diet
92309000 Tea, iced, bottled, black
92309010 Tea, iced, bottled, black, decaffeinated
92309020 Tea, iced, bottled, black, diet
92309030 Tea, iced, bottled, black, decaffeinated, diet
92309040 Tea, iced, bottled, black, unsweetened
92309050 Tea, iced, bottled, black, decaffeinated, unsweetened
92309500 Tea, iced, bottled, green
92309510 Tea, iced, bottled, green, diet
92309520 Tea, iced, bottled, green, unsweetened

Foods adjusted for being present in dried form (not reconstituted)
Reconstitution factor of 16

92307000 Tea, iced, instant, black, unsweetened, dry
92307400 Tea, iced, instant, black, pre-sweetened, dry

Dairy Product Analogues

Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers)
[FermentIQ Pea Protein] = 10 g/100 g

11300100	Non-dairy milk, NFS
11320000	Soy milk
11320100	Soy milk, light
11320200	Soy milk, nonfat
11321000	Soy milk, chocolate
11321100	Soy milk, light, chocolate
11321200	Soy milk, nonfat, chocolate
11350000	Almond milk, sweetened
11350010	Almond milk, sweetened, chocolate
11350020	Almond milk, unsweetened
11350030	Almond milk, unsweetened, chocolate
11360000	Rice milk
11370000	Coconut milk
12200100	Coffee creamer, NFS
12210200	Coffee creamer, liquid
12210210	Coffee creamer, liquid, flavored
12210260	Coffee creamer, liquid, fat free
12210270	Coffee creamer, liquid, fat free, flavored
12210280	Coffee creamer, liquid, fat free, sugar free, flavored
12210310	Coffee creamer, liquid, sugar free, flavored
12210400	Coffee creamer, powder
12210420	Coffee creamer, powder, flavored
12210430	Coffee creamer, powder, fat free
12210440	Coffee creamer,powder, fat free, flavored
12210505	Coffee creamer,powder, sugar free, flavored
12210520	Coffee creamer, soy, liquid
42401010	Coconut milk, used in cooking
42402010	Coconut cream, canned, sweetened

<u>Mixed foods containing non-dairy milk or cream</u>
Adjusted for non-dairy or cream content of 77.5%
[FermentIQ Pea Protein] = 7.75 g/100 g

11512030	Hot chocolate / Cocoa, ready to drink, made with non-dairy milk
11512120	Hot chocolate / Cocoa, ready to drink, made with non-dairy milk and whipped cream
11513310	Chocolate milk, made from dry mix with non-dairy milk
11513375	Chocolate milk, made from reduced sugar mix with non-dairy milk
11513385	Chocolate milk, made from dry mix with non-dairy milk (Nesquik)
11513395	Chocolate milk, made from no sugar added dry mix with non-dairy milk (Nesquik)
11513750	Chocolate milk, made from syrup with non-dairy milk
11513805	Chocolate milk, made from light syrup with non-dairy milk
11513855	Chocolate milk, made from sugar free syrup with non-dairy milk
11514150	Hot chocolate / Cocoa, made with dry mix and non-dairy milk
11514360	Hot chocolate / Cocoa, made with no sugar added dry mix and non-dairy milk

11519215 Strawberry milk, non-dairy

Cream Cheese Substitutes
[FermentIQ Pea Protein] = 12 g/100 g

14301010 Cream cheese, regular, plain
14301100 Cream cheese, regular, flavored
14303010 Cream cheese, light
14410380 Cream cheese spread, fat free
14420200 Cheese spread, cream cheese, regular
14420210 Cheese spread, cream cheese, light

Non-Dairy Frozen Desserts
[FermentIQ Pea Protein] = 10 g/100 g

41480020 Frozen dessert, non-dairy

Non-Dairy Dips
[FermentIQ Pea Protein] = 10 g/100 g

12320100 Sour cream, imitation
12350010 Dip, NFS
41205050 Bean dip, made with refried beans
41205070 Hummus, plain
41205075 Hummus, flavored
63409010 Guacamole, NFS
63409015 Guacamole with tomatoes
63409020 Chutney
75412030 Eggplant dip

Non-Dairy Yogurt
[FermentIQ Pea Protein] = 25 g/100 g

41420380 Yogurt, soy
42401100 Yogurt, coconut milk

Imitation Cheese
[FermentIQ Pea Protein] = 25 g/100 g

14502000 Imitation cheese

Grain Products and Pastas

Cereal Bars, Nutritional Bars, and Meal Replacement Bars
[FermentIQ Pea Protein] = 20 g/100 g

53710400 Cereal or granola bar (General Mills Fiber One Chewy Bar)
53710500 Cereal or granola bar (Kellogg's Nutri-Grain Cereal Bar)
53710502 Cereal or granola bar (Kellogg's Nutri-Grain Yogurt Bar)
53710504 Cereal or granola bar (Kellogg's Nutri-Grain Fruit and Nut Bar)
53710600 Milk 'n Cereal bar
53710700 Cereal or granola bar (Kellogg's Special K bar)
53710800 Cereal or granola bar (Kashi Chewy)
53710802 Cereal or granola bar (Kashi Crunchy)
53710810 Cereal or granola bar (KIND Fruit and Nut Bar)
53710900 Cereal or granola bar (General Mills Nature Valley Chewy Trail Mix)
53710902 Cereal or granola bar, with yogurt coating (General Mills Nature Valley Chewy Granola Bar)
53710904 Cereal or granola bar (General Mills Nature Valley Sweet and Salty Granola Bar)
53710906 Cereal or granola bar (General Mills Nature Valley Crunchy Granola Bar)
53711000 Cereal or granola bar (Quaker Chewy Granola Bar)
53711002 Cereal or granola bar (Quaker Chewy 90 Calorie Granola Bar)
53711004 Cereal or granola bar (Quaker Chewy 25% Less Sugar Granola Bar)
53711006 Cereal or granola bar (Quaker Chewy Dipps Granola Bar)
53711100 Cereal or granola bar (Quaker Granola Bites)
53712000 Snack bar, oatmeal
53712100 Cereal or Granola bar, NFS
53712200 Cereal or granola bar, lowfat, NFS
53712210 Cereal or granola bar, nonfat
53713000 Cereal or granola bar, reduced sugar, NFS
53713010 Cereal or granola bar, fruit and nut
53713100 Cereal or granola bar, peanuts , oats, sugar, wheat germ
53714200 Cereal or granola bar, chocolate coated, NFS
53714210 Cereal or granola bar, with coconut, chocolate coated
53714220 Cereal or granola bar with nuts, chocolate coated
53714230 Cereal or granola bar, oats, nuts, coated with non-chocolate coating
53714250 Cereal or granola bar, coated with non-chocolate coating
53714300 Cereal or granola bar, high fiber, coated with non-chocolate yogurt coating
53714400 Cereal or granola bar, with rice cereal
53714500 Breakfast bar, NFS
53714510 Breakfast bar, date, with yogurt coating
53714520 Breakfast bar, cereal crust with fruit filling, lowfat
53720100 Nutrition bar (Balance Original Bar)
53720200 Nutrition bar (Clif Bar)
53720210 Nutrition bar (Clif Kids Organic Zbar)
53720300 Nutrition bar (PowerBar)
53720400 Nutrition bar (Slim Fast Original Meal Bar)
53720500 Nutrition bar (Snickers Marathon Protein Bar)
53720600 Nutrition bar (South Beach Living Meal Bar)
53720610 Nutrition bar (South Beach Living High Protein Bar)
53720700 Nutrition bar (Tiger's Milk)

53720800 Nutrition bar (Zone Perfect Classic Crunch)
53729000 Nutrition bar or meal replacement bar, NFS

Milk Products

Milk-Based Meal Replacements and Protein Drinks
[FermentIQ Pea Protein] = 15 g/100 g

95101000 Nutritional drink or shake, ready-to-drink (Boost)
95101010 Nutritional drink or shake, ready-to-drink (Boost Plus)
95102000 Nutritional drink or shake, ready-to-drink (Carnation Instant Breakfast)
95103000 Nutritional drink or shake, ready-to-drink (Ensure)
95103010 Nutritional drink or shake, ready-to-drink (Ensure Plus)
95104000 Nutritional drink or shake, ready-to-drink, sugar free (Glucerna)
95105000 Nutritional drink or shake, ready-to-drink (Kellogg's Special K Protein)
95106000 Nutritional drink or shake, ready-to-drink (Muscle Milk)
95106010 Nutritional drink or shake, ready-to-drink, light (Muscle Milk)
95110000 Nutritional drink or shake, ready-to-drink (Slim Fast)
95110010 Nutritional drink or shake, ready-to-drink, sugar free (Slim Fast)
95110020 Nutritional drink or shake, high protein, ready-to-drink (Slim Fast)
95120000 Nutritional drink or shake, ready-to-drink, NFS
95120010 Nutritional drink or shake, high protein, ready-to-drink, NFS
95120020 Nutritional drink or shake, high protein, light, ready-to-drink, NFS

Foods adjusted for being present in dried form (not reconstituted)
Reconstitution factor of 6 to 10

95201000 Nutritional powder mix (Carnation Instant Breakfast)
95201010 Nutritional powder mix, sugar free (Carnation Instant Breakfast)
95201200 Nutritional powder mix (EAS Whey Protein Powder)
95201500 Nutritional powder mix, high protein (Herbalife)
95201600 Nutritional powder mix (Isopure)
95201700 Nutritional powder mix (Kellogg's Special K20 Protein Water)
95202000 Nutritional powder mix (Muscle Milk)
95202010 Nutritional powder mix, light (Muscle Milk)
95210000 Nutritional powder mix (Slim Fast)
95210010 Nutritional powder mix, sugar free (Slim Fast)
95210020 Nutritional powder mix, high protein (Slim Fast)
95220000 Nutritional powder mix, NFS
95220010 Nutritional powder mix, high protein, NFS
95230000 Nutritional powder mix, whey based, NFS
95230020 Nutritional powder mix, protein, light, NFS
95230030 Nutritional powder mix, protein, NFS

Nut and Nut Products

Nut Butters and Spreads
[FermentIQ Pea Protein] = 10 g/100 g

42200500	Almond butter
42200510	Almond butter, lower sodium
42200600	Almond paste
42201000	Cashew butter
42202000	Peanut butter
42202010	Peanut butter, lower sodium
42202100	Peanut butter, lower sodium and lower sugar
42202130	Peanut butter, lower sugar
42202150	Peanut butter, reduced fat
42202200	Peanut butter, vitamin and mineral fortified
42203000	Peanut butter and jelly
42203100	Peanut butter and chocolate spread

Mixed foods containing nut butters or spreads
Adjusted for nut butter or spread content of 28.57 to 34.78%
[FermentIQ Pea Protein] = 2.857 to 3.478 g/100 g

42301010	Peanut butter sandwich, NFS
42301015	Peanut butter sandwich, with regular peanut butter, on white bread
42301020	Peanut butter sandwich, with regular peanut butter, on wheat bread
42301025	Peanut butter sandwich, with regular peanut butter, on whole wheat bread
42301115	Peanut butter sandwich, with reduced fat peanut butter, on white bread
42301120	Peanut butter sandwich, with reduced fat peanut butter, on wheat bread
42301125	Peanut butter sandwich, with reduced fat peanut butter, on whole wheat bread
42302010	Peanut butter and jelly sandwich, NFS
42302015	Peanut butter and jelly sandwich, with regular peanut butter, regular jelly, on white bread
42302020	Peanut butter and jelly sandwich, with regular peanut butter, regular jelly, on wheat bread
42302025	Peanut butter and jelly sandwich, with regular peanut butter, regular jelly, on whole wheat bread
42302055	Peanut butter and jelly sandwich, with reduced fat peanut butter, regular jelly, on white bread
42302060	Peanut butter and jelly sandwich, with reduced fat peanut butter, regular jelly, on wheat bread
42302065	Peanut butter and jelly sandwich, with reduced fat peanut butter, regular jelly, on whole wheat bread
42302105	Peanut butter and jelly sandwich, with regular peanut butter, reduced sugar jelly, on white bread
42302110	Peanut butter and jelly sandwich, with regular peanut butter, reduced sugar jelly, on wheat bread
42302115	Peanut butter and jelly sandwich, with regular peanut butter, reduced sugar jelly, on whole wheat bread
42302155	Peanut butter and jelly sandwich, with reduced fat peanut butter, reduced sugar jelly, on white bread

42302160	Peanut butter and jelly sandwich, with reduced fat peanut butter, reduced sugar jelly, on wheat bread
42302165	Peanut butter and jelly sandwich, with reduced fat peanut butter, reduced sugar jelly, on whole wheat bread
42303100	Peanut butter and jelly sandwich, frozen commercial product without crusts

Plant Protein Products

Meat Analogs and Substitutes

[FermentIQ Pea Protein] = 30 g/100 g

27450130	Crab salad made with imitation crab
27564420	Frankfurter or hot dog sandwich, meatless, plain, on bun
27564430	Frankfurter or hot dog sandwich, meatless, plain, on bread
27564500	Frankfurter or hot dog sandwich, with meatless chili, on white bun
27564501	Frankfurter or hot dog sandwich, with meatless chili, on wheat bun
27564502	Frankfurter or hot dog sandwich, with meatless chili, on whole wheat bun
27564503	Frankfurter or hot dog sandwich, with meatless chili, on whole grain white bun
27564504	Frankfurter or hot dog sandwich, with meatless chili, on multigrain bun
27564510	Frankfurter or hot dog sandwich, with meatless chili, on white bread
27564520	Frankfurter or hot dog sandwich, with meatless chili, on wheat bread
27564530	Frankfurter or hot dog sandwich, with meatless chili, on whole wheat bread
27564540	Frankfurter or hot dog sandwich, with meatless chili, on whole grain white bread
27564550	Frankfurter or hot dog sandwich, with meatless chili, on multigrain bread
27564560	Frankfurter or hot dog sandwich, meatless, on bun, with meatless chili
27564570	Frankfurter or hot dog sandwich, meatless, on bread, with meatless chili
41421010	Soybean curd, deep fried
41421020	Soybean curd, breaded, fried
41440000	Textured vegetable protein, dry
41810200	Bacon strip, meatless
41810250	Bacon bits
41810400	Breakfast link, pattie, or slice, meatless
41810600	Chicken, meatless, NFS
41810610	Chicken, meatless, breaded, fried
41811400	Frankfurter or hot dog, meatless
41811600	Luncheon slice, meatless-beef, chicken, salami or turkey
41811800	Meatball, meatless
41811890	Vegetarian burger or patty, meatless, no bun
41811950	Swiss steak, with gravy, meatless
41812400	Vegetarian pot pie
41812450	Vegetarian chili, made with meat substitute
41812500	Tofu and vegetables including carrots, broccoli, and/or dark-green leafy; no potatoes, with soy-based sauce
41812510	Tofu and vegetables excluding carrots, broccoli, and dark-green leafy; no potatoes, with soy-based sauce

41812600 Vegetarian, fillet
41812800 Vegetarian stew
41812850 Vegetarian stroganoff
41901020 Soyburger, meatless, with cheese on bun
59003000 Meat substitute, cereal- and vegetable protein-based, fried

Butter and Spread Alternative
[FermentIQ Pea Protein] = 12 g/100 g

41812000 Sandwich spread, meat substitute type
42203200 Soy nut butter
81102000 Margarine, NFS
81102010 Margarine, stick
81102020 Margarine, tub
81103035 Margarine-oil blend, NFS
81103040 Margarine-oil blend, stick
81103080 Margarine-oil blend, tub
81103090 Butter replacement, liquid
81104010 Margarine-oil blend, tub, light
81104020 Margarine-oil blend, stick, light
81106010 Butter replacement, powder
83108000 Vegan mayonnaise

Snack Foods

Snack Foods (including potato chips, pretzels, corn-based savory snacks, and popcorn)
[FermentIQ Pea Protein] = 4 g/100 g

54401011 Corn nuts
54401021 Corn chips, plain
54401026 Corn chips, flavored
54401031 Corn chips, plain (Fritos)
54401035 Corn chips, flavored (Fritos)
54401055 Cheese flavored corn snacks
54401065 Cheese flavored corn snacks, reduced fat
54401075 Tortilla chips, plain
54401081 Cheese flavored corn snacks (Cheetos)
54401085 Tortilla chips, flavored
54401090 Corn chips, reduced sodium
54401095 Tortilla chips, popped
54401110 Tortilla chips, nacho cheese flavor (Doritos)
54401111 Tortilla chips, cool ranch flavor (Doritos)
54401112 Tortilla chips, other flavors (Doritos)
54401121 Tortilla chips, reduced fat, plain
54401122 Tortilla chips, reduced fat, flavored

54401170	Tortilla chips, low fat, unsalted
54402080	Tortilla chips, reduced sodium
54402200	Snack mix
54402610	Potato chips, restructured, multigrain
54402700	Pita chips
54403001	Popcorn, NFS
54403005	Popcorn, movie theater, with added butter
54403006	Popcorn, movie theater, unbuttered
54403010	Popcorn, air-popped, unbuttered
54403040	Popcorn, air-popped, with added butter or margarine
54403051	Popcorn, microwave, NFS
54403052	Popcorn, microwave, plain
54403053	Popcorn, microwave, plain, light
54403054	Popcorn, microwave, low sodium
54403055	Popcorn, microwave, unsalted
54403056	Popcorn, microwave, butter flavored
54403057	Popcorn, microwave, butter flavored, light
54403058	Popcorn, microwave, cheese flavored
54403059	Popcorn, microwave, kettle corn
54403061	Popcorn, microwave, kettle corn, light
54403062	Popcorn, microwave, other flavored
54403080	Popcorn, ready-to-eat packaged, NFS
54403081	Popcorn, ready-to-eat packaged, plain
54403082	Popcorn, ready-to-eat packaged, plain, light
54403083	Popcorn, ready-to-eat packaged, low sodium
54403084	Popcorn, ready-to-eat packaged, unsalted
54403085	Popcorn, ready-to-eat packaged, butter flavored
54403086	Popcorn, ready-to-eat packaged, butter flavored, light
54403087	Popcorn, ready-to-eat packaged, cheese flavored
54403088	Popcorn, ready-to-eat packaged, cheese flavored, light
54403089	Popcorn, ready-to-eat-packaged, kettle corn
54403091	Popcorn, ready-to-eat packaged, kettle corn, light
54403092	Popcorn, ready-to-eat packaged, other flavored
54403110	Popcorn, caramel coated
54403120	Popcorn, caramel coated, with nuts
54403160	Popcorn, chocolate coated
54404000	Popcorn chips, plain
54404010	Popcorn chips, other flavors
54404020	Popcorn chips, sweet flavors
54406010	Onion flavored rings
54406200	Shrimp chips
54408000	Pretzels, NFS
54408015	Pretzels, hard, NFS
54408016	Pretzels, hard, plain, salted

54408017	Pretzels, hard, plain, lightly salted
54408030	Pretzels, hard, plain, unsalted
54408035	Pretzels, hard, flavored
54408070	Pretzels, hard, multigrain
54408081	Pretzels, hard, plain, gluten free
54408082	Pretzels, hard, flavored, gluten free
54408105	Pretzel chips, hard, plain
54408110	Pretzel chips, hard, flavored
54408115	Pretzel chips, hard, gluten free
54408190	Pretzels, hard, coated, NFS
54408200	Pretzels, hard, chocolate coated
54408210	Pretzels, hard, white chocolate coated
54408250	Pretzels, hard, yogurt coated
54408260	Pretzels, hard, coated, gluten free
54408290	Pretzels, hard, filled, NFS
54408300	Pretzels, hard, cheese filled
54408310	Pretzels, hard, peanut butter filled
54420210	Multigrain chips (Sun Chips)
54420220	Snack mix, plain (Chex Mix)
54440010	Bagel chips
54440020	Cracker chips
71200010	Potato chips, NFS
71200100	Potato chips, plain
71200110	Potato chips, barbecue flavored
71200120	Potato chips, sour cream and onion flavored
71200130	Potato chips, cheese flavored
71200140	Potato chips, other flavored
71200200	Potato chips, ruffled, plain
71200210	Potato chips, ruffled, barbecue flavored
71200220	Potato chips, ruffled, sour cream and onion flavored
71200230	Potato chips, ruffled, cheese flavored
71200240	Potato chips, ruffled, other flavored
71200300	Potato chips, restructured, plain
71200310	Potato chips, restructured, flavored
71200400	Potato chips, baked, plain
71200410	Potato chips, baked, flavored
71201050	Potato chips, reduced fat
71201060	Potato chips, fat free
71201200	Potato chips, restructured, reduced fat, lightly salted
71201210	Potato chips, restructured, fat free
71202000	Potato chips, unsalted
71202100	Potato chips, reduced fat, unsalted
71202500	Potato chips, lightly salted
71202510	Potato chips, restructured, lightly salted

71203010 Potato chips, popped, plain
71203020 Potato chips, popped, flavored
71203030 Potato chips, popped, NFS
71205020 Potato sticks, plain
71205030 Potato sticks, flavored
71205040 Potato sticks, fry shaped
71220000 Vegetable chips
71905410 Plantain chips
71980200 Taro chips
73410210 Sweet potato chips

Mixed foods containing snack foods
Adjusted for snack food content of 12.9 to 22.2%
[FermentIQ Pea Protein] = 0.516 to 0.888 g/100 g

58104090 Nachos with cheese and sour cream
58104120 Nachos with cheese
58104130 Nachos with meat and cheese
58104150 Nachos with chicken and cheese
58104160 Nachos with chili
58104180 Nachos with meat, cheese, and sour cream
58104190 Nachos with chicken, cheese, and sour cream

Soups and Soup Mixes

Soups and Soup Mixes
[FermentIQ Pea Protein] = 5 g/100 g

14710100 Cheddar cheese soup, home recipe, canned or ready-to-serve
14710200 Beer cheese soup, made with milk
28310150 Oxtail soup
28310320 Beef noodle soup, Puerto Rican style
28310330 Pho
28310420 Beef and rice soup, Puerto Rican style
28311010 Pepperpot soup
28311030 Menudo soup, canned, prepared with water or ready-to-serve
28315050 Beef vegetable soup with potato, pasta, or rice, chunky style, canned, or ready-to-serve
28315160 Italian Wedding Soup
28317010 Beef stroganoff soup, chunky style, home recipe, canned or ready-to-serve
28320140 Ham, noodle, and vegetable soup, Puerto Rican style
28320160 Pork vegetable soup with potato, pasta, or rice, stew type, chunky style
28320300 Pork with vegetable excluding carrots, broccoli and/or dark-green leafy; soup, Asian Style
28321130 Bacon soup, cream of, prepared with water
28331110 Lamb, pasta, and vegetable soup, Puerto Rican style
28340110 Chicken or turkey broth, bouillon, or consomme

28340150	Mexican style chicken broth soup stock
28340180	Chicken or turkey broth, less or reduced sodium, canned or ready-to-serve
28340210	Chicken rice soup, Puerto Rican style
28340220	Chicken soup with noodles and potatoes, Puerto Rican style
28340310	Chicken or turkey gumbo soup, home recipe, canned or ready-to-serve
28340510	Chicken or turkey noodle soup, chunky style, canned or ready-to-serve
28340550	Sweet and sour soup
28340580	Chicken or turkey soup with vegetables, broccoli, carrots, celery, potatoes and onions, Asian style
28340600	Chicken or turkey vegetable soup, canned, prepared with water or ready-to-serve
28340610	Chicken or turkey vegetable soup, stew type
28340630	Chicken or turkey vegetable soup with rice, stew type, chunky style
28340640	Chicken or turkey vegetable soup with noodles, stew type, chunky style, canned or ready-to-serve
28340690	Chicken or turkey vegetable soup with potato and cheese, chunky style, canned or ready-to-serve
28340700	Bird's nest soup
28340750	Hot and sour soup
28340800	Chicken or turkey soup with vegetables and fruit, Asian Style
28345010	Chicken or turkey soup, cream of, canned, reduced sodium, NS as to made with milk or water
28345020	Chicken or turkey soup, cream of, canned, reduced sodium, made with milk
28345030	Chicken or turkey soup, cream of, canned, reduced sodium, made with water
28345110	Chicken or turkey soup, cream of, NS as to prepared with milk or water
28345120	Chicken or turkey soup, cream of, prepared with milk
28345130	Chicken or turkey soup, cream of, prepared with water
28345160	Chicken or turkey mushroom soup, cream of, prepared with milk
28350050	Fish chowder
28350110	Crab soup, NS as to tomato-base or cream style
28350120	Crab soup, tomato-base
28350210	Clam chowder, NS as to Manhattan or New England style
28350220	Clam chowder, Manhattan
28350310	Turtle and vegetable soup
28351110	Fish and vegetable soup, no potatoes, Mexican style
28351120	Fish soup with potatoes, Mexican style
28351160	Codfish, rice, and vegetable soup, Puerto Rican style
28351170	Codfish soup with noodles, Puerto Rican style
28355110	Clam chowder, New England, NS as to prepared with water or milk
28355120	Clam chowder, New England, prepared with milk
28355130	Clam chowder, New England, prepared with water
28355140	Clam chowder, New England, reduced sodium, canned or ready-to-serve
28355210	Crab soup, cream of, prepared with milk
28355250	Lobster bisque
28355260	Lobster gumbo
28355310	Oyster stew

28355350	Salmon soup, cream style
28355410	Shrimp soup, cream of, NS as to prepared with milk or water
28355420	Shrimp soup, cream of, prepared with milk
28355430	Shrimp soup, cream of, prepared with water
28355440	Shrimp gumbo
28355450	Seafood soup with potatoes and vegetables including carrots, broccoli, and/or dark-green leafy
28355460	Seafood soup with potatoes, and vegetables excluding carrots, broccoli, and dark-green leafy
28355470	Seafood soup with vegetables including carrots, broccoli, and/or dark-green leafy; no potatoes
28355480	Seafood soup with vegetables excluding carrots, broccoli, and dark-green leafy; no potatoes
28360100	Meat broth, Puerto Rican style
28360210	Spanish vegetable soup, Puerto Rican style
32300100	Egg drop soup
32301100	Garlic egg soup, Puerto Rican style
41601010	Bean soup, NFS
41601020	Bean with bacon or ham soup, canned or ready-to-serve
41601030	Black bean soup, home recipe, canned or ready-to-serve
41601040	Lima bean soup, home recipe, canned or ready-to-serve
41601070	Soybean soup, miso broth
41601080	Pinto bean soup, home recipe, canned or ready-to-serve
41601090	Bean soup, with macaroni, home recipe, canned, or ready-to-serve
41601110	Bean and ham soup, chunky style, canned or ready-to-serve
41601130	Bean soup, mixed beans, home recipe, canned or ready-to-serve
41601160	Bean and ham soup, canned, reduced sodium, prepared with water or ready-to-serve
41601200	Liquid from stewed kidney beans, Puerto Rican style
41602010	Pea and ham soup, chunky style, canned or ready-to-serve
41602020	Garbanzo bean or chickpea soup, home recipe, canned or ready-to-serve
41602030	Split pea and ham soup
41602050	Split pea soup
41602070	Split pea soup, canned, reduced sodium, prepared with water or ready-to-serve
41602090	Split pea and ham soup, canned, reduced sodium, prepared with water or ready-to-serve
41603010	Lentil soup, home recipe, canned, or ready-to-serve
58400000	Soup, NFS
58400100	Noodle soup, NFS
58400200	Rice soup, NFS
58401010	Barley soup, home recipe, canned, or ready-to-serve
58401200	Barley soup, sweet, with or without nuts, Asian Style
58402010	Beef noodle soup, canned or ready-to-serve
58402020	Beef dumpling soup, home recipe, canned or ready-to-serve
58402030	Beef rice soup, home recipe, canned or ready-to-serve
58403010	Chicken or turkey noodle soup, canned or ready-to-serve
58403050	Chicken or turkey noodle soup, cream of, home recipe, canned, or ready-to-serve
58403060	Chicken or turkey noodle soup, reduced sodium, canned or ready-to-serve

58403100	Noodle and potato soup, Puerto Rican style
58404010	Chicken or turkey rice soup, canned, or ready-to-serve
58404040	Chicken or turkey rice soup, reduced sodium, canned, prepared with water or ready-to-serve
58404050	Chicken or turkey rice soup, reduced sodium, canned, prepared with milk
58404100	Rice and potato soup, Puerto Rican style
58404500	Matzo ball soup
58404510	Chicken or turkey soup with dumplings and potatoes, home recipe, canned, or ready-to-serve
58404520	Chicken or turkey soup with dumplings, home recipe, canned or ready-to-serve
58407010	Instant soup, noodle
58407030	Soup, mostly noodles
58407035	Soup, mostly noodles, reduced sodium
58407050	Instant soup, noodle with egg, shrimp or chicken
58408010	Wonton soup
58408500	Noodle soup with vegetables, Asian style
58409000	Noodle soup, with fish ball, shrimp, and dark green leafy vegetable
58421000	Sopa seca, Mexican style, NFS
63415100	Soup, fruit
71801000	Potato soup, NS as to made with milk or water
71801010	Potato soup, cream of, prepared with milk
71801020	Potato soup, prepared with water
71801100	Potato and cheese soup
71803010	Potato chowder
71851010	Plantain soup, Puerto Rican style
72302000	Broccoli soup, prepared with milk, home recipe, canned or ready-to-serve
72302020	Broccoli soup, prepared with water, home recipe, canned, or ready-to-serve
72302100	Broccoli cheese soup, prepared with milk, home recipe, canned, or ready-to-serve
72306000	Watercress broth with shrimp
72307000	Spinach soup
72308000	Dark-green leafy vegetable soup with meat, Asian style
72308500	Dark-green leafy vegetable soup, meatless, Asian style
73501000	Carrot soup, cream of, prepared with milk, home recipe, canned or ready-to-serve
73501010	Carrot with rice soup, cream of, prepared with milk, home recipe, canned or ready-to-serve
73502000	Squash, winter type, soup, home recipe, canned, or ready-to-serve
74601000	Tomato soup, NFS
74601010	Tomato soup, cream of, prepared with milk
74602010	Tomato soup, prepared with water, or ready-to-serve
74602050	Tomato soup, instant type, prepared with water
74602200	Tomato soup, canned, reduced sodium, prepared with water, or ready-to-serve
74602300	Tomato soup, canned, reduced sodium, prepared with milk
74603010	Tomato beef soup, prepared with water
74604010	Tomato beef noodle soup, prepared with water
74604100	Tomato beef rice soup, prepared with water
74604500	Tomato noodle soup, canned, prepared with water or ready-to-serve

74604600	Tomato noodle soup, canned, prepared with milk
74605010	Tomato rice soup, prepared with water
74606010	Tomato vegetable soup, prepared with water
74606020	Tomato vegetable soup with noodles, prepared with water
75600150	Soup, cream of, NFS
75601000	Asparagus soup, cream of, NS as to made with milk or water
75601010	Asparagus soup, cream of, prepared with milk
75601020	Asparagus soup, cream of, prepared with water
75601100	Borscht
75601200	Cabbage soup, home recipe, canned or ready-to-serve
75601210	Cabbage with meat soup, home recipe, canned or ready-to-serve
75603010	Celery soup, cream of, prepared with milk, home recipe, canned or ready-to-serve
75603020	Celery soup, cream of, prepared with water, home recipe, canned or ready-to-serve
75604010	Corn soup, cream of, prepared with milk
75604020	Corn soup, cream of, prepared with water
75604600	Gazpacho
75605010	Leek soup, cream of, prepared with milk
75607000	Mushroom soup, NFS
75607010	Mushroom soup, cream of, prepared with milk
75607020	Mushroom soup, cream of, prepared with water
75607040	Mushroom soup, with meat broth, prepared with water
75607050	Mushroom soup, cream of, low sodium, prepared with water
75607060	Mushroom soup, cream of, NS as to made with milk or water
75607080	Mushroom with chicken soup, cream of, prepared with milk
75607090	Mushroom soup, cream of, canned, reduced sodium, NS as to made with milk or water
75607100	Mushroom soup, cream of, canned, reduced sodium, prepared with milk
75607140	Mushroom soup, cream of, canned, reduced sodium, prepared with water
75608010	Onion soup, cream of, prepared with milk
75608100	Onion soup, French
75608200	Onion soup, made from dry mix
75609010	Pea soup, prepared with milk
75611010	Vegetable soup, cream of, prepared with milk
75612010	Zucchini soup, cream of, prepared with milk
75646010	Shav soup
75647000	Seaweed soup
75649010	Vegetable soup, canned, prepared with water or ready-to-serve
75649040	Vegetable soup, reduced sodium, canned, ready to serve
75649050	Vegetable soup, made from dry mix
75650990	Minestrone soup, reduced sodium, canned or ready-to-serve
75651010	Minestrone soup, canned, prepared with water, or ready-to-serve
75651020	Vegetable beef soup, canned, prepared with water, or ready-to-serve
75651030	Vegetable beef noodle soup, prepared with water
75651040	Vegetable noodle soup, canned, prepared with water, or ready-to-serve
75651070	Vegetable rice soup, canned, prepared with water or ready-to-serve

75651080	Vegetable beef soup with rice, canned, prepared with water or ready-to-serve
75651110	Vegetable chicken rice soup, canned, prepared with water or ready-to-serve
75651150	Vegetable noodle soup, reduced sodium, canned, prepared with water or ready-to-serve
75652030	Vegetable beef soup, canned, prepared with milk
75654010	Vegetarian vegetable soup, prepared with water
75656010	Vegetable soup, Spanish style, stew type
75656020	Vegetable soup, chunky style
75656040	Vegetable soup, with pasta, chunky style
75656060	Vegetable beef soup, chunky style

ESTIMATED DAILY INTAKE OF FERMENTIQ PEA PROTEIN THE U.S. POPULATION FROM PROPOSED FOOD USES (2017-2018 NHANES)

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24 March 2022

Estimated Daily Intake of FermentIQ Pea Protein by the U.S. Population from Proposed Food Uses (2017-2018 NHANES)

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Estimated Daily Intake of FermentIQ Pea Protein by the U.S. Population from Proposed Food Uses (2017-2018 NHANES)

1.0 INTRODUCTION

FermentIQ Pea Protein is proposed for use in the United States (U.S.) in foods, such as baked goods and baking mixes, beverages and beverage bases, breakfast cereals, coffee and tea, dairy product analogues, grain products, milk products, nut and nut products, plant protein products, snack foods, and soups and soup mixes.

Estimates for the intake of FermentIQ Pea Protein were based on the proposed food uses and use levels for FermentIQ Pea Protein in conjunction with food consumption data included in the U.S. National Center for Health Statistics' National Health and Nutrition Examination Surveys (NHANES) 2017-2018. Calculations for the mean and 90th percentile *per capita* and consumer-only intakes were performed for all proposed food uses of FermentIQ Pea Protein and the percentage of consumers was determined. Similar calculations were used to estimate the intake of FermentIQ Pea Protein resulting from each individual proposed food use, including the calculations of percent consumers. In both cases, the per person and per kilogram body weight intakes were reported for the following population groups:

- Children, ages 2 to 5 years;
- Children, ages 6 to 11 years;
- Female teenagers, ages 12 to 19 years;
- Male teenagers, ages 12 to 19 years;
- Female adults, ages 20 years and older;
- Male adults, ages 20 years and older; and
- Total population (ages 2 years and older, and both gender groups combined).

2.0 FOOD CONSUMPTION SURVEY DATA

2.1 Survey Description

NHANES for the years 2017-2018 are available for public use (USDA, 2021a,b; CDC, 2022a,b). NHANES are conducted as continuous, annual surveys, and they are released in 2-year cycles. During each year of the ongoing NHANES program, individuals from the U.S. are sampled from up to 30 different study locations in a complex multi-stage probability design intended to ensure the data are a nationally representative sample of the U.S. population.

NHANES 2017-2018 dietary survey data were collected from individuals and households *via* 24-hour dietary recalls administered on 2 non-consecutive days (Day 1 and Day 2) throughout all 4 seasons of the year. Day 1 data were collected in-person, and Day 2 data were collected by telephone in the following 3 to 10 days, on different days of the week, to achieve the desired degree of statistical independence. The data were collected by first selecting primary sampling units (PSUs), which were counties throughout the U.S., of which 30 PSUs are visited per year. Smaller contiguous counties were combined to attain a minimum population size. These PSUs were segmented, and households were chosen within each segment. One or more participants within a household were interviewed. For NHANES 2017-2018, 16,211 individuals were selected for the sample, 9,254 were interviewed (51.9%), and 8,704 were examined (48.8%).

In addition to collecting information on the types and quantities of foods being consumed, NHANES 2017-2018 collected socio-economic, physiological, and demographic information from individual participants in the survey, such as sex, age, body weight, and other variables (such as height and race-ethnicity) that may be useful in characterizing consumption. The inclusion of this information allows for further assessment of food intake based on consumption by specific population groups of interest within the total population. The primary sample design for NHANES 2017-2018 includes an oversample of non-Hispanic Asian persons, Hispanic persons, non-Hispanic black persons, non-Hispanic white and "other" older persons (≥80 years), and non-Hispanic low-income white and "others" persons (≤185% of the Department of Health and Human Services poverty guidelines); however, sample weights were incorporated to allow estimates from these subgroups to be combined to obtain national estimates that reflect the relative proportions of these groups in the population as a whole (USDA, 2021a,b; CDC, 2022a,b).

2.2 Statistical Methods

For the intake assessment, consumption data from individual dietary records, detailing food items ingested by each survey participant, were collated by computer and used to generate estimates for the intake of FermentIQ Pea Protein by the U.S. population[1]. Estimates for the daily intake of FermentIQ Pea Protein represent projected 2-day averages for each individual from Day 1 and Day 2 of NHANES 2017-2018 (*i.e.*, a value was established for each person). From these average amounts, a distribution was established from which the mean and percentile intake estimates for the cohort of interest were determined, which incorporated survey weights in order to provide representative intakes for the entire U.S. population. "*Per capita*" intake refers to the estimated intake of FermentIQ Pea Protein averaged over all individuals surveyed, regardless of whether they consumed food products in which FermentIQ Pea Protein is proposed for use, and therefore includes individuals with "zero" intakes (*i.e.*, including individuals who reported no intake of food products containing FermentIQ Pea Protein during the 2 survey days). "Consumer-only" intake refers to the estimated intake of FermentIQ Pea Protein by only those individuals who reported consuming food products of interest on either Day 1 or Day 2 of the survey.

Mean and 90th percentile intake estimates based on sample sizes of less than 30 and 80, respectively, may not be considered statistically reliable due to the limited sampling size (CDC, 2013). As such, the reliability of estimates for the intake of FermentIQ Pea Protein based on consumption estimates derived from individual population groups of a limited sample size should be interpreted with caution. These values are marked with an asterisk in the relevant data tables.

3.0 FOOD USAGE DATA

The proposed food uses and use levels for FermentIQ Pea Protein employed in the current intake analysis are summarized in Table 3-1. Food codes representative of each proposed food use were chosen from the NHANES 2017-2018 (CDC, 2022b). Food codes were grouped in food use categories according to Title 21, Section §170.3 of the *Code of Federal Regulations* (U.S. FDA, 2021). If necessary, product-specific adjustment factors were developed for composite foods/mixtures based on data provided in the Food and Nutrient Database for Dietary Studies (USDA ARS, 2021a,b) or the Food Commodity Intake Database (U.S. EPA & USDA, 2022). All food codes included in the current intake assessment are listed in Appendix C.

[1] Statistical analysis and data management were conducted in DaDiet Software (Dazult Ltd., 2018). DaDiet Software is a web-based software tool that allows accurate estimate of exposure to nutrients and to substances added to foods, including contaminants, food additives and novel ingredients. The main input components are concentration (use level) data and food consumption data. Data sets are combined in the software to provide accurate and efficient exposure assessments.

Table 3-1 Summary of the Individual Proposed Food Uses and Use Levels for FermentIQ Pea Protein in the U.S.

Food Category (21 CFR §170.3) (U.S. FDA, 2021)	Food Uses[a]	FermentIQ Pea Protein Use Levels (%)	FermentIQ Pea Protein, on Protein Basis[b] (g protein/100 g of food as consumed)
Baked Goods and Baking Mixes	Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	5	4.0
	Crackers	5	4.0
	Biscuits; Cookies	10	7.9
	French Toast, Pancakes, and Waffles	10	7.9
	Bread (high protein)	15	11.9
Beverages and Beverage Bases	Non-Milk Meal Replacements and Protein Drinks	40	31.7
Breakfast Cereals	Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	15	11.9
	Ready-To-Eat Cereals	15	11.9
Coffee and Tea	Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	10	7.9
	Ready-To-Drink Tea Beverages; Instant Tea	10	7.9
Dairy Product Analogues	Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	10	7.9
	Cream Cheese Substitute[d]	12	9.5
	Non-Dairy Frozen Desserts	10	7.9
	Non-Dairy Dips (includes imitation sour cream)	10	7.9
	Non-Dairy Yogurt	25	19.8
	Imitation Cheese	25	19.8
Grain Products and Pastas	Cereal Bars, Nutritional Bars, and Meal Replacement Bars	20	15.9
Milk Products	Milk-Based Meal Replacements and Protein Drinks	15	11.9
Nut and Nut Products	Nut Butters and Spread	10	7.9
Plant Protein Products	Meat Analogs and Substitutes	30	23.8
	Butter and Spread Alternative	12	9.5
Snack Foods	Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	4	3.2
Soups and Soup Mixes	Soups and Soup Mixes	5	4.0

CFR = *Code of Federal Regulations*; U.S. = United States.

[a] FermentIQ Pea Protein is intended for use in unstandardized products when standards of identity, as established under 21 CFR §130 to 169, do not permit its addition.

[b] Calculation: (FermentIQ Pea Protein use level)*(Maximum protein content, 79.31%).

[c] Includes ready-to-drink and powdered forms.

[d] Food codes for were not available; therefore, food codes for the conventional product were used as surrogates.

4.0 FOOD SURVEY RESULTS

Estimates for the total daily intakes of FermentIQ Pea Protein from proposed food uses are provided in Section 4.1. Estimates for the daily intake of protein from FermentIQ Pea Protein are summarized in

Section 4.2. Estimates for the daily intake of FermentIQ Pea Protein from individual proposed food uses in the U.S. are summarized in Section 4.3 and presented in Tables A-1 to A-7 and B-1 to B-7 of Appendices A and B, respectively.

The percentage of consumers was high among all age groups evaluated in the current intake assessment; more than 96.5% of the population groups consisted of consumers of food products in which FermentIQ Pea Protein is currently proposed for use (Table 4.1-1). Children ages 2 to 5 years had the greatest proportion of consumers at 99.8%. The consumer-only estimates are more relevant to risk assessments as they represent exposures in the target population; consequently, only the consumer-only intake results are discussed in detail herein.

4.1 Estimated Daily Intake of FermentIQ Pea Protein from All Proposed Food Uses in the U.S.

Table 4.1-1 summarizes the estimated total intake of FermentIQ Pea Protein (g/person/day) from all proposed food uses in the U.S. population groups. Table 4.1-2 presents this data on a per kilogram body weight basis (g/kg body weight/day).

Among the total population (ages 2 years and older), the mean and 90th percentile consumer-only intakes of FermentIQ Pea Protein were determined to be 22 and 54 g/person/day, respectively. Of the individual population groups, male adults were determined to have the greatest mean and 90th percentile consumer-only intakes of FermentIQ Pea Protein on an absolute basis, at 25 and 60 g/person/day, respectively, while children ages 2 to 5 years had the lowest mean and 90th percentile consumer-only intakes of 12 and 27 g/person/day, respectively (Table 4.1-1).

Table 4.1-1 Summary of the Estimated Daily Intake of FermentIQ Pea Protein from Proposed Food Uses in the U.S. by Population Group (2017-2018 NHANES Data)

Population Group	Age Group (Years)	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Children	2 to 5	12	27	99.8	468	12	27
Children	6 to 11	15	31	99.0	672	15	31
Female Teenagers	12 to 19	20	43	97.8	432	21	43
Male Teenagers	12 to 19	19	41	97.8	429	19	41
Female Adults	20 and older	22	56	96.5	2,076	23	56
Male Adults	20 and older	24	59	96.8	1,888	25	60
Total Population	2 and older	21	53	97.1	5,965	22	54

n = sample size; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

On a body weight basis, the total population (ages 2 years and older) mean and 90th percentile consumer-only intakes of FermentIQ Pea Protein were determined to be 0.34 and 0.79 g/kg body weight/day, respectively. Among the individual population groups, children ages 2 to 5 years were identified as having the highest mean and 90th percentile consumer-only intakes of any population group, of 0.75 and 1.48 g/kg body weight/day, respectively. Male adults had the lowest mean consumer-only intake of 0.29 g/kg body weight/day, while male teenagers had the lowest 90th percentile consumer-only intake of 0.70 g/kg body weight/day, respectively (Table 4.1-2).

Table 4.1-2 Summary of the Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Proposed Food Uses in the U.S. by Population Group (2017-2018 NHANES Data)

Population Group	Age Group (Years)	*Per Capita* Intake (g/kg bw/day)		Consumer-Only Intake (g/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Children	2 to 5	0.75	1.48	99.8	460	0.75	1.48
Children	6 to 11	0.46	0.89	99.0	670	0.46	0.91
Female Teenagers	12 to 19	0.34	0.73	97.8	425	0.35	0.73
Male Teenagers	12 to 19	0.29	0.70	97.8	426	0.30	0.70
Female Adults	20 and older	0.30	0.76	96.5	2,058	0.31	0.77
Male Adults	20 and older	0.28	0.71	96.8	1,873	0.29	0.72
Total Population	2 and older	0.33	0.79	97.1	5,912	0.34	0.79

bw = body weight; n = sample size; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

4.2 Estimated Daily Intake of Protein from FermentIQ Pea Protein from All Proposed Food Uses in the U.S.

Table 4.2-1 summarizes the estimated total intake of protein from FermentIQ Pea Protein (g/person/day) from all proposed food uses in the U.S. population groups. Table 4.2-2 presents this data on a per kilogram body weight basis (g/kg body weight/day). Protein intakes were calculated using the estimated intakes of FermentIQ Pea Protein and assuming a maximum protein content of 79.31% for the ingredient.

Among the total population (ages 2 years and older), the mean and 90th percentile consumer-only intakes of protein from FermentIQ Pea Protein were determined to be 17 and 43 g/person/day, respectively. Of the individual population groups, male adults were determined to have the greatest mean and 90th percentile consumer-only intakes of protein on an absolute basis, at 20 and 48 g/person/day, respectively, while children ages 2 to 5 years had the lowest mean and 90th percentile consumer-only intakes of 10 and 22 g/person/day, respectively (Table 4.1-1).

Table 4.2-1 Summary of the Estimated Daily Intake of FermentIQ Pea Protein as Protein[a] from Proposed Food Uses in the U.S. by Population Group (2017-2018 NHANES Data)

Population Group	Age Group (Years)	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Children	2 to 5	10	22	99.8	468	10	22
Children	6 to 11	12	24	99.0	672	12	24
Female Teenagers	12 to 19	16	34	97.8	432	16	34
Male Teenagers	12 to 19	15	33	97.8	429	15	33
Female Adults	20 and older	17	44	96.5	2,076	18	45

Table 4.2-1 Summary of the Estimated Daily Intake of FermentIQ Pea Protein as Protein[a] from Proposed Food Uses in the U.S. by Population Group (2017-2018 NHANES Data)

Population Group	Age Group (Years)	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Male Adults	20 and older	19	47	96.8	1,888	20	48
Total Population	2 and older	17	42	97.1	5,965	17	43

n = sample size; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.
[a] Calculation: (Estimated daily intake of FermentIQ Pea Protein)*(Maximum protein content, 79.31%).

On a body weight basis, the total population (ages 2 years and older) mean and 90th percentile consumer-only intakes of protein from FermentIQ Pea Protein were determined to be 0.27 and 0.63 g/kg body weight/day, respectively. Among the individual population groups, children ages 2 to 5 years were identified as having the highest mean and 90th percentile consumer-only intakes of any population group, of 0.59 and 1.18 g/kg body weight/day, respectively. Male adults had the lowest mean consumer-only intake of 0.23 g/kg body weight/day, while male teenagers had the lowest 90th percentile consumer-only intake of 0.55 g/kg body weight/day, respectively (Table 4.2-2).

Table 4.2-2 Summary of the Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein as Protein[a] from Proposed Food Uses in the U.S. by Population Group (2017-2018 NHANES Data)

Population Group	Age Group (Years)	*Per Capita* Intake (g/kg bw/day)		Consumer-Only Intake (g/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Children	2 to 5	0.59	1.18	99.8	460	0.59	1.18
Children	6 to 11	0.36	0.71	99.0	670	0.37	0.72
Female Teenagers	12 to 19	0.27	0.58	97.8	425	0.27	0.58
Male Teenagers	12 to 19	0.23	0.55	97.8	426	0.24	0.55
Female Adults	20 and older	0.24	0.60	96.5	2,058	0.25	0.61
Male Adults	20 and older	0.22	0.56	96.8	1,873	0.23	0.57
Total Population	2 and older	0.26	0.62	97.1	5,912	0.27	0.63

bw = body weight; n = sample size; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.
[a] Calculation: (Estimated daily intake of FermentIQ Pea Protein)*(Maximum protein content, 79.31%).

4.3 Estimated Daily Intake of FermentIQ Protein from Individual Proposed Food Uses in the U.S.

Estimates for the mean and 90th percentile daily intakes of FermentIQ Pea Protein from each individual food category are summarized in Tables A-1 to A-7 and B-1 to B-7 on a g/day and g/kg body weight/day basis, respectively. The total U.S. population (ages 2 years and older) was identified as being significant consumers of “snack foods” (47 to 66% consumers), “biscuits and cookies” (34 to 58% consumers), “ready-to-eat breakfast cereals” (26 to 58% consumers), “crackers” (17 to 42% consumers), and “bagels, English muffins, cornbread, corn muffins, and tortillas” (31 to 40% consumers).

In terms of contribution to total mean intake of FermentIQ Pea Protein, “tea drinks” (which contributed 8 to 23% to total mean intakes) and “hot breakfast cereals” (which contributed 6 to 22% to total mean intakes) were the 2 main sources of intake across all population groups. High protein bread, cream cheese substitutes, non-dairy frozen desserts, non-dairy yogurt, imitation cheese, and butter and spread alternatives all individually contributed ≤1% to total mean FermentIQ Pea Protein intakes across all population groups (see Tables A-1 to A-7 and/or B-1 to B-7 for further details).

5.0 SUMMARY AND CONCLUSIONS

Consumption data and information pertaining to the individual proposed food uses of FermentIQ Pea Protein were used to estimate the *per capita* and consumer-only intakes of FermentIQ Pea Protein for specific demographic groups and for the total U.S. population. There were a number of assumptions included in the assessment which render exposure estimates that may be considered suitably conservative. For example, it has been assumed in both exposure assessments that all food products within a food category contain FermentIQ Pea Protein at the maximum specified level of use. In reality, the levels added to specific foods will vary depending on the nature of the food product and it is unlikely that FermentIQ Pea Protein will have 100% market penetration in all identified food categories.

In summary, on a consumer-only basis, the resulting mean and 90th percentile intakes of FermentIQ Pea Protein by the total U.S. population (ages 2 years and older) from all proposed food uses, were estimated to be 22 g/person/day (0.34 g/kg body weight/day) and 54 g/person/day (0.79 g/kg body weight/day), respectively. Among the individual population groups, the highest mean and 90th percentile consumer-only intakes of FermentIQ Pea Protein were determined to be 25 g/person/day (0.29 g/kg body weight/day) and 60 g/person/day (0.72 g/kg body weight/day), respectively, as identified among male adults. Children ages 2 to 5 years had the lowest mean and 90th percentile consumer-only intakes of 12 g/person/day and 27 g/person/day, respectively; however, when intakes were expressed on a body weight basis, children ages 2 to 5 years had the highest mean and 90th percentile consumer-only intakes of 0.75 and 1.48 g/kg body weight/day.

Consumer-only protein intakes from FermentIQ Pea Protein among the total population were determined to be 17 g/person/day (0.27 g/kg body weight/day) and 43 g/person/day (0.63 g/kg body weight/day) at the mean and 90th percentile, respectively. Among the individual population groups, male adults were determined to have the greatest mean and 90th percentile consumer-only intakes of 20 g/person/day (0.23 g/kg body weight/day) and 48 g/person/day (0.57 g/kg body weight/day), respectively. On a body weight basis, children ages 2 to 5 years were identified as having the highest mean and 90th percentile consumer-only intakes of protein of 0.59 and 1.18 g/kg body weight/day, respectively.

6.0 REFERENCES

CDC (2013). *National Health and Nutrition Examination Survey: Analytic Guidelines, 1999–2010*. (Vital and Health Statistics. Series 2, Number 161). Hyattsville (MD): Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS). Available at: https://www.cdc.gov/nchs/data/series/sr_02/sr02_161.pdf [Last accessed October 30, 2016].

CDC (2022a). *National Health and Nutrition Examination Survey (NHANES): 2017-2018*. Hyattsville (MD): Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS). Available at: https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx?BeginYear=2017 [page last reviewed: March 17, 2022].

CDC (2022b). *National Health and Nutrition Examination Survey (NHANES): 2017-2018 – Dietary Data*. Hyattsville (MD): Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS). Available at: https://wwwn.cdc.gov/nchs/nhanes/Search/DataPage.aspx?Component=Dietary&CycleBeginYear=2017 [page last reviewed: March 17, 20221].

Dazult Ltd. (2018). *DaDiet - The Dietary Intake Evaluation Tool [Software]*. (Version 17.04). Straffan, Ireland: Dazult Ltd. Available online: http://dadiet.daanalysis.com.

U.S. EPA & USDA (2022). Commodity consumption calculator. In: *Food Commodity Intake Database: What We Eat in America [2005-2010]*. [FCID]. Washington (DC): U.S. Environmental Protection Agency (U.S. EPA), Office of Pesticide Programs/ Beltsville (MD): United States Department of Agriculture (USDA). Available at: http://fcid.foodrisk.org/ ; http://fcid.foodrisk.org/dbc/ ; http://fcid.foodrisk.org/percentiles [© University of Maryland 2012 – 2022].

U.S. FDA (2021). Part 170—Food additives. Section §170.3—Definitions. In: *U.S. Code of Federal Regulations (CFR). Title 21: Food and Drugs* (Food and Drug Administration). Washington (DC): U.S. Government Printing Office (GPO). Available at: https://www.govinfo.gov/app/collection/cfr/.

USDA (2021a). *What We Eat in America: National Health and Nutrition Examination Survey (NHANES): 2017-2018.* Riverdale (MD): U.S. Department of Agriculture (USDA). Available at: https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/wweianhanes-overview/#release [last modified: 1/29/2021].

USDA (2021b). *What We Eat in America: National Health and Nutrition Examination Survey (NHANES): 2017-2018: Documentation and Data Sets*. Beltsville (MD): U.S. Department of Agriculture (USDA). Available at: https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/wweia-documentation-and-data-sets/ [last modified: 1/29/2021].

USDA ARS (2021a). *USDA Food and Nutrient Database for Dietary Studies 2017-2018 [FNDDS]*. Beltsville (MD): U.S. Department of Agriculture (USDA), Agricultural Research Service (ARS), Food Surveys Research Group. Available at: https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/fndds/ [last modified: 1/7/2021].

USDA ARS (2021b). *USDA Food and Nutrient Database for Dietary Studies 2017-2018 [FNDDS]: Documentation and Databases*. Beltsville (MD): U.S. Department of Agriculture (USDA), Agricultural Research Service (ARS), Food Surveys Research Group. Available at: https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/fndds-download-databases/ [last modified: 1/7/2021].

APPENDIX A
Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Different Population Groups within the U.S. (2017-2018 NHANES Data)

Table A-1 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Children Ages 2 to 5 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***12***	***27***	***99.8***	***468***	***12***	***27***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	4.8	1	2	31.0	133	2	4
Crackers	3.3	<1	2	42.3	201	1	2
Biscuits; Cookies	9.4	1	4	44.8	213	3	6
French Toast, Pancakes, and Waffles	9.2	1	4	27.7	118	4	8
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	0.3	<1*	na	0.4	1	8*	8*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	22.5	3	11	14.6	81	19	36
Ready-to-Eat Cereals	14.1	2	5	58.4	275	3	6
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	0.1	<1*	na	0.3	2	5*	5*
Ready-to-Drink Tea beverages; Instant Tea	8.0	1*	na	5.7	21	17*	33*
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	5.1	1*	na	6.5	26	10*	17*
Cream Cheese Substitute[d]	0.3	<1*	na	3.3	21	1*	2*
Non-Dairy Frozen Desserts	0	0	0	0	0	0	0
Non-Dairy Dips (includes imitation sour cream)	1.2	<1*	na	4.2	13	3*	6*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.1	<1*	na	0.3	1	4*	4*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	5.0	1	2*	14.2	59	4	9*
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	2.6	<1*	na	2.0	10	16*	23*
Nut and Nut Products							
Nut Butters and Spread	3.4	<1	2	25.7	122	2	3
Plant Protein Products							
Meat Analogs and Substitutes	0.5	<1*	na	1.3	6	5*	16*
Butter and Spread Alternative	0.2	<1*	na	7.6	26	<1*	1*

Table A-1 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Children Ages 2 to 5 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	4.0	1	1	62.2	300	1	2
Soups and Soup Mixes							
Soups and Soup Mixes	5.9	1	3*	13.9	72	5	9*

n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table A-2 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Children Ages 6 to 11 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***15***	***31***	***99.0***	***672***	***15***	***31***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	5.9	1	3	34.0	223	3	6
Crackers	2.4	<1	1	30.7	189	1	2
Biscuits; Cookies	12.9	2	5	58.3	346	3	6
French Toast, Pancakes, and Waffles	10.7	2	6	25.9	157	6	12
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	0.4	<1*	na	0.4	1	17*	17*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	6.0	1	na	5.4	46	16	24*
Ready-to-Eat Cereals	17.9	3	7	56.9	404	5	9
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	1.6	<1*	na	1.6	9	14*	31*
Ready-to-Drink Tea beverages; Instant Tea	11.5	2	na	8.6	55	20	39*
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	3.9	1*	na	4.7	25	12*	25*
Cream Cheese Substitute[d]	0.7	<1*	na	5.3	25	2*	4*
Non-Dairy Frozen Desserts	0	0	0	0	0	0	0
Non-Dairy Dips (includes imitation sour cream)	1.0	<1*	na	2.6	13	6*	9*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	<0.1	<1*	na	0.2	1	4*	4*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	5.0	1	4*	16.1	75	5	9*
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	2.7	<1*	na	1.5	9	28*	45*
Nut and Nut Products							
Nut Butters and Spread	2.7	<1	2	23.6	120	2	3
Plant Protein Products							
Meat Analogs and Substitutes	0.3	<1*	na	1.4	9	3*	6*
Butter and Spread Alternative	0.4	<1	na	8.6	51	1	2*

Table A-2 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Children Ages 6 to 11 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	5.3	1	2	66.2	446	1	2
Soups and Soup Mixes							
Soups and Soup Mixes	8.7	1	5	15.0	102	9	13

n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table A-3 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Female Teenagers Ages 12 to 19 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***20***	***43***	***97.8***	***432***	***21***	***43***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	5.0	1	3	36.4	148	3	5
Crackers	1.4	<1	1	22.1	82	1	3
Biscuits; Cookies	6.3	1	3	41.9	165	3	6
French Toast, Pancakes, and Waffles	5.5	1	5*	15.9	61	7	14*
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	3.3	1*	na	0.2	1	353*	353*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	6.2	1	na	6.1	40	20	36*
Ready-to-Eat Cereals	10.3	2	7	36.9	155	6	12
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	7.9	2*	na	6.5	24	24*	35*
Ready-to-Drink Tea beverages; Instant Tea	23.0	5	19*	19.7	62	24	45*
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	8.0	2	2*	13.2	46	12	25*
Cream Cheese Substitute[d]	0.8	<1*	na	8.7	26	2*	4*
Non-Dairy Frozen Desserts	0	0	0	0	0	0	0
Non-Dairy Dips (includes imitation sour cream)	0.7	<1*	na	4.3	12	3*	7*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.1	<1*	na	1.2	1	1*	1*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.6	1	4*	15.4	51	5	8*
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	5.6	1*	na	4.7	10	24*	28*
Nut and Nut Products							
Nut Butters and Spread	1.4	<1	1*	12.6	38	2	4*
Plant Protein Products							
Meat Analogs and Substitutes	0.1	<1*	na	1.1	5	2*	1*
Butter and Spread Alternative	0.3	<1*	na	7.1	20	1*	1*

Table A-3 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Female Teenagers Ages 12 to 19 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	2.9	1	2	56.7	276	1	2
Soups and Soup Mixes							
Soups and Soup Mixes	7.5	2	7	16.1	88	9	17

n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table A-4 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Male Teenagers Ages 12 to 19 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***19***	***41***	***97.8***	***429***	***19***	***41***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	7.1	1	4	38.1	152	3	7
Crackers	1.3	<1	1*	16.6	50	1	3*
Biscuits; Cookies	6.6	1	3	34.7	164	4	8
French Toast, Pancakes, and Waffles	7.0	1	5*	14.7	61	9	21*
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	0.3	<1*	na	<0.1	1	151*	151*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	7.3	1*	na	5.1	22	27*	71*
Ready-to-Eat Cereals	14.1	3	9	41.3	178	6	12
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	3.9	1*	na	3.9	17	19*	26*
Ready-to-Drink Tea beverages; Instant Tea	20.1	4	12*	12.6	53	30	52*
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	3.0	1*	na	6.9	29	8*	12*
Cream Cheese Substitute[d]	0.6	<1*	na	5.3	17	2*	3*
Non-Dairy Frozen Desserts	0	0	0	0	0	0	0
Non-Dairy Dips (includes imitation sour cream)	0.5	<1*	na	2.5	7	4*	6*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	<0.1	<1*	na	0.1	1	3*	3*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.2	1	2*	10.3	46	6	12*
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	12.0	2*	na	6.3	21	36*	53*
Nut and Nut Products							
Nut Butters and Spread	1.3	<1	<1*	10.6	43	2	3*
Plant Protein Products							
Meat Analogs and Substitutes	0	0	0	0	0	0	0
Butter and Spread Alternative	0.1	<1*	na	4.0	13	1*	1*

Table A-4 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Male Teenagers Ages 12 to 19 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	3.8	1	2	52.6	239	1	2
Soups and Soup Mixes							
Soups and Soup Mixes	7.8	1	6*	13.0	66	11	21*

n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table A-5 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Female Adults Ages 20 Years and Older within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***22***	***56***	***96.5***	***2,076***	***23***	***56***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	4.4	1	3	36.5	786	3	5
Crackers	0.8	<1	1	23.6	482	1	2
Biscuits; Cookies	5.1	1	4	35.0	745	3	7
French Toast, Pancakes, and Waffles	3.0	1	2	11.0	218	6	11
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	3.1	1*	na	1.2	11	56*	101*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	14.5	3	14	14.4	394	22	42
Ready-to-Eat Cereals	6.5	1	5	26.2	525	5	10
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	9.2	2	na	9.4	159	21	31
Ready-to-Drink Tea beverages; Instant Tea	19.1	4	13	12.2	249	35	72
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	8.1	2	5	32.8	722	5	14
Cream Cheese Substitute[d]	0.5	<1	na	6.5	109	2	3
Non-Dairy Frozen Desserts	0.2	<1*	na	0.4	2	11*	14*
Non-Dairy Dips (includes imitation sour cream)	1.3	<1	na	7.4	120	4	7
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.1	<1*	na	0.4	4	6*	7*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.3	1	3	11.6	177	6	11
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	8.2	2	na	5.5	100	33	63
Nut and Nut Products							
Nut Butters and Spread	0.9	<1	1	12.9	250	1	2
Plant Protein Products							
Meat Analogs and Substitutes	1.6	<1	na	2.8	61	13	34*
Butter and Spread Alternative	0.4	<1	<1	11.2	227	1	2

Table A-5 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Female Adults Ages 20 Years and Older within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	2.1	<1	1	48.7	990	1	2
Soups and Soup Mixes							
Soups and Soup Mixes	7.6	2	7	15.5	400	11	20

n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table A-6 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Male Adults Ages 20 Years and Older within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***24***	***59***	***96.8***	***1,888***	***25***	***60***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	5.7	1	4	39.5	714	3	7
Crackers	1.0	<1	1	21.2	363	1	2
Biscuits; Cookies	6.7	2	5	34.1	707	5	9
French Toast, Pancakes, and Waffles	2.5	1	na	8.7	171	7	13
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	0.1	<1*	na	<0.1	1	101*	101*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	14.6	4	14	12.9	303	27	51
Ready-to-Eat Cereals	7.1	2	7	26.0	508	7	13
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	5.7	1	na	5.4	89	25	49
Ready-to-Drink Tea beverages; Instant Tea	21.8	5	18	13.3	244	39	99
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	5.7	1	3	24.0	513	6	14
Cream Cheese Substitute[d]	0.3	<1	na	4.1	52	2	3*
Non-Dairy Frozen Desserts	<0.1	<1*	na	0.4	2	3*	3*
Non-Dairy Dips (includes imitation sour cream)	1.2	<1	na	5.3	76	5	12*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	<0.1	<1*	na	0.2	3	4*	4*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.2	1	3	11.6	143	7	14
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	10.0	2	na	5.9	94	40	62
Nut and Nut Products							
Nut Butters and Spread	1.4	<1	2	13.0	230	3	4
Plant Protein Products							
Meat Analogs and Substitutes	0.6	<1	na	1.8	33	8	14*
Butter and Spread Alternative	0.3	<1	na	7.8	210	1	2

Table A-6 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Male Adults Ages 20 Years and Older within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	2.5	1	2	46.6	864	1	3
Soups and Soup Mixes							
Soups and Soup Mixes	9.6	2	9	16.1	321	14	24

n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table A-7 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by the U.S. Population Ages 2 Years and Older (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***21***	***53***	***97.1***	***5,965***	***22***	***54***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	5.2	1	4	37.2	2,156	3	6
Crackers	1.1	<1	1	23.8	1,367	1	2
Biscuits; Cookies	6.4	1	5	37.4	2,340	4	7
French Toast, Pancakes, and Waffles	3.7	1	3	12.7	786	6	11
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	1.5	<1*	na	0.5	16	58*	101*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	13.6	3	10	12.2	886	24	45
Ready-to-Eat Cereals	8.2	2	6	31.6	2,045	6	10
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	6.8	1	na	6.4	300	22	37
Ready-to-Drink Tea beverages; Instant Tea	19.7	4	12	12.4	684	34	73
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	6.5	1	3	23.6	1,361	6	15
Cream Cheese Substitute[d]	0.4	<1	na	5.4	250	2	4
Non-Dairy Frozen Desserts	0.1	<1*	na	0.3	4	7*	12*
Non-Dairy Dips (includes imitation sour cream)	1.2	<1	na	5.7	241	4	9
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.1	<1*	na	0.3	11	4*	7*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.4	1	3	12.2	551	6	11
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	8.6	2	na	5.2	244	35	62
Nut and Nut Products							
Nut Butters and Spread	1.3	<1	1	14.3	803	2	3
Plant Protein Products							
Meat Analogs and Substitutes	0.9	<1	na	2.0	114	10	25
Butter and Spread Alternative	0.3	<1	na	8.9	547	1	2

Table A-7 Estimated Daily Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by the U.S. Population Ages 2 Years and Older (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	2.6	1	2	50.7	3,115	1	2
Soups and Soup Mixes							
Soups and Soup Mixes	8.5	2	8	15.5	1,049	12	22

n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

APPENDIX B

Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Different Population Groups within the U.S. (2017-2018 NHANES Data)

Table B-1 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Children Ages 2 to 5 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***0.75***	***1.48***	***99.8***	***460***	***0.75***	***1.48***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	4.7	0.04	0.13	30.9	131	0.12	0.23
Crackers	3.3	0.02	0.08	43.0	201	0.06	0.13
Biscuits; Cookies	9.5	0.07	0.21	44.8	210	0.16	0.36
French Toast, Pancakes, and Waffles	9.2	0.07	0.23	27.9	117	0.25	0.41
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	0.3	<0.01*	na	0.4	1	0.64*	0.64*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	22.9	0.17	0.65*	14.4	79	1.19	2.20*
Ready-to-Eat Cereals	14.2	0.11	0.29	58.3	271	0.18	0.34
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	0.1	<0.01*	na	0.3	2	0.27*	0.31*
Ready-to-Drink Tea beverages; Instant Tea	7.1	0.05*	na	5.8	21	0.91*	1.77*
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	5.2	0.04*	na	6.6	25	0.59*	1.14*
Cream Cheese Substitute[d]	0.3	<0.01*	na	3.3	21	0.06*	0.10*
Non-Dairy Frozen Desserts	0	0	0	0	0	0	0
Non-Dairy Dips (includes imitation sour cream)	1.3	0.01*	na	4.3	13	0.22*	0.43*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.1	<0.01*	na	0.3	1	0.30*	0.30*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	4.7	0.04	0.16*	14.4	59	0.24	0.37*
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	2.6	0.02*	na	2.1	10	0.95*	1.63*
Nut and Nut Products							
Nut Butters and Spread	3.6	0.03	0.10	26.0	121	0.10	0.20
Plant Protein Products							
Meat Analogs and Substitutes	0.6	<0.01*	na	1.3	6	0.34*	1.20*
Butter and Spread Alternative	0.2	<0.01*	na	7.8	26	0.02*	0.03*

Table B-1 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Children Ages 2 to 5 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	4.0	0.03	0.08	62.3	295	0.05	0.10
Soups and Soup Mixes							
Soups and Soup Mixes	5.8	0.04	0.19*	13.8	69	0.32	0.61*

bw = body weight; n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table B-2 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Children Ages 6 to 11 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***0.46***	***0.89***	***99.0***	***670***	***0.46***	***0.91***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	5.5	0.03	0.09	34.0	222	0.07	0.14
Crackers	2.4	0.01	0.04	30.8	189	0.04	0.08
Biscuits; Cookies	13.1	0.06	0.17	58.3	345	0.10	0.22
French Toast, Pancakes, and Waffles	11.6	0.05	0.19	25.9	157	0.21	0.43
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	0.6	<0.01*	na	0.4	1	0.69*	0.69*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	6.0	0.03	na	5.4	46	0.51	0.84*
Ready-to-Eat Cereals	18.1	0.08	0.23	56.9	403	0.15	0.29
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	1.3	0.01*	na	1.7	9	0.35*	0.72*
Ready-to-Drink Tea beverages; Instant Tea	10.2	0.05	na	8.6	55	0.54	0.95*
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	4.0	0.02*	na	4.7	25	0.39*	0.93*
Cream Cheese Substitute[d]	0.7	<0.01*	na	5.3	25	0.06*	0.14*
Non-Dairy Frozen Desserts	0	0	0	0	0	0	0
Non-Dairy Dips (includes imitation sour cream)	1.1	0.01*	na	2.6	13	0.20*	0.34*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.1	<0.01*	na	0.2	1	0.16*	0.16*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	5.0	0.02	0.11*	16.1	75	0.14	0.30*
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	2.5	0.01*	na	1.5	9	0.78*	1.10*
Nut and Nut Products							
Nut Butters and Spread	3.0	0.01	0.05	23.6	120	0.06	0.14
Plant Protein Products							
Meat Analogs and Substitutes	0.3	<0.01*	na	1.4	9	0.09*	0.17*
Butter and Spread Alternative	0.4	<0.01	na	8.7	51	0.02	0.06*

Table B-2 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Children Ages 6 to 11 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	5.3	0.02	0.06	66.2	444	0.04	0.07
Soups and Soup Mixes							
Soups and Soup Mixes	8.8	0.04	0.15	15.0	101	0.27	0.45

bw = body weight; n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table B-3 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Female Teenagers Ages 12 to 19 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***0.34***	***0.73***	***97.8***	***425***	***0.35***	***0.73***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	4.9	0.02	0.06	36.2	145	0.05	0.09
Crackers	1.4	<0.01	0.02	22.4	81	0.02	0.05
Biscuits; Cookies	6.5	0.02	0.06	41.9	163	0.05	0.14
French Toast, Pancakes, and Waffles	5.7	0.02	0.08*	16.2	61	0.12	0.20*
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	3.1	0.01*	na	0.2	1	5.49*	5.49*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	5.1	0.02	na	5.8	38	0.30	0.50*
Ready-to-Eat Cereals	10.1	0.03	0.11	36.5	152	0.09	0.19
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	7.3	0.02*	na	6.6	24	0.37*	0.51*
Ready-to-Drink Tea beverages; Instant Tea	23.3	0.08	0.31*	20.0	62	0.39	0.75*
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	7.6	0.03	0.03*	13.1	45	0.20	0.39*
Cream Cheese Substitute[d]	0.8	<0.01*	na	8.8	26	0.03*	0.06*
Non-Dairy Frozen Desserts	0	0	0	0	0	0	0
Non-Dairy Dips (includes imitation sour cream)	0.6	<0.01*	na	4.0	11	0.05*	0.11*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.1	<0.01*	na	1.2	1	0.02*	0.02*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.9	0.01	0.06*	15.6	51	0.09	0.18*
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	7.2	0.02*	na	4.7	10	0.52*	0.56*
Nut and Nut Products							
Nut Butters and Spread	1.4	<0.01	0.02*	12.8	38	0.04	0.07*
Plant Protein Products							
Meat Analogs and Substitutes	0.1	<0.01*	na	1.2	5	0.04*	0.01*
Butter and Spread Alternative	0.3	<0.01*	na	7.1	19	0.01*	0.02*

Table B-3 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Female Teenagers Ages 12 to 19 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	2.9	0.01	0.03	56.7	271	0.02	0.04
Soups and Soup Mixes							
Soups and Soup Mixes	7.8	0.03	0.11	16.2	87	0.16	0.28

bw = body weight; n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table B-4 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Male Teenagers Ages 12 to 19 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***0.29***	***0.70***	***97.8***	***426***	***0.30***	***0.70***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	6.7	0.02	0.06	38.0	151	0.05	0.13
Crackers	1.6	<0.01	0.01*	16.5	49	0.03	0.07*
Biscuits; Cookies	7.5	0.02	0.06	34.3	162	0.06	0.14
French Toast, Pancakes, and Waffles	7.4	0.02	0.07*	14.8	61	0.15	0.36*
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	0.2	<0.01*	na	<0.1	1	2.03*	2.03*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	7.1	0.02*	na	4.9	21	0.43*	1.07*
Ready-to-Eat Cereals	14.2	0.04	0.14	41.4	177	0.10	0.17
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	3.7	0.01*	na	3.9	17	0.27*	0.34*
Ready-to-Drink Tea beverages; Instant Tea	19.3	0.06	0.18*	12.4	52	0.46	0.87*
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	3.1	0.01*	na	6.9	29	0.13*	0.21*
Cream Cheese Substitute[d]	0.7	<0.01*	na	5.3	17	0.04*	0.07*
Non-Dairy Frozen Desserts	0	0	0	0	0	0	0
Non-Dairy Dips (includes imitation sour cream)	0.4	<0.01*	na	2.5	7	0.05*	0.07*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	<0.1	<0.01*	na	0.1	1	0.03*	0.03*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.1	0.01	0.02*	10.3	46	0.09	0.21*
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	11.1	0.03*	na	6.3	21	0.51*	0.80*
Nut and Nut Products							
Nut Butters and Spread	1.5	<0.01	0.01*	10.7	43	0.04	0.06*
Plant Protein Products							
Meat Analogs and Substitutes	0	0	0	0	0	0	0
Butter and Spread Alternative	0.1	<0.01*	na	3.8	12	0.01*	0.01*

Table B-4 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Male Teenagers Ages 12 to 19 Years within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	4.0	0.01	0.03	52.6	237	0.02	0.05
Soups and Soup Mixes							
Soups and Soup Mixes	8.4	0.02	0.10*	12.8	65	0.19	0.35*

bw = body weight; n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table B-5 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Female Adults Ages 20 Years and Older within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***0.30***	***0.76***	***96.5***	***2,058***	***0.31***	***0.77***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	4.3	0.01	0.04	36.5	781	0.04	0.07
Crackers	0.8	<0.01	0.01	23.7	476	0.01	0.02
Biscuits; Cookies	5.0	0.02	0.05	35.0	738	0.04	0.09
French Toast, Pancakes, and Waffles	2.9	0.01	0.02	11.0	217	0.08	0.14
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	3.2	0.01*	na	1.2	11	0.81*	1.45*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	15.2	0.05	0.17	14.4	389	0.32	0.67
Ready-to-Eat Cereals	6.5	0.02	0.07	26.3	519	0.08	0.15
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	8.9	0.03	na	9.4	156	0.29	0.49
Ready-to-Drink Tea beverages; Instant Tea	17.8	0.05	0.15	12.2	249	0.44	0.94
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	8.3	0.03	0.07	32.7	715	0.08	0.21
Cream Cheese Substitute[d]	0.5	<0.01	na	6.5	108	0.02	0.04
Non-Dairy Frozen Desserts	0.2	<0.01*	na	0.4	2	0.14*	0.16*
Non-Dairy Dips (includes imitation sour cream)	1.3	<0.01	na	7.4	119	0.05	0.11
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.2	<0.01*	na	0.4	4	0.11*	0.13*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.5	0.01	0.03	11.6	177	0.09	0.17
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	8.9	0.03	na	5.5	100	0.49	0.75
Nut and Nut Products							
Nut Butters and Spread	0.9	<0.01	0.01	12.9	246	0.02	0.04
Plant Protein Products							
Meat Analogs and Substitutes	1.6	<0.01	na	2.8	61	0.18	0.62*
Butter and Spread Alternative	0.4	<0.01	<0.01	11.1	223	0.01	0.02

Table B-5 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Female Adults Ages 20 Years and Older within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	2.0	0.01	0.02	48.8	983	0.01	0.03
Soups and Soup Mixes							
Soups and Soup Mixes	7.6	0.02	0.10	15.5	395	0.15	0.28

bw = body weight; n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table B-6 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Male Adults Ages 20 Years and Older within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***0.28***	***0.71***	***96.8***	***1,873***	***0.29***	***0.72***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	5.7	0.02	0.05	39.6	709	0.04	0.08
Crackers	1.0	<0.01	0.01	21.2	359	0.01	0.02
Biscuits; Cookies	6.6	0.02	0.06	34.1	703	0.05	0.11
French Toast, Pancakes, and Waffles	2.6	0.01	na	8.7	171	0.08	0.16
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	0.1	<0.01*	na	<0.1	1	0.90*	0.90*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	14.9	0.04	0.15	12.9	301	0.32	0.59
Ready-to-Eat Cereals	7.2	0.02	0.08	26.0	504	0.08	0.14
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	6.6	0.02	na	5.4	89	0.34	0.65
Ready-to-Drink Tea beverages; Instant Tea	20.8	0.06	0.19	13.3	240	0.44	0.91
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	5.7	0.02	0.04	24.0	510	0.07	0.18
Cream Cheese Substitute[d]	0.3	<0.01	na	4.1	51	0.02	0.03*
Non-Dairy Frozen Desserts	<0.1	<0.01*	na	0.4	2	0.03*	0.03*
Non-Dairy Dips (includes imitation sour cream)	1.2	<0.01	na	5.3	76	0.06	0.13*
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	<0.1	<0.01*	na	0.2	3	0.04*	0.04*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.2	0.01	0.03	11.6	142	0.08	0.16
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	9.8	0.03	na	5.9	93	0.46	0.79
Nut and Nut Products							
Nut Butters and Spread	1.3	<0.01	0.02	13.0	225	0.03	0.05
Plant Protein Products							
Meat Analogs and Substitutes	0.6	<0.01	na	1.8	33	0.09	0.17*
Butter and Spread Alternative	0.3	<0.01	na	7.8	208	0.01	0.03

Table B-6 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by Male Adults Ages 20 Years and Older within the U.S. (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	2.4	0.01	0.02	46.7	859	0.01	0.03
Soups and Soup Mixes							
Soups and Soup Mixes	9.7	0.03	0.10	16.2	320	0.17	0.34

bw = body weight; n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.
* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

Table B-7 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by the U.S. Population Ages 2 Years and Older (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***0.33***	***0.79***	***97.1***	***5,912***	***0.34***	***0.79***
Baked Goods and Baking Mixes							
Bagels and English Muffins; Cornbread, Corn Muffins, or Tortillas	5.1	0.02	0.05	37.2	2,139	0.05	0.09
Crackers	1.4	<0.01	0.01	23.9	1,355	0.02	0.04
Biscuits; Cookies	7.1	0.02	0.07	37.4	2,321	0.06	0.13
French Toast, Pancakes, and Waffles	4.9	0.02	0.05	12.7	784	0.13	0.26
Bread (high protein)	0	0	0	0	0	0	0
Beverages and Beverage Bases							
Non-Milk Meal Replacements and Protein Drinks	1.5	<0.01*	na	0.5	16	0.89*	1.46*
Breakfast Cereals							
Hot Breakfast Cereals (*e.g.*, oatmeal, grits)	14.1	0.05	0.15	12.2	874	0.38	0.76
Ready-to-Eat Cereals	9.5	0.03	0.11	31.6	2,026	0.10	0.21
Coffee and Tea							
Specialty Coffee Drinks (lattes, cappuccinos, mochas)[c]	6.0	0.02	na	6.4	297	0.31	0.53
Ready-to-Drink Tea beverages; Instant Tea	17.0	0.06	0.17	12.4	679	0.45	0.94
Dairy Product Analogues							
Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers); Soy- and/or Rice-Based Beverages	6.4	0.02	0.04	23.5	1,349	0.09	0.24
Cream Cheese Substitute[d]	0.4	<0.01	na	5.4	248	0.03	0.06
Non-Dairy Frozen Desserts	0.1	<0.01*	na	0.3	4	0.09*	0.15*
Non-Dairy Dips (includes imitation sour cream)	1.2	<0.01	na	5.7	239	0.07	0.13
Non-Dairy Yogurt	0	0	0	0	0	0	0
Imitation Cheese	0.1	<0.01*	na	0.3	11	0.09*	0.14*
Grain Products and Pastas							
Cereal Bars, Nutritional Bars, and Meal Replacement Bars	3.7	0.01	0.04	12.2	550	0.10	0.20
Milk Products							
Milk-Based Meal Replacements and Protein Drinks	7.8	0.03	na	5.2	243	0.49	0.81
Nut and Nut Products							
Nut Butters and Spread	1.6	0.01	0.02	14.3	793	0.04	0.07
Plant Protein Products							
Meat Analogs and Substitutes	0.9	<0.01	na	2.0	114	0.14	0.34
Butter and Spread Alternative	0.3	<0.01	na	8.9	539	0.01	0.03

Table B-7 Estimated Daily Per Kilogram Body Weight Intake of FermentIQ Pea Protein from Individual Proposed Food Uses by the U.S. Population Ages 2 Years and Older (2017-2018 NHANES Data)

Food Use Category	% Contribution to Total Mean Intake	*Per Capita* Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Snack Foods							
Snack Foods (includes potato chips, pretzels, corn-based savory snacks, and popcorn)	2.9	0.01	0.03	50.7	3,089	0.02	0.04
Soups and Soup Mixes							
Soups and Soup Mixes	8.2	0.03	0.10	15.5	1,037	0.18	0.35

bw = body weight; n = sample size; na = not available; NHANES = National Health and Nutrition Examination Surveys; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements (mean n<30; 90th percentile n<80).

APPENDIX C
Representative Food Codes for Proposed Food Uses of FermentIQ Pea Protein in the U.S. (2017-2018 NHANES Data)

Representative Food Codes for Proposed Food Uses of FermentIQ Pea Protein in the U.S. (2017-2018 NHANES Data)

Baked Goods and Baking Mixes

Bagels and English Muffins, Cornbread, Corn Muffins, or Tortillas
[FermentIQ Pea Protein] = 5 g/100 g

51180010	Bagel
51180030	Bagel, with raisins
51180080	Bagel, with fruit other than raisins
51186010	Muffin, English
51186100	Muffin, English, with raisins
51186130	Muffin, English, cheese
51186160	Muffin, English, with fruit other than raisins
51187000	Melba toast
51300100	Bagel, whole grain white
51301700	Bagel, wheat
51301750	Bagel, whole wheat
51301800	Bagel, wheat, with raisins
51301805	Bagel, whole wheat, with raisins
51301820	Bagel, wheat, with fruit and nuts
51301900	Bagel, wheat bran
51302500	Muffin, English, wheat bran
51302520	Muffin, English, wheat bran, with raisins
51303010	Muffin, English, wheat or cracked wheat
51303030	Muffin, English, whole wheat
51303050	Muffin, English, wheat or cracked wheat, with raisins
51303070	Muffin, English, whole wheat, with raisins
51303100	Muffin, English, whole grain white
51401200	Muffin, English, rye
51404500	Bagel, pumpernickel
51404550	Muffin, English, pumpernickel
51501080	Bagel, oat bran
51503000	Muffin, English, oat bran
51503040	Muffin, English, oat bran, with raisins
51630000	Bagel, multigrain
51630100	Bagel, multigrain, with raisins
51630200	Muffin, English, multigrain
52101040	Crumpet
52201000	Cornbread, prepared from mix
52204000	Cornbread stuffing
52206010	Cornbread muffin, stick, round
52207010	Corn flour patty or tart, fried

52208010 Corn pone, baked
52208020 Corn pone, fried
52208760 Gordita/sope shell, plain, no filling
52209010 Hush puppy
52211010 Johnnycake
52213010 Spoonbread
52215000 Tortilla, NFS
52215100 Tortilla, corn
52215200 Tortilla, flour
52215260 Tortilla, whole wheat
52215300 Taco shell, corn
52215350 Taco shell, flour
52220110 Arepa Dominicana

Mixed foods containing bagels and English muffins, cornbread, corn muffins, or tortillas
Adjusted for baked good content of 5.1 to 79.0%
[FermentIQ Pea Protein] = 0.26 to 3.95 g/100 g

32202010 Egg, cheese, and ham on English muffin
32202025 Egg, cheese and ham on bagel
32202030 Egg, cheese, and sausage on English muffin
32202045 Egg, cheese, and steak on bagel
32202080 Egg, cheese, and bacon on English muffin
32202085 Egg, cheese and bacon on bagel
32202120 Egg, cheese and sausage on bagel
58100000 Burrito, taco, or quesadilla with egg
58100005 Burrito, taco, or quesadilla with egg and potato
58100010 Burrito, taco, or quesadilla with egg and breakfast meat
58100013 Burrito, taco, or quesadilla with egg and breakfast meat, from fast food
58100015 Burrito, taco, or quesadilla with egg, potato, and breakfast meat
58100017 Burrito, taco, or quesadilla with egg, potato, and breakfast meat, from fast food
58100020 Burrito, taco, or quesadilla with egg, beans, and breakfast meat
58100100 Burrito with meat
58100120 Burrito with meat and beans
58100125 Burrito with meat and beans, from fast food
58100135 Burrito with meat and sour cream
58100140 Burrito with meat, beans, and sour cream
58100145 Burrito with meat, beans, and sour cream, from fast food
58100160 Burrito with meat, beans, and rice
58100165 Burrito with meat, beans, rice, and sour cream
58100200 Burrito with chicken
58100220 Burrito with chicken and beans
58100235 Burrito with chicken and sour cream
58100245 Burrito with chicken, beans, and sour cream

58100255 Burrito with chicken, beans, and rice
58100260 Burrito with chicken, beans, rice, and sour cream
58100300 Burrito with beans and rice, meatless
58100320 Burrito with beans, meatless
58100325 Burrito with beans, meatless, from fast food
58100330 Burrito with beans, rice, and sour cream, meatless
58100360 Chilaquiles, tortilla casserole with salsa, cheese, and egg
58100370 Chilaquiles, tortilla casserole with salsa and cheese, no egg
58100500 Enchilada, no sauce
58100520 Enchilada with meat and beans, red-chile or enchilada sauce
58100525 Enchilada with meat and beans, green-chile or enchilada sauce
58100530 Enchilada with meat, red-chile or enchilada sauce
58100535 Enchilada with meat, green-chile or enchilada sauce
58100620 Enchilada with chicken and beans, red-chile or enchilada sauce
58100625 Enchilada with chicken and beans, green-chile or enchilada sauce
58100630 Enchilada with chicken, red-chile or enchilada sauce
58100635 Enchilada with chicken, green-chile or enchilada sauce
58100720 Enchilada with beans, meatless, red-chile or enchilada sauce
58100725 Enchilada with beans, green-chile or enchilada sauce
58100800 Enchilada, just cheese, meatless, no beans, red-chile or enchilada sauce
58100805 Enchilada, just cheese, meatless, no beans, green-chile or enchilada sauce
58101320 Taco or tostada with meat
58101323 Taco or tostada with meat, from fast food
58101325 Taco or tostada with meat and sour cream
58101345 Soft taco with meat
58101347 Soft taco with meat, from fast food
58101350 Soft taco with meat and sour cream
58101357 Soft taco with meat and sour cream, from fast food
58101450 Soft taco with chicken
58101457 Soft taco with chicken, from fast food
58101460 Soft taco with chicken and sour cream
58101520 Taco or tostada with chicken
58101525 Taco or tostada with chicken and sour cream
58101540 Taco or tostada with fish
58101555 Soft taco with fish
58101610 Soft taco with beans
58101615 Soft taco with beans and sour cream
58101620 Soft taco with meat and beans
58101625 Soft taco with chicken and beans
58101630 Soft taco with meat, beans, and sour cream
58101635 Soft taco with chicken, beans, and sour cream
58101720 Taco or tostada with beans
58101725 Taco or tostada with beans and sour cream
58101730 Taco or tostada with meat and beans

58101733	Taco or tostada with meat and beans, from fast food
58101735	Taco or tostada with chicken and beans
58101745	Taco or tostada with meat, beans, and sour cream
58101750	Taco or tostada with chicken, beans, and sour cream
58101800	Ground beef with tomato sauce and taco seasonings on a cornbread crust
58101930	Taco or tostada salad with meat
58101935	Taco or tostada salad with chicken
58101940	Taco or tostada salad, meatless
58101945	Taco or tostada salad with meat and sour cream
58101950	Taco or tostada salad with chicken and sour cream
58101955	Taco or tostada salad, meatless with sour cream
58103120	Tamale with meat
58103130	Tamale with chicken
58103210	Tamale, meatless, with sauce, Puerto Rican or Caribbean style
58103250	Tamale, plain, meatless, no sauce, Mexican style
58103310	Tamale casserole with meat
58104260	Gordita, sope, or chalupa with beans
58104270	Gordita, sope, or chalupa with beans and sour cream
58104280	Gordita, sope, or chalupa with meat and sour cream
58104290	Gordita, sope, or chalupa with meat
58104320	Gordita, sope, or chalupa with chicken and sour cream
58104340	Gordita, sope, or chalupa with chicken
58104500	Chimichanga with meat
58104520	Chimichanga, meatless
58104530	Chimichanga with chicken
58104535	Chimichanga with meat and sour cream
58104540	Chimichanga, meatless, with sour cream
58104550	Chimichanga with chicken and sour cream
58104710	Quesadilla, just cheese, meatless
58104720	Quesadilla, just cheese, from fast food
58104730	Quesadilla with meat
58104740	Quesadilla with chicken
58104745	Quesadilla with chicken, from fast food
58104750	Quesadilla with vegetables
58104760	Quesadilla with vegetables and meat
58104770	Quesadilla with vegetables and chicken
58104800	Taquito or flauta with cheese
58104820	Taquito or flauta with meat
58104825	Taquito or flauta with meat and cheese
58104830	Taquito or flauta with chicken
58104835	Taquito or flauta with chicken and cheese
58104900	Taquito or flauta with egg
58104905	Taquito or flauta with egg and breakfast meat
58105000	Fajita with chicken and vegetables

58105050 Fajita with meat and vegetables
58105075 Fajita with vegetables
58105100 Pupusa, cheese-filled
58105105 Pupusa, bean-filled
58105110 Pupusa, meat-filled
58115110 Tamale casserole, Puerto Rican style
58115150 Tamal in a leaf, Puerto Rican style
58115210 Taco with crab meat, Puerto Rican style
58128110 Chicken cornbread
58200250 Wrap sandwich, filled with vegetables
58306010 Beef enchilada dinner, NFS, frozen meal
58306020 Beef enchilada, chili gravy, rice, refried beans, frozen meal
58306070 Cheese enchilada, frozen meal

Crackers

[FermentIQ Pea Protein] = 5 g/100 g

54001000 Crackers, NFS
54102010 Graham crackers
54102015 Graham crackers (Teddy Grahams)
54102020 Graham crackers, chocolate covered
54102050 Crackers, oatmeal
54102060 Crackers, Cuban
54102100 Graham crackers, reduced fat
54102200 Graham crackers, sandwich, with filling
54103000 Crackers, breakfast biscuit
54200100 Crackers, butter, reduced sodium
54201010 Crackers, matzo, reduced sodium
54202020 Crackers, saltine, reduced sodium
54204020 Crackers, wheat, reduced sodium
54204030 Crackers, woven wheat, reduced sodium
54301010 Crackers, butter, plain
54301020 Crackers, butter, flavored
54301030 Crackers, butter (Ritz)
54301100 Crackers, butter, reduced fat
54304000 Crackers, cheese
54304005 Crackers, cheese (Cheez-It)
54304020 Crackers, cheese (Goldfish)
54304100 Crackers, cheese, reduced fat
54304110 Crackers, cheese, reduced sodium
54304150 Crackers, cheese, whole grain
54305010 Crackers, crispbread
54305020 Crackers, flatbread
54307000 Crackers, matzo

54308000 Crackers, milk
54313000 Crackers, oyster
54318000 Chips, rice
54318500 Rice cake
54319000 Crackers, rice
54319005 Crackers, rice and nuts
54319020 Popcorn cake
54319500 Rice paper
54325000 Crackers, saltine
54325010 Crackers, saltine, reduced fat
54325060 Crackers, saltine, multigrain
54326000 Crackers, multigrain
54328000 Crackers, sandwich
54328100 Crackers, sandwich, peanut butter filled
54328105 Crackers, sandwich, peanut butter filled (Ritz)
54328110 Crackers, sandwich, reduced fat, peanut butter filled
54328120 Crackers, whole grain, sandwich, peanut butter filled
54328200 Crackers, sandwich, cheese filled
54328210 Crackers, sandwich, cheese filled (Ritz)
54336000 Crackers, water
54336100 Crackers, wonton
54337010 Crackers, woven wheat
54337020 Crackers, woven wheat, plain (Triscuit)
54337030 Crackers, woven wheat, flavored (Triscuit)
54337060 Crackers, woven wheat, reduced fat
54338000 Crackers, wheat
54338010 Crackers, wheat, plain (Wheat Thins)
54338020 Crackers, wheat, flavored (Wheat Thins)
54338100 Crackers, wheat, reduced fat
54339000 Crackers, corn
54340100 Crackers, gluten free, plain
54340110 Crackers, gluten free, flavored

Biscuits, Cookies
[FermentIQ Pea Protein] = 10 g/100 g

52101000 Biscuit, NFS
52102040 Biscuit, from refrigerated dough
52103000 Biscuit, from fast food / restaurant
52104040 Biscuit, wheat
52104100 Biscuit, cheese
52104200 Biscuit with fruit
52105100 Scone
52105200 Scone, with fruit

53200100 Cookie, batter or dough, raw
53201000 Cookie, NFS
53202000 Cookie, almond
53203000 Cookie, applesauce
53203500 Cookie, biscotti
53204000 Cookie, brownie, NS as to icing
53204010 Cookie, brownie, without icing
53204100 Cookie, brownie, with icing or filling
53204840 Cookie, brownie, reduced fat, NS as to icing
53204860 Cookie, brownie, fat free, NS as to icing
53205250 Cookie, butterscotch, brownie
53205260 Cookie, bar, with chocolate
53206000 Cookie, chocolate chip
53206020 Cookie, chocolate chip, made from home recipe or purchased at a bakery
53206030 Cookie, chocolate chip, reduced fat
53206100 Cookie, chocolate chip sandwich
53206500 Cookie, chocolate, made with rice cereal
53206550 Cookie, chocolate, made with oatmeal and coconut, no bake
53207000 Cookie, chocolate or fudge
53207020 Cookie, chocolate or fudge, reduced fat
53207050 Cookie, chocolate, with chocolate filling or coating, fat free
53208000 Cookie, marshmallow, chocolate-covered
53208200 Cookie, marshmallow pie, chocolate covered
53209005 Cookie, chocolate, with icing or coating
53209010 Cookie, sugar wafer, chocolate-covered
53209015 Cookie, chocolate sandwich
53209020 Cookie, chocolate sandwich, reduced fat
53209100 Cookie, chocolate, sandwich, with extra filling
53209500 Cookie, chocolate and vanilla sandwich
53210000 Cookie, chocolate wafer
53210900 Cookie, graham cracker with chocolate and marshmallow
53211000 Cookie bar, with chocolate, nuts, and graham crackers
53215500 Cookie, coconut
53220000 Cookie, fruit-filled bar
53220010 Cookie, fruit-filled bar, fat free
53220030 Cookie, fig bar
53220040 Cookie, fig bar, fat free
53222010 Cookie, fortune
53222020 Cookie, cone shell, ice cream type, wafer or cake
53223000 Cookie, gingersnaps
53223100 Cookie, granola
53224000 Cookie, ladyfinger
53224250 Cookie, lemon bar
53225000 Cookie, macaroon

53226000 Cookie, marshmallow, with coconut
53226500 Cookie, marshmallow, with rice cereal, no bake
53226550 Cookie, marshmallow, with rice cereal and chocolate chips
53226600 Cookie, marshmallow and peanut butter, with oat cereal, no bake
53228000 Cookie, meringue
53230000 Cookie, molasses
53231000 Cookie, Lebkuchen
53231400 Cookie, multigrain, high fiber
53233000 Cookie, oatmeal
53233010 Cookie, oatmeal, with raisins
53233040 Cookie, oatmeal, reduced fat, NS as to raisins
53233050 Cookie, oatmeal sandwich, with creme filling
53233060 Cookie, oatmeal, with chocolate chips
53233080 Cookie, oatmeal sandwich, with peanut butter and jelly filling
53233100 Cookie, oatmeal, with chocolate and peanut butter, no bake
53234000 Cookie, peanut butter
53234100 Cookie, peanut butter, with chocolate
53234250 Cookie, peanut butter with rice cereal, no bake
53235000 Cookie, peanut butter sandwich
53235500 Cookie, with peanut butter filling, chocolate-coated
53235600 Cookie, Pfeffernusse
53236000 Cookie, Pizzelle
53236100 Cookie, pumpkin
53237000 Cookie, raisin
53237010 Cookie, raisin sandwich, cream-filled
53237500 Cookie, rum ball, no bake
53238000 Cookie, sandwich-type, not chocolate or vanilla
53239000 Cookie, shortbread
53239010 Cookie, shortbread, reduced fat
53239050 Cookie, shortbread, with icing or filling
53239100 Pocky
53240000 Cookie, animal
53240010 Cookie, animal, with frosting or icing
53241500 Cookie, butter or sugar
53241510 Marie biscuit
53241600 Cookie, butter or sugar, with fruit and/or nuts
53242000 Cookie, sugar wafer
53242500 Cookie, toffee bar
53243000 Cookie, vanilla sandwich
53243010 Cookie, vanilla sandwich, extra filling
53243050 Cookie, vanilla sandwich, reduced fat
53244010 Cookie, butter or sugar, with chocolate icing or filling
53244020 Cookie, butter or sugar, with icing or filling other than chocolate
53246000 Cookie, tea, Japanese

53247000 Cookie, vanilla wafer
53247050 Cookie, vanilla wafer, reduced fat
53247500 Cookie, vanilla with caramel, coconut, and chocolate coating
53251100 Cookie, rugelach
53260030 Cookie, chocolate chip, sugar free
53260200 Cookie, oatmeal, sugar free
53260300 Cookie, sandwich, sugar free
53260400 Cookie, sugar or plain, sugar free
53260500 Cookie, sugar wafer, sugar free
53260600 Cookie, peanut butter, sugar free
53261000 Cookie, gluten free
53270100 Cookies, Puerto Rican style

Mixed foods containing biscuits or cookies
Adjusted for biscuit or cookie content of 33.16 to 87.20%
[FermentIQ Pea Protein] = 3.32 to 8.72 g/100 g

27515080 Steak sandwich, plain, on biscuit
27520170 Bacon on biscuit
27520250 Ham on biscuit
27540145 Chicken fillet biscuit, from fast food
27560650 Sausage on biscuit
27560705 Sausage balls, made with biscuit mix and cheese
32202020 Egg, cheese, and ham on biscuit
32202050 Egg, cheese, and sausage on biscuit
32202060 Egg and sausage on biscuit
32202070 Egg, cheese, and bacon on biscuit
32202090 Egg and bacon on biscuit
32202110 Egg and ham on biscuit
32202130 Egg and steak on biscuit
32202200 Egg and cheese on biscuit

French Toast, Pancakes, and Waffles
[FermentIQ Pea Protein] = 10 g/100 g

53344300 Dessert pizza
53400200 Blintz, cheese-filled
53400300 Blintz, fruit-filled
53430000 Crepe, NS as to filling
53430100 Crepe, chocolate filled
53430200 Crepe, fruit filled
55100005 Pancakes, NFS
55100010 Pancakes, plain, from frozen
55100015 Pancakes, plain, reduced fat, from fozen
55100020 Pancakes, with fruit, from frozen

55100025	Pancakes, with chocolate, from frozen
55100030	Pancakes, whole grain, from frozen
55100035	Pancakes, whole grain, reduced fat, from frozen
55100040	Pancakes, gluten free, from frozen
55100050	Pancakes, plain, from fast food / restaurant
55100055	Pancakes, with fruit, from fast food / restaurant
55100060	Pancakes, with chocolate, from fast food / restaurant
55100065	Pancakes, whole grain, from fast food / restaurant
55100070	Pancakes, whole grain and nuts, from fast food / restaurant
55100080	Pancakes, from school, NFS
55101000	Pancakes, plain
55101015	Pancakes, plain, reduced fat
55103000	Pancakes, with fruit
55103020	Pancakes, pumpkin
55103100	Pancakes, with chocolate
55105000	Pancakes, buckwheat
55105100	Pancakes, cornmeal
55105200	Pancakes, whole grain
55105205	Pancakes, whole grain, reduced fat
55106000	Pancakes, gluten free
55200010	Waffle, NFS
55200020	Waffle, plain, from frozen
55200030	Waffle, plain, reduced fat, from frozen
55200040	Waffle, fruit, from frozen
55200050	Waffle, chocolate, from frozen
55200060	Waffle, whole grain, from frozen
55200070	Waffle, whole grain, reduced fat, from frozen
55200080	Waffle, whole grain, fruit, from frozen
55200090	Waffle, gluten free, from frozen
55200100	Waffle, plain, from fast food / restaurant
55200110	Waffle, chocolate, from fast food / restaurant
55200120	Waffle, fruit, from fast food / restaurant
55200130	Waffle, whole grain, from fast food / restaurant
55200200	Waffle, from school, NFS
55201000	Waffle, plain
55203000	Waffle, fruit
55203600	Waffle, chocolate
55203700	Waffle, cinnamon
55204000	Waffle, cornmeal
55205000	Waffle, whole grain
55208000	Waffle, gluten free
55211050	Waffle, plain, reduced fat
55212000	Waffle, whole grain, reduced fat
55300010	French toast, NFS

55300020 French toast, plain, from frozen
55300030 French toast, whole grain, from frozen
55300040 French toast, gluten free, from frozen
55300050 French toast, plain, from fast food / restaurant
55300055 French toast, whole grain, from fast food / restaurant
55300060 French toast, from school, NFS
55301000 French toast, plain
55301010 French toast, plain, reduced fat
55301015 French toast, whole grain
55301020 French toast, whole grain, reduced fat
55301025 French toast, gluten free
55301030 French toast sticks, NFS
55301031 French toast sticks, plain, from frozen
55301040 French toast sticks, plain, from fast food / restaurant
55301048 French toast sticks, from school, NFS
55301050 French toast sticks, plain
55301055 French toast sticks, whole grain
55310100 Fried bread, Puerto Rican style
55400010 Crepe, NFS
55401000 Crepe, plain
55501000 Chinese pancake
55610300 Dumpling, plain
55701000 Cake made with glutinous rice
55702000 Cake or pancake made with rice flour and/or dried beans
55702100 Dosa (Indian), plain
55703000 Cake made with glutinous rice and dried beans
58128000 Biscuit with gravy
58174100 Dosa (Indian), with filling
58310210 Sausage and french toast, frozen meal
58310310 Pancakes and sausage, frozen meal

Bread (high protein)
[FermentIQ Pea Protein] = 15 g/100 g

51123010 Bread, high protein
51123020 Bread, high protein, toasted

Beverages and Beverage Bases

Non-Milk Meal Replacements and Protein Drinks
[FermentIQ Pea Protein] = 40 g/100 g

95120050 Nutritional drink or shake, liquid, soy-based

Foods adjusted for being present in dried form (not reconstituted)
Reconstitution factor of 7

95201300	Nutritional powder mix (EAS Soy Protein Powder)
95230010	Nutritional powder mix, protein, soy based, NFS

Breakfast Cereals

Hot Breakfast Cereals
[FermentIQ Pea Protein] = 15 g/100 g

56200300	Cereal, cooked, NFS
56200390	Barley, NS as to fat
56200400	Barley, no added fat
56200410	Barley, fat added
56200490	Buckwheat groats, NS as to fat
56200500	Buckwheat groats, no added fat
56200510	Buckwheat groats, fat added
56200990	Grits, NS as to regular, quick, or instant, NS as to fat
56201000	Grits, NS as to regular, quick, or instant, no added fat
56201040	Grits, NS as to regular, quick, or instant, fat added
56201050	Grits, regular or quick, made with water, NS as to fat
56201051	Grits, regular or quick, made with water, no added fat
56201052	Grits, regular or quick, made with water, fat added
56201055	Grits, regular or quick, made with milk, NS as to fat
56201056	Grits, regular or quick, made with milk, no added fat
56201057	Grits, regular or quick, made with milk, fat added
56201065	Grits, regular or quick, made with non-dairy milk, NS as to fat
56201066	Grits, regular or quick, made with non-dairy milk, no added fat
56201067	Grits, regular or quick, made with non-dairy milk, fat added
56201090	Grits, with cheese, NS as to fat
56201091	Grits, with cheese, no added fat
56201092	Grits, with cheese, fat added
56201210	Grits, instant, made with water, no added fat
56201220	Grits, instant, made with water, fat added
56201230	Grits, instant, made with water, NS as to fat
56201340	Grits, instant, made with milk, fat added
56201342	Grits, instant, made with milk, no added fat
56201344	Grits, instant, made with milk, NS as to fat
56201350	Grits, instant, made with non-dairy milk, NS as to fat
56201355	Grits, instant, made with non-dairy milk, no added fat
56201360	Grits, instant, made with non-dairy milk, fat added
56201515	Cornmeal mush, NS as to fat
56201516	Cornmeal mush, no added fat
56201517	Cornmeal mush, fat added

56201540	Cornmeal, Puerto Rican Style
56201550	Cornmeal dumpling
56201600	Masa harina, cooked
56201990	Millet, NS as to fat
56202000	Millet, no added fat
56202100	Millet, fat added
56202900	Oatmeal, from fast food, plain
56202905	Oatmeal, from fast food, maple flavored
56202910	Oatmeal, from fast food, fruit flavored
56202920	Oatmeal, from fast food, other flavors
56202960	Oatmeal, NS as to regular, quick, or instant, NS as to fat
56203000	Oatmeal, NS as to regular, quick, or instant, no added fat
56203040	Oatmeal, NS as to regular, quick, or instant, fat added
56203055	Oatmeal, regular or quick, made with water, NS as to fat
56203056	Oatmeal, regular or quick, made with water, no added fat
56203057	Oatmeal, regular or quick, made with water, fat added
56203065	Oatmeal, regular or quick, made with milk, NS as to fat
56203066	Oatmeal, regular or quick, made with milk, no added fat
56203067	Oatmeal, regular or quick, made with milk, fat added
56203075	Oatmeal, regular or quick, made with non-dairy milk, NS as to fat
56203076	Oatmeal, regular or quick, made with non-dairy milk, no added fat
56203077	Oatmeal, regular or quick, made with non-dairy milk, fat added
56203085	Oatmeal, instant, plain, made with water, NS as to fat
56203086	Oatmeal, instant, plain, made with water, no added fat
56203087	Oatmeal, instant, plain, made with water, fat added
56203095	Oatmeal, instant, plain, made with milk, NS as to fat
56203096	Oatmeal, instant, plain, made with milk, no added fat
56203097	Oatmeal, instant, plain, made with milk, fat added
56203105	Oatmeal, instant, plain, made with non-dairy milk, NS as to fat
56203106	Oatmeal, instant, plain, made with non-dairy milk, no added fat
56203107	Oatmeal, instant, plain, made with non-dairy milk, fat added
56203125	Oatmeal, instant, maple flavored, NS as to fat
56203130	Oatmeal, instant, maple flavored, no added fat
56203135	Oatmeal, instant, maple flavored, fat added
56203150	Oatmeal, instant, fruit flavored, NS as to fat
56203155	Oatmeal, instant, fruit flavored, no added fat
56203160	Oatmeal, instant, fruit flavored, fat added
56203170	Oatmeal, instant, other flavors, NS as to fat
56203175	Oatmeal, instant, other flavors, no added fat
56203180	Oatmeal, instant, other flavors, fat added
56203500	Oatmeal, reduced sugar, plain, NS as to fat
56203510	Oatmeal, reduced sugar, plain, no added fat
56203520	Oatmeal, reduced sugar, plain, fat added
56203540	Oatmeal, made with milk and sugar, Puerto Rican style

56203550	Oatmeal, reduced sugar, flavored, NS as to fat
56203555	Oatmeal, reduced sugar, flavored, no added fat
56203560	Oatmeal, reduced sugar, flavored, fat added
56203600	Oatmeal, multigrain, NS as to fat
56203610	Oatmeal, multigrain, no added fat
56203620	Oatmeal, multigrain, fat added
56205050	Rice, cream of, cooked, no added fat
56205080	Rice, creamed, made with milk and sugar, Puerto Rican style
56205090	Rice, cream of, cooked, fat added
56205092	Rice, cream of, cooked, NS as to fat
56205094	Rice, cream of, cooked, made with milk
56205101	Congee
56206990	Cream of wheat, NS as to regular, quick, or instant, NS as to fat
56207000	Cream of wheat, NS as to regular, quick, or instant, no added fat
56207005	Cream of wheat, NS as to regular, quick, or instant, fat added
56207015	Cream of wheat, regular or quick, made with water, NS as to fat
56207016	Cream of wheat, regular or quick, made with water, no added fat
56207017	Cream of wheat, regular or quick, made with water, fat added
56207021	Cream of wheat, regular or quick, made with milk, NS as to fat
56207022	Cream of wheat, regular or quick, made with milk, no added fat
56207023	Cream of wheat, regular or quick, made with milk, fat added
56207025	Cream of wheat, regular or quick, made with non-dairy milk, NS as to fat
56207026	Cream of wheat, regular or quick, made with non-dairy milk, no added fat
56207027	Cream of wheat, regular or quick, made with non-dairy milk, fat added
56207030	Cream of wheat, instant, made with water, no added fat
56207050	Wheat, cream of, cooked, made with milk and sugar, Puerto Rican style
56207060	Cream of wheat, instant, made with water, fat added
56207070	Cream of wheat, instant, made with water, NS as to fat
56207094	Cream of wheat, instant, made with milk, fat added
56207095	Cream of wheat, instant, made with milk, no added fat
56207096	Cream of wheat, instant, made with milk, NS as to fat
56207101	Cream of wheat, instant, made with non-dairy milk, NS as to fat
56207102	Cream of wheat, instant, made with non-dairy milk, no added fat
56207103	Cream of wheat, instant, made with non-dairy milk, fat added
56207190	Whole wheat cereal, cooked, NS as to fat
56207200	Whole wheat cereal, cooked, no added fat
56207210	Whole wheat cereal, cooked, fat added
56207370	Wheat cereal, chocolate flavored, cooked
56208500	Oat bran cereal, cooked, no added fat
56208510	Oat bran cereal, cooked, fat added
56208520	Oat bran cereal, cooked, NS as to fat
56209000	Cream of rye
57601100	Wheat bran, unprocessed
57602100	Oats, raw

57602500 Oat bran, uncooked
58157300 Congee, with meat, poultry, and/or seafood
58157310 Congee, with meat, poultry, and/or seafood, and vegetables
58157320 Congee, with vegetables
58174000 Upma, Indian breakfast dish

Ready-to-Eat Cereals

[FermentIQ Pea Protein] = 15 g/100 g

57000100 Cereal, oat, NFS
57100100 Cereal, ready-to-eat, NFS
57101000 Cereal (Kellogg's All-Bran)
57103000 Cereal (Post Alpha-Bits)
57103100 Cereal (General Mills Cheerios Apple Cinnamon)
57104000 Cereal (Kellogg's Apple Jacks)
57106050 Cereal (Post Great Grains Banana Nut Crunch)
57106060 Cereal (General Mills Cheerios Banana Nut)
57106260 Cereal (General Mills Cheerios Berry Burst)
57117000 Cereal (Quaker Cap'n Crunch)
57117500 Cereal (Quaker Christmas Crunch)
57119000 Cereal (Quaker Cap'n Crunch's Crunchberries)
57120000 Cereal (Quaker Cap'n Crunch's Peanut Butter Crunch)
57123000 Cereal (General Mills Cheerios)
57124030 Cereal (General Mills Chex Chocolate)
57124050 Cereal (General Mills Chex Cinnamon)
57124100 Cereal (General Mills Cheerios Chocolate)
57124200 Cereal, chocolate flavored, frosted, puffed corn
57124300 Cereal (General Mills Lucky Charms Chocolate)
57125000 Cereal (General Mills Cinnamon Toast Crunch)
57125010 Cereal (General Mills 25% Less Sugar Cinnamon Toast Crunch)
57125900 Cereal (General Mills Honey Nut Clusters)
57126000 Cereal (Kellogg's Cocoa Krispies)
57127000 Cereal (Post Cocoa Pebbles)
57128000 Cereal (General Mills Cocoa Puffs)
57130000 Cereal (General Mills Cookie Crisp)
57132000 Cereal (General Mills Chex Corn)
57134000 Cereal, corn flakes
57135000 Cereal (Kellogg's Corn Flakes)
57137000 Cereal, corn puffs
57139000 Cereal (General Mills Count Chocula)
57143000 Cereal (Kellogg's Cracklin' Oat Bran)
57143500 Cereal (Post Great Grains, Cranberry Almond Crunch)
57148000 Cereal (Kellogg's Crispix)
57151000 Cereal, crispy rice

57206700 Cereal (General Mills Fiber One)
57206710 Cereal (General Mills Fiber One Honey Clusters)
57206715 Cereal (General Mills Fiber One Raisin Bran Clusters)
57207000 Cereal, bran flakes
57208000 Cereal (Kellogg's All-Bran Complete Wheat Flakes)
57209000 Cereal (Post Bran Flakes)
57211000 Cereal (General Mills Frankenberry)
57213000 Cereal (Kellogg's Froot Loops)
57213010 Cereal (Kellogg's Froot Loops Marshmallow)
57213850 Cereal (General Mills Cheerios Frosted)
57214000 Cereal (Kellogg's Frosted Mini-Wheats)
57216000 Cereal, frosted rice
57221700 Cereal, fruit rings
57221810 Cereal (General Mills Cheerios Fruity)
57223000 Cereal (Post Fruity Pebbles)
57224000 Cereal (General Mills Golden Grahams)
57227000 Cereal, granola
57228000 Granola, homemade
57229000 Cereal (Kellogg's Low Fat Granola)
57230000 Cereal (Post Grape-Nuts)
57231200 Cereal (Post Great Grains Raisins, Dates, and Pecans)
57237100 Cereal (Post Honey Bunches of Oats Honey Roasted)
57237200 Cereal (Post Honey Bunches of Oats with Vanilla Bunches)
57237300 Cereal (Post Honey Bunches of Oats with Almonds)
57238000 Cereal (Post Honeycomb)
57240100 Cereal (General Mills Chex Honey Nut)
57241000 Cereal (General Mills Cheerios Honey Nut)
57241200 Cereal (Post Shredded Wheat Honey Nut)
57243000 Cereal (Kellogg's Honey Smacks)
57301500 Cereal (Kashi 7 Whole Grain Puffs)
57301505 Cereal (Kashi Autumn Wheat)
57301510 Cereal (Kashi GOLEAN)
57301511 Cereal (Kashi GOLEAN Crunch)
57301512 Cereal (Kashi GOLEAN Crunch Honey Almond Flax)
57301530 Cereal (Kashi Heart to Heart Honey Toasted Oat)
57303100 Cereal (General Mills Kix)
57303105 Cereal (General Mills Honey Kix)
57303200 Cereal (Kellogg's Krave)
57304100 Cereal (Quaker Life)
57305100 Cereal (General Mills Lucky Charms)
57305150 Cereal, frosted oat cereal with marshmallows
57305160 Cereal (Malt-O-Meal Blueberry Muffin Tops)
57305165 Cereal (Malt-O-Meal Cinnamon Toasters)
57305170 Cereal (Malt-O-Meal Coco-Roos)

57305174 Cereal (Malt-O-Meal Colossal Crunch)
57305175 Cereal (Malt-O-Meal Cocoa Dyno-Bites)
57305180 Cereal (Malt-O-Meal Corn Bursts)
57305210 Cereal (Malt-O-Meal Frosted Flakes)
57305300 Cereal (Malt-O-Meal Fruity Dyno-Bites)
57305400 Cereal (Malt-O-Meal Honey Graham Squares)
57305500 Cereal (Malt-O-Meal Honey Nut Toasty O's)
57305600 Cereal (Malt-O-Meal Marshmallow Mateys)
57306500 Cereal (Malt-O-Meal Golden Puffs)
57306700 Cereal (Malt-O-Meal Toasted Oat Cereal)
57306800 Cereal (Malt-O-Meal Tootie Fruities)
57308190 Cereal, muesli
57308400 Cereal (General Mills Cheerios Multigrain)
57309100 Cereal (Nature Valley Granola)
57316380 Cereal (General Mills Cheerios Oat Cluster Crunch)
57316385 Cereal (General Mills Cheerios Protein)
57316450 Cereal (General Mills Oatmeal Crisp with Almonds)
57316710 Cereal (Quaker Honey Graham Oh's)
57320500 Cereal (Quaker Granola with Oats, Honey, and Raisins)
57321900 Cereal (Nature's Path Organic Flax Plus)
57326000 Cereal (Barbara's Puffins)
57327450 Cereal (Quaker Toasted Oat Bran)
57327500 Cereal (Quaker Oatmeal Squares)
57329000 Cereal, raisin bran
57330000 Cereal (Kellogg's Raisin Bran)
57330010 Cereal (Kellogg's Raisin Bran Crunch)
57331000 Cereal (Post Raisin Bran)
57332100 Cereal (General Mills Raisin Nut Bran)
57335550 Cereal (General Mills Reese's Puffs)
57336000 Cereal (General Mills Chex Rice)
57337000 Cereal, rice flakes
57339000 Cereal (Kellogg's Rice Krispies)
57339500 Cereal (Kellogg's Rice Krispies Treats Cereal)
57340000 Cereal, puffed rice
57341200 Cereal (Kellogg's Smart Start Strong)
57341300 Cereal (Kellogg's Smorz)
57344000 Cereal (Kellogg's Special K)
57344001 Cereal (Kellogg's Special K Blueberry)
57344005 Cereal (Kellogg's Special K Chocolatey Delight)
57344010 Cereal (Kellogg's Special K Red Berries)
57344015 Cereal (Kellogg's Special K Fruit & Yogurt)
57344020 Cereal (Kellogg's Special K Vanilla Almond)
57344025 Cereal (Kellogg's Special K Cinnamon Pecan)
57347000 Cereal (Kellogg's Corn Pops)

57348000 Cereal, frosted corn flakes
57349000 Cereal (Kellogg's Frosted Flakes)
57355000 Cereal (Post Golden Crisp)
57401100 Cereal, toasted oat
57407100 Cereal (General Mills Trix)
57408100 Cereal (Uncle Sam)
57411000 Cereal (General Mills Chex Wheat)
57412000 Wheat germ, plain
57416000 Cereal, puffed wheat, plain
57416010 Cereal, puffed wheat, sweetened
57417000 Cereal (Post Shredded Wheat)
57418000 Cereal (General Mills Wheaties)

Coffee and Tea

Specialty Coffee Drinks (lattes, cappuccinos, mochas)
[FermentIQ Pea Protein] = 10 g/100 g

92101600 Coffee, Turkish
92101610 Coffee, espresso
92101630 Coffee, espresso, decaffeinated
92101800 Coffee, Cuban
92101810 Coffee, macchiato
92101820 Coffee, macchiato, sweetened
92101850 Coffee, cafe con leche
92101851 Coffee, cafe con leche, decaffeinated
92101900 Coffee, Latte
92101901 Coffee, Latte, nonfat
92101903 Coffee, Latte, with non-dairy milk
92101904 Coffee, Latte, flavored
92101905 Coffee, Latte, nonfat, flavored
92101906 Coffee, Latte, with non-dairy milk, flavored
92101910 Coffee, Latte, decaffeinated
92101911 Coffee, Latte, decaffeinated, nonfat
92101913 Coffee, Latte, decaffeinated, with non-dairy milk
92101917 Coffee, Latte, decaffeinated, flavored
92101918 Coffee, Latte, decaffeinated, nonfat, flavored
92101919 Coffee, Latte, decaffeinated, with non-dairy milk, flavored
92101920 Frozen coffee drink
92101921 Frozen coffee drink, nonfat
92101923 Frozen coffee drink, with non-dairy milk
92101925 Frozen coffee drink, with whipped cream
92101926 Frozen coffee drink, nonfat, with whipped cream
92101928 Frozen coffee drink, with non-dairy milk and whipped cream

92101930 Frozen coffee drink, decaffeinated
92101931 Frozen coffee drink, decaffeinated, nonfat
92101933 Frozen coffee drink, decaffeinated, with non-dairy milk
92101935 Frozen coffee drink, decaffeinated, with whipped cream
92101936 Frozen coffee drink, decaffeinated, nonfat, with whipped cream
92101938 Frozen coffee drink, decaffeinated, with non-dairy milk and whipped cream
92101950 Coffee, Cafe Mocha
92101955 Coffee, Cafe Mocha, nonfat
92101960 Coffee, Cafe Mocha, with non-dairy milk
92101965 Coffee, Cafe Mocha, decaffeinated
92101970 Coffee, Cafe Mocha, decaffeinated, nonfat
92101975 Coffee, Cafe Mocha, decaffeinated, with non-dairy milk
92102000 Frozen mocha coffee drink
92102010 Frozen mocha coffee drink, nonfat
92102020 Frozen mocha coffee drink, with non-dairy milk
92102030 Frozen mocha coffee drink, with whipped cream
92102040 Frozen mocha coffee drink, nonfat, with whipped cream
92102050 Frozen mocha coffee drink, with non-dairy milk and whipped cream
92102060 Frozen mocha coffee drink, decaffeinated
92102070 Frozen mocha coffee drink, decaffeinated, nonfat
92102080 Frozen mocha coffee drink, decaffeinated, with non-dairy milk
92102090 Frozen mocha coffee drink, decaffeinated, with whipped cream
92102100 Frozen mocha coffee drink, decaffeinated, nonfat, with whipped cream
92102110 Frozen mocha coffee drink, decaffeinated, with non-dairy milk and whipped cream
92102500 Coffee, Iced Latte
92102501 Coffee, Iced Latte, nonfat
92102502 Coffee, Iced Latte, with non-dairy milk
92102503 Coffee, Iced Latte, flavored
92102504 Coffee, Iced Latte, nonfat, flavored
92102505 Coffee, Iced Latte, with non-dairy milk, flavored
92102510 Coffee, Iced Latte, decaffeinated
92102511 Coffee, Iced Latte, decaffeinated, nonfat
92102512 Coffee, Iced Latte, decaffeinated, with non-dairy milk
92102513 Coffee, Iced Latte, decaffeinated, flavored
92102514 Coffee, Iced Latte, decaffeinated, nonfat, flavored
92102515 Coffee, Iced Latte, decaffeinated, with non-dairy milk, flavored
92102600 Coffee, Iced Cafe Mocha
92102601 Coffee, Iced Cafe Mocha, nonfat
92102602 Coffee, Iced Cafe Mocha, with non-dairy milk
92102610 Coffee, Iced Cafe Mocha, decaffeinated
92102611 Coffee, Iced Cafe Mocha, decaffeinated, nonfat
92102612 Coffee, Iced Cafe Mocha, decaffeinated, with non-dairy milk
92152000 Coffee and chicory, brewed
92152010 Coffee and chicory, brewed, decaffeinated

92161000 Coffee, Cappuccino
92161001 Coffee, Cappuccino, nonfat
92161002 Coffee, Cappuccino, with non-dairy milk
92162000 Coffee, Cappuccino, decaffeinated
92162001 Coffee, Cappuccino, decaffeinated, nonfat
92162002 Coffee, Cappuccino, decaffeinated, with non-dairy milk
92171000 Coffee, bottled/canned
92171010 Coffee, bottled/canned, light

Ready-to-Drink Tea Beverages; Instant Tea
[FermentIQ Pea Protein] = 10 g/100 g

92305010 Tea, iced, instant, black, unsweetened
92305040 Tea, iced, instant, black, pre-sweetened with sugar
92305050 Tea, iced, instant, black, decaffeinated, pre-sweetened with sugar
92305090 Tea, iced, instant, black, pre-sweetened with low calorie sweetener
92305110 Tea, iced, instant, black, decaffeinated, pre-sweetened with low calorie sweetener
92305180 Tea, iced, instant, black, decaffeinated, unsweetened
92305900 Tea, iced, instant, green, unsweetened
92305910 Tea, iced, instant, green, pre-sweetened with sugar
92305920 Tea, iced, instant, green, pre-sweetened with low calorie sweetener
92307500 Iced Tea / Lemonade juice drink
92307510 Iced Tea / Lemonade juice drink, light
92307520 Iced Tea / Lemonade juice drink, diet
92309000 Tea, iced, bottled, black
92309010 Tea, iced, bottled, black, decaffeinated
92309020 Tea, iced, bottled, black, diet
92309030 Tea, iced, bottled, black, decaffeinated, diet
92309040 Tea, iced, bottled, black, unsweetened
92309050 Tea, iced, bottled, black, decaffeinated, unsweetened
92309500 Tea, iced, bottled, green
92309510 Tea, iced, bottled, green, diet
92309520 Tea, iced, bottled, green, unsweetened

Foods adjusted for being present in dried form (not reconstituted)
Reconstitution factor of 16

92307000 Tea, iced, instant, black, unsweetened, dry
92307400 Tea, iced, instant, black, pre-sweetened, dry

Dairy Product Analogues

Non-Dairy Milk Beverages and Cream (including coffee whiteners, non-dairy creamers)
[FermentIQ Pea Protein] = 10 g/100 g

11300100	Non-dairy milk, NFS
11320000	Soy milk
11320100	Soy milk, light
11320200	Soy milk, nonfat
11321000	Soy milk, chocolate
11321100	Soy milk, light, chocolate
11321200	Soy milk, nonfat, chocolate
11350000	Almond milk, sweetened
11350010	Almond milk, sweetened, chocolate
11350020	Almond milk, unsweetened
11350030	Almond milk, unsweetened, chocolate
11360000	Rice milk
11370000	Coconut milk
12200100	Coffee creamer, NFS
12210200	Coffee creamer, liquid
12210210	Coffee creamer, liquid, flavored
12210260	Coffee creamer, liquid, fat free
12210270	Coffee creamer, liquid, fat free, flavored
12210280	Coffee creamer, liquid, fat free, sugar free, flavored
12210310	Coffee creamer, liquid, sugar free, flavored
12210400	Coffee creamer, powder
12210420	Coffee creamer, powder, flavored
12210430	Coffee creamer, powder, fat free
12210440	Coffee creamer,powder, fat free, flavored
12210505	Coffee creamer,powder, sugar free, flavored
12210520	Coffee creamer, soy, liquid
42401010	Coconut milk, used in cooking
42402010	Coconut cream, canned, sweetened

<u>Mixed foods containing non-dairy milk or cream</u>
Adjusted for non-dairy or cream content of 77.5%
[FermentIQ Pea Protein] = 7.75 g/100 g

11512030	Hot chocolate / Cocoa, ready to drink, made with non-dairy milk
11512120	Hot chocolate / Cocoa, ready to drink, made with non-dairy milk and whipped cream
11513310	Chocolate milk, made from dry mix with non-dairy milk
11513375	Chocolate milk, made from reduced sugar mix with non-dairy milk
11513385	Chocolate milk, made from dry mix with non-dairy milk (Nesquik)
11513395	Chocolate milk, made from no sugar added dry mix with non-dairy milk (Nesquik)
11513750	Chocolate milk, made from syrup with non-dairy milk
11513805	Chocolate milk, made from light syrup with non-dairy milk
11513855	Chocolate milk, made from sugar free syrup with non-dairy milk
11514150	Hot chocolate / Cocoa, made with dry mix and non-dairy milk
11514360	Hot chocolate / Cocoa, made with no sugar added dry mix and non-dairy milk

11519215 Strawberry milk, non-dairy

Cream Cheese Substitutes
[FermentIQ Pea Protein] = 12 g/100 g

14301010 Cream cheese, regular, plain
14301100 Cream cheese, regular, flavored
14303010 Cream cheese, light
14410380 Cream cheese spread, fat free
14420200 Cheese spread, cream cheese, regular
14420210 Cheese spread, cream cheese, light

Non-Dairy Frozen Desserts
[FermentIQ Pea Protein] = 10 g/100 g

41480020 Frozen dessert, non-dairy

Non-Dairy Dips
[FermentIQ Pea Protein] = 10 g/100 g

12320100 Sour cream, imitation
12350010 Dip, NFS
41205050 Bean dip, made with refried beans
41205070 Hummus, plain
41205075 Hummus, flavored
63409010 Guacamole, NFS
63409015 Guacamole with tomatoes
63409020 Chutney
75412030 Eggplant dip

Non-Dairy Yogurt
[FermentIQ Pea Protein] = 25 g/100 g

41420380 Yogurt, soy
42401100 Yogurt, coconut milk

Imitation Cheese
[FermentIQ Pea Protein] = 25 g/100 g

14502000 Imitation cheese

Grain Products and Pastas

Cereal Bars, Nutritional Bars, and Meal Replacement Bars
[FermentIQ Pea Protein] = 20 g/100 g

53710400 Cereal or granola bar (General Mills Fiber One Chewy Bar)
53710500 Cereal or granola bar (Kellogg's Nutri-Grain Cereal Bar)
53710502 Cereal or granola bar (Kellogg's Nutri-Grain Yogurt Bar)
53710504 Cereal or granola bar (Kellogg's Nutri-Grain Fruit and Nut Bar)
53710600 Milk 'n Cereal bar
53710700 Cereal or granola bar (Kellogg's Special K bar)
53710800 Cereal or granola bar (Kashi Chewy)
53710802 Cereal or granola bar (Kashi Crunchy)
53710810 Cereal or granola bar (KIND Fruit and Nut Bar)
53710900 Cereal or granola bar (General Mills Nature Valley Chewy Trail Mix)
53710902 Cereal or granola bar, with yogurt coating (General Mills Nature Valley Chewy Granola Bar)
53710904 Cereal or granola bar (General Mills Nature Valley Sweet and Salty Granola Bar)
53710906 Cereal or granola bar (General Mills Nature Valley Crunchy Granola Bar)
53711000 Cereal or granola bar (Quaker Chewy Granola Bar)
53711002 Cereal or granola bar (Quaker Chewy 90 Calorie Granola Bar)
53711004 Cereal or granola bar (Quaker Chewy 25% Less Sugar Granola Bar)
53711006 Cereal or granola bar (Quaker Chewy Dipps Granola Bar)
53711100 Cereal or granola bar (Quaker Granola Bites)
53712000 Snack bar, oatmeal
53712100 Cereal or Granola bar, NFS
53712200 Cereal or granola bar, lowfat, NFS
53712210 Cereal or granola bar, nonfat
53713000 Cereal or granola bar, reduced sugar, NFS
53713010 Cereal or granola bar, fruit and nut
53713100 Cereal or granola bar, peanuts , oats, sugar, wheat germ
53714200 Cereal or granola bar, chocolate coated, NFS
53714210 Cereal or granola bar, with coconut, chocolate coated
53714220 Cereal or granola bar with nuts, chocolate coated
53714230 Cereal or granola bar, oats, nuts, coated with non-chocolate coating
53714250 Cereal or granola bar, coated with non-chocolate coating
53714300 Cereal or granola bar, high fiber, coated with non-chocolate yogurt coating
53714400 Cereal or granola bar, with rice cereal
53714500 Breakfast bar, NFS
53714510 Breakfast bar, date, with yogurt coating
53714520 Breakfast bar, cereal crust with fruit filling, lowfat
53720100 Nutrition bar (Balance Original Bar)
53720200 Nutrition bar (Clif Bar)
53720210 Nutrition bar (Clif Kids Organic Zbar)
53720300 Nutrition bar (PowerBar)
53720400 Nutrition bar (Slim Fast Original Meal Bar)
53720500 Nutrition bar (Snickers Marathon Protein Bar)
53720600 Nutrition bar (South Beach Living Meal Bar)
53720610 Nutrition bar (South Beach Living High Protein Bar)
53720700 Nutrition bar (Tiger's Milk)

53720800 Nutrition bar (Zone Perfect Classic Crunch)
53729000 Nutrition bar or meal replacement bar, NFS

Milk Products

Milk-Based Meal Replacements and Protein Drinks
[FermentIQ Pea Protein] = 15 g/100 g

95101000 Nutritional drink or shake, ready-to-drink (Boost)
95101010 Nutritional drink or shake, ready-to-drink (Boost Plus)
95102000 Nutritional drink or shake, ready-to-drink (Carnation Instant Breakfast)
95103000 Nutritional drink or shake, ready-to-drink (Ensure)
95103010 Nutritional drink or shake, ready-to-drink (Ensure Plus)
95104000 Nutritional drink or shake, ready-to-drink, sugar free (Glucerna)
95105000 Nutritional drink or shake, ready-to-drink (Kellogg's Special K Protein)
95106000 Nutritional drink or shake, ready-to-drink (Muscle Milk)
95106010 Nutritional drink or shake, ready-to-drink, light (Muscle Milk)
95110000 Nutritional drink or shake, ready-to-drink (Slim Fast)
95110010 Nutritional drink or shake, ready-to-drink, sugar free (Slim Fast)
95110020 Nutritional drink or shake, high protein, ready-to-drink (Slim Fast)
95120000 Nutritional drink or shake, ready-to-drink, NFS
95120010 Nutritional drink or shake, high protein, ready-to-drink, NFS
95120020 Nutritional drink or shake, high protein, light, ready-to-drink, NFS

Foods adjusted for being present in dried form (not reconstituted)
Reconstitution factor of 6 to 10

95201000 Nutritional powder mix (Carnation Instant Breakfast)
95201010 Nutritional powder mix, sugar free (Carnation Instant Breakfast)
95201200 Nutritional powder mix (EAS Whey Protein Powder)
95201500 Nutritional powder mix, high protein (Herbalife)
95201600 Nutritional powder mix (Isopure)
95201700 Nutritional powder mix (Kellogg's Special K20 Protein Water)
95202000 Nutritional powder mix (Muscle Milk)
95202010 Nutritional powder mix, light (Muscle Milk)
95210000 Nutritional powder mix (Slim Fast)
95210010 Nutritional powder mix, sugar free (Slim Fast)
95210020 Nutritional powder mix, high protein (Slim Fast)
95220000 Nutritional powder mix, NFS
95220010 Nutritional powder mix, high protein, NFS
95230000 Nutritional powder mix, whey based, NFS
95230020 Nutritional powder mix, protein, light, NFS
95230030 Nutritional powder mix, protein, NFS

Nut and Nut Products

Nut Butters and Spreads
[FermentIQ Pea Protein] = 10 g/100 g

42200500	Almond butter
42200510	Almond butter, lower sodium
42200600	Almond paste
42201000	Cashew butter
42202000	Peanut butter
42202010	Peanut butter, lower sodium
42202100	Peanut butter, lower sodium and lower sugar
42202130	Peanut butter, lower sugar
42202150	Peanut butter, reduced fat
42202200	Peanut butter, vitamin and mineral fortified
42203000	Peanut butter and jelly
42203100	Peanut butter and chocolate spread

Mixed foods containing nut butters or spreads
Adjusted for nut butter or spread content of 28.57 to 34.78%
[FermentIQ Pea Protein] = 2.857 to 3.478 g/100 g

42301010	Peanut butter sandwich, NFS
42301015	Peanut butter sandwich, with regular peanut butter, on white bread
42301020	Peanut butter sandwich, with regular peanut butter, on wheat bread
42301025	Peanut butter sandwich, with regular peanut butter, on whole wheat bread
42301115	Peanut butter sandwich, with reduced fat peanut butter, on white bread
42301120	Peanut butter sandwich, with reduced fat peanut butter, on wheat bread
42301125	Peanut butter sandwich, with reduced fat peanut butter, on whole wheat bread
42302010	Peanut butter and jelly sandwich, NFS
42302015	Peanut butter and jelly sandwich, with regular peanut butter, regular jelly, on white bread
42302020	Peanut butter and jelly sandwich, with regular peanut butter, regular jelly, on wheat bread
42302025	Peanut butter and jelly sandwich, with regular peanut butter, regular jelly, on whole wheat bread
42302055	Peanut butter and jelly sandwich, with reduced fat peanut butter, regular jelly, on white bread
42302060	Peanut butter and jelly sandwich, with reduced fat peanut butter, regular jelly, on wheat bread
42302065	Peanut butter and jelly sandwich, with reduced fat peanut butter, regular jelly, on whole wheat bread
42302105	Peanut butter and jelly sandwich, with regular peanut butter, reduced sugar jelly, on white bread
42302110	Peanut butter and jelly sandwich, with regular peanut butter, reduced sugar jelly, on wheat bread
42302115	Peanut butter and jelly sandwich, with regular peanut butter, reduced sugar jelly, on whole wheat bread
42302155	Peanut butter and jelly sandwich, with reduced fat peanut butter, reduced sugar jelly, on white bread

42302160	Peanut butter and jelly sandwich, with reduced fat peanut butter, reduced sugar jelly, on wheat bread
42302165	Peanut butter and jelly sandwich, with reduced fat peanut butter, reduced sugar jelly, on whole wheat bread
42303100	Peanut butter and jelly sandwich, frozen commercial product without crusts

Plant Protein Products

Meat Analogs and Substitutes

[FermentIQ Pea Protein] = 30 g/100 g

27450130	Crab salad made with imitation crab
27564420	Frankfurter or hot dog sandwich, meatless, plain, on bun
27564430	Frankfurter or hot dog sandwich, meatless, plain, on bread
27564500	Frankfurter or hot dog sandwich, with meatless chili, on white bun
27564501	Frankfurter or hot dog sandwich, with meatless chili, on wheat bun
27564502	Frankfurter or hot dog sandwich, with meatless chili, on whole wheat bun
27564503	Frankfurter or hot dog sandwich, with meatless chili, on whole grain white bun
27564504	Frankfurter or hot dog sandwich, with meatless chili, on multigrain bun
27564510	Frankfurter or hot dog sandwich, with meatless chili, on white bread
27564520	Frankfurter or hot dog sandwich, with meatless chili, on wheat bread
27564530	Frankfurter or hot dog sandwich, with meatless chili, on whole wheat bread
27564540	Frankfurter or hot dog sandwich, with meatless chili, on whole grain white bread
27564550	Frankfurter or hot dog sandwich, with meatless chili, on multigrain bread
27564560	Frankfurter or hot dog sandwich, meatless, on bun, with meatless chili
27564570	Frankfurter or hot dog sandwich, meatless, on bread, with meatless chili
41421010	Soybean curd, deep fried
41421020	Soybean curd, breaded, fried
41440000	Textured vegetable protein, dry
41810200	Bacon strip, meatless
41810250	Bacon bits
41810400	Breakfast link, pattie, or slice, meatless
41810600	Chicken, meatless, NFS
41810610	Chicken, meatless, breaded, fried
41811400	Frankfurter or hot dog, meatless
41811600	Luncheon slice, meatless-beef, chicken, salami or turkey
41811800	Meatball, meatless
41811890	Vegetarian burger or patty, meatless, no bun
41811950	Swiss steak, with gravy, meatless
41812400	Vegetarian pot pie
41812450	Vegetarian chili, made with meat substitute
41812500	Tofu and vegetables including carrots, broccoli, and/or dark-green leafy; no potatoes, with soy-based sauce
41812510	Tofu and vegetables excluding carrots, broccoli, and dark-green leafy; no potatoes, with soy-based sauce

41812600 Vegetarian, fillet
41812800 Vegetarian stew
41812850 Vegetarian stroganoff
41901020 Soyburger, meatless, with cheese on bun
59003000 Meat substitute, cereal- and vegetable protein-based, fried

Butter and Spread Alternative
[FermentIQ Pea Protein] = 12 g/100 g

41812000 Sandwich spread, meat substitute type
42203200 Soy nut butter
81102000 Margarine, NFS
81102010 Margarine, stick
81102020 Margarine, tub
81103035 Margarine-oil blend, NFS
81103040 Margarine-oil blend, stick
81103080 Margarine-oil blend, tub
81103090 Butter replacement, liquid
81104010 Margarine-oil blend, tub, light
81104020 Margarine-oil blend, stick, light
81106010 Butter replacement, powder
83108000 Vegan mayonnaise

Snack Foods

Snack Foods (including potato chips, pretzels, corn-based savory snacks, and popcorn)
[FermentIQ Pea Protein] = 4 g/100 g

54401011 Corn nuts
54401021 Corn chips, plain
54401026 Corn chips, flavored
54401031 Corn chips, plain (Fritos)
54401035 Corn chips, flavored (Fritos)
54401055 Cheese flavored corn snacks
54401065 Cheese flavored corn snacks, reduced fat
54401075 Tortilla chips, plain
54401081 Cheese flavored corn snacks (Cheetos)
54401085 Tortilla chips, flavored
54401090 Corn chips, reduced sodium
54401095 Tortilla chips, popped
54401110 Tortilla chips, nacho cheese flavor (Doritos)
54401111 Tortilla chips, cool ranch flavor (Doritos)
54401112 Tortilla chips, other flavors (Doritos)
54401121 Tortilla chips, reduced fat, plain
54401122 Tortilla chips, reduced fat, flavored

54401170	Tortilla chips, low fat, unsalted
54402080	Tortilla chips, reduced sodium
54402200	Snack mix
54402610	Potato chips, restructured, multigrain
54402700	Pita chips
54403001	Popcorn, NFS
54403005	Popcorn, movie theater, with added butter
54403006	Popcorn, movie theater, unbuttered
54403010	Popcorn, air-popped, unbuttered
54403040	Popcorn, air-popped, with added butter or margarine
54403051	Popcorn, microwave, NFS
54403052	Popcorn, microwave, plain
54403053	Popcorn, microwave, plain, light
54403054	Popcorn, microwave, low sodium
54403055	Popcorn, microwave, unsalted
54403056	Popcorn, microwave, butter flavored
54403057	Popcorn, microwave, butter flavored, light
54403058	Popcorn, microwave, cheese flavored
54403059	Popcorn, microwave, kettle corn
54403061	Popcorn, microwave, kettle corn, light
54403062	Popcorn, microwave, other flavored
54403080	Popcorn, ready-to-eat packaged, NFS
54403081	Popcorn, ready-to-eat packaged, plain
54403082	Popcorn, ready-to-eat packaged, plain, light
54403083	Popcorn, ready-to-eat packaged, low sodium
54403084	Popcorn, ready-to-eat packaged, unsalted
54403085	Popcorn, ready-to-eat packaged, butter flavored
54403086	Popcorn, ready-to-eat packaged, butter flavored, light
54403087	Popcorn, ready-to-eat packaged, cheese flavored
54403088	Popcorn, ready-to-eat packaged, cheese flavored, light
54403089	Popcorn, ready-to-eat-packaged, kettle corn
54403091	Popcorn, ready-to-eat packaged, kettle corn, light
54403092	Popcorn, ready-to-eat packaged, other flavored
54403110	Popcorn, caramel coated
54403120	Popcorn, caramel coated, with nuts
54403160	Popcorn, chocolate coated
54404000	Popcorn chips, plain
54404010	Popcorn chips, other flavors
54404020	Popcorn chips, sweet flavors
54406010	Onion flavored rings
54406200	Shrimp chips
54408000	Pretzels, NFS
54408015	Pretzels, hard, NFS
54408016	Pretzels, hard, plain, salted

54408017	Pretzels, hard, plain, lightly salted
54408030	Pretzels, hard, plain, unsalted
54408035	Pretzels, hard, flavored
54408070	Pretzels, hard, multigrain
54408081	Pretzels, hard, plain, gluten free
54408082	Pretzels, hard, flavored, gluten free
54408105	Pretzel chips, hard, plain
54408110	Pretzel chips, hard, flavored
54408115	Pretzel chips, hard, gluten free
54408190	Pretzels, hard, coated, NFS
54408200	Pretzels, hard, chocolate coated
54408210	Pretzels, hard, white chocolate coated
54408250	Pretzels, hard, yogurt coated
54408260	Pretzels, hard, coated, gluten free
54408290	Pretzels, hard, filled, NFS
54408300	Pretzels, hard, cheese filled
54408310	Pretzels, hard, peanut butter filled
54420210	Multigrain chips (Sun Chips)
54420220	Snack mix, plain (Chex Mix)
54440010	Bagel chips
54440020	Cracker chips
71200010	Potato chips, NFS
71200100	Potato chips, plain
71200110	Potato chips, barbecue flavored
71200120	Potato chips, sour cream and onion flavored
71200130	Potato chips, cheese flavored
71200140	Potato chips, other flavored
71200200	Potato chips, ruffled, plain
71200210	Potato chips, ruffled, barbecue flavored
71200220	Potato chips, ruffled, sour cream and onion flavored
71200230	Potato chips, ruffled, cheese flavored
71200240	Potato chips, ruffled, other flavored
71200300	Potato chips, restructured, plain
71200310	Potato chips, restructured, flavored
71200400	Potato chips, baked, plain
71200410	Potato chips, baked, flavored
71201050	Potato chips, reduced fat
71201060	Potato chips, fat free
71201200	Potato chips, restructured, reduced fat, lightly salted
71201210	Potato chips, restructured, fat free
71202000	Potato chips, unsalted
71202100	Potato chips, reduced fat, unsalted
71202500	Potato chips, lightly salted
71202510	Potato chips, restructured, lightly salted

71203010 Potato chips, popped, plain
71203020 Potato chips, popped, flavored
71203030 Potato chips, popped, NFS
71205020 Potato sticks, plain
71205030 Potato sticks, flavored
71205040 Potato sticks, fry shaped
71220000 Vegetable chips
71905410 Plantain chips
71980200 Taro chips
73410210 Sweet potato chips

Mixed foods containing snack foods
Adjusted for snack food content of 12.9 to 22.2%
[FermentIQ Pea Protein] = 0.516 to 0.888 g/100 g

58104090 Nachos with cheese and sour cream
58104120 Nachos with cheese
58104130 Nachos with meat and cheese
58104150 Nachos with chicken and cheese
58104160 Nachos with chili
58104180 Nachos with meat, cheese, and sour cream
58104190 Nachos with chicken, cheese, and sour cream

Soups and Soup Mixes

Soups and Soup Mixes
[FermentIQ Pea Protein] = 5 g/100 g

14710100 Cheddar cheese soup, home recipe, canned or ready-to-serve
14710200 Beer cheese soup, made with milk
28310150 Oxtail soup
28310320 Beef noodle soup, Puerto Rican style
28310330 Pho
28310420 Beef and rice soup, Puerto Rican style
28311010 Pepperpot soup
28311030 Menudo soup, canned, prepared with water or ready-to-serve
28315050 Beef vegetable soup with potato, pasta, or rice, chunky style, canned, or ready-to-serve
28315160 Italian Wedding Soup
28317010 Beef stroganoff soup, chunky style, home recipe, canned or ready-to-serve
28320140 Ham, noodle, and vegetable soup, Puerto Rican style
28320160 Pork vegetable soup with potato, pasta, or rice, stew type, chunky style
28320300 Pork with vegetable excluding carrots, broccoli and/or dark-green leafy; soup, Asian Style
28321130 Bacon soup, cream of, prepared with water
28331110 Lamb, pasta, and vegetable soup, Puerto Rican style
28340110 Chicken or turkey broth, bouillon, or consomme

28340150	Mexican style chicken broth soup stock
28340180	Chicken or turkey broth, less or reduced sodium, canned or ready-to-serve
28340210	Chicken rice soup, Puerto Rican style
28340220	Chicken soup with noodles and potatoes, Puerto Rican style
28340310	Chicken or turkey gumbo soup, home recipe, canned or ready-to-serve
28340510	Chicken or turkey noodle soup, chunky style, canned or ready-to-serve
28340550	Sweet and sour soup
28340580	Chicken or turkey soup with vegetables, broccoli, carrots, celery, potatoes and onions, Asian style
28340600	Chicken or turkey vegetable soup, canned, prepared with water or ready-to-serve
28340610	Chicken or turkey vegetable soup, stew type
28340630	Chicken or turkey vegetable soup with rice, stew type, chunky style
28340640	Chicken or turkey vegetable soup with noodles, stew type, chunky style, canned or ready-to-serve
28340690	Chicken or turkey vegetable soup with potato and cheese, chunky style, canned or ready-to-serve
28340700	Bird's nest soup
28340750	Hot and sour soup
28340800	Chicken or turkey soup with vegetables and fruit, Asian Style
28345010	Chicken or turkey soup, cream of, canned, reduced sodium, NS as to made with milk or water
28345020	Chicken or turkey soup, cream of, canned, reduced sodium, made with milk
28345030	Chicken or turkey soup, cream of, canned, reduced sodium, made with water
28345110	Chicken or turkey soup, cream of, NS as to prepared with milk or water
28345120	Chicken or turkey soup, cream of, prepared with milk
28345130	Chicken or turkey soup, cream of, prepared with water
28345160	Chicken or turkey mushroom soup, cream of, prepared with milk
28350050	Fish chowder
28350110	Crab soup, NS as to tomato-base or cream style
28350120	Crab soup, tomato-base
28350210	Clam chowder, NS as to Manhattan or New England style
28350220	Clam chowder, Manhattan
28350310	Turtle and vegetable soup
28351110	Fish and vegetable soup, no potatoes, Mexican style
28351120	Fish soup with potatoes, Mexican style
28351160	Codfish, rice, and vegetable soup, Puerto Rican style
28351170	Codfish soup with noodles, Puerto Rican style
28355110	Clam chowder, New England, NS as to prepared with water or milk
28355120	Clam chowder, New England, prepared with milk
28355130	Clam chowder, New England, prepared with water
28355140	Clam chowder, New England, reduced sodium, canned or ready-to-serve
28355210	Crab soup, cream of, prepared with milk
28355250	Lobster bisque
28355260	Lobster gumbo
28355310	Oyster stew

28355350	Salmon soup, cream style
28355410	Shrimp soup, cream of, NS as to prepared with milk or water
28355420	Shrimp soup, cream of, prepared with milk
28355430	Shrimp soup, cream of, prepared with water
28355440	Shrimp gumbo
28355450	Seafood soup with potatoes and vegetables including carrots, broccoli, and/or dark-green leafy
28355460	Seafood soup with potatoes, and vegetables excluding carrots, broccoli, and dark-green leafy
28355470	Seafood soup with vegetables including carrots, broccoli, and/or dark-green leafy; no potatoes
28355480	Seafood soup with vegetables excluding carrots, broccoli, and dark-green leafy; no potatoes
28360100	Meat broth, Puerto Rican style
28360210	Spanish vegetable soup, Puerto Rican style
32300100	Egg drop soup
32301100	Garlic egg soup, Puerto Rican style
41601010	Bean soup, NFS
41601020	Bean with bacon or ham soup, canned or ready-to-serve
41601030	Black bean soup, home recipe, canned or ready-to-serve
41601040	Lima bean soup, home recipe, canned or ready-to-serve
41601070	Soybean soup, miso broth
41601080	Pinto bean soup, home recipe, canned or ready-to-serve
41601090	Bean soup, with macaroni, home recipe, canned, or ready-to-serve
41601110	Bean and ham soup, chunky style, canned or ready-to-serve
41601130	Bean soup, mixed beans, home recipe, canned or ready-to-serve
41601160	Bean and ham soup, canned, reduced sodium, prepared with water or ready-to-serve
41601200	Liquid from stewed kidney beans, Puerto Rican style
41602010	Pea and ham soup, chunky style, canned or ready-to-serve
41602020	Garbanzo bean or chickpea soup, home recipe, canned or ready-to-serve
41602030	Split pea and ham soup
41602050	Split pea soup
41602070	Split pea soup, canned, reduced sodium, prepared with water or ready-to-serve
41602090	Split pea and ham soup, canned, reduced sodium, prepared with water or ready-to-serve
41603010	Lentil soup, home recipe, canned, or ready-to-serve
58400000	Soup, NFS
58400100	Noodle soup, NFS
58400200	Rice soup, NFS
58401010	Barley soup, home recipe, canned, or ready-to-serve
58401200	Barley soup, sweet, with or without nuts, Asian Style
58402010	Beef noodle soup, canned or ready-to-serve
58402020	Beef dumpling soup, home recipe, canned or ready-to-serve
58402030	Beef rice soup, home recipe, canned or ready-to-serve
58403010	Chicken or turkey noodle soup, canned or ready-to-serve
58403050	Chicken or turkey noodle soup, cream of, home recipe, canned, or ready-to-serve
58403060	Chicken or turkey noodle soup, reduced sodium, canned or ready-to-serve

58403100	Noodle and potato soup, Puerto Rican style
58404010	Chicken or turkey rice soup, canned, or ready-to-serve
58404040	Chicken or turkey rice soup, reduced sodium, canned, prepared with water or ready-to-serve
58404050	Chicken or turkey rice soup, reduced sodium, canned, prepared with milk
58404100	Rice and potato soup, Puerto Rican style
58404500	Matzo ball soup
58404510	Chicken or turkey soup with dumplings and potatoes, home recipe, canned, or ready-to-serve
58404520	Chicken or turkey soup with dumplings, home recipe, canned or ready-to-serve
58407010	Instant soup, noodle
58407030	Soup, mostly noodles
58407035	Soup, mostly noodles, reduced sodium
58407050	Instant soup, noodle with egg, shrimp or chicken
58408010	Wonton soup
58408500	Noodle soup with vegetables, Asian style
58409000	Noodle soup, with fish ball, shrimp, and dark green leafy vegetable
58421000	Sopa seca, Mexican style, NFS
63415100	Soup, fruit
71801000	Potato soup, NS as to made with milk or water
71801010	Potato soup, cream of, prepared with milk
71801020	Potato soup, prepared with water
71801100	Potato and cheese soup
71803010	Potato chowder
71851010	Plantain soup, Puerto Rican style
72302000	Broccoli soup, prepared with milk, home recipe, canned or ready-to-serve
72302020	Broccoli soup, prepared with water, home recipe, canned, or ready-to-serve
72302100	Broccoli cheese soup, prepared with milk, home recipe, canned, or ready-to-serve
72306000	Watercress broth with shrimp
72307000	Spinach soup
72308000	Dark-green leafy vegetable soup with meat, Asian style
72308500	Dark-green leafy vegetable soup, meatless, Asian style
73501000	Carrot soup, cream of, prepared with milk, home recipe, canned or ready-to-serve
73501010	Carrot with rice soup, cream of, prepared with milk, home recipe, canned or ready-to-serve
73502000	Squash, winter type, soup, home recipe, canned, or ready-to-serve
74601000	Tomato soup, NFS
74601010	Tomato soup, cream of, prepared with milk
74602010	Tomato soup, prepared with water, or ready-to-serve
74602050	Tomato soup, instant type, prepared with water
74602200	Tomato soup, canned, reduced sodium, prepared with water, or ready-to-serve
74602300	Tomato soup, canned, reduced sodium, prepared with milk
74603010	Tomato beef soup, prepared with water
74604010	Tomato beef noodle soup, prepared with water
74604100	Tomato beef rice soup, prepared with water
74604500	Tomato noodle soup, canned, prepared with water or ready-to-serve

74604600	Tomato noodle soup, canned, prepared with milk
74605010	Tomato rice soup, prepared with water
74606010	Tomato vegetable soup, prepared with water
74606020	Tomato vegetable soup with noodles, prepared with water
75600150	Soup, cream of, NFS
75601000	Asparagus soup, cream of, NS as to made with milk or water
75601010	Asparagus soup, cream of, prepared with milk
75601020	Asparagus soup, cream of, prepared with water
75601100	Borscht
75601200	Cabbage soup, home recipe, canned or ready-to-serve
75601210	Cabbage with meat soup, home recipe, canned or ready-to-serve
75603010	Celery soup, cream of, prepared with milk, home recipe, canned or ready-to-serve
75603020	Celery soup, cream of, prepared with water, home recipe, canned or ready-to-serve
75604010	Corn soup, cream of, prepared with milk
75604020	Corn soup, cream of, prepared with water
75604600	Gazpacho
75605010	Leek soup, cream of, prepared with milk
75607000	Mushroom soup, NFS
75607010	Mushroom soup, cream of, prepared with milk
75607020	Mushroom soup, cream of, prepared with water
75607040	Mushroom soup, with meat broth, prepared with water
75607050	Mushroom soup, cream of, low sodium, prepared with water
75607060	Mushroom soup, cream of, NS as to made with milk or water
75607080	Mushroom with chicken soup, cream of, prepared with milk
75607090	Mushroom soup, cream of, canned, reduced sodium, NS as to made with milk or water
75607100	Mushroom soup, cream of, canned, reduced sodium, prepared with milk
75607140	Mushroom soup, cream of, canned, reduced sodium, prepared with water
75608010	Onion soup, cream of, prepared with milk
75608100	Onion soup, French
75608200	Onion soup, made from dry mix
75609010	Pea soup, prepared with milk
75611010	Vegetable soup, cream of, prepared with milk
75612010	Zucchini soup, cream of, prepared with milk
75646010	Shav soup
75647000	Seaweed soup
75649010	Vegetable soup, canned, prepared with water or ready-to-serve
75649040	Vegetable soup, reduced sodium, canned, ready to serve
75649050	Vegetable soup, made from dry mix
75650990	Minestrone soup, reduced sodium, canned or ready-to-serve
75651010	Minestrone soup, canned, prepared with water, or ready-to-serve
75651020	Vegetable beef soup, canned, prepared with water, or ready-to-serve
75651030	Vegetable beef noodle soup, prepared with water
75651040	Vegetable noodle soup, canned, prepared with water, or ready-to-serve
75651070	Vegetable rice soup, canned, prepared with water or ready-to-serve

75651080	Vegetable beef soup with rice, canned, prepared with water or ready-to-serve
75651110	Vegetable chicken rice soup, canned, prepared with water or ready-to-serve
75651150	Vegetable noodle soup, reduced sodium, canned, prepared with water or ready-to-serve
75652030	Vegetable beef soup, canned, prepared with milk
75654010	Vegetarian vegetable soup, prepared with water
75656010	Vegetable soup, Spanish style, stew type
75656020	Vegetable soup, chunky style
75656040	Vegetable soup, with pasta, chunky style
75656060	Vegetable beef soup, chunky style

November 27, 2023

Dr. Lane Highbarger
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
U.S. Food and Drug Administration

Re: GRN 1125: Technical Review Questions

Dear Dr. Highbarger:

We are writing to respond to the technical review questions attached to your email on October 16, 2023. Please find responses below from MycoTechnology, Inc.

Chemistry:

1. Please indicate if "Aflatoxin Total" in table 2.3.2-1 is the sum of Aflatoxins (G1 + G2 + B1 + B2).

   Response:
   Yes, "Aflatoxin Total" is the sum of Aflatoxins (G1+G2+B1+B2).

2. On page 5 of Appendix C, the use level for cream cheese substitute is indicated as 12%, corresponding to 7.9 g protein /100 g of food consumed on a protein basis. However, for other food categories, a use level of 10% corresponds to a use level of 7.9 g/100 g on a protein basis. Please clarify this inconsistency.

   Response:
   The proposed use level for cream cheese substitutes is intended to be 12% FermentIQ Pea protein, corresponding to 9.5 g protein / 100 g of food consumed. Therefore, this inconsistency has been corrected in Table 3-1 on page 5 of the revised Appendix C (see Addendum).

3. On page 54 of appendix C, you stated that the use level in non-milk meal replacements and protein drinks adjusted for being present in the dried form is 280 g/100 g. On page 62, you stated that the use level in ready-to-drink tea beverages and instant tea, adjusted for being present in the dried form is 160 g/100 g and on page 67, the use level

in milk-based meal replacements and protein drinks, adjusted for being present in the dried form is 90-150 g/100 g. Please clarify if these use levels are correct and indicate what the weight of 100 g refers to in this use level.

Response:
In the current assessment, the proposed conditions of use for FermentIQ Pea Protein are expressed on an 'as consumed' basis. Therefore, for the dietary intake assessment, reconstitution factors were applied to the proposed beverage uses (meal replacements, protein drinks, and instant powdered tea) for which a powder format was reported in the U.S. NHANES food consumption survey (i.e. food diaries) to correct for this. The reconstitution factors for each product type were established based on preparation instructions for similar products previously identified on the U.S. market. Taking instant powdered tea as an example, the applied reconstitution factor is 16, considering an approximate reconstitution of 16 g powder to 240 ml of milk/water. Another example, pertaining to meal replacements, has been provided below:

<u>Meal Replacements in Powdered Format</u>

- Based on preparation instructions, 2 scoops of the meal replacement powder (36.5g) are mixed with 250ml of milk before consumption. This results in a reconstitution factor for the powder of 7.9 (Calculation: 36.5 + 250 = 286.5 (Total weight of powder and water); 286.5 / 36.5 = 7.85)
- In the US NHANES Food Consumption Survey, a number of individuals reported consumption of these products in the powdered format (e.g. 36.5g powder), before they reconstituted the product for consumption.
- As the use levels for a GRAS application are reported on an 'as consumed' basis, the reconstitution factor (7.9) was applied to these products, to account for the final product that the individual would consume (e.g. a 286.5 g ml beverage, not 36.5 g powder).

Considering the above information, we acknowledge the presentation of g/100g for powdered meal replacements, protein drinks, and instant tea in the current assessment is not appropriate as it may lead to confusion and does not accurately represent the intended conditions of use. As such, Appendix C has been updated to remove the g/100g and solely provide the reconstitution factor.

Toxicology:

In the GRN, the human exposure calculation from NOAEL is incorrect. Please provide the correct calculation based on the following text.

1. On page 28 of the GRN, the notifier states that the rat NOAEL (2000 mg/kg bw/day) is the equivalent to a dietary exposure of 120 g of L.E.M. extract per day for a 60 kg human. To obtain 120 g of L.E.M. per day for a 60 kg human, one has to multiply 2000 mg/kg bw/d by 60 kg bw. This is not correct.

   If the human exposure is calculated based on the NOAEL from a 90-day rat study, then the ADI in humans = NOAEL in the rat study/100 (the default safety factor or SF).

   Since the pivotal study used in this GRN is a 28-day rat study (instead of a 90-day rat study), the SF should be greater than 100, which will reduce the ADI. The most conservative approach is to use a default additional SF of 10, making the total SF = 1000. This will reduce the ADI to 120 mg/kg bw/day [NOAEL/1000) x 60]. Since the 90th percentile EDI is 54 mg/person/day, the derived ADI is still greater than the proposed EDI.

   Response:

   ADI calculation on page 28 of the GRN is corrected as below:

   "Yoshioka et al. (2010) did not report any unscheduled deaths or clinical signs suggesting toxicity. Body weight and food consumption were slightly decreased compared to the control groups, particularly for males. The lower body weights were statistically significant at Day 14 through 28 for males and Day 7 through 11 for females. Lower food consumption was statistically significant at Day 0 through 21 for males and not statistically significant for females. At the study termination, male body weights were only 8% less than control groups (associated with slightly [not statistically significant] decreased food consumption) and female body weights were only 5% less than control groups. These minor differences were not considered adverse. None of the hematological parameters were statistically significantly different from respective controls after the 28-day dosing phase. Serum biochemistry revealed very few statistically significantly different parameters compared to respective controls, including increased phosphorus in both sexes; however, all values were reported as being within the laboratory's normal reference ranges. Although females had slightly increased organ weights relative to bodyweight (thyroid gland, kidneys, adrenals, uterus/ovaries) as did males (thyroid gland, adrenals), these

differences were minor and without histopathological correlates. There were no pathological alterations in any examined tissues or organs. The no observed adverse effect level (NOAEL) of L.E.M. extract determined in this study was 2,000 mg/kg/day, which was the highest and the only dose tested and provides evidence of safety at high dose levels albeit over a relatively short 28-day period. The use of short-term rodent toxicity tests is however recommended for those materials of a low concern level (FDA, 2006). Data generated from short term 28-day studies are not commonly used to derive an ADI or margin of safety due to the limited study time frame, which warrants a higher safety factor (SF) than the default value of 100 used for studies of 90 days and longer. A conservative approach would be to use an additional default SF of 10, resulting in a total SF of 1000. Therefore, while not commonplace, using a NOAEL of 2000 mg/kg/day and a safety factor of 1000 would result in a safe dietary exposure level of 120 mg of L.E.M. extract per day for a 60kg human. As discussed above in section 3.3, the worst-case estimated dietary exposure of shiitake mycelia from FPP consumption for proposed uses, at the 90th percentile is 54 mg per day (or 0.9 mg/kg bw/day). The calculated safe level of L.E.M human exposure (120 mg) determined from the Yoshioka study (120 mg) therefore still provides a margin of safety to the estimated daily intake at the 90th percentile of exposure as estimated from the NOAEL from the highest dose tested using a conservative SF. MycoTechnology, Inc. therefore concludes that this 28-day oral repeated-dose study conducted in Wistar rats provides an adequate Margin of Safety for FPP at the estimated levels of consumption."

2. On page 35 of the GRN, a similar erroneous argument was made for a 30-day study. Based on a NOAEL of 100 mg/kg bw/day the human equivalent dose of L. edodes for a 60 kg person is calculated to be 6000 mg/day. It should be 6 mg/day after applying the default SF of 1000.

Response:

MycoTechnology accepts that for short term studies less than 90 days, safety factors greater than the default 100-fold value would be required to establish a margin of safety to the estimated daily intake. As it is not commonplace to establish margins of safety in relation to commonly consumed foods such as shiitake mushrooms, it was considered inappropriate in this case to calculate a margin of safety, especially when it is widely understood that the daily consumption of shiitake mushrooms has been estimated to be 27.4 g/person/day in the Chinese population (Grotto et al., 2016). As a result, the incorrect calculation has been deleted from the published study review.

"Four groups (6/group) of male Wistar rats received dry and powdered *L. edodes* (shiitake mushroom) reconstituted in water at daily gavage doses of 100, 400, or 800 mg/kg for 30 days. Reductions in hemoglobin concentration and leukocytes were reported at 400 and 800 mg/kg compared to controls; only the leukocyte differences were dose-dependent. The authors concluded that the NOAEL of *L. edodes* determined in this study was 100 mg/kg. (Grotto et al., 2016)."

3. Please note that FDA has applied the default additional SF of 10 on top of the standard default SF of 100. The notifier may decide to reduce the additional SF of 10 to a lower number, making the total SF less than 1000. If the notifier chooses to do that, it needs to provide a rationale why the additional SF should be less than 10 (making the total SF less than 1000), and the conclusion needs to be backed up by appropriate references.

Response:
MycoTechnology was in agreement with the FDA that a safety factor greater than the default 100-fold value would need to be applied to the short-term toxicity studies to determine an appropriate safety margin. While MycoTechnology was of the opinion that a 1000-fold safety factor was conservative number to be applied to short term studies with materials of a low concern level, such as shiitake mushroom, especially since such large safety factors are usually applied to materials of potential toxicological concerns (i.e., reproductive toxicants) for example, a figure more in the region of 500 was considered more appropriate. However, regulatory publications supporting the adoption of safety factors for short term studies could not be identified. Since the figure of 1000 was recommended by the FDA as a conservative number this numerical value was used to calculate a margin of safety for the actual L.E.M. extract as this is the ingredient along with pea protein used to manufacture the fermented pea protein. While the 1000-fold safety factor was applied to calculate a margin of safety for the mycelium product, it was felt to be inappropriate to use such a large safety factor when assessing the toxicology study for the actual shiitake mushroom as this is a commonly consumed food that has been eaten safely for thousands of years without any published adverse toxicological effects. In this case the safety margin analysis was deleted from the safety narrative as it was not the ingredient used in the manufacture and therefore was considered inappropriate scientifically.

Reference

FDA (U.S. Food & Drug Administration). Center for Food Safety and Applied Nutrition (CFSAN). (2006). Guidance for industry: summary table of recommended toxicological testing for additives used in food. (Docket No. FDA-2013-S-0610). Retrieved from https://www.regulations.gov/docket/FDA-2020-D-1936/document

Addendum

Appendix C Estimated Daily Intake of FermentIQ PEA Protein by the U.S. Population from Proposed Food Uses (2017-2018 NHANES)

Ten pages have been removed in accordance with copyright laws. The removed reference citation is:

D. Grotto, D. Bueno, G. Ramos, et al., “Assessment of the Safety of the Shiitake Culinary-Medicinal Mushroom, Lentinus edodes (Agaricomycetes), in Rats: Biochemical, Hematological, and Antioxidative Parameters,” International Journal of Medicinal Mushrooms, 18(10), pp. 861–870, 2016.