ToxStrategies

Innovative solutions
Sound science

RECEIVED
AUG 18 2022
OFFICE OF
FOOD ADDITIVE SAFETY

August 17, 2022

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

Subject: GRAS Notification – Chickpea Protein

Dear Sir:

On behalf of Tate & Lyle., ToxStrategies, Inc. (its agent) is submitting, for FDA review, a copy of the GRAS notification as required. The enclosed document provides notice of a claim that the food ingredient, chickpea protein, described in the enclosed notification is exempt from the premarket approval requirement of the Federal Food, Drug, and Cosmetic Act because it has been determined to be generally recognized as safe (GRAS), based on scientific procedures, for addition to food.

If you have any questions or require additional information, please do not hesitate to contact me at 630-352-0303, or dschmitt@toxstrategies.com.

Sincerely,

Donald F. Schmitt, M.P.H.
Senior Managing Scientist

GRAS Determination of Chickpea Protein for Use as an Ingredient in Human Food

JULY 29, 2022

ToxStrategies

Innovative solutions
Sound science

GRAS Determination of Chickpea Protein for Use as an Ingredient in Human Food

SUBMITTED BY:

Tate & Lyle
5450 Prairie Stone Parkway
Hoffman Estates, IL 60192

SUBMITTED TO:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
HFS-200
5100 Paint Branch Parkway
College Park MD 20740-3835

CONTACT FOR TECHNICAL OR OTHER INFORMATION

Donald F. Schmitt, MPH
ToxStrategies, Inc.
Naperville, IL 60540

July 29, 2022

Table of Contents

List of Figures

List of Tables

Acronyms

BMI	body-mass index
bw	body weight
CAS	casein
CFR	Code of Federal Regulations
cGMP	current Good Manufacturing Practice
CI	confidence interval
COA	Certificate of Analysis
DHHS	U.S. Department of Health and Human Services
EDI	estimated daily intake
FBG	fasting blood glucose
FDA	U.S. Food and Drug Administration
FNDDS	Food and Nutrient Database for Dietary Studies
GRAS	Generally Recognized as Safe
GRN	Generally Recognized as Safe Notification
HDL	high-density lipoprotein
HFD	high-fat diet
HOMA	homeostasis model assessment
IOM	Institute of Medicine
LDL	low-density lipoprotein
NCHS	National Center for Health Statistics
NHANES	National Health and Nutrition Examination Survey
PDCAAS	Protein Digestibility Corrected Amino Acid Score
PRI	Population Reference Intake
RDA	Recommended Dietary Allowance
T&L	Tate and Lyle
TAG	triacylglycerol
TG	triglycerides
USDA	United States Department of Agriculture
VLDL	very low-density lipoprotein
WHO	World Health Organization
WWEIA	What We Eat in America

§ 170.225 Part 1, GRAS Notice: Signed Statements and Certification

(1) GRAS Notice Submission

Tate & Lyle (T&L), through its agent, ToxStrategies, Inc., hereby notifies the U.S. Food and Drug Administration (FDA) of the submission of a Generally Recognized as Safe (GRAS) notice for the use of chickpea protein in certain specified foods for human consumption, in accordance with Subpart E of 21 CFR § 170.

(2) Name and Address

Tate & Lyle
5450 Prairie Stone Parkway
Hoffman Estates, IL 60192

(3) Name of Notified Substance

The name of the substance that is the subject of this GRAS determination is a chickpea protein concentrate from the seeds of *Cicer arietinum*, of the family *Fabaceae*, also known as chickpeas or garbanzo beans.

(4) Intended Use in Food

The chickpea protein is proposed for use as a protein ingredient in certain specified foods for human consumption (except for infant formula), and the daily consumption of protein is not expected to increase as a result of its introduction.

(5) Statutory Basis for GRAS Determination

T&L, through its agent, ToxStrategies, confirms that the chickpea protein ingredient, which meets the specifications described herein, has been determined to be GRAS through scientific procedures in accordance with 21 CFR § 170.30(a) and (b).

(6) Premarket Approval Statement

T&L further asserts that the use of the chickpea protein ingredient, as described herein, is exempt from the pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act, based on a conclusion that the substance is GRAS under the conditions of its intended use.

(7) Availability of Information

The data and information that serve as the basis for this GRAS determination, as well any information that has become available since the GRAS determination, will be sent on request, or are available for the FDA's review and copying during customary business hours from ToxStrategies, Inc., Naperville, IL.

(8) Data and Information Confidentiality Statement

None of the data and information in the GRAS notice are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552.

(9) GRAS Certification

To the best of our knowledge, the GRAS determination is a complete, representative, and balanced document. T&L is not aware of any information that would be inconsistent with a finding that the proposed uses and use levels of the chickpea protein ingredient in certain specified foods, meeting the appropriate specifications described herein, and used according to current Good Manufacturing Practice (cGMP), is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

(10) Name/Position of Notifier

[redacted]

Donald F. Schmitt, M.P.H.
Senior Managing Scientist
ToxStrategies, Inc.
Agent for Tate & Lyle

08/17/2022
Date

(11) FSIS Statement

The chickpea protein ingredient will not be used in products under the jurisdiction of the U.S. Department of Agriculture (USDA).

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

A. Identity

The chickpea protein ingredient is an extract of chickpeas consisting of ≥60% protein. It is a white, free-flowing, concentrated protein powder with a pH range of 5.5–7.5 and particle size of 8–11 microns. The chickpeas used to produce this ingredient are grown in the USA and Canada and the chickpea protein ingredient is manufactured in the USA.

B. Common or Usual Name

Chickpea protein or chickpea protein concentrate. The ingredient will be referred to as chickpea protein throughout the document.

C. CAS Registry Number

Not applicable.

D. Trade Name

The trade name for this chickpea protein is Artesa® Chickpea Protein.

E. Chickpea Protein Composition

Typical nutritional data for chickpea protein are summarized in Table 1. Chickpea protein, due to its high protein content, is also rich in amino acids, and Table 2 presents a comparison of its amino acid profile to a few other common food-derived proteins. The typical nutritional data and amino acid profile are also illustrated in the specification sheets in Appendix A. The % Protein Digestibility Corrected Amino Acid Score (PDCAAS)[1] has been calculated to be 0.83, and an *in vitro* digestibility score has been reported as 0.92. Morts and Silva (2019) reported a pepsin-pancreatin digestibility score for ground chickpea of >98%.

[1] The Protein Digestibilty Corrected Amino Acid Score (PDCAAS), adopted by the FDA, is the preferred method for the measurement of protein value and quality in human nutrition.

Table 1. Typical nutritional data for chickpea protein (per 100 g)

Protein	61 g
Moisture	4 g
Carbohydrates	29 g
Ash	5 g
Fat	2 g
Sodium	11.4 mg
Calcium	66.8 mg
Iron	9.0 mg
Potassium	1880 mg
Folate	337 µg
Phosphorus	992 mg
Magnesium	343 mg
Zinc	7.2 mg
Caloric value	374 kcal

Table 2. Typical amino acid profile (g per 100 g product)

Amino Acid	Chickpea[2]	Chickpea[3]	Oat	Wheat	Rice	Soy	Whey
Alanine	2.11	4.6	4.37	4.0	5.67	NA	NA
Arginine	5.10	10.4	7.17	2.7	7.64	NA	NA
Aspartic Acid	6.15	13.5	7.48	3.2	9.33	NA	NA
Cysteine	NA	1.1	2.45	1.3	2.09	NA	NA
Glutamic Acid	8.32	18.7	22.5	33.7	17.22	NA	NA
Glycine	1.93	4.3	4.13	5.1	4.33	NA	NA
Histidine	1.36	2.3	2.22	2.14	2.12	2.3	2.2
Isoleucine	2.32	3.6	4.38	3.39	4.4	4.7	5.8
Leucine	3.98	8.0	8.42	6.67	8.3	6.6	12
Lysine	3.56	7.2	3.38	2.5	3.4	5.4	10.8
Methionine	NA	0.8	2.23	1.4	2.66	NA	NA
Methionine + Cysteine	1.69	1.9	4.68	4.33	5.61	2.9	4.2
Phenylalanine	NA	6.0	5.95	4.2	5.38	NA	NA

Amino Acid	Chickpea[2]	Chickpea[3]	Oat	Wheat	Rice	Soy	Whey
Phenylalanine + Tyrosine	4.63	8.3	10	7.6	10.85	9.8	5.1
Proline	2.18	1.8	5.57	14.2	4.49	NA	NA
Serine	2.46	5.9	3.98	5.9	4.75	NA	NA
Threonine	1.78	4.1	3.5	2.96	3.7	4	7.2
Tryptophan	0.56	0.8	1.1	1.21	1.2	1.2	2.1
Tyrosine	NA	2.3	4.05	2.7	4.84	NA	NA
Valine	2.31	4.1	5.78	4.42	6	4.2	5.8

[1] Amino acid values for the other food proteins were excerpted from GRAS Notification (GRN) No. 575 for oat protein, GRN Nos. 26 and 575 for wheat protein, GRN Nos. 609 and 575 for rice protein, GRN No. 575 for soy protein, and GRN No. 575 for whey protein.

[2] Hydrated amino acids per *in vitro* PDCAAS analysis (See Appendix A)

[3] From Table 2; Juarez-Chairez et al. (2020). From chickpea seeds (g/100 g protein).

F. Manufacturing Process

A diagram of the chickpea protein ingredient manufacturing process is shown in Figure 1.

The chickpea protein ingredient (≥60% protein) is produced by an ethanol extraction process from commercially available chickpeas. The starting material for the chickpea protein extraction process is raw chickpeas. Following a dehulling step, the chickpeas are extracted with ethanol to remove oil. The de-oiled chickpea is then milled and dry-fractionated to obtain the protein product.

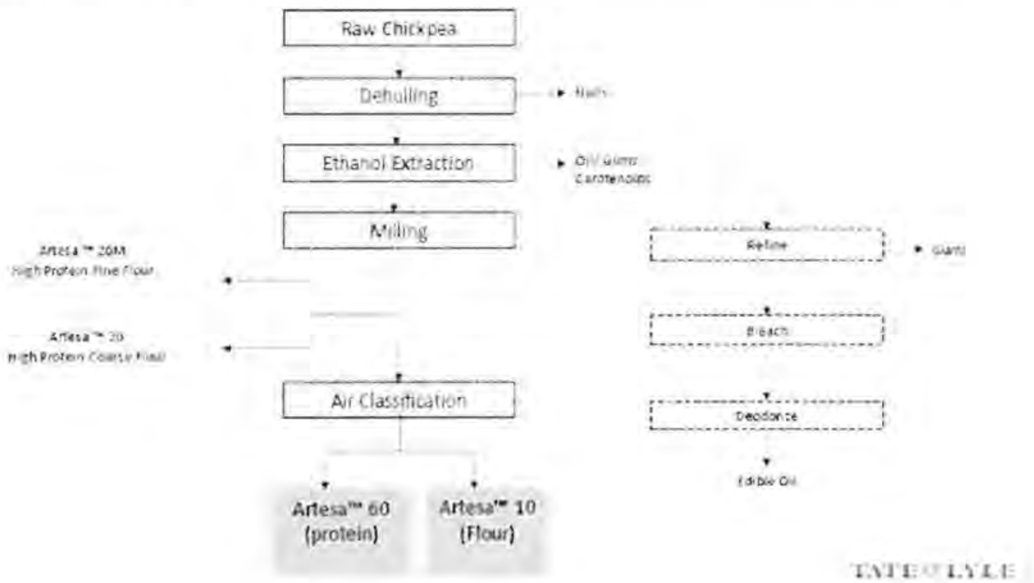

Figure 1. Steps in the chickpea protein production process

The only processing aid (ethanol) employed is safe and suitable for use in production of the chickpea protein ingredient. It is commonly used in food ingredient manufacturing processes, as described in Table 3.

Table 3. Processing aids

Processing Aid	CAS Number(s)	21 CFR/GRN Citation(s)
Ethyl alcohol (ethanol)	64-17-5	21 CFR §184.1293

G. Characterization of *Vicia faba* L.

Chickpea (*C. arietinum* L.) is one of the most ancient legumes consumed around the world, probably originating in Turkey (Madurapperumage et al., 2021). It is cultivated mainly in Asia, Europe, Australia, and North America, usually as a winter crop. Southeast Asia accounts for ~80% of world production, with India being the main producing country (Juarez-Chairez et al., 2020). According to the U.S. Department of Agriculture's (USDA's) National Nutrient Database, one cup of cooked chickpeas provides 269 calories, 45 g of carbohydrate, 15 g of protein, 13 g of dietary fiber, and 4 g of fat (Gupta et al., 2017). Chickpea seeds contain a percentage of protein similar to that of legumes, beans, and soybeans and have high bioavailability and good digestibility (48%–89%) (Juarez-Chiarez et al., 2020; Chavan et al., 1986). Chickpeas are a good source of vitamins such as riboflavin, niacin, thiamin, folate, and the vitamin A precursor, β-carotene. Chickpea seeds, like other legumes, also contain anti-nutritional factors (e.g., trypsin inhibitors, chymotrypsin inhibitors, lectins, and antifungal peptides), which are reduced or eliminated by different cooking techniques, such as soaking, cooking, boiling, and autoclaving (Jukanti et al. 2012; Gupta et al., 2017).

H. Product Specifications

Specifications for the product are presented in Table 4. Analytical results from three non-consecutive lots are provided in Appendix A. A comparison of three non-consecutive lots of product to the specifications below can be found in Table 5.

Table 4. Specifications for chickpea protein

Parameter	Specification	Method
Physical specifications		
Protein (%, db)	≥60	DUMAS: AOAC 990.03; 2000
Moisture (%)	<10	LOD: AOAC 930.15
Microbiological specifications		
Aerobic Plate Count (cfu/g)	<50,000	FDA BAM: AOAC 966.23
Yeast (cfu/g)	<100	Petrifilm: AOAC 2014.05
Mold (cfu/g)	<100	Petrifilm: AOAC 2014.05
Total coliforms (cfu/g)	<10	FDA BAM: 8^{th} edition Ch.4
E. coli (cfu/g)	<10	FDA BAM: 8^{th} edition Ch.4
Salmonella (/375 g)	Negative	FDA BAM: 8^{th} edition Ch.5
Staph. Aureus (cfu/g)	<10	FDA BAM: 8^{th} edition Ch. 12
Chemical specifications		
Arsenic (ppb)	<50	ICP-MS: AOAC 2013.06
Lead (ppb)	<20	ICP-MS: AOAC 2013.06
Mercury (ppb)	<20	ICP-MS: AOAC 2013.06
Cadmium (ppb)	<50	ICP-MS: AOAC 2013.06
Pesticides (raw material)	<MRL per USP 565	FDA BAM: 302 E7C6 Modified
Gluten (ppm)	<10	Neogen Veratox

Table 5. Analytical results for three non-consecutive lots of chickpea protein

Specification		Lot No. A60-235-21	Lot No. A60-240-21	Lot No. A60-245-21
Protein (%)	≥60	60.3	60.8	60.7
Moisture (%)	<10	5.6	5.8	6.1
Aerobic Plate Count (cfu/g)	<50,000	340	5,200	870
Yeast (cfu/g)	<100	<10	<10	<10
Mold (cfu/g)	<100	<10	<10	<10
Total coliforms (cfu/g)	<10	<10	<10	<10
E. coli (cfu/g)	<10	<10	<10	<10
Salmonella (/375 g)	Negative	Negative	Negative	Negative
Staph. Aureus (cfu/g)	<10	<10	<10	<10
Arsenic (ppb)	<50	<10	<10	<10
Lead (ppb)	<20	<5	<5	<5
Mercury (ppb)	<20	<5	<5	<5
Cadmium (ppb)	<50	<5	<5	<5
Pesticides (raw material)	<MRL per USP 565	<MRL	<MRL	<MRL
Gluten (ppm)	<10	<10	<10	<10

T&L monitors the chickpea protein ingredient for mycotoxins. The results of such monitoring for three batches of product are summarized in Table 6. Mycotoxin levels were below the limits of detection.

Table 6. Mycotoxin Data for Chickpea Protein

Parameter	Batch No. A60P200428	Batch No. A60P200429	Batch No. A60P200430
Aflatoxin B1 (ppb)	<0.5	<0.5	<0.5
Aflatoxin B2 (ppb)	<0.5	<0.5	<0.5
Aflatoxin G1 (ppb)	<0.5	<0.5	<0.5
Aflatoxin G2 (ppb)	<0.5	<0.5	<0.5
Aflatoxin M1 (ppb)	<0.5	<0.5	<0.5

Aflatoxin M2 (ppb)	<0.5	<0.5	<0.5
Deoxynivalenol (ppb)	<100	<100	<100
T-2 Toxin (ppb)	<10	<10	<10
HT-2 Toxin (ppb)	<100	<100	<100
Fumonisin Ba (ppb)	<25	<25	<25
Fumonisin B2 (ppb)	<25	<25	<25
Ochratoxin A (ppb)	<1	<1	<1
Zearalenone (ppb)	<30	<30	<30

Because ethanol is employed as the extraction solvent, representative lots of chickpea protein were analyzed for residual ethanol. The results are found in Table 7.

Table 7. Residual alcohol data

Parameter	Result
Lot # A60-173-19	
Ethanol (ppm)	95
Lot # A60-251-19	
Ethanol (ppm)	86
Lot # A60-331-19	
Ethanol (ppm)	146

The analytical results for the chickpea protein ingredient—summarized in the above tables and included in Certificates of Analysis (COAs) in Appendix A—confirm that the finished product meets the analytical specifications, demonstrate that T&L's manufacturing process results in a consistently reproducible product, and confirm the lack of significant levels of impurities and/or contaminants (e.g., heavy metals, pesticides, anti-nutrients, and microbiological contaminants).

I. Stability Data

The chickpea protein product has been tested for stability under normal conditions (below 100°F) for 25 months. Technical specifications for the product include shelf-life storage conditions of 24 months from the date of manufacture when stored in a closed container in a cool, dry place (below 25°C). Stability testing data can be found in Table 8.

Table 8. Stability testing data

	Time (Months)	
Parameter	**Initial**	**25**
Lot # A60-173-19		
Aerobic Plate Count (cfu/g)	5900	23600
Yeast (cfu/g)	<10	<10
Mold (cfu/g)	<10	<10
Moisture (%)	NA*	5.52
Lot # A60-247-19		
Aerobic Plate Count (cfu/g)	1710	14400
Yeast (cfu/g)	<10	<10
Mold (cfu/g)	<10	<10
Moisture (%)	NA*	5.83
Lot # A60-331-19		
Aerobic Plate Count (cfu/g)	3400	7900
Yeast (cfu/g)	<10	<10
Mold (cfu/g)	<10	<10
Moisture (%)	NA*	5.00

*Moisture specification is <10%

§ 170.235 Part 3, Dietary Exposure

Proposed Use

The focus of this GRAS determination is the use of chickpea protein as an alternative source for other plant-based proteins used in processed foods, or as an alternative source of protein for individuals who wish to limit or reduce their intake of animal-sourced proteins.

Table 9 summarizes the ten proposed food categories—bakery products (sugar free, gluten free, or high fiber); non-dairy nutritional beverages; dry-blend protein powders; meal replacement/nutritional bars; plant-based protein products/meat analogs; imitation dairy analogs, including milk alternatives, cheese, cream cheese, coffee creamer, frozen dessert, yogurt, and whipped topping); pasta products; snack foods; extruded snack products; and soups)—and associated use levels. An intake assessment was conducted to estimate the mean and 90th percentile daily intakes of chickpea protein, as well as the corresponding protein intake, based on its intended use in foods, as shown in Appendix B.

The total estimated daily intake (EDI) of chickpea protein, as well as the corresponding protein intake from proposed uses of chickpea protein, was based on food consumption records collected in the What We Eat in America (WWEIA) component from the 2015–2018 National Health and Nutrition Examination Survey (NHANES). Estimates of intake were provided for the total U.S. population 2 years (y) and older (U.S. 2+ y) and three subpopulations, including children 2–12 y, adolescents 13–18 y, and adults 19+ y. The sections below summarize the data, methods, and results.

Table 9. Proposed food uses and use levels

Proposed Use Category	Description of Foods Selected for Analysis	Chickpea Protein Maximum Use Level (%)
Bakery products, sugar free, gluten free, or high fiber	Bakery products limited to sugar free, gluten free, high fiber, or not-further-specified/not-specified (NFS/NS) products[1] (e.g., gluten free bread, sugar free cookies, NFS cereal or granola bar, and NS bread and rolls)	30
Beverages, nutritional beverages, non-dairy	Soy-based nutritional drink or shake and NFS nutritional drinks or shakes[1]	50
Dry-blend protein powders[2]	Protein powders (e.g., EAS Whey, Isopure, Muscle Milk, NFS protein powders[1])	90
Meal replacement/ nutritional bars	Nutrition bars (e.g., Clif Bar, PowerBar, Slim Fast Original Meal Bar, Zone Perfect)	60
Plant-based protein products/meat analogs[3]	Plant-based burgers, frankfurters, bacon, links/patties, chicken, luncheon meat, meatball, sandwich spread, meat loaf, and fillet	13.3 - 53.3
Dairy products–imitation		
Milk alternatives	Milk alternatives such as soy milk, almond milk, rice milk, and coconut milks	25
Cheese	Imitation cheese and NFS cheese[1]	25
Cream cheese	Non-dairy cream cheese was not reported consumed in NHANES; therefore, dairy-based cream cheeses were selected as surrogates	25

Proposed Use Category	Description of Foods Selected for Analysis	Chickpea Protein Maximum Use Level (%)
Coffee creamer	Soy coffee creamer and NFS coffee creamer[1]	25
Frozen dessert	Non-dairy frozen dessert, rice dessert bar, and NFS frozen yogurt, ice cream, and NFS frozen novelty products[1]	25
Yogurt	Soy yogurt, coconut milk yogurt, and NFS/NS yogurt[1]	25
Whipped topping	Whipped topping including regular, fat free, and sugar free (e.g., Cool Whip, Dream Whip)	25
Pasta products	All pasta, noodles, and macaroni as prepared; excludes pasta mixtures containing meat, poultry, and/or seafood	30
Snack foods	Crackers, breadsticks, Melba toast, hard pretzels, and other snacks (e.g., plantain chips, taro chips, sweet potato chips)	30
Extruded snack products	Bean chips, rice chips, corn snacks (e.g., Cheetos), popcorn chips, multigrain chips (e.g., Sun Chips), cracker chips, vegetable chips, potato sticks, etc.; excludes corn chips, tortilla chips, and potato chips	50
Soups[4]	Vegetarian soups; excludes home recipe soups and poultry and beef broths	10

[1] Due to limited NHANES foods reported consumed that correspond to the proposed food use, NFS and/or NS products were identified and selected as a surrogate for the proposed food use.
[2] Use level corresponds to the non-reconstituted powder.
[3] Chickpea protein is intended to be substitutional in plant protein products to provide protein at the protein concentration currently in these foods.
[4] Non-reconstituted, condensed soup amounts were adjusted to the prepared/reconstituted soup amount and included in the assessment.

Food Consumption Data

Chickpea protein intake estimates from proposed foods were based on food consumption records collected in the What We Eat in America (WWEIA) component of the National Health and Nutrition Examination Survey (NHANES) conducted in 2015–2016 and 2017–2018. This continuous survey is a complex, multistage probability sample designed to be representative of the civilian U.S. population (CDC, 2018, 2020). The NHANES data sets provide nationally representative nutrition and health data and prevalence estimates for nutrition and health status measures in the U.S. Statistical weights are provided by the National Center for Health Statistics (NCHS) for the surveys, to adjust for the differential probabilities of selection. As part of the examination, trained dietary interviewers collect detailed information on all foods and beverages consumed by respondents in the previous 24-hr time period (midnight to midnight).

A second dietary recall is administered by telephone 3 to 10 days after the first dietary interview, but not on the same day of the week as the first interview. The dietary component of the survey is conducted as a partnership between the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS). DHHS is responsible for the collection method, maintenance of the databases used to code and process the data, and data review and processing. A total of 13,666 individuals in the survey period 2015–2018 provided two complete days of dietary recalls.

Representative NHANES Foods for the Proposed Use

The list of food codes reported consumed in the WWEIA, NHANES 2015–2018 was reviewed and foods corresponding to each proposed food use of chickpea protein were identified. Foods in which only a component corresponds to a chickpea protein use (e.g., noodles in a lasagna dish, gluten-free crust in pizza, non-dairy milk in coffee) were also identified by using USDA's Food and Nutrient Database for Dietary Studies (FNDDS), which translates the food reported as consumed by participants in NHANES into its corresponding ingredients (and gram amounts) or recipes. FNDDS version 2017–2018 recipes (which corresponds to dietary consumption for NHANES 2017-2018) (USDA 2020) were applied to process dietary recall data reported during NHANES 2015-2018 and FNDDS 2015-2016 recipes (which corresponds to dietary consumption for NHANES 2015-2016) (USDA 2018) for foods that were reported as consumed only in NHANES 2015–2016. The proportion of foods (as a percentage of total weight) corresponding to a proposed use of chickpea protein was identified using the USDA FNDDS, and only this portion of the food weight was used to determine the amount of chickpea protein that may be added. The list of NHANES food codes (and their descriptions) included in the analysis is provided in Appendix B.

Analysis

Using the NHANES 2015–2018 consumption data, the 2-day average daily intake of chickpea protein on a *per-capita* and *per-user* basis was calculated. *Per capita* estimates refer to the intake based on the entire population of interest, whereas *per-user* estimates refer to those who reported consuming the particular food use of chickpea protein on either of the survey days. Thus, if a participant reported consuming the food on day 1 but not on day 2, they would be considered a "user," and their 2-day average consumption is the amount they reported consuming on day 1 divided by 2. For each subject with a complete 2-day dietary recall, a 2-day average intake estimate of the food use of interest was derived by dividing the cumulative intake of the select food over the two 24-hr recalls by two. The 2-day average intake of chickpea protein per subject was derived by multiplying the reported intake of selected foods from the 24-hr recall with the corresponding maximum chickpea protein use level (see Table 9), and the cumulative sum over the two 24-hr recalls was divided by two. The corresponding protein intake from proposed uses of chickpea protein was also derived assuming 60% protein in chickpea protein (Table 11). The estimated daily intakes were derived on an absolute basis (i.e., grams per day) and on a body-weight basis (i.e., grams per kilogram body weight per day) based on each participant's measured body weight.

Results

Two-day average chickpea protein intake estimates from the proposed use in ten food categories were derived based on food consumption data collected in NHANES 2015–2018. Intake estimates of chickpea protein and the corresponding protein intake from chickpea protein uses for the U.S. population 1+ y and selected age-sex subpopulations are provided in Tables 10 and 11, respectively, on a *per-capita* and *per-user* basis at the mean the and 90th percentile. Chickpea protein and protein intake estimates are expressed in grams per day (g/day) and grams per kilogram body weight per day (g/kg bw/day).

Table 10. Two-day average estimated daily intake (EDI) of chickpea protein from all proposed food uses among the U.S. population one year and older (1+ y), and gender and age groups

			Per Capita		Per User		Per Capita		Per User	
			Mean	90th Percentile	Mean	90th Percentile	Mean	90th Percentile	Mean	90th Percentile
Gender and age	N[†]	% User	---- g/day ----				--- g/kg-bw/day ----			
Males:										
1-3 y	390	66	17.5	43.4	20.3	48.4	1.27	3.17	1.47	3.50
4-8 y	445	77	15.6	40.8	20.4	43.2	0.65	1.60	0.84	1.79
9-13 y	425	72	18.2	46.0	25.1	53.4	0.44	1.15	0.61	1.33
14-18 y	352	60	18.5	49.0	30.9	69.5	0.29	0.72	0.48	1.08
19-30 y	448	64	19.9	58.5	30.9	71.0	0.26	0.80	0.40	0.93
31-50 y	682	62	18.9	56.2	30.5	79.6	0.21	0.59	0.34	0.88
51-70 y	820	65	15.1	46.1	23.2	62.6	0.17	0.51	0.27	0.66
71+ y	404	65	13.0	37.2	20.2	44.7	0.15	0.45	0.24	0.52
Females:										
1-3 y	349	83	17.1	44.7	20.6	47.9	1.33	3.09	1.61	3.32
4-8 y	468	79	14.9	37.5	18.9	41.7	0.66	1.78	0.84	1.91
9-13 y	468	77	17.8	45.2	23.3	51.3	0.42	1.25	0.55	1.36
14-18 y	392	70	16.4	48.7	23.5	53.7	0.27	0.81	0.39	1.01
19-30 y	553	69	19.5	55.6	28.2	69.8	0.29	0.85	0.42	1.02
31-50 y	949	72	18.7	47.7	26.0	59.6	0.25	0.68	0.35	0.87
51-70 y	1,043	72	14.2	43.4	19.7	48.4	0.20	0.58	0.27	0.70
71+ y	447	73	14.0	37.8	19.2	42.6	0.20	0.52	0.28	0.57
Males and females:										
1+ y	8,635	69	17.0	46.1	24.5	57.8	0.31	0.83	0.44	1.07

[†] Un-weighted number of users; % user, *per capita*, and *per user* estimates were based on NHANES 2015-2018 and derived using the statistical weights provided by the NCHS.

Table 11. Two-day average estimated daily intake (EDI) of protein from proposed uses of chickpea protein among the U.S. population one year and older (1+ y) and gender and age groups based on protein content of 60% from chickpea protein

			Per Capita		Per User		Per Capita		Per User	
		%	Mean	90th Percentile	Mean	90th Percentile	Mean	90th Percentile	Mean	90th Percentile
Gender and age	N[1]	User	---- g/day ----				--- g/kg-bw/day ----			
Males:										
1-3 y	390	86	10.5	26.0	12.2	29.0	0.76	1.90	0.88	2.10
4-8 y	445	77	9.5	24.5	12.2	25.9	0.39	0.96	0.51	1.07
9-13 y	425	72	10.9	27.6	15.1	32.0	0.27	0.69	0.37	0.80
14-18 y	352	60	11.1	29.4	18.6	41.7	0.17	0.43	0.29	0.65
19-30 y	448	64	11.9	35.1	18.5	42.6	0.15	0.48	0.24	0.56
31-50 y	682	62	11.3	33.7	18.3	47.8	0.13	0.35	0.20	0.53
51-70 y	820	65	9.1	27.6	13.9	37.6	0.10	0.31	0.16	0.40
71+ y	404	65	7.8	22.3	12.1	26.8	0.09	0.27	0.14	0.31
Females:										
1-3 y	349	83	10.2	26.8	12.4	28.8	0.80	1.65	0.97	1.99
4-8 y	468	79	9.0	22.5	11.3	25.0	0.40	1.07	0.50	1.15
9-13 y	468	77	10.7	27.1	14.0	30.8	0.25	0.75	0.33	0.81
14-18 y	392	70	9.8	29.2	14.1	32.2	0.16	0.49	0.24	0.60
19-30 y	553	69	11.7	33.4	16.9	41.9	0.17	0.51	0.25	0.61
31-50 y	949	72	11.2	28.6	15.6	35.8	0.15	0.41	0.21	0.52
51-70 y	1,043	72	8.5	26.0	11.8	29.0	0.12	0.35	0.16	0.42
71+ y	447	73	8.4	22.7	11.5	25.5	0.12	0.31	0.17	0.34
Males and females:										
1+ y	8,635	69	10.2	27.7	14.7	34.7	0.18	0.50	0.27	0.64

[1] Un-weighted number of users. % user, *per capita*, and *per user* estimates were based on NHANES 2015-2018 and derived using the statistical weights provided by the NCHS.

Note: Based on protein content of 60% from chickpea protein.

It is important to note that the EDIs represent conservatively high estimates of intake. In calculating the EDIs, it is assumed that all foods in each proposed use category will contain the maximum intended use of chickpea protein. However, not all consumers may select products with chickpea protein for all eating occasions. Furthermore, consumption of protein from chickpea protein can reasonably be assumed to replace other sources of protein in the diet.

The Institute of Medicine (IOM, 2005) recommends that adults consume 0.8 grams of protein per kilogram of body weight. IOM also set a wide range for acceptable protein intake, ranging from 10% to 35% of calories each day. In the U.S., the recommended daily allowance (RDA) of protein is 46 grams/day for women over 19 years of age, and 56 grams/day for men over 19 years of age. A further breakdown of RDAs by age and sex are presented in Table 12 in the Safety section of Part 6, below.

The RDA, however, does not represent an upper limit of consumption. Physically active persons on normal diets are known to exceed this level, and individuals involved in bodybuilding ingest much higher levels of protein (WHO, 2002). The accepted WHO safe level of intake is 0.83 g/kg per day, for proteins with a protein digestibility-corrected amino acid score value of 1.0. While WHO has stated that no safe upper limit has been identified, they also indicated that it is unlikely that intakes of twice the safe level are associated with any risk to healthy individuals.

As previously submitted GRNs on plant-derived proteins have demonstrated, the proposed food uses and use levels, combined with the large average daily consumption of the described foods, results in a calculated daily intake of these protein ingredients that are a substantial fraction of the RDA (i.e., 46 g/day for women over 19 years of age and 56 g/day for men over 19 years of age); the 90^{th} percentile consumption is exceeded in some cases for specific age groups. As was concluded in the other plant-based protein GRAS notifications, we do not realistically expect that the actual consumption of foods containing chickpea protein would be expected to result in daily consumption greater than the RDA for protein. Most of the population's intake of protein is, and will remain, in the form of unprocessed foods, including meat, poultry, fish, and legumes.

In summary, the proposed uses of chickpea protein will not result in an increase in the overall consumption of protein but will simply provide an alternative source of well-characterized protein from chickpeas for use in specified foods.

§ 170.240 Part 4, Self-Limiting Levels of Use

The use of chickpea protein in protein-enriched foods is self-limiting for technological reasons, such as product texture and/or flavor profile, either of which could affect consumer acceptance.

§ 170.245 Part 5, Experience Based on Common Use in Food

While there exists broad historical evidence regarding the intake of chickpeas and the protein contained therein as food for human consumption, the statutory basis for our conclusion of its GRAS status in this notice is based on scientific procedures and not on its common use in food.

§ 170.250 Part 6, GRAS Narrative

History of Use and Regulatory Approval

There is no current formal approval for the use of chickpea protein in human foods in the United States. Chickpeas (*C. arietinum* L.) are one of the most ancient, consumed legumes around the world, probably originating in Turkey. It is cultivated in Asia, Europe, Australia, and North America, usually as a winter crop; Southeast Asia contributes around 80% of world production, with India being the main producing country in this region (Juarez-Chairez et al., 2020). According to the U.S. Department of Agriculture's National Nutrient Database, one cup of cooked chickpeas provides 269 calories, 45 g of carbohydrate, 15 g of protein, 13 g of dietary fiber, and 4 g of fat (Gupta et al., 2017). The mean protein content in chickpeas is nearly 18% (kabuli contains 18.4% [range 16.2%–22.4%]; desi contains 18.2% [range 15.6%–21.4%]), which is higher than lentils and field peas. Chickpeas are rich in lysine and arginine and low in sulfur-containing amino acids such as cysteine and methionine (Madurapperumage et al., 2021; Jukanti et al., 2012). Chickpeas are also a rich source of minerals, including iron, zinc, and selenium. Consumption of chickpeas has been reported to have benefits on weight control, glucose and insulin response, cardiovascular disease, cancer, and gastrointestinal-tract health (Wallace et al., 2016; Juarez-Chairez et al., 2021).

Chickpea seeds have a percentage of protein similar to that of legumes, beans, and soybeans, and they have high bioavailability and good digestibility (48%–89%) (Juarez-Chairez et al., 2020; Chavan et al., 1986). Chickpeas are a good source of vitamins such as riboflavin, niacin, thiamin, folate, and the vitamin A precursor, β-carotene. Chickpea seeds, like other legumes, also contain anti-nutritional factors (e.g., trypsin inhibitors, chymotrypsin inhibitors, lectins), which are reduced or eliminated by different cooking techniques such as soaking, cooking, boiling, and autoclaving (Jukanti et al. 2012; Gupta et al., 2017).

Chickpea-based foods and snacks have been marketed in the United States and other countries around the world and include hummus (2 g protein/serving), snack foods, and snack bars (3–6 g protein/serving) (Acevedo-Martinez et al., 2021).

Safety

Introduction

Literature searches were performed to identify available safety data for chickpeas and chickpea protein (through June 2022). This included searching sources of information such as publicly available assessments, databases, or reviews from organizations, including EFSA, Joint FAO/WHO Expert Committee on Food Additives (JECFA), U.S. FDA, and the World Health Organization (WHO), general internet searching, and searching databases such as Embase, MedLine, ToxLine, and PubMed.

As described previously, chickpeas are consumed in both cooked and processed forms. The biological value of eating uncooked chickpeas can be affected negatively by the presence of anti-nutritional factors such as trypsin inhibitor, phytic acid, tannins, lectins, stachyose, and raffinose. However, these anti-nutrition factors are reduced with cooking and are now removed routinely during commercial processing of chickpeas.

Safety Data

Chickpeas and/or Chickpea Protein

Given the long history of global human consumption of chickpeas as food (and the protein contained therein), the safety of the chickpea protein ingredient derived from them is supported by their consumption and general lack of toxicity. As would be expected for a food that has been consumed by humans for centuries, chickpeas and chickpea proteins have not been subjected to traditional toxicology studies. Furthermore, given the available information and data on the safe consumption of chickpeas and their associated proteins, conduct of toxicity studies was considered unnecessary and not an ethical use of animals. The available safety-related information for chickpeas and associated chickpea proteins can be extracted from studies of their potential health benefits and are summarized below.

Animal Studies

In a study in rats, an increase in body weight was prevented by chickpea (CP) supplementation of a high-fat diet fed to rats. Thirty healthy male rats were randomly assigned to three groups (10 per group), and fed diets containing normal fat (5 g fat, 22 g protein and 1381 kJ/100 g), high fat (lard, 20% w/w; sugar, 4%, w/w; milk powder 2%, w/w; and cholesterol 1%, w/w), and high fat supplemented with chickpea (same as HFD, but 10% crushed chickpea seed replaced the standard chow - 25.11 g fat, 19.36 g protein, and 1965 kJ/100 g) were given for 8 months. No treatment-related adverse effects were noted. Addition of 10% (w/w) CPs to the high-fat diet reduced the weight gain from 6 months to the end of the experiment. In addition, chickpea treatment resulted in a 45% decrease in the serum triacylglycerol (TAG), a 23% decrease in low-density lipoprotein (LDL), a 35% rise in high-density lipoprotein (HDL), and a 30% reduction in LDL/HDL compared to the high-fat diet group. In their results, the authors pointed out that the chickpea diet reversed visceral adiposity, dyslipidemia, and insulin resistance. (Yang et al., 2007).

Boualga et al. (2009) analyzed the effect of a diet supplemented with chickpea proteins administered to Wistar rats for 28 days. Weaning male Wistar rats were fed *ad libitum* one of the following diets: 200 g/kg diet of purified proteins of lentil (L), or chickpea (CP) or casein (CAS). No adverse effects were noted. At day 28, very-low-density lipoprotein (VLDL) was isolated from plasma samples by a single ultracentrifugation flotation. Hepatic lipase and LPL activity in epididymal fat, gastrocnemius, and heart were also measured. Compared with a casein diet, the chickpea and lentil protein diets exhibited similar cholesterolemia, but lower triglyceridemia and VLDL particle number, as measured by their reduced contents of triglycerides (TG) and apolipoproteins. CP and L protein diets reduced liver TG and cholesterol by 31% and 45%, respectively, compared to the CAS diet. Furthermore, LPL activity in adipose tissue of rats fed CP or L was 1.6-fold lower than that of rats fed CAS. There was no significant difference in heart and gastrocnemius LPL activities among the three proteins. In contrast, hepatic lipase activity was higher in rats fed CP and L diets. The authors concluded that the low food efficiency ratio of purified CP and L proteins compared to CAS is associated with decreased plasma VLDL and adipose tissue LPL activity.

Wang and McIntosh (1996) investigated the effect of feeding peas or chickpeas on growth performance, plasma cholesterol concentrations, and organ weights of rats. Eighty-four healthy male Sprague Dawley rats were divided into fourteen treatment groups (6 rats/groups). Diets 1 and 2 served as control groups using casein as a protein source; diets 3 to 8 used peas as a protein source; diets 9 to 14 used chickpeas as the protein source. The legumes were presented as raw, extruded or boiled. Each diet was designed to provide approximately 15.5% protein, 8.5% dietary fiber and 8% fat, and fed for 35 days. Rats fed processed chickpeas and those fed casein had similar body weight gains. Rats fed legumes resulted in lower levels of plasma cholesterol compared to rats fed casein. The decrease in cholesterol levels varied with the processing method used; extrusion and boiling had similar effects for chickpeas, whereas extrusion was most effective in peas. Chickpea-fed rats had lower spleen, thymus, and relative liver weights and higher cecum and colon relative weights compared to fed rats fed casein. There were no differences in growth, protein efficiency ratio, organ relative weights, or plasma cholesterol concentration between rats fed extruded legumes and those fed boiled legumes. The authors concluded that extrusion improves the nutritional value of these selected legumes to the same extent as the traditional boiling method (Wang and McIntosh, 1996).

Human Studies

Numerous studies have been conducted with chickpeas and their bioactive constituents that examined health benefits such as antioxidant activity, inhibition of colon/breast cancer, hypocholesterolemic activity, hypoglycemic activity, and antifungal and anti-inflammatory activity (Juarez-Chairez et al., 2020; Ferreira et al., 2021; Shevkani et al., 2019).

Pittaway and Ahuja (2006) compared the effects of a chickpea-supplemented diet and that of a wheat-supplemented diet on human serum lipids and lipoproteins. Forty-seven adults participated in the randomized, crossover study that compared a weight maintenance dietary intervention involving two dietary periods, feeding both chickpea-supplemented and wheat-supplemented diets, each of which lasted at least 5 weeks. Subjects consumed approximately 280 g of chickpeas per day as canned chickpeas, chickpea bread, and chickpea biscuits. The serum total cholesterol and low-density lipoprotein cholesterol levels were significantly lower (both $p<0.01$) by 3.9% and 4.6%, respectively, after consuming the chickpea-supplemented diet, compared to the wheat-supplemented diet. Protein (0.9% of energy, $p = 0.01$) and monounsaturated fat (3.3% of total fat, $p<0.001$) intakes were slightly but significantly lower, and the carbohydrate intake was significantly higher (1.7% of energy, $p<0.001$) on the chickpea-supplemented diet as compared with the wheat-supplemented diet. Statistical analyses suggested that the differences in serum lipids were mainly due to small differences in polyunsaturated fatty acid and dietary fiber contents between the two diets. No treatment-related adverse effects were noted by the authors. The authors concluded that inclusion of chickpeas in an intervention diet results in lower serum total and low-density lipoprotein cholesterol levels, as compared with a wheat-supplemented diet.

Pittaway et al. (2008) assessed the effect of incorporating chickpeas in the diet of adult subjects (N=45). Participants consumed a minimum of 728 grams of canned, drained chickpeas per week as part of their normal diet for 12 weeks (chickpea phase), followed by 4 weeks of a normal diet without chickpeas (usual phase). In the chickpea phase, mean dietary fiber intake was 6.77 g/day more, and mean polyunsaturated fatty acid consumption (as a percentage of total fat) was 2.66% more (both $p<0.001$), resulting in the polyunsaturated-to-saturated-fatty-acids ratio to change from 0.39 to 0.47 ($p=0.045$). Serum total cholesterol and low-density lipoprotein cholesterol were 7.7 mg/dL (0.20 mmol/L) and 7.3 mg/dL (0.19 mmol/L) less, respectively, after the chickpea phase ($p\leq0.01$), fasting insulin was 0.75 μIU/mL (5.21 pmol/L) less ($p=0.045$), and the homeostasis assessment model of insulin resistance was 0.21 less ($p=0.01$). Statistical analysis revealed that dietary fiber had the greatest single effect, reducing serum total cholesterol by 15.8 mg/dL (0.41 mmol/L) ($P=0.01$). Polyunsaturated and saturated fatty acids had equivalent but opposing effects on serum total cholesterol and insulin. No treatment-related adverse effects were noted by the authors.

A study was conducted on thirty obese subjects (body-mass index [BMI] of 2.0±5.3 kg/m^2) with a mean age of 36±8 years. The subjects were divided into two groups of 15 and fed a hypocaloric diet consisting of chickpea-containing pulse (LD) mixture and a control diet (CD; no pulses) for a period of 8 weeks (4 days/week). After 8 weeks, the total cholesterol levels in the LD-fed group decreased from 215 mg/dL to 182 mg/dL, whereas a smaller decrease was observed for the CD-fed group. No treatment-related adverse effects were noted. The authors proposed that the observed hypocholesterolemic effect was a result of the inhibition of fatty acid synthesis in the liver by fiber fermentation products such as propionate, butyrate, and acetate (Crujeiras et al., 2007).

A chickpea-based diet has been shown to have a positive effect on diabetes and obesity. Adiponectin is a hormone that prevents type two diabetes and atherosclerosis (Achari and Jain, 2017). Several studies have examined legume-based diets and their effect on increasing the levels of adiponectin. A randomized cross-over clinical trial was conducted in diabetic patients (n = 24) served a legume diet containing chickpeas (substituting for two servings of red meat: 3 days/week) or a legume-free diet for 8 weeks. Leptin and adiponectin levels were measured at baseline and after 8 weeks of consumption. No treatment-related adverse effects were reported. The legume-based diet significantly increased adiponectin concentrations compared to the legume-free diet. There was no significant change in leptin concentrations after either intervention diet (Mirmiran et al., 2019).

Nestel et al. (2004) studied the effects on insulin sensitivity of chickpea-based and wheat-based foods when eaten as single meals or over 6 weeks. Acute and long-term studies were conducted in healthy, middle-aged men and women. In an acute study (n=19), plasma glucose, insulin, and calculated homeostasis model assessment (HOMA; an index of insulin sensitivity) were measured on three separate days over a 3-hour period following the consumption of 50-g available carbohydrate loads from either chickpeas, wheat-based foods, or white bread. The long-term study (n=20) was a randomized, crossover study in which chickpea-based and wheat-based foods were consumed for 6 weeks each. Plasma glucose, insulin, and HOMA were measured in the fasting state and 2 hours after a 75-g glucose load. No treatment-related adverse effects were noted during the studies. After single meals, plasma glucose was substantially lower 30 and 60 minutes after the chickpea meal than after the other meals ($p<0.05$), and plasma insulin and HOMA were lower at 120 minutes ($p<0.05$). However, the long-term study did not show significant differences in plasma glucose, insulin, or HOMA, either in the fasting state or after a glucose load. The authors concluded that a single chickpea-based meal led to a lesser response in plasma glucose and insulin concentrations, but this did not translate into long-term improvement in insulin sensitivity over a 6-week period in healthy subjects.

Systematic Review of Pulses

While the following systemic reviews did not directly address the safety of chickpeas or chickpea protein, they are included for completeness and demonstration of the significant amount of research that has been conducted with chickpeas and other pulses, and their potential beneficial health effects.

Ferreira et al. (2021) conducted a systematic review of randomized controlled trials that examined the health benefits of pulse consumption (including chickpeas). PubMed searches, including keywords [("dietary pulses", "pulses", "legumes", "grain legumes", "bean", "chickpea", "pea", "lentil", "cowpea", "faba bean", "lupin") and ("inflammation", "inflammatory markers", "C-reactive protein", "blood lipids", "cholesterol", "cardiometabolic health", "cardiovascular disease", "diabetes", "glycaemia", "insulin", "HOMA-IR", "body weight", "body fat", "obesity", "overweight", "metabolome", "metabolic prole", "metabolomics", "biomarkers", "microbiome", "microbiota", "gut")], were performed. Twenty eligible publications reported improvements in blood lipid profile, blood pressure, and inflammation biomarkers, as well as in body composition, resulting from pulse daily amounts of 150 g (minimum–maximum: 54–360 g/day; cooked). No treatment-related adverse effects were noted.

Sievenpiper et al. (2009) conducted a systematic review and meta-analyses of randomized, controlled experimental trials of non-oil-seed pulses (including chickpeas) in diabetic and non-diabetic subjects. Similar to Ferreira et al. (2021), the authors searched Medline, EmBase, Cinahl, and the Cochrane Library for relevant controlled trials of ≥7 days. Data were pooled using the generic inverse variance method and expressed as standardized mean differences (SMDs) with 95% confidence intervals. Heterogeneity was assessed by X^2 and quantified by I^2. Meta-regression models identified independent predictors of effects. A total of 41 trials were included and demonstrated that pulses alone (11 trials) lowered fasting blood glucose (FBG) (–0.82, 95% CI = –1.36 to –0.27) and insulin (–0.49, 95% CI = –0.93 to –0.04). Pulses in low-glycemic index diets (19 trials) lowered glycosylated blood proteins (GP), measured as HbA1c or fructosamine (–0.28, 95% CI = -0.42 to –0.14). Finally, pulses in high-fiber diets (11 trials) lowered FBG (–0.32, 95% CI = -0.49 to –0.15) and GP (–0.27, 95% CI = -0.45 to –0.09). Inter-study heterogeneity was high and unexplained for most outcomes, with benefits modified or predicted by diabetes status, pulse type, dose, physical form, duration of follow-up, study quality, macronutrient profile of background diets, feeding control, and design. The authors concluded that their pooled analyses demonstrated that pulses, alone or in low-GI or high-fiber diets, improve markers of longer-term glycemic control in humans, with the extent of the improvements subject to significant interstudy heterogeneity. No treatment-related adverse effects were noted.

Anti-Nutritional Components

It has been recognized that chickpeas, like other legumes, contain "anti-nutritional" compounds. As noted previously, those discussed most often are protease inhibitors, amylase inhibitors, phytolectins, and oligosaccharides (e.g., stachyose, raffinose). Large intakes of anti-nutritional components can impair the digestion process. In contrast, they are also known to have beneficial effects on human health (Gupta et al., 2017).

These components are neutralized efficiently by various processing methods such as soaking, thermal treatment (cooking or boiling), and autoclaving. The levels of lectin, phytic acid, raffinose, stachyose, verbascose (a pentasaccharide that is stachiose which has an additional unit of alpha-D-galactopyranose attached by a 1->6 glycosidic linkage to the terminal galactosyl residue), tannins, total polyphenols, and trypsin inhibitor activity in the chickpea protein product have been measured, and the analytical results can be found in Appendix A.

Allergy

Numerous authors have discussed the cross-reactivity of legumes, including chickpeas, and the occurrence of allergic reactions in sensitive individuals, especially in areas of higher consumption such as Spain and India (Cox et al., 2021; Gupta et al., 2017; Hildebrand et al., 2021; Verma et al., 2013).

Chan et al. (2019) reported one case of a 7-year-old boy with a diagnosed peanut allergy during infancy who developed an itchy throat following consumption of soy milk and chickpeas. The authors stressed the need to manage the cross-reactivity of individuals with peanut allergy.

Hildebrand et al. (2021) summarized the following studies that assessed the prevalence of allergy to chickpeas, peas, lentils, and lupine. In a study by Dey et al. (2014, as cited in Hildebrand et al., 2021) of 3161 participants, the prevalence rate to chickpea was 7.7% in <15-year-old subjects, 8.0% in 15- to 40-year-old subjects, and 5.5% in those participants older than 40 years. Crespo et al. (1995, as cited in Hildebrand et al., 2021) studied 355 children and reported that 3.9% were allergic to chickpeas. Kilic and Taskin (2015, as cited in Hildebrand et al., 2021) also studied children (n=186) and reported that 2.3% were allergic to chickpeas. In two smaller studies, San Ireno et al. (2008, as cited in Hildebrand et al., 2021) reported that, of 54 children with known legume allergy, 59% were allergic to chickpeas. Also, Wells and Chambers (2017, as cited in Hildebrand et al., 2021) reported that 72% of parents (n=50) of toddlers with legume allergy said their children were allergic to chickpeas. Yavuz et al. (2011, as cited in Hildebrand et al., 2021) studied 315 children with IgE-mediated food allergy and reported a prevalence of 2.5%.

Gupta et al. (2017) have described the mechanistic aspects of IgE-mediated allergy to chickpeas. The allergic reactions and anaphylactic symptoms induced by chickpea allergens are found to be associated with IgE and IgG antibodies, suggesting that the allergic symptoms appear via IgE-, as well as IgG-mediated allergic reactions. The authors reported that, like many food allergens, exposure to 100 μg of chickpea crude protein extract induced a mixed cytokine (Th1/Th2) response as higher levels of Th1 and Th2 cytokines (IL-4, IL-6, IL-10, TNF-α, and IFN-γ), as well as IL-17, were found in splenocyte supernatant. Therefore, the inflammatory cytokines may trigger and aggravate the chickpea allergy and related inflammatory responses. Secondary exposure to CP allergens induces cross-linking of IgE bound to mast cells/basophils and resulted in the release of various allergic mediators such as histamine, mouse mast cell protease (MMCP−1), hexosaminidase, leukotrienes, and prostaglandin D2. In summary, CP allergens have the potential to elicit allergic responses using a multidimensional mechanism.

The potential for chickpea proteins to cause an immune response is relatively rare but consistent with similar, known allergies to other legumes. Although chickpeas are not listed as one of the major allergen groups by the FDA under the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II)), the fact that the allergenicity of chickpea protein has been shown clinically (Chan et al., 2019) and reviewed by many other researchers (Cox et al., 2021; Gupta et al., 2017; Hildebrand et al., 2021; Verma et al., 2013) suggests that labeling the presence of chickpea protein is both warranted and recommended. The Panel recommends that the ingredient labeling for the chickpea protein product clearly state that it contains "chickpea protein," and that individuals who wish to avoid chickpeas or chickpea protein consumption for any reason would be able to identify the presence of a chickpea–derived ingredient.

Other Protein-Related Safety Concerns

Protein Intake and Toxicity

IOM recommends that adults not consume more than twice the 0.8-g/kg protein RDA per day. The RDAs for various age groups and gender are presented in Table 12 below. However, physically active persons on normal diets easily exceed this level, and individuals involved in bodybuilding ingest much higher levels of protein (WHO, 2002). WHO (2002) recommends body-weight-based protein consumption rates for both genders. For example, the protein consumption level for a 40-kg adult is 33 g/day, and that for an 80-kg adult is 66 g/day. While WHO has stated that no safe upper limit has been identified, they also indicated that it is unlikely that intakes of twice the safe level are associated with any risk to healthy individuals. It is important to note that the RDA is not a safety benchmark but rather a minimum nutrition-based standard.

Table 12. Recommended dietary allowances for protein (IOM, 2005)

Life stage group	Protein (grams/day)
0–6 months	9.1*
6–12 months	11.0
1–3 years	13
4–8 years	19
9–13 years (M and F)	34
14–18 years (M)	52
14–18 years (F)	46
19–30 years (M)	56
19–30 years (F)	46
31–50 years (M)	56
31–50 years (F)	46
51–70 years (M)	56
51–70 years (F)	46
>70 years (M)	56
>70 years (F)	46
Pregnancy/Lactation	
14–18 years	71
19–30 years	71
31–50 years	71

*Adequate intake

The European Food Safety Authority (EFSA) has concluded that the available data are insufficient to establish a tolerable upper intake level (UL) for protein (EFSA, 2012). However, they did indicate that consumption of protein at a level twice the Population Reference Intake (PRI) is safe, and that intakes of 3-4 times that of the PRI are not associated with adverse effects. The EFSA PRIs are 12-13 g/day for 2-3 years (female and male), 14-15 g/day for 4 years (female and male), 48-58 g/day for 17 years (female and male), and 52-62 g/day for adults 18-59 years (female and male). In all population groups, the estimated mean intake of protein from the intended uses (Table 10) is below the RDA and reference protein intake, and well below a level 3–4 times the PRI, which is identified by EFSA as a level not associated with adverse effects. The 90th percentile estimated intake of protein for children 1–3 years (approximately 29 g/day) is approximately 2x the RDA and PRI but is still considered safe, as noted above.

A recent GRN, (GRN 944; FDA 2020) summarized systematic reviews of the evidence regarding dietary protein intake in children since the IOM's review and concluded that "high protein diets in infancy and very early childhood (<2 years of life) were associated with increased BMI, but the effects of higher protein intake later in childhood on body weight status were less conclusive."

Again, it must be emphasized that the EDIs represent conservatively high estimates of intake. In calculating the EDIs, it is assumed that all foods in each proposed use category will contain the maximum intended use of chickpea protein. However, in practice, not all consumers may select products with chickpea protein for all eating occasions.

Kidney Function

Dietary protein is known to alter renal function, and increased protein intakes lead to increased excretion of urea and creatinine from an increased renal blood flow, causing a higher glomerular filtration rate. Excess protein intake has been found to advance chronic kidney disease due to the noted increase in glomerular pressure and hyperfiltration (Martin et al., 2005; WHO, 2002). However, Martin et al. (2005) state that, although protein restriction may be indicated in treatment of existing kidney disease, the existing evidence does not indicate an adverse effect of high protein consumption on renal function in healthy individuals who have consumed high-protein Western diets for centuries. In addition, studies indicate that hyperfiltration, the reported mechanism for kidney effects, is a normal adaptive response to increased demands for renal clearance due to higher nitrogen load. The intake of the chickpea protein ingredient will result in daily intake levels below those associated with effects on renal function. Individuals who have a known risk of kidney stone formation should consume the recommended safe level of protein (0.83 g/kg-day), preferably from vegetable sources, but not high levels (>1.4 g/kg/day) (WHO, 2002).

Calcium Balance/Bone Health

An excess of protein intake can adversely affect calcium balance and calcium concentration in bone. While consumers of high-protein diets are known to excrete increased amounts of urinary calcium, and doubling protein intake is known to increase urinary calcium excretion by 50%, WHO (2002) states that "the existing scientific evidence indicates that dietary protein, when consumed as part of a well-balanced diet, is likely beneficial for bone, potentially even at dietary levels exceeding the recommended consumption rates."

Summary

The proposed uses and consumption of chickpea protein in the foods specified in Part 3 do not raise concerns regarding the noted protein safety-related outcomes.

Basis for the GRAS Determination

Introduction

The regulatory framework for determining whether a substance can be considered GRAS in accordance with Section 201(s) (21 U.S.C. § 321(s)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et. Seq.) ("the Act") is set forth at 21 CFR 170.30, which states:

> General recognition of safety may be based only on the view of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.
>
> General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies, which may be corroborated by unpublished studies and other data and information.

These criteria are applied in the analysis below to determine whether the use of the chickpea protein ingredient in human food that is the subject of this GRAS determination is GRAS, based on scientific procedures. All data relied upon in this GRAS determination are publicly available and generally known, and therefore meet the "general recognition" standard under the Federal Food, Drug, and Cosmetic Act (FFDCA).

Safety Determination

The subject of this GRAS determination is the use of chickpea protein as an alternative source of dietary protein for addition to certain specified processed foods. Humans have consumed chickpeas and other legumes, as well as proteins from these sources, for centuries, along with proteins from many food sources such as meats, dairy, fruits, vegetables, nuts, and seeds. Other natural, plant-based sources of protein concentrates that have been safely consumed for years include soy, canola, potato, wheat, whey, and mung bean.

Chickpea (*C. arietinum* L.) is one of the most ancient, consumed legumes around the world. The mean protein content in chickpeas is nearly 18% (kabuli contains 18.4% [range 16.2%–22.4%]; desi contains 18.2% [range 15.6%–21.4%]), which is higher than lentils and field peas. Chickpea seeds contain a percentage of protein similar to that of legumes, beans, and soybeans, and have high bioavailability and good digestibility (48%–89%) (Juarez-Chairez et al., 2020; Chavan et al., 1986). Chickpeas are a good source of vitamins such as riboflavin, niacin, thiamin, folate, and the vitamin A precursor, β-carotene.

IOM (2005) recommends that adults consume a minimum of 0.8 g protein/kg and has set a range for acceptable protein intake of 10%–35% of daily calories. In the US, the recommended daily allowances of protein are 56 g/day and 46 g/day, for adult men and women (>19 years of age), respectively. However, it should be noted that the RDA does not represent an upper limit of consumption.

T&L proposes the use of chickpea protein in 10 food categories: bakery products (sugar free, gluten free, or high fiber); non-dairy nutritional beverages; dry-blend protein powders; meal replacement/nutritional bars; plant-based protein products/meat analogs; imitation dairy analogs (including milk alternatives, cheese, cream cheese, coffee creamer, frozen dessert, yogurt, and whipped topping); pasta products; snack foods; extruded snack products; and soups. As described in numerous GRAS Notifications, including GRN No. 386 for canola protein isolate and hydrolyzed canola protein isolate, the typical uses of protein for enrichment of foods include bakery products, snack foods, ready-to-drink beverages, soups and nutritional beverages, high-protein drinks and milkshakes, powdered nutritional/ protein beverages, nutrition bars, vegetarian food products, meat analogs, processed meat products, dairy and imitation dairy products, and meal replacements/nutrition bars.

It is reasonable to expect that most of the population's daily intake of protein will remain in the form of unprocessed foods, including meat, poultry, fish, and legumes (FDA, 2010, 2011).

The potential for chickpea protein to cause an immune response is rare but consistent with similar, known allergies to other legumes. Although chickpeas are not listed as one of the major allergen groups by the FDA under the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II)), the fact that the allergenicity of chickpeas has been shown clinically (Hildebrand et al., 2020) suggests that labeling the presence of chickpea protein is warranted and recommended. Therefore, it is recommended that the ingredient labeling for the chickpea protein product clearly state that it contains "chickpea protein," and that individuals who wish to avoid chickpeas or chickpea protein consumption for any reason would be able to identify the presence of a chickpea-derived ingredient.

General Recognition of the Safety of the Chickpea Protein Ingredient

The intended use of the chickpea protein ingredient in human food has been determined to be safe through scientific procedures set forth in 21 CFR§170.3(b), thus satisfying the so-called "technical" element of the GRAS determination, based on the following:

- Chickpea protein is manufactured from commercially available chickpeas, following current cGMP for food (21 CFR § Part 110). The raw materials and processing aids used in the manufacturing process are food grade and/or approved for use in food. The chickpea protein product has been characterized appropriately, contains a minimum of 60% protein, and meets appropriate food-grade specifications.
- Chickpeas have been consumed as food (and the protein contained therein) for centuries, along with many other food sources of protein (e.g., meats, dairy, fruits, vegetables, nuts).
- For the population ages 1 year and older, the per-user mean and 90th percentile EDIs of protein from the intended use are 14.7 and 34.7 g/day, respectively. The proposed uses of the chickpea protein ingredient will provide an alternative

to other dietary sources of protein, and the estimates of intake are comparable to estimates of protein intake concluded previously to be GRAS. A tolerable upper intake level (UL) for protein intake has not been established by IOM.

- FDA has reviewed extensive published information and data on many protein products as part of GRAS Notifications for animal and plant-based protein isolates and concentrates and subsequently issued "no objection letters." Examples include GRN No. 26 (isolated wheat protein); GRN No. 37 (whey protein isolate and dairy product solids); GRN No. 168 (poultry protein); GRN No. 182 (hydrolyzed wheat gluten isolate; pea protein isolate); GRN No. 313 (beef protein); GRN No. 314 (pork protein); GRN 386 (canola protein isolate and hydrolyzed canola protein isolate); GRN No. 447 (potato protein isolates); GRN No. 575 (oat protein); GRNs No. 58, 608, 788 (pea protein), GRN 879 (fava bean protein), and GRN 944 (rice protein hydrolysate).
- Given the long history of global human consumption of chickpeas as food (and the protein contained therein), the safety of the chickpea protein ingredient derived from them is supported by their consumption and general lack of toxicity. As would be expected for a food that has been consumed by humans for centuries, chickpeas and chickpea proteins have not been subjected to traditional toxicology studies. However, the available summarized preclinical and clinical study data support its safe use as proposed.
- Antinutritional components are known to exist in numerous foods, including chickpeas. These components are neutralized efficiently by various processing methods such as soaking, thermal treatment (cooking or boiling), and autoclaving. The levels of lectin, phytic acid, raffinose, stachyose, verbascose, tannins, total polyphenols, and trypsin inhibitor activity in the chickpea protein product have been measured, and levels are within typical levels found in common plant-based foods (Popova and Mihaylova, 2019).
- Concerns related to the allergenicity of chickpea protein can be addressed through appropriate labeling of food products as containing chickpea protein, and individuals who wish to avoid chickpea protein consumption would be able to identify the presence of a chickpea-derived ingredient.
- The body of publicly available scientific literature on the consumption and safety of chickpeas and chickpea protein is sufficient to support the safety and GRAS status of the proposed chickpea protein ingredient.

Because this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

Determination of the safety and GRAS status of the chickpea protein ingredient that is the subject of this self-determination has been made through the deliberations of a GRAS Panel of qualified experts, convened by Tate & Lyle and composed of Paul Damian, Ph.D., M.P.H., DABT, ERT, Stanley M. Tarka, Jr., Ph.D., F.A.T.S., and Thomas A. Vollmuth, Ph.D. These individuals are qualified by scientific training and experience to evaluate the safety of substances intended to be added to food. They have critically reviewed and evaluated the publicly available information summarized in this document and have individually and collectively concluded that the chickpea protein ingredient, produced in a manner consistent with cGMP and meeting the specifications described herein, is safe under its intended conditions of use. The Panel further unanimously concluded that use of the chickpea protein ingredient in specified human foods is GRAS, based on scientific procedures, and that other experts qualified to assess the safety of food and food ingredients for human consumption would concur with these conclusions. The Panel's GRAS opinion is included as Exhibit 1 to this document.

It is also Tate & Lyle's opinion that other qualified scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. Tate & Lyle has concluded that the chickpea protein ingredient is GRAS under the intended conditions of use, on the basis of scientific procedures; therefore, it is excluded from the definition of a food additive and may be marketed and sold for its intended purpose in the U.S. without the promulgation of a food additive regulation under Title 21 of the CFR.

Tate & Lyle is not aware of any information that would be inconsistent with a finding that the use of the chickpea protein ingredient in the specified foods for human consumption, meeting appropriate specifications, and used according to GMP, is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

§ 170.250 Part 7, Supporting Data and Information

References

Acevedo-Martinez KA, Yang MM, de Mejia EG. 2021. Technological properties of chickpea (Cicer arietinum): production of snacks and health benefits related to type-2 diabetes. Compr Rev Food Sci Food Saf 20:3762–2787.

Achari AE, Jain SK. 2017. Adiponectin, a therapeutic target for obesity, diabetes, and endothelial dysfuntion. Int J Mol Sci 18:1321–1336.

Boualga A, Prost J, Taleb-Senouci D, Krouf D, Kharoubi O, Lamri-Senhadj M, et al. 2009. Purified chickpea or lentil proteins impair VLDL metabolism and lipoprotein lipase activity in epididymal fat, but not in muscle, compared to casein, in growing rats. Eur J Nutr 48:162–169.

CDC (Centers for Disease Control and Prevention), NCHS (National Center for Health Statistics). 2018. National Health and Nutrition Examination Survey Data 2015–2016. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.
https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx?BeginYear=2015.

CDC (Centers for Disease Control and Prevention), NCHS (National Center for Health Statistics). 2020. National Health and Nutrition Examination Survey Data 20172018. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.
https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx?BeginYear=2017.

Chan ES, Greenhawt MJ, Fleischer DM, Cauber J-C. 2019. Managing cross-reactivity in those with peanut allergy. J Allergy Clin Immunol Pract 7(2): 381–386.

Chavan JK, Kadam SS, Salunkhe DK, Beuchat LR. 1987. Biochemistry and technology of chickpea (Cicer arietinum L.) seeds. Crit Rev Food Sci Nutr 25(2):107–158, DOI: 10.1080/10408398709527449

Cox AL, Eigenmann PA, Sicherer. 2021. Clinical relevance of cross-reactivity in food allergy. J Allergy Clin Immunol Pract 9(1):82–99.

Crujeiras AB, Parra D, Abete I, Martinez JA. 2007. A hypocaloric diet enriched in legumes specifically mitigates lipid peroxidation in obese subjects. Free Radical Res 41(4):498–506, DOI: 10.1080/10715760601131935.

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies). 2012. Scientific opinion on dietary reference values for protein. EFSA Journal 10(2):2557, 66 pp, doi:10.2903/j.efsa.2012.2557.

Ferreira H, Vasconcelos M, Gil AM, Pinto E. 2021. Benefits of pulse consumption on metabolism and health: a systematic review of randomized controlled trials. Crit Rev Food Sci Nutr 61(1):1–3.

Food and Drug Administration (US FDA). 2010. GRN No. 327. GRAS Notification for cruciferin-rich canola/rapeseed and napin-rich canola/rapeseed protein isolate.

Food and Drug Administration (US FDA). 2011. GRN No. 386. GRAS Assessment of canola protein isolate and hydrolyzed canola protein isolate.

FDA (US Food and Drug Administration). 2020. GRN 944. GRAS assessment of rice protein hydrolysate.

Gupta RK, Gupta K, Sharma A, Das M, Ansari IA, Dwivedi PD. 2017. Health risks and benefits of chickpea (Cicer arietinum) consumption. J Agric Food Chem 65:6–22.

Hildebrand HV, Aries A, Simons E, Gerdts J, Povolo B, Rothney J, Protudjer JLP. 2021. Adult and pediatric food allergy to chickpea, pea, lentil, and lupine: A scoping review. J Allergy Clin Immunol Pract 9:290–301.

IOM (Institute of Medicine of the National Academies). 2005. Dietary, functional and total fiber. Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids. National Academies Press, Washington DC.

Juarez-Chairez MF, Cid-Gallegos MS, Meza-Marquez OG, Jimenez-Martinez C. 2020. Biological activities of chickpea in human health. Plant Foods Hum Nutr 75:142–153.

Jukanti A, Gaur PM, Gowda CL, Chibbar R. 2012. Nutritional quality and health benefits of chickpea (Cicer arietinum L.): A review. Br J Nutr 108(S1):S11–S26.

Madurapperumage A, Tang L, Thavarajah P, Bridges W, Shipe E, Vandemark G, Thavarajah D. 2021. Chickpea (Cicer arietinum) as a source of essential fatty acids – a biofortification approach. Front Plant Sci 12:734980.

Martin WF, Armstrong LE, Rodriguez NR. 2005. Dietary protein intake and renal function. Nutr Metab (Lond) 2(25,. doi:10.1186/1743-7075-2-25.

Mirmiran P, Hisseini S, Hosseinpour-Niazi S, Azizi F. 2019. Legume consumption increase adiponectin concentrations among type 2 diabetic patients: A randomized crossover clinical trial. Endocrinol Diabetes Nutr 66(1):49–55.

Morts ME, Silva I. 2019. PSIII-38 pepsin-pancreatin protein digestibility of various protein sources intended for pet food. J An Sci 97(Suppl 3):282.

Nestel P, Cehun M, Chronopoulos A. 2004. Effects of long-term consumption and single meals of chickpeas on plasma glucose, insulin, and triacylglycerol concentrations. Am J Clin Nutr 79:390–395.

Pittaway J, Ahuja KDK. 2006. Dietary supplementation with chickpeas for at least 5 weeks results in small but significant reductions in serum total and low-density lipoprotein cholesterols in adult women and men. Ann Nutr Metab 50:512–518.

Pittaway JK, Robertson IK, Ball MJ. 2008. Chickpeas may influence fatty acid and fiber intake in an ad libitum diet, leading to small improvements in serum lipid profile and glycemic control. J Am Diet Assoc 108:1009–1013.

Popova A, Mihaylova D. 2019. Antinutrients in plant-based foods: as review. The Open Biotechnology Journal 13:68-76.

Sievenpiper JL, Kendall CWC, Esfahani A, Wong JMW, Carleton AJ, Jiang HY, et al. 2009. Effect of non-oil-seed pulses on glycaemic control: A systematic review and meta-analysis of randomised controlled experimental trials in people with and without diabetes. Diabetologia 52:1479–1495.

Shevkani K, Singh N, chen Y, Kaur A. 2019. Pulse proteins: secondary structure, functionality and applications. J Food Sci Technol 56(6):2787–2798.

USDA (U.S. Department of Agriculture). 2018. USDA Food and Nutrient Database for Dietary Studies (FNDDS), 2015–2016. Beltsville, MD: US Department of Agriculture, Agricultural Research Service, Food Surveys Research Group. http://www.ars.usda.gov/ba/bhnrc/fsrg.

U.S. Department of Agriculture (USDA). 2020. USDA Food and Nutrient Database for Dietary Studies (FNDDS), 2017-2018. Beltsville, MD: US Department of Agriculture, Agricultural Research Service, Food Surveys Research Group. http://www.ars.usda.gov/ba/bhnrc/fsrg.

Verma AK, Kumar S, Das M, Dwivedi PD. 2013. A comprehensive review of legume allergy. Clinic Rev Allerg Immunol 45(1):30–46.

Wallace TC, Murray R, Zelman KM. 2016. The nutritional value and health benefits of chickpeas and hummus. Nutrients 8:766.

Wang YHA, McIntosh GH. 1996. Extrusion and boiling improve rat body weight gain and plasma cholesterol lowering ability of peas and chickpeas. J Nutr 126:3054–3062.

WHO (World Health Organization). 2002. Technical report series 935: Protein and amino acid requirements in human nutrition. Report of a Joint WHO/FAO/UNU Expert Consultation.

Yang Y, Zhou L, Gu Y, Zhang Y, Tang J, Li F, et al. 2007. Dietary chickpeas reverse visceral adiposity, dyslipidemia and insulin resistance in rats induced by a chronic high-fat diet. Br J Nutr 98:720–726.

APPENDIX A

Certificates of Analysis and Other Analytical Data

NUTRIATI
Nutrition . Taste . Wellness

NUTRITIONAL INFORMATION

Company Name: Nutriati, Inc.

Product Name: Artesa Chickpea Protein, 100-P-1

Nutrient	Amount	Units	Calculated or Analyzed
Moisture	4.17	**g/100g**	A
Ash	5.04	**g/100g**	A
Calories (Energy)	373.91	**Kcal/100g**	C (4-4-9)
Calories from Saturated Fat	3.16	*Kcal/100g*	C
Total Fat	2.15	**g/100g**	A
Saturated Fat	0.351	**g/100g**	A
Trans Fat	0	**g/100g**	A
Polyunsaturated Fat	1.19	*g/100g*	A
Monounsaturated Fat	0.514	*g/100g*	A
Cholesterol	0	**mg/100g**	A
Sodium	11.4	**mg/100g**	A
Fluoride		*mg/100g*	
Total Carbohydrate**	29.44	**g/100g**	C
Dietary Fiber*	14.0	**g/100g**	A
Soluble Fiber	0	*g/100g*	A
Insoluble Fiber	14.0	*g/100g*	A
Total Sugars	2.4	**g/100g**	A
Added Sugars	0	**g/100g**	
Sugar Alcohol	0	*g/100g*	
Protein	61.0	**g/100g**	A
Vitamin D	0	**mcg/100g**	A
Calcium	66.8	**mg/100g**	A
Iron	9.02	**mg/100g**	A
Potassium	1880	**mg/100g**	A
Vitamin A	0	*mcg(RAE)/100g*	A (as beta carotene)
Vitamin C (Ascorbic acid)		*mg/100g*	
Vitamin E		*mg/100g*	
Vitamin K		*mcg/100g*	

NUTRIATI
Nutrition . Taste . Wellness

Thiamin Vitamin (B_1)		*mg/100g*	
Riboflavin (Vitamin B2)		*mg/100g*	
Niacin		*mg(NE)/100g*	
Vitamin B6		*mg/100g*	
Folate (Folic acid or Folacin)	337	*mcg(DFE)/100g*	A
Vitamin B12		*mcg/100g*	
Biotin		*mcg/100g*	
Pantothenic acid		*mg/100g*	
Phosphorus	992	*mg/100g*	A
Iodine		*mcg/100g*	
Magnesium	343	*mg/100g*	A
Zinc	7.24	*mg/100g*	A

Note: All nutrients in **BOLD** type must have a value assigned in the Amount column

Total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrates, dietary fiber, sugars, protein, vitamin D, potassium, calcium, and iron must be listed when they are present in measurable amounts. A measurable amount is an amount that exceeds the amount that can be declared as "zero" in the nutrition label of conventional foods, as specified in 21 CFR 101.9(c).

Nutrients with a Recommended Daily Intake (RDI) that are less than 2% of the Daily Values (DV) are not required to be listed.

artesa
CHICKPEA PROTEIN

In-Vitro Amino Acid Profile

Artesa™Chickpea Protein, 100-P-1

Amino Acid	AA Conc. (g/100g sample)*
Aspartic Acid/Asparagine	6.15
Threonine**	1.78
Serine	2.46
GlutamicAcid/Glutamate	8.32
Proline	2.18
Glycine	1.93
Alanine	2.11
Cystine + Methionine**	1.69
Valine**	2.31
Isoleucine**	2.32
Leucine**	3.98
Tyrosine + Phenylalanine**	4.63
Histidine**	1.36
Lysine**	3.56
Arginine	5.10
Tryptophan**	0.56
PDCAAS	0.83

In Vitro Digestibility: 0.92
Amino Acid score: 0.904*
PDCAAS: 0.83*
First limiting amino acid: Tryptophan*

*Results reported as hydrated amino acids per *In-Vitro* PDCAAS analysis; test method uses 1991 reference standard
**Essential amino acids
PLEASE NOTE: THESE RESULTS ARE ONLY RECOMMENDED FOR PURPOSES OF RESEARCH & PRODUCT DEVELOPMENT

Revision 5 3/21/2019-TS

Nutriati, Inc.
9722 Gayton Rd., Henrico, VA
23238

NUTRIATI

NUTRIATI
Nutrition · Taste · Wellness

artesa

Certificate of Analysis: Artesa® **Chickpea Protein**

Part of Plant: Seed
Product Code: 100-P-1
Family Name: Fabaceae
Botanical Name: Cicer arietinum
Ingredient Declaration: Chickpea Protein

Lot: A60-235-21
DOM: 08/23/21
Expires: 08/22/23
Package: 20 kg bag
Shelf life: 2 years from DOM

Product Description: white in color, free flowing powder; typical particle size 8-11 micron, typical solubility >90%.

PHYSICAL ATTIBUTES:			
Attribute	**Target**	**Result**	**Method**
Total Protein	Min. 60% dry basis	60.3 %	DUMAS: AOAC 990.03;2000
Moisture	<10%	5.6 %	LOD: AOAC 930.15
Botanical ID	Complies	Complies **	USP Compliant

MICROBIOLOGICAL REPORT:			
Analysis	**Target**	**Result**	**Method**
Aerobic plate count	<50,000 cfu/g	340 cfu/g	FDA BAM: AOAC 996.23
Yeast	<100 cfu/g	<10 cfu/g	Petrifilm: AOAC 2014.05
Mold	<100 cfu/g	<10 cfu/g	Petrifilm: AOAC 2014.05
Total coliforms	<10 cfu/g	<10 cfu/g	FDA BAM: 8th Edition Ch.4
E. coli	<10 cfu/g	<10 cfu/g	FDA BAM: 8th Edition Ch.4
Salmonella	Negative /375g	Negative /375g	FDA BAM: 8th Edition Ch.5
Staph. aureus	<10 cfu/g	<10 cfu/g	FDA BAM: 8th Edition Ch.12

CHEMICAL ANALYSIS:			
Analysis	**Limit**	**Result**	**Method**
Arsenic	<250 ppb	<10 ppb**	ICP-MS: AOAC 2013.06
Lead	<50 ppb	<5 ppb**	ICP-MS: AOAC 2013.06
Mercury	<50 ppb	<5 ppb**	ICP-MS: AOAC 2013.06
Cadmium	<50 ppb	<5 ppb**	ICP-MS: AOAC 2013.06
Pesticides	<MRL per USP 565	<MRL **	FDA BAM: 302 E7C6 Modified
Gliadin	<10 ppm	<10 ppm***	Neogen Veratox

Manufactured By: Custom Processing Services: 2 Birchmont Drive, Reading, PA 19606
Storage Conditions: Store in a cool and dry place away from odorous materials below 25°C
** Testing is performed on raw material
***Gluten testing is performed according to GFCO requirements

NUTRIATI
Nutrition · Taste · Wellness

artesa

Certificate of Analysis: Artesa® Chickpea Protein

Part of Plant: Seed
Product Code: 100-P-1
Family Name: Fabaceae
Botanical Name: Cicer arietinum
Ingredient Declaration: Chickpea Protein

Lot: A60-245-21
DOM: 09/02/21
Expires: 09/01/23
Package: 20 kg bag
Shelf life: 2 years from DOM

Product Description: white in color, free flowing powder; typical particle size 8-11 micron, typical solubility >90%.

PHYSICAL ATTIBUTES:			
Attribute	**Target**	**Result**	**Method**
Total Protein	Min. 60% dry basis	60.7 %	DUMAS: AOAC 990.03;2000
Moisture	<10%	6.1 %	LOD: AOAC 930.15
Botanical ID	Complies	Complies **	USP Compliant

MICROBIOLOGICAL REPORT:			
Analysis	**Target**	**Result**	**Method**
Aerobic plate count	<50,000 cfu/g	870 cfu/g	FDA BAM: AOAC 996.23
Yeast	<100 cfu/g	<10 cfu/g	Petrifilm: AOAC 2014.05
Mold	<100 cfu/g	<10 cfu/g	Petrifilm: AOAC 2014.05
Total coliforms	<10 cfu/g	<10 cfu/g	FDA BAM: 8th Edition Ch.4
E. coli	<10 cfu/g	<10 cfu/g	FDA BAM: 8th Edition Ch.4
Salmonella	Negative /375g	Negative /375g	FDA BAM: 8th Edition Ch.5
Staph. aureus	<10 cfu/g	<10 cfu/g	FDA BAM: 8th Edition Ch.12

CHEMICAL ANALYSIS:			
Analysis	**Limit**	**Result**	**Method**
Arsenic	<250 ppb	<10 ppb**	ICP-MS: AOAC 2013.06
Lead	<50 ppb	<5 ppb**	ICP-MS: AOAC 2013.06
Mercury	<50 ppb	<5 ppb**	ICP-MS: AOAC 2013.06
Cadmium	<50 ppb	<5 ppb**	ICP-MS: AOAC 2013.06
Pesticides	<MRL per USP 565	<MRL **	FDA BAM: 302 E7C6 Modified
Gliadin	<10 ppm	<10 ppm***	Neogen Veratox

Manufactured By: Custom Processing Services: 2 Birchmont Drive, Reading, PA 19606
Storage Conditions: Store in a cool and dry place away from odorous materials below 25°C
** Testing is performed on raw material
***Gluten testing is performed according to GFCO requirements

NUTRIATI
Nutrition · Taste · Wellness

artesa

Certificate of Analysis: Artesa® **Chickpea Protein**

Part of Plant: Seed
Product Code: 100-P-1
Family Name: Fabaceae
Botanical Name: Cicer arietinum
Ingredient Declaration: Chickpea Protein

Lot: A60-240-21
DOM: 08/28/21
Expires: 08/27/23
Package: 20 kg bag
Shelf life: 2 years from DOM

Product Description: white in color, free flowing powder; typical particle size 8-11 micron, typical solubility >90%.

PHYSICAL ATTIBUTES:			
Attribute	**Target**	**Result**	**Method**
Total Protein	Min. 60% dry basis	60.8 %	DUMAS: AOAC 990.03;2000
Moisture	<10%	5.8 %	LOD: AOAC 930.15
Botanical ID	Complies	Complies **	USP Compliant

MICROBIOLOGICAL REPORT:			
Analysis	**Target**	**Result**	**Method**
Aerobic plate count	<50,000 cfu/g	5,200 cfu/g	FDA BAM: AOAC 996.23
Yeast	<100 cfu/g	<10 cfu/g	Petrifilm: AOAC 2014.05
Mold	<100 cfu/g	<10 cfu/g	Petrifilm: AOAC 2014.05
Total coliforms	<10 cfu/g	<10 cfu/g	FDA BAM: 8th Edition Ch.4
E. coli	<10 cfu/g	<10 cfu/g	FDA BAM: 8th Edition Ch.4
Salmonella	Negative /375g	Negative /375g	FDA BAM: 8th Edition Ch.5
Staph. aureus	<10 cfu/g	<10 cfu/g	FDA BAM: 8th Edition Ch.12

CHEMICAL ANALYSIS:			
Analysis	**Limit**	**Result**	**Method**
Arsenic	<250 ppb	<10 ppb**	ICP-MS: AOAC 2013.06
Lead	<50 ppb	<5 ppb**	ICP-MS: AOAC 2013.06
Mercury	<50 ppb	<5 ppb**	ICP-MS: AOAC 2013.06
Cadmium	<50 ppb	<5 ppb**	ICP-MS: AOAC 2013.06
Pesticides	<MRL per USP 565	<MRL **	FDA BAM: 302 E7C6 Modified
Gliadin	<10 ppm	<10 ppm***	Neogen Veratox

Manufactured By: Custom Processing Services: 2 Birchmont Drive, Reading, PA 19606
Storage Conditions: Store in a cool and dry place away from odorous materials below 25°C
** Testing is performed on raw material
***Gluten testing is performed according to GFCO requirements

eurofins Food Integrity & Innovation

Report Number:	**2870233-0**
Report Date:	**12-May-2020**
Report Status:	**Final**

Certificate of Analysis

Nutriati, Inc.
9722 Gayton Road
Henrico Virginia 23238

Sample Name:	**Artesa Chickpea Protein A60-PB**	**Eurofins Sample:**	**9498515**
Project ID	NUTRIATI-20200506-0003	**Receipt Date**	06-May-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Sample Serving Size		**Login Date**	06-May-2020
Description	A60P200428	**Date Started**	07-May-2020
		Sampled	Sample results apply as received

Analysis	Limit	Result
Mycotoxins in Raw Materials		
Aflatoxin B1		<0.500 ppb
Aflatoxin B2		<0.500 ng/g
Aflatoxin G1		<0.500 ng/g
Aflatoxin G2		<0.500 ng/g
Aflatoxin M1		<0.500 ng/g
Aflatoxin M2		<0.500 ng/g
Deoxynivalenol		<100 ng/g
T-2 Toxin		<10.0 ng/g
HT-2 Toxin		<100 ng/g
Fumonisin B1		<25.0 ng/g
Fumonisin B2		<25.0 ng/g
Ochratoxin A		<1.00 ppb
Zearalenone		<30.0 ng/g
Sum of B1 B2 G1 and G2		<2.00 ppb

Method References — **Testing Location**

Mycotoxins in Raw Materials (MYCO_REG_S) — **Food Integrity Innovation-Madison**, 3301 Kinsman Blvd Madison, WI 53704 USA

Varga, E., Glauner, T., Koppen, R., Mayer, K., Sulyok, M., Schumacher, R., Krska, R. and Berthiller, F., "Stable isotope dilution assay for the accurate determination of mycotoxins in maize by UHPLC-MS/MS," Analytical and BioAnalytical Chemistry, 402:2675-2686 (2012).

Testing Location(s) — **Released on Behalf of Eurofins by**

Food Integrity Innovation-Madison — **Edward Ladwig - Director**

Eurofins Food Chemistry Testing Madison, Inc.
3301 Kinsman Blvd
Madison WI 53704
800-675-8375

ilac-MRA A2LA ACCREDITED 2918.01

eurofins

Food Integrity
& Innovation

Report Number: 2870233-0
Report Date: 12-May-2020
Report Status: Final

Certificate of Analysis

Nutriati, Inc.
9722 Gayton Road
Henrico Virginia 23238

eurofins | Food Integrity & Innovation

Report Number:	**2870234-0**
Report Date:	**12-May-2020**
Report Status:	**Final**

Certificate of Analysis

Nutriati, Inc.
9722 Gayton Road
Henrico Virginia 23238

Sample Name:	**Artesa Chickpea Protein A60-PB**	**Eurofins Sample:**	**9498516**
Project ID	NUTRIATI-20200506-0003	**Receipt Date**	06-May-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Sample Serving Size		**Login Date**	06-May-2020
Description	A60P200429	**Date Started**	07-May-2020
		Sampled	Sample results apply as received

Analysis	**Limit**	**Result**
Mycotoxins in Raw Materials		
Aflatoxin B1		<0.500 ppb
Aflatoxin B2		<0.500 ng/g
Aflatoxin G1		<0.500 ng/g
Aflatoxin G2		<0.500 ng/g
Aflatoxin M1		<0.500 ng/g
Aflatoxin M2		<0.500 ng/g
Deoxynivalenol		<100 ng/g
T-2 Toxin		<10.0 ng/g
HT-2 Toxin		<100 ng/g
Fumonisin B1		<25.0 ng/g
Fumonisin B2		<25.0 ng/g
Ochratoxin A		<1.00 ppb
Zearalenone		<30.0 ng/g
Sum of B1 B2 G1 and G2		<2.00 ppb

Method References	**Testing Location**
Mycotoxins in Raw Materials (MYCO_REG_S)	**Food Integrity Innovation-Madison** 3301 Kinsman Blvd Madison, WI 53704 USA

Varga, E., Glauner, T., Koppen, R., Mayer, K., Sulyok, M., Schumacher, R., Krska, R. and Berthiller, F., "Stable isotope dilution assay for the accurate determination of mycotoxins in maize by UHPLC-MS/MS," Analytical and BioAnalytical Chemistry, 402:2675-2686 (2012).

Testing Location(s)	**Released on Behalf of Eurofins by**
Food Integrity Innovation-Madison	**Edward Ladwig - Director**

Eurofins Food Chemistry Testing Madison, Inc.
3301 Kinsman Blvd
Madison WI 53704
800-675-8375

ilac-MRA A2LA ACCREDITED
2918.01

eurofins | Food Integrity & Innovation

Report Number: 2870234-0
Report Date: 12-May-2020
Report Status: Final

Certificate of Analysis

Nutriati, Inc.
9722 Gayton Road
Henrico Virginia 23238

These results apply only to the items tested. This certificate of analysis shall not be reproduced, except in its entirety, without the written approval of Eurofins.

eurofins Food Integrity & Innovation

Report Number:	2870235-0
Report Date:	12-May-2020
Report Status:	Final

Certificate of Analysis

Nutriati, Inc.
9722 Gayton Road
Henrico Virginia 23238

Sample Name:	Artesa Chickpea Protein A60-PB	Eurofins Sample:	9498517
Project ID	NUTRIATI-20200506-0003	Receipt Date	06-May-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Sample Serving Size		Login Date	06-May-2020
Description	A60P200430	Date Started	07-May-2020
		Sampled	Sample results apply as received

Analysis	Limit	Result
Mycotoxins in Raw Materials		
Aflatoxin B1		<0.500 ppb
Aflatoxin B2		<0.500 ng/g
Aflatoxin G1		<0.500 ng/g
Aflatoxin G2		<0.500 ng/g
Aflatoxin M1		<0.500 ng/g
Aflatoxin M2		<0.500 ng/g
Deoxynivalenol		<100 ng/g
T-2 Toxin		<10.0 ng/g
HT-2 Toxin		<100 ng/g
Fumonisin B1		<25.0 ng/g
Fumonisin B2		<25.0 ng/g
Ochratoxin A		<1.00 ppb
Zearalenone		<30.0 ng/g
Sum of B1 B2 G1 and G2		<2.00 ppb

Method References — **Testing Location**

Mycotoxins in Raw Materials (MYCO_REG_S) — **Food Integrity Innovation-Madison**, 3301 Kinsman Blvd Madison, WI 53704 USA

Varga, E., Glauner, T., Koppen, R., Mayer, K., Sulyok, M., Schumacher, R., Krska, R. and Berthiller, F., "Stable isotope dilution assay for the accurate determination of mycotoxins in maize by UHPLC-MS/MS," Analytical and BioAnalytical Chemistry, 402:2675-2686 (2012).

Testing Location(s) — **Released on Behalf of Eurofins by**

Food Integrity Innovation-Madison — **Edward Ladwig - Director**

Eurofins Food Chemistry Testing Madison, Inc.
3301 Kinsman Blvd
Madison WI 53704
800-675-8375

ilac-MRA A2LA ACCREDITED
2918.01

eurofins | Food Integrity & Innovation

Report Number: 2870235-0
Report Date: 12-May-2020
Report Status: Final

Certificate of Analysis

Nutriati, Inc.
9722 Gayton Road
Henrico Virginia 23238

eurofins | Food Integrity & Innovation

Report Number:	**3525419-0**
Report Date:	**07-Jan-2022**
Report Status:	**Final**

Certificate of Analysis

Nutriati, Inc.
9722 Gayton Road
Henrico Virginia 23238

Sample Name:	**Artesa Chickpea Protein**	**Eurofins Sample:**	**11289212**
Project ID	NUTRIATI-20211227-0002	**Receipt Date**	23-Dec-2021
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	A60-251-19	**Login Date**	27-Dec-2021
		Date Started	05-Jan-2022
		Sampled	Sample results apply as received

Analysis	**Result**
Residual Ethanol and Methanol	
Methanol	40.9 ppm
Ethanol	86.2 ppm
Isopropanol	<10.0 ppm

Method References	**Testing Location**
Residual Ethanol and Methanol (ETME_S)	**Food Integrity Innovation-Madison** 6304 Ronald Reagan Ave Madison, WI 53704 USA
Internally Developed Method	

Testing Location(s)	**Released on Behalf of Eurofins by**
Food Integrity Innovation-Madison	**Edward Ladwig - President Eurofins Food Chemistry Testing Madison**

Eurofins Food Chemistry Testing Madison, Inc.
6304 Ronald Reagan Ave
Madison WI 53704
800-675-8375

These results apply only to the items tested. This certificate of analysis shall not be reproduced, except in its entirety, without the written approval of Eurofins. Measurement uncertainty for individual analyses can be obtained upon request.

eurofins Food Integrity & Innovation

Report Number:	**3524367-0**
Report Date:	**06-Jan-2022**
Report Status:	**Final**

Certificate of Analysis

Nutriati, Inc.
9722 Gayton Road
Henrico Virginia 23238

Sample Name:	**Artesa Chickpea Protein**	**Eurofins Sample:**	**11289211**
Project ID	NUTRIATI-20211227-0002	**Receipt Date**	23-Dec-2021
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	A60-173-19	**Login Date**	27-Dec-2021
		Date Started	05-Jan-2022
		Sampled	Sample results apply as received

Analysis	**Result**
Residual Ethanol and Methanol	
Methanol	45.4 ppm
Ethanol	95.2 ppm
Isopropanol	<10.0 ppm

Method References	**Testing Location**
Residual Ethanol and Methanol (ETME_S)	**Food Integrity Innovation-Madison** 6304 Ronald Reagan Ave Madison, WI 53704 USA
Internally Developed Method	

Testing Location(s)	**Released on Behalf of Eurofins by**
Food Integrity Innovation-Madison	**Edward Ladwig - President Eurofins Food Chemistry Testing Madison**

Eurofins Food Chemistry Testing Madison, Inc.
6304 Ronald Reagan Ave
Madison WI 53704
800-675-8375

eurofins | Food Integrity & Innovation

Report Number:	**3524366-0**
Report Date:	**06-Jan-2022**
Report Status:	**Final**

Certificate of Analysis

Nutriati, Inc.
9722 Gayton Road
Henrico Virginia 23238

Sample Name:	**Artesa Chickpea Protein**	**Eurofins Sample:**	**11289210**
Project ID	NUTRIATI-20211227-0002	**Receipt Date**	23-Dec-2021
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	A60-331-19	**Login Date**	27-Dec-2021
		Date Started	05-Jan-2022
		Sampled	Sample results apply as received

Analysis	**Result**
Residual Ethanol and Methanol	
Methanol	30.8 ppm
Ethanol	146 ppm
Isopropanol	<10.0 ppm

Method References	**Testing Location**
Residual Ethanol and Methanol (ETME_S)	**Food Integrity Innovation-Madison** 6304 Ronald Reagan Ave Madison, WI 53704 USA
Internally Developed Method	

Testing Location(s)	**Released on Behalf of Eurofins by**
Food Integrity Innovation-Madison	**Edward Ladwig - President Eurofins Food Chemistry Testing Madison**

Eurofins Food Chemistry Testing Madison, Inc.
6304 Ronald Reagan Ave
Madison WI 53704
800-675-8375

Medallion Labs

www.medallionlabs.com 800-245-5615 info@medlabs.com

Order Number:	**2022-002169**	Completed Date:	21-Mar-2022
		Submitted Date:	02-Mar-2022
Submitter:	Zheng You		
Company:	Tate & Lyle		
Company Address:	5450 Prarie Stone Pkwy		
	Hoffman Estates, IL 60192		
Results Email:	zheng.you@tateandlyle.com		
Invoice Email:	annette.evans@tateandlyle.com		
Purchase Order:	CC		

Medallion Labs

www.medallionlabs.com 800-245-5615 info@medlabs.com

Order # Sample ID:	2022-002169-01	Company:	Tate & Lyle
Customer Sample ID:	Chickpea protein 1		Tate and Lyle Solutions USA LLC
Sample Description:	Chickpea protein Lot A60-40-21		

Analytical Testing

Method:	Component:	Result:	Test Date:
[1,2] Lectin	Lectin	<0.05 mg/g	18-Mar-2022
[2] Phytic Acid	Phytic Acid	1.89 g/100 g	18-Mar-2022
[1,2] Raffinose, Stachyose, Verbascose	Raffinose	14.3320 g/kg	18-Mar-2022
	Stachyose	46.4580 g/kg	18-Mar-2022
	Verbascose	0.5450 g/kg	18-Mar-2022
[1,2] Tannins	Tannins	0.160 %	18-Mar-2022
[2] Total Polyphenols	Total Polyphenols	316 mg/kg	18-Mar-2022
[2] Trypsin Inhibitor Activity	Trypsin Inhibitor Activity	93466 TIU/g	08-Mar-2022

Results Approved By: Jamie Reese
(Authorized Reviewer)

Medallion Labs maintains A2LA accreditation to ISO/IEC 17025 for the specific tests listed in certificates # 2769.01 and 2769.02.
Medallion Labs' services, including this report, are provided subject to all provisions of Medallion's Standard Terms and Conditions, a copy of which appears at www.medallionlabs.com. Unless otherwise noted above, samples were received in acceptable condition and analyzed as received.

[1] This analysis is performed by a partner lab.

[2] This test is not considered in-scope of our current A2LA accreditation. For a listing of in-scope tests, please visit www.medallionlabs.com.

Analytical Method References:

Method Name	Method Reference
Lectin	Please contact for Method Details
Phytic Acid	Megazyme K-PHYT 12/12*
Raffinose, Stachyose, Verbascose	Please contact for Method Details
Tannins	Please contact for Method Details
Total Polyphenols	Miletic et al (2012) Phenolic Content of Plum AJCS 6 (4) 681-687*
Trypsin Inhibitor Activity	AACC 71-10*

* This method has been modified.

[1] This analysis is performed by a partner lab.

[2] This test is not considered in-scope of our current A2LA accreditation. For a listing of in-scope tests, please visit www.medallionlabs.com.

Medallion Labs

www.medallionlabs.com 800-245-5615 info@medlabs.com

Order Number:	**2022-002172**	Completed Date:	04-Apr-2022
		Initiated Date:	02-Mar-2022
Submitter:	Zheng You		
Company:	Tate & Lyle		
Company Address:	5450 Prarie Stone Pkwy Hoffman Estates, IL 60192		
Results Email:	zheng.you@tateandlyle.com		
Invoice Email:	annette.evans@tateandlyle.com		
Purchase Order:	CC		

Medallion Labs

www.medallionlabs.com 800-245-5615 info@medlabs.com

Order # Sample ID:	2022-002172-01	Company:	Tate & Lyle
Customer Sample ID:	Chickpea protein 2		Tate and Lyle Solutions USA LLC
Sample Description:	chickpea protein Lot A60-266-21		

Analytical Testing

Method:	Component:	Result:	Test Date:
[1] [2] Lectin	Lectin	<0.05 mg/g	04-Apr-2022
[2] Phytic Acid	Phytic Acid	1.93 g/100 g	18-Mar-2022
[1] [2] Raffinose, Stachyose, Verbascose	Raffinose	13.8660 g/kg	29-Mar-2022
	Stachyose	42.2740 g/kg	29-Mar-2022
	Verbascose	1.0920 g/kg	29-Mar-2022
[1] [2] Tannins	Tannins	0.130 %	29-Mar-2022
[2] Total Polyphenols	Total Polyphenols	123 mg/kg	29-Mar-2022
[2] Trypsin Inhibitor Activity	Trypsin Inhibitor Activity	84236 TIU/g	08-Mar-2022

Results Approved By: Jill Zigan
(Authorized Reviewer)

[1] This analysis is performed by a partner lab.

[2] This test is not considered in-scope of our current A2LA accreditation. For a listing of in-scope tests, please visit www.medallionlabs.com.

Analytical Method References

Method Name	Method Reference
Lectin	Please contact for Method Details
Phytic Acid	Megazyme K-PHYT 12/12*
Raffinose, Stachyose, Verbascose	Please contact for Method Details
Tannins	Please contact for Method Details
Total Polyphenols	Miletic et al (2012) Phenolic Content of Plum AJCS 6 (4) 681-687*
Trypsin Inhibitor Activity	AACC 71-10*

* This method has been modified.

[1] This analysis is performed by a partner lab.

[2] This test is not considered in-scope of our current A2LA accreditation. For a listing of in-scope tests, please visit www.medallionlabs.com.

Medallion Labs

www.medallionlabs.com 800-245-5615 info@medlabs.com

Order Number:	**2022-002171**	Completed Date:	21-Mar-2022
		Submitted Date:	02-Mar-2022
Submitter:	Zheng You		
Company:	Tate & Lyle		
Company Address:	5450 Prarie Stone Pkwy Hoffman Estates, IL 60192		
Results Email:	zheng.you@tateandlyle.com		
Invoice Email:	annette.evans@tateandlyle.com		
Purchase Order:	CC		

Medallion Labs

www.medallionlabs.com 800-245-5615 info@medlabs.com

Order # Sample ID:	2022-002171-01	Company:	Tate & Lyle
Customer Sample ID:	Chickpea protein 3		Tate and Lyle Solutions USA LLC
Sample Description:	chickpea protein Lot A60-280-21		

Analytical Testing

Method:	Component:	Result:	Test Date:
[1,2] Lectin	Lectin	<0.05 mg/g	18-Mar-2022
[2] Phytic Acid	Phytic Acid	2.03 g/100 g	18-Mar-2022
[1,2] Raffinose, Stachyose, Verbascose	Raffinose	15.5100 g/kg	18-Mar-2022
	Stachyose	50.9370 g/kg	18-Mar-2022
	Verbascose	0.9730 g/kg	18-Mar-2022
[1,2] Tannins	Tannins	0.160 %	18-Mar-2022
[2] Total Polyphenols	Total Polyphenols	157 mg/kg	18-Mar-2022
[2] Trypsin Inhibitor Activity	Trypsin Inhibitor Activity	101927 TIU/g	08-Mar-2022

Results Approved By: Jamie Reese
(Authorized Reviewer)

[1] This analysis is performed by a partner lab.

[2] This test is not considered in-scope of our current A2LA accreditation. For a listing of in-scope tests, please visit www.medallionlabs.com.

Medallion Labs

www.medallionlabs.com 800-245-5615 info@medlabs.com

Analytical Method References

Method Name	Method Reference
Lectin	Please contact for Method Details
Phytic Acid	Megazyme K-PHYT 12/12*
Raffinose, Stachyose, Verbascose	Please contact for Method Details
Tannins	Please contact for Method Details
Total Polyphenols	Miletic et al (2012) Phenolic Content of Plum AJCS 6 (4) 681-687*
Trypsin Inhibitor Activity	AACC 71-10*

* This method has been modified.

[1] This analysis is performed by a partner lab.

[2] This test is not considered in-scope of our current A2LA accreditation. For a listing of in-scope tests, please visit www.medallionlabs.com.

APPENDIX B

Intake Assessment Report

Center for Chemical Regulation and Food Safety

Exponent®

Estimated Daily Intake of Chickpea Protein from Proposed Uses in Select Foods by the U.S. Population

Center for Chemical Regulation and Food Safety

Exponent

Estimated Daily Intake of Chickpea Protein from Proposed Uses in Select Foods by the U.S. Population

Prepared for

Lore Kolberg
Director, Regulatory and Scientific Affairs
Innovation and Commercial Development
Tate & Lyle
5450 Prairie Stone Pkwy
Hoffman Estates, IL 60192

Prepared by

Exponent
1150 Connecticut Ave, NW
Suite 1100
Washington, DC 20036

June 29, 2022

2201824.000 – 9699

Contents

List of Tables

List of Acronyms

DHHS	U.S. Department of Health and Human Services
EDI	Estimated Daily Intake
FNDDS	Food and Nutrient Database for Dietary Studies
g	Gram
kg-bw	Kilogram bodyweight
NCHS	National Center for Health Statistics
NHANES	National Health and Nutrition Examination Survey
USDA	U.S. Department of Agriculture
WWEIA	What We Eat In America
y	Years

Introduction

At the request of Tate & Lyle, Exponent, Inc. (Exponent) conducted a dietary intake assessment to estimate the total daily intake of chickpea protein proposed for use in the following ten categories: bakery products (sugar free, gluten free, or high fiber); non-dairy nutritional beverages; dry-blend protein powders; meal replacement/nutritional bars; plant-based protein products/meat analogs; imitation dairy analogs including milk alternatives, cheese, cream cheese, coffee creamer, frozen dessert, yogurt, and whipped topping); pasta products; snack foods; extruded snack products; and soups. The total estimated daily intake (EDI) of chickpea protein as well as the corresponding protein intake from proposed uses of chickpea protein was based on food consumption records collected in the What We Eat in America (WWEIA) component from the 2015-2018 National Health and Nutrition Examination Survey (NHANES). Estimates of intake were provided for the total U.S. population 1 year (y) and older (U.S. 1+ y) and eight age-sex sub-populations including 1-3 y (males, females), 4-8 y (males, females), 9-13 y (males, females), 14-18 y (males, females), 19-30 y (males, females), 31-50 y (males, females), 51-70 y (males, females), and 71+ y (males, females). The data and methods used to conduct the intake assessment and results are summarized in this report.

Data and Methods

Proposed Use

Chickpea protein is proposed for use in ten categories including bakery products (sugar free, gluten free, or high fiber); non-dairy nutritional beverages; dry-blend protein powders; meal replacement/nutritional bars; plant-based protein products/meat analogs; imitation dairy analogs including milk alternatives, cheese, cream cheese, coffee creamer, frozen dessert, yogurt, and whipped topping); pasta products; snack foods; extruded snack products; and soups. Table 1 presents the food use categories for which chickpea protein is proposed for use, descriptions of representative foods selected for the analysis, and the corresponding maximum proposed use level of chickpea protein.

Table 1. Proposed food uses and maximum use levels of chickpea protein

Proposed Use Category	Description of Foods Selected for Analysis	Chickpea Protein Maximum Use Level (%)
Bakery products, sugar free, gluten free, or high fiber	Bakery products limited to sugar free, gluten free, high fiber, or not-further-specified/not-specified (NFS/NS) products[1] (e.g., gluten free bread, sugar free cookies, NFS cereal or granola bar, and NS bread and rolls)	30
Beverages, nutritional beverages, non-dairy	Soy-based nutritional drink or shake and NFS nutritional drinks or shakes[1]	50
Dry-blend protein powders[2]	Protein powders (e.g., EAS Whey, Isopure, Muscle Milk, NFS protein powders[1])	90
Meal replacement/ nutritional bars	Nutrition bars (e.g., Clif Bar, PowerBar, Slim Fast Original Meal Bar, Zone Perfect)	60
Plant-based protein products/meat analogs[3]	Plant-based burgers, frankfurters, bacon, links/patties, chicken, luncheon meat, meatball, sandwich spread, meat loaf, and fillet	13.3 - 53.3
Dairy products–imitation		
Milk alternatives	Milk alternatives such as soy milk, almond milk, rice milk, and coconut milks	25
Cheese	Imitation cheese and NFS cheese[1]	25
Cream cheese	Non-dairy cream cheese was not reported consumed in NHANES; therefore, dairy-based cream cheeses were selected as surrogates	25

Proposed Use Category	Description of Foods Selected for Analysis	Chickpea Protein Maximum Use Level (%)
Coffee creamer	Soy coffee creamer and NFS coffee creamer[1]	25
Frozen dessert	Non-dairy frozen dessert, rice dessert bar, and NFS frozen yogurt, ice cream, and NFS frozen novelty products[1]	25
Yogurt	Soy yogurt, coconut milk yogurt, and NFS/NS yogurt[1]	25
Whipped topping	Whipped topping including regular, fat free, and sugar free (e.g., Cool Whip, Dream Whip)	25
Pasta products	All pasta, noodles, and macaroni as prepared; excludes pasta mixtures containing meat, poultry, and/or seafood	30
Snack foods	Crackers, breadsticks, Melba toast, hard pretzels, and other snacks (e.g., plantain chips, taro chips, sweet potato chips)	30
Extruded snack products	Bean chips, rice chips, corn snacks (e.g., Cheetos), popcorn chips, multigrain chips (e.g., Sun Chips), cracker chips, vegetable chips, potato sticks, etc.; excludes corn chips, tortilla chips, and potato chips	50
Soups[4]	Vegetarian soups; excludes home recipe soups and poultry and beef broths	10

[1] Due to limited NHANES foods reported consumed that correspond to the proposed food use, NFS and/or NS products were identified and selected as a surrogate for the proposed food use.
[2] Use level corresponds to the non-reconstituted powder.
[3] Chickpea protein is intended to be substitutional in plant protein products to provide protein at the protein concentration currently in these foods.
[4] Non-reconstituted, condensed soup amounts were adjusted to the prepared/reconstituted soup amount and included in the assessment.

Consumption Data

Chickpea protein intake estimates from proposed foods were based on food consumption records collected in the What We Eat in America (WWEIA) component of the National Health and Nutrition Examination Survey (NHANES) conducted in 2015-2016 and 2017-2018. This continuous survey is a complex multistage probability sample designed to be representative of the civilian U.S. population (CDC 2018, 2020). The NHANES datasets provide nationally representative nutrition and health data and prevalence estimates for nutrition and health status measures in the U.S. Statistical weights are provided by the National Center for Health Statistics (NCHS) for the surveys to adjust for the differential probabilities of selection. As part of the examination, trained dietary interviewers collect detailed information on all foods and beverages consumed by respondents in the previous 24-hr time period (midnight to midnight).

A second dietary recall is administered by telephone 3 to 10 days after the first dietary interview, but not on the same day of the week as the first interview. The dietary component of the survey is conducted as a partnership between the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS). DHHS is responsible for the sample design and data collection, and USDA is responsible for the survey's dietary data collection methodology, maintenance of the databases used to code and process the data, and data review and processing. A total of 13,666 individuals in the survey period 2015-2018 provided 2 complete days of dietary recalls.

Representative NHANES Foods for the Proposed Use

The list of food codes reported consumed in the WWEIA, NHANES 2015-2018 was reviewed, and foods corresponding to each proposed food use of chickpea protein were identified. Foods in which only a component corresponds to a chickpea protein use (e.g., noodles in a lasagna dish, gluten-free crust in pizza, non-dairy milk in coffee) were also identified by utilizing USDA's Food and Nutrient Database for Dietary Studies (FNDDS) that translates the food reported as consumed by participants in NHANES into its corresponding ingredients (and gram amounts) or recipes. Exponent applied FNDDS version 2017-2018 recipes (which corresponds to dietary consumption for NHANES 2017-2018) (USDA 2020) to process dietary recall data reported during NHANES 2015-2018 and FNDDS 2015-2016 recipes (which corresponds to dietary consumption for NHANES 2015-2016) (USDA 2018) for foods that were only reported consumed in NHANES 2015-2016. The proportion of foods (as a percentage of total weight) corresponding to a proposed use of chickpea protein was identified using the USDA FNNDS and only this portion of the food weight was used to determine the amount of chickpea protein that may be added.

The list of NHANES food codes (and their descriptions) that were included in this assessment is provided in Appendix A.

Analysis

Using the NHANES 2015-2018 consumption data, Exponent estimated the 2-day average daily intake of chickpea protein on a *per capita* and *per user* basis. *Per capita* estimates refer to the intake based on the entire population of interest whereas *per user* estimates refer to those who reported consuming the particular food use of chickpea protein on either of the survey days. Thus, if a participant reported consuming the food on day 1 but not on day 2, they would be considered a "user" and their 2-day average consumption is the amount they reported consumed on day 1 divided by 2. For each subject with a complete 2-day dietary recall, a 2-day average intake estimate of the food use of interest was derived by dividing the cumulative intake of the select food over the two 24-hr recalls by two. The 2-day average intake of chickpea protein per subject was derived by multiplying the reported intake of select foods from the 24-hr recall with the corresponding maximum chickpea protein use level (see Table 1) and the cumulative sum over the two 24-hr recalls was divided by two. The corresponding protein intake from proposed uses of chickpea protein was also derived assuming 60% protein in chickpea protein as provided by Tate & Lyle. The estimated daily intakes were derived on an absolute basis (i.e., grams per day) and on a bodyweight basis (i.e., grams per kilogram bodyweight per day) based on each participant's measured bodyweight.

Results

Two-day average chickpea protein intake estimates from the proposed use in ten food categories were derived based on food consumption data collected in NHANES 2015-2018. Intake estimates of chickpea protein and the corresponding protein intake from chickpea protein uses for the U.S. population 1+ y and select age-sex sub-populations are provided in Tables 2 and 3, respectively, on a *per capita* and *per user* basis at the mean and 90th percentile. Chickpea protein and protein intake estimates are expressed in grams per day (g/day) and grams per kilogram bodyweight (bw) per day (g/kg-bw/day).

Table 2. Two-day average estimated daily intake (EDI) of chickpea protein from all proposed food uses among the U.S. population one year and older (1+ y) and gender and age groups

			Per Capita		Per User		Per Capita		Per User	
Gender and age	N[1]	% User	Mean (g/day)	90th Percentile (g/day)	Mean (g/day)	90th Percentile (g/day)	Mean (g/kg-bw/day)	90th Percentile (g/kg-bw/day)	Mean (g/kg-bw/day)	90th Percentile (g/kg-bw/day)
Males:										
1-3 y	390	86	17.5	43.4	20.3	48.4	1.27	3.17	1.47	3.50
4-8 y	445	77	15.8	40.8	20.4	43.2	0.65	1.60	0.84	1.79
9-13 y	425	72	18.2	46.0	25.1	53.4	0.44	1.15	0.61	1.33
14-18 y	352	60	18.5	49.0	30.9	69.5	0.29	0.72	0.48	1.08
19-30 y	448	64	19.9	58.5	30.9	71.0	0.26	0.80	0.40	0.93
31-50 y	682	62	18.9	56.2	30.5	79.6	0.21	0.59	0.34	0.88
51-70 y	820	65	15.1	46.1	23.2	62.6	0.17	0.51	0.27	0.66
71+ y	404	65	13.0	37.2	20.2	44.7	0.15	0.45	0.24	0.52
Females:										
1-3 y	349	83	17.1	44.7	20.6	47.9	1.33	3.09	1.61	3.32
4-8 y	468	79	14.9	37.5	18.9	41.7	0.66	1.78	0.84	1.91
9-13 y	468	77	17.8	45.2	23.3	51.3	0.42	1.25	0.55	1.36
14-18 y	392	70	16.4	48.7	23.5	53.7	0.27	0.81	0.39	1.01
19-30 y	553	69	19.5	55.6	28.2	69.8	0.29	0.85	0.42	1.02
31-50 y	949	72	18.7	47.7	26.0	59.6	0.25	0.68	0.35	0.87
51-70 y	1,043	72	14.2	43.4	19.7	48.4	0.20	0.58	0.27	0.70
71+ y	447	73	14.0	37.8	19.2	42.6	0.20	0.52	0.28	0.57
Males and females:										
1+ y	8,635	69	17.0	46.1	24.5	57.8	0.31	0.83	0.44	1.07

[1] Un-weighted number of users; % user, *per capita*, and *per user* estimates were based on NHANES 2015-2018 and derived using the statistical weights provided by the NCHS.

Table 3. Two-day average estimated daily intake (EDI) of protein from proposed uses of chickpea protein among the U.S. population one year and older (1+ y) and gender and age groups

			Per Capita		Per User		Per Capita		Per User	
		%	Mean	90th Percentile	Mean	90th Percentile	Mean	90th Percentile	Mean	90th Percentile
Gender and age	N[1]	User	---- g/day ----				--- g/kg-bw/day ----			
Males:										
1-3 y	390	86	10.5	26.0	12.2	29.0	0.76	1.90	0.88	2.10
4-8 y	445	77	9.5	24.5	12.2	25.9	0.39	0.96	0.51	1.07
9-13 y	425	72	10.9	27.6	15.1	32.0	0.27	0.69	0.37	0.80
14-18 y	352	60	11.1	29.4	18.6	41.7	0.17	0.43	0.29	0.65
19-30 y	448	64	11.9	35.1	18.5	42.6	0.15	0.48	0.24	0.56
31-50 y	682	62	11.3	33.7	18.3	47.8	0.13	0.35	0.20	0.53
51-70 y	820	65	9.1	27.6	13.9	37.6	0.10	0.31	0.16	0.40
71+ y	404	65	7.8	22.3	12.1	26.8	0.09	0.27	0.14	0.31
Females:										
1-3 y	349	83	10.2	26.8	12.4	28.8	0.80	1.85	0.97	1.99
4-8 y	468	79	9.0	22.5	11.3	25.0	0.40	1.07	0.50	1.15
9-13 y	468	77	10.7	27.1	14.0	30.8	0.25	0.75	0.33	0.81
14-18 y	392	70	9.8	29.2	14.1	32.2	0.16	0.49	0.24	0.60
19-30 y	553	69	11.7	33.4	16.9	41.9	0.17	0.51	0.25	0.61
31-50 y	949	72	11.2	28.6	15.6	35.8	0.15	0.41	0.21	0.52
51-70 y	1,043	72	8.5	26.0	11.8	29.0	0.12	0.35	0.16	0.42
71+ y	447	73	8.4	22.7	11.5	25.5	0.12	0.31	0.17	0.34
Males and females:										
1+ y	8,635	69	10.2	27.7	14.7	34.7	0.18	0.50	0.27	0.64

[1] Un-weighted number of users; % user, *per capita*, and *per user* estimates were based on NHANES 2015-2018 and derived using the statistical weights provided by the NCHS.

Note: Based on protein content of 60% from chickpea protein.

References

Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS). 2018. National Health and Nutrition Examination Survey Data 2015-2016. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Available via: https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx?BeginYear=2015.

Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS). 2020. National Health and Nutrition Examination Survey Data 2017-2018. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Available via: https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx?BeginYear=2017.

U.S. Department of Agriculture (USDA). 2018. USDA Food and Nutrient Database for Dietary Studies (FNDDS), 2015-2016. Beltsville, MD: US Department of Agriculture, Agricultural Research Service, Food Surveys Research Group. Available via: http://www.ars.usda.gov/ba/bhnrc/fsrg.

U.S. Department of Agriculture (USDA). 2020. USDA Food and Nutrient Database for Dietary Studies (FNDDS), 2017-2018. Beltsville, MD: US Department of Agriculture, Agricultural Research Service, Food Surveys Research Group. Available via: http://www.ars.usda.gov/ba/bhnrc/fsrg.

Appendix A. NHANES food codes selected for inclusion in each proposed use category

Food code	Food description
Bakery products	
14640000	Cheese sandwich, NFS*
14640100	Grilled cheese sandwich, NFS*
27500050	Sandwich, NFS*
27500100	Meat sandwich, NFS*
27500300	Wrap sandwich, NFS*
27510000	Beef sandwich, NFS*
27510155	Cheeseburger, NFS*
27540132	Chicken fillet sandwich, NFS*
27550300	Fish sandwich, NFS*
42302010	Peanut butter and jelly sandwich, NFS*
51000100	Bread, NS as to major flour
51000110	Bread, NS as to major flour, toasted
51000180	Bread, made from home recipe or purchased at a bakery, NS as to major flour
51000200	Roll, NS as to major flour
51000300	Roll, hard, NS as to major flour
51121015	Garlic bread, NFS
51122000	Bread, reduced calorie and/or high fiber, white or NFS
51122100	Bread, reduced calorie and/or high fiber, white or NFS, with fruit and/or nuts
51122110	Bread, reduced calorie and/or high fiber, white or NFS, with fruit and/or nuts, toasted
51183990	Breadsticks, NFS
51184200	Breadsticks, soft, NFS
51301510	Bread, wheat or cracked wheat, reduced calorie and/or high fiber
51602020	Bread, multigrain, reduced calorie and/or high fiber, toasted
51806010	Bread, rice
51808000	Bread, gluten free
51808010	Bread, gluten free, toasted
51808100	Roll, gluten free
52101000	Biscuit, NFS
52215000	Tortilla, NFS
52301000	Muffin, NFS
53116600	Cake, rice flour, without icing or filling
53201000	Cookie, NFS
53206500	Cookie, chocolate, made with rice cereal
53226500	Cookie, marshmallow, with rice cereal, no bake
53226550	Cookie, marshmallow, with rice cereal and chocolate chips
53231400	Cookie, multigrain, high fiber
53234250	Cookie, peanut butter with rice cereal, no bake
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

Food code	Food description
53261000	Cookie, gluten free
53300100	Pie, NFS
53300170	Pie, individual size or tart, NFS
53520000	Doughnut, NFS
53520600	Cruller, NFS
53710400	Cereal or granola bar (General Mills Fiber One Chewy Bar)
53712100	Cereal or Granola bar, NFS
53712200	Cereal or granola bar, lowfat, NFS
53714200	Cereal or granola bar, chocolate coated, NFS
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
54408400	Pretzels, soft, NFS
54408405	Pretzels, soft, ready-to-eat, NFS
54408485	Pretzels, soft, gluten free
54408487	Pretzels, soft, gluten free, coated or flavored
55100005	Pancakes, NFS
55100040	Pancakes, gluten free, from frozen
55100080	Pancakes, from school, NFS
55106000	Pancakes, gluten free
55200010	Waffle, NFS
55200090	Waffle, gluten free, from frozen
55200200	Waffle, from school, NFS
55208000	Waffle, gluten free
55300010	French toast, NFS
55300060	French toast, from school, NFS
55301025	French toast, gluten free
55301030	French toast sticks, NFS
55301048	French toast sticks, from school, NFS
58106210	Pizza, cheese, from restaurant or fast food, NS as to type of crust*
58106540	Pizza with pepperoni, from restaurant or fast food, NS as to type of crust*
58106610	Pizza with meat other than pepperoni, from restaurant or fast food, NS as to type of crust*
58109100	Pizza, cheese, gluten-free thin crust*
58109120	Pizza, with meat, gluten-free thin crust*
58109130	Pizza, with meat, gluten-free thick crust*
58109140	Pizza, cheese and vegetables, gluten-free thin crust*
58109150	Pizza, cheese and vegetables, gluten-free thick crust*
Meal replacement/nutritional bars	
53710800	Cereal or granola bar (Kashi Chewy)
53710802	Cereal or granola bar (Kashi Crunchy)
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)

Food code	Food description
53729000	Nutrition bar or meal replacement bar, NFS
Plant based protein products/meat analogs	
27564420	Frankfurter or hot dog sandwich, meatless, plain, on bun*
27564430	Frankfurter or hot dog sandwich, meatless, plain, on bread*
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
41812000	Sandwich spread, meat substitute type
41812450	Vegetarian chili, made with meat substitute*
41812600	Vegetarian, fillet
41812900	Vegetarian meat loaf
75140500	Broccoli salad with cauliflower, cheese, bacon bits, and dressing*
Dairy products-imitation	
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
11400000	Yogurt, NFS
11400010	Yogurt, Greek, NS as to type of milk or flavor
11410000	Yogurt, NS as to type of milk or flavor
11411010	Yogurt, NS as to type of milk, plain
11411390	Yogurt, Greek, NS as to type of milk, plain
11430000	Yogurt, NS as to type of milk, fruit
11433990	Yogurt, Greek, NS as to type of milk, fruit
11434090	Yogurt, NS as to type of milk, flavors other than fruit
11435000	Yogurt, Greek, NS as to type of milk, flavors other than fruit
11459990	Frozen yogurt, NFS
11512030	Hot chocolate / Cocoa, ready to drink, made with non-dairy milk*
11513310	Chocolate milk, made from dry mix with non-dairy milk*
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*
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*
12200100	Coffee creamer, NFS
12210520	Coffee creamer, soy, liquid

Food code	Food description
12220200	Whipped topping
12220270	Whipped topping, fat free
12220280	Whipped topping, sugar free
13110000	Ice cream, NFS
13120740	Ice cream cone, NFS
13121000	Ice cream sundae, NFS
13252600	Tiramisu*
14010000	Cheese, NFS
14301010	Cream cheese, regular, plain
14301100	Cream cheese, regular, flavored
14303010	Cream cheese, light
14410380	Cream cheese spread, fat free
14410600	Cheese, processed, with vegetables*
14420200	Cheese spread, cream cheese, regular
14420210	Cheese spread, cream cheese, light
14502000	Imitation cheese
14610520	Cheese ball*
27500300	Wrap sandwich, NFS*
41420380	Yogurt, soy
41480020	Frozen dessert, non-dairy
42401100	Yogurt, coconut milk
53102200	Cake or cupcake, applesauce, with icing or filling*
53102700	Cake or cupcake, banana, with icing or filling*
53104260	Cake or cupcake, carrot, with icing or filling*
53116510	Cake or cupcake, pumpkin, with icing or filling*
53117200	Cake or cupcake, spice, with icing or filling*
53124110	Cake or cupcake, zucchini*
53344200	Mixed fruit tart filled with custard or cream cheese*
56201360	Grits, instant, made with non-dairy 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*
56203106	Oatmeal, instant, plain, made with non-dairy milk, no added fat*
56205230	Rice dessert bar, frozen, flavors other than chocolate, nondairy, carob covered
56207027	Cream of wheat, regular or quick, made with non-dairy milk, fat added*
56207102	Cream of wheat, instant, made with non-dairy milk, no added fat*
58111200	Puffs, fried, crab meat and cream cheese filled*
58200250	Wrap sandwich, filled with vegetables*
63402970	Fruit salad, excluding citrus fruits, with nondairy whipped topping*
64134025	Fruit smoothie, with whole fruit, non-dairy*
75410550	Stuffed jalapeno pepper*
78101115	Fruit and vegetable smoothie, non-dairy*
91306040	Dessert dip*
91501050	Gelatin dessert with cream cheese*
92101903	Coffee, Latte, with non-dairy milk*
92101906	Coffee, Latte, with non-dairy milk, flavored*
92101923	Frozen coffee drink, with non-dairy milk*
92101960	Coffee, Cafe Mocha, with non-dairy milk*
92101975	Coffee, Cafe Mocha, decaffeinated, with non-dairy milk*
92102020	Frozen mocha coffee drink, with non-dairy milk*

Food code	Food description
92102050	Frozen mocha coffee drink, with non-dairy milk and whipped cream*
92102502	Coffee, Iced Latte, with non-dairy milk*
92102505	Coffee, Iced Latte, with non-dairy milk, flavored*
92102602	Coffee, Iced Cafe Mocha, with non-dairy milk*
92121000	Coffee, instant, pre-lightened and pre-sweetened with sugar, reconstituted*
92121001	Coffee, instant, decaffeinated, pre-lightened and pre-sweetened with sugar, reconstituted*
92121020	Coffee, mocha, instant, pre-lightened and pre-sweetened with sugar, reconstituted*
92121040	Coffee, instant, pre-lightened and pre-sweetened with low calorie sweetener, reconstituted*
92121041	Coffee, instant, decaffeinated, pre-lightened and pre-sweetened with low calorie sweetener, reconstituted*
92130000	Coffee, pre-lightened and pre-sweetened with sugar*
92130005	Coffee, pre-lightened and pre-sweetened with low calorie sweetener*
92130010	Coffee, pre-lightened*
92130011	Coffee, decaffeinated, pre-lightened*
92161002	Coffee, Cappuccino, with non-dairy milk*
92193000	Coffee, instant, pre-lightened and pre-sweetened with sugar, not reconstituted*
Pasta products	
56104000	Pasta, vegetable, cooked
56112000	Noodles, cooked
56113000	Noodles, whole grain, cooked
56113990	Noodles, vegetable, cooked
56116990	Long rice noodles, made from mung beans, cooked
56117090	Rice noodles, cooked
56130000	Pasta, cooked
56132990	Pasta, whole grain, cooked
56140100	Pasta, gluten free
58130310	Lasagna, meatless*
58130320	Lasagna, meatless, with vegetables*
58131110	Ravioli, NS as to filling, with tomato sauce*
58131120	Ravioli, NS as to filling, with cream sauce*
58131510	Ravioli, cheese-filled, no sauce*
58131520	Ravioli, cheese-filled, with tomato sauce*
58131523	Ravioli, cheese-filled, with tomato sauce, canned*
58131535	Ravioli, cheese-filled, with cream sauce*
58131590	Ravioli, cheese and spinach-filled, no sauce*
58131600	Ravioli, cheese and spinach-filled, with cream sauce*
58131610	Ravioli, cheese and spinach filled, with tomato sauce*
58133120	Manicotti, cheese-filled, with tomato sauce, meatless*
58134120	Stuffed shells, cheese-filled, with tomato sauce, meatless*
58134160	Stuffed shells, cheese- and spinach- filled, no sauce*
58134620	Tortellini, cheese-filled, meatless, with tomato sauce*
58134640	Tortellini, cheese-filled, meatless, with vinaigrette dressing*
58134660	Tortellini, cheese-filled, with cream sauce*
58134680	Tortellini, cheese-filled, no sauce*
58134710	Tortellini, spinach-filled, with tomato sauce*
58134720	Tortellini, spinach-filled, no sauce*
58135120	Chow fun noodles with vegetables, meatless*
58145110	Macaroni or noodles with cheese*
58145111	Macaroni or noodles with cheese, from restaurant*
58145112	Macaroni or noodles with cheese, made from packaged mix*

Food code	Food description
58145113	Macaroni or noodles with cheese, canned*
58145117	Macaroni or noodles with cheese, Easy Mac type*
58145119	Macaroni or noodles with cheese, made from reduced fat packaged mix*
58145140	Macaroni or noodles with cheese and tomato*
58145170	Macaroni or noodles with cheese and egg*
58145300	Macaroni or noodles with cheese, whole grain*
58146150	Pasta with tomato-based sauce and cheese*
58146160	Pasta with vegetables, no sauce or dressing*
58146210	Pasta with sauce, NFS*
58146215	Pasta with sauce, meatless, school lunch*
58146221	Pasta with tomato-based sauce, restaurant*
58146222	Pasta with tomato-based sauce, home recipe*
58146223	Pasta with tomato-based sauce, ready-to-heat*
58146301	Pasta with tomato-based sauce, and added vegetables, restaurant*
58146302	Pasta with tomato-based sauce, and added vegetables, home recipe*
58146303	Pasta with tomato-based sauce, and added vegetables, ready-to-heat*
58146381	Pasta with cream sauce, restaurant*
58146382	Pasta with cream sauce, home recipe*
58146383	Pasta with cream sauce, ready-to-heat*
58146391	Pasta with cream sauce and added vegetables, restaurant*
58146392	Pasta with cream sauce and added vegetables, from home recipe*
58146393	Pasta with cream sauce and added vegetables, ready-to-heat*
58146601	Pasta, whole grain, with tomato-based sauce, restaurant*
58146602	Pasta, whole grain, with tomato-based sauce, home recipe*
58146603	Pasta, whole grain, with tomato-based sauce, ready-to-heat*
58146612	Pasta, whole grain, with tomato-based sauce and added vegetables, home recipe*
58146613	Pasta, whole grain, with tomato-based sauce and added vegetables, ready-to-heat*
58146682	Pasta, whole grain, with cream sauce, home recipe*
58146683	Pasta, whole grain, with cream sauce, ready-to-heat*
58146692	Pasta, whole grain, with cream sauce, and added vegetables, home recipe*
58146693	Pasta, whole grain, with cream sauce, and added vegetables, ready-to-heat*
58147330	Macaroni or noodles, creamed, with cheese*
58147510	Flavored pasta*
58148110	Macaroni or pasta salad, made with mayonnaise*
58148111	Macaroni or pasta salad, made with light mayonnaise*
58148112	Macaroni or pasta salad, made with mayonnaise-type salad dressing*
58148114	Macaroni or pasta salad, made with Italian dressing*
58148117	Macaroni or pasta salad, made with light creamy dressing*
58148118	Macaroni or pasta salad, made with any type of fat free dressing*
58148120	Macaroni or pasta salad with egg*
58148180	Macaroni or pasta salad with cheese*
58301110	Vegetable lasagna, frozen meal*
58302000	Macaroni and cheese, diet frozen meal*
58302080	Noodles with vegetables in tomato-based sauce, diet frozen meal*
58304200	Ravioli, cheese-filled, with tomato sauce, diet frozen meal*
58305250	Pasta with vegetable and cheese sauce, diet frozen meal*
58421010	Sopa Seca de Fideo, Mexican style, made with dry noodles, home recipe*
58421020	Sopa de Fideo Aguada, Mexican style noodle soup, home recipe*
72202010	Broccoli casserole with noodles*

Food code	Food description
75340160	Vegetable and pasta combinations with cream or cheese sauce, broccoli, pasta, carrots, corn, zucchini, peppers, cauliflower, peas, etc., cooked*
75460700	Vegetable combinations, including carrots, broccoli, and/or dark-green leafy; cooked, with pasta*
75460710	Vegetable combinations, excluding carrots, broccoli, and dark-green leafy; cooked, with pasta*
75460800	Vegetable combinations, including carrots, broccoli, and/or dark-green leafy; cooked, with butter sauce and pasta*
75649150	Vegetable noodle soup, home recipe*
75651000	Minestrone soup, home recipe*
Snack foods	
51184000	Breadsticks, hard, NFS
51184100	Breadsticks, hard, reduced sodium
51187000	Melba toast
51187020	Anisette toast
51188500	Zwieback toast
51306000	Breadsticks, hard, whole wheat
51808050	Breadsticks, hard, gluten free
53240000	Cookie, animal
53240010	Cookie, animal, with frosting or icing
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
54318500	Rice cake
54319000	Crackers, rice
54319005	Crackers, rice and nuts

Food code	Food description
54319020	Popcorn cake
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
54401011	Corn nuts
54402200	Snack mix
54402700	Pita 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
54408190	Pretzels, hard, coated, NFS
54408200	Pretzels, hard, chocolate coated
54408210	Pretzels, hard, white chocolate coated
54408250	Pretzels, hard, yogurt coated
54408290	Pretzels, hard, filled, NFS
54408300	Pretzels, hard, cheese filled
54408310	Pretzels, hard, peanut butter filled
54420220	Snack mix, plain (Chex Mix)
54440010	Bagel chips
56116000	Noodles, chow mein
71905410	Plantain chips

Food code	Food description
71980200	Taro chips
73410210	Sweet potato chips
Extruded snack products	
41310900	Bean chips
54318000	Chips, rice
54401055	Cheese flavored corn snacks
54401065	Cheese flavored corn snacks, reduced fat
54401081	Cheese flavored corn snacks (Cheetos)
54404000	Popcorn chips, plain
54404010	Popcorn chips, other flavors
54404020	Popcorn chips, sweet flavors
54406010	Onion flavored rings
54406200	Shrimp chips
54420210	Multigrain chips (Sun Chips)
54440020	Cracker chips
71205040	Potato sticks, fry shaped
71220000	Vegetable chips
Soups	
14710100	Cheddar cheese soup, home recipe, canned or ready-to-serve
32300100	Egg drop soup
41601030	Black bean soup, home recipe, canned or ready-to-serve
41601200	Liquid from stewed kidney beans, Puerto Rican style
41602050	Split pea soup
41602070	Split pea soup, canned, reduced sodium, prepared with water or ready-to-serve
58400100	Noodle soup, NFS
58401200	Barley soup, sweet, with or without nuts, Asian Style
58403100	Noodle and potato soup, Puerto Rican style
58407030	Soup, mostly noodles
58407035	Soup, mostly noodles, reduced sodium
63415100	Soup, fruit
71801000	Potato soup, NS as to made with milk orr water
71801010	Potato soup, cream of, prepared with milk
71801020	Potato soup, prepared with water
72202020	Broccoli casserole with rice*
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
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
74602200	Tomato soup, canned, reduced sodium, prepared with water, or ready-to-serve
74602300	Tomato soup, canned, reduced sodium, prepared with milk
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
75403020	Green bean casserole*
75403022	Beans, string, green, cooked, from frozen, with mushroom sauce*

Food code	Food description
75417022	Peas, cooked, from frozen, with mushroom sauce*
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
75603010	Celery soup, cream of, prepared with milk, home recipe, canned or ready-to-serve
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
75607060	Mushroom soup, cream of, NS as to made with milk or water
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
75608100	Onion soup, French
75608200	Onion soup, made from dry mix
75611010	Vegetable soup, cream of, prepared with milk
75646010	Shav soup
75649010	Vegetable soup, canned, prepared with water or ready-to-serve
75649040	Vegetable soup, reduced sodium, canned, ready to serve
75650990	Minestrone soup, reduced sodium, canned or ready-to-serve
75651010	Minestrone soup, canned, prepared with water, or ready-to-serve
75651040	Vegetable noodle soup, canned, prepared with water, or ready-to-serve
75651070	Vegetable rice soup, canned, prepared with water or ready-to-serve
75651150	Vegetable noodle soup, reduced sodium, canned, prepared with water or ready-to-serve
75656020	Vegetable soup, chunky style
75656040	Vegetable soup, with pasta, chunky style
75657000	Vegetable broth, bouillon

*Only the proportion of the food mixture corresponding to the proposed food uses of chickpea protein was included in the analysis.

EXHIBIT 1

Report of the Expert Panel

OPINION OF A GRAS PANEL ON THE SAFETY AND GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF CHICKPEA PROTEIN FOR USE AS AN INGREDIENT IN HUMAN FOOD

Introduction

An independent panel of experts (GRAS Panel), qualified by scientific training and experience to evaluate the safety of food and food ingredients, was requested by Tate & Lyle (T&L) to determine the safety and Generally Recognized as Safe (GRAS) status of the use of chickpea protein as an ingredient in human food. The chickpea protein is proposed for use as a source of protein in certain specified foods for human consumption (except for infant formula), and the daily consumption of protein is not expected to increase as a result of its introduction. The chickpea protein ingredient is manufactured in accordance with current Good Manufacturing Practice (cGMP) guidelines and meets the proposed specifications.

A detailed review based on the existing scientific literature (through June 2022) on the safety of chickpeas and chickpea protein was conducted by ToxStrategies and is summarized in the attached dossier. The GRAS Panel members reviewed the dossier prepared by ToxStrategies and other pertinent information and convened on August 9, 2022, via teleconference. Based on their independent, critical evaluation of all of the available information, the GRAS Panel unanimously concluded that the intended uses and use levels described herein for T&L's chickpea protein ingredient, meeting appropriate food-grade specifications as described in the supporting dossier (**GRAS Determination of Chickpea Protein for Use as an Ingredient in Human Food**) and manufactured according to cGMP, is safe, suitable, and GRAS based on scientific procedures. A summary of the basis for the GRAS Panel's conclusion is provided below.

Summary and Basis for GRAS Determination

Description

The subject of this GRAS determination is a chickpea protein concentrate from the seeds of *Cicer arietinum*, of the family *Fabaceae*, also known as chickpeas or garbanzo beans. It is an extract of chickpeas consisting of ≥60% protein. It is a white, free-flowing, concentrated protein powder with a pH range of 5.5–7.5 and particle size of 8–11 microns.

Manufacturing Process

The chickpea protein ingredient (≥60% protein) is produced by an ethanol extraction process from commercially available chickpeas. The starting material for the chickpea protein extraction process is raw chickpeas. Following a dehulling step, the chickpeas are extracted with ethanol to remove oil. The de-oiled chickpea is then milled and dry-fractionated to obtain the protein product. The chickpea protein product has been characterized appropriately and meets appropriate food-grade specifications. The ingredient is stable for 24 months from the date of manufacture when stored in a closed container in a cool, dry place (below 25°C).

History of Use and Regulatory Approval

There is no current formal approval for the use of chickpea protein in human foods in the United States. Chickpeas (*C. arietinum* L.) are one of the most ancient, consumed legumes around the world, probably originating in Turkey. It is cultivated in Asia, Europe, Australia, and North America, usually as a winter crop; Southeast Asia contributes around 80% of world production, with India being the main producing country in this region (Juarez-Chairez et al., 2020). According to the U.S. Department of Agriculture's National Nutrient Database, one cup of cooked chickpeas provides 269 calories, 45 g of carbohydrate, 15 g of protein, 13 g of dietary fiber, and 4 g of fat (Gupta et al., 2017). The mean protein content in chickpeas is nearly 18% (kabuli contains 18.4% [range 16.2%–22.4%]; desi contains 18.2% [range 15.6%–21.4%]), which is higher than lentils and field peas. Chickpeas are rich in lysine and arginine and low in sulfur-containing amino acids such as cysteine and methionine (Madurapperumage et al., 2021; Jukanti et al., 2012). Chickpeas are also a rich source of minerals, including iron, zinc, and selenium. Chickpea seeds have a percentage of protein similar to that of other legumes like beans, and soybeans, and they have high bioavailability and good digestibility (48%–89%) (Juarez-Chairez et al., 2020; Chavan et al., 1986).

Chickpea-based foods and snacks have been marketed in the United States and other countries around the world and include hummus (2 g protein/serving), snack foods, and snack bars (3–6 g protein/serving) (Acevedo-Martinez et al., 2021).

Intended Use and Intake Assessment

T&L intends to market the chickpea protein ingredient as an alternative source to other plant-based proteins used in specified foods, or as an alternative source of protein for individuals who wish to limit or reduce their intake of animal-sourced proteins.

T&L proposes the use of chickpea protein in ten food categories—bakery products (sugar free, gluten-free, or high fiber); non-dairy nutritional beverages; dry-blend protein powders; meal replacement/nutritional bars; plant-based protein products/meat analogs; imitation dairy analogs, including milk alternatives, cheese, cream cheese, coffee creamer, frozen dessert, yogurt, and whipped topping); pasta products; snack foods; extruded snack products; and soups). An intake assessment was conducted to estimate the mean and 90th percentile daily intakes of chickpea protein, as well as the corresponding protein intake, based on its intended use in foods. Proposed food uses and maximum use levels are summarized in the table below.

The total estimated daily intake (EDI) of chickpea protein, as well as the corresponding protein intake from proposed uses of chickpea protein, was based on food consumption records collected in the What We Eat in America (WWEIA) component from the 2015–

2018 National Health and Nutrition Examination Survey (NHANES). Estimates of intake were provided for the total U.S. population 2 years (y) and older (U.S. 2+ y) and three subpopulations, including children 2–12 y, adolescents 13–18 y, and adults 19+ y.

Table 1. Proposed food uses and use levels

Proposed Use Category	Description of Foods Selected for Analysis	Chickpea Protein Maximum Use Level (%)
Bakery products, sugar free, gluten free, or high fiber	Bakery products limited to sugar free, gluten free, high fiber, or not-further-specified/not-specified (NFS/NS) products[1] (e.g., gluten free bread, sugar free cookies, NFS cereal or granola bar, and NS bread and rolls)	30
Beverages, nutritional beverages, non-dairy	Soy-based nutritional drink or shake and NFS nutritional drinks or shakes[1]	50
Dry-blend protein powders[2]	Protein powders (e.g., EAS Whey, Isopure, Muscle Milk, NFS protein powders[1])	90
Meal replacement/ nutritional bars	Nutrition bars (e.g., Clif Bar, PowerBar, Slim Fast Original Meal Bar, Zone Perfect)	60
Plant-based protein products/meat analogs[3]	Plant-based burgers, frankfurters, bacon, links/patties, chicken, luncheon meat, meatball, sandwich spread, meat loaf, and fillet	13.3 - 53.3
Dairy products–imitation		
Milk alternatives	Milk alternatives such as soy milk, almond milk, rice milk, and coconut milks	25
Cheese	Imitation cheese and NFS cheese[1]	25
Cream cheese	Non-dairy cream cheese was not reported consumed in NHANES; therefore, dairy-based cream cheeses were selected as surrogates	25
Coffee creamer	Soy coffee creamer and NFS coffee creamer[1]	25
Frozen dessert	Non-dairy frozen dessert, rice dessert bar, and NFS frozen yogurt, ice cream, and NFS frozen novelty products[1]	25
Yogurt	Soy yogurt, coconut milk yogurt, and NFS/NS yogurt[1]	25
Whipped topping	Whipped topping including regular, fat free, and sugar free (e.g., Cool Whip, Dream Whip)	25
Pasta products	All pasta, noodles, and macaroni as prepared; excludes pasta mixtures containing meat, poultry, and/or seafood	30
Snack foods	Crackers, breadsticks, Melba toast, hard pretzels, and other snacks (e.g., plantain chips, taro chips, sweet potato chips)	30
Extruded snack products	Bean chips, rice chips, corn snacks (e.g., Cheetos), popcorn chips, multigrain chips (e.g., Sun Chips), cracker chips, vegetable chips, potato sticks, etc.; excludes corn chips, tortilla chips, and potato chips	50
Soups[4]	Vegetarian soups; excludes home recipe soups and poultry and beef broths	10

[1] Due to limited NHANES foods reported consumed that correspond to the proposed food use, NFS and/or NS products were identified and selected as a surrogate for the proposed food use.
[2] Use level corresponds to the non-reconstituted powder.
[3] Chickpea protein is intended to be substitutional in plant protein products to provide protein at the protein concentration currently in these foods.
[4] Non-reconstituted, condensed soup amounts were adjusted to the prepared/reconstituted soup amount and included in the assessment.

Two-day average chickpea protein intake estimates from its proposed use in ten food categories were derived. Intake estimates of chickpea protein and the corresponding protein intake from chickpea protein uses for the U.S. population 1+ y and selected age-sex subpopulations are provided in Tables 2 and 3, respectively, on a *per-capita* and *per-user* basis at the mean the and 90th percentile.

The EDIs represent conservatively high estimates of intake. In calculating the EDIs, it is assumed that all foods in each proposed use category will contain the maximum intended use of chickpea protein. However, not all consumers may select products with chickpea protein for all eating occasions. Furthermore, consumption of protein from chickpea protein can reasonably be assumed to replace other sources of protein in the diet.

The Institute of Medicine (IOM, 2005) recommends that adults consume 0.8 grams of protein per kilogram of body weight. IOM also set a wide range for acceptable protein intake, ranging from 10% to 35% of calories each day. In the U.S., the recommended daily allowance (RDA) of protein is 46 grams/day for women over 19 years of age, and 56 grams/day for men over 19 years of age.

The RDA, however, does not represent an upper limit of consumption. Physically active persons on normal diets are known to exceed this level, and individuals involved in bodybuilding ingest much higher levels of protein (WHO, 2002). The accepted WHO safe level of intake is 0.83 g/kg per day, for proteins with a protein digestibility-corrected amino acid score value of 1.0. While WHO has stated that no safe upper limit has been identified, they also indicated that it is unlikely that intakes of twice the safe level are associated with any risk to healthy individuals.

As was concluded in the other plant-based protein GRAS notifications, we do not realistically expect that the actual consumption of foods containing chickpea protein would be expected to result in daily consumption greater than the RDA for protein. Most of the population's intake of protein is, and will remain, in the form of unprocessed foods, including meat, poultry, fish, and legumes.

In summary, the proposed uses of chickpea protein will not result in an increase in the overall consumption of protein but will simply provide an alternative source of well-characterized protein from chickpeas for use in specified foods.

Table 2. Two-day average estimated daily intake (EDI) of chickpea protein from all proposed food uses among the U.S. population one year and older (1+ y), and gender and age groups

			Per Capita		Per User		Per Capita		Per User	
Gender and age	N[1]	% User	Mean	90th Percentile	Mean	90th Percentile	Mean	90th Percentile	Mean	90th Percentile
			---- g/day ----				--- g/kg-bw/day ----			
Males:										
1-3 y	390	86	17.5	43.4	20.3	48.4	1.27	3.17	1.47	3.50
4-8 y	445	77	15.8	40.8	20.4	43.2	0.65	1.60	0.84	1.79
9-13 y	425	72	18.2	46.0	25.1	53.4	0.44	1.15	0.61	1.33
14-18 y	352	60	18.5	49.0	30.9	69.5	0.29	0.72	0.48	1.08
19-30 y	448	64	19.9	58.5	30.9	71.0	0.26	0.80	0.40	0.93
31-50 y	682	62	18.9	56.2	30.5	79.6	0.21	0.59	0.34	0.88
51-70 y	820	65	15.1	46.1	23.2	62.6	0.17	0.51	0.27	0.66
71+ y	404	65	13.0	37.2	20.2	44.7	0.15	0.45	0.24	0.52
Females:										
1-3 y	349	83	17.1	44.7	20.6	47.9	1.33	3.09	1.61	3.32
4-8 y	468	79	14.9	37.5	18.9	41.7	0.66	1.78	0.84	1.91
9-13 y	468	77	17.8	45.2	23.3	51.3	0.42	1.25	0.55	1.36
14-18 y	392	70	16.4	48.7	23.5	53.7	0.27	0.81	0.39	1.01
19-30 y	553	69	19.5	55.6	28.2	69.8	0.29	0.85	0.42	1.02
31-50 y	949	72	18.7	47.7	26.0	59.6	0.25	0.68	0.35	0.87
51-70 y	1,043	72	14.2	43.4	19.7	48.4	0.20	0.58	0.27	0.70
71+ y	447	73	14.0	37.8	19.2	42.6	0.20	0.52	0.28	0.57
Males and females:										
1+ y	8,635	69	17.0	46.1	24.5	57.8	0.31	0.83	0.44	1.07

[1] Un-weighted number of users, % user, *per capita*, and *per user* estimates were based on NHANES 2015-2018 and derived using the statistical weights provided by the NCHS.

Table 3. Two-day average estimated daily intake (EDI) of protein from proposed uses of chickpea protein among the U.S. population one year and older (1+ y) and gender and age groups based on protein content of 60% from chickpea protein

			Per Capita		Per User		Per Capita		Per User	
		%	Mean	90th Percentile	Mean	90th Percentile	Mean	90th Percentile	Mean	90th Percentile
Gender and age	N[1]	User	---- g/day ----				--- g/kg-bw/day ----			
Males:										
1-3 y	390	86	10.5	26.0	12.2	29.0	0.76	1.90	0.88	2.10
4-8 y	445	77	9.5	24.5	12.2	25.9	0.39	0.96	0.51	1.07
9-13 y	425	72	10.9	27.6	15.1	32.0	0.27	0.69	0.37	0.80
14-18 y	352	60	11.1	29.4	18.6	41.7	0.17	0.43	0.29	0.65
19-30 y	448	64	11.9	35.1	18.5	42.6	0.15	0.48	0.24	0.56
31-50 y	682	62	11.3	33.7	18.3	47.8	0.13	0.35	0.20	0.53
51-70 y	820	65	9.1	27.6	13.9	37.6	0.10	0.31	0.16	0.40
71+ y	404	65	7.8	22.3	12.1	26.8	0.09	0.27	0.14	0.31
Females:										
1-3 y	349	83	10.2	26.8	12.4	28.8	0.80	1.85	0.97	1.99
4-8 y	468	79	9.0	22.5	11.3	25.0	0.40	1.07	0.50	1.15
9-13 y	468	77	10.7	27.1	14.0	30.8	0.25	0.75	0.33	0.81
14-18 y	392	70	9.8	29.2	14.1	32.2	0.16	0.49	0.24	0.60
19-30 y	553	69	11.7	33.4	16.9	41.9	0.17	0.51	0.25	0.61
31-50 y	949	72	11.2	28.6	15.6	35.8	0.15	0.41	0.21	0.52
51-70 y	1,043	72	8.5	26.0	11.8	29.0	0.12	0.35	0.16	0.42
71+ y	447	73	8.4	22.7	11.5	25.5	0.12	0.31	0.17	0.34
Males and females:										
1+ y	8,635	69	10.2	27.7	14.7	34.7	0.18	0.50	0.27	0.64

[1] Un-weighted number of users; % user, *per capita*, and *per user* estimates were based on NHANES 2015-2018 and derived using the statistical weights provided by the NCHS.

Note: Based on protein content of 60% from chickpea protein.

Safety Data

Given the long history of global human consumption of chickpeas as food (and the protein contained therein), the safety of the chickpea protein ingredient derived from them is supported by their consumption and general lack of toxicity. As would be expected for a food that has been consumed by humans for centuries, chickpeas and chickpea proteins have not been subjected to traditional toxicology studies. Furthermore, given the available information and data on the safe consumption of chickpeas and their associated proteins, conduct of toxicity studies was considered unnecessary and not an ethical use of animals.

Many protein products are currently available in the marketplace. To date, FDA has reviewed extensive published information and data as part of GRAS notifications for animal and plant-based protein isolates and concentrates and subsequently issued "no questions letters".

Available safety-related information for chickpeas and associated chickpea proteins were extracted and summarized from animal studies, clinical studies, and systematic reviews of pulses related to their potential health benefits such as antioxidant activity, inhibition of colon/breast cancer, hypocholesterolemic activity, hypoglycemic activity, and antifungal and anti-inflammatory activity (Juarez-Chairez et al., 2020; Ferreira et al., 2021; Shevkani et al., 2019). No treatment-related adverse effects have been noted in the reviewed studies.

The potential for chickpea proteins to cause an immune response is relatively rare but consistent with similar, known allergies to other legumes. Although chickpeas are not listed as one of the major allergen groups by the FDA under the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II)), the fact that the allergenicity of chickpea protein has been shown clinically (Chan et al., 2019) and reviewed by many other researchers (Cox et al., 2021; Gupta et al., 2017; Hildebrand et al., 2021; Verma et al., 2013) suggests that labeling the presence of chickpea protein is both warranted and recommended. The Panel also recommends that the ingredient labeling for the chickpea protein in all food products where it is used clearly state that it contains "chickpea protein," and that individuals who wish to avoid chickpeas or chickpea protein consumption for any reason would be able to easily identify the presence of a chickpea–derived ingredient.

The totality of information available on chickpea protein that have been reviewed as part of this current GRAS assessment is considered sufficient to support the safe use of the proposed chickpea protein ingredient for its maximum intended use in specified foods.

General Recognition of the Safety of Chickpea Protein

The intended use of the chickpea protein ingredient has been determined to be safe through scientific procedures as set forth in 21 CFR § 170.3(b), thus satisfying the so-called "technical" element of the GRAS determination, and this determination is based on the following:

- Chickpea protein is manufactured from commercially available chickpeas, following current cGMP for food (21 CFR § Part 110). The raw materials and processing aids used in the manufacturing process are food grade and/or approved for use in food. The chickpea protein product has been characterized appropriately, contains a minimum of 60% protein, and meets appropriate food-grade specifications.
- Chickpeas have been consumed as food (and the protein contained therein) for centuries, along with many other food sources of protein (e.g., meats, dairy, fruits, vegetables, nuts).
- For the population ages 1 year and older, the per-user mean and 90th percentile EDIs of protein from the intended use are 14.7 and 34.7 g/day, respectively. The proposed uses of the chickpea protein ingredient will provide an alternative to other dietary sources of protein, and the estimates of intake are comparable to estimates of protein intake from various other sources concluded previously to be GRAS. A tolerable upper intake level (UL) for protein intake has not been established by IOM.
- FDA has reviewed extensive published information and data on many protein products as part of GRAS Notifications for animal and plant-based protein isolates and concentrates and subsequently issued "no objection letters." Examples include GRN No. 26 (isolated wheat protein); GRN No. 37 (whey protein isolate and dairy product solids); GRN No. 168 (poultry protein); GRN No. 182 (hydrolyzed wheat gluten isolate; pea protein isolate); GRN No. 313 (beef protein); GRN No. 314 (pork protein); GRN 386 (canola protein isolate and hydrolyzed canola protein isolate); GRN No. 447 (potato protein isolates); GRN No. 575 (oat protein); GRNs No. 58, 608, 788 (pea protein), GRN 879 (fava bean protein), and GRN 944 (rice protein hydrolysate).
- Given the long history of global human consumption of chickpeas as food (and the protein contained therein), the safety of the chickpea protein ingredient derived from them is supported by their consumption and general lack of toxicity. As would be expected for a food that has been consumed by humans for centuries, chickpeas and chickpea proteins have not been subjected to traditional toxicology studies. However, the available summarized preclinical and clinical study data support its safe use as proposed.
- Antinutritional components are known to exist in numerous foods, including chickpeas. These components are neutralized efficiently by various processing methods such as soaking, thermal treatment (cooking or boiling), and autoclaving. The levels of lectin, phytic acid, raffinose, stachyose, verbascose, tannins, total polyphenols, and trypsin inhibitor activity in the chickpea protein product have been measured, and levels are well within typical levels found in common plant-based foods (Popova and Mihaylova, 2019).

- Concerns related to the allergenicity of chickpea protein are addressed through appropriate labeling of food products as containing chickpea protein, and individuals who wish to avoid chickpea protein consumption would be able to identify the presence of a chickpea-derived ingredient.
- The body of publicly available scientific literature on the consumption and safety of chickpeas and chickpea protein is sufficient to support the safety and GRAS status of the proposed chickpea protein ingredient.

Because this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

Conclusions of the GRAS Panel

We, the undersigned independent, qualified members of the GRAS Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Tate & Lyle's chickpea protein ingredient for use an alternative source of protein in specified foods. We unanimously conclude that the intended use of Tate & Lyle's chickpea protein ingredient, produced consistent with current good manufacturing practice (cGMP) and meeting the appropriate food-grade specifications, as presented in the supporting dossier "GRAS Determination of Chickpea Protein for Use as an Ingredient in Human Food", is safe.

We, the members of the GRAS Panel, further unanimously conclude that the intended uses and use levels of Tate & Lyle's chickpea protein ingredient in specified foods, produced consistent with current good manufacturing practice (cGMP) and meeting the appropriate food-grade specifications as presented in the supporting dossier is Generally Recognized as Safe (GRAS) based on scientific procedures under the conditions of intended use in foods as described herein.

It is our professional opinion that other qualified experts critically evaluating the same information would concur with this conclusion.

Paul Damian, Ph.D., M.P.H, DABT, ERT — Date
Principal
Damian Applied Toxicology, LLC

Stanley M. Tarka, Jr., Ph.D., Fellow, ATS — Date
The Tarka Group, Inc.
The Pennsylvania State University, College of Medicine

Thomas A. Vollmuth, Ph.D. — Date
Consultant
Vollmuth and Associates, LLC

Conclusions of the GRAS Panel

We, the undersigned independent, qualified members of the GRAS Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Tate & Lyle's chickpea protein ingredient for use an alternative source of protein in specified foods. We unanimously conclude that the intended use of Tate & Lyle's chickpea protein ingredient, produced consistent with current good manufacturing practice (cGMP) and meeting the appropriate food-grade specifications, as presented in the supporting dossier "GRAS Determination of Chickpea Protein for Use as an Ingredient in Human Food", is safe.

We, the members of the GRAS Panel, further unanimously conclude that the intended uses and use levels of Tate & Lyle's chickpea protein ingredient in specified foods, produced consistent with current good manufacturing practice (cGMP) and meeting the appropriate food-grade specifications as presented in the supporting dossier is Generally Recognized as Safe (GRAS) based on scientific procedures under the conditions of intended use in foods as described herein.

It is our professional opinion that other qualified experts critically evaluating the same information would concur with this conclusion.

8/16/2022

Paul Damian, Ph.D., M.P.H. DABT, ERT — Date
Principal
Damian Applied Toxicology, LLC

Stanley M. Tarka, Jr., Ph.D., Fellow, ATS — Date
The Tarka Group, Inc.
The Pennsylvania State University, College of Medicine

Thomas A. Vollmuth, Ph.D. — Date
Consultant
Vollmuth and Associates, LLC

Conclusions of the GRAS Panel

We, the undersigned independent, qualified members of the GRAS Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Tate & Lyle's chickpea protein ingredient for use an alternative source of protein in specified foods. We unanimously conclude that the intended use of Tate & Lyle's chickpea protein ingredient, produced consistent with current good manufacturing practice (cGMP) and meeting the appropriate food-grade specifications, as presented in the supporting dossier "GRAS Determination of Chickpea Protein for Use as an Ingredient in Human Food", is safe.

We, the members of the GRAS Panel, further unanimously conclude that the intended uses and use levels of Tate & Lyle's chickpea protein ingredient in specified foods, produced consistent with current good manufacturing practice (cGMP) and meeting the appropriate food-grade specifications as presented in the supporting dossier is Generally Recognized as Safe (GRAS) based on scientific procedures under the conditions of intended use in foods as described herein.

It is our professional opinion that other qualified experts critically evaluating the same information would concur with this conclusion.

________________________ ____________

Paul Damian, Ph.D., M.P.H, DABT, ERT — Date
Principal
Damian Applied Toxicology, LLC

15 August 2022

Stanley M. Tarka, Jr., Ph.D., Fellow, ATS — Date
The Tarka Group, Inc.
The Pennsylvania State University, College of Medicine

________________________ ____________

Thomas A. Vollmuth, Ph.D. — Date
Consultant
Vollmuth and Associates, LLC

Conclusions of the GRAS Panel

We, the undersigned independent, qualified members of the GRAS Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Tate & Lyle's chickpea protein ingredient for use an alternative source of protein in specified foods. We unanimously conclude that the intended use of Tate & Lyle's chickpea protein ingredient, produced consistent with current good manufacturing practice (cGMP) and meeting the appropriate food-grade specifications, as presented in the supporting dossier "GRAS Determination of Chickpea Protein for Use as an Ingredient in Human Food", is safe.

We, the members of the GRAS Panel, further unanimously conclude that the intended uses and use levels of Tate & Lyle's chickpea protein ingredient in specified foods, produced consistent with current good manufacturing practice (cGMP) and meeting the appropriate food-grade specifications as presented in the supporting dossier is Generally Recognized as Safe (GRAS) based on scientific procedures under the conditions of intended use in foods as described herein.

It is our professional opinion that other qualified experts critically evaluating the same information would concur with this conclusion.

Paul Damian, Ph.D., M.P.H, DABT, ERT — Date
Principal
Damian Applied Toxicology, LLC

Stanley M. Tarka, Jr., Ph.D., Fellow, ATS — Date
The Tarka Group, Inc.
The Pennsylvania State University, College of Medicine

Thomas A. Vollmuth, Ph.D. — August 15, 2022
Date
Consultant
Vollmuth and Associates, LLC

References

Acevedo-Martinez KA, Yang MM, de Mejia EG. 2021. Technological properties of chickpea (Cicer arietinum): production of snacks and health benefits related to type-2 diabetes. Compr Rev Food Sci Food Saf 20:3762–2787.

Chan ES, Greenhawt MJ, Fleischer DM, Cauber J-C. 2019. Managing cross-reactivity in those with peanut allergy. J Allergy Clin Immunol Pract 7(2): 381–386.

Chavan JK, Kadam SS, Salunkhe DK, Beuchat LR. 1987. Biochemistry and technology of chickpea (Cicer arietinum L.) seeds. Crit Rev Food Sci Nutr 25(2):107–158, DOI: 10.1080/10408398709527449

Cox AL, Eigenmann PA, Sicherer. 2021. Clinical relevance of cross-reactivity in food allergy. J Allergy Clin Immunol Pract 9(1):82–99.

Ferreira H, Vasconcelos M, Gil AM, Pinto E. 2021. Benefits of pulse consumption on metabolism and health: a systematic review of randomized controlled trials. Crit Rev Food Sci Nutr 61(1):1–3.

Gupta RK, Gupta K, Sharma A, Das M, Ansari IA, Dwivedi PD. 2017. Health risks and benefits of chickpea (Cicer arietinum) consumption. J Agric Food Chem 65:6–22.

Hildebrand HV, Aries A, Simons E, Gerdts J, Povolo B, Rothney J, Protudjer JLP. 2021. Adult and pediatric food allergy to chickpea, pea, lentil, and lupine: A scoping review. J Allergy Clin Immunol Pract 9:290–301.

IOM (Institute of Medicine of the National Academies). 2005. Dietary, functional and total fiber. Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids. National Academies Press, Washington DC.

Juarez-Chairez MF, Cid-Gallegos MS, Meza-Marquez OG, Jimenez-Martinez C. 2020. Biological activities of chickpea in human health. Plant Foods Hum Nutr 75:142–153.

Jukanti A, Gaur PM, Gowda CL, Chibbar R. 2012. Nutritional quality and health benefits of chickpea (Cicer arietinum L.): A review. Br J Nutr 108(S1):S11–S26.

Madurapperumage A, Tang L, Thavarajah P, Bridges W, Shipe E, Vandemark G, Thavarajah D. 2021. Chickpea (Cicer arietinum) as a source of essential fatty acids – a biofortification approach. Front Plant Sci 12:734980.

Popova A, Mihaylova D. 2019. Antinutrients in plant-based foods: as review. The Open Biotechnology Journal 13:68-76.

Shevkani K, Singh N, chen Y, Kaur A. 2019. Pulse proteins: secondary structure, functionality and applications. J Food Sci Technol 56(6):2787–2798.

Verma AK, Kumar S, Das M, Dwivedi PD. 2013. A comprehensive review of legume allergy. Clinic Rev Allerg Immunol 45(1):30–46.

WHO (World Health Organization). 2002. Technical report series 935: Protein and amino acid requirements in human nutrition. Report of a Joint WHO/FAO/UNU Expert Consultation.

GRN 1098 Items for Clarification

1. In Table 4 (page 13), you include a specification limit of "< MRL per USP 565" on pesticide residues in raw material. Please clarify the basis for inclusion of a pesticide residue limit for raw material in the specifications for the finished ingredient. We generally ask notifiers not include pesticide residue as a specification parameter for ingredients manufactured using food-grade plant materials produced in accordance with good agricultural practices. Please confirm that you do not expect pesticide residues to be present in the final ingredient produced using the controlled method of manufacture. We also note that the USP <565> refers to USP <561> for limits on pesticide residues and that the limits specified in USP <561> are not applicable in the United States when articles of botanical origin are labeled for food purposes.

   Response: Tate & Lyle does not expect pesticide residues to be present in the final product. We have removed pesticide residues from the specifications in Table 4 (p. 13). Please see newly revised Table 4.

2. In Table 5 (page 14), you provide batch analyses for heavy metals reported as less than a specific value. Please clarify if these values represent the limits of detection (LOD) for the analytical methods used to analyze for heavy metals.

   Response: The values represent the limits of detection (LOD).

3. In Table 7 (page 15), you provide batch analyses for residual ethanol. We request that you include a limit for residual ethanol in the specifications for the final ingredient.

   Response: A specification of <200 ppm ethanol is specified.

4. On page 12, you state that the only processing aid used in the manufacturing process is ethanol. However, in Appendix A, you provide batch analyses for residual methanol and isopropanol in the final ingredient. Please clarify the source of these residual solvents in the final ingredient. Because the batch analyses show detectable levels of methanol, we request that you include a limit for residual methanol in the specifications for the final ingredient. In addition, please clarify whether you expect isopropanol to be present at detectable levels in the final ingredient and confirm that 10 mg/kg is an LOD of isopropanol.

   For the clarity, please provide a revised Table 4 (page 13) including the additional specification parameters along with the corresponding analytical methods.

   Response: A specification of <50 ppm methanol is specified. Methanol is not used in the production of the chickpea protein ingredient. It is believed to be naturally-occuring in chickpeas. Analysis for isopropanol is commonly included by Eurofins as part of their alcohol-related analysis. The values are all below the limit of detection (<10ppm) and isopropanol is not expected to be present in the final product. A new Table 4 can be found at the end of this document.

5. Please confirm that all analytical methods used to analyze for the specification parameters listed in a revised Table 4 are validated and fit for purpose.

   Response: All analytical methods used to analyze for the specification parameters listed in the revised Table 4 are validated and fit for intended purpose.

6. In Table 9 (page 17), you provide a range of maximum use levels for the food category, "Plant-based protein products/meat analogs". Please provide specific maximum use levels for subcategories rather than one broad range.

   Response: See the following table provided by Exponent. Exponent conducted the intake assessment.

   As the Table footnote indicates, chickpea protein is intended to be **substitutional i**n plant protein products to provide protein at the protein concentration **currently** in these foods. As such, for each plant protein food, we calculated the chickpea protein equivalent based on each foods' protein content from the USDA FNDDS. Using this approach, the use level for each food code within this category is summarized in the table below. So, for Table 9, the range of use levels from 13.3% - 53.3% was reported.

Plant based protein products/meat analogs

Food code	Food description	Protein g/100 g [a]	Chickpea protein use level % [b]
27564420	Frankfurter or hot dog sandwich, meatless, plain, on bun*	15.76	32.7
27564430	Frankfurter or hot dog sandwich, meatless, plain, on bread*	16.7	32.7
41810200	Bacon strip, meatless	11.69	19.5
41810250	Bacon bits	32	53.3
41810400	Breakfast link, pattie, or slice, meatless	20.28	33.8
41810600	Chicken, meatless, NFS	23.64	39.4
41810610	Chicken, meatless, breaded, fried	21.28	35.5
41811400	Frankfurter or hot dog, meatless	19.61	32.7
41811600	Luncheon slice, meatless-beef, chicken, salami or turkey	17.78	29.6
41811800	Meatball, meatless	21	35.0
41811890	Vegetarian burger or patty, meatless, no bun	15.7	26.2
41811950	Swiss steak, with gravy, meatless	12.67	21.1
41812000	Sandwich spread, meat substitute type	8	13.3
41812450	Vegetarian chili, made with meat substitute*	7.44	26.2
41812600	Vegetarian, fillet	23	38.3
41812900	Vegetarian meat loaf	21	35.0
75140500	Broccoli salad with cauliflower, cheese, bacon bits, and dressing*	5.88	53.3

[a] Based on the USDA Food and Nutrient Database for Dietary Studies (FNDDS).

7. According to the flowchart on page 11, the manufacturing process results in two products described as Artesa™ 60 (protein) and Artesa™ 10 (flour). Please confirm that only the protein product, and not the flour product, is the subject of GRN 001093.

   Response: Only the protein product, and not the flour product, is the subject of GRN 001098.

8. Section G (page 12) is titled "Characterization of *Vicia faba* L.". Please confirm that the title should refer to *Cicer arietinum* L.

   Response: The title should refer to *Cicer arietinum* L., not *Vicia faba* L.

9. For completeness of the safety narrative, please identify the search terms used in the literature search described on page 26 of the notice. Please also perform an updated literature search from June 2022 to present and discuss if any data were found that would contradict the current GRAS conclusion.

   Response: An updated literature search was conducted, and no data were found that would contradict the current GRAS conclusion. See the following literature search terms:

   ToxStrategies conducted a targeted scientific literature search, and compiled information and data on chickpeas and chickpea protein relevant to a determination of safety under the intended conditions of use in human food. Studies included, but were not limited to, toxicology studies of chickpeas or chickpea protein including *in vitro* studies, animal studies, and clinical trials.

   PubMed:

   1. Chickpea OR "chickpea" OR "garbanzo" OR ("Cicer arietinum" OR ("Cicer"[MeSH Terms] AND arietinum [All Fields])) OR 92113-26-3[EC/RN Number]
      Results: 3,106 on 7/18/22

   2. (Chickpea OR "chickpea" OR "garbanzo" OR ("Cicer arietinum" OR ("Cicer"[MeSH Terms] AND arietinum [All Fields])) OR 92113-26-3[EC/RN Number])
      AND
      (safe OR safety OR toxic OR toxicity OR NOAEL OR LD50 OR LC50 OR "consumer product safety"[MeSH Terms] OR "Toxicity Tests"[MeSH Terms] OR absorption OR distribution OR metabolism OR excretion OR ADME[tiab] OR allergy OR allergen OR allergenicity OR allergic OR allergens[MeSH Terms] OR sensitiz* OR "hypersensitivity"[MeSH Terms] OR "hypersensitivity"[All Fields] OR "allergy and immunology"[MeSH Terms] OR atopic[All Fields] OR LLNA OR "Local Lymph Node Assay"[MeSH Terms] OR "Local Lymph Node Assay" OR (toxicity AND (development OR developmental OR reproductive)) OR "Teratogenesis"[MeSH Terms] OR teratogen OR teratogenic OR "Reproductive and

Urinary Physiological Phenomena"[MeSH Terms] OR neoplastic OR cancer OR carcinogen* OR carcinoma OR tumor OR tumors OR "animal bioassay" OR oncogenic* OR malignant OR malignancy OR malignancies OR genotoxic OR genotoxicity OR clastogen* OR mutagen OR mutagenic OR mutation* OR "cytogenetic aberration" OR "chromosome aberrations"[MeSH Terms] OR micronucle* OR "DNA damage" OR "DNA fragmentation"[Mesh] OR "Mutagenicity Tests"[MeSH Terms] OR "comet assay")

Embase:

('chickpea'/exp OR 'chickpea' OR 'cicer arietinum extract' OR 92113-26-3:rn)

10. On page 27, you conclude that toxicity studies on chickpea protein were not considered necessary, and that "safety-related information for chickpeas and associated chickpea proteins can be extracted from studies of their potential health benefits." We note that risk-benefit analyses are not used in food safety assessment, and benefits studies are rarely designed with appropriate toxicological endpoints, and thus cannot be considered pivotal to the safety determination of GRAS ingredients. In fact, depending on the reported findings, these studies may even raise safety questions. For clarification, do you consider all studies listed under this section as supportive data only?

    Response: The studies are supportive only.

11. On page 30 you state that Ferreira et al., (2021) reported improvements in blood pressure as a health benefit to pulse consumption. Additionally, you reference an article specific to the safety of chickpea consumption (Gupta et al., 2017), which notes that chickpea protein is a good source for ACE-inhibitory bioactive peptides. Please briefly discuss if chickpea protein consumption from your intended use would be expected to pose a safety concern in individuals taking antihypertensive medications?

    Response: The paper by Ferriera et al., (2021) described the patient population in the reviewed studies to be individuals with health conditions; only one study exclusively included only healthy individuals. Chickpea consumption in most of the reviewed studies lasted 4-8 weeks, with one study lasting 18 months. No significant cardiovascular adverse effects were noted. Gupta et al. (2017) noted that for the ACE-inhibitory bioactive peptides to be effective, they must escape digestion and enter the circulatory system prior to entering the target cells and more research is needed to confirm their discussed findings. It is reasonable to assume that some individuals in the reviewed clinical trials were taking antihypertensive medications while consuming chickpeas, but no notable cardiovascular adverse effects were noted. Therefore, the consumption of chickpea protein from the proposed uses would not be expected to pose a safety concern in individuals taking antihypertensive medications.

12. Gupta et al., (2017) also discuss that chickpea protein contains a variety of phytoestrogens, whose safety is not discussed in the current GRAS notice. Please provide

a discussion on the safety of the phytoestrogens found in chickpea protein, and state why their exposure from your intended use would or wouldn't pose a risk to consumers.

Response: Phytoestrogens (e.g., isoflavones, lignans) are commonly found in many foods, not just chickpeas. Other everyday foods that are significant sources of phytoestrogens include soy, flax seeds, walnuts, dairy and meat, sesame seeds, wheat, and other legumes including red beans and peas. US consumption of phytoestrogens is typically cited as approximately 3-5 mg/day, while in Asia it ranges from 30-50 mg/day. Given that chickpeas are one of the most ancient legumes consumed around the world and many common foods contain phytoestrogens, the presence of naturally occurring phytoestrogens in the chickpea protein ingredient present no new safety concern.

13. You discuss allergenicity concerns on page 31 of the notice but do not mention if chickpea protein carries the same allergenic potential as whole chickpeas themselves. Are chickpea-associated proteins capable of eliciting an allergic reaction, like 2S albumin, concentrated or expected to be concentrated in the final chickpea protein product? If so, please discuss if this would pose any additional safety concerns for consumers. Please also discuss whether or not analytical data is needed to support this conclusion.

    Response: It is not clear whether the chickpea protein ingredient contains higher levels of protein as compared to cooked chickpeas, but considering chickpeas contain approximately 20% protein, it can be assumed that the protein content is concentrated approximately 3-fold. However, it should be noted that the proposed uses of the chickpea protein ingredient (containing approximately 60% protein) will be incorporated into select foods only, and at maximum use levels of 10 – 60%, the only exception being dry-blend protein powders (90% use level). However, even this protein powder will be significantly diluted by whatever liquid it is mixed with. As such, if 2S albumin were concentrated in the protein ingredient, it would similarly be diluted in the food item it was added to. For these reasons, it is not expected that the proposed uses of the chickpea protein ingredient will pose any additional safety concern for consumers and analytical data is not needed to support this conclusion. Tate & Lyle recognizes the importance to clearly label products as required by current food labelling laws, especially where the product is one that the customer might not normally expect to contain chickpeas or chickpea proteins.

14. You conclude that an immune response (i.e., allergic reaction) to chickpea protein is relatively rare. However, on page 31, you discuss the cross-reactivity of chickpea and peanut allergens, as well as the prevalence of chickpea allergy in the general population (~2-8%), which is similar for allergies to other legumes, like peanuts. While you recommend that products containing chickpea protein be clearly labeled as such, labeling requirements as a condition of safe use do not fall under the GRAS provision. Additionally, we note that simply indicating the presence of "chickpea protein" in the ingredients label may not suffice in addressing the cross-reactivity concerns that you raised from the published literature (Chen et al., 2019).

a. Please provide a short narrative describing why allergic reactions to chickpea protein in consumers with a peanut allergy would not be expected to increase with the availability of chickpea protein as a food ingredient from the intended uses.

Response: Chickpea-based foods and snacks have been marketed in the United States and other countries around the world and include hummus (2 g protein/serving), snack foods, and snack bars (3–6 g protein/serving) (Acevedo-Martinez et al., 2021). In addition, chickpea flour has been used in foods around the world for centuries. Allergy to chickpea has been much less frequently reported than to peanut or soybean but does exist. The symptoms of chickpea allergic individuals are similar to those of other food allergies with urticaria (hives) and other reactions of the skin being the most common symptom. Given the current knowledge among consumers with a peanut allergy of the possibility of cross-reactivity with legumes, we would not expect an increase in the incidence of allergic reactions in this consumer population.

15. In Appendix A, on pgs. 55-57 of the notice, the Eurofins certificates of analysis demonstrate there are resides of methanol (30.8-45.4 ppm) and ethanol (86.2-146 ppm) in the chickpea protein ingredient. However, the GRAS notice lacks a discussion on the safe ingestion of methanol and ethanol residues from consumption of chickpea protein. Please discuss if residues of methanol and ethanol at the levels detected pose a safety risk for consumers of chickpea protein from the intended uses.

Response:

As noted in the response to Question 4 above, a specification of <50 ppm methanol is specified. Methanol is not used in the production of the chickpea protein ingredient. It is believed to be naturally-occur in chickpeas.

The first notice of the permitted use of methanol was to manufacture spice oleoresins and appeared in the Federal Register in 1965, (30 FR 15907, 1965) as 21 CFR 121.1045, moved in 1977 to 21 CFR 173.250 (42 FR 14530, 1977). In both instances the maximum residue of methanol was 50 ppm. It is also permitted for use in dietary ingredients and USP limits the residual methanol to <3000 ppm. Methanol is a natural component of fruits and fruit products and is found in beer, wine, and distilled beverages. Methanol was found at levels of 12 mg/L in apple juice to 150 mg/L in black currant nectar (Possner et al., 2014) and at 6-27 mg/L in beer, 96-321 mg/L in wines, and 10-220 mg/L in distilled spirits, (INCHEM, 1997).

The methanol content of some common foods from the TNO Volatile Compounds in Foods database, as reported by Magnuson (Magnuson, 2007) are as follows:

Anise Brandy Trace, 563 ppm
Banana, 15 ppm
Dates, 28 ppm
Grape Brandies, 150-332 ppm
Grape Juice, 12-680 ppm

Orange Juice, 0.8-80 ppm
Rums, 8-36 ppm
Tomato, 64-229 ppm
Tomato Juice, 180-218 ppm
Whiskeys, 15-160 ppm
Wine, Red 0-209 ppm
Wine, White 8-116 ppm

The background level of methanol in the diet ranges from 0.55 to 2.25 mg/kg bw/day depending on if an individual consumes alcoholic beverages. The safe exposure to methanol from the consumption of aspartame is 5.43 mg/kg bw/day (Magnuson et al, 2007). The estimated cumulative exposure from all current sources includes the background from foods (33.3 mg/day) as well as aspartame consumption (5.43 mg/day). A worst-case theoretical intake of methanol based on conservative EDI's (90th percentile per user; total US population) of the chickpea protein ingredient is 2.62 mg/day or 0.0437 mg/kg/day for a 60 kg individual. The safe exposure to methanol from the consumption of aspartame is 5.43 mg/kg bw/day (Magnuson et al., 2007) or approximately 330 mg/day and endogenous methanol production in the body results in blood methanol concentrations of approximately 15 mg/L (range 2 - 30 mg/L) (Mundkinajeddu and Agarwal, 2014). Potential exposure to methanol from the proposed uses of B. serrata extract are well below the maximum level of 5.43 mg/kg/day that FDA deemed to be safe for the highest cumulative exposure to aspartame and would not result in significant incremental exposure to methanol.

Likewise, consumers are routinely exposed to incidental amounts of ethanol from consumption of food items such as orange juice, soft drinks, and breads. GRN 151 (FDA, 2004) received a "no questions letter" for the use of ethyl alcohol as a preservative in the filling used in shelf-stable croissants at a concentration of 3,000 ppm. In addition, GRN 151 reported ethanol levels in ripening fruit and fruit juice ranging from 117 to 1,900 ppm, and Logan and Distefano (1998) reported levels of ethanol in various baked goods ranging from 0 to 1.66 %. A worst-case theoretical intake of ethanol based on conservative EDI's (90th percentile per user; total US population) of the chickpea protein ingredient is 8.44 mg/day or 0.1406 mg/kg/day for a 60 kg individual. It is reasonable to conclude that the oral exposure is negligible and does not present any safety concern related to ethanol exposure.

References:

Food and Drug Administration (US FDA). 2004. GRN No. 151. GRAS Notification for Ethanol (Ethyl Alcohol). Prepared by Frito-Lay, Inc.

InChem, 1997. Environmental Health Criteria, 196, Methanol.

Logan BK, Distefano S. 1998. Ethanol content of various foods and soft drinks and their potential interference with a breath-alcohol test. Journal of Analytical Toxicology 32:181-183.

Magnuson BA, Burdock GA, Doull J, Kroes RM, Marsh GM, Pariza MW, Spencer PS, Waddell WJ, Walker R, Williams GM. 2007. Aspartame: A safety evaluation based on current use levels, regulations, and toxicological and epidemiological studies. Critical Reviews in Toxicology 37:629–727.

Mundkinajeddu D, Agarwal A. 2014. Residual methanol in botanical dietary ingredients – Perspectives of a manufacturer. HerbalIEGram:1(8).

Possner D, Zimmer T, Kurbel P, Dietrich H. 2014. Methanol contents of fruit juices and smoothies in comparison to fruits and a simple method for the determination thereof. Deutsche Lebensmittle-Rundschau February:65-69.

Table 1. Specifications for chickpea protein

Parameter	Specification	Method
Physical specifications		
Protein (%, db)	≥60	DUMAS: AOAC 990.03; 2000
Moisture (%)	<10	LOD: AOAC 930.15
Microbiological specifications		
Aerobic Plate Count (cfu/g)	<50,000	FDA BAM: AOAC 966.23
Yeast (cfu/g)	<100	Petrifilm: AOAC 2014.05
Mold (cfu/g)	<100	Petrifilm: AOAC 2014.05
Total coliforms (cfu/g)	<10	FDA BAM: 8th edition Ch.4
E. coli (cfu/g)	<10	FDA BAM: 8th edition Ch.4
Salmonella (/375 g)	Negative	FDA BAM: 8th edition Ch.5
Staph. Aureus (cfu/g)	<10	FDA BAM: 8th edition Ch. 12
Chemical specifications		
Arsenic (ppb)	<50	ICP-MS: AOAC 2013.06
Lead (ppb)	<20	ICP-MS: AOAC 2013.06
Mercury (ppb)	<20	ICP-MS: AOAC 2013.06
Cadmium (ppb)	<50	ICP-MS: AOAC 2013.06
Gluten (ppm)	<10	Neogen Veratox
Ethanol (ppm)	<200	ETME_S; Eurofins Internally Developed Method
Methanol (ppm)	<50	ETME_S; Eurofins Internally Developed Method