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March 4, 2022

Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Dr.
College Park, Maryland 20740

Re: GRAS Notice for Non-Animal β-Lactoglobulin Whey Protein from Fermentation by *Komagataella phaffi*

Dear Sir/Madam:

Pursuant to 21 C.F.R. part 170, subpart E, Remilk Ltd. hereby submits the enclosed notice, that use of its non-animal β-Lactoglobulin whey protein produced via fermentation by *Komagataella phaffi* as a non-animal source replacement for milk and plant proteins for use in foods that currently use protein from milk or plants as a source of dietary protein is excluded from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because the notifier has determined that such use is generally recognized as safe (GRAS) for its intended use, consistent with Section 201(s) of the Federal Food, Drug, and Cosmetic Act.

Sincerely,

Brian P. Sylvester

GRAS Notice for Non-Animal β-Lactoglobulin Whey Protein from Fermentation by *Komagataella phaffi*

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

Submitted by: Covington & Burling LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001-4956

On behalf of our client:

Remilk Ltd.
Holtzman 2
Rehovot, Israel 7670402

Date: March 4, 2022

GRAS Notice for Non-Animal β-Lactoglobulin Whey Protein from Fermentation by *Komagataella phaffii*

Table of Contents

List Of Tables

List Of Figures

Part 1. Signed statements and certification

1.1. Applicability of 21 C.F.R. part 170, subpart E

We submit this generally recognized as safe (GRAS) notice in accordance with 21 C.F.R. 170, subpart E.

1.2. Name and address of the notifier

Company:	Remilk Ltd.
Address:	Holtzman 2, Rehovot, Israel, 7670402
Phone:	972-505890867
Contact Name:	Ester Abramov
Contact email:	ester@remilk.com

All communications on this matter are to be sent to Counsel for Remilk Ltd.:

Name:	Brian P. Sylvester
Company:	Covington & Burling LLP
Address:	One CityCenter, 850 Tenth Street, NW, Washington, DC 20001-4956
Phone:	+1 202 662-5988
e-mail:	bsylvester@cov.com

1.3. Names of the notified substance

Non-Animal Whey Protein (β-Lactoglobulin)

Non-Animal Whey Protein

1.4. Applicable conditions of use of the notified substance

Remilk intends to market non-animal whey protein produced via fermentation by *Komagataella phaffii (*previously known as *Pichia Pastoris)* as a non-animal source replacement for milk and plant proteins for use in foods that currently use protein from milk or plants as a source of dietary protein. This ingredient is not intended for use in products regulated under U.S. Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) jurisdiction or in infant formula.

1.5. Basis for the GRAS determination

Covington & Burling LLP, on behalf of Remilk Ltd., hereby notifies the Agency of Remilk's determination that its non-animal whey protein composed of β-lactoglobulin from fermentation by *Komagataella phaffii* is GRAS for its intended use, consistent with Section 201(s) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This GRAS conclusion is based on scientific procedures in accordance with 21 C.F.R. § 170.30(b) and conforms to the guidance issued by the Food and Drug Administration (FDA) under 21 C.F.R. § 170.36, 81 Fed. Reg. 54,960 (Aug. 17, 2016). The statutory basis for Remilk's conclusion of GRAS status is through scientific procedures in accordance with proposed 21 C.F.R. § 170.36.

The GRAS status of β-lactoglobulin from fermentation by *Komagataella phaffii* is supported by data generally available in the public domain and by the long history of milk and milk derived protein consumption in human foods.

1.6. Exclusion from premarket approval

The notified substance is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on our conclusion that the notified substance is GRAS under the conditions of its intended use.

1.7. Availability of data and information

The data and information that serve as the basis for this GRAS conclusion are available to FDA upon request either in an electronic format or on paper as required by 21 C.F.R. § 170.225(c)(7)(ii) (A) or (B). FDA may direct such requests to Covington & Burling LLP at the below address:

Brian P. Sylvester
Covington & Burling LLP
One CityCenter, 850 Tenth Street, NW
Washington, DC 20001-4956
e-mail: bsylvester@cov.com

1.8. Freedom of Information Act statement

The information provided in Parts 2 through 7 in this application does not contain confidential or proprietary information, and therefore no FOIA exemptions are claimed. Thus, all information and data in this submission are not exempt from the Freedom of Information Act (FOIA), 5 U.S.C. Section 552.

1.9. Certification

On behalf of Remilk Ltd., we certify that, to the best of our knowledge, this GRAS notice is a complete and representative and balanced submission that includes unfavorable information, as well as favorable information, known to us and Remilk, and pertinent to the evaluation of the safety and GRAS status of β-lactoglobulin protein for its intended use.

1.10. Signature and name and title of the person signing this GRAS notice:

Date: March 4, 2022

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

2.1. Scientific data and information that identifies the notified substance

2.1.1. Common or usual name

Non-Animal Whey Protein (β-Lactoglobulin)

Non-Animal Whey Protein

2.1.2. Identity

β-lactoglobulin is the major whey protein of ruminant species. In bovine milk, the concentration of β-lactoglobulin ranges from 2-3 g/L, which represents approximately 7-9% of the total protein content.[1] Remilk produces a highly purified protein extract comprised of ≥ 80% β-lactoglobulin via fermentation, using a yeast strain *Komagataella phaffii*. The resulting product is a homogenous white to off-white powder that can be incorporated into foods at usage levels matching other purified dairy protein products.

2.1.3. Material Specifications

(a) Host strain

The host microorganism used to construct the β-lactoglobulin producing strain is *Komagataella phaffii (*previously known as *Pichia Pastoris). P. pastoris* was re-classified in 1995 into a new phylogenetically distinct genus, *Komagataella*, and identified based on 26S rRNA sequencing data as *K. phaffii*. *K. phaffii* CBS 7435 is also known as NRRL Y-11430.[2] Y-11430 is classified as a Biosafety Level 1 (BSL-1) organism by the American Type Culture Collection (ATCC) organization based on U.S. Public Health Service Guidelines, a category reserved for well-characterized agents not known to cause disease in healthy human adults and to be of minimal hazard to laboratory personnel and the environment.[3]

(b) Production strain

To optimize expression of β-lactoglobulin and obtain the purest product possible, Remilk employs several common and well-characterized genetic modification techniques. The native sequence of bovine β-lactoglobulin variant B is introduced into the recipient strain under the strong native *K. phaffii* alcohol oxidase promoter followed by the *K. phaffii* alcohol oxidase terminator. The introduction cassette contains β-lactoglobulin gene which has been codon-optimized for expression in the host strain. Nevertheless, the amino acid sequence remained unchanged.

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[1] G. Kontopidis, et al., *Invited review: β-lactoglobulin: binding properties, structure, and function*, 87 J. Dairy Sci. 785 (2004).

[2] Cletus P. Kurtzman, *Description of Komagataella phaffii sp. nov. and the transfer of Pichia pseudopastoris to the methylotrophic yeast genus Komagataella*, 55 Int. J. Syst. Evol. Microbiol. 973 (2005).

[3] Centers for Disease Control and Prevention National Institutes of Health, Biosafety in Microbiological and Biomedical Laboratories (6th ed. 2020).

The general taxonomy of *P. pastoris* (*K. phaffii*) is as follows:

Name: Komagataella phaffii

Kingdom: Fungi

Phylum: Ascomycota

Class: Saccharomycetes

Order: Saccharomycetales

Family: Phaffomycetaceae

Genus: Komagataella

Species: Komagataella phaffii (pseudonym - *Pichia pastoris*, the strain is still often referred to as *Pichia pastoris*)

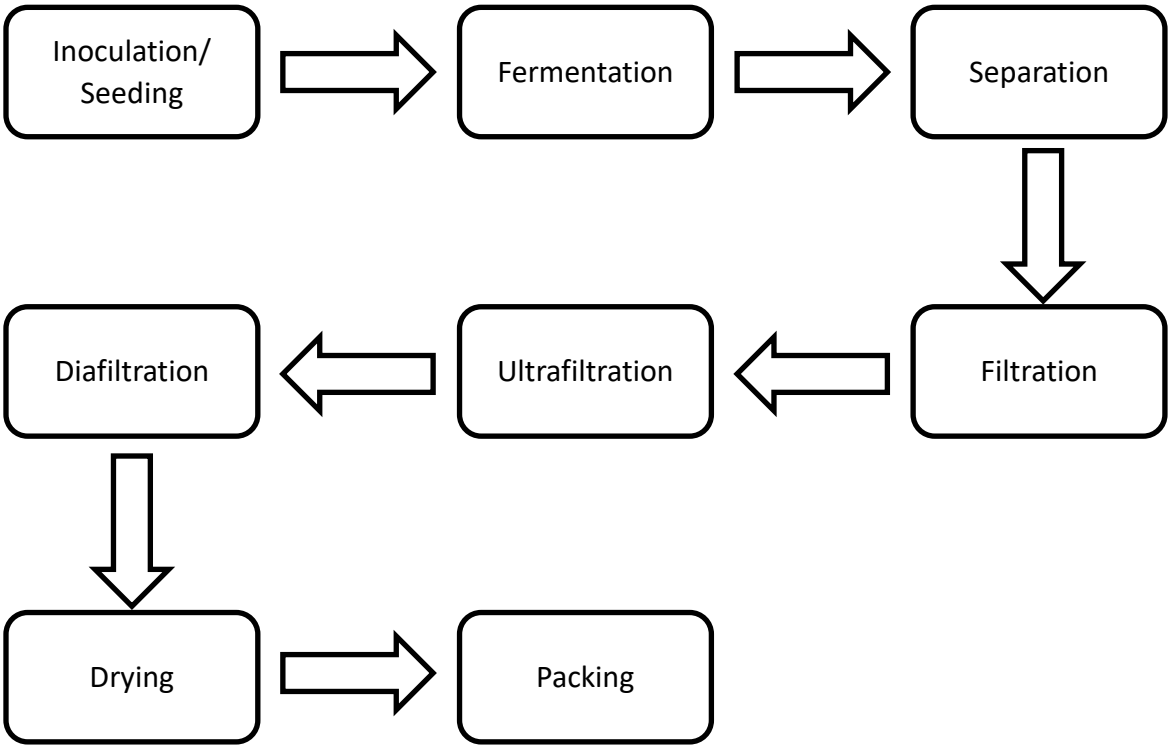
2.2. Method of manufacture

Remilk's non-animal β-Lactoglobulin is manufactured in compliance with Current Good Manufacturing Practice (CGMP) and Hazard Analysis and Risk-Based Preventive Controls (HARPC) for human food (21 C.F.R. Part 117, Subparts B and C) and meets appropriate food grade specifications. β-lactoglobulin is manufactured as follows:

1. A vial of modified *K. phaffii* from a working cell bank is used for inoculation/seeding stages.
2. The seed is transferred to the production fermenter to produce a biomass, followed by protein expression. The expressed protein is secreted from the yeast and remains solubilized in the fermentation media.
3. The media containing the β-lactoglobulin is then separated from the biomass and filtrated. The filtrate is then concentrated via ultrafiltration and diafiltrated to exchange the media to water.
4. The solution is dried to obtain the finished product of white to off-white powder with ≥80% β-lactoglobulin protein.

All equipment is carefully designed, constructed, operated, cleaned, and maintained to prevent contamination by undesired microorganisms. Physical and chemical control measures are implemented during all process steps, and microbiological analyses are conducted periodically to ensure the absence of foreign microorganisms and confirm the identity of the production strain.

Figure 1: Manufacturing Process of β-lactoglobulin



2.2.1. Raw Materials

All materials (raw materials, processing aids, filtration aids, and pH adjusters) used in the fermentation and recovery processes for β-lactoglobulin are standard ingredients used in the food/enzyme industry and follow internal specifications (in line with Food Chemicals Codex). These specifications include limits on lead and other pertinent heavy metals. The raw materials are of a purity and quality suitable for their intended use; they are food grade and GRAS, or high-quality chemical or pharmaceutical grades (USP, NF or ACS grades) from approved suppliers.

None of the materials that are used in the production of β-lactoglobulin are derived from major allergens.

2.3. Specifications for food-grade material and batch analyses

2.3.1. Physical, Chemical, and Microbiological Specifications

The product specifications for β-lactoglobulin produced by fermentation of *Komagataella phaffii* are presented in Table 1.

Table 1: Physical and Microbiological Characteristics of β-Lactoglobulin Produced by Fermentation

Analysis	Specification	Reference Method
Protein (Dumas/Kjeldahl)	≥70 wt%	AOAC 968.06, AOAC 992.15, AOAC 984.13
β-Lactoglobulin as % of Protein	≥80 %	HPLC (qualified method in accredited laboratory)
Moisture	≤7 wt%	AOAC 926.08, AOAC 925.09, AOAC 935.29
Ash	≤4 wt%	AOAC 923.03, AOAC 942.05
Fat	≤4 wt%	AOAC 989.05, AOAC 932.05, AOAC 986.25
Total Carbohydrates	≤20 wt%	By difference
pH	5.0-7.5	AOAC 981.12
Arsenic	≤0.1 ppm	ICP-MS
Cadmium	≤0.1 ppm	ICP-MS
Lead	≤0.1 ppm	ICP-MS
Mercury	≤0.1 ppm	ICP-MS
Total Aerobic Count	≤10,000 CFU/g	AOAC 966.23, FDA BAM Chapter 3
Yeast	≤50 CFU/g	FDA BAM Chapter 18
Mold	≤50 CFU/g	FDA BAM Chapter 18
Enterobacteriaceae	≤10 CFU/g	AOAC 2003.01

2.4. Batch Analyses

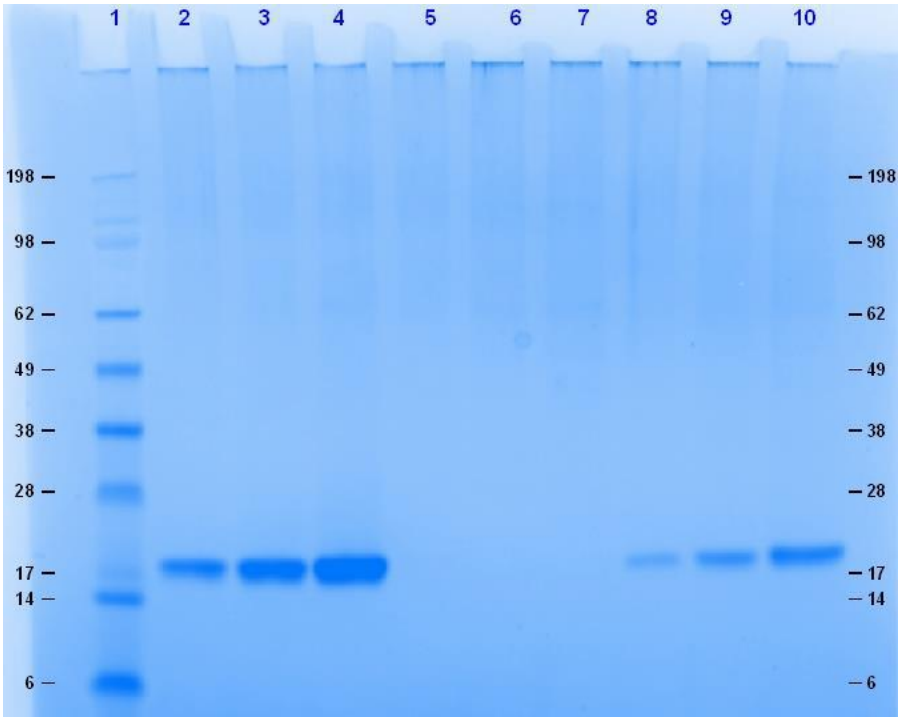
Data from the analysis of three representative lots that demonstrate the consistency of the manufacturing process and compliance with the physical and chemical specifications are presented in Table 2 (results from testing labs are provided in Appendix 1).

Table 2: Physical, Chemical, and Microbiological Product Analysis for Three Non-Consecutive Lots Produced by Fermentation

Analysis	Specification	Batch 1	Batch 2	Batch 3
Protein (Dumas/Kjeldahl)	≥70 wt%	86.9	90.6	84.3
β-Lactoglobulin as % of Protein	≥80 %	91	93	83
Moisture	≤7 wt%	4.91	3.43	3.47
Ash	≤4 wt%	3.17	1.95	2.95
Fat	≤4 wt%	1.0	0.2	0.6
Total Carbohydrates	≤20 wt%	4.0	3.9	8.7
pH	5.0-7.5	6.58	5.25	6.48
Arsenic	≤0.1 ppm	<0.0100	0.0603	0.0146
Cadmium	≤0.1 ppm	<0.00500	<0.00500	<0.00500
Lead	≤0.1 ppm	0.0277	0.00535	0.00534
Mercury	≤0.1 ppm	<0.00500	<0.00500	0.00500
Total Plate Count	≤10,000 CFU/g	<10	<10	10
Yeast	≤50 CFU/g	<10	<10	<10
Mold	≤50 CFU/g	<10	<10	<10
Enterobacteriaceae	≤10 CFU/g	<10	<10	<10

As shown in Figure 2, below, β-lactoglobulin obtained from fermentation of *Komagataella phaffii* has a molecular weight of approximately 18 kDa, corresponding to its predicted molecular weight, and displays a similar gel migration pattern to a commercial bovine β-lactoglobulin reference (Sigma; Catalog # L8005) while the supernatant of the mock strain (*K. phaffii* without insertion of the β-lactoglobulin gene) displays no β-lactoglobulin bands.

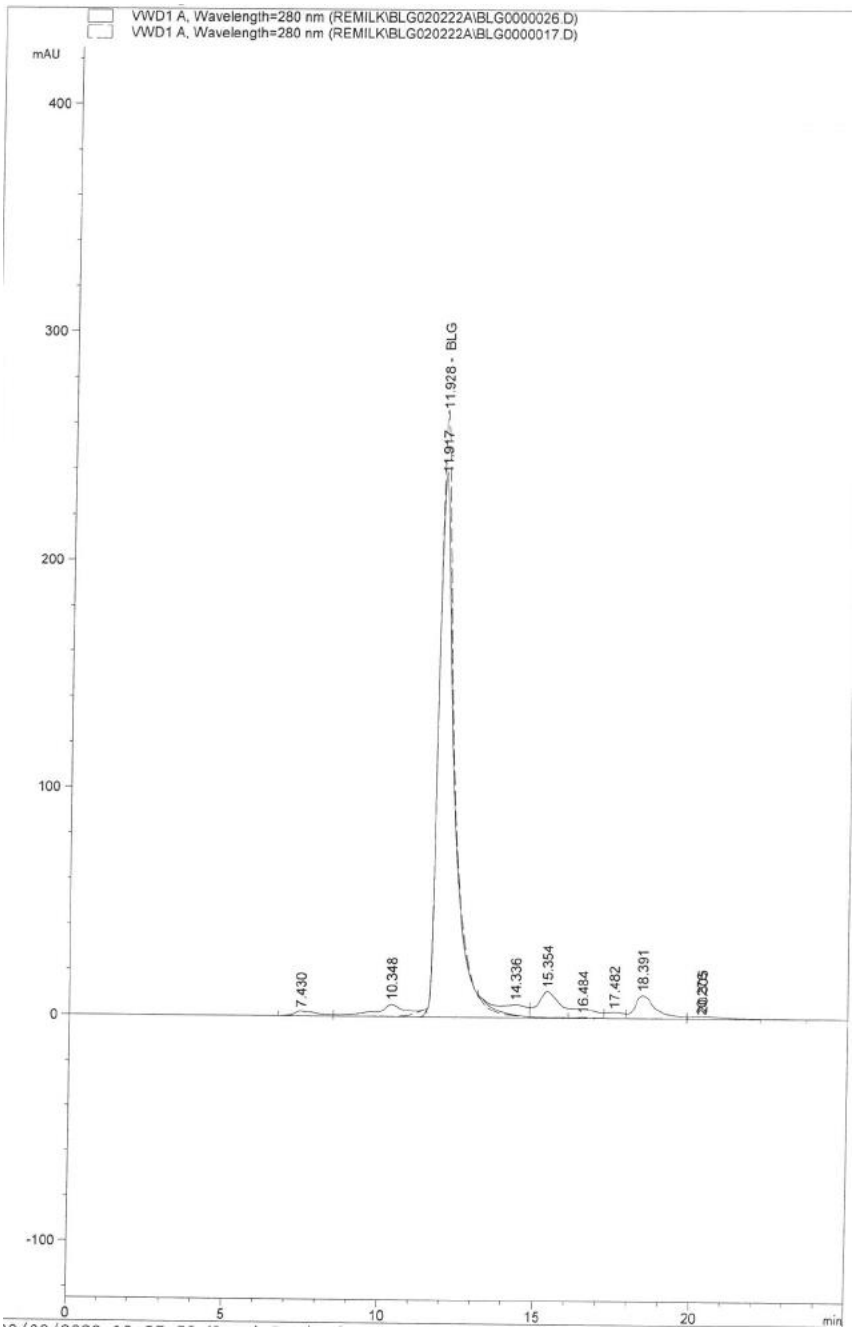
Figure 2: SDS-PAGE Analysis of β-lactoglobulin from Different Samples



Lane 1:	SeeBlue Prestained Protein Marker (marker proteins in kDa given)
Lanes 2-4:	Supernatant of yRMK-66 strain – different loading volumes
Lanes 5-7:	Supernatant of mock strain – different loading volumes
Lanes 8-10:	β-lactoglobulin reference – different loading volumes

Similar findings were observed in the size exclusion chromatography (SEC) profiles where β-lactoglobulin obtained from the fermentation of *K. phaffii* was compared to a commercial standard, demonstrating high purity and similarity in retention times. See Figure 3 below in this regard.

Figure 3: Characterization of β-lactoglobulin by Size Exclusion Chromatography



Remilk\BLG020222A\BLG0000026.D- Remilk non animal β-lactoglobulin

Remilk\BLG020222A\BLG0000017.D- bovine β-lactoglobulin (standard)

Part 3. Dietary Exposure

3.1. Estimate of Dietary Exposure

Remilk's non-animal β-lactoglobulin whey protein, produced via fermentation by *K. phaffii*, is intended for use as a non-animal source of protein in select foods including nutritional products, dairy and dairy-based products, sugar-based products, baked goods, dressing, and egg substitutes. Remilk's non-animal β-lactoglobulin whey protein is intended for use at the maximum proposed use levels in select foods from 5% to 35% by weight (i.e., 5 to 35 g β-lactoglobulin per 100 g food). Table 3, below, outlines the proposed food categories to which Remilk's non-animal β-lactoglobulin is intended to be added and the corresponding intended maximum use levels.

Table 3: Intended use of Remilk's Non-Animal β-lactoglobulin Whey Protein in select foods

Food category	Remilk's proposed food use	Proposed max use level, % [a]
Nutritional Products	Meal replacements and supplements	15
	Powdered nutritional beverages	25
	Electrolyte-type sports drinks	6
	Performance nutritional beverages, high protein	25
	Nutritional bars	35
Dairy and Dairy-Based Products	Fluid milk, powdered milk, flavored milk, milk-based drinks and drink mixes (e.g., dairy smoothies, hot chocolate from mix), milk substitutes	6
	Cream, half & half, cream cheese, cheese spread, whipped cream	15
	Spreads, dips	10
	Cream substitutes	15
	Yogurt and fermented milk products	8
	Ice cream, frozen yogurt	8
	Cheese used primarily as ingredients, e.g. ricotta cheese	15
	Semi-hard cheese (e.g., feta, Camembert, brie)	25
	Desserts and mousses	5

Food category	Remilk's proposed food use	Proposed max use level, % [a]
Sugar-Based Products	Confections (including chocolate confections)	10
	Coatings and fillings	10
	Cookies and brownies, crackers, popcorn, potato chips, tortilla chips, hard pretzels/snack mix	5
	Doughnuts, toaster pastries, muffins	10
Baked Goods	French toast, crepes, pancakes, bagels, scones, biscuits, croissants	10
	Breads & rolls, English muffins, pizza crust	10
Dressings	Creamy salad dressings	5
	Minor main entrée sauces (e.g., Alfredo sauce, white sauce, cheese sauce)	6
Egg Products	Egg substitutes	10

[a]Use level represents the concentration of non-animal β-lactoglobulin whey protein in the food.

Non-animal, bovine-identical β-lactoglobulin whey protein produced by *Trichoderma reesei* was previously concluded to be GRAS for select uses in food by way of GRN 863 as a source of protein. The estimates presented in this analysis therefore include estimates of intake of non-animal β-lactoglobulin from existing GRAS uses, from Remilk's proposed uses, and the cumulative intake of non-animal β-lactoglobulin from Remilk's intended use in combination with existing recognized use of non-animal β-lactoglobulin.

Remilk's estimates of the intended intake of non-animal β-lactoglobulin were developed from food consumption records collected in the What We Eat in America (WWEIA) component of the National Health and Nutrition Examination Surveys (NHANES) conducted in 2015-2016 and 2017-2018.[4] Estimates of non-animal β-lactoglobulin intake were developed for the U.S. population ages 2 years and older and subpopulations of children, adolescents, and adults.

Table 4, below, presents the concentration of non-animal β-lactoglobulin representative of the existing GRAS uses (i.e., derived from GRN 863) and applied in the current analysis. The Table also presents the concentration of non-animal β-lactoglobulin that represents Remilk's proposed uses. Additionally, the Table presents the total maximum

[4] USDA, *What We Eat in America (WWEIA), National Health and Nutrition Examination Surveys (NHANES)* (2015-2018).

use of non-animal β-lactoglobulin to reflect both existing GRAS uses and proposed uses across all applicable food categories.

Table 4: Intended use of Remilk's non-animal β-lactoglobulin in select foods vs. existing GRAS uses of non-animal β-lactoglobulin in foods and use levels applied in estimates of intake

Food Category	**GRN 863 Existing GRAS Use[2]**	**Remilk's Proposed Use**	**Use Levels Applied in Estimates of Intake[1]**		
			Existing GRAS Use	**Proposed Use**	**Total Use**
Nutritional Products	Meal Replacements and Supplements	Meal Replacements and Supplements	15	15	15
	Powdered Nutritional Beverages	Powdered Nutritional Beverages	25	25	25
	Sports beverages	Electrolyte-type sports drinks	6	6	6
		Performance nutritional beverages, high protein	25	25	25
	Nutritional Bars	Nutritional Bars	35	35	35
Dairy and Dairy-Based Products	Milk products (including beverages and coffee creamer)	Fluid milk, powdered milk, flavored milk, milk-based drinks and drink mixes (e.g., dairy smoothies, hot chocolate from mix), milk substitutes	6	6	6
		Cream, half & half, cream cheese, cheese spread, whipped cream	15	15	15
		Spreads, Dips	10	10	10

Food Category	GRN 863 Existing GRAS Use[2]	Remilk's Proposed Use	Use Levels Applied in Estimates of Intake[1]		
			Existing GRAS Use	Proposed Use	Total Use
	Spreads, dips, and cream substitutes	Cream substitutes	15	15	15
	Yogurt and fermented milk products	Yogurt and fermented milk products	5	8	8
	Frozen dairy desserts and mixes	Ice cream, frozen yogurt	10	8	10
	-	Cheese used primarily as ingredients, e.g. ricotta cheese.	-	15	15
		Semi-hard cheese (e.g., feta, Camembert, brie)	-	25	25
Sugar Based Products	Desserts and Mousses	Desserts and Mousses	5	5	5
	Confections (including chocolate confections)	Confections (including chocolate confections)	10	10	10
	Coatings and Fillings	Coatings and Fillings	10	10	10
	Snack Foods	Cookies and brownies, crackers, popcorn, potato chips, tortilla chips, hard pretzels/snack mix	5	5	5
		Doughnuts, toaster pastries, muffins	10	10	10

Food Category	GRN 863 Existing GRAS Use[2]	Remilk's Proposed Use	Use Levels Applied in Estimates of Intake[1]		
			Existing GRAS Use	Proposed Use	Total Use
Dressings	Salad dressings	Creamy salad dressings	5	5	5
	-	Minor main entree sauces (e.g., Alfredo sauce, white sauce, cheese sauce)	-	6	6
Baked Goods	-	French toast, crepes, pancakes, bagels, scones, biscuits, croissants	-	10	10
		Breads & rolls, English muffins, pizza crust	-	10	10
Egg Products	-	Egg Substitutes	-	10	10

1 All levels represent maximum use levels within each food category

2 Use level represents the concentration of non-animal β-lactoglobulin in the food

Two-day average intake estimates of non-animal β-lactoglobulin at the mean and 90th percentile of intake from proposed uses are summarized in Table 5. Among the U.S. population ages 2 years and older, nearly all individuals (99.7%) were estimated to consume one or more foods during the two days of recall that may contain added non-animal β-lactoglobulin from proposed uses. Both the per capita and per user mean and 90th percentile intake in the population ages 2 years and older is 31.0 g/day and 56.4 g/day, respectively. We append the detailed dietary exposure assessment report at Appendix 4.

Table 5: Two-day average daily intake of Remilk's non-animal β-lactoglobulin from all proposed uses (g/day) by the U.S. population 2+ years and select sub-populations, NHANES 2015-2018

Population	Total Sample, n	Users		Per Capita		Per User	
		n	%	Mean	90th Per-centile	Mean	90th Per-centile
U.S. 2+ y	12717	12670	99.7	31.0	56.4	31.0	56.4
Children 2-5 y	999	998	100.0	33.2	53.6	33.2	53.6
Children 6-12 y	1744	1743	99.9	36.2	59.4	36.3	59.4
Adolescents 13-18 y	1433	1431	99.9	33.5	59.6	33.5	59.6
Adults 19+ y	8541	8498	99.6	29.9	55.8	30.0	55.9

Among the U.S. population ages 2 years and older, nearly the entire population was estimated to consume a food that currently or potentially may contain non-animal β-lactoglobulin as an ingredient. At the per user 90th percentile of intake, intake from current, proposed, and cumulative sources of non-animal β-lactoglobulin are 45.2 g/day, 56.4 g/day, and 57.6 g/day, respectively. The proposed uses of non-animal β-lactoglobulin are substitutional for existing uses of β-lactoglobulin, and also slightly expand the uses of this protein source. All uses of non-animal β-lactoglobulin are assumed to be substitutional for added dietary protein ingredients, and therefore will not increase overall intake of dietary protein. The typical U.S. diet provides approximately 1.4 g β-lactoglobulin from milk proteins. This value was calculated assuming 78.3 g total protein intake,[5] 20% of total protein is from dairy sources,[6] and

[5] USDA, *Dietary Guideline for Americans, 2020-2025*.

[6] C. J. Cifelli, N. Auestad, V. L. Fulgoni, III, *Protein in the U.S. Diet and the Contribution of Dairy Foods. Dairy Research Institute Data Brief No. 1502* (2015). Available at: https://www.usdairy.com/getmedia/6d314cf0-e776-4f9f-9bb9-97c039f8a96e/ndc%20protein%20data%20brief%20october%202015.pdf.

9% of dairy protein is β-lactoglobulin.[7] Use of non-animal β-lactoglobulin as an ingredient may provide additional intake of this protein.

The estimates presented in this part provide conservatively high estimates of non-animal β-lactoglobulin intake from the intended uses. In calculating the estimates of intake, it was assumed that all foods in each use category will contain the maximum intended use level of the ingredient. In reality, Remilk may not use the maximum intended use level of non-animal β-lactoglobulin in all products, and not all consumers may select products with non-animal β-lactoglobulin at all eating occasions.

[7] G. D. Miller, J. K. Jarvis, L. D. McBean, *Handbook of Dairy Foods and Nutrition, National Dairy Council*, CRC Press: Boca Raton, FL (3rd ed. 2007).

Part 4. Self-Limiting Levels of Use

The use of β-lactoglobulin is not self-limiting. The maximum use levels in food are described above.

Part 5. Experience Based on Common Use in Food Before 1958

The conclusion that the intended use of Remilk's non-animal β-lactoglobulin is GRAS is based on scientific procedures rather than experience based on common use in food prior to 1958.

That said, β-lactoglobulin is a component of milk. Milk and products derived from milk, such as whey, have a long history of safe consumption by humans at all ages in the form of fluid milk, in dried form (i.e., milk powder), or as milk-derived ingredients. Therefore, the history of milk consumption provides support for the GRAS status of the notified substance when used as intended.

Part 6. Narrative

6.1. Safety

Safety considerations regarding Remilk's β-lactoglobulin whey protein produced via fermentation of *Komagataella phaffii* involve the safety of both the production organism (modified *K. phaffii*) and the safety of the end use product (non-animal β-lactoglobulin). *Komagataella phaffii* has a long history of safe use in industrial scale food enzyme production. The safety of this species as an industrial enzyme production organism has been reviewed multiple times; it is considered non-pathogenic for humans and does not produce toxins or antibiotics under submerged fermentation conditions.

6.1.1. Safety of the Parental Strain

Komagataella phaffii (previously known as *Pichia pastoris or P. pastoris*) is a well-characterized expression host. *P. pastoris* was re-classified in 1995 to the genus *Komagataella* following phylogenetic analysis of gene sequences. Results from multigene sequence analyses show that the strain of '*Pichia pastoris*' commonly used in gene expression studies is actually *K. phaffii*. *K. phaffii* CBS 7435 is also known as NRRL Y-11430.[8] Y-11430 is classified as a Biosafety Level 1 (BSL-1) organism.

P. pastoris has a long history of safe use in food production. As examples of the widespread use of *P. pastoris*, which lend support for its safety, we note that *P. pastoris* is used for production of nitrate reductase (The Nitrate Elimination Co. Lake Linden, MI), an enzyme used for treatment of potable water. *P. pastoris* itself is also approved by FDA as an animal feed protein source allowed in broiler feed at up to 10% of the total feed.[9] In addition, the American Association of Feed Control Officials (AAFCO) has approved the *E. coli* enzyme phytase derived from the fermentation of recombinant *P. pastoris* for use in animal feed.[10]

Further, an extensive review of literature databases failed to reveal any documentation of toxigenic effects associated with *P. pastoris*.[11] As discussed in Pariza and Foster[12] and

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[8] Cletus P. Kurtzman, *Description of Komagataella phaffii sp. nov. and the transfer of Pichia pseudopastoris to the methylotrophic yeast genus Komagataella*, 55 Int. J. Syst. Evol. Microbiol. 973 (2005); James M. Cregg et al., *Recombinant Protein Expression in* Pichia pastoris, 16 Molecular Biotechnology 23 (2000).

[9] 21 C.F.R. Part 573 (Food additives permitted in feed and drinking water of animals: Pichia pastoris dried yeast).

[10] American Association of Feed Control Officials Inc. (AAFCO), *2013 Official Publication* (2013).

[11] Vince Ciofalo et al., *Safety evaluation of a lipase enzyme preparation, expressed in Pichia pastoris, intended for use in the degumming of edible vegetable oil*, 45 Regulatory Toxicology and Pharmacology 1 (2006).

[12] M. W. Pariza et al., *Determining the safety of enzymes used in food processing*, 46 J. Food Protection 453 (1983).

Pariza and Johnson,[13] the two papers that set forth the gold standard used by the enzyme industry for assessing the safety of enzyme products, the primary consideration in the evaluation of microbial enzyme preparations to be used in food is the safety of the production organism. Yeasts are not known to produce toxins that are active by the oral route.[14] Additionally, *P. pastoris* has been classified as Biosafety Level 1 (BSL-1) by the American Type Culture Collection (ATCC) organization based on U.S. Public Health Service Guidelines, a category reserved for well-characterized agents not known to cause disease in healthy human adults and requiring minimal safety precautions in handling and storage.[15] Toxicity studies performed in support of the above-referenced *P. pastoris*-approved animal feed (including a pathogenicity study in mice, an acute oral toxicity study in rats, a subacute oral toxicity study in rats, and a two generation teratology study in rats) also demonstrated—per FDA's review in 1993—that *P. pastoris* is neither pathogenic nor toxigenic.[16] Additionally, the species is not present either on the list of pathogens used by the EU,[17] on NIAID's pathogen list,[18] nor on FDA's List of Qualifying Pathogens.[19]

The *P. pastoris* expression system has gained acceptance as an important host organism for the production of foreign proteins. *P. pastoris* has been safely used for the production of over 300 recombinant proteins since the mid-1980s and fulfills the criteria of several safety evaluations. Many human genes have been expressed in *P. pastoris* for pharmaceutical use. For example, a Hepatitis B surface antigen is currently on the market as a subunit vaccine against the hepatitis B virus in South America. Additionally, the following drugs expressed in *P. pastoris* were approved by FDA for human use: insulin for diabetes treatment, a plasma kallikrein inhibitor indicated for treatment of acute attacks of hereditary angioedema, a proteolytic enzyme indicated for the treatment of symptomatic vitreomacular adhesion, and a calcitonin gene-related peptide antagonist indicated for the preventive treatment of migraine.[20]

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[13] M. W. Pariza et al., *Evaluating the safety of microbial enzyme preparations used in food processing: update for a new century*, 33 Regulatory Toxicology and Pharmacology 173 (2001).

[14] *Id.*

[15] Centers for Disease Control and Prevention National Institutes of Health, Biosafety in Microbiological and Biomedical Laboratories (6th ed. 2020).

[16] Vince Ciofalo et al., *Safety evaluation of a lipase enzyme preparation, expressed in Pichia pastoris, intended for use in the degumming of edible vegetable oil*, 45 Regulatory Toxicology and Pharmacology 1 (2006).

[17] Directive 2000/54/EC of the European Parliament and of the Council (2000).

[18] National Institute of Allergy and Infectious Diseases, NIAID, *Emerging Infectious Diseases/Pathogens*, https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens.

[19] 21 C.F.R. § 317.2.

[20] Vince Ciofalo et al., *Safety evaluation of a lipase enzyme preparation, expressed in Pichia pastoris, intended for use in the degumming of edible vegetable oil*, 45 Regulatory Toxicology and Pharmacology 1 (2006); James M. Cregg et al., *Recombinant Protein Expression in* Pichia pastoris, 16 Molecular Biotechnology 23 (2000); J. L. Cereghino & James M. Cregg, *Heterologous protein expression in the*

The most important breakthrough for the usage of *P. pastoris* in food technology is its GRAS status as an animal feed protein source allowed in broiler feed by the Food and Drug Administration (FDA), and FDA's approval of recombinant proteins.[21] In addition, FDA's GRAS Notice Inventory lists 3 successful notices involving use of *P. pastoris* that have received "no questions" letters from the FDA (Table 6). We incorporate by reference the relevant safety data on *P. pastoris* in the notices listed below.

Table 6: Summary of GRAS Notices for Substances Produced Using *P. Pastoris* Fermentation

GRN No.	Notified Substance	Use
204	Phospholipase C enzyme preparation from Pichia pastoris expressing a heterologous phospholipase C gene	As an enzyme in degumming vegetable oils for food use
737	Soy leghemoglobin preparation from a strain of Pichia pastoris	For use at levels up to 0.8% soybean leghemoglobin protein to optimize flavor in ground beef analogue products intended to be cooked.
1001	Myoglobin preparation from a strain of Pichia pastoris expressing the myoglobin gene from Bos taurus	To impart flavor and aroma at levels up to 2% myoglobin in ground meat and poultry analogue products.

Because *P. pastoris* secretes relatively small amounts of endogenous proteins, secretory production constitutes a highly efficient first purification step and obviates the need for cell disruption procedures that may be cost-prohibitive at an industrial scale. Over the years, *P. pastoris* has been established as an efficient industrial host. In the context of therapeutic proteins, a clear advantage of the yeast over *E. coli* is the absence of endotoxins.[22]

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methylotrophic yeast Pichia pastoris, 24 FEMS Microbiology Reviews 45 (2000); D. Weinacker et al., *Applications of recombinant* Pichia pastoris *in the healthcare industry*, 44 Brazilian J. Microbiology 1043 (2013); M. Ahmad et al., *Protein expression in* Pichia pastoris*: recent achievements and perspectives for heterologous protein production*, 98 Appl. Microbiol. Biotechnol. 5301 (2014).

[21] 21 C.F.R. Part 573 (Food additives permitted in feed and drinking water of animals: Pichia pastoris dried yeast); S. C. Spohnera et al., *Expression of enzymes for the usage in food and feed industry with* Pichia pastoris, 202 J. Biotechnology 118 (2015).

[22] M. W. T. Werten et al., *Production of protein-based polymers in* Pichia pastoris, 37 Biotechnology Advances, 642 (2019).

Bioinformatic evaluations conducted on the production strain by Jin et al.[23] and Reyes et al.[24] have demonstrated that residual proteins from the *P. pastoris* strain are non-toxigenic and of low allergenic potential for cross-reactivity to major food allergens. The *Pichia* proteins share significant sequence homology with proteins from common yeasts, such as *Saccharomyces spp*.

6.1.2. Safety of Production Strain

Production strain *Komagataella phaffii* yRMK-66 is derived from *P. pastoris* CBS 7435 (also known as NRRL Y-11430), a strain lineage with a long history of safe use.

The parental strain CBS 7435 is modified by well-characterized genetic modification techniques. The protein coding sequence for bovine β-lactoglobulin variant B is introduced to the recipient strain under the strong native *K. phaffii* alcohol oxidase promoter (pAOX1) and followed by *K. phaffii* alcohol oxidase terminator, without inclusion of any antibiotic resistance genes or mobile genetic elements. This promoter has been demonstrated to produce high levels of recombinant proteins after producing biomass on glycerol and inducing pAOX1 with methanol.[25] The introduction cassette is codon-optimized for expression in the host strain, but the amino acid sequence nonetheless remains unchanged.

Remilk's genetically modified *Komagataella phaffii* production strain complies with the OECD (Organization for Economic Development) criteria for GILSP (Good Industrial Large Scale Practice) microorganisms.[26] It also meets the criteria for a safe production microorganism as described by Pariza et al, Pariza et al, and several expert groups.[27]

Strain identification is performed using either ITS (Internal transcribed spacer) region sequence comparison or 18S rRNA sequencing. These methods are widely used for taxonomy and molecular phylogeny.

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[23] Yuan Jin et al., *Evaluating potential risks of food allergy and toxicity of soy leghemoglobin expressed in* Pichia pastoris, 62 Mol. Nutr. Food Res. 1700297 (2018).

[24] Teresa F. Reyes et al., *Assessment of the potential allergenicity and toxicity of Pichia proteins in a novel leghemoglobin preparation*, 119 Regul. Toxicol. Pharmacol. 104817 (2021) (Assessment of the potential allergenicity and toxicity of Pichia proteins in a novel leghemoglobin preparation).

[25] J. L. Cereghino & James M. Cregg, *Heterologous protein expression in the methylotrophic yeast* Pichia pastoris, 24 FEMS Microbiology Reviews 45 (2000).

[26] OECD, *Safety Considerations for Biotechnology* (1992).

[27] EU Scientific Committee for Food, *Report for the Scientific Committee for Food (Twenty-seventy series)* (1992); FAO/WHO, *Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety* (1996).; OECD, *OEDC Safety Evaluation of Foods Derived by Modern Biotechnology Concepts and Principles* (1993); D. A. Jonas et al., *The safety assessment of novel foods, Guidelines prepared by ILSI Europe Novel Food Task Force*, 34 Food and Chemical Toxicology 931 (1996); M. W. Pariza et al., *Determining the safety of enzymes used in food processing*, 46 J. Food Protection 453 (1983); M. W. Pariza et al., *Evaluating the safety of microbial enzyme preparations used in food processing: update for a new century*, 33 Regulatory Toxicology and Pharmacology 173 (2001); International Food Biotechnology Council, *Chapter 4: Safety evaluation of foods and food ingredients derived from microorganisms*, 12 Regulatory Toxicology and Pharmacology S114 (1990).

β-lactoglobulin gene has been inserted into *Komagataella phaffii* genome and its integration stability was assessed by reverse transcription-quantitative PCR (RT-qPCR). Figure 4 below, displays confirmation of constant β-lactoglobulin gene copy levels over the course of three independent fermentation processes.

Host proteins in the final product were identified by mass spectrometry (LC-MS/MS). Samples from three non-consecutive batches were analyzed along a commercial bovine β-lactoglobulin. LC-MS/MS analysis identified Remilk's β-lactoglobulin with 100% sequence coverage against the P02754 β-lactoglobulin (Bos Taurus) sequence from the Uniprot database.

Moreover, the analysis showed that β-lactoglobulin was the dominant protein with >99.4% of the total abundance of the identified proteins. Residual *K. phaffii* proteins that were identified by the presence of at least two peptides with > 0.001% of the total protein content are listed in the LC-MS/MS analysis report attached as Appendix 2.

Post translational modifications such as phosphorylation and glycosylation were evaluated using LC-MS/MS analysis. No modifications were detected in the ten most abundant peptides of β-lactoglobulin in both the standard and the Remilk samples. In addition, both HPLC and SDS-PAGE analyses show identical migration patterns that are in line with the lack of post-translational modifications.

Based on the safety of the host strain and the nature of the genetic modifications made to the host, it can be concluded that the production strain poses no risk to human health.

Figure 4: β-lactoglobulin Gene Copy Levels During Fermentation Process

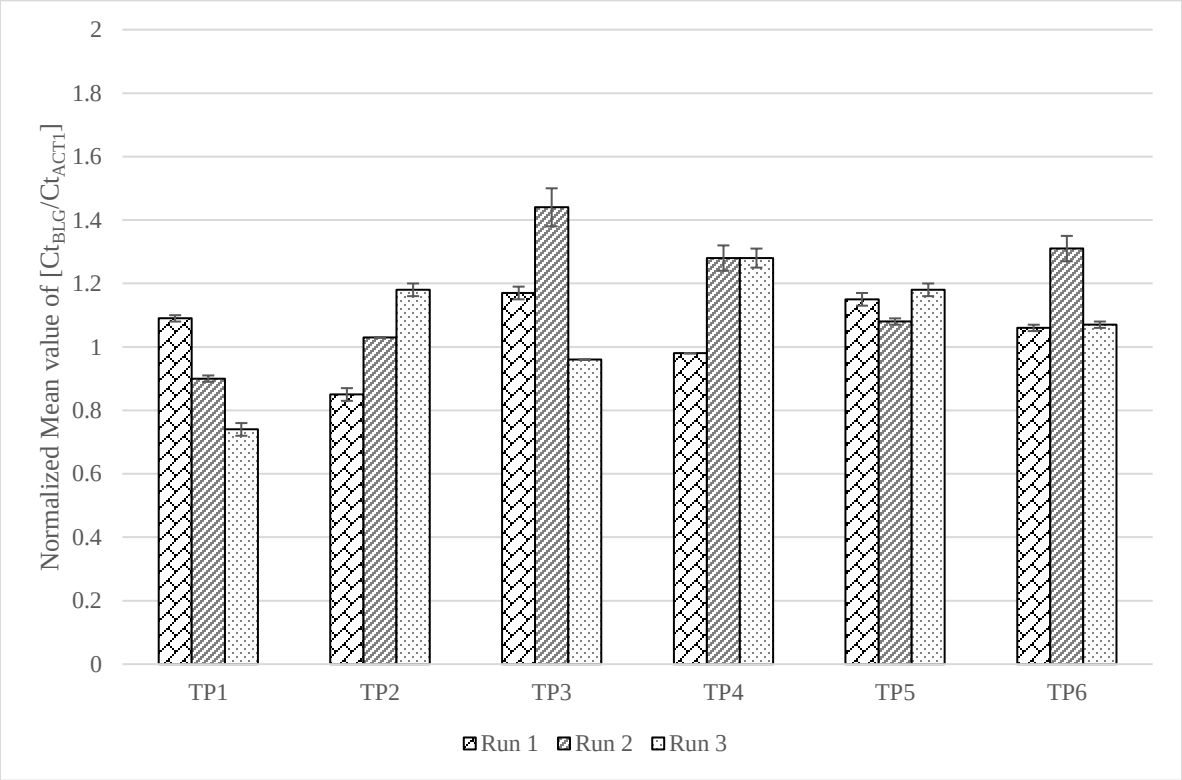

Figure 4 displays constant β-lactoglobulin gene copy levels throughout the fermentation process (6 time points, TP- Time Point) for three different fermentations (Run 1, Run 2 and Run 3). The genomic DNA levels were normalized against housekeeping gene ACT1. The variances between the results are not statistically significant (t-test and f-test were performed on the first and last time points).

6.1.3. Safety of β-lactoglobulin

β-Lactoglobulin is a small protein, soluble in dilute salt solution as befits a globulin, with 162 amino acid residues (MW ~18.4 KDa). It is the major whey protein found in the milk of ruminants, including cows and sheep, and also monogastric, e.g. pigs, horses, dogs and cats.[28] While high purity β-lactoglobulin products are relatively novel, they are equivalent to traditional whey protein and other purified milk protein products from the standpoint of nutritional properties and safety.

In light of the substantial similarities between β-lactoglobulin and traditional whey protein, together with the substantial similarities between these products and the concentrated milk proteins that are the subject of GRN 504 (American Dairy Products

[28] T.R. Kim et al., *High-level expression of bovine beta-lactoglobulin in* Pichia pastoris *and characterization of its physical properties*, 10 Protein Engineering 1339 (1997).

Institute, Concentrated Milk Proteins[29]) and GRN 863 (Perfect Day, Inc., Non-Animal Whey Protein from Fermentation by *Trichoderma reesei*[30]), the safety discussions related to concentrated milk proteins in both submissions directly apply to establishing the safety and GRAS status of Remilk's β-lactoglobulin. In particular, we view the safety overviews set forth in GRN 504 and GRN 863 concerning the safety of concentrated milk protein as being relevant to Remilk's β-lactoglobulin, as follows:

> Due to the long history of human consumption of milk, milk and milk proteins pose little toxicological concern to humans or animals. With the exception of certain sensitive populations (e.g., milk-allergic and lactose-intolerant individuals), we are not aware of adverse effects associated with consumption of concentrated milk proteins. Our literature search similarly did not yield any reported adverse effects.

As is the case presented in GRN 863, Remilk's β-lactoglobulin is identical to the β-lactoglobulin present in cow's milk. Therefore, the safety conclusion in GRN 863, with which we agree, applies to Remilk's β-lactoglobulin. With the exception of sensitive populations who are allergic to milk proteins such as β-lactoglobulin or who are lactose-intolerant, we are not aware of adverse effects associated with consumption of milk or milk derived products in general or β-lactoglobulin specifically. Notably, lactose-intolerant populations are not at risk from consumption of β-lactoglobulin from fermentation of *Komagataella phaffii* due to the notified product not being sourced from milk directly and, therefore, lacking any lactose content. A literature search in known scientific databases (such as PubMed) through January 2022 did not yield any reported adverse effects other than allergy issues, discussed below.

Remilk is not aware of any studies in the literature indicating that either β- lactoglobulin or *Komagataella phaffii* is not safe for the intended use proposed in this GRAS notification.

In addition, as explained above, the proposed uses of non-animal β-lactoglobulin are substitutional for existing uses of β-lactoglobulin, and also slightly expand the uses of this protein source. All uses of non-animal β-lactoglobulin are assumed to be substitutional for added dietary protein ingredients, and therefore will not increase overall intake of dietary protein.

In light of the history of β-lactoglobulin's presence in the diet from dairy sources and as discussed in this part, we believe that the non-animal β-lactoglobulin described in this notice is safe at the proposed levels enumerated above.

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[29] American Dairy Products Institute, GRN 504, Concentrated Milk Proteins, https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=504&sort=GRN_No&order=DESC&startrow=1&type=basic&search=504.

[30] Perfect Day, Inc., GRAS Notice for Non-Animal Whey Protein from Fermentation by *Trichoderma reesei*, GRN 863, https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=863&sort=GRN_No&order=DESC&startrow=1&type=basic&search=863.

6.2. Allergenicity

Milk is one of the major food allergens in the United States.[31] As explained above, the notified substance β-lactoglobulin is chemically identical to β-lactoglobulin found in bovine milk and isolated milk proteins. Therefore, the notified substance may produce a milk protein allergic response when consumed. All products containing the notified substance will indicate that the product contains an allergen (e.g., a protein also found in milk) to inform those consumers who are allergic to milk and comply with food allergen labeling requirements.

To examine allergenic potential posed by residual *K. phaffii* proteins that remain in the β-lactoglobulin product after processing, Remilk sponsored an analysis of its β-lactoglobulin.

First, the Smoler Proteomics Center at the Technion Israel Institute of Technology analyzed samples via LC-MS/MS from the production strain using three different batches and compared the results to commercial β-lactoglobulin. The analysis also attempted to identify levels and identity of residual *K. phaffii* proteins in the Remilk samples. The analysis showed that β-lactoglobulin was the dominant protein with >99.4% of the total abundance of the identified proteins. Residual *Komagataella phaffii* proteins that were identified by the presence of at least two peptides with > 0.001% of the total protein content (see Appendix 2).

Subsequently, a sequence homology search was conducted by Dr. Richard E. Goodman, research professor at the Food Allergy and Resource Program (FARRP) of the University of Nebraska, using the AllergenOnline database version 21 maintained by the Food Allergy Research and Resource Program of the University of Nebraska. The aim of the study was to determine whether the residual host proteins that are present in the final product share significant sequence homology to known allergens.

Dr. Goodman performed a literature search for evidence that proteins from the host organism (*Komagataella phaffii*, or *P. pastoris*) are potential allergens. There are no reports that proteins from the host are IgE mediated allergens.

To predict potential allergy or allergenic cross-reactivity for the yeast proteins, the CODEX standard of >35% identity over 80 AA was used. Two *Komagataella pastoris* proteins known to be highly conserved in evolution exceeded this threshold: heat shock-70 and superoxide dismutase. However, these results are not significant, as they occur for most eukaryotic organisms with those two proteins. Two other proteins were matched with low identities of < 38% ID to minor allergens. All of the yeast's proteins are at low abundance and are unlikely to represent a risk for consumers. The sequence of β-lactoglobulin was a 100% match to the bovine milk protein allergen, β-lactoglobulin.

The literature search and bioinformatics for the β-lactoglobulin protein cloned into *Komagataella phaffii* for yeast expression and the small amount of residual yeast proteins were completed on February 7, 2022. These results show that food products produced from this fermentation would carry the risk of food allergy to β-lactoglobulin.

[31] Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), Pub. L. No. 108-282, 18 Stat. 891.

There appears to be no added risk from the residual proteins of the host. There is no science-based rationale for conducting serum IgE binding studies on this product. It would be a risk for milk allergic subjects sensitized to β-lactoglobulin. The risks from the yeast proteins are not relevant to a great extent because each represents less than 0.15% of the total protein and because they are not highly identical to an immunodominant allergen.

The full assessment of the potential allergenicity of Remilk's product is attached as Appendix 3.

6.3. Summary of Basis for GRAS Determination

Remilk, Inc. has determined that β-lactoglobulin produced by fermentation of *Komagataella phaffii* is GRAS for the intended use in food based on the following:

- The fact that β-lactoglobulin will be manufactured under CGMP for food (21 C.F.R. Part 117) and meets appropriate food grade specifications.
- Potential contaminants, such as heavy metals and pathogenic microbes, are either absent (not detected) or below toxicological and regulatory limits.
- The intended uses and the estimated consumption of β-lactoglobulin.
- The proper labeling of the products.
- The GRAS status of production organism and data supporting the organism's non-pathogenic and non-toxigenic nature.
- The long history of safe use of milk and milk protein as food.
- Supportive evidence from the successful GRAS Notice for Non-Animal Whey Protein (from Fermentation by *Trichoderma reesei*, GRN 863).

Part 7. List of supporting data and information

1. American Association of Feed Control Officials Inc. (AAFCO), *2013 Official Publication* (2013).
2. M. Ahmad et al., *Protein expression in* Pichia pastoris*: recent achievements and perspectives for heterologous protein production*, 98 Appl. Microbiol. Biotechnol. 5301 (2014).
3. Centers for Disease Control and Prevention National Institutes of Health, Biosafety in Microbiological and Biomedical Laboratories (6th ed. 2020).
4. J. L. Cereghino & James M. Cregg, *Heterologous protein expression in the methylotrophic yeast* Pichia pastoris, 24 FEMS Microbiology Reviews 45 (2000).
5. Vince Ciofalo et al., *Safety evaluation of a lipase enzyme preparation, expressed in Pichia pastoris, intended for use in the degumming of edible vegetable oil*, 45 Regulatory Toxicology and Pharmacology 1 (2006).
6. James M. Cregg et al., *Recombinant Protein Expression in* Pichia pastoris, 16 Molecular Biotechnology 23 (2000).
7. Directive 2000/54/EC of the European Parliament and of the Council (2000).
8. EU Scientific Committee for Food, *Report for the Scientific Committee for Food (Twenty-seventy series)* (1992).
9. FAO/WHO, *Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety* (1996).
10. FAO/WHO, *Evaluation of Allergenicity of Genetically Modified Foods, Report of a Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology*, 22-25 (2001), http://www.who.int/foodsafety/publications/gmo-allergenicity/en.
11. 21 C.F.R. Part 573 (Food additives permitted in feed and drinking water of animals: Pichia pastoris dried yeast).
12. 21 C.F.R. § 317.2.
13. FDA, *Guidance for Industry: Estimating Dietary Intake of Substances in Food* (2006), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-estimating-dietary-intake-substances-food.
14. Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), Pub. L. No. 108-282, 18 Stat. 891.
15. American Dairy Products Institute, GRN 504, Concentrated Milk Proteins, https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=504&sort=GRN_No&order =DESC&startrow=1&type=basic&search=504.
16. Impossible Foods Inc. Gras Notification For Soy Leghemoglobin Protein Preparation Derived From Pichia Pastoris, GRN 737, https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=737&sort=GRN_No&order=DESC&startrow=1&type=basic&search=737.

17. Perfect Day, Inc., GRAS Notice for Non-Animal Whey Protein from Fermentation by *Trichoderma reesei*, GRN 863, https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=863&sort=GRN_No&order=DESC&startrow=1&type=basic&search=863.

18. International Food Biotechnology Council, *Chapter 4: Safety evaluation of foods and food ingredients derived from microorganisms*, 12 Regulatory Toxicology and Pharmacology S114 (1990).

19. Yuan Jin et al., *Evaluating potential risks of food allergy and toxicity of soy leghemoglobin expressed in* Pichia pastoris, 62 Mol. Nutr. Food Res. 1700297 (2018).

20. D. A. Jonas et al., *The safety assessment of novel foods, Guidelines prepared by ILSI Europe Novel Food Task Force*, 34 Food and Chemical Toxicology 931 (1996).

21. T.R. Kim et al., *High-level expression of bovine beta-lactoglobulin in* Pichia pastoris *and characterization of its physical properties*, 10 Protein Engineering 1339 (1997).

22. G. Kontopidis, et al., *Invited review: β-lactoglobulin: binding properties, structure, and function*, 87 J. Dairy Sci. 785 (2004).

23. Cletus P. Kurtzman, *Description of Komagataella phaffii sp. nov. and the transfer of Pichia pseudopastoris to the methylotrophic yeast genus Komagataella*, 55 Int. J. Syst. Evol. Microbiol. 973 (2005).

24. National Institute of Allergy and Infectious Diseases, NIAID, *Emerging Infectious Diseases/Pathogens*, https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens.

25. OECD, *Safety Considerations for Biotechnology* (1992).

26. OECD, *OEDC Safety Evaluation of Foods Derived by Modern Biotechnology Concepts and Principles* (1993).

27. M. W. Pariza et al., *Determining the safety of enzymes used in food processing*, 46 J. Food Protection 453 (1983).

28. M. W. Pariza et al., *Evaluating the safety of microbial enzyme preparations used in food processing: update for a new century*, 33 Regulatory Toxicology and Pharmacology 173 (2001).

29. Stefan M. Pasiakos et al., *Sources and Amounts of Animal, Dairy, and Plant Protein Intake of US Adults in 2007–2010*, 7 Nutrients 7058 (2015).

30. Teresa F. Reyes et al., *Assessment of the potential allergenicity and toxicity of Pichia proteins in a novel leghemoglobin preparation*, 119 Regul. Toxicol. Pharmacol. 104817 (2021) (Assessment of the potential allergenicity and toxicity of Pichia proteins in a novel leghemoglobin preparation).

31. S. C. Spohnera et al., *Expression of enzymes for the usage in food and feed industry with* Pichia pastoris, 202 J. Biotechnology 118 (2015).

32. USDA, *Dietary Guideline for Americans, 2020-2025*.

33. D. Weinacker et al., *Applications of recombinant* Pichia pastoris *in the healthcare industry*, 44 Brazilian J. Microbiology 1043 (2013).

34. M. W. T. Werten et al., *Production of protein-based polymers in* Pichia pastoris*,* 37 Biotechnology Advances, 642 (2019).

35. USDA, *What We Eat in America (WWEIA), National Health and Nutrition Examination Surveys (NHANES)* (2015-2018).

36. C. J. Cifelli, N. Auestad, V. L. Fulgoni, III, *Protein in the U.S. Diet and the Contribution of Dairy Foods. Dairy Research Institute Data Brief No. 1502* (2015). Available at: https://www.usdairy.com/getmedia/6d314cf0-e776-4f9f-9bb9-97c039f8a96e/ndc%20protein%20data%20brief%20october%202015.pdf.

37. G. D. Miller, J. K. Jarvis, L. D. McBean, *Handbook of Dairy Foods and Nutrition, National Dairy Council*, CRC Press: Boca Raton, FL (3rd ed. 2007).

Appendix 1
Batch Analysis Results

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Report Number:	**3550518-0**
Report Date:	**31-Jan-2022**
Report Status:	**Final**

Certificate of Analysis

Remilk Ltd

Holtzman 2
Rehovot Israel 7670402 Israel

Sample Name:	**BLG powder**	**Eurofins Sample:**	**11347285**
Project ID	REMILK-20220116-0011	**Receipt Date**	18-Jan-2022
PO Number	cvd	**Receipt Condition**	Cold on Wet Ice or Ice Packs
Lot Number	PT-22.0006	**Login Date**	16-Jan-2022
		Date Started	19-Jan-2022
		Sampled	Sample results apply as received
		Online Order	18613-16A67BA1

Analysis	Result
Fat by Base Hydrolysis	
Fat	1.0 %
Carbohydrates	
Total Carbohydrates	4.0 %
Protein (N x 6.25) Kjeldahl method	
Protein	86.9 %
Ash	
Ash	3.17 %
Moisture by M100_T100	
Moisture	4.91 %
Total Solids	95.1 %
pH	
pH	6.58
Yeast and Mold Plate Count *	
Yeast Plate Count	<10 CFU/g
Mold Plate Count	<10 CFU/g
Aerobic Plate Count *	
Standard Plate Count	<10 CFU/g
Elements by ICP Mass Spectrometry	
Arsenic	<0.0100 ppm
Cadmium	<0.00500 ppm
Lead	0.0277 ppm
Mercury	<0.00500 ppm
Enterobacteriaceae Plate Count *	
Enterobacteriaceae	<10 CFU/g

Method References	Testing Location
Aerobic Plate Count (APC)	**EML New Berlin** 2345 S 170th St New Berlin, WI 53151 USA

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

Remilk Ltd

Holtzman 2
Rehovot Israel 7670402 Israel

Method References	Testing Location

Aerobic Plate Count (APC)

EML New Berlin
2345 S 170th St New Berlin, WI 53151 USA

FDA BAM Ch. 3
AOAC 966.23
CMMEF Ch. 8

Ash (ASHM_S)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods of Analysis of AOAC INTERNATIONAL, 18th Ed., Method 923.03, AOAC INTERNATIONAL, Gaithersburg, MD, USA, (2005). (Modified)

Carbohydrates (CHO)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

United States Department of Agriculture, "Energy Value of Foods", Agriculture Handbook No. 74, pp. 2-11, (1973).

Elements by ICP Mass Spectrometry (ICP_MS_S)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods of Analysis, Method 2011.19 and 993.14, AOAC INTERNATIONAL, (Modified).
Paquette, L.H., Szabo, A., Thompson, J.J., "Simultaneous Determination of Chromium, Selenium, and Molybdenum in Nutritional Products by Inductively Coupled Plasma/Mass Spectrometry: Single-Laboratory Validation," Journal of AOAC International, 94(4): 1240 - 1252 (2011).

Enterobacteriaceae Plate Count (EBPC)

EML New Berlin
2345 S 170th St New Berlin, WI 53151 USA

Compendium of Methods for the Microbiological Examination of Foods: Enterobacteriaceae, Coliforms, and Escherichia coli as Quality and Safety Indicators, Chapter 8, 4th Edition, 2001.

Fat by Base Hydrolysis (FAT_BH_S)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods of Analysis, Methods 989.05, 932.06, 986.25, 945.48B, AOAC INTERNATIONAL (modified)

Moisture by M100_T100 (M100T100_S)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods of Analysis of AOAC INTERNATIONAL, 18th Ed., Methods 925.09 and 926.08, AOAC INTERNATIONAL, Gaithersburg, MD, USA,(2005). (Modified).

*** This analysis or component is not ISO accredited.**

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Report Number:	**3550518-0**
Report Date:	**31-Jan-2022**
Report Status:	**Final**

Certificate of Analysis

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Holtzman 2
Rehovot Israel 7670402 Israel

Method References	Testing Location

pH (PHAL_S)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods of Analysis of AOAC INTERNATIONAL. 18th Ed., Method 981.12, AOAC INTERNATIONAL. Gaithersburg, MD.

Food Chemical Codex 7th Ed., The United States Pharmacopeia Convention (2010) Appendix II.

United States Pharmacopeia, 32nd Rev.-National Formulary 27th Ed., USP Convention, Inc., Rockville, MD (2009) General Chapter 791.

Protein (N x 6.25) Kjeldahl method (PGEN_S)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods and Recommended Practices of the American Oil Chemists' Society, Champaign, IL, Official Methods Ac 4-91 (2011). (Modified)

Yeast and Mold Plate Count (YM_SPRD)

EML New Berlin
2345 S 170th St New Berlin, WI 53151 USA

FDA BAM Chapter 18 (modified)

Testing Location(s)	Released on Behalf of Eurofins by

Food Integrity Innovation-Madison

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

Edward Ladwig - President Eurofins Food Chemistry Testing Madison

ilac-MRA A2LA ACCREDITED
2918.01

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.

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Report Number:	**3543659-0**
Report Date:	**25-Jan-2022**
Report Status:	**Final**

Certificate of Analysis

Remilk Ltd

Holtzman 2
Rehovot Israel 7670402 Israel

Sample Name:	**BLG powder**	**Eurofins Sample:**	**11327674**
Project ID	REMILK-20220111-0005	**Receipt Date**	14-Jan-2022
PO Number		**Receipt Condition**	Ambient temperature
Lot Number	PT-21.0082	**Login Date**	11-Jan-2022
		Date Started	19-Jan-2022
		Sampled	Sample results apply as received
		Number Composited	2
		Online Order	18613-16A007CE

Analysis	Result
Fat by Base Hydrolysis	
Fat	0.2 %
Carbohydrates	
Total Carbohydrates	3.9 %
Protein (N x 6.25) Kjeldahl method	
Protein	90.6 %
Ash	
Ash	1.95 %
Moisture by M100_T100	
Moisture	3.43 %
Total Solids	96.6 %
pH	
pH	5.25
Yeast and Mold Plate Count *	
Yeast Plate Count	<10 CFU/g
Mold Plate Count	<10 CFU/g
Aerobic Plate Count *	
Standard Plate Count	<10 CFU/g
Elements by ICP Mass Spectrometry	
Arsenic	0.0603 ppm
Cadmium	<0.00500 ppm
Lead	0.00535 ppm
Mercury	<0.00500 ppm
Enterobacteriaceae Plate Count *	
Enterobacteriaceae	<10 CFU/g

Method References	Testing Location
Aerobic Plate Count (APC)	**EML New Berlin** 2345 S 170th St New Berlin, WI 53151 USA

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

Remilk Ltd

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Rehovot Israel 7670402 Israel

Method References	Testing Location

Aerobic Plate Count (APC)

EML New Berlin
2345 S 170th St New Berlin, WI 53151 USA

FDA BAM Ch. 3
AOAC 966.23
CMMEF Ch. 8

Ash (ASHM_S)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods of Analysis of AOAC INTERNATIONAL, 18th Ed., Method 923.03, AOAC INTERNATIONAL, Gaithersburg, MD, USA, (2005). (Modified)

Carbohydrates (CHO)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

United States Department of Agriculture, "Energy Value of Foods", Agriculture Handbook No. 74, pp. 2-11, (1973).

Elements by ICP Mass Spectrometry (ICP_MS_S)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods of Analysis, Method 2011.19 and 993.14, AOAC INTERNATIONAL, (Modified).
Paquette, L.H., Szabo, A., Thompson, J.J., "Simultaneous Determination of Chromium, Selenium, and Molybdenum in Nutritional Products by Inductively Coupled Plasma/Mass Spectrometry: Single-Laboratory Validation," Journal of AOAC International, 94(4): 1240 - 1252 (2011).

Enterobacteriaceae Plate Count (EBPC)

EML New Berlin
2345 S 170th St New Berlin, WI 53151 USA

Compendium of Methods for the Microbiological Examination of Foods: Enterobacteriaceae, Coliforms, and Escherichia coli as Quality and Safety Indicators, Chapter 8, 4th Edition, 2001.

Fat by Base Hydrolysis (FAT_BH_S)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods of Analysis, Methods 989.05, 932.06, 986.25, 945.48B, AOAC INTERNATIONAL (modified)

Moisture by M100_T100 (M100T100_S)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods of Analysis of AOAC INTERNATIONAL, 18th Ed., Methods 925.09 and 926.08, AOAC INTERNATIONAL, Gaithersburg, MD, USA,(2005). (Modified).

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Report Number:	**3543659-0**
Report Date:	**25-Jan-2022**
Report Status:	**Final**

Certificate of Analysis

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Rehovot Israel 7670402 Israel

Method References	Testing Location

pH (PHAL_S)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods of Analysis of AOAC INTERNATIONAL. 18th Ed., Method 981.12, AOAC INTERNATIONAL. Gaithersburg, MD.

Food Chemical Codex 7th Ed., The United States Pharmacopeia Convention (2010) Appendix II.

United States Pharmacopeia, 32nd Rev.-National Formulary 27th Ed., USP Convention, Inc., Rockville, MD (2009) General Chapter 791.

Protein (N x 6.25) Kjeldahl method (PGEN_S)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods and Recommended Practices of the American Oil Chemists' Society, Champaign, IL, Official Methods Ac 4-91 (2011). (Modified)

Yeast and Mold Plate Count (YM_SPRD)

EML New Berlin
2345 S 170th St New Berlin, WI 53151 USA

FDA BAM Chapter 18 (modified)

Testing Location(s)	Released on Behalf of Eurofins by

Food Integrity Innovation-Madison

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

Edward Ladwig - President Eurofins Food Chemistry Testing Madison

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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.

*** This analysis or component is not ISO accredited.**

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Report Number:	**3540056-0**
Report Date:	**21-Jan-2022**
Report Status:	**Final**

Certificate of Analysis

Remilk Ltd

Holtzman 2
Rehovot Israel 7670402 Israel

Sample Name:	**BLG powder**	**Eurofins Sample:**	**11310545**
Project ID	REMILK-20220105-0004	**Receipt Date**	10-Jan-2022
PO Number		**Receipt Condition**	Ambient temperature
Lot Number	PT-22.0005	**Login Date**	05-Jan-2022
		Date Started	13-Jan-2022
		Sampled	Sample results apply as received
		Online Order	18613-16984852

Analysis	Result
Fat by Base Hydrolysis	
Fat	0.6 %
Carbohydrates	
Total Carbohydrates	8.7 %
Protein (N x 6.25) Kjeldahl method	
Protein	84.3 %
Ash	
Ash	2.95 %
Moisture by M100_T100	
Moisture	3.47 %
Total Solids	96.5 %
pH	
pH	6.48
Elements by ICP Mass Spectrometry	
Arsenic	0.0146 ppm
Cadmium	<0.00500 ppm
Lead	0.00534 ppm
Mercury	<0.00500 ppm

Method References	**Testing Location**
Ash (ASHM_S)	**Food Integrity Innovation-Madison** 6304 Ronald Reagan Ave Madison, WI 53704 USA
Official Methods of Analysis of AOAC INTERNATIONAL, 18th Ed., Method 923.03, AOAC INTERNATIONAL, Gaithersburg, MD, USA, (2005). (Modified)	
Carbohydrates (CHO)	**Food Integrity Innovation-Madison** 6304 Ronald Reagan Ave Madison, WI 53704 USA
United States Department of Agriculture, "Energy Value of Foods", Agriculture Handbook No. 74, pp. 2-11, (1973).	

Certificate of Analysis

Remilk Ltd
Holtzman 2
Rehovot Israel 7670402 Israel

Method References	Testing Location

Elements by ICP Mass Spectrometry (ICP_MS_S)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods of Analysis, Method 2011.19 and 993.14, AOAC INTERNATIONAL, (Modified).
Paquette, L.H., Szabo, A., Thompson, J.J., "Simultaneous Determination of Chromium, Selenium, and Molybdenum in Nutritional Products by Inductively Coupled Plasma/Mass Spectrometry: Single-Laboratory Validation," Journal of AOAC International, 94(4): 1240 - 1252 (2011).

Fat by Base Hydrolysis (FAT_BH_S)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods of Analysis, Methods 989.05, 932.06, 986.25, 945.48B, AOAC INTERNATIONAL (modified)

Moisture by M100_T100 (M100T100_S)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods of Analysis of AOAC INTERNATIONAL, 18th Ed., Methods 925.09 and 926.08, AOAC INTERNATIONAL, Gaithersburg, MD, USA,(2005). (Modified).

pH (PHAL_S)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods of Analysis of AOAC INTERNATIONAL. 18th Ed., Method 981.12, AOAC INTERNATIONAL. Gaithersburg, MD.

Food Chemical Codex 7th Ed., The United States Pharmacopeia Convention (2010) Appendix II.

United States Pharmacopeia, 32nd Rev.-National Formulary 27th Ed., USP Convention, Inc., Rockville, MD (2009) General Chapter 791.

Protein (N x 6.25) Kjeldahl method (PGEN_S)

Food Integrity Innovation-Madison
6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods and Recommended Practices of the American Oil Chemists' Society, Champaign, IL, Official Methods Ac 4-91 (2011). (Modified)

Certificate of Analysis

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Holtzman 2
Rehovot Israel 7670402 Israel

Testing Location(s)	Released on Behalf of Eurofins by
Food Integrity Innovation-Madison Eurofins Food Chemistry Testing Madison, Inc. 6304 Ronald Reagan Ave Madison WI 53704 800-675-8375	**Edward Ladwig - President Eurofins Food Chemistry Testing Madison** ilac-MRA A2LA ACCREDITED 2918.01

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Report Number:	**3536417-0**
Report Date:	**19-Jan-2022**
Report Status:	**Final**

Certificate of Analysis

Remilk Ltd

Holtzman 2
Rehovot Israel 7670402 Israel

Sample Name:	**BLG powder**	**Eurofins Sample:**	**11310545**
Project ID	REMILK-20220105-0004	**Receipt Date**	10-Jan-2022
PO Number		**Receipt Condition**	Ambient temperature
Lot Number	PT-22.0005	**Login Date**	05-Jan-2022
		Date Started	13-Jan-2022
		Sampled	Sample results apply as received
		Online Order	18613-16984852

Analysis	Result
Yeast and Mold Plate Count	
Yeast Plate Count	<10 CFU/g
Mold Plate Count	<10 CFU/g
Aerobic Plate Count	
Standard Plate Count	10 (est) CFU/g
Enterobacteriaceae Plate Count	
Enterobacteriaceae	<10 CFU/g

Method References	**Testing Location**
Aerobic Plate Count (APC)	**EML New Berlin** 2345 S 170th St New Berlin, WI 53151 USA
FDA BAM Ch. 3 AOAC 966.23 CMMEF Ch. 8	
Enterobacteriaceae Plate Count (EBPC)	**EML New Berlin** 2345 S 170th St New Berlin, WI 53151 USA
Compendium of Methods for the Microbiological Examination of Foods: Enterobacteriaceae, Coliforms, and Escherichia coli as Quality and Safety Indicators, Chapter 8, 4th Edition, 2001.	
Yeast and Mold Plate Count (YM_SPRD)	**EML New Berlin** 2345 S 170th St New Berlin, WI 53151 USA
FDA BAM Chapter 18 (modified)	

Certificate of Analysis

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Holtzman 2
Rehovot Israel 7670402 Israel

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

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

Analyst
Research Laboratories
מעבדות שרות ומחקר
A Tentamus Company

Ester Abramov
Remilk
Ester@remilk.com

Re: Determination of β-Lactoglobulin assay and impurities in non-animal milk protein by size exclusion chromatography by HPLC

Samples:
Four samples were brought in for analysis on February 08, 2022.
The samples were kept at room temperature until analysis.

Date of analysis:

The work was conducted between February 27 and February 28, 2022.

Analytical method:

The samples were analyzed according to Analyst SOP 09.771.01.

Results:

Table 1: Assay results

Analyst no.	Batch no	BLG (%w/w)
22-00199-1	PT-21.0082	92.7
22-00199-2		92.6
Mean		**93**
22-00200-1	PT-21.0083	94.7
22-00200-2		94.1
Mean		**94**
22-00201-1	PT-22.0005	82.6
22-00201-2		83.0
Mean		**83**
22-00202-1	PT-22.0006	91.2
22-00202-2		91.2
Mean		**91**
Assay specifications NLT 80% (w/w)		

Table 2: Impurities results

Analyst No.	Batch No.	Retention time (minutes)	Replicate 1	Replicate 2	Average
			Content (%w/w)		
22-00199	PT-21.0082	15.433	0.531	0.494	0.51
		16.576	0.436	0.405	0.42
		18.600	1.34	1.41	1.4
		Total (%w/w)	**2.3**	**2.3**	**2.3**
Analyst No.	**Batch No.**	**Retention time (minutes)**	**Replicate 1**	**Replicate 2**	**Average**
			Content (%w/w)		
22-00200	PT-21.0083	15.516	0.378	0.376	0.38
		16.366	1.29	1.28	1.3
		Total (%w/w)	**1.7**	**1.7**	**1.7**
Analyst No.	**Batch No.**	**Retention time (minutes)**	**Replicate 1**	**Replicate 2**	**Average**
			Content (%w/w)		
22-00201	PT-22.0005	10.063	1.56	1.58	1.6
		15.449	0.801	0.803	0.80
		16.727	0.678	0.687	0.68
		17.823	0.278	0.286	0.28
		18.589	1.94	1.97	2.0
		20.554	0.370	0.399	0.38
		Total (%w/w)	**5.6**	**5.7**	**5.7**
Analyst No.	**Batch No.**	**Retention time (minutes)**	**Replicate 1**	**Replicate 2**	**Average**
			Content (%w/w)		
22-00202	PT-22.0006	15.402	0.577	0.548	0.56
		17.731	0.136	0.129	0.13
		18.587	1.11	1.12	1.1
		Total (%w/w)	**1.8**	**1.8**	**1.8**

Impurities specifications: NMT 20% (w/w) for total impurities.

Certification statement:

The above information is authentic and accurate. The samples have been tested in compliance with current Good Manufacturing Practice (cGMP).

Approvals

Function	Name	Signature	Date
Study Director	N. Baritzy B.Sc	[redacted]	03 March 22
Quality assurance	Rosy Ben Arie	[redacted]	03 March 2022.

Appendix 2
LC-MS/MS Analysis Report

Technion
Israel Institute of Technology
Department of Biology
Smoler Proteomics Center

מ וסזהטכני ולמחקר ופיתוח
הפקו לטהלביולוגיה
מרכז סמו לולחקר החלבונ ימפרוטאומיקה

January 6, 2022

Dear Vera,

Enclosed please find a report of the mass spectrometry results.

To avoid doubt, it is hereby emphasized that the Investigator, the Technion Research and Development Foundation Ltd as well as the Technion the Israeli Technology Institute are not and will not be liable for any injury and/or damages and/or expenses and/or loss, of any kind or sort, that is caused or may be caused to the recipient of this report or any third party, directly or incidentally, due to this report or in any relation to it or its implementation.

Regards,

Tamar Ziv

Aim:

The purpose of this work is to analyze the contaminating proteins of the BLG samples.

Samples

BLG samples were delivered from Remilk and analyzed at the Smoler proteomics Center by mass spectrometry.

A	BLG std
B	PT-21.0076
C	PT-21.0073
D	PT-21.0070

Mass spectrometry analysis:

Proteolysis

The proteins were diluted in 8M Urea and 100mM ammonium bicarbonate then reduced with 3mM DTT (60ºC for 30 min), modified with 10mM iodoacetamide in 100mM ammonium bicarbonate (room temperature for 30 min in the dark) and digested in 2M Urea, 25mM ammonium bicarbonate with modified trypsin, overnight at 37oC in a 1:50 (M/M) enzyme-to-substrate ratio.

Mass spectrometry analysis

The tryptic peptides were desalted using C18 tips (Homemade stage tips) dried and re-suspended in 0.1% Formic acid. The resulting peptides were analyzed by LC-MS/MS using an Q Exactive plus mass spectrometer (Thermo) fitted with a capillary HPLC (Dionex). The peptides were loaded onto a homemade capillary column (30 cm, 75 micron ID) packed with Reprosil C18-Aqua (Dr Maisch GmbH, Germany) in solvent A (0.1% formic acid in water). The peptides were eluted at flow rates of 0.15 µl/min with 3 steps of acetonitrile gradient with 0.1% formic acid in water: a linear 30 minutes of 5% to 28%, 15 minutes gradient of 28% to 95% and 15 minutes at 95% acetonitrile with 0.1% formic acid in water. Mass spectrometry was performed in a

positive mode using repetitively full MS scan (m/z 300–1800) followed by High energy Collision Dissociation (HCD) of the 10 most dominant ions selected from the full MS scan. A dynamic exclusion list was enabled with exclusion duration of 20 s.

Data Analysis—

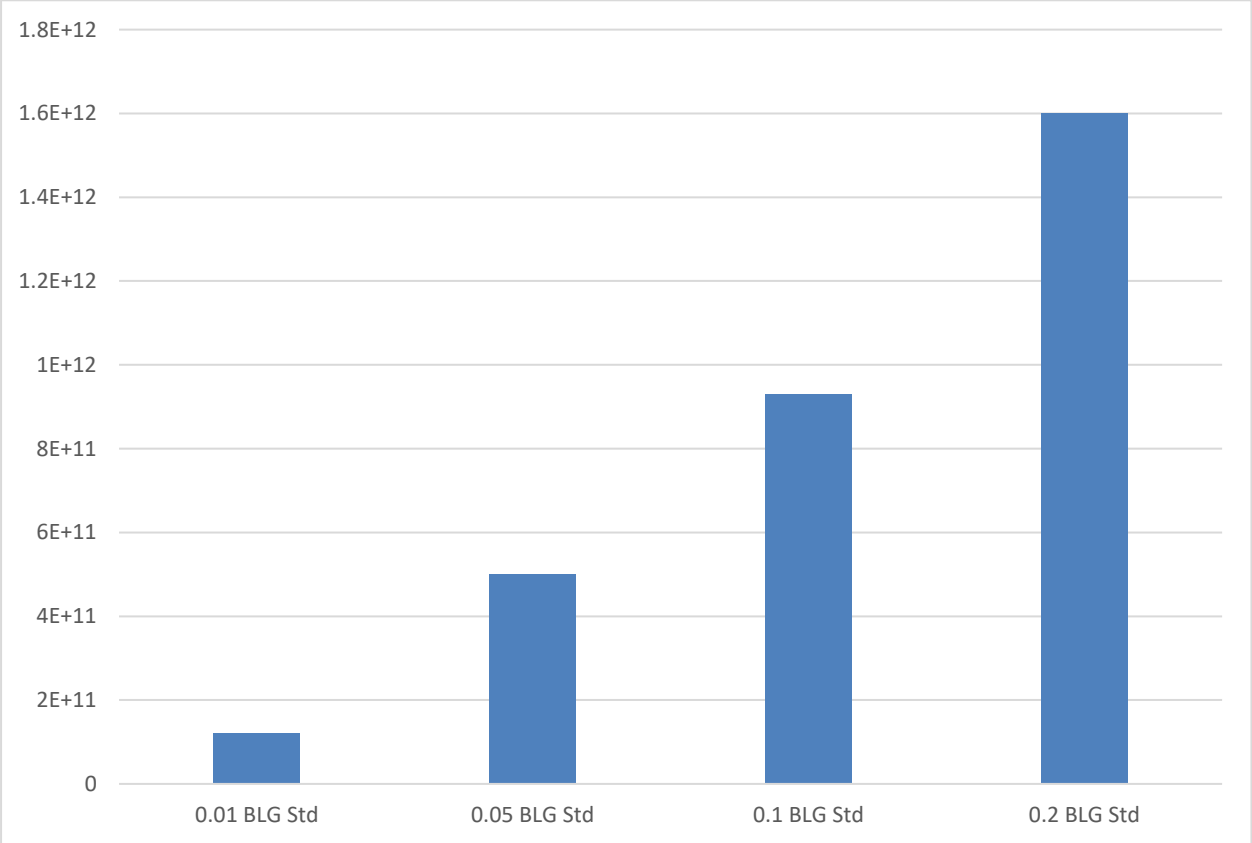
The mass spectrometry data was analyzed using Proteome Discoverer software version 2.4 using the Sequest search engine vs the Komagataella pastoris section of the uniport database with the BLG bovine sequence. Mass tolerance of 10 ppm for the precursor masses and 0.02 amu for the fragment ions. Oxidation on methionine and were accepted as variable modifications and carbamidomethyl on cysteine was accepted as static modifications on the denatured samples. Minimal peptide length was set to six amino acids and a maximum of two miscleavages was allowed. Peptide- and protein-level false discovery rates (FDRs) were filtered to 1% using the target-decoy strategy. Protein table were filtered to eliminate the identifications from the reverse database, and common contaminants and single peptide identifications. The data was quantified by using the same software, based on extracted ion currents (XICs) of each peptide (peak area). The intensity of each protein is calculated as the average area of the three unique peptides with the largest peak area.

Results:

The protein sample was cleaved with trypsin and analyzed by LC/MSMS using an Q Exactive plus mass spectrometer (Thermo). The data was analyzed with Discoverer software version 2.4 Semi quantitation was done by calculating the peak area of each peptide.

Part 1 :

Sample A, BLG std was analyzed in 4 quantities: 0.01, 0.05, 0.1, 0.2 ug protein were injected to the HPLC that is connected to the mass spectrometer. Beta lactoglobulin was identified with 100% coverage with the expected changes in the abundance.



Part 2:

0.2 protein was analyzed from each one of the samples.

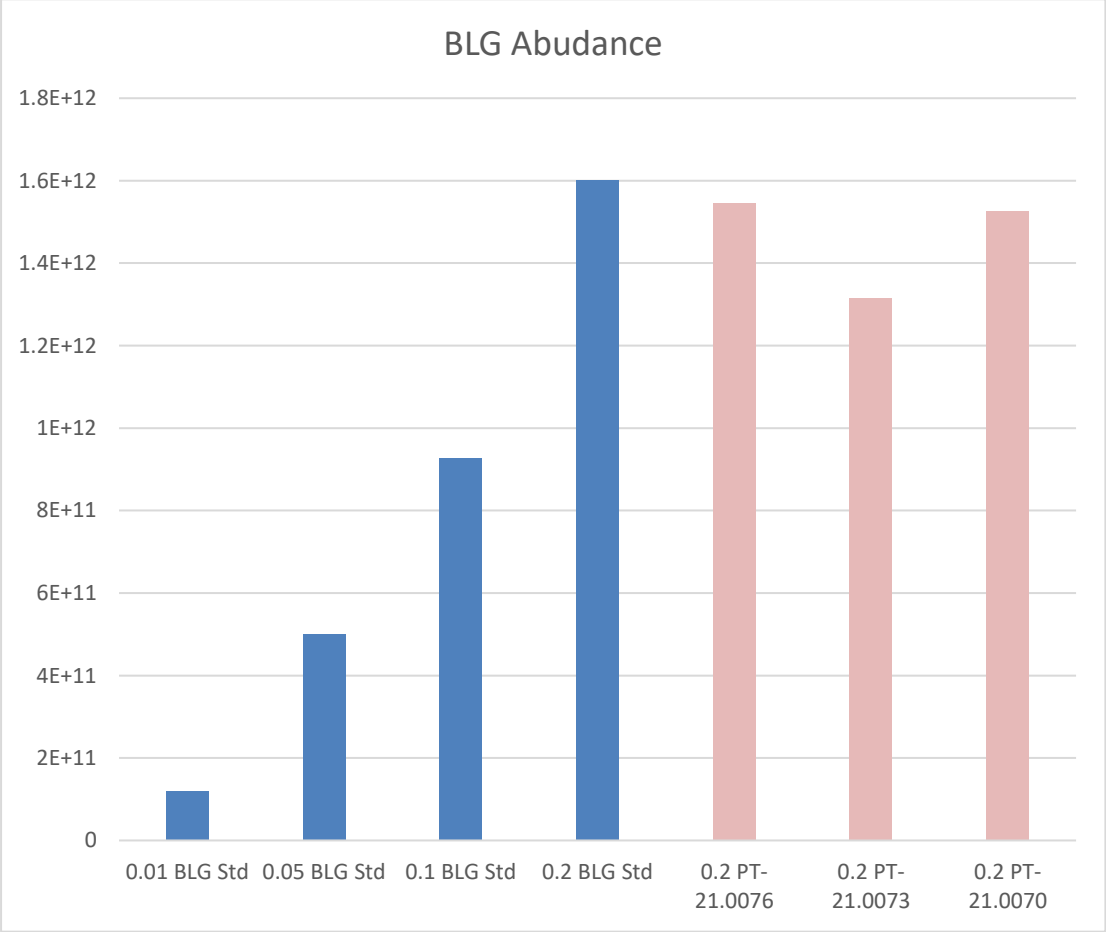
In all 3 samples, BLG (bovine) was identified with 100% coverage compared to the P02754 Beta-lactoglobulin (Bos Taurus) from the Uniprot database as can be seen

below. Peptides mared in green on the map are peptides that were identified in high confidence(1% FDR).

Sequence Comparison

		1	11	21	31	41	51	61	71
P02754	1	LIVTQTMKGL	DIQKVAGTWY	SLAMAASDIS	LLDAQSAPLR	VYVEELKPTP	EGDLEILLQK	WENGECAQKK	IIAEKTKIPA
P02754	81	VFKIDALNEN	KVLVLDTDYK	KYLLFCMENS	AEPEQSLACQ	CLVRTPEVDD	EALEKFDKAL	KALPMHIRLS	FNPTQLEEQC
P02754	161	HI							

BLG was the dominant protein with>99.4% of the total abundance of the identififed proteins.



Contaminating proteins from the host Komagataella pastoris that were identified with at least 2 peptides with > 0.001% of the total are listed below.

PT-21.0076

Accession	Protein Name	Gene Symbol	Coverage [%]	# Peptides	% from Total
P02754	Beta-lactoglobulin - B taurus (Bovine).		100	157	99.5022%
A0A1B2JDE1	BA75_01931T0	ATY40_BA7501931	13	4	0.1146%
A0A1B2JG30	BA75_04321T0	ATY40_BA7504321	15	4	0.1097%
A0A1B2J5U4	BA75_00070T0	PRY2	6	2	0.0936%
A0A1B2JDU3	BA75_03273T0	ATY40_BA7503273	14	5	0.0465%
A0A1B2JHZ1	Superoxide dismutase [Cu-Zn]	ATY40_BA7504526	38	5	0.0230%
A0A1B2JFJ3	Chitinase	CTS1	7	4	0.0171%
A0A1B2J841	BA75_00021T0	ATY40_BA7500021	5	2	0.0146%
A0A1B2J755	BA75_01624T0	ATY40_BA7501624	18	4	0.0104%
A0A1B2JIU6	Cellulase	ATY40_BA7504680	5	3	0.0090%
A0A1B2JJ78	BA75_05209T0	SCW11	4	3	0.0084%
A0A1B2JCC4	BA75_02724T0	EXG1	13	4	0.0060%
A0A1B2JAS9	Ubiquitin	RPL40B	46	6	0.0058%
A0A1B2J5A4	1,3-beta-glucanyltransferase	GAS1	14	5	0.0057%
A0A1B2JD90	BA75_02630T0	ATY40_BA7502630	7	2	0.0051%
A0A1B2JJE0	Glycidase	ATY40_BA7504772	10	4	0.0044%
A0A1B2JGR3	1,3-beta-glucanyltransferase	GAS3	23	7	0.0040%
A0A1B2JF97	BA75_03970T0	BGL2	8	2	0.0036%
A0A1B2J5H5	Endo-1,3(4)-beta-glucanase	DSE4	7	6	0.0034%
A0A1B2JGS7	BA75_04779T0	ATY40_BA7504779	11	6	0.0022%
A0A1B2J5W9	BA75_00236T0	ATY40_BA7500236	8	6	0.0022%
A0A1B2JAX4	BA75_02022T0	ATY40_BA7502022	4	2	0.0016%
A0A1B2JEK3	Phphatidylglycerol/ phphatidylinitol transfer protein	NPC2	13	2	0.0014%
A0A1B2JIU4	Acid phphatase	ATY40_BA7505161	8	4	0.0010%
A0A1B2JDI7	BA75_02055T0	SHB17	12	3	0.0009%
A0A1B2JA31	BA75_01440T0	CDA2	9	2	0.0007%
A0A1B2JF94	BA75_03408T0	PEP4	12	4	0.0006%
A0A1B2JGG7	Formate dehydrogenase	FDH1	5	2	0.0005%
A0A1B2JD05	Thioredoxin	TRX1	20	2	0.0004%
A0A1B2JBK5	Alcohol oxidase	ATY40_BA7503165	6	3	0.0003%
A0A1B2JD51	BA75_02990T0	YMR244W	5	2	0.0003%
A0A1B2JCS6	Amine oxidase	ATY40_BA7502878	2	2	0.0003%
A0A1B2J758	BA75_01312T0	PRB1	5	2	0.0002%
A0A1B2JCI4	Nucleide diphphate kinase	YNK1	17	2	0.0002%

PT-21.0073

Accession	Protein Name	Gene Symbol	Coverage [%]	# Peptides	% from Total
P02754	Beta-lactoglobulin - B taurus (Bovine).		100	165	99.6249%
A0A1B2J5U4	BA75_00070T0	PRY2	6	2	0.1321%
A0A1B2JG30	BA75_04321T0	ATY40_BA7504321	15	4	0.0869%
A0A1B2JDE1	BA75_01931T0	ATY40_BA7501931	11	3	0.0323%
A0A1B2JHZ1	Superoxide dismutase [Cu-Zn]	ATY40_BA7504526	43	6	0.0259%
A0A1B2JDU3	BA75_03273T0	ATY40_BA7503273	10	3	0.0202%
A0A1B2J841	BA75_00021T0	ATY40_BA7500021	5	2	0.0137%
A0A1B2JFJ3	Chitinase	CTS1	7	4	0.0127%
A0A1B2JIU6	Cellulase	ATY40_BA7504680	4	2	0.0099%
A0A1B2JJ78	BA75_05209T0	SCW11	6	3	0.0090%
A0A1B2J5A4	1,3-beta-glucanyltransferase	GAS1	16	7	0.0078%
A0A1B2JD90	BA75_02630T0	ATY40_BA7502630	7	2	0.0066%
A0A1B2J5H5	Endo-1,3(4)-beta-glucanase	DSE4	9	7	0.0056%
A0A1B2JF97	BA75_03970T0	BGL2	8	2	0.0036%
A0A1B2JCC4	BA75_02724T0	EXG1	6	2	0.0027%
A0A1B2JJE0	Glycidase	ATY40_BA7504772	5	2	0.0015%
A0A1B2JAS9	Ubiquitin	RPL40B	19	3	0.0012%
A0A1B2J661	BA75_00354T0	ATY40_BA7500354	5	3	0.0008%
A0A1B2J758	BA75_01312T0	PRB1	5	3	0.0006%
A0A1B2J755	BA75_01624T0	ATY40_BA7501624	12	3	0.0005%
A0A1B2JGW9	Alanine--glyoxylate transaminase	AGX1	10	3	0.0005%
A0A1B2JF94	BA75_03408T0	PEP4	9	3	0.0003%
A0A1B2JGR3	1,3-beta-glucanyltransferase	GAS3	10	4	0.0003%
A0A1B2JCS6	Amine oxidase	ATY40_BA7502878	4	2	0.0003%
A0A1B2JIU4	Acid phphatase	ATY40_BA7505161	4	2	0.0002%

PT-21.0070

Accession	Protein Name	Gene Symbol	Coverage [%]	# Peptides	% from Total
P02754	Beta-lactoglobulin - B taurus (Bovine).		100	176	99.4273%
A0A1B2J5U4	BA75_00070T0	PRY2	6	2	0.1218%
A0A1B2JG30	BA75_04321T0	ATY40_BA7504321	15	4	0.0782%

A0A1B2JHZ1	Superoxide dismutase [Cu-Zn]	ATY40_BA7504526	46	7	0.0782%
A0A1B2J841	BA75_00021T0	ATY40_BA7500021	5	2	0.0695%
A0A1B2JDU3	BA75_03273T0	ATY40_BA7503273	11	4	0.0585%
A0A1B2J755	BA75_01624T0	ATY40_BA7501624	17	5	0.0359%
A0A1B2JDE1	BA75_01931T0	ATY40_BA7501931	11	3	0.0162%
A0A1B2JJ78	BA75_05209T0	SCW11	7	4	0.0133%
A0A1B2JEK0	BA75_03428T0	TEF4	36	7	0.0116%
A0A1B2J5W9	BA75_00236T0	ATY40_BA7500236	11	11	0.0111%
A0A1B2JGS7	BA75_04779T0	ATY40_BA7504779	14	9	0.0088%
A0A1B2JFJ3	Chitinase	CTS1	7	3	0.0083%
A0A1B2JGG7	Formate dehydrogenase	FDH1	24	8	0.0066%
A0A1B2JD51	BA75_02990T0	YMR244W	8	4	0.0064%
A0A1B2JGF8	S-formylglutathione hydrolase	YJL068C	33	8	0.0057%
A0A1B2J5A4	1,3-beta-glucanyltransferase	GAS1	14	6	0.0048%
A0A1B2JCC4	BA75_02724T0	EXG1	7	4	0.0038%
A0A1B2JBK5	Alcohol oxidase	ATY40_BA7503165	19	9	0.0028%
A0A1B2JIU6	Cellulase	ATY40_BA7504680	3	2	0.0024%
A0A1B2JF97	BA75_03970T0	BGL2	8	2	0.0023%
A0A1B2JJE0	Glycidase	ATY40_BA7504772	8	3	0.0021%
A0A1B2JD90	BA75_02630T0	ATY40_BA7502630	7	2	0.0021%
A0A1B2JIW1	5-methyltetrahydropteroyltriglutamate--homocysteine S-methyltransferase	MET6	17	11	0.0019%
A0A1B2JGW9	Alanine--glyoxylate transaminase	AGX1	19	6	0.0017%
A0A1B2JDI7	BA75_02055T0	SHB17	12	3	0.0017%
A0A1B2JEK3	Phphatidylglycerol/ phphatidylinitol transfer protein	NPC2	13	2	0.0016%
A0A1B2J5H5	Endo-1,3(4)-beta-glucanase	DSE4	7	6	0.0016%
A0A1B2J6S7	BA75_00945T0	HSP82	8	7	0.0016%
A0A1B2JGQ7	BA75_03684T0	DAK2	21	8	0.0015%
A0A1B2JGR5	Fructe-bisphphatase	FBP1	8	3	0.0013%
A0A1B2JCI4	Nucleide diphphate kinase	YNK1	26	4	0.0010%
A0A1B2JJE1	Aspartate aminotransferase	AAT2	11	4	0.0008%
A0A1B2J655	BA75_00387T0	SSC1	4	3	0.0008%
A0A1B2JBK0	BA75_02392T0	CMD1	18	3	0.0007%
A0A1B2JE34	BA75_03373T0	ATY40_BA7503373	17	2	0.0007%

A0A1B2J8X6	BA75_01031T0	SBA1	8	2	0.0005%
A0A1B2JAS9	Ubiquitin	RPL40B	12	2	0.0005%
A0A1B2JFA7	Triephphate isomerase	TPI1	15	4	0.0005%
A0A1B2JD05	Thioredoxin	TRX1	24	2	0.0005%
A0A1B2JGR3	1,3-beta-glucanyltransferase	GAS3	11	3	0.0004%
A0A1B2J8L9	Pyrophphate phpho-hydrolase	IPP1	7	2	0.0004%
A0A1B2J8V2	Phphopyruvate hydratase	ENO1	8	2	0.0004%
A0A1B2JBI0	BA75_03280T0	SSP120	10	2	0.0004%
A0A1B2J758	BA75_01312T0	PRB1	5	2	0.0003%
A0A1B2JEZ2	BA75_03924T0	CRP1	8	2	0.0003%
A0A1B2JAJ8	Catalase	CTA1	5	2	0.0003%
A0A1B2JFF8	Phphotransferase	ATY40_BA7504121	4	2	0.0003%
A0A1B2JF94	BA75_03408T0	PEP4	10	3	0.0002%
A0A1B2JHD1	Endoplasmic reticulum chaperone BiP	KAR2	5	3	0.0002%
A0A1B2J7T4	BA75_01855T0	ATY40_BA7501855	10	2	0.0002%
A0A1B2J6E8	Fructe-bisphphate aldolase	FBA1	5	2	0.0002%
A0A1B2JAL9	Glyceraldehyde-3-phphate dehydrogenase	TDH3	8	2	0.0001%
A0A1B2JFW3	Phphoglycerate mutase	GPM1	13	3	0.0001%

Appendix 3
Potential Allergenicity Assessment Report

STUDY TITLE

Assessment of the Potential Allergenicity of Remilk Beta-Lactoglobulin Protein and Residual Host Proteins Based on Literature and Bioinformatics

AUTHOR

Richard E. Goodman

STUDY COMPLETED ON

9 February 2022

PERFORMING LABORATORY

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LABORATORY STUDY ID

REG-2022 Remilk Bioinformatics

SUMMARY

Remilk Ltd. has developed a fermentation system to produce a bovine (*Bos taurus*) milk protein, beta-lactoglobulin in *Komatagaella pastoris.* The host organism was previously known as *Pichia pastoris*. The beta lactoglobulin (BLG) is a major milk whey protein. It is a lipocalin that is often dimeric in milk, and monomeric below pH 3. It has 162 amino acids at a monomeric size of 18.4 kDa. The protein is used in a variety of foods that vary by physical treatment. It is known to be one of the primary food allergens in milk that effects between 0.5% and 2.5% of milk allergic children by IgE mediated allergy. It is an important functional food ingredient in dairy foods including ice-cream, cheese and butter and many processed foods. Yet the function of this protein in cow's milk is not completely understood even though it has been studied during the last 80 years.

The protein is being produced as a recombinant protein in the yeast *Komagataella pastoris,* previously known as *Pichia pastoris*. The company transformed the yeast organism with the bovine gene, UniProt Accession P02754 that encodes a protein of 178 amino acids. The mature protein is reduced by removal of the signal peptide of 16 AA as was done in cloning into the yeast. Remilk had the proteins from three batches of production characterized by liquid chromatography, tandem mass spectrometry (LC-MSMS) by Technion, Israel Institute of Technology, Department of Biology, Smoler Proteomics Center. Remilk supplied the report from Technion to me for completion of bioinformatics evaluation that examined the BLG protein sequence and the most abundant proteins from the yeast for comparison to known allergens. That was accomplished by comparing the amino acid sequences of BLG and the proteins from *Komagataella pastoris* to version 21 of the www.AllergenOnline.org database by FASTA. The LC-MSMS results confirmed the identity of BLG matched the UniProt sequence. The purity was >99% for all three batches.

I performed a literature search to search for evidence that proteins from the host organism (*Komagataella pastoris*, or *Pichia pastoris*) might have allergenic activity. There are no reports that proteins from the host are IgE mediated allergens, only reports of producing allergenic recombinant proteins in the host for scientific study.

The standard for predicting potential allergy or allergenic cross-reactivity for the yeast proteins was the CODEX standard of >35% identity over 80 AA, which was meaningfully exceeded by two *Komagataella pastoris* proteins known to be highly conserved in evolution, heat shock-70 and superoxide dismutase. These results are not significant as they occur for most eukaryotic organisms with those two proteins. Two other proteins were matched with low identities of < 38% ID to minor allergens. All of the yeast proteins are at low abundance in formation product and unlikely to represent a risk for consumers. The sequence of BLG was a 100% match to the bovine milk protein allergen, BLG. BLG also matched a few other mammalian proteins such as cat allergen Fel d 4 at 30% identity, Can f 6, a dog allergen and homologous proteins of horses, dogs and mice at lower identities.

Remilk Ltd. is aware of food allergen labeling laws in the United States, and they will label food product with BLG as milk allergens. There are no other labels or warnings that would be necessary for this protein product based on science.

Study Conduct

This study was performed using public allergenonline.org database and the NCBI PubMed database in January and February 2022. I manage the www.AllergenOnline.org database and version 21 was the public database, maintained in the Department of Food Allergy Research and Resource Program in the Department of Food Science & Technology, University of Nebraska-Lincoln.

The amino acid (AA) sequence of Beta-lactoglobulin is from the UniProt Accession P02754 and was confirmed by the report by Technion. The publications reported in this study were read from public records of the reported journals.

The data from these searches are held by the Principal Investigator and copies were supplied to Remilk Limited.

PRINCIPAL INVESTIGATOR:

Richard E. Goodman

9 February 2022
Date

TABLE OF CONTENTS

Abbreviations

AA	Amino acids
AOL	AllergenOnline.org, version 21
FASTA	Local search alignment for protein sequences developed by William Pearson, version 35.05 and 36
HCC	Holland Computing Center at the University of Nebraska-Lincoln

1.0 Introduction

Remilk Limited of Israel developed the recombinant yeast, *Komagataella pastoris* to produce pure bovine beta-lactoglobulin without the rest of milk. They produce the protein in controlled fermentation facilities. The protein is highly pure and very low levels of host-related proteins, less than 1% of total protein load. This study was conducted to evaluate possible risks of food allergy for this protein if it is used in food production.

2. Study Objectives

2.1. A literature search was performed to review the historical reports of allergy to the recombinant yeast host *Komagataella pastoris* for possible allergy or cross-reactivity. The primary search was of the PubMed database.

2.2. The amino acid sequence of the Bovine beta-lactoglobulin protein and the identified yeast proteins from three fermentation production lots were compared to the www.AllergenOnline.org allergen database for matches to proteins that are putative or proven allergens. The primary criteria for possible risk follows the CODEX Alimentarius guideline for proteins in genetically modified organisms. However, it is clear that a limit of >35% identity over 80 AA is not very predictive of risk or safety. As shown in Abdelmoteleb et al. (2021), many proteins of very low risk have matches > 35% ID over 80, often up to 40% identity. Some likely safe proteins with very little risk of cross-reactive allergy have matches as high as 70% identity to evolutionarily conserved proteins like profilins and heat-shock proteins. Thus, matches need to be evaluated based on scientific information about allergens and allergy.

3. Historical Food Use

Humans from most countries commonly consume bovine milk as an important food source. Milk proteins do cause food allergy in from 0.5% to 2.5% of the population of young children and probably less than 1% of the adult population in most countries (Sicherer and Sampson, 1999; Shoormasti et al., 2016; Huang et al., 2020). Beta-lactoglobulin of whey protein is one of the most important food allergens. A number of yeasts have been used for food production over centuries. Very few yeasts commonly used in food production have been shown to cause food allergy.

4. Literature Search for Allergenicity

The PubMed database was searched using the terms beta-lactoglobulin (BLG) AND milk AND allergy as search terms. Many publications were found. BLG has been known as an important food allergen in cow's milk allergy since before 1990. BLG has interesting food processing activities that provide physical characteristics to food, such as gelation. BLG is in the www.AllergenOnline.org database as an allergen that can activate basophils and mast cells in consumers that have developed specific IgE to two or more epitopes of the protein (Host et al., 1992; Shek et al., 2005; Lin et al., 2009; Lopez-Exposito et al., 2012; Huang et al., 2020). Literature searches for the host organism, *Komagataella pastoris* or *Pichia pastoris* did not identify publications demonstrating a risk of allergy.

5. Bioinformatics

The sequence of BLG was confirmed by the LC-MSMS data of the Technion protein center at the Israel Institute of Technology, as provided by Remilk. The sequence was compared to the UniProt entry accession P02754 shown in Figure 1. The gene encodes 178 AA sequence, but as expressed the 16 AA signal sequence has been removed, so it is 162 amino acids.

Figure 1. Bovine beta-lactoglobulin full-length sequence from UniProt accession P02754. The sixteen AA signal peptide is underlined. The signal peptide was not included in the bioinformatics searches.

```
>sp|P02754|LACB_BOVIN Beta-lactoglobulin OS=Bos taurus OX=9913
GN=LGB PE=1 SV=3

MKCLLLALALTCGAQALIVTQTMKGLDIQKVAGTWYSLAMAASDISLLDAQSAPLRVYVE
ELKPTPEGDLEILLQKWENGECAQKKIIAEKTKIPAVFKIDALNENKVLVLDTDYKKYLL
FCMENSAEPEQSLACQCLVRTPEVDDEALEKFDKALKALPMHIRLSFNPTQLEEQCHI
```

5.1 Bioinformatics of mature sequence of BLG. The amino acid sequence of BLG mature protein of 162 AA was used to search the AllergenOnline.org database using both versions of FASTA. This was on the public database website www.AllergenOnline.org using full-length FASTA with version 35.04 and version 36. Results of the full-length search are shown in Figure 2. Results were the same using either FASTA version 35.04 or 36. A 100% identity match was found to bovine beta-lactoglobulin (having 178 AA), with the match of 162 AA having an *E* score valuate of 1.1e-67. There were also high scoring matches to two versions of BLG with 98.8% identity and 98.1% identity to minor variants of sequence with details available in the linked sequence entries of AOL. As shown in Figure 2, the fourth highest match was 65.9% identity to a cat protein Fel d 4 with 29.5% identity and an *E* score value of 1.6e-9 (Smith et al., 2004). Then to dog Can f 6 with similar low identity match of 24.8% identity. Those are both lipocalins and are thought to be evolutionary homologues with cross-reactivity to bovine lipocalin Bos d 2 (Rautiainen et al 1998). The Smith et al (2004) paper demonstrated that bovine milk inhibited binding of IgE from milk allergic subjects to Bos d 2, but that is likely due to Bos d 2 binding IgE rather than Bos d 5. Hilgers et al., 2012 and Madhurantakam , 2010 show multiple lipocalins in bovine milk and in saliva and skin of dogs and cats that are allergens with cross-reactivity of lipocalins, but not to BLG of cow's milk. No publications were found that demonstrate IgE binding to Bos d 5 is cross-reactive with other lipocalin proteins. The sliding 80mer window search was performed using both FASTA 35.04 and FASTA 36. Both showed equal matches, only to the three bovine beta-lactoglobulin sequences matched by Full-length FASTA (Figure 3).

5.2 AllergenOnline.org at FARRP, (http://allergenonline.org/databasefasta.shtml) was searched against version 21 which includes 2233 proteins in 912 protein allergen groups. Searches included a Full-Length FASTA search, a sliding 80 AA search by FASTA and an 8 AA identity match.

Figure 2. Full-length FASTA alignment in www.AllergenOnline.org version 21.

Firefox http://allergenonline.org/search36.php

AllergenOnline Search Results

Note: As of August 2015 we have included gid: groupid in the fasta results that provides detailed information on the allergenicity references for the group, type of allergen, other sequences belonging to the same group and more.

%_id 1 = 100% identity, alen=alignment length

AllergenOnline Database v21 (February 14, 2021)

NOTE Addition of Allergenicity* column on the Browse Database page with classification based on Group references was added on 10 May 2018. Please review the "allergenicity" of any matches you find here with the Browse page and look at Group References (gid) if you want to further evaluate relevance of alignments.

fasta36.exe -q -B -m 9i -w 80 -E 1 -d 20 C:\Windows\Temp\all85B1.tmp version2136.fasta
User Query #1 >sp|P02754|LACB_BOVIN Beta-lactoglobulin OS=Bos taurus OX=9913

User Query #1

```
     >sp|P02754|LACB_BOVIN Beta-lactoglobulin OS=Bos taurus OX=9913
     GNLGBPESVL IVTQTMKGLD IQKVAGTWYS LAMAASDISL LDAQSAPLRV YVEELKPTPE GDLEILLQKW ENGECAQKKI IAEKTKIPAV
     FKIDALNENK VLVLDTDYKK YLLFCMENSA EPEQSLACQC LVRTPEVDDE ALEKFDKALK ALPMHIRLSF NPTQLEEQCH I

# fasta36.exe -q -B -m 9i -w 80 -E 1 -d 20 C:\Windows\Temp\all85B1.tmp version2136.fasta
FASTA searches a protein or DNA sequence data bank
 version 36.3.8g Oct, 2018
Please cite:
 W.R. Pearson & D.J. Lipman PNAS (1988) 85:2444-2448

Query: C:\Windows\Temp\all85B1.tmp
  1>>>sp|P02754|LACB_BOVIN Beta-lactoglobulin OS=Bos taurus OX=9913  - 171 aa
Library: version2136.fasta
   540227 residues in  2233 sequences

Statistics: Altschul/Gish params: n0: 171 Lambda: 0.158 K: 0.019 H: 0.100
 statistics sampled from 365 (391) to 365 sequences
Algorithm: FASTA (3.8 Nov 2011) [optimized]
Parameters: BL50 matrix (15:-5), open/ext: -10/-2
 ktup: 2, E-join: 1 (0.49), E-opt: 0.2 (0.175), width:  16
 Scan time:  0.000

The best scores are:                                      opt bits E(2233) %_id  %_sim  alen
gi|125910|gid|362|Beta-lactoglobulin precursor (Beta ( 178) 1059 248.4 1.1e-067 1.000 1.000  162
gi|195957138|gid|362|major allergen beta-lactoglobul ( 178) 1045 245.2  1e-066 0.988 0.994  162
gi|520|gid|362|beta-lactoglobulin [Bos taurus]       ( 178) 1036 243.2 4.2e-066 0.981 0.988  162
gi|45775300|gid|538|Fel d 4 allergen [Felis catus]   ( 186)  212 55.3 1.6e-009 0.295 0.659  129
gi|1374502923|gid|1925|Chain D, Lipocalin-Can f 6 al ( 177)  203 53.3 6.1e-009 0.245 0.639  155
gi|374092884|gid|1925|lipocalin-Can f 6 allergen [Ca ( 190)  203 53.3 6.7e-009 0.245 0.639  155
gi|81690324|gid|96|Alpha-2u globulin                 ( 181)  193 51.0  3e-008 0.287 0.620  129
gi|1575778|gid|524|Equ c1 [Equus caballus]           ( 187)  183 48.7 1.5e-007 0.255 0.628  137
gi|204261|gid|96|alpha-2u globulin precursor(), part ( 177)  178 47.6 3.2e-007 0.259 0.597  139
gi|127533|gid|96|Major urinary protein precursor (MU ( 181)  178 47.6 3.3e-007 0.259 0.597  139
gi|301072397|gid|1768|Fel d 7 allergen precursor [Fe ( 180)  169 45.5 1.2e-006 0.275 0.542  153
gi|29292272|gid|402|precursor Can f II [Canis famili ( 177)  164 44.4 2.9e-006 0.222 0.637  135
gi|2598976|gid|402|Can f 2 [Canis lupus familiaris]  ( 180)  164 44.4  3e-006 0.222 0.637  135
gi|29292274|gid|402|precursor Can f II [Canis famili ( 179)  156 42.6  1e-005 0.246 0.609  138
gi|2598974|gid|401|Can f 1 [Canis lupus familiaris]  ( 174)  155 42.4 1.2e-005 0.294 0.527  136
gi|199881|gid|671|major urinary protein II [Mus musc ( 180)  148 40.8 3.7e-005 0.207 0.607  135
gi|20176291|gid|671|Major urinary protein 6 precurso ( 180)  146 40.3 5.1e-005 0.203 0.617  133
gi|980952242|gid|671|RecName: Full=Major urinary pro ( 181)  146 40.3 5.1e-005 0.203 0.617  133
gi|295910|gid|671|major urinary protein [Mus musculu ( 180)  142 39.4 9.5e-005 0.203 0.609  133
gi|557943216|gid|2199|lipocalin allergen Ory c 4 pre ( 172)  133 37.4 0.00027 0.230 0.563  126
gi|1604536255|gid|418|allergen lipocalin Cav p 1 iso ( 166)  131 36.9 0.00048 0.225 0.596  151
gi|1492010380|gid|522|Equ c 2 allergen [Equus caball ( 174)  128 36.2 0.00083 0.212 0.591  132
gi|1604536257|gid|418|allergen lipocalin Cav p 1 iso ( 166)  122 34.9   0.002 0.192 0.616  151
gi|530376029|gid|2450|odorant-binding protein, parti ( 151)  105 31.1   0.026 0.273 0.667   66
gi|13124669|gid|2477|male-specific submandibular pro ( 172)  105 31.0   0.031 0.333 0.682   66
```

1 of 8 2/7/2022, 11:22 AM

Figure 3. Bovine beta-lactoglobulin sliding 80mer window comparison to AllergenOnline.org. Both FASTA 35.04 and FASTA 36 sliding window alignments to version 21 of AOL provide the same alignments to the three bovine beta-lactoglobulin proteins. No other alignments were found to non-BLG proteins.

80mer Sliding Window Search Results

Database	AllergenOnline Database v21 (February 14, 2021)
Input Query	>sp|P02754|LACB_BOVIN Beta-lactoglobulin OS=Bos taurus OX=9913 GNLGBPESVLIVTQTMKGLDIQKVAGTWYSLAMAASDISLLDAQSAPLRVYVEELKPTPE GDLEILLQKWENGECAQKKIIAEKTKIPAVFKIDALNENKVLVLDTDYKKYLLFCMENSA EPEQSLACQCLVRTPEVDDEALEKFDKALKALPMHIRLSFNPTQLEEQCHI
Length	171
Number of 80 mers	92
Number of Sequences with hits	3

Hit #	Defline	Species	Best %ID	# Hits >35%	Full Alignment			Links	
					E-val	%ID	length	NCBI	Details
1	gi|125910|gid|363|Beta-lactoglobulin precursor (Beta-LG)	Bos taurus	100.00%	92of92	1.1e-067	100.00%	162	gi|125910	GO!
2	gi|520|gid|363|beta-lactoglobulin [Bos taurus]	Bos taurus	98.80%	92of92	4.2e-066	98.10%	162	gi|520	GO!
3	gi|195957138|gid|363|major allergen beta-lactoglobulin [B	Bos taurus	98.80%	92of92	1e-066	98.80%	162	gi|195957138	GO!

AllergenOnline Database v21 (February 14, 2021)

5.3 *Komagataella pastoris* proteins in BLG fermentation products. The proteomics evaluation of three batches of fermentation products from Remilk by the Technion laboratory showed greater than 99.5% purity of the BLG. The residual proteins were identified by UniProt accession numbers with measures of percent coverage of the sequence, the number of peptides identified, and the % of total protein represented by each specific protein. In all cases P02754, bovine beta-lactoglobulin was identified by 100% coverage and >99% of the total protein content detected by the specific sample. The table output from Technion was presented by sample batch.

5.3.1 PT-21.0076. First batch analyzed.

Accession	protein	Gene descript.	% coverage	# peptides	Total cover	Matched allergen
P02754	Bovine BLG 178 AA	Mature 162 AA	100%	157	99.5%	Bos d 5 BLG
A0A1B2JDE1	430 AA	None	13%	4	0.115%	Asp f 7 25.8%
A0A1B2JG30	441 AA	None	15%	4	0.110%	Asp f 4 24.4%

A0A1B2J5U4	313 AA	None	6%	2	0.094%	Cuc m 3 37.5%
A0A1B2JDU3	351 AA	None	14%	5	0.047%	Asp f 4 26.4%
A0A1B12JHZ1	316 AA	Superoxide dismutase	38%	5	0.023%	Ole e 5 57%
A0A1B2JFJ3	851 AA	Chitinase	7%	4	0.017%	Pun g 14 35.8%
A0A1B2J841	777 AA	None	5%	2	0.015%	Man e 5 30.5%
A0A1B2J755	510 AA	None	18%	4	0.01%	Mus a 5 25.7%

5.3.2 PT-21.0073. Second batch analyzed.

Accession	protein	Gene descript.	% coverage	# peptides	Total cover	Matched allergen
P02754	Bovine BLG 178 AA	Mature 162 AA	100%	157	99.6%	Bos d 5 BLG
A0A1B2J5U4	475 AA	None	6%	2	0.013%	Cuc m 3 37.5%
A0A1B2JG30	603 AA	None	15%	4	0.087%	Asp f 4 24.4%
A0A1B2JDE1	592 AA	None	11%	3	0.032%	Asp f 7 25.8%
A0A1B2JHZ1	316 AA	Superoxide dismutase	46%	7	0.078%	Ole e 57.2%
A0A1B2JDU3	513 AA	None	10%	3	0.07%	Asp f 4 24.4%
A0A1B2J841	615 AA	None	5%	2	0.014%	Man e 5 30.5%
A0A1B2JFJ3	689 AA	Chitinase	7%	4	0.012%	Pun g 14 35.8%

5.3.3 PT-21.0070. Third batch analyzed.

Accession	protein	Gene descript.	% coverage	# peptides	Total cover	Matched allergen
P02754	Bovine BLG 178 AA	Mature 162 AA	100%	157	99.5%	Bos d 5 BLG
A0A1B2J5U4	313 AA	None	6%	2	0.12%	Cuc m 3 37.5%
A0A1B2JG30	441 AA	None	15%	4	0.078%	Asp f 4 24.4%

A0A1B2JHZ1	154 AA	Superoxide dismutase	46%	7	0.078%	Ole e 5 57.2%
A0A1B2J841	615 AA	None	5%	2	0.07%	Man e 2 30.5%
A0A1B2JDU3	351 AA	None	11%	4	0.06%	Asp f 4 24.4%
A0A1B2J755	348 AA	None	17%	5	0.036%	Mus a 5 25.7%
A0A1B2JDE1	430 AA	None	11%	3	0.016%	Asp f 7 25.8%
A0A1B2JJ78	469 AA	None	7%	4	0.013%	Asp f 7 27.3%
A0A1B2JEK0	216 AA	None	36%	7	0.016%	Bla GST 22.3%
A0A1B2J5W9	656 AA	None	11%	11	0.011%	Tyr p 28 75.5%

5.3.4 Summary of bioinformatics sequence identities to *Komagataella pastoris* protein residues in final BLG. The searches of these minor residual proteins that together represent less than one-half of one percent of the total protein are generally clean, with identities of less than 35% identity to putative allergens. However, two proteins have more substantial matches. The superoxide dismutase homologue is nearly 58% identical to olive tree superoxide dismutase. The www.AllergenOnline.org has a few publications listed for this group of highly identical proteins in olive pollen, but they evidence of potency is weak (Rodriguez et al., 2001; Butteroni et al., 2005). Though that is a rather minor allergen at best in olive pollen and Ole e 1 is the dominant allergen in olive pollen (Gonzalez et al, 2006). The other high identity match is to a mite Heat-Shock 70 protein Tyr p 28 (Cui et al., 2016). HSP are highly conserved and yet the evidence of shared IgE mediated allergy is quite limited (Pockley et al., 1998; Gruehn et al., 2003). The Tyr p 28 protein was named by the WHO/IUIS Allergen Nomenclature committee in 2016, but the evidence was mostly based on sequence identity to another house dust mite allergen, Der f 28. The protein was not shown to cause biological activity from that publication. The two proteins with sequence identities just above 35% identity (Cuc m 3 at 37.5% and Pun g 14 with 35.8%) are not common or dominant allergens. Cuc m 3 was identified by Asensio et al., in 2004 as a relatively small melon fruit protein that binds IgE from a small percentage of melon allergic subjects in the study by Asensio (2004). Pun g 14 is a chitinase that was described from Pomegranate by Tuppo et al., (2018). The 29 kDa protein is a homologue of a chitinase in *Hevea braziliensis* (Hev b 14) and raspberry although the IgE binding cross-reactivity was not clearly demonstrated. These proteins (Cuc m 3 and Pun g 14) are minor proteins in the respective sources and the clinical importance of all of the superoxide dismutase, the HSP-70 and certainly Cuc m 3 and Pun g 14 have not been clearly demonstrated in terms of severity of allergy or risk. The sequence matches of minor amounts of *Komagataella pastoris* proteins is highly unlikely to represent a clinical risk for consumers compared to protein mixtures

present in foods produced from major allergen sources of cow milk, eggs, peanut, tree nuts, crustacean shell fish, fish, soybeans, wheat or sesame.

6. Conclusions

The results of the literature search and bioinformatics for the bovine beta-lactoglobulin protein cloned into *Komagataella pastoris* for yeast expression and the small amount of residual yeast proteins were completed on 7 February 2022. These results show that food products produced from this fermentation would carry the risk of food allergy to bovine lactoglobulin. There appears to be no added risk from the residual proteins of *Komagataella pastoris*. There is no science-based rationale for conducting serum IgE binding studies on this product. It would be a risk for milk allergic subjects sensitized to BLG. The risks from the yeast proteins are not relevant to a great extent because each represents less than 0.15% of the total protein and because they are not highly identical to an immunodominant allergen.

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Annex I AllergenOnline.org version 21 (43 pages)

Annex II Technion Proteomics report on three batches of fermented BLG (9 pages)

Appendix 4
Dietary Exposure Assessment Report

Center for Chemical Regulation and Food Safety

Exponent®

Estimates of Daily Intake of Bovine-Identical β-Lactoglobulin from Intended Uses in Select Foods

Estimates of Daily Intake of Bovine-Identical β-Lactoglobulin from Intended Uses in Select Foods

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February 10, 2022

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Table of Contents

List of Tables

List of Acronyms

DHHS	U.S. Department of Health and Human Services
EDI	Estimated Daily Intake
FARE®	Foods Analysis and Residues Evaluation Program
FDA	U.S. Food and Drug Administration
FNDDS	Food and Nutrient Database for Dietary Studies
g	gram
GRAS	Generally Recognized As Safe
NCHS	National Center for Health Statistics
NHANES	National Health and Nutrition Examination Survey
U.S.	United States
USDA	U.S. Department of Agriculture
WWEIA	What We Eat in America
y	year

Introduction

Remilk, Ltd. ("Remilk") produces bovine-identical β-lactoglobulin from the fermentation of *Pichia pastoris.* At the request of Remilk, Exponent, Inc. ("Exponent") conducted an intake assessment to estimate the daily intake of bovine-identical β-lactoglobulin proposed for use in select food categories to support development of a Generally Recognized As Safe (GRAS) conclusion for the intended use of the ingredient.

The typical U.S. diet provides approximately 1.4 g β-lactoglobulin. This value was calculated assuming 78.3 g total protein intake (USDA, 2020), 20% of total protein is from dairy sources (Cifelli et al., 2015), and 9% of dairy protein is β-lactoglobulin (Miller et al., 2007). Use of bovine-identical β-lactoglobulin as an ingredient may provide additional intake of this protein.

Bovine-identical β-lactoglobulin produced by *Trichoderma reesei* was previously concluded to be GRAS for select uses in food (GRN 863) by Perfect Day, Inc. ("Perfect Day") as a source of protein. The estimates presented in this analysis therefore include estimates of intake of bovine-identical β-lactoglobulin from existing GRAS uses, from Remilk's proposed uses, and the cumulative intake of bovine-identical β-lactoglobulin from Remilk's intended use in combination with existing recognized use of bovine-identical β-lactoglobulin.

The estimated daily intake (EDI) of bovine-identical β-lactoglobulin were developed from dietary consumption data collected in the What We Eat in America (WWEIA) dietary component of the National Health and Nutrition Examination Survey (NHANES) 2015-2018. Estimates of bovine-identical β-lactoglobulin intake were developed for the U.S. population ages 2 years and older and subpopulations of children, adolescents, and adults. The data and methods used to conduct the intake assessment and results are summarized in this report.

Intended Use in Foods

Proposed Uses of Bovine-Identical β-Lactoglobulin

Remilk's bovine-identical β-lactoglobulin is intended for use as a source of protein in select foods including nutritional products, dairy and dairy-based products, sugar-based products, baked goods, dressing, and egg substitutes. Remilk's bovine-identical β-lactoglobulin is intended at the maximum proposed use level in select foods from 5% to 35% by weight (i.e., 5 to 35 g β-lactoglobulin per 100 g food). The proposed food categories to which bovine-identical β-lactoglobulin is intended to be added and the intended use level in each category are listed in Table 1.

Table 1. Intended use of Remilk's bovine-identical β-lactoglobulin in select foods

Food category	Remilk's proposed food use	Proposed max use level, % [a]
Nutritional Products	Meal replacements and supplements	15
	Powdered nutritional beverages	25
	Electrolyte-type sports drinks	6
	Performance nutritional beverages, high protein	25
	Nutritional bars	35
Dairy and Dairy-Based Products	Fluid milk, powdered milk, flavored milk, milk-based drinks and drink mixes (e.g., dairy smoothies, hot chocolate from mix), milk substitutes	6
	Cream, half & half, cream cheese, cheese spread, whipped cream	15
	Spreads, dips	10
	Cream substitutes	15
	Yogurt and fermented milk products	8
	Ice cream, frozen yogurt	8
	Cheese used primarily as ingredients, e.g. ricotta cheese	15
	Semi-hard cheese (e.g., feta, Camembert, brie)	25
Sugar-Based Products	Desserts and mousses	5
	Confections (including chocolate confections)	10
	Coatings and fillings	10
	Cookies and brownies, crackers, popcorn, potato chips, tortilla chips, hard pretzels/snack mix	5

Food category	Remilk's proposed food use	Proposed max use level, % [a]
	Doughnuts, toaster pastries, muffins	10
Baked Goods	French toast, crepes, pancakes, bagels, scones, biscuits, croissants	10
	Breads & rolls, English muffins, pizza crust	10
Dressings	Creamy salad dressings	5
	Minor main entrée sauces (e.g., Alfredo sauce, white sauce, cheese sauce)	6
Egg Products	Egg substitutes	10

[a]Use level represents the concentration of bovine-equivalent β-lactoglobulin in the food.

Proposed vs Existing Uses of Bovine-Identical β-Lactoglobulin

As detailed in GRN 863 and supplemental correspondence with FDA regarding GRN 863, β-lactoglobulin, produced by *Trichoderma reesei*, intended for use in select foods at levels up to 35% is GRAS. The β-lactoglobulin produced by Perfect Day as specified in GRN 863 is also a bovine-identical β-lactoglobulin that is ≥ 85% protein, which in turn is ≥ 90% β-lactoglobulin. The U.S. population therefore may currently have exposure to bovine identical β-lactoglobulin from use of the ingredient as summarized in GRN 863. The uses of Perfect Day's bovine-identical β-lactoglobulin are broad and ranges of intended use levels are wide. No estimates of intake were developed in GRN 863 and consequently no food code list was created to serve as a baseline for the current assessment. The list of intended uses as specified in GRN 863 is provided in Appendix A.

Table 2 below presents the concentration of bovine-identical β-lactoglobulin representative of the existing GRAS uses (i.e., derived from GRN 863) and applied in the current analysis. The table also presents the concentration of bovine-identical β-lactoglobulin that represents Remilk's proposed uses. Additionally, the table presents the total maximum use of bovine-identical β-lactoglobulin to reflect both existing GRAS uses and proposed uses across all applicable food categories.

Table 2. Intended use of Remilk's bovine-identical β-lactoglobulin in select foods vs existing GRAS uses of bovine-identical β-lactoglobulin in foods and use levels applied in estimates of intake

Food category	GRN 863 Existing GRAS Use[b]	Remilk's Proposed Use	Use Levels Applied in Estimates of Intake[a]		
			Existing GRAS Use	Proposed Use	Total Use
Nutritional Products	Meal replacements and supplements	Meal replacements and supplements	15	15	15
	Powdered nutritional beverages	Powdered nutritional beverages	25	25	25
	Sports beverages	Electrolyte-type sports drinks	6	6	6
		Performance nutritional beverages, high protein	20	25	25
	Nutritional bars	Nutritional bars	35	35	35
Dairy and Dairy-Based Products	Milk products (including beverages and coffee creamer)	Fluid milk, powdered milk, flavored milk, milk-based drinks and drink mixes (e.g., dairy smoothies, hot chocolate from mix), milk substitutes	6	6	6
		Cream, half & half, cream cheese, cheese spread, whipped cream	15	15	15
	Yogurt and fermented milk products	Yogurt and fermented milk products	5	8	8
	Spreads, dips, and cream substitutes	Spreads, dips	10	10	10
		Cream substitutes	15	15	15
	Frozen dairy desserts and mixes	Ice cream, frozen yogurt	10	8	10
	-	Cheese used primarily as ingredients, e.g., ricotta cheese	-	15	15
		Semi-hard cheese (e.g., feta, Camembert, brie)	-	25	25
Sugar-Based Products	Desserts and mousses	Desserts and mousses	5	5	5
	Confections (including chocolate confections)	Confections (including chocolate confections)	10	10	10
	Coatings and fillings	Coatings and fillings	10	10	10

Food category	GRN 863 Existing GRAS Use[b]	Remilk's Proposed Use	Use Levels Applied in Estimates of Intake[a]		
			Existing GRAS Use	Proposed Use	Total Use
	Snack Foods	Cookies and brownies, crackers, popcorn, potato chips, tortilla chips, hard pretzels/snack mix	5	5	5
		Doughnuts, toaster pastries, muffins	10	10	10
Baked Goods	-	French toast, crepes, pancakes, bagels, scones, biscuits, croissants	-	10	10
	-	Breads & rolls, English muffins, pizza crust	-	10	10
Dressings	Salad dressings	Creamy salad dressings	5	5	5
	-	Minor main entrée sauces (e.g., Alfredo sauce, white sauce, cheese sauce)	-	6	6
Egg Products	-	Egg substitutes	-	10	10

[a] All levels represent maximum use levels within each food category
[b] Use level represents the concentration of bovine-equivalent β-lactoglobulin in the food.

Data and Methods

Food Consumption Data

Estimates of the intended intake of bovine-identical β-lactoglobulin intake were developed from food consumption records collected in the What We Eat in America (WWEIA) component of the National Health and Nutrition Examination Surveys (NHANES) conducted in 2015-2016 and 2017-2018 (NHANES 2015-2018). The NHANES is a continuous survey that uses a complex multistage probability sample designed to be representative of the civilian U.S. population (CDC 2022). Statistical weights are provided by the National Center for Health Statistics (NCHS) to adjust for the differential probabilities of selection and non-response.

As part of the examination, trained dietary interviewers collected detailed information on all foods and beverages consumed by respondents in the previous 24-hour time period (midnight to midnight). A second dietary recall was administered by telephone three-to-ten 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 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 Food Codes

The list of all food codes reported consumed in NHANES 2015-2018 was reviewed, and food codes corresponding to bovine-identical β-lactoglobulin uses (proposed uses from Remilk and existing uses from Perfect Day) were identified. To develop estimates of cumulative bovine-identical β-lactoglobulin intake, existing intended uses were compared with Remilk's proposed uses. Many of the intended uses of Remilk's bovine-identical β-lactoglobulin are identical to and therefore substitutional with the existing uses of Perfect Day's β-lactoglobulin ingredient (GRN 863). As noted above and detailed in Table 2, the intended use of Remilk's bovine-identical β-lactoglobulin is substitutional for some though not all uses of bovine-identical β-lactoglobulin previously determined to be GRAS (GRN 863). The intended uses of Remilk's bovine-identical β-lactoglobulin also include use in select additional food categories (cheeses, baked goods, minor main entrée sauces, and egg products) and a higher use level in the yogurt and fermented milk products category.

GRN 863 noted that the intended use of Perfect Day's bovine-identical β-lactoglobulin was substitutional for existing sources of protein in the diet and therefore would not increase dietary protein intake. The use categories of Perfect Day's bovine-identical β-lactoglobulin are broad and ranges of intended use levels are wide (see Appendix A). The food codes selected to develop representative estimates of intake were selected to broadly represent each specified food category.

When only a component of a food corresponds to the proposed use, USDA's Food and Nutrient Database for Dietary Studies (FNDDS) was used to identify relevant ingredients in each food as grams per 100 gram (g/100 g) food. The FNDDS translates food as reported consumed into its corresponding ingredients (and gram amounts) or recipes. FNDDS version 2017-2018 was used to process dietary recall data reported in either survey; for the limited foods consumed only in NHANES 2015-2016, FNDDS version 2015-2016 was used to process dietary recalls (USDA, 2018a,b). In select cases where the FNDDS recipes for a specific food code do not disaggregate a food mixture into component ingredients of interest for this analysis (e.g., the coating component on a cookie or bar), the component ingredient weight (g/100 g) was calculated as the average proportion from similar foods with a complete recipe.

The list of all food codes in NHANES 2015-2018 that were reported consumed and included in the analysis to represent Remilk's intended use as well as GRN 863 uses are provided in Appendix B.

Analysis

Using the NHANES 2015-2018 consumption data, the 2-day average daily intakes of bovine-identical β-lactoglobulin from the proposed uses were estimated on a *per capita* and *per user* basis. *Per capita* estimates refer to the intake based on the population of interest whereas *per user* estimates refer to those who reported consuming any of the foods of interest on either of the survey days. For each subject with a complete 2-day dietary recall, the 2-day average intake estimate was derived by summing the intake(s) of interest on day 1 and day 2 of the survey, expressed as grams per day (g/day), multiplied by the corresponding maximum bovine-identical β-lactoglobulin use level (%) (see Table 2), and then dividing that sum by two to express intake in grams per day (g/day). If a survey participant consumed a food of interest on only one of the survey days, their resulting bovine-identical β-lactoglobulin intake after accounting for bovine-identical β-lactoglobulin use level for that food was divided by two to obtain their 2-day average intake. The mean and 90th percentile intakes of the 2-day average bovine-identical β-lactoglobulin ingredient intake from proposed uses were calculated for the U.S. population aged 2 years and older (2+ y) and the following subpopulations: children 2-5 y, children 6-12 y, adolescents 13-18 y, and adults 19+ y. Estimates of intake per person were generated using Exponent's Foods Analysis and Residue Evaluation Program (FARE® version 14.06) software, which uses the statistically weighted values from the survey in the analysis.

Cumulative intake of bovine-identical β-lactoglobulin from existing uses (GRN 863) and proposed uses of Remilk's bovine-identical β-lactoglobulin was also estimated. To estimate the cumulative intake, the maximum use level from existing uses and Remilk's proposed uses were applied to the consumption estimates for each food use (see Table 2).

Results

Intake from Existing GRAS Uses

Two-day average intake estimates of bovine-identical β-lactoglobulin at the mean and 90th percentile of intake from the existing GRAS uses are summarized in Table 3. Among the U.S. population ages 2 years and older, 98.7% of individuals were estimated to consume one or more foods during the two days of recall that may contain added bovine-identical β-lactoglobulin from existing GRAS uses. The per capita mean and 90th percentile intake in the population ages 2 years and older is 21.6 g/day and 44.8 g/day, respectively, while the per user mean and 90th percentile intake in the population ages 2 years and older is 21.9 g/day and 45.2 g/day, respectively.

Table 3. Two-day average daily intake of bovine-identical β-lactoglobulin from existing GRAS uses (g/day) by the U.S. population 2+ years and select sub-populations, NHANES 2015-2018

Population	Total sample, n	Users		Per Capita		Per User	
				Mean	90th Per-centile	Mean	90th Per-centile
		n	%	---- g/day ----			
U.S. 2+ y	12717	12524	98.7	21.6	44.8	21.9	45.2
Children 2-5 y	999	998	100.0	25.9	45.8	25.9	45.8
Children 6-12 y	1744	1738	99.7	26.2	48.5	26.3	48.6
Adolescents 13-18 y	1433	1414	99.1	22.6	45.3	22.8	45.4
Adults 19+ y	8541	8374	98.5	20.7	44.3	21.0	44.7

Note: Existing GRAS uses as defined in GRN 863 (Table 2, Appendix A).

Intake from Remilk's Proposed Uses

Two-day average intake estimates of bovine-identical β-lactoglobulin at the mean and 90th percentile of intake from proposed uses are summarized in Table 4. Among the U.S. population ages 2 years and older, nearly all individuals (99.7%) were estimated to consume one or more foods during the two days of recall that may contain added bovine-identical β-lactoglobulin from proposed uses. Both the per capita and per user mean and 90th percentile intake in the population ages 2 years and older is 31.0 g/day and 56.4 g/day, respectively.

Table 4. Two-day average daily intake of Remilk's bovine-identical β-lactoglobulin from all proposed uses (g/day) by the U.S. population 2+ years and select sub-populations, NHANES 2015-2018

Population	Total sample, n	Users		Per Capita		Per User	
				Mean	90th Per-centile	Mean	90th Per-centile
		n	%	---- g/day ----			
U.S. 2+ y	12717	12670	99.7	31.0	56.4	31.0	56.4
Children 2-5 y	999	998	100.0	33.2	53.6	33.2	53.6
Children 6-12 y	1744	1743	99.9	36.2	59.4	36.3	59.4
Adolescents 13-18 y	1433	1431	99.9	33.5	59.6	33.5	59.6
Adults 19+ y	8541	8498	99.6	29.9	55.8	30.0	55.9

Note: Proposed uses as defined by Remilk (Table 1, Table 2).

Total Intake from Existing GRAS and Proposed Uses

The 2-day average total (i.e., cumulative) estimates of bovine-identical β-lactoglobulin at the mean and 90th percentile of intake from the existing GRAS and proposed uses are summarized in Table 5. Among the U.S. population ages 2 years and older, nearly all individuals (99.7%) were estimated to consume one or more foods during the two days of recall that may contain added bovine-identical β-lactoglobulin from existing GRAS or proposed uses. The per capita mean and 90th percentile intake in the population ages 2 years and older is 31.4 g/day and 57.5 g/day, respectively, while the per user mean and 90th percentile intake is very similar at 31.5 g/day and 57.6 g/day, respectively.

Table 5. Two-day average cumulative daily intake of bovine-identical β-lactoglobulin from existing GRAS and proposed uses (g/day) by the U.S. population 2+ years and select sub-populations, NHANES 2015-2018

Population	Total sample, n	Users		Per Capita		Per User	
				Mean	90th Per-centile	Mean	90th Per-centile
		n	%	---- g/day ----			
U.S. 2+ y	12717	12670	99.7	31.4	57.5	31.5	57.6
Children 2-5 y	999	998	100.0	33.5	53.9	33.5	53.9
Children 6-12 y	1744	1743	99.9	36.8	60.3	36.9	60.3
Adolescents 13-18 y	1433	1431	99.9	34.0	60.4	34.0	60.5
Adults 19+ y	8541	8498	99.6	30.3	57.0	30.5	57.0

Note: Cumulative uses from existing GRAS and proposed uses (Table 2).

Discussion

This analysis presents estimates of potential intake of bovine-identical β-lactoglobulin from existing, proposed, and cumulative sources from bovine-identical β-lactoglobulin added as an ingredient.

Among the U.S. population ages 2 years and older, nearly the entire population was estimated to consume a food that currently or potentially may contain bovine-identical β-lactoglobulin as an ingredient. At the per user 90th percentile of intake, intake from current, proposed, and cumulative sources of bovine-identical β-lactoglobulin are 45.2 g/day, 56.4 g/day, and 57.6 g/day, respectively. The proposed uses of bovine-identical β-lactoglobulin are substitutional for existing uses of bovine-identical β-lactoglobulin, and also slightly expand the uses of this protein source. All uses of bovine-identical β-lactoglobulin are assumed to be substitutional for added dietary protein ingredients, and therefore will not increase overall intake of dietary protein. The typical U.S. diet provides approximately 1.4 g β-lactoglobulin from milk proteins.

The estimates presented in this assessment provide conservatively high estimates of bovine-identical β-lactoglobulin intake from the intended uses. In calculating the estimates of intake, it was assumed that all foods in each use category will contain the maximum intended use of the ingredient. In reality, manufacturers may not use the maximum intended use of bovine-identical β-lactoglobulin in all products, and not all consumers may select products with bovine-identical β-lactoglobulin at all eating occasions.

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Appendices

Appendix A. GRN 863 Intended Uses

Proposed Uses as Specified in GRN 863

Table 3. Typical Food Uses and Use Levels of β-Lactoglobulin from Fermentation of *T. reesei*.

Nutritional Products	Meal Replacements and Supplements	Emulsifier, source of high-quality protein	5-15%
	Powdered Nutritional Beverages	Source of high-quality protein	10-25%
	Nutritional Bars	Source of high-quality protein, texturizer	5-35%
	Sports Beverages	Source of high-quality protein	5-20%
Dairy and Dairy-Based Products	Milk Products (including beverages and coffee creamer)	Source of high-quality protein, texturizer	1-15%
	Yogurt and Fermented Milk Products	Texturizer, thickener	1-5%
	Spreads, Dips, and Cream Substitutes	Texturizer	1-15%
	Frozen Dairy Desserts and Mixes	Emulsifier	1-10%
Sugar Based Products	Desserts and Mousses	Texturizer	<5%
	Confections (including chocolate confections)	Texturizer, flavor	1-10%
	Snack Foods	Texturizer, flavor	1-10%
	Coatings and Fillings	Texturizer, flavor	1-10%
Dressings	Salad Dressings	Emulsification, flavor	<5%

Appendix B. NHANES Food Codes in the Analysis of Intake

Food Code	Food Description
Nutritional Products	
Meal Replacements and Supplements	
95101000	Nutritional drink or shake, ready-to-drink (Boost)
95101010	Nutritional drink or shake, ready-to-drink (Boost Plus)
95102000	Nutritional drink or shake, ready-to-drink (Carnation Instant Breakfast)
95103000	Nutritional drink or shake, ready-to-drink (Ensure)
95103010	Nutritional drink or shake, ready-to-drink (Ensure Plus)
95104000	Nutritional drink or shake, ready-to-drink, sugar free (Glucerna)
95110000	Nutritional drink or shake, ready-to-drink (Slim Fast)
95110010	Nutritional drink or shake, ready-to-drink, sugar free (Slim Fast)
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)
53729000	Nutrition bar or meal replacement bar, NFS
Powdered Nutritional Beverages	
11553120	Fruit smoothie, with whole fruit and dairy, added protein*
64134020	Fruit smoothie, with whole fruit, no dairy, added protein*
78101110	Fruit and vegetable smoothie, added protein*
78101118	Fruit and vegetable smoothie, non-dairy, added protein*
95201000	Nutritional powder mix (Carnation Instant Breakfast)
95201010	Nutritional powder mix, sugar free (Carnation Instant Breakfast)
95201200	Nutritional powder mix (EAS Whey Protein Powder)
95201300	Nutritional powder mix (EAS Soy Protein Powder)
95201500	Nutritional powder mix, high protein (Herbalife)
95201600	Nutritional powder mix (Isopure)
95201700	Nutritional powder mix (Kellogg's Special K20 Protein Water)
95202000	Nutritional powder mix (Muscle Milk)
95210000	Nutritional powder mix (Slim Fast)
95210020	Nutritional powder mix, high protein (Slim Fast)

Food Code	Food Description
95220000	Nutritional powder mix, NFS
95220010	Nutritional powder mix, high protein, NFS
95230000	Nutritional powder mix, whey based, NFS
95230010	Nutritional powder mix, protein, soy based, NFS
95230020	Nutritional powder mix, protein, light, NFS
95230030	Nutritional powder mix, protein, NFS
Performance Nutritional Beverages, high protein	
95105000	Nutritional drink or shake, ready-to-drink (Kellogg's Special K Protein)
95106000	Nutritional drink or shake, ready-to-drink (Muscle Milk)
95106010	Nutritional drink or shake, ready-to-drink, light (Muscle Milk)
95110020	Nutritional drink or shake, high protein, ready-to-drink (Slim Fast)
95120000	Nutritional drink or shake, ready-to-drink, NFS
95120010	Nutritional drink or shake, high protein, ready-to-drink, NFS
95120020	Nutritional drink or shake, high protein, light, ready-to-drink, NFS
95120050	Nutritional drink or shake, liquid, soy-based
Electrolyte-based Sports Drinks	
92900300	Sports drink, dry concentrate, not reconstituted**
95320200	Sports drink (Gatorade G)
95320500	Sports drink (Powerade)
95321000	Sports drink, NFS
95322200	Sports drink, low calorie (Gatorade G2)
95322500	Sports drink, low calorie (Powerade Zero)
95323000	Sports drink, low calorie
Dairy and Dairy-Based Products	
Fluid milk, powdered milk, flavored milk, milk-based drinks and drink mixes (e.g., dairy smoothies, hot chocolate from mix), milk substitutes	
11100000	Milk, NFS
11111000	Milk, whole
11111170	Milk, calcium fortified, fat free (skim)
11112110	Milk, reduced fat (2%)
11112120	Milk, acidophilus, low fat (1%)
11112210	Milk, low fat (1%)
11113000	Milk, fat free (skim)
11114300	Milk, lactose free, low fat (1%)
11114320	Milk, lactose free, fat free (skim)
11114330	Milk, lactose free, reduced fat (2%)
11114350	Milk, lactose free, whole
11116000	Goat's milk, whole
11120000	Milk, dry, reconstituted, NS as to fat content
11121100	Milk, dry, reconstituted, whole
11121300	Milk, dry, reconstituted, fat free (skim)
11210050	Milk, evaporated, NS as to fat content

Food Code	Food Description
11211050	Milk, evaporated, whole
11211400	Milk, evaporated, reduced fat (2%)
11212050	Milk, evaporated, fat free (skim)
11220000	Milk, condensed, sweetened
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
11511000	Chocolate milk, NFS
11511100	Chocolate milk, ready to drink, whole
11511200	Chocolate milk, ready to drink, reduced fat
11511300	Chocolate milk, ready to drink, fat free
11511400	Chocolate milk, ready to drink, low fat
11511550	Chocolate milk, ready to drink, reduced sugar, NS as to milk
11511600	Chocolate milk, ready to drink, low fat (Nesquik)
11511610	Chocolate milk, ready to drink, fat free (Nesquik)
11511700	Chocolate milk, ready to drink, low fat, no sugar added (Nesquik)
11512010	Hot chocolate / Cocoa, ready to drink
11512020	Hot chocolate / Cocoa, ready to drink, made with nonfat milk
11512030	Hot chocolate / Cocoa, ready to drink, made with non-dairy milk
11512100	Hot chocolate / Cocoa, ready to drink, with whipped cream*
11512110	Hot chocolate / Cocoa, ready to drink, made with nonfat milk and whipped cream*
11513000	Chocolate milk, made from dry mix, NS as to type of milk
11513100	Chocolate milk, made from dry mix with whole milk
11513150	Chocolate milk, made from dry mix with reduced fat milk
11513200	Chocolate milk, made from dry mix with low fat milk
11513300	Chocolate milk, made from dry mix with fat free milk
11513310	Chocolate milk, made from dry mix with non-dairy milk
11513355	Chocolate milk, made from reduced sugar mix with whole milk
11513360	Chocolate milk, made from reduced sugar mix with reduced fat milk
11513365	Chocolate milk, made from reduced sugar mix with low fat milk
11513380	Chocolate milk, made from dry mix, NS as to type of milk (Nesquik)
11513381	Chocolate milk, made from dry mix with whole milk (Nesquik)
11513382	Chocolate milk, made from dry mix with reduced fat milk (Nesquik)

Food Code	Food Description
11513383	Chocolate milk, made from dry mix with low fat milk (Nesquik)
11513384	Chocolate milk, made from dry mix with fat free milk (Nesquik)
11513391	Chocolate milk, made from no sugar added dry mix with whole milk (Nesquik)
11513392	Chocolate milk, made from no sugar added dry mix with reduced fat milk (Nesquik)
11513393	Chocolate milk, made from no sugar added dry mix with low fat milk (Nesquik)
11513395	Chocolate milk, made from no sugar added dry mix with non-dairy milk (Nesquik)
11513400	Chocolate milk, made from syrup, NS as to type of milk
11513500	Chocolate milk, made from syrup with whole milk
11513550	Chocolate milk, made from syrup with reduced fat milk
11513600	Chocolate milk, made from syrup with low fat milk
11513700	Chocolate milk, made from syrup with fat free milk
11513750	Chocolate milk, made from syrup with non-dairy milk
11513801	Chocolate milk, made from light syrup with whole milk
11513802	Chocolate milk, made from light syrup with reduced fat milk
11513803	Chocolate milk, made from light syrup with low fat milk
11513804	Chocolate milk, made from light syrup with fat free milk
11514100	Hot chocolate / Cocoa, made with dry mix and water
11514110	Hot chocolate / Cocoa, made with dry mix and whole milk
11514120	Hot chocolate / Cocoa, made with dry mix and reduced fat milk
11514130	Hot chocolate / Cocoa, made with dry mix and low fat milk
11514140	Hot chocolate / Cocoa, made with dry mix and fat free milk
11514150	Hot chocolate / Cocoa, made with dry mix and non-dairy milk
11514310	Hot chocolate / Cocoa, made with no sugar added dry mix and water
11514320	Hot chocolate / Cocoa, made with no sugar added dry mix and whole milk
11514330	Hot chocolate / Cocoa, made with no sugar added dry mix and reduced fat milk
11514340	Hot chocolate / Cocoa, made with no sugar added dry mix and low fat milk
11514350	Hot chocolate / Cocoa, made with no sugar added dry mix and fat free milk
11514360	Hot chocolate / Cocoa, made with no sugar added dry mix and non-dairy milk
11519040	Strawberry milk, NFS
11519050	Strawberry milk, whole
11519105	Strawberry milk, reduced fat
11519200	Strawberry milk, low fat
11519205	Strawberry milk, fat free
11519210	Strawberry milk, reduced sugar
11526000	Milk, malted
11531000	Eggnog
11551050	Licuado or Batido
11553100	Fruit smoothie, NFS*
11553110	Fruit smoothie, with whole fruit and dairy*
11553120	Fruit smoothie, with whole fruit and dairy, added protein*
11553130	Fruit smoothie juice drink, with dairy
11560000	Chocolate milk drink

Food Code	Food Description
11810000	Milk, dry, not reconstituted, NS as to fat content**
11811000	Milk, dry, not reconstituted, whole**
11813000	Milk, dry, not reconstituted, fat free (skim)**
11830100	Hot chocolate / Cocoa, dry mix, not reconstituted**
11830115	Hot chocolate / Cocoa, dry mix, no sugar added, not reconstituted**
11830160	Chocolate beverage powder, dry mix, not reconstituted**
11830165	Chocolate beverage powder, light, dry mix, not reconstituted**
11830260	Milk, malted, dry mix, not reconstituted**
11830400	Strawberry beverage powder, dry mix, not reconstituted**
14610520	Cheese ball*
14630200	Cheese souffle*
14710100	Cheddar cheese soup, home recipe, canned or ready-to-serve*
21103110	Beef steak, breaded or floured, baked or fried, NS as to fat eaten*
21103120	Beef steak, breaded or floured, baked or fried, lean and fat eaten*
21103130	Beef steak, breaded or floured, baked or fried, lean only eaten*
22101410	Pork chop, battered, fried, lean and fat eaten*
22101420	Pork chop, battered, fried, lean only eaten*
22201050	Pork steak or cutlet, battered, fried, NS as to fat eaten*
22201060	Pork steak or cutlet, battered, fried, lean and fat eaten*
22201070	Pork steak or cutlet, battered, fried, lean only eaten*
24201360	Turkey, light or dark meat, fried, coated, skin not eaten*
24201370	Turkey, light or dark meat, fried, coated, skin eaten*
24301210	Duck, coated, fried*
26100130	Fish, NS as to type, coated, baked or broiled, made with oil*
26100133	Fish, NS as to type, coated, baked or broiled, no added fat*
26107130	Catfish, coated, baked or broiled, made with oil*
26107131	Catfish, coated, baked or broiled, made with butter*
26107133	Catfish, coated, baked or broiled, no added fat*
26109130	Cod, coated, baked or broiled, made with oil*
26109133	Cod, coated, baked or broiled, no added fat*
26109134	Cod, coated, baked or broiled, made with cooking spray*
26115130	Flounder, coated, baked or broiled, made with oil*
26117130	Haddock, coated, baked or broiled, fat added*
26117131	Haddock, coated, baked or broiled, no added fat*
26118030	Halibut, coated, baked or broiled, made with oil*
26119130	Herring, coated, baked or broiled, fat added*
26127130	Perch, coated, baked or broiled, made with oil*
26131131	Pompano, coated, baked or broiled, no added fat*
26133130	Porgy, coated, baked or broiled, fat added*
26137130	Salmon, coated, baked or broiled, made with oil*
26137131	Salmon, coated, baked or broiled, made with butter*
26137133	Salmon, coated, baked or broiled, no added fat*

Food Code	Food Description
26137134	Salmon, coated, baked or broiled, made with cooking spray*
26141130	Sea bass, coated, baked or broiled, fat added*
26151130	Trout, coated, baked or broiled, made with oil*
26151133	Trout, coated, baked or broiled, no added fat*
26153131	Tuna, fresh, coated, baked or broiled, no added fat*
26157132	Whiting, coated, baked or broiled, made with margarine*
26157133	Whiting, coated, baked or broiled, no added fat*
26158020	Tilapia, coated, baked or broiled, made with oil*
26158021	Tilapia, coated, baked or broiled, made with butter*
26158023	Tilapia, coated, baked or broiled, no added fat*
26158024	Tilapia, coated, baked or broiled, made with cooking spray*
26305130	Crab, coated, baked or broiled, fat added*
26319160	Shrimp, coated, baked or broiled, made with oil*
26319161	Shrimp, coated, baked or broiled, made with butter*
26319163	Shrimp, coated, baked or broiled, no added fat*
27114000	Beef with mushroom sauce*
27116300	Beef with sweet and sour sauce*
27120090	Ham or pork with mushroom sauce*
27120120	Sausage gravy*
27144000	Chicken or turkey with mushroom sauce*
27212050	Beef and macaroni with cheese sauce*
27212100	Beef and noodles with tomato-based sauce*
27212400	Beef and noodles with mushroom sauce*
27213010	Biryani with meat*
27213400	Beef and rice with mushroom sauce*
27214100	Meat loaf made with beef*
27214110	Meat loaf made with beef, with tomato-based sauce*
27220010	Meat loaf made with ham*
27235000	Meat loaf made with venison/deer*
27243100	Biryani with chicken*
27246100	Chicken or turkey with dumplings*
27246500	Meat loaf made with chicken or turkey*
27246505	Meat loaf made with chicken or turkey, with tomato-based sauce*
27250080	Salmon loaf*
27250630	Tuna noodle casserole with mushroom sauce*
27260010	Meat loaf, NS as to type of meat*
27260050	Meatballs, with breading, NS as to type of meat, with gravy*
27260080	Meat loaf made with beef and pork*
27260100	Meat loaf made with beef and pork, with tomato-based sauce*
27311510	Shepherd's pie with beef*
27347240	Chicken or turkey, dumplings, and vegetables including carrots, broccoli, and/or dark green leafy; gravy*

Food Code	Food Description
27347250	Chicken or turkey, dumplings, and vegetables excluding carrots, broccoli, and dark green leafy; gravy*
27414100	Beef with vegetables including carrots, broccoli, and/or dark-green leafy; no potatoes, mushroom sauce*
27443150	Chicken or turkey divan*
27450660	Shellfish mixture and vegetables excluding carrots, broccoli, and dark-green leafy; no potatoes, mushroom sauce*
27550200	Fish sandwich, from school cafeteria*
28110330	Salisbury steak with gravy, whipped potatoes, vegetable, dessert, frozen meal*
28110380	Salisbury steak with gravy, macaroni and cheese, frozen meal*
28140810	Chicken, fried, with potatoes, vegetable, dessert, frozen meal*
28143180	Chicken in butter sauce with potatoes and vegetable, diet frozen meal*
28160310	Meat loaf with potatoes, vegetable, frozen meal*
28315160	Italian Wedding Soup*
28345120	Chicken or turkey soup, cream of, prepared with milk*
28345160	Chicken or turkey mushroom soup, cream of, prepared with milk*
28350210	Clam chowder, NS as to Manhattan or New England style*
28355120	Clam chowder, New England, prepared with milk*
28355210	Crab soup, cream of, prepared with milk*
28355250	Lobster bisque*
28355310	Oyster stew*
28355350	Salmon soup, cream style*
28355420	Shrimp soup, cream of, prepared with milk*
32105190	Egg casserole with bread, cheese, milk and meat*
42204100	Gravy, vegetarian*
53115410	Cake or cupcake, oatmeal*
53116570	Cake, Ravani*
53118550	Cake, tres leche*
53122070	Cake, shortcake, biscuit type, with whipped cream and fruit*
53122080	Cake, shortcake, biscuit type, with fruit*
53344200	Mixed fruit tart filled with custard or cream cheese*
53347600	Pie, squash*
53410100	Cobbler, apple*
53410300	Cobbler, berry*
53410500	Cobbler, cherry*
53410800	Cobbler, peach*
53410900	Cobbler, rhubarb*
53441210	Basbousa*
53451500	Turnover, guava*
56201055	Grits, regular or quick, made with milk, NS as to fat*
56201056	Grits, regular or quick, made with milk, no added fat*
56201057	Grits, regular or quick, made with milk, fat added*
56201340	Grits, instant, made with milk, fat added*

Food Code	Food Description
56201342	Grits, instant, made with milk, no added fat*
56201360	Grits, instant, made with non-dairy milk, fat added*
56201540	Cornmeal, Puerto Rican Style*
56203065	Oatmeal, regular or quick, made with milk, NS as to fat*
56203066	Oatmeal, regular or quick, made with milk, no added fat*
56203067	Oatmeal, regular or quick, made with milk, fat added*
56203075	Oatmeal, regular or quick, made with non-dairy milk, NS as to fat*
56203076	Oatmeal, regular or quick, made with non-dairy milk, no added fat*
56203077	Oatmeal, regular or quick, made with non-dairy milk, fat added*
56203096	Oatmeal, instant, plain, made with milk, no added fat*
56203097	Oatmeal, instant, plain, made with milk, fat added*
56203106	Oatmeal, instant, plain, made with non-dairy milk, no added fat*
56205060	Rice, cooked, with milk*
56205080	Rice, creamed, made with milk and sugar, Puerto Rican style*
56207022	Cream of wheat, regular or quick, made with milk, no added fat*
56207023	Cream of wheat, regular or quick, made with milk, fat added*
56207027	Cream of wheat, regular or quick, made with non-dairy milk, fat added*
56207094	Cream of wheat, instant, made with milk, fat added*
56207095	Cream of wheat, instant, made with milk, no added fat*
56207102	Cream of wheat, instant, made with non-dairy milk, no added fat*
58101800	Ground beef with tomato sauce and taco seasonings on a cornbread crust*
58122220	Gnocchi, potato*
58124220	Pastry, egg and cheese filled*
58124230	Pastry, meat / poultry-filled*
58127150	Vegetables and cheese in pastry*
58127210	Croissant sandwich, filled with ham and cheese*
58128000	Biscuit with gravy*
58128120	Cornmeal dressing with chicken or turkey and vegetables*
58131120	Ravioli, NS as to filling, with cream sauce*
58131330	Ravioli, meat-filled, with cream sauce*
58131535	Ravioli, cheese-filled, with cream sauce*
58131600	Ravioli, cheese and spinach-filled, with cream sauce*
58133120	Manicotti, cheese-filled, with tomato sauce, meatless*
58134120	Stuffed shells, cheese-filled, with tomato sauce, meatless*
58134130	Stuffed shells, cheese-filled, with meat sauce*
58134310	Stuffed shells, with fish and/or shellfish, with tomato sauce*
58134660	Tortellini, cheese-filled, with cream sauce*
58301110	Vegetable lasagna, frozen meal*
58304010	Spaghetti and meatballs dinner, NFS, frozen meal*
58304060	Spaghetti with meat sauce, diet frozen meal*
58305250	Pasta with vegetable and cheese sauce, diet frozen meal*
58306100	Chicken enchilada, diet frozen meal*

Food Code	Food Description
58310210	Sausage and french toast, frozen meal*
58403050	Chicken or turkey noodle soup, cream of, home recipe, canned, or ready-to-serve*
64134025	Fruit smoothie, with whole fruit, non-dairy*
64134100	Fruit smoothie, light*
71305015	Potato, scalloped, NFS*
71305030	Potato, scalloped, from fresh*
71305040	Potato, scalloped, from fresh, with meat*
71305050	Potato, scalloped, from dry mix*
71305060	Potato, scalloped, from dry mix, with meat*
71305070	Potato, scalloped, ready-to-heat*
71401039	Potato, french fries, with cheese, fast food / restaurant*
71401050	Potato, french fries, with chili and cheese, fast food / restaurant*
71402500	Potato, french fries, with cheese*
71402510	Potato, french fries, with chili and cheese*
71501018	Potato, mashed, from school lunch*
71702000	Potato pudding*
71801000	Potato soup, NS as to made with milk or water*
71801010	Potato soup, cream of, prepared with milk*
71801100	Potato and cheese soup*
71803010	Potato chowder*
72125240	Spinach souffle*
72302000	Broccoli soup, prepared with milk, home recipe, canned or ready-to-serve*
72302100	Broccoli cheese soup, prepared with milk, home recipe, canned, or ready-to-serve*
72307000	Spinach soup*
73304010	Squash fritter or cake*
73305020	Squash, winter, souffle*
73501000	Carrot soup, cream of, prepared with milk, home recipe, canned or ready-to-serve*
74202051	Tomatoes, red, from fresh, fried*
74601010	Tomato soup, cream of, prepared with milk*
74602300	Tomato soup, canned, reduced sodium, prepared with milk*
74604600	Tomato noodle soup, canned, prepared with milk*
75216070	Corn, dried, cooked*
75340160	Vegetable and pasta combinations with cream or cheese sauce, broccoli, pasta, carrots, corn, zucchini, peppers, cauliflower, peas, etc., cooked*
75403020	Green bean casserole*
75403022	Beans, string, green, cooked, from frozen, with mushroom sauce*
75411010	Corn, scalloped or pudding*
75411020	Corn fritter*
75412060	Eggplant parmesan casserole, regular*
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*

Food Code	Food Description
75601010	Asparagus soup, cream of, prepared with milk*
75603010	Celery soup, cream of, prepared with milk, home recipe, canned or ready-to-serve*
75604010	Corn soup, cream of, prepared with milk*
75605010	Leek soup, cream of, prepared with milk*
75607010	Mushroom soup, cream of, prepared with milk*
75607060	Mushroom soup, cream of, NS as to made with milk or water*
75607100	Mushroom soup, cream of, canned, reduced sodium, prepared with milk*
75611010	Vegetable soup, cream of, prepared with milk*
75612010	Zucchini soup, cream of, prepared with milk*
75652030	Vegetable beef soup, canned, prepared with milk*
77272010	Puerto Rican pasteles*
78101100	Fruit and vegetable smoothie, with dairy
78101110	Fruit and vegetable smoothie, added protein*
78101115	Fruit and vegetable smoothie, non-dairy
78101118	Fruit and vegetable smoothie, non-dairy, added protein*
78101130	Vegetable smoothie
91304070	Topping, peanut butter, thick, fudge type*
92101810	Coffee, macchiato*
92101820	Coffee, macchiato, sweetened*
92101850	Coffee, cafe con leche*
92101851	Coffee, cafe con leche, decaffeinated*
92101900	Coffee, Latte*
92101901	Coffee, Latte, nonfat*
92101903	Coffee, Latte, with non-dairy milk*
92101904	Coffee, Latte, flavored*
92101905	Coffee, Latte, nonfat, flavored*
92101906	Coffee, Latte, with non-dairy milk, flavored*
92101910	Coffee, Latte, decaffeinated*
92101911	Coffee, Latte, decaffeinated, nonfat*
92101917	Coffee, Latte, decaffeinated, flavored*
92101918	Coffee, Latte, decaffeinated, nonfat, flavored*
92101920	Frozen coffee drink*
92101921	Frozen coffee drink, nonfat*
92101923	Frozen coffee drink, with non-dairy milk*
92101925	Frozen coffee drink, with whipped cream*
92101926	Frozen coffee drink, nonfat, with whipped cream*
92101930	Frozen coffee drink, decaffeinated*
92101935	Frozen coffee drink, decaffeinated, with whipped cream*
92101950	Coffee, Cafe Mocha*
92101955	Coffee, Cafe Mocha, nonfat*
92101960	Coffee, Cafe Mocha, with non-dairy milk*
92101965	Coffee, Cafe Mocha, decaffeinated*

Food Code	Food Description
92101975	Coffee, Cafe Mocha, decaffeinated, with non-dairy milk*
92102000	Frozen mocha coffee drink*
92102010	Frozen mocha coffee drink, nonfat*
92102020	Frozen mocha coffee drink, with non-dairy milk*
92102030	Frozen mocha coffee drink, with whipped cream*
92102040	Frozen mocha coffee drink, nonfat, with whipped cream*
92102050	Frozen mocha coffee drink, with non-dairy milk and whipped cream*
92102500	Coffee, Iced Latte*
92102501	Coffee, Iced Latte, nonfat*
92102502	Coffee, Iced Latte, with non-dairy milk*
92102503	Coffee, Iced Latte, flavored*
92102505	Coffee, Iced Latte, with non-dairy milk, flavored*
92102600	Coffee, Iced Cafe Mocha*
92102602	Coffee, Iced Cafe Mocha, with non-dairy milk*
92161000	Coffee, Cappuccino*
92161001	Coffee, Cappuccino, nonfat*
92161002	Coffee, Cappuccino, with non-dairy milk*
92162000	Coffee, Cappuccino, decaffeinated*
92162001	Coffee, Cappuccino, decaffeinated, nonfat*
92171010	Coffee, bottled/canned, light*
92306800	Tea, hot, chai, with milk*
92610030	Horchata beverage, made with milk*
92611100	Oatmeal beverage with milk*
92613010	Cornmeal beverage*
92613510	Cornmeal beverage with chocolate milk*

Cream, half & half, cream-cheese, cheese spread, and whipped cream

11512100	Hot chocolate / Cocoa, ready to drink, with whipped cream*
11512110	Hot chocolate / Cocoa, ready to drink, made with nonfat milk and whipped cream*
12100100	Cream, NS as to light, heavy, or half and half
12110100	Cream, light
12120100	Cream, half and half
12120106	Cream, half and half, flavored
12120110	Cream, half and half, fat free
12130100	Cream, heavy
12140000	Cream, whipped
12200100	Coffee creamer, NFS
12210200	Coffee creamer, liquid
12210210	Coffee creamer, liquid, flavored
12210260	Coffee creamer, liquid, fat free
12210270	Coffee creamer, liquid, fat free, flavored
12210280	Coffee creamer, liquid, fat free, sugar free, flavored
12210310	Coffee creamer, liquid, sugar free, flavored

Food Code	Food Description
12210400	Coffee creamer, powder
12210420	Coffee creamer, powder, flavored
12210430	Coffee creamer, powder, fat free
12210440	Coffee creamer,powder, fat free, flavored
12210505	Coffee creamer,powder, sugar free, flavored
12210520	Coffee creamer, soy, liquid
12220200	Whipped topping
12220270	Whipped topping, fat free
12220280	Whipped topping, sugar free
13252600	Tiramisu*
14301010	Cream cheese, regular, plain
14301100	Cream cheese, regular, flavored
14303010	Cream cheese, light
14410330	Cheese spread, American or Cheddar cheese base, reduced fat
14410380	Cream cheese spread, fat free
14410600	Cheese, processed, with vegetables*
14420100	Cheese spread, American or Cheddar cheese base
14420160	Cheese spread, Swiss cheese base
14420200	Cheese spread, cream cheese, regular
14420210	Cheese spread, cream cheese, light
14420300	Cheese spread, pressurized can
14610520	Cheese ball*
27500300	Wrap sandwich, NFS*
28140100	Chicken dinner, NFS, frozen meal*
28143080	Chicken with noodles and cheese sauce, diet frozen meal*
28311010	Pepperpot soup*
28350050	Fish chowder*
53101250	Cake, angel food, with fruit and icing or filling*
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*
53106500	Cake, cream, without icing or topping*
53116510	Cake or cupcake, pumpkin, with icing or filling*
53117200	Cake or cupcake, spice, with icing or filling*
53118500	Cake, torte*
53118550	Cake, tres leche*
53122070	Cake, shortcake, biscuit type, with whipped cream and fruit*
53123070	Cake, shortcake, sponge type, with whipped cream and fruit*
53124110	Cake or cupcake, zucchini*
53341750	Pie, chess*
53344200	Mixed fruit tart filled with custard or cream cheese*
53344300	Dessert pizza*

Food Code	Food Description
53360000	Pie, sweet potato*
56202900	Oatmeal, from fast food, plain*
56202905	Oatmeal, from fast food, maple flavored*
56202910	Oatmeal, from fast food, fruit flavored*
56202920	Oatmeal, from fast food, other flavors*
58111200	Puffs, fried, crab meat and cream cheese filled*
58125110	Quiche with meat, poultry or fish*
58125120	Spinach quiche, meatless*
58125180	Cheese quiche, meatless*
58127150	Vegetables and cheese in pastry*
58200250	Wrap sandwich, filled with vegetables*
63402960	Fruit salad, excluding citrus fruits, with whipped cream*
63402970	Fruit salad, excluding citrus fruits, with nondairy whipped topping*
63403020	Fruit salad, including citrus fruit, with whipped cream*
63403100	Fruit dessert with cream and/or pudding and nuts*
71305020	Potato, scalloped, from fast food or restaurant*
71501000	Potato, mashed, NFS*
71501010	Potato, mashed, from fresh, made with milk*
71501011	Potato, mashed, from fresh, made with milk, with cheese*
71501012	Potato, mashed, from fresh, made with milk, with gravy*
71501013	Potato, mashed, from fresh, NFS*
71501016	Potato, mashed, from restaurant*
71501017	Potato, mashed, from restaurant, with gravy*
71501035	Potato, mashed, from dry mix, NFS*
71501040	Potato, mashed, from dry mix, made with milk*
71501045	Potato, mashed, from dry mix, made with milk, with cheese*
71501054	Potato, mashed, from dry mix, made with milk, with gravy*
72202010	Broccoli casserole with noodles*
73409000	Sweet potato, casserole or mashed*
73502000	Squash, winter type, soup, home recipe, canned, or ready-to-serve*
74404090	Vodka sauce with tomatoes and cream*
75410550	Stuffed jalapeno pepper*
91306040	Dessert dip*
91501030	Gelatin dessert with whipped cream*
91501050	Gelatin dessert with cream cheese*
91511030	Gelatin dessert, dietetic, with whipped topping, sweetened with low calorie sweetener*
92101925	Frozen coffee drink, with whipped cream*
92101926	Frozen coffee drink, nonfat, with whipped cream*
92101935	Frozen coffee drink, decaffeinated, with whipped cream*
92102030	Frozen mocha coffee drink, with whipped cream*
92102040	Frozen mocha coffee drink, nonfat, with whipped cream*
92102050	Frozen mocha coffee drink, with non-dairy milk and whipped cream*

Food Code	Food Description
92121000	Coffee, instant, pre-lightened and pre-sweetened with sugar, reconstituted*
92121001	Coffee, instant, decaffeinated, pre-lightened and pre-sweetened with sugar, reconsitituted*
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*
92193000	Coffee, instant, pre-lightened and pre-sweetened with sugar, not reconstituted*
93301010	Alexander*
93301250	White Russian*
93301400	Irish Coffee*
Spreads and Dips	
11440010	Chipotle dip, yogurt based
11440020	Dill dip, yogurt based
11440040	Ranch dip, yogurt based
11440050	Spinach dip, yogurt based
11440060	Tzatziki dip
11440070	Vegetable dip, yogurt based
12350010	Dip, NFS
12350200	Chipotle dip, regular
12350210	Dill dip, regular
12350220	Onion dip, regular
12350225	Onion dip, light
12350230	Ranch dip, regular
12350235	Ranch dip, light
12350240	Spinach dip, regular
12350245	Spinach dip, light
12350250	Vegetable dip, regular
12350255	Vegetable dip, light
14620110	Artichoke dip
14620115	Spinach and artichoke dip
14620130	Seafood dip
14620150	Cheese dip with chili pepper
14620200	Cheese dip
41205055	Layer dip
Yogurt, Yogurt Alternatives, and Fermented Milk Products	
11115000	Buttermilk, fat free (skim)
11115100	Buttermilk, low fat (1%)

Food Code	Food Description
11115200	Buttermilk, reduced fat (2%)
11115300	Buttermilk, whole
11115400	Kefir, NS as to fat content
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
11411100	Yogurt, whole milk, plain
11411200	Yogurt, low fat milk, plain
11411300	Yogurt, nonfat milk, plain
11411390	Yogurt, Greek, NS as to type of milk, plain
11411400	Yogurt, Greek, whole milk, plain
11411410	Yogurt, Greek, low fat milk, plain
11411420	Yogurt, Greek, nonfat milk, plain
11430000	Yogurt, NS as to type of milk, fruit
11431000	Yogurt, whole milk, fruit
11432000	Yogurt, low fat milk, fruit
11433000	Yogurt, nonfat milk, fruit
11433990	Yogurt, Greek, NS as to type of milk, fruit
11434000	Yogurt, Greek, whole milk, fruit
11434010	Yogurt, Greek, low fat milk, fruit
11434020	Yogurt, Greek, nonfat milk, fruit
11434090	Yogurt, NS as to type of milk, flavors other than fruit
11434100	Yogurt, whole milk, flavors other than fruit
11434200	Yogurt, low fat milk, flavors other than fruit
11434300	Yogurt, nonfat milk, flavors other than fruit
11435000	Yogurt, Greek, NS as to type of milk, flavors other than fruit
11435010	Yogurt, Greek, whole milk, flavors other than fruit
11435020	Yogurt, Greek, low fat milk, flavors other than fruit
11435030	Yogurt, Greek, nonfat milk, flavors other than fruit
11435100	Yogurt, Greek, with oats
11436000	Yogurt, liquid
11446000	Yogurt parfait, low fat, with fruit
11553100	Fruit smoothie, NFS*
11553110	Fruit smoothie, with whole fruit and dairy*
11553120	Fruit smoothie, with whole fruit and dairy, added protein*
12310100	Sour cream, regular
12310300	Sour cream, reduced fat
12310350	Sour cream, light
12310370	Sour cream, fat free
27113100	Beef stroganoff*
27116100	Beef curry*

Food Code	Food Description
27116110	Beef curry with rice*
27120080	Ham stroganoff*
27120160	Pork curry*
27130100	Lamb or mutton curry*
27146150	Chicken curry*
27146155	Chicken curry with rice*
27150100	Shrimp curry*
27150320	Fish curry*
27150325	Fish curry with rice*
27212050	Beef and macaroni with cheese sauce*
27212350	Beef stroganoff with noodles*
27213010	Biryani with meat*
27213600	Beef and rice with cheese sauce*
27243100	Biryani with chicken*
27516010	Gyro sandwich (pita bread, beef, lamb, onion, condiments), with tomato and spread*
28110660	Meatballs, Swedish, in gravy, with noodles, diet frozen meal*
32101530	Egg curry*
41311030	Lentil curry*
41311040	Lentil curry with rice*
41420380	Yogurt, soy
41812850	Vegetarian stroganoff*
42401100	Yogurt, coconut milk
53119000	Cake, pineapple, upside down*
53341500	Pie, buttermilk*
53441210	Basbousa*
58100135	Burrito with meat and sour cream*
58100140	Burrito with meat, beans, and sour cream*
58100145	Burrito with meat, beans, and sour cream, from fast food*
58100165	Burrito with meat, beans, rice, and sour cream*
58100235	Burrito with chicken and sour cream*
58100245	Burrito with chicken, beans, and sour cream*
58100260	Burrito with chicken, beans, rice, and sour cream*
58100330	Burrito with beans, rice, and sour cream, meatless*
58101325	Taco or tostada with meat and sour cream*
58101350	Soft taco with meat and sour cream*
58101357	Soft taco with meat and sour cream, from fast food*
58101460	Soft taco with chicken and sour cream*
58101525	Taco or tostada with chicken and sour cream*
58101615	Soft taco with beans and sour cream*
58101630	Soft taco with meat, beans, and sour cream*
58101635	Soft taco with chicken, beans, and sour cream*
58101725	Taco or tostada with beans and sour cream*

Food Code	Food Description
58101745	Taco or tostada with meat, beans, and sour cream*
58101750	Taco or tostada with chicken, beans, and sour cream*
58101945	Taco or tostada salad with meat and sour cream*
58101950	Taco or tostada salad with chicken and sour cream*
58101955	Taco or tostada salad, meatless with sour cream*
58104090	Nachos with cheese and sour cream*
58104180	Nachos with meat, cheese, and sour cream*
58104190	Nachos with chicken, cheese, and sour cream*
58104270	Gordita, sope, or chalupa with beans and sour cream*
58104280	Gordita, sope, or chalupa with meat and sour cream*
58104320	Gordita, sope, or chalupa with chicken and sour cream*
58104535	Chimichanga with meat and sour cream*
58104550	Chimichanga with chicken and sour cream*
58105000	Fajita with chicken and vegetables*
58105050	Fajita with meat and vegetables*
58105075	Fajita with vegetables*
58124500	Pastry, filled with potatoes and peas, fried*
58306100	Chicken enchilada, diet frozen meal*
64134100	Fruit smoothie, light*
71507010	Potato, baked, peel not eaten, with sour cream*
71507020	Potato, baked, peel not eaten, with cheese*
71507025	Potato, baked, peel not eaten, with meat*
71508010	Potato, baked, peel eaten, with sour cream*
71508020	Potato, baked, peel eaten, with cheese*
71508025	Potato, baked, peel eaten, with meat*
75142500	Cucumber salad, made with sour cream dressing*
75440600	Vegetable curry*
75440610	Vegetable curry with rice*
75601100	Borscht*
77316600	Eggplant and meat casserole*
81312100	Curry sauce*
91306040	Dessert dip*
91501060	Gelatin dessert with sour cream*
91511060	Gelatin dessert, dietetic, with sour cream, sweetened with low calorie sweetener*
Ice cream, frozen yogurt	
11459990	Frozen yogurt, NFS
11460000	Frozen yogurt, vanilla
11460100	Frozen yogurt, chocolate
11460160	Yogurt, frozen, chocolate, lowfat milk
11460170	Yogurt, frozen, flavors other than chocolate, lowfat milk
11460200	Yogurt, frozen, chocolate, nonfat milk
11460250	Yogurt, frozen, flavors other than chocolate, with sorbet or sorbet-coated*

Food Code	Food Description
11460300	Yogurt, frozen, flavors other than chocolate, nonfat milk
11460400	Yogurt, frozen, chocolate, nonfat milk, with low-calorie sweetener
11460410	Yogurt, frozen, flavors other than chocolate, nonfat milk, with low-calorie sweetener
11460500	Frozen yogurt, soft serve, vanilla
11460510	Frozen yogurt, soft serve, chocolate
11461000	Yogurt, frozen, chocolate-coated*
11461200	Frozen yogurt sandwich
11461210	Frozen yogurt bar, vanilla
11461250	Frozen yogurt cone, chocolate
11461260	Frozen yogurt cone, vanilla
11461270	Yogurt, frozen, cone, flavors other than chocolate, lowfat milk
11461300	Frozen yogurt cone, vanilla, waffle cone
11541110	Milk shake, home recipe, chocolate
11541120	Milk shake, home recipe, flavors other than chocolate
11541130	Milk shake, home recipe, chocolate, light
11541135	Milk shake, home recipe, flavors other than chocolate, light
11542100	Milk shake, fast food, chocolate
11542200	Milk shake, fast food, flavors other than chocolate
11543000	Milk shake, bottled, chocolate
11543010	Milk shake, bottled, flavors other than chocolate
13110000	Ice cream, NFS
13110100	Ice cream, vanilla
13110102	Ice cream, vanilla, with additional ingredients
13110110	Ice cream, chocolate
13110112	Ice cream, chocolate, with additional ingredients
13110120	Ice cream, rich, flavors other than chocolate
13110130	Ice cream, rich, chocolate
13110200	Ice cream, soft serve, vanilla
13110210	Ice cream, soft serve, chocolate
13110220	Ice cream, soft serve, NS as to flavor
13110320	Ice cream, no sugar added, flavors other than chocolate
13110330	Ice cream, no sugar added, chocolate
13110460	Gelato, vanilla
13110470	Gelato, chocolate
13120050	Ice cream bar, vanilla
13120100	Ice cream bar, vanilla, chocolate coated*
13120110	Ice cream candy bar
13120120	Ice cream bar or stick, rich chocolate ice cream, thick chocolate covering*
13120121	Ice cream bar or stick, rich ice cream, thick chocolate covering*
13120130	Ice cream bar or stick, rich ice cream, chocolate covered, with nuts*
13120140	Ice cream bar, chocolate
13120300	Ice cream bar, cake covered

Food Code	Food Description
13120310	Ice cream bar, stick or nugget, with crunch coating
13120400	Ice cream bar or stick with fruit
13120500	Ice cream sandwich, vanilla
13120510	Ice cream sandwich, chocolate
13120550	Ice cream cookie sandwich
13120700	Ice cream cone with nuts, flavors other than chocolate
13120710	Ice cream cone, chocolate covered, with nuts, flavors other than chocolate*
13120720	Ice cream cone, chocolate covered or dipped, flavors other than chocolate*
13120730	Ice cream cone, scooped, vanilla
13120735	Ice cream cone, scooped, vanilla, waffle cone
13120740	Ice cream cone, NFS
13120760	Ice cream cone, chocolate covered or dipped, chocolate ice cream*
13120770	Ice cream cone, scooped, chocolate
13120775	Ice cream cone, scooped, chocolate, waffle cone
13120782	Ice cream cone, soft serve, vanilla
13120784	Ice cream cone, soft serve, chocolate
13120786	Ice cream cone, soft serve, vanilla, waffle cone
13120788	Ice cream cone, soft serve, chocolate, waffle cone
13120790	Ice cream cone, vanilla, prepackaged
13120792	Ice cream cone, chocolate, prepackaged
13120800	Ice cream soda, flavors other than chocolate*
13120810	Ice cream soda, chocolate*
13121000	Ice cream sundae, NFS
13121100	Ice cream sundae, fruit topping
13121120	Banana split
13121300	Ice cream sundae, hot fudge topping*
13121400	Ice cream sundae, caramel topping*
13122100	Ice cream pie, no crust
13127000	Dippin' Dots, flash frozen ice cream snacks, flavors other than chocolate
13127010	Dippin' Dots, flash frozen ice cream snacks, chocolate
13130300	Light ice cream, vanilla
13130310	Light ice cream, chocolate
13130320	Light ice cream, no sugar added, NS as to flavor
13130330	Light ice cream, no sugar added, flavors other than chocolate
13130340	Light ice cream, no sugar added, chocolate
13130600	Light ice cream, soft serve, flavors other than chocolate
13130620	Light ice cream, soft serve cone, flavors other than chocolate
13130630	Light ice cream, soft serve cone, chocolate
13130700	Soft serve, blended with candy or cookies, from fast food
13135000	Light ice cream sandwich, vanilla
13135010	Light ice cream sandwich, chocolate
13136000	Ice cream sandwich, made with light, no sugar added ice cream

Food Code	Food Description
13140000	Light ice cream bar, vanilla
13140100	Light ice cream bar, vanilla, chocolate coated*
13140115	Light ice cream bar, chocolate
13140500	Light ice cream, cone, flavors other than chocolate
13140575	Light ice cream, no sugar added, cone, flavors other than chocolate
13140580	Light ice cream, no sugar added, cone, chocolate
13140660	Light ice cream, sundae, soft serve, chocolate or fudge topping, without whipped cream*
13140700	Creamsicle
13140900	Fudgesicle
13142100	Light ice cream cone, vanilla, prepackaged
13142110	Light ice cream cone, chocolate, prepackaged
13150000	Sherbet, all flavors
13160160	Fat free ice cream, no sugar added, flavors other than chocolate
13160400	Fat free ice cream, flavors other than chocolate
13160410	Fat free ice cream, chocolate
13161500	Milk dessert sandwich bar, frozen, made from lowfat milk
13161600	Fudgesicle, light
13161630	Light ice cream, bar or stick, with low-calorie sweetener, chocolate coated*
53112000	Cake, ice cream and cake roll, chocolate*
53112100	Ice cream cake*
56205230	Rice dessert bar, frozen, flavors other than chocolate, nondairy, carob covered*
92510730	Fruit punch, made with soda, fruit juice, and sherbet or ice cream*
Cheese used primarily as ingredients, e.g. ricotta cheese	
14201500	Cheese, Ricotta
53440800	Strudel, cheese and fruit*
58107205	White pizza, cheese, thin crust*
58107212	White pizza, cheese, with vegetables, thin crust*
58107222	White pizza, cheese, with meat, thin crust*
58107224	White pizza, cheese, with meat, thick crust*
58107232	White pizza, cheese, with meat and vegetables, thin crust*
58108000	Calzone, with cheese, meatless*
58108010	Calzone, with meat and cheese*
58122210	Gnocchi, cheese*
58124250	Spanakopitta*
58130011	Lasagna with meat*
58130013	Lasagna with meat, canned*
58130014	Lasagna with meat, from restaurant*
58130015	Lasagna with meat, home recipe*
58130016	Lasagna with meat, frozen*
58130020	Lasagna with meat and spinach*
58130140	Lasagna with chicken or turkey*
58130150	Lasagna, with chicken or turkey, and spinach*

Food Code	Food Description
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*
58134130	Stuffed shells, cheese-filled, with meat sauce*
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*
58146120	Pasta with tomato-based sauce, cheese and meat*
58146150	Pasta with tomato-based sauce and cheese*
58301050	Lasagna with cheese and meat sauce, diet frozen meal*
58301110	Vegetable lasagna, frozen meal*
58304200	Ravioli, cheese-filled, with tomato sauce, diet frozen meal*
Semi Hard cheese (e.g., feta, Camembert, brie)	
14103020	Cheese, Brie
14104400	Cheese, Feta
14133000	Queso Fresco
14203510	Puerto Rican white cheese
58124250	Spanakopitta*
58421080	Sopa de tortilla, Mexican style tortilla soup, home recipe*
75146000	Greek Salad, no dressing*
Sugar Based Products	
Desserts and Mousses	
13200110	Pudding, chocolate, NFS
13210110	Pudding, bread
13210180	Pudding, Mexican bread
13210220	Pudding, chocolate, NS as to from dry mix or ready-to-eat
13210250	Pudding, chocolate, low calorie, containing artificial sweetener, NS as to from dry mix or ready-to-eat
13210270	Custard, Puerto Rican style
13210280	Pudding, flavors other than chocolate, NFS

Food Code	Food Description
13210290	Pudding, flavors other than chocolate, low calorie, containing artificial sweetener, NS as to from dry mix or ready-to-eat
13210300	Custard
13210350	Flan
13210370	Creme brulee
13210410	Pudding, rice
13210450	Firni, Indian pudding
13210500	Pudding, tapioca, made from home recipe, made with milk
13210520	Pudding, tapioca, made from dry mix
13210810	Pumpkin pudding, Puerto Rican style
13220110	Pudding, flavors other than chocolate, made from dry mix
13220120	Pudding, chocolate, made from dry mix
13220210	Pudding, flavors other than chocolate, made from dry mix, sugar free
13220220	Pudding, chocolate, made from dry mix, sugar free
13220235	Pudding, ready-to-eat, chocolate, fat free
13230110	Pudding, flavors other than chocolate, ready-to-eat
13230120	Pudding, flavors other than chocolate, ready-to-eat, sugar free
13230130	Pudding, chocolate, ready-to-eat
13230140	Pudding, chocolate, ready-to-eat, sugar free
13230200	Pudding, ready-to-eat, chocolate and non-chocolate flavors combined
13230500	Pudding, tapioca, ready-to-eat
13241000	Banana pudding
13250000	Mousse
13252200	Milk dessert or milk candy, Puerto Rican style
13252500	Barfi or Burfi, Indian dessert
13252590	Trifle
14610200	Cheese, cottage cheese, with gelatin dessert*
32401000	Meringues
53105275	Cake or cupcake, chocolate, devil's food or fudge, without icing or filling*
53106500	Cake, cream, without icing or topping*
53114000	Cake or cupcake, lemon, without icing or filling*
53114100	Cake or cupcake, lemon, with icing or filling*
53115100	Cake or cupcake, marble, without icing or filling*
53115310	Cake or cupcake, nut, without icing or filling*
53115320	Cake or cupcake, nut, with icing or filling*
53115450	Cake or cupcake, peanut butter*
53118500	Cake, torte*
53120275	Cake or cupcake, white, without icing or filling*
53121275	Cake or cupcake, yellow, without icing or filling*
58157210	Rice pudding made with coconut milk, Puerto Rican style
63402990	Fruit salad, including citrus fruits, with pudding*
63403000	Fruit salad, excluding citrus fruits, with pudding*

Food Code	Food Description
63403100	Fruit dessert with cream and/or pudding and nuts*
74501010	Tomato aspic*
91501010	Gelatin dessert
91501020	Gelatin dessert with fruit*
91501030	Gelatin dessert with whipped cream*
91501050	Gelatin dessert with cream cheese*
91501060	Gelatin dessert with sour cream*
91501090	Gelatin dessert with fruit, vegetable, and nuts*
91511010	Gelatin dessert, sugar free
91511020	Gelatin dessert, sugar free, with fruit*
91511030	Gelatin dessert, dietetic, with whipped topping, sweetened with low calorie sweetener*
91511060	Gelatin dessert, dietetic, with sour cream, sweetened with low calorie sweetener*
91550300	Pineapple custard, Puerto Rican style
91560100	Haupia
93301045	Gelatin shot, alcoholic*
Confections (including chocolate confections)	
91700010	Candy, NFS
91700500	M&M's Almond Chocolate Candies
91701010	Almonds, chocolate covered
91701020	Almonds, sugar-coated
91702010	Butterscotch morsels
91703010	Caramel, chocolate-flavored roll
91703020	Caramel, flavor other than chocolate
91703030	Caramel, with nuts
91703040	Caramel candy, chocolate covered
91703050	Caramel with nuts and cereal, chocolate covered
91703060	Caramel with nuts, chocolate covered
91703070	Rolo
91703080	Caramel, all flavors, sugar free
91703150	Toblerone, milk chocolate with honey and almond nougat
91703200	TWIX Caramel Cookie Bars
91703250	TWIX Chocolate Fudge Cookie Bars
91703400	Whatchamacallit
91703500	Nuts, carob-coated
91703600	Espresso coffee beans, chocolate-covered
91705010	Milk chocolate candy, plain
91705020	Milk chocolate candy, with cereal
91705030	Kit Kat
91705040	Chocolate, milk, with nuts, not almond or peanuts
91705050	Milk chocolate candy, with fruit and nuts
91705060	Milk chocolate candy, with almonds
91705070	Chocolate, milk, with peanuts

Food Code	Food Description
91705090	Chocolate candy with fondant and caramel
91705200	Chocolate, semi-sweet morsel
91705300	Chocolate, sweet or dark
91705310	Chocolate, sweet or dark, with almonds
91705400	Chocolate, white
91705410	Chocolate, white, with almonds
91705420	Chocolate, white, with cereal
91705430	Kit Kat White
91705500	Mexican chocolate, tablet
91706000	Coconut candy, chocolate covered
91706100	Coconut candy, no chocolate covering
91707000	Fondant
91707010	Fondant, chocolate covered
91708000	Fruit peel, candied
91708010	Date candy
91708020	Soft fruit confections
91708030	Fruit leather and fruit snacks candy
91708070	Tamarind candy
91708100	Fruit snacks candy, with high vitamin C
91708150	Yogurt covered fruit snacks candy, with added vitamin C
91709000	Gumdrops, chocolate covered
91713030	Fudge, chocolate
91713040	Fudge, chocolate, with nuts
91713050	Fudge, peanut butter
91713070	Fudge, vanilla
91715100	SNICKERS Bar
91715200	Baby Ruth
91715300	100 GRAND Bar
91716010	Halvah, plain
91718000	Honey-combed hard candy with peanut butter
91718100	Butterfinger
91718110	Butterfinger Crisp
91718200	Chocolate-flavored sprinkles
91718300	Ladoo, round ball, Asian-Indian dessert
91721000	Licorice
91723000	Marshmallow
91723010	Marshmallow, chocolate covered
91723020	Marshmallow, candy-coated
91726000	Nougat, plain
91726130	MILKY WAY Bar
91726140	MILKY WAY MIDNIGHT Bar
91726150	MARS Almond Bar

Food Code	Food Description
91726410	Nougat, chocolate covered
91726420	3 MUSKETEERS Bar
91727010	Nuts, chocolate covered, not almonds or peanuts
91728000	Nut roll, fudge or nougat, caramel and nuts
91728500	Sugared pecans, sugar and egg white coating
91731000	Peanuts, chocolate covered
91731010	M&M's Peanut Chocolate Candies
91731060	M&M's Peanut Butter Chocolate Candies
91731100	Peanuts, sugar-coated
91731150	Peanuts, yogurt covered
91732000	Peanut bar
91733000	Peanut brittle
91733200	Peanut Bar, chocolate covered candy
91734000	Peanut butter, chocolate covered
91734100	Reese's Peanut Butter Cup
91734200	Reese's Pieces
91734300	Reese's Sticks
91734400	Reese's Fast Break
91734450	Reese's Crispy Crunchy Bar
91734500	Peanut butter morsels
91735000	Pralines
91736000	Pineapple candy, Puerto Rican style
91739010	Raisins, chocolate covered
91739600	Raisins, yogurt covered
91742010	Sesame Crunch, Sahadi
91745010	Gumdrops
91745020	Hard candy
91745040	Butterscotch hard candy
91745100	Skittles
91746100	M&M's Milk Chocolate Candies
91746120	Sixlets
91746150	Easter egg, candy coated chocolate
91746200	M&M's Pretzel Chocolate Candies
91750000	Taffy
91760000	Toffee, plain
91760100	Toffee, chocolate covered
91760200	Toffee, chocolate-coated, with nuts
91760500	Truffles
91770010	Dietetic or low calorie gumdrops
91770020	Dietetic or low calorie hard candy
91770030	Dietetic or low calorie candy, chocolate covered
91800100	Chewing gum, NFS

Food Code	Food Description
91801000	Chewing gum, regular
91802000	Chewing gum, sugar free
Coatings and Fillings	
11460250	Yogurt, frozen, flavors other than chocolate, with sorbet or sorbet-coated*
11461000	Yogurt, frozen, chocolate-coated*
13120100	Ice cream bar, vanilla, chocolate coated*
13120120	Ice cream bar or stick, rich chocolate ice cream, thick chocolate covering*
13120121	Ice cream bar or stick, rich ice cream, thick chocolate covering*
13120130	Ice cream bar or stick, rich ice cream, chocolate covered, with nuts*
13120710	Ice cream cone, chocolate covered, with nuts, flavors other than chocolate*
13120720	Ice cream cone, chocolate covered or dipped, flavors other than chocolate*
13120760	Ice cream cone, chocolate covered or dipped, chocolate ice cream*
13121300	Ice cream sundae, hot fudge topping*
13121400	Ice cream sundae, caramel topping*
13140100	Light ice cream bar, vanilla, chocolate coated*
13140660	Light ice cream, sundae, soft serve, chocolate or fudge topping, without whipped cream*
13161630	Light ice cream, bar or stick, with low-calorie sweetener, chocolate coated*
53103000	Cake, Boston cream pie*
53104500	Cheesecake*
53104550	Cheesecake with fruit*
53104600	Cheesecake, chocolate*
53108200	Snack cake, chocolate, with icing or filling*
53109200	Snack cake, not chocolate, with icing or filling*
53109220	Snack cake, not chocolate, with icing or filling, reduced fat and calories*
53116270	Cake, pound, chocolate*
53207050	Cookie, chocolate, with chocolate filling or coating, fat free*
53208000	Cookie, marshmallow, chocolate-covered*
53208200	Cookie, marshmallow pie, chocolate covered*
53209005	Cookie, chocolate, with icing or coating*
53209010	Cookie, sugar wafer, chocolate-covered*
53233050	Cookie, oatmeal sandwich, with creme filling*
53234100	Cookie, peanut butter, with chocolate*
53235500	Cookie, with peanut butter filling, chocolate-coated*
53237010	Cookie, raisin sandwich, cream-filled*
53238000	Cookie, sandwich-type, not chocolate or vanilla*
53239050	Cookie, shortbread, with icing or filling*
53247500	Cookie, vanilla with caramel, coconut, and chocolate coating*
53341000	Pie, banana cream*
53342000	Pie, chocolate cream*
53343000	Pie, coconut cream*
53344000	Pie, custard*
53344070	Pie, custard, individual size or tart*

Food Code	Food Description
53346000	Pie, peanut butter cream*
53346500	Pie, pineapple cream*
53348000	Pie, strawberry cream*
53348070	Pie, strawberry cream, individual size or tart*
53365000	Pie, vanilla cream*
53381000	Pie, lemon meringue*
53381070	Pie, lemon meringue, individual size or tart*
53386000	Pie, pudding, flavors other than chocolate*
53420000	Cream puff, eclair, custard or cream filled, NS as to icing*
53420100	Cream puff, eclair, custard or cream filled, not iced*
53420200	Cream puff, eclair, custard or cream filled, iced*
53430000	Crepe, NS as to filling*
53430100	Crepe, chocolate filled*
53521210	Doughnut, custard-filled*
53521230	Doughnut, custard-filled, with icing*
53710902	Cereal or granola bar, with yogurt coating (General Mills Nature Valley Chewy Granola Bar)*
53714200	Cereal or granola bar, chocolate coated, NFS*
53714210	Cereal or granola bar, with coconut, chocolate coated*
53714220	Cereal or granola bar with nuts, chocolate coated*
53714230	Cereal or granola bar, oats, nuts, coated with non-chocolate coating*
53714250	Cereal or granola bar, coated with non-chocolate coating*
53714300	Cereal or granola bar, high fiber, coated with non-chocolate yogurt coating*
54102020	Graham crackers, chocolate covered*
54102200	Graham crackers, sandwich, with filling*
54403110	Popcorn, caramel coated*
54403120	Popcorn, caramel coated, with nuts*
54403160	Popcorn, chocolate coated*
54408190	Pretzels, hard, coated, NFS*
54408200	Pretzels, hard, chocolate coated*
54408210	Pretzels, hard, white chocolate coated*
54408250	Pretzels, hard, yogurt coated*
56205230	Rice dessert bar, frozen, flavors other than chocolate, nondairy, carob covered*
63401070	Fruit, chocolate covered*
63401990	Banana, chocolate-covered with nuts*
91304010	Topping, butterscotch or caramel
91304020	Topping, chocolate
91304090	Topping, chocolate flavored hazelnut spread
91304300	Topping, chocolate, hard coating
Cookies and brownies, crackers, popcorn, potato chips, tortilla chips, hard pretzels/snack mix	
41310900	Bean chips
51184000	Breadsticks, hard, NFS

Food Code	Food Description
51184100	Breadsticks, hard, reduced sodium
51185000	Croutons
51187000	Melba toast
51187020	Anisette toast
51188500	Zwieback toast
51306000	Breadsticks, hard, whole wheat
51808050	Breadsticks, hard, gluten free
53200100	Cookie, batter or dough, raw
53201000	Cookie, NFS
53202000	Cookie, almond
53203000	Cookie, applesauce
53203500	Cookie, biscotti
53204000	Cookie, brownie, NS as to icing
53204010	Cookie, brownie, without icing
53204100	Cookie, brownie, with icing or filling
53204840	Cookie, brownie, reduced fat, NS as to icing
53204860	Cookie, brownie, fat free, NS as to icing
53205250	Cookie, butterscotch, brownie
53205260	Cookie, bar, with chocolate
53206000	Cookie, chocolate chip
53206020	Cookie, chocolate chip, made from home recipe or purchased at a bakery
53206030	Cookie, chocolate chip, reduced fat
53206100	Cookie, chocolate chip sandwich
53206500	Cookie, chocolate, made with rice cereal
53206550	Cookie, chocolate, made with oatmeal and coconut, no bake
53207000	Cookie, chocolate or fudge
53207020	Cookie, chocolate or fudge, reduced fat
53207050	Cookie, chocolate, with chocolate filling or coating, fat free*
53208000	Cookie, marshmallow, chocolate-covered*
53208200	Cookie, marshmallow pie, chocolate covered*
53209005	Cookie, chocolate, with icing or coating*
53209010	Cookie, sugar wafer, chocolate-covered*
53209015	Cookie, chocolate sandwich
53209020	Cookie, chocolate sandwich, reduced fat
53209100	Cookie, chocolate, sandwich, with extra filling
53209500	Cookie, chocolate and vanilla sandwich
53210000	Cookie, chocolate wafer
53210900	Cookie, graham cracker with chocolate and marshmallow
53211000	Cookie bar, with chocolate, nuts, and graham crackers
53215500	Cookie, coconut
53220000	Cookie, fruit-filled bar
53220030	Cookie, fig bar

Food Code	Food Description
53220040	Cookie, fig bar, fat free
53222010	Cookie, fortune
53222020	Cookie, cone shell, ice cream type, wafer or cake
53223000	Cookie, gingersnaps
53223100	Cookie, granola
53224000	Cookie, ladyfinger
53224250	Cookie, lemon bar
53225000	Cookie, macaroon
53226000	Cookie, marshmallow, with coconut
53226500	Cookie, marshmallow, with rice cereal, no bake
53226550	Cookie, marshmallow, with rice cereal and chocolate chips
53226600	Cookie, marshmallow and peanut butter, with oat cereal, no bake
53228000	Cookie, meringue
53230000	Cookie, molasses
53231400	Cookie, multigrain, high fiber
53233000	Cookie, oatmeal
53233010	Cookie, oatmeal, with raisins
53233040	Cookie, oatmeal, reduced fat, NS as to raisins
53233050	Cookie, oatmeal sandwich, with creme filling*
53233060	Cookie, oatmeal, with chocolate chips
53233080	Cookie, oatmeal sandwich, with peanut butter and jelly filling
53233100	Cookie, oatmeal, with chocolate and peanut butter, no bake
53234000	Cookie, peanut butter
53234100	Cookie, peanut butter, with chocolate*
53234250	Cookie, peanut butter with rice cereal, no bake
53235000	Cookie, peanut butter sandwich
53235500	Cookie, with peanut butter filling, chocolate-coated*
53236000	Cookie, Pizzelle
53236100	Cookie, pumpkin
53237000	Cookie, raisin
53237010	Cookie, raisin sandwich, cream-filled*
53238000	Cookie, sandwich-type, not chocolate or vanilla*
53239000	Cookie, shortbread
53239010	Cookie, shortbread, reduced fat
53239050	Cookie, shortbread, with icing or filling*
53239100	Pocky
53240000	Cookie, animal
53240010	Cookie, animal, with frosting or icing
53241500	Cookie, butter or sugar
53241510	Marie biscuit
53241600	Cookie, butter or sugar, with fruit and/or nuts
53242000	Cookie, sugar wafer

Food Code	Food Description
53243000	Cookie, vanilla sandwich
53243050	Cookie, vanilla sandwich, reduced fat
53244010	Cookie, butter or sugar, with chocolate icing or filling
53244020	Cookie, butter or sugar, with icing or filling other than chocolate
53246000	Cookie, tea, Japanese
53247000	Cookie, vanilla wafer
53247050	Cookie, vanilla wafer, reduced fat
53247500	Cookie, vanilla with caramel, coconut, and chocolate coating*
53260030	Cookie, chocolate chip, sugar free
53260200	Cookie, oatmeal, sugar free
53260300	Cookie, sandwich, sugar free
53260400	Cookie, sugar or plain, sugar free
53260500	Cookie, sugar wafer, sugar free
53260600	Cookie, peanut butter, sugar free
53261000	Cookie, gluten free
53270100	Cookies, Puerto Rican style
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

Food Code	Food Description
54307000	Crackers, matzo
54308000	Crackers, milk
54313000	Crackers, oyster
54318000	Chips, rice
54318500	Rice cake
54319000	Crackers, rice
54319005	Crackers, rice and nuts
54319020	Popcorn cake
54319500	Rice paper
54325000	Crackers, saltine
54325010	Crackers, saltine, reduced fat
54325060	Crackers, saltine, multigrain
54326000	Crackers, multigrain
54328000	Crackers, sandwich
54328100	Crackers, sandwich, peanut butter filled
54328105	Crackers, sandwich, peanut butter filled (Ritz)
54328110	Crackers, sandwich, reduced fat, peanut butter filled
54328120	Crackers, whole grain, sandwich, peanut butter filled
54328200	Crackers, sandwich, cheese filled
54328210	Crackers, sandwich, cheese filled (Ritz)
54336000	Crackers, water
54336100	Crackers, wonton
54337010	Crackers, woven wheat
54337020	Crackers, woven wheat, plain (Triscuit)
54337030	Crackers, woven wheat, flavored (Triscuit)
54337060	Crackers, woven wheat, reduced fat
54338000	Crackers, wheat
54338010	Crackers, wheat, plain (Wheat Thins)
54338020	Crackers, wheat, flavored (Wheat Thins)
54338100	Crackers, wheat, reduced fat
54339000	Crackers, corn
54340100	Crackers, gluten free, plain
54340110	Crackers, gluten free, flavored
54401011	Corn nuts
54401021	Corn chips, plain
54401026	Corn chips, flavored
54401031	Corn chips, plain (Fritos)
54401035	Corn chips, flavored (Fritos)
54401055	Cheese flavored corn snacks
54401065	Cheese flavored corn snacks, reduced fat
54401075	Tortilla chips, plain
54401081	Cheese flavored corn snacks (Cheetos)

Food Code	Food Description
54401085	Tortilla chips, flavored
54401090	Corn chips, reduced sodium
54401110	Tortilla chips, nacho cheese flavor (Doritos)
54401111	Tortilla chips, cool ranch flavor (Doritos)
54401112	Tortilla chips, other flavors (Doritos)
54401121	Tortilla chips, reduced fat, plain
54401122	Tortilla chips, reduced fat, flavored
54401170	Tortilla chips, low fat, unsalted
54402080	Tortilla chips, reduced sodium
54402200	Snack mix
54402700	Pita chips
54403001	Popcorn, NFS
54403005	Popcorn, movie theater, with added butter
54403006	Popcorn, movie theater, unbuttered
54403010	Popcorn, air-popped, unbuttered
54403040	Popcorn, air-popped, with added butter or margarine
54403045	Popcorn, popped in oil, unbuttered
54403046	Popcorn, popped in oil, with added butter or margarine
54403051	Popcorn, microwave, NFS
54403052	Popcorn, microwave, plain
54403053	Popcorn, microwave, plain, light
54403054	Popcorn, microwave, low sodium
54403055	Popcorn, microwave, unsalted
54403056	Popcorn, microwave, butter flavored
54403057	Popcorn, microwave, butter flavored, light
54403058	Popcorn, microwave, cheese flavored
54403059	Popcorn, microwave, kettle corn
54403061	Popcorn, microwave, kettle corn, light
54403062	Popcorn, microwave, other flavored
54403080	Popcorn, ready-to-eat packaged, NFS
54403081	Popcorn, ready-to-eat packaged, plain
54403082	Popcorn, ready-to-eat packaged, plain, light
54403083	Popcorn, ready-to-eat packaged, low sodium
54403085	Popcorn, ready-to-eat packaged, butter flavored
54403086	Popcorn, ready-to-eat packaged, butter flavored, light
54403087	Popcorn, ready-to-eat packaged, cheese flavored
54403088	Popcorn, ready-to-eat packaged, cheese flavored, light
54403089	Popcorn, ready-to-eat-packaged, kettle corn
54403091	Popcorn, ready-to-eat packaged, kettle corn, light
54403092	Popcorn, ready-to-eat packaged, other flavored
54403110	Popcorn, caramel coated*
54403120	Popcorn, caramel coated, with nuts*

Food Code	Food Description
54403160	Popcorn, chocolate coated*
54404000	Popcorn chips, plain
54404010	Popcorn chips, other flavors
54404020	Popcorn chips, sweet flavors
54406010	Onion flavored rings
54406200	Shrimp chips
54408000	Pretzels, NFS
54408015	Pretzels, hard, NFS
54408016	Pretzels, hard, plain, salted
54408017	Pretzels, hard, plain, lightly salted
54408030	Pretzels, hard, plain, unsalted
54408035	Pretzels, hard, flavored
54408070	Pretzels, hard, multigrain
54408081	Pretzels, hard, plain, gluten free
54408082	Pretzels, hard, flavored, gluten free
54408105	Pretzel chips, hard, plain
54408110	Pretzel chips, hard, flavored
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
54420210	Multigrain chips (Sun Chips)
54420220	Snack mix, plain (Chex Mix)
54440010	Bagel chips
54440020	Cracker chips
56116000	Noodles, chow mein
58101820	Mexican casserole made with ground beef, beans, tomato sauce, cheese, taco seasonings, and corn chips*
58101830	Mexican casserole made with ground beef, tomato sauce, cheese, taco seasonings, and corn chips*
58104090	Nachos with cheese and sour cream*
58104120	Nachos with cheese*
58104130	Nachos with meat and cheese*
58104150	Nachos with chicken and cheese*
58104160	Nachos with chili*
58104180	Nachos with meat, cheese, and sour cream*
58104190	Nachos with chicken, cheese, and sour cream*
71200010	Potato chips, NFS
71200100	Potato chips, plain

Food Code	Food Description
71200110	Potato chips, barbecue flavored
71200120	Potato chips, sour cream and onion flavored
71200130	Potato chips, cheese flavored
71200140	Potato chips, other flavored
71200200	Potato chips, ruffled, plain
71200210	Potato chips, ruffled, barbecue flavored
71200220	Potato chips, ruffled, sour cream and onion flavored
71200230	Potato chips, ruffled, cheese flavored
71200240	Potato chips, ruffled, other flavored
71200300	Potato chips, restructured, plain
71200310	Potato chips, restructured, flavored
71200400	Potato chips, baked, plain
71200410	Potato chips, baked, flavored
71201050	Potato chips, reduced fat
71201060	Potato chips, fat free
71201200	Potato chips, restructured, reduced fat, lightly salted
71201210	Potato chips, restructured, fat free
71202000	Potato chips, unsalted
71202100	Potato chips, reduced fat, unsalted
71202500	Potato chips, lightly salted
71202510	Potato chips, restructured, lightly salted
71203010	Potato chips, popped, plain
71203020	Potato chips, popped, flavored
71205020	Potato sticks, plain
71205030	Potato sticks, flavored
71205040	Potato sticks, fry shaped
71220000	Vegetable chips
71905410	Plantain chips
71980200	Taro chips
73410210	Sweet potato chips
Doughnuts, toaster pastries, muffins	
52206010	Cornbread muffin, stick, round
52206060	Cornbread muffin, stick, round, made from home recipe
52301000	Muffin, NFS
52302010	Muffin, fruit
52302020	Muffin, fruit, low fat
52302500	Muffin, chocolate chip
52302600	Muffin, chocolate
52303010	Muffin, whole wheat
52303500	Muffin, wheat
52304000	Muffin, whole grain
52304010	Muffin, wheat bran

Food Code	Food Description
52304040	Muffin, bran with fruit, lowfat
52304100	Muffin, oatmeal
52304150	Muffin, oat bran
52306010	Muffin, plain
52306500	Muffin, pumpkin
52306550	Muffin, zucchini
52306700	Muffin, carrot
53510000	Danish pastry, plain or spice
53510100	Danish pastry, with fruit
53520000	Doughnut, NFS
53520100	Doughnut, cake type, plain
53520110	Doughnut, cake type
53520120	Doughnut, chocolate
53520130	Doughnut, cake type, powdered sugar
53520135	Doughnut, cake type, with icing
53520140	Doughnut, cake type, chocolate icing
53520160	Doughnut, chocolate, with chocolate icing
53520170	Doughnut holes
53521100	Doughnut, chocolate, raised or yeast, with chocolate icing
53521110	Doughnut, yeast type
53521120	Doughnut, chocolate, raised or yeast
53521130	Doughnut, yeast type, with chocolate icing
53521140	Doughnut, jelly
53521210	Doughnut, custard-filled*
53521230	Doughnut, custard-filled, with icing*
53530000	Breakfast tart
53530010	Breakfast tart, lowfat
Baked	
French toast, crepes, pancakes, bagels, scones, biscsuits, croissants	
27515080	Steak sandwich, plain, on biscuit*
27520170	Bacon on biscuit*
27520250	Ham on biscuit*
27540145	Chicken fillet biscuit, from fast food*
27540180	Chicken patty sandwich or biscuit*
27560650	Sausage on biscuit*
27560705	Sausage balls, made with biscuit mix and cheese*
32202025	Egg, cheese and ham on bagel*
32202045	Egg, cheese, and steak on bagel*
32202050	Egg, cheese, and sausage on biscuit*
32202060	Egg and sausage on biscuit*
32202070	Egg, cheese, and bacon on biscuit*
32202085	Egg, cheese and bacon on bagel*

Food Code	Food Description
32202090	Egg and bacon on biscuit*
32202110	Egg and ham on biscuit*
32202120	Egg, cheese and sausage on bagel*
32202130	Egg and steak on biscuit*
32202200	Egg and cheese on biscuit*
51160000	Roll, sweet, no frosting
51160100	Roll, sweet, cinnamon bun, no frosting
51160110	Roll, sweet, cinnamon bun, frosted
51161000	Pan Dulce, with fruit, no frosting
51161020	Roll, sweet, with fruit, frosted
51161050	Roll, sweet, frosted
51161250	Pan Dulce, no topping
51161270	Pan Dulce, with sugar topping
51161280	Pan Dulce, with raisins and icing
51165000	Coffee cake, yeast type
51166000	Croissant
51166100	Croissant, cheese
51166200	Croissant, chocolate
51166500	Croissant, fruit
51167000	Brioche
51180010	Bagel
51180030	Bagel, with raisins
51180080	Bagel, with fruit other than raisins
51188100	Pannetone
51300100	Bagel, whole grain white
51301700	Bagel, wheat
51301750	Bagel, whole wheat
51301800	Bagel, wheat, with raisins
51301805	Bagel, whole wheat, with raisins
51301820	Bagel, wheat, with fruit and nuts
51404500	Bagel, pumpernickel
51501080	Bagel, oat bran
51630000	Bagel, multigrain
51630100	Bagel, multigrain, with raisins
52101000	Biscuit, NFS
52101030	Biscuit dough, fried
52101100	Biscuit, baking powder or buttermilk type, made from mix
52102040	Biscuit, from refrigerated dough
52103000	Biscuit, from fast food / restaurant
52104010	Biscuit, home recipe
52104040	Biscuit, wheat
52104100	Biscuit, cheese

Food Code	Food Description
52104200	Biscuit with fruit
52105100	Scone
52105200	Scone, with fruit
52201000	Cornbread, prepared from mix
52202060	Cornbread, made from home recipe
52208010	Corn pone, baked
52208020	Corn pone, fried
52209010	Hush puppy
52220110	Arepa Dominicana
52311010	Popover
52401000	Bread, Boston Brown
52403000	Bread, nut
52404060	Bread, pumpkin
52405010	Bread, fruit
52407000	Bread, zucchini
52408000	Bread, Irish soda
53400200	Blintz, cheese-filled
53415120	Fritter, apple
53415200	Fritter, banana
53415220	Fritter, berry
53420000	Cream puff, eclair, custard or cream filled, NS as to icing*
53420100	Cream puff, eclair, custard or cream filled, not iced*
53420200	Cream puff, eclair, custard or cream filled, iced*
53420300	Air filled fritter or fried puff, without syrup, Puerto Rican style
53420310	Wheat flour fritter, without syrup
53420400	Sopaipilla, without syrup or honey
53430000	Crepe, NS as to filling*
53430100	Crepe, chocolate filled*
53430200	Crepe, fruit filled
53430700	Tamale, sweet
53452100	Pastry, fruit-filled
53452120	Pastry, made with bean or lotus seed paste filling, baked
53452130	Pastry, made with bean paste and salted egg yolk filling, baked
53452200	Pastry, Italian, with cheese
53452400	Pastry, puff
53452420	Pastry, puff, custard or cream filled, iced or not iced
53452450	Cheese pastry puffs
53452500	Pastry, mainly flour and water, fried
53511000	Danish pastry, with cheese
53520200	Churros
53520510	Beignet
53520600	Cruller, NFS

Food Code	Food Description
53610100	Coffee cake, crumb or quick-bread type
53610170	Coffee cake, crumb or quick-bread type, with fruit
53610200	Coffee cake, crumb or quick-bread type, cheese-filled
55100005	Pancakes, NFS
55100010	Pancakes, plain, from frozen
55100015	Pancakes, plain, reduced fat, from frozen
55100020	Pancakes, with fruit, from frozen
55100025	Pancakes, with chocolate, from frozen
55100030	Pancakes, whole grain, from frozen
55100035	Pancakes, whole grain, reduced fat, from frozen
55100040	Pancakes, gluten free, from frozen
55100050	Pancakes, plain, from fast food / restaurant
55100055	Pancakes, with fruit, from fast food / restaurant
55100060	Pancakes, with chocolate, from fast food / restaurant
55100065	Pancakes, whole grain, from fast food / restaurant
55100080	Pancakes, from school, NFS
55101000	Pancakes, plain
55101015	Pancakes, plain, reduced fat
55103000	Pancakes, with fruit
55103020	Pancakes, pumpkin
55103100	Pancakes, with chocolate
55105000	Pancakes, buckwheat
55105100	Pancakes, cornmeal
55105200	Pancakes, whole grain
55105205	Pancakes, whole grain, reduced fat
55106000	Pancakes, gluten free
55200010	Waffle, NFS
55200020	Waffle, plain, from frozen
55200030	Waffle, plain, reduced fat, from frozen
55200040	Waffle, fruit, from frozen
55200050	Waffle, chocolate, from frozen
55200060	Waffle, whole grain, from frozen
55200070	Waffle, whole grain, reduced fat, from frozen
55200080	Waffle, whole grain, fruit, from frozen
55200090	Waffle, gluten free, from frozen
55200100	Waffle, plain, from fast food / restaurant
55200110	Waffle, chocolate, from fast food / restaurant
55200120	Waffle, fruit, from fast food / restaurant
55200130	Waffle, whole grain, from fast food / restaurant
55200200	Waffle, from school, NFS
55201000	Waffle, plain
55203000	Waffle, fruit

Food Code	Food Description
55203600	Waffle, chocolate
55203700	Waffle, cinnamon
55204000	Waffle, cornmeal
55205000	Waffle, whole grain
55208000	Waffle, gluten free
55211050	Waffle, plain, reduced fat
55212000	Waffle, whole grain, reduced fat
55300010	French toast, NFS
55300020	French toast, plain, from frozen
55300050	French toast, plain, from fast food / restaurant
55300055	French toast, whole grain, from fast food / restaurant
55300060	French toast, from school, NFS
55301000	French toast, plain
55301015	French toast, whole grain
55301020	French toast, whole grain, reduced fat
55301025	French toast, gluten free
55301030	French toast sticks, NFS
55301031	French toast sticks, plain, from frozen
55301040	French toast sticks, plain, from fast food / restaurant
55301048	French toast sticks, from school, NFS
55301050	French toast sticks, plain
55301055	French toast sticks, whole grain
55310100	Fried bread, Puerto Rican style
55401000	Crepe, plain
55501000	Chinese pancake
55610300	Dumpling, plain
55702100	Dosa (Indian), plain
55801000	Funnel cake with sugar
55801010	Funnel cake with sugar and fruit
56201550	Cornmeal dumpling
58117110	Cornmeal fritter, Puerto Rican style
58120110	Crepe, filled with meat, poultry, or seafood, with sauce
58120120	Crepe, filled with meat, poultry, or seafood, no sauce
58123120	Sweet bread dough, filled with bean paste, meatless, steamed
58124210	Pastry, cheese-filled
58127210	Croissant sandwich, filled with ham and cheese*
58127270	Croissant sandwich with sausage and egg*
58127290	Croissant sandwich with bacon and egg*
58127310	Croissant sandwich with ham, egg, and cheese*
58127330	Croissant sandwich with sausage, egg, and cheese*
58127350	Croissant sandwich with bacon, egg, and cheese*
58128000	Biscuit with gravy*

Food Code	Food Description
58310210	Sausage and french toast, frozen meal*
58310310	Pancakes and sausage, frozen meal*
71930200	Casabe, cassava bread
71945020	Yam buns; Puerto Rican style
Breads & rolls, English muffins, pizza crust	
14640000	Cheese sandwich, NFS*
14640002	Cheese sandwich, American cheese, on white bread, no spread*
14640004	Cheese sandwich, American cheese, on wheat bread, no spread*
14640006	Cheese sandwich, American cheese, on whole wheat bread, no spread*
14640008	Cheese sandwich, Cheddar cheese, on white bread, no spread*
14640010	Cheese sandwich, Cheddar cheese, on wheat bread, no spread*
14640012	Cheese sandwich, Cheddar cheese, on whole wheat bread, no spread*
14640014	Cheese sandwich, reduced fat American cheese, on white bread, no spread*
14640018	Cheese sandwich, reduced fat American cheese, on whole wheat bread, no spread*
14640020	Cheese sandwich, reduced fat Cheddar cheese, on white bread, no spread*
14640024	Cheese sandwich, reduced fat Cheddar cheese, on whole wheat bread, no spread*
14640026	Cheese sandwich, American cheese, on white bread, with mayonnaise*
14640028	Cheese sandwich, American cheese, on wheat bread, with mayonnaise*
14640030	Cheese sandwich, American cheese, on whole wheat bread, with mayonnaise*
14640032	Cheese sandwich, Cheddar cheese, on white bread, with mayonnaise*
14640034	Cheese sandwich, Cheddar cheese, on wheat bread, with mayonnaise*
14640036	Cheese sandwich, Cheddar cheese, on whole wheat bread, with mayonnaise*
14640042	Cheese sandwich, reduced fat American cheese, on whole wheat bread, with mayonnaise*
14640046	Cheese sandwich, reduced fat Cheddar cheese, on wheat bread, with mayonnaise*
14640048	Cheese sandwich, reduced fat Cheddar cheese, on whole wheat bread, with mayonnaise*
14640050	Cheese sandwich, American cheese, on white bread, with butter*
14640052	Cheese sandwich, American cheese, on wheat bread, with butter*
14640054	Cheese sandwich, American cheese, on whole wheat bread, with butter*
14640056	Cheese sandwich, Cheddar cheese, on white bread, with butter*
14640058	Cheese sandwich, Cheddar cheese, on wheat bread, with butter*
14640060	Cheese sandwich, Cheddar cheese, on whole wheat bread, with butter*
14640062	Cheese sandwich, reduced fat American cheese, on white bread, with butter*
14640068	Cheese sandwich, reduced fat Cheddar cheese, on white bread, with butter*
14640100	Grilled cheese sandwich, NFS*
14640105	Grilled cheese sandwich, American cheese, on white bread*
14640110	Grilled cheese sandwich, American cheese, on wheat bread*
14640115	Grilled cheese sandwich, American cheese, on whole wheat bread*
14640125	Grilled cheese sandwich, Cheddar cheese, on white bread*
14640130	Grilled cheese sandwich, Cheddar cheese, on wheat bread*
14640135	Grilled cheese sandwich, Cheddar cheese, on whole wheat bread*
14640155	Grilled cheese sandwich, reduced fat American cheese, on white bread*

Food Code	Food Description
14640160	Grilled cheese sandwich, reduced fat American cheese, on wheat bread*
14640165	Grilled cheese sandwich, reduced fat American cheese, on whole wheat bread*
14640185	Grilled cheese sandwich, reduced fat Cheddar cheese, on white bread*
14640190	Grilled cheese sandwich, reduced fat Cheddar cheese, on wheat bread*
14640195	Grilled cheese sandwich, reduced fat Cheddar cheese, on whole wheat bread*
27214100	Meat loaf made with beef*
27214110	Meat loaf made with beef, with tomato-based sauce*
27235000	Meat loaf made with venison/deer*
27246500	Meat loaf made with chicken or turkey*
27246505	Meat loaf made with chicken or turkey, with tomato-based sauce*
27250080	Salmon loaf*
27260010	Meat loaf, NS as to type of meat*
27260050	Meatballs, with breading, NS as to type of meat, with gravy*
27260080	Meat loaf made with beef and pork*
27260100	Meat loaf made with beef and pork, with tomato-based sauce*
27260510	Liver dumpling*
27500050	Sandwich, NFS*
27500100	Meat sandwich, NFS*
27510000	Beef sandwich, NFS*
27510140	Cheeseburger slider, from fast food*
27510145	Cheeseburger, 1 miniature patty, with condiments, on miniature bun, from fast food / restaurant*
27510150	Cheeseburger, 1 miniature patty, on miniature bun, from school*
27510155	Cheeseburger, NFS*
27510160	Cheeseburger, from fast food, 1 small patty*
27510165	Cheeseburger, 1 small patty, with condiments, on bun, from fast food / restaurant*
27510170	Cheeseburger (Burger King)*
27510171	Whopper Jr with cheese (Burger King)*
27510172	Cheeseburger (McDonalds)*
27510173	Cheeseburger, 1 small patty, with condiments, on bun, from fast food / restaurant (Wendy's Kid's Cheeseburger)*
27510174	Cheeseburger, 1 small patty, with condiments, on bun, from fast food / restaurant (Wendy's Jr. Cheeseburger)*
27510175	Cheeseburger, 1 small patty, with condiments, on bun, from fast food / restaurant (Wendy's Jr. Cheeseburger Deluxe)*
27510190	Cheeseburger, from school cafeteria*
27510191	Cheeseburger slider*
27510195	Cheeseburger, on white bun, 1 small patty*
27510196	Cheeseburger, on wheat bun, 1 small patty*
27510205	Cheeseburger, 1 small patty, with condiments, on white bun*
27510206	Cheeseburger, 1 small patty, with condiments, on wheat bun*
27510207	Cheeseburger, 1 small patty, with condiments, on whole wheat bun*
27510215	Cheeseburger, from fast food, 1 medium patty*

Food Code	Food Description
27510225	Cheeseburger, 1 medium patty, with condiments, on bun, from fast food / restaurant*
27510229	Quarter Pounder (McDonalds)*
27510231	Whopper with cheese (Burger King)*
27510232	Quarter Pounder with cheese (McDonalds)*
27510233	Cheeseburger, 1 medium patty, with condiments, on bun, from fast food / restaurant (Wendy's 1/4 lb. Single with cheese)*
27510235	Cheeseburger submarine sandwich with lettuce, tomato and spread*
27510241	Cheeseburger, on white bun, 1 medium patty*
27510242	Cheeseburger, on wheat bun, 1 medium patty*
27510243	Cheeseburger, 1 medium patty, plain, on whole wheat bun*
27510245	Cheeseburger, on white bun, 1 large patty*
27510246	Cheeseburger, on wheat bun, 1 large patty*
27510251	Cheeseburger, 1 medium patty, with condiments, on white bun*
27510252	Cheeseburger, 1 medium patty, with condiments, on wheat bun*
27510253	Cheeseburger, 1 medium patty, with condiments, on whole wheat bun*
27510254	Double cheeseburger, on white bun, 2 small patties*
27510257	Double cheeseburger, on white bun, 2 medium patties*
27510258	Double cheeseburger, on wheat bun, 2 medium patties*
27510261	Cheeseburger, from fast food, 1 large patty*
27510262	Double cheeseburger, on white bun, 2 large patties*
27510266	Cheeseburger, 1 large patty, with condiments, on bun, from fast food / restaurant*
27510276	Bacon cheeseburger, 1 small patty, with condiments, on bun, from fast food / restaurant*
27510281	Bacon cheeseburger, 1 small patty, with condiments, on bun, from fast food / restaurant (Wendy's Jr. Bacon Cheeseburger)*
27510305	Bacon cheeseburger, 1 medium patty, plain, on bun, from fast food / restaurant*
27510312	Bacon cheeseburger, 1 medium patty, with condiments, on bun, from fast food / restaurant*
27510331	Bacon cheeseburger, 1 medium patty, plain, on white bun*
27510341	Bacon cheeseburger, 1 medium patty, with condiments, on white bun*
27510342	Bacon cheeseburger, 1 medium patty, with condiments, on wheat bun*
27510343	Bacon cheeseburger, 1 medium patty, with condiments, on whole wheat bun*
27510346	Bacon cheeseburger, 1 large patty, with condiments, on bun, from fast food / restaurant*
27510371	Double cheeseburger, from fast food, 2 small patties*
27510376	Double cheeseburger, 2 small patties, with condiments, on bun, from fast food / restaurant*
27510386	Double cheeseburger (Burger King)*
27510387	Double cheeseburger (McDonalds)*
27510388	McDouble (McDonalds)*
27510389	Big Mac (McDonalds)*
27510391	Double cheeseburger, 2 small patties, with condiments, on bun, from fast food / restaurant (Wendy's Double Stack)*
27510401	Double cheeseburger, from fast food, 2 medium patties*
27510405	Double cheeseburger, from fast food, 2 large patties*

Food Code	Food Description
27510406	Double cheeseburger, 2 medium patties, with condiments, on bun, from fast food / restaurant*
27510412	Double cheeseburger, 2 medium patties, with condiments, on bun, from fast food / restaurant (McDonald's Double Quarter Pounder with Cheese)*
27510413	Double cheeseburger, 2 medium patties, with condiments, on bun, from fast food / restaurant (Wendy's 1/2 lb. Double with cheese)*
27510431	Double bacon cheeseburger, 2 small patties, with condiments, on bun, from fast food / restaurant (Burger King Bacon Double Cheeseburger)*
27510446	Double bacon cheeseburger, 2 medium patties, plain, on bun, from fast food / restaurant*
27510451	Double bacon cheeseburger, 2 medium patties, with condiments, on bun, from fast food / restaurant*
27510465	Double bacon cheeseburger, 2 medium patties, with condiments, on bun, from fast food / restaurant (Wendy's Baconator)*
27510475	Double bacon cheeseburger, 2 large patties, with condiments, on bun, from fast food / restaurant*
27510486	Triple cheeseburger, 3 medium patties, with condiments, on bun, from fast food / restaurant*
27510501	Hamburger slider, from fast food*
27510506	Hamburger, 1 miniature patty, with condiments, on miniature bun, from fast food / restaurant*
27510511	Hamburger, 1 miniature patty, on miniature bun, from school*
27510531	Hamburger, from fast food, 1 small patty*
27510536	Hamburger, 1 small patty, with condiments, on bun, from fast food / restaurant*
27510551	Hamburger (Burger King)*
27510552	Whopper Jr (Burger King)*
27510553	Hamburger (McDonalds)*
27510555	Hamburger, 1 small patty, with condiments, on bun, from fast food / restaurant (Wendy's Jr. Hamburger)*
27510565	Hamburger, from school cafeteria*
27510573	Hamburger slider*
27510575	Hamburger, on white bun, 1 small patty*
27510576	Hamburger, on wheat bun, 1 small patty*
27510577	Hamburger, 1 small patty, plain, on whole wheat bun*
27510585	Hamburger, 1 small patty, with condiments, on white bun*
27510587	Hamburger, 1 small patty, with condiments, on whole wheat bun*
27510601	Hamburger, from fast food, 1 medium patty*
27510605	Hamburger, from fast food, 1 large patty*
27510606	Hamburger, 1 medium patty, with condiments, on bun, from fast food / restaurant*
27510615	Whopper (Burger King)*
27510616	Hamburger, 1 medium patty, with condiments, on bun, from fast food / restaurant (Wendy's 1/4 lb. Single)*
27510631	Hamburger, on white bun, 1 medium patty*
27510632	Hamburger, on wheat bun, 1 medium patty*
27510633	Hamburger, 1 medium patty, plain, on whole wheat bun*
27510635	Hamburger, on white bun, 1 large patty*

Food Code	Food Description
27510636	Hamburger, on wheat bun, 1 large patty*
27510641	Hamburger, 1 medium patty, with condiments, on white bun*
27510642	Hamburger, 1 medium patty, with condiments, on wheat bun*
27510643	Hamburger, 1 medium patty, with condiments, on whole wheat bun*
27510649	Double hamburger, on white bun, 2 small patties*
27510655	Double hamburger, on white bun, 2 medium patties*
27510657	Double hamburger, on wheat bun, 2 medium patties*
27510658	Double hamburger, on white bun, 2 large patties*
27510661	Double hamburger, from fast food, 2 small patties*
27510667	Double hamburger, 2 small patties, with condiments, on bun, from fast food / restaurant*
27510671	Double hamburger, from fast food, 2 medium patties*
27510675	Double hamburger, from fast food, 2 large patties*
27510676	Double hamburger, 2 medium patties, with condiments, on bun, from fast food / restaurant*
27510681	Double hamburger, 2 medium patties, with condiments, on bun, from fast food / restaurant (Burger King Double WHOPPER)*
27510682	Double hamburger, 2 medium patties, with condiments, on bun, from fast food / restaurant (Wendy's 1/2 lb. Double)*
27510700	Meatball and spaghetti sauce submarine sandwich*
27510705	Chiliburger, with or without cheese, on bun*
27510910	Corned beef sandwich*
27510950	Reuben sandwich, corned beef sandwich with sauerkraut and cheese, with spread*
27513010	Roast beef sandwich*
27513040	Roast beef submarine sandwich, with lettuce, tomato and spread*
27513041	Roast beef submarine sandwich, with cheese, lettuce, tomato and spread*
27513050	Roast beef sandwich with cheese*
27515010	Steak sandwich, plain, on roll*
27515020	Steak and cheese submarine sandwich, with lettuce and tomato*
27515030	Steak and cheese sandwich, plain, on roll*
27515040	Steak and cheese submarine sandwich, plain, on roll*
27515070	Steak and cheese submarine sandwich, with fried peppers and onions, on roll*
27516010	Gyro sandwich (pita bread, beef, lamb, onion, condiments), with tomato and spread*
27520135	Bacon, chicken, and tomato club sandwich, with cheese, lettuce and spread*
27520140	Bacon and egg sandwich*
27520150	Bacon, lettuce, and tomato sandwich with spread*
27520155	Bacon, lettuce, and tomato submarine sandwich, with spread*
27520156	Bacon, lettuce, tomato, and cheese submarine sandwich, with spread*
27520160	Bacon, chicken, and tomato club sandwich, on multigrain roll with lettuce and spread*
27520166	Bacon, breaded fried chicken fillet, and tomato club sandwich with cheese, lettuce and spread*
27520310	Ham sandwich with lettuce and spread*
27520320	Ham and cheese sandwich, with lettuce and spread*
27520350	Ham and cheese sandwich, with spread, grilled*

Food Code	Food Description
27520370	Hot ham and cheese sandwich, on bun*
27520390	Ham and cheese submarine sandwich, with lettuce, tomato and spread*
27520410	Cuban sandwich, with spread*
27520500	Pork sandwich, on white roll, with onions, dill pickles and barbecue sauce*
27520510	Pork barbecue sandwich or Sloppy Joe, on bun*
27520520	Pork sandwich*
27540110	Sliced chicken sandwich, with spread*
27540111	Sliced chicken sandwich, with cheese and spread*
27540120	Chicken salad or chicken spread sandwich*
27540132	Chicken fillet sandwich, NFS*
27540139	Chicken fillet sandwich, from school cafeteria*
27540140	Chicken fillet, breaded, fried, sandwich*
27540146	Chicken fillet sandwich, fried, from fast food*
27540147	Chicken fillet sandwich, fried, from fast food, with cheese*
27540150	Chicken fillet, breaded, fried, sandwich with lettuce, tomato and spread*
27540151	Chicken fillet, breaded, fried, sandwich with cheese, lettuce, tomato and spread*
27540152	Chicken fillet sandwich, grilled, from fast food*
27540153	Chicken fillet sandwich, grilled, from fast food, with cheese*
27540160	Chicken fillet sandwich, NS as to fried or grilled, from fast food*
27540170	Chicken patty sandwich, miniature, with spread*
27540175	Chicken fillet sandwich, fried, on white bun*
27540176	Chicken fillet sandwich, fried, on white bun; with cheese*
27540185	Chicken fillet sandwich, fried, on wheat bun*
27540186	Chicken fillet sandwich, fried, on wheat bun, with cheese*
27540190	Chicken patty sandwich, with lettuce and spread*
27540195	Chicken fillet sandwich, grilled, on white bun*
27540196	Chicken fillet sandwich, grilled, on white bun, with cheese*
27540200	Fajita-style chicken sandwich with cheese, on pita bread, with lettuce and tomato*
27540205	Chicken fillet sandwich, grilled, on wheat bun*
27540206	Chicken fillet sandwich, grilled, on wheat bun, with cheese*
27540235	Chicken fillet, broiled, sandwich with lettuce, tomato, and spread*
27540240	Chicken fillet, broiled, sandwich, on whole wheat roll, with lettuce, tomato and spread*
27540250	Chicken fillet, broiled, sandwich with cheese, on whole wheat roll, with lettuce, tomato and non-mayonnaise type spread*
27540280	Chicken fillet, broiled, sandwich with cheese, on bun, with lettuce, tomato and spread*
27540285	Chicken, bacon, and tomato club sandwich, with lettuce and spread*
27540290	Chicken submarine sandwich, with lettuce, tomato and spread*
27540291	Chicken submarine sandwich, with cheese, lettuce, tomato and spread*
27540295	Buffalo chicken submarine sandwich*
27540296	Buffalo chicken submarine sandwich with cheese*
27540310	Turkey sandwich, with spread*
27540350	Turkey submarine sandwich, with cheese, lettuce, tomato and spread*

Food Code	Food Description
27540360	Turkey and bacon submarine sandwich, with lettuce, tomato and spread*
27540361	Turkey and bacon submarine sandwich, with cheese, lettuce, tomato and spread*
27541000	Turkey, ham, and roast beef club sandwich, with lettuce, tomato and spread*
27541001	Turkey, ham, and roast beef club sandwich with cheese, lettuce, tomato, and spread*
27545000	Turkey or chicken burger, plain, on bun, from fast food / restaurant*
27545010	Turkey or chicken burger, with condiments, on bun, from fast food / restaurant*
27545100	Turkey or chicken burger, on white bun*
27545110	Turkey or chicken burger, on wheat bun*
27545200	Turkey or chicken burger, with condiments, on white bun*
27545210	Turkey or chicken burger, with condiments, on wheat bun*
27545220	Turkey or chicken burger, with condiments, on whole wheat bun*
27550000	Fish sandwich, fried, from fast food*
27550100	Fish sandwich, fried, from fast food, with cheese*
27550110	Crab cake sandwich*
27550120	Salmon cake sandwich*
27550150	Fried seafood sandwich*
27550200	Fish sandwich, from school cafeteria*
27550300	Fish sandwich, NFS*
27550400	Fish sandwich, fried, on white bun*
27550405	Fish sandwich, fried, on white bun, with cheese*
27550410	Fish sandwich, fried, on wheat bun*
27550420	Fish sandwich, grilled*
27550510	Sardine sandwich*
27550720	Tuna salad sandwich, on bread*
27550730	Tuna salad sandwich, on bread, with cheese*
27550740	Tuna salad sandwich, on bun*
27550745	Tuna salad sandwich, on bun, with cheese*
27550750	Tuna salad submarine sandwich, with lettuce and tomato*
27550751	Tuna salad submarine sandwich, with cheese, lettuce and tomato*
27550800	Seafood salad sandwich*
27560120	Bologna and cheese sandwich, with spread*
27560350	Pig in a blanket, frankfurter or hot dog wrapped in dough*
27560500	Pepperoni and salami submarine sandwich, with lettuce, tomato and spread*
27560670	Sausage and cheese on English muffin*
27560710	Sausage sandwich*
27560910	Cold cut submarine sandwich, with cheese, lettuce, tomato and spread*
27564000	Frankfurter or hot dog sandwich, NFS, plain, on white bun*
27564001	Frankfurter or hot dog sandwich, NFS, plain, on wheat bun*
27564002	Frankfurter or hot dog sandwich, NFS, plain, on whole wheat bun*
27564010	Frankfurter or hot dog sandwich, NFS, plain, on white bread*
27564020	Frankfurter or hot dog sandwich, NFS, plain, on wheat bread*
27564030	Frankfurter or hot dog sandwich, NFS, plain, on whole wheat bread*

Food Code	Food Description
27564060	Frankfurter or hot dog sandwich, beef, plain, on white bun*
27564061	Frankfurter or hot dog sandwich, beef, plain, on wheat bun*
27564062	Frankfurter or hot dog sandwich, beef, plain, on whole wheat bun*
27564064	Frankfurter or hot dog sandwich, beef, plain, on multigrain bun*
27564070	Frankfurter or hot dog sandwich, beef, plain, on white bread*
27564080	Frankfurter or hot dog sandwich, beef, plain, on wheat bread*
27564090	Frankfurter or hot dog sandwich, beef, plain, on whole wheat bread*
27564100	Frankfurter or hot dog sandwich, beef, plain, on whole grain white bread*
27564110	Frankfurter or hot dog sandwich, beef, plain, on multigrain bread*
27564120	Frankfurter or hot dog sandwich, beef and pork, plain, on white bun*
27564121	Frankfurter or hot dog sandwich, beef and pork, plain, on wheat bun*
27564122	Frankfurter or hot dog sandwich, beef and pork, plain, on whole wheat bun*
27564130	Frankfurter or hot dog sandwich, beef and pork, plain, on white bread*
27564140	Frankfurter or hot dog sandwich, beef and pork, plain, on wheat bread*
27564150	Frankfurter or hot dog sandwich, beef and pork, plain, on whole wheat bread*
27564180	Frankfurter or hot dog sandwich, meat and poultry, plain, on white bun*
27564182	Frankfurter or hot dog sandwich, meat and poultry, plain, on whole wheat bun*
27564190	Frankfurter or hot dog sandwich, meat and poultry, plain, on white bread*
27564200	Frankfurter or hot dog sandwich, meat and poultry, plain, on wheat bread*
27564210	Frankfurter or hot dog sandwich, meat and poultry, plain, on whole wheat bread*
27564220	Frankfurter or hot dog sandwich, meat and poultry, plain, on whole grain white bread*
27564240	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on white bun*
27564241	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on wheat bun*
27564243	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on whole grain white bun*
27564250	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on white bread*
27564260	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on wheat bread*
27564270	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on whole wheat bread*
27564290	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on multigrain bread*
27564300	Frankfurter or hot dog sandwich, reduced fat or light, plain, on white bun*
27564301	Frankfurter or hot dog sandwich, reduced fat or light, plain, on wheat bun*
27564330	Frankfurter or hot dog sandwich, reduced fat or light, plain, on whole wheat bread*
27564360	Frankfurter or hot dog sandwich, fat free, plain, on white bun*
27564370	Frankfurter or hot dog sandwich, fat free, plain, on white bread*
27564380	Frankfurter or hot dog sandwich, fat free, plain, on wheat bread*
27564418	Frankfurter or hot dog sandwich, reduced sodium*
27564420	Frankfurter or hot dog sandwich, meatless, plain, on bun*
27564430	Frankfurter or hot dog sandwich, meatless, plain, on bread*
27564440	Frankfurter or hot dog sandwich, with chili, on white bun*
27564441	Frankfurter or hot dog sandwich, with chili, on wheat bun*
27564442	Frankfurter or hot dog sandwich, with chili, on whole wheat bun*
27564443	Frankfurter or hot dog sandwich, with chili, on whole grain white bun*

Food Code	Food Description
27564450	Frankfurter or hot dog sandwich, with chili, on white bread*
27564500	Frankfurter or hot dog sandwich, with meatless chili, on white bun*
27564510	Frankfurter or hot dog sandwich, with meatless chili, on white bread*
27564520	Frankfurter or hot dog sandwich, with meatless chili, on wheat bread*
28141050	Chicken patty parmigiana, breaded, with vegetable, diet frozen meal*
28145100	Turkey with gravy, dressing, vegetable and fruit, diet frozen meal*
32101500	Egg, Benedict*
32105190	Egg casserole with bread, cheese, milk and meat*
32202000	Egg, cheese, ham, and bacon on bun*
32202010	Egg, cheese, and ham on English muffin*
32202030	Egg, cheese, and sausage on English muffin*
32202034	Egg, cheese, and sausage on bun*
32202035	Egg, extra cheese, and extra sausage, on bun*
32202080	Egg, cheese, and bacon on English muffin*
32204010	Scrambled egg sandwich*
32301100	Garlic egg soup, Puerto Rican style*
42301015	Peanut butter sandwich, with regular peanut butter, on white bread*
42301020	Peanut butter sandwich, with regular peanut butter, on wheat bread*
42301025	Peanut butter sandwich, with regular peanut butter, on whole wheat bread*
42301115	Peanut butter sandwich, with reduced fat peanut butter, on white bread*
42301120	Peanut butter sandwich, with reduced fat peanut butter, on wheat bread*
42301125	Peanut butter sandwich, with reduced fat peanut butter, on whole wheat bread*
42302010	Peanut butter and jelly sandwich, NFS*
42302015	Peanut butter and jelly sandwich, with regular peanut butter, regular jelly, on white bread*
42302020	Peanut butter and jelly sandwich, with regular peanut butter, regular jelly, on wheat bread*
42302025	Peanut butter and jelly sandwich, with regular peanut butter, regular jelly, on whole wheat bread*
42302055	Peanut butter and jelly sandwich, with reduced fat peanut butter, regular jelly, on white bread*
42302060	Peanut butter and jelly sandwich, with reduced fat peanut butter, regular jelly, on wheat bread*
42302065	Peanut butter and jelly sandwich, with reduced fat peanut butter, regular jelly, on whole wheat bread*
42302105	Peanut butter and jelly sandwich, with regular peanut butter, reduced sugar jelly, on white bread*
42302110	Peanut butter and jelly sandwich, with regular peanut butter, reduced sugar jelly, on wheat bread*
42302115	Peanut butter and jelly sandwich, with regular peanut butter, reduced sugar jelly, on whole wheat bread*
42302155	Peanut butter and jelly sandwich, with reduced fat peanut butter, reduced sugar jelly, on white bread*
42302160	Peanut butter and jelly sandwich, with reduced fat peanut butter, reduced sugar jelly, on wheat bread*

Food Code	Food Description
42302165	Peanut butter and jelly sandwich, with reduced fat peanut butter, reduced sugar jelly, on whole wheat bread*
42303100	Peanut butter and jelly sandwich, frozen commercial product without crusts*
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
51101000	Bread, white
51101010	Bread, white, toasted
51101050	Bread, white, made from home recipe or purchased at a bakery
51101060	Bread, white, made from home recipe or purchased at a bakery, toasted
51102010	Bread, white with whole wheat swirl
51105010	Bread, Cuban
51105040	Bread, Cuban, toasted
51106010	Bread, native, water, Puerto Rican style
51107010	Bread, French or Vienna
51107040	Bread, French or Vienna, toasted
51108010	Focaccia, Italian flatbread, plain
51108100	Naan, Indian flatbread
51109010	Bread, Italian, Grecian, Armenian
51109040	Bread, Italian, Grecian, Armenian, toasted
51109100	Bread, pita
51109150	Bread, pita with fruit
51111010	Bread, cheese
51111040	Bread, cheese, toasted
51113010	Bread, cinnamon
51113100	Bread, cinnamon, toasted
51115020	Bread, cornmeal and molasses, toasted
51119010	Bread, egg, Challah
51119040	Bread, egg, Challah, toasted
51121015	Garlic bread, NFS
51121025	Garlic bread, from fast food / restaurant
51121035	Garlic bread, from frozen
51121045	Garlic bread, with parmesan cheese, from fast food / restaurant
51121055	Garlic bread, with parmesan cheese, from frozen
51121065	Garlic bread, with melted cheese, from fast food / restaurant
51121075	Garlic bread, with melted cheese, from frozen
51121110	Bread, onion
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

Food Code	Food Description
51127010	Bread, potato
51127020	Bread, potato, toasted
51129010	Bread, raisin
51129020	Bread, raisin, toasted
51133010	Bread, sour dough
51133020	Bread, sour dough, toasted
51134000	Bread, sweet potato
51135000	Bread, vegetable
51136000	Bruschetta*
51140100	Bread, dough, fried
51150000	Roll, white, soft
51153000	Roll, white, hard
51154010	Roll, white, hot dog bun
51154100	Roll, white, hamburger bun
51154550	Roll, egg bread
51154600	Roll, cheese
51155000	Roll, French or Vienna
51156500	Roll, garlic
51157000	Roll, white, hoagie, submarine
51158100	Roll, Mexican, bolillo
51159000	Roll, sour dough
51183990	Breadsticks, NFS
51184200	Breadsticks, soft, NFS
51184210	Breadsticks, soft, from fast food / restaurant
51184220	Breadsticks, soft, from frozen
51184230	Breadsticks, soft, with parmesan cheese, from fast food / restaurant
51184240	Breadsticks, soft, with parmesan cheese, from frozen
51184250	Breadsticks, soft, topped with melted cheese
51184260	Breadsticks, soft, stuffed with melted cheese
51186010	Muffin, English
51186100	Muffin, English, with raisins
51186160	Muffin, English, with fruit other than raisins
51300050	Bread, whole grain white
51300060	Bread, whole grain white, toasted
51300110	Bread, whole wheat
51300120	Bread, whole wheat, toasted
51300140	Bread, whole wheat, made from home recipe or purchased at bakery
51300150	Bread, whole wheat, made from home recipe or purchased at bakery, toasted
51300175	Bread, chappatti or roti, wheat
51300180	Bread, puri, wheat
51300185	Bread, paratha, wheat
51300210	Bread, whole wheat, with raisins

Food Code	Food Description
51300220	Bread, whole wheat, with raisins, toasted
51300300	Bread, sprouted wheat
51300310	Bread, sprouted wheat, toasted
51301010	Bread, wheat or cracked wheat
51301020	Bread, wheat or cracked wheat, toasted
51301040	Bread, wheat or cracked wheat, made from home recipe or purchased at bakery
51301050	Bread, wheat or cracked wheat, made from home recipe or purchased at bakery, toasted
51301120	Bread, wheat or cracked wheat, with raisins
51301130	Bread, wheat or cracked wheat, with raisins, toasted
51301510	Bread, wheat or cracked wheat, reduced calorie and/or high fiber
51301540	Bread, French or Vienna, whole wheat
51301550	Bread, French or Vienna, whole wheat, toasted
51301600	Bread, pita, whole wheat
51301620	Bread, pita, wheat or cracked wheat
51302500	Muffin, English, wheat bran
51303010	Muffin, English, wheat or cracked wheat
51303030	Muffin, English, whole wheat
51303050	Muffin, English, wheat or cracked wheat, with raisins
51303070	Muffin, English, whole wheat, with raisins
51303100	Muffin, English, whole grain white
51320010	Roll, wheat or cracked wheat
51320060	Roll, wheat or cracked wheat, hot dog bun
51320070	Roll, wheat or cracked wheat, hamburger bun
51320500	Roll, whole wheat
51320550	Roll, whole wheat, hot dog bun
51320560	Roll, whole wheat, hamburger bun
51320700	Roll, whole grain white
51320710	Roll, whole grain white, hot dog bun
51320720	Roll, whole grain white, hamburger bun
51401010	Bread, rye
51401020	Bread, rye, toasted
51401030	Bread, marble rye and pumpernickel
51404010	Bread, pumpernickel
51404020	Bread, pumpernickel, toasted
51404550	Muffin, English, pumpernickel
51407010	Bread, black
51420000	Roll, rye
51421000	Roll, pumpernickel
51501010	Bread, oatmeal
51501020	Bread, oatmeal, toasted
51501040	Bread, oat bran
51501050	Bread, oat bran, toasted

Food Code	Food Description
51502010	Roll, oatmeal
51601010	Bread, multigrain, toasted
51601020	Bread, multigrain
51601210	Bread, multigrain, with raisins
51602020	Bread, multigrain, reduced calorie and/or high fiber, toasted
51620000	Roll, multigrain
51620030	Roll, multigrain, hamburger bun
51630200	Muffin, English, multigrain
51801010	Bread, barley
51801020	Bread, barley, toasted
51805010	Bread, sunflower meal
51806010	Bread, rice
51807000	Injera, Ethiopian bread
51808000	Bread, gluten free
51808010	Bread, gluten free, toasted
51808100	Roll, gluten free
53116650	Cake, Quezadilla, El Salvadorian style
53415100	Crisp, apple, apple dessert*
54408400	Pretzels, soft, NFS
54408405	Pretzels, soft, ready-to-eat, NFS
54408410	Pretzels, soft, ready-to-eat, salted, buttered
54408411	Pretzels, soft, ready-to-eat, unsalted, buttered
54408415	Pretzels, soft, ready-to-eat, salted, no butter
54408416	Pretzels, soft, ready-to-eat, unsalted, no butter
54408420	Pretzels, soft, ready-to-eat, cinnamon sugar coated
54408422	Pretzels, soft, ready-to-eat, coated or flavored
54408430	Pretzels, soft, ready-to-eat, topped with meat
54408432	Pretzels, soft, ready-to-eat, topped with cheese
54408456	Pretzels, soft, from frozen, unsalted
54408470	Pretzels, soft, filled with cheese
54408475	Pretzels, soft, from school lunch
54408480	Pretzels, soft, multigrain
54408485	Pretzels, soft, gluten free
54408487	Pretzels, soft, gluten free, coated or flavored
58101800	Ground beef with tomato sauce and taco seasonings on a cornbread crust*
58106200	Pizza, cheese, from frozen, thin crust*
58106205	Pizza, cheese, from frozen, thick crust*
58106210	Pizza, cheese, from restaurant or fast food, NS as to type of crust*
58106220	Pizza, cheese, from restaurant or fast food, thin crust*
58106225	Pizza, cheese, from restaurant or fast food, medium crust*
58106230	Pizza, cheese, from restaurant or fast food, thick crust*
58106233	Pizza, cheese, stuffed crust*

Food Code	Food Description
58106234	Pizza, cheese, from school lunch, medium crust*
58106235	Pizza, cheese, from school lunch, thin crust*
58106236	Pizza, cheese, from school lunch, thick crust*
58106250	Pizza, extra cheese, thin crust*
58106260	Pizza, extra cheese, thick crust*
58106300	Pizza, cheese, with vegetables, from frozen, thin crust*
58106305	Pizza, cheese with vegetables, from frozen, thick crust*
58106320	Pizza, cheese, with vegetables, from restaurant or fast food, thin crust*
58106325	Pizza, cheese, with vegetables, from restaurant or fast food, medium crust*
58106330	Pizza, cheese, with vegetables, from restaurant or fast food, thick crust*
58106345	Pizza with cheese and extra vegetables, thin crust*
58106347	Pizza with cheese and extra vegetables, medium crust*
58106358	Pizza, cheese, with fruit, thin crust*
58106359	Pizza, cheese, with fruit, medium crust*
58106360	Pizza, cheese, with fruit, thick crust*
58106512	Pizza with pepperoni, from frozen, thin crust*
58106514	Pizza with pepperoni, from frozen, medium crust*
58106516	Pizza with pepperoni, from frozen, thick crust*
58106540	Pizza with pepperoni, from restaurant or fast food, NS as to type of crust*
58106550	Pizza with pepperoni, from restaurant or fast food, thin crust*
58106555	Pizza with pepperoni, from restaurant or fast food, medium crust*
58106560	Pizza with pepperoni, from restaurant or fast food, thick crust*
58106565	Pizza with pepperoni, stuffed crust*
58106570	Pizza with pepperoni, from school lunch, thin crust*
58106578	Pizza, with pepperoni, from school lunch, medium crust*
58106580	Pizza with pepperoni, from school lunch, thick crust*
58106602	Pizza with meat other than pepperoni, from frozen, thin crust*
58106604	Pizza with meat other than pepperoni, from frozen, medium crust*
58106606	Pizza with meat other than pepperoni, from frozen, thick crust*
58106610	Pizza with meat other than pepperoni, from restaurant or fast food, NS as to type of crust*
58106620	Pizza with meat other than pepperoni, from restaurant or fast food, thin crust*
58106625	Pizza with meat other than pepperoni, from restaurant or fast food, medium crust*
58106630	Pizza with meat other than pepperoni, from restaurant or fast food, thick crust*
58106633	Pizza, with meat other than pepperoni, stuffed crust*
58106634	Pizza, with meat other than pepperoni, from school lunch, medium crust*
58106635	Pizza, with meat other than pepperoni, from school lunch, thin crust*
58106636	Pizza, with meat other than pepperoni, from school lunch, thick crust*
58106650	Pizza with extra meat, thin crust*
58106655	Pizza with extra meat, medium crust*
58106660	Pizza with extra meat, thick crust*
58106700	Pizza with meat and vegetables, from frozen, thin crust*

Food Code	Food Description
58106702	Pizza with meat and vegetables, from frozen, medium crust*
58106705	Pizza with meat and vegetables, from frozen, thick crust*
58106720	Pizza with meat and vegetables, from restaurant or fast food, thin crust*
58106725	Pizza with meat and vegetables, from restaurant or fast food, medium crust*
58106730	Pizza with meat and vegetables, from restaurant or fast food, thick crust*
58106736	Pizza with extra meat and extra vegetables, thin crust*
58106737	Pizza with extra meat and extra vegetables, thick crust*
58106738	Pizza with extra meat and extra vegetables, medium crust*
58106750	Pizza with meat and fruit, thin crust*
58106755	Pizza with meat and fruit, medium crust*
58106760	Pizza with meat and fruit, thick crust*
58106830	Pizza with beans and vegetables, thick crust*
58107050	Pizza, no cheese, thin crust*
58107205	White pizza, cheese, thin crust*
58107212	White pizza, cheese, with vegetables, thin crust*
58107222	White pizza, cheese, with meat, thin crust*
58107224	White pizza, cheese, with meat, thick crust*
58107232	White pizza, cheese, with meat and vegetables, thin crust*
58108000	Calzone, with cheese, meatless*
58108010	Calzone, with meat and cheese*
58108050	Pizza rolls*
58109015	Pizza, cheese, whole wheat thin crust*
58109020	Pizza, cheese, whole wheat thick crust*
58109030	Pizza, with meat, whole wheat thin crust*
58109040	Pizza, with meat, whole wheat thick crust*
58109050	Pizza, cheese and vegetables, whole wheat thin crust*
58109060	Pizza, cheese and vegetables, whole wheat thick 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*
58109210	Breakfast pizza with egg*
58126130	Turnover, meat- and cheese-filled, no gravy*
58126150	Turnover, meat- and cheese-filled, tomato-based sauce*
58126270	Turnover, chicken- or turkey-, and cheese-filled, no gravy*
58127500	Vegetable submarine sandwich, with fat free spread*
58128210	Dressing with oysters*
58128220	Dressing with chicken or turkey and vegetables*
58128250	Dressing with meat and vegetables*
58201005	Jelly sandwich, regular jelly, on white bread*
58201015	Jelly sandwich, regular jelly, on wheat bread*

Food Code	Food Description
58201025	Jelly sandwich, regular jelly, on whole wheat bread*
58201035	Jelly sandwich, reduced sugar jelly, on white bread*
58201045	Jelly sandwich, reduced sugar jelly, on wheat bread*
74701000	Tomato sandwich*
75608100	Onion soup, French*

Dressings

Creamy Salad Dressings

14640026	Cheese sandwich, American cheese, on white bread, with mayonnaise*
14640028	Cheese sandwich, American cheese, on wheat bread, with mayonnaise*
14640030	Cheese sandwich, American cheese, on whole wheat bread, with mayonnaise*
14640032	Cheese sandwich, Cheddar cheese, on white bread, with mayonnaise*
14640034	Cheese sandwich, Cheddar cheese, on wheat bread, with mayonnaise*
14640036	Cheese sandwich, Cheddar cheese, on whole wheat bread, with mayonnaise*
14640042	Cheese sandwich, reduced fat American cheese, on whole wheat bread, with mayonnaise*
14640046	Cheese sandwich, reduced fat Cheddar cheese, on wheat bread, with mayonnaise*
14640048	Cheese sandwich, reduced fat Cheddar cheese, on whole wheat bread, with mayonnaise*
27220080	Ham croquette*
27246300	Chicken or turkey cake, patty, or croquette*
27250040	Crab cake*
27250070	Salmon cake or patty*
27250160	Tuna cake or patty*
27250400	Shrimp cake or patty*
27416250	Beef salad*
27420020	Ham or pork salad*
27446200	Chicken or turkey salad, made with mayonnaise*
27446205	Chicken or turkey salad with nuts and/or fruits*
27446220	Chicken or turkey salad with egg*
27446225	Chicken or turkey salad, made with light mayonnaise*
27446230	Chicken or turkey salad, made with mayonnaise-type salad dressing*
27446235	Chicken or turkey salad, made with light mayonnaise-type salad dressing*
27446240	Chicken or turkey salad, made with creamy dressing*
27446245	Chicken or turkey salad, made with light creamy dressing*
27446260	Chicken or turkey salad, made with any type of fat free dressing*
27450010	Crab salad*
27450020	Lobster salad*
27450060	Tuna salad, made with mayonnaise*
27450061	Tuna salad, made with light mayonnaise*
27450062	Tuna salad, made with mayonnaise-type salad dressing*
27450063	Tuna salad, made with light mayonnaise-type salad dressing*
27450064	Tuna salad, made with creamy dressing*
27450068	Tuna salad, made with any type of fat free dressing*

Food Code	Food Description
27450070	Shrimp salad*
27450080	Seafood salad*
27450090	Tuna salad with cheese*
27450100	Tuna salad with egg*
27450130	Crab salad made with imitation crab*
27500050	Sandwich, NFS*
27500100	Meat sandwich, NFS*
27510000	Beef sandwich, NFS*
27510145	Cheeseburger, 1 miniature patty, with condiments, on miniature bun, from fast food / restaurant*
27510165	Cheeseburger, 1 small patty, with condiments, on bun, from fast food / restaurant*
27510171	Whopper Jr with cheese (Burger King)*
27510175	Cheeseburger, 1 small patty, with condiments, on bun, from fast food / restaurant (Wendy's Jr. Cheeseburger Deluxe)*
27510205	Cheeseburger, 1 small patty, with condiments, on white bun*
27510206	Cheeseburger, 1 small patty, with condiments, on wheat bun*
27510207	Cheeseburger, 1 small patty, with condiments, on whole wheat bun*
27510225	Cheeseburger, 1 medium patty, with condiments, on bun, from fast food / restaurant*
27510235	Cheeseburger submarine sandwich with lettuce, tomato and spread*
27510251	Cheeseburger, 1 medium patty, with condiments, on white bun*
27510252	Cheeseburger, 1 medium patty, with condiments, on wheat bun*
27510253	Cheeseburger, 1 medium patty, with condiments, on whole wheat bun*
27510266	Cheeseburger, 1 large patty, with condiments, on bun, from fast food / restaurant*
27510276	Bacon cheeseburger, 1 small patty, with condiments, on bun, from fast food / restaurant*
27510312	Bacon cheeseburger, 1 medium patty, with condiments, on bun, from fast food / restaurant*
27510341	Bacon cheeseburger, 1 medium patty, with condiments, on white bun*
27510342	Bacon cheeseburger, 1 medium patty, with condiments, on wheat bun*
27510343	Bacon cheeseburger, 1 medium patty, with condiments, on whole wheat bun*
27510346	Bacon cheeseburger, 1 large patty, with condiments, on bun, from fast food / restaurant*
27510376	Double cheeseburger, 2 small patties, with condiments, on bun, from fast food / restaurant*
27510406	Double cheeseburger, 2 medium patties, with condiments, on bun, from fast food / restaurant*
27510431	Double bacon cheeseburger, 2 small patties, with condiments, on bun, from fast food / restaurant (Burger King Bacon Double Cheeseburger)*
27510451	Double bacon cheeseburger, 2 medium patties, with condiments, on bun, from fast food / restaurant*
27510465	Double bacon cheeseburger, 2 medium patties, with condiments, on bun, from fast food / restaurant (Wendy's Baconator)*
27510475	Double bacon cheeseburger, 2 large patties, with condiments, on bun, from fast food / restaurant*
27510486	Triple cheeseburger, 3 medium patties, with condiments, on bun, from fast food / restaurant*

Food Code	Food Description
27510506	Hamburger, 1 miniature patty, with condiments, on miniature bun, from fast food / restaurant*
27510536	Hamburger, 1 small patty, with condiments, on bun, from fast food / restaurant*
27510552	Whopper Jr (Burger King)*
27510585	Hamburger, 1 small patty, with condiments, on white bun*
27510587	Hamburger, 1 small patty, with condiments, on whole wheat bun*
27510606	Hamburger, 1 medium patty, with condiments, on bun, from fast food / restaurant*
27510641	Hamburger, 1 medium patty, with condiments, on white bun*
27510642	Hamburger, 1 medium patty, with condiments, on wheat bun*
27510643	Hamburger, 1 medium patty, with condiments, on whole wheat bun*
27510667	Double hamburger, 2 small patties, with condiments, on bun, from fast food / restaurant*
27510676	Double hamburger, 2 medium patties, with condiments, on bun, from fast food / restaurant*
27510950	Reuben sandwich, corned beef sandwich with sauerkraut and cheese, with spread*
27513040	Roast beef submarine sandwich, with lettuce, tomato and spread*
27513041	Roast beef submarine sandwich, with cheese, lettuce, tomato and spread*
27516010	Gyro sandwich (pita bread, beef, lamb, onion, condiments), with tomato and spread*
27520135	Bacon, chicken, and tomato club sandwich, with cheese, lettuce and spread*
27520150	Bacon, lettuce, and tomato sandwich with spread*
27520155	Bacon, lettuce, and tomato submarine sandwich, with spread*
27520156	Bacon, lettuce, tomato, and cheese submarine sandwich, with spread*
27520160	Bacon, chicken, and tomato club sandwich, on multigrain roll with lettuce and spread*
27520166	Bacon, breaded fried chicken fillet, and tomato club sandwich with cheese, lettuce and spread*
27520310	Ham sandwich with lettuce and spread*
27520320	Ham and cheese sandwich, with lettuce and spread*
27520350	Ham and cheese sandwich, with spread, grilled*
27520370	Hot ham and cheese sandwich, on bun*
27520390	Ham and cheese submarine sandwich, with lettuce, tomato and spread*
27520410	Cuban sandwich, with spread*
27540110	Sliced chicken sandwich, with spread*
27540111	Sliced chicken sandwich, with cheese and spread*
27540120	Chicken salad or chicken spread sandwich*
27540150	Chicken fillet, breaded, fried, sandwich with lettuce, tomato and spread*
27540151	Chicken fillet, breaded, fried, sandwich with cheese, lettuce, tomato and spread*
27540170	Chicken patty sandwich, miniature, with spread*
27540190	Chicken patty sandwich, with lettuce and spread*
27540235	Chicken fillet, broiled, sandwich with lettuce, tomato, and spread*
27540240	Chicken fillet, broiled, sandwich, on whole wheat roll, with lettuce, tomato and spread*
27540280	Chicken fillet, broiled, sandwich with cheese, on bun, with lettuce, tomato and spread*
27540285	Chicken, bacon, and tomato club sandwich, with lettuce and spread*
27540290	Chicken submarine sandwich, with lettuce, tomato and spread*
27540291	Chicken submarine sandwich, with cheese, lettuce, tomato and spread*

Food Code	Food Description
27540295	Buffalo chicken submarine sandwich*
27540296	Buffalo chicken submarine sandwich with cheese*
27540310	Turkey sandwich, with spread*
27540350	Turkey submarine sandwich, with cheese, lettuce, tomato and spread*
27540360	Turkey and bacon submarine sandwich, with lettuce, tomato and spread*
27540361	Turkey and bacon submarine sandwich, with cheese, lettuce, tomato and spread*
27541000	Turkey, ham, and roast beef club sandwich, with lettuce, tomato and spread*
27541001	Turkey, ham, and roast beef club sandwich with cheese, lettuce, tomato, and spread*
27545010	Turkey or chicken burger, with condiments, on bun, from fast food / restaurant*
27545200	Turkey or chicken burger, with condiments, on white bun*
27545210	Turkey or chicken burger, with condiments, on wheat bun*
27545220	Turkey or chicken burger, with condiments, on whole wheat bun*
27550110	Crab cake sandwich*
27550120	Salmon cake sandwich*
27550720	Tuna salad sandwich, on bread*
27550730	Tuna salad sandwich, on bread, with cheese*
27550740	Tuna salad sandwich, on bun*
27550745	Tuna salad sandwich, on bun, with cheese*
27550755	Tuna salad wrap sandwich*
27550800	Seafood salad sandwich*
27560120	Bologna and cheese sandwich, with spread*
27560500	Pepperoni and salami submarine sandwich, with lettuce, tomato and spread*
27560910	Cold cut submarine sandwich, with cheese, lettuce, tomato and spread*
32102000	Egg, deviled*
32103000	Egg salad, made with mayonnaise*
32103015	Egg salad, made with light mayonnaise*
32103020	Egg salad, made with mayonnaise-type salad dressing*
32103025	Egg salad, made with light mayonnaise-type salad dressing*
32103050	Egg Salad, made with any type of fat free dressing*
32202025	Egg, cheese and ham on bagel*
41420100	Miso sauce
58127500	Vegetable submarine sandwich, with fat free spread*
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*
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*
58148130	Macaroni or pasta salad with tuna*
58148150	Macaroni or pasta salad with shrimp*
58148160	Macaroni or pasta salad with tuna and egg*
58148170	Macaroni or pasta salad with chicken*

Food Code	Food Description
58148180	Macaroni or pasta salad with cheese*
58148550	Macaroni or pasta salad with meat*
63401010	Apple salad with dressing*
63402950	Fruit salad, excluding citrus fruits, with salad dressing or mayonnaise*
63402980	Fruit salad, excluding citrus fruits, with marshmallows*
63403040	Fruit salad, including citrus fruits, with marshmallows*
71600950	Potato salad with egg, from restaurant*
71601010	Potato salad with egg, made with mayonnaise*
71601015	Potato salad with egg, made with light mayonnaise*
71601020	Potato salad with egg, made with mayonnaise-type salad dressing*
71601025	Potato salad with egg, made with light mayonnaise-type salad dressing*
71601035	Potato salad with egg, made with light creamy dressing*
71601050	Potato salad with egg, made with any type of fat free dressing*
71602950	Potato salad, from restaurant*
71603010	Potato salad, made with mayonnaise*
71603015	Potato salad, made with light mayonnaise*
71603020	Potato salad, made with mayonnaise-type salad dressing*
71603050	Potato salad, made with any type of fat free dressing*
73101110	Carrots, raw, salad*
73101210	Carrots, raw, salad with apples*
74701000	Tomato sandwich*
75140500	Broccoli salad with cauliflower, cheese, bacon bits, and dressing*
75140510	Broccoli slaw salad*
75141000	Cabbage salad or coleslaw, made with coleslaw dressing*
75141005	Cabbage salad or coleslaw, made with light coleslaw dressing*
75141030	Cabbage salad or coleslaw, made with creamy dressing*
75141035	Cabbage salad or coleslaw, made with light creamy dressing*
75141040	Cabbage salad or coleslaw, made with any type of fat free dressing*
75141100	Cabbage salad or coleslaw with apples and/or raisins, with dressing*
75141200	Cabbage salad or coleslaw with pineapple, with dressing*
75416600	Pea salad with cheese*
81302040	Sandwich spread
81302050	Tartar sauce
81308100	Fry sauce*
83100100	Salad dressing, NFS, for salads
83100200	Salad dressing, NFS, for sandwiches
83101000	Blue or roquefort cheese dressing
83102000	Caesar dressing
83103000	Coleslaw dressing
83104000	French or Catalina dressing
83105500	Honey mustard dressing
83107000	Mayonnaise, regular

Food Code	Food Description
83108000	Vegan mayonnaise
83109000	Russian dressing
83110000	Mayonnaise-type salad dressing
83112000	Avocado dressing
83112500	Creamy dressing
83112950	Poppy seed dressing
83112990	Sesame dressing
83114000	Thousand Island dressing
83115000	Yogurt dressing
83200100	Salad dressing, light, NFS
83201000	Blue or roquefort cheese dressing, light
83202020	French or Catalina dressing, light
83203000	Caesar dressing, light
83204000	Mayonnaise, light
83204030	Mayonnaise, reduced fat, with olive oil
83204050	Mayonnaise-type salad dressing, light
83204500	Honey mustard dressing, light
83206500	Sesame dressing, light
83207000	Thousand Island dressing, light
83210100	Creamy dressing, light
83300100	Blue or roquefort cheese dressing, fat free
83300200	Caesar dressing, fat free
83300300	Creamy dressing, fat free
83300400	French or Catalina dressing, fat free
83300500	Honey mustard dressing, fat free
83300700	Mayonnaise, fat free
83300900	Salad dressing, fat free, NFS
83301000	Thousand Island dressing, fat free
Minor main entree sauces (e.g., Alfredo sauce, white sauce, cheese sauce)	
13411000	White sauce or gravy
13412000	Milk gravy, quick gravy
14650100	Cheese sauce
14650150	Cheese sauce made with lowfat cheese
14650160	Alfredo sauce
27113000	Beef with cream or white sauce*
27113200	Creamed chipped or dried beef*
27113300	Swedish meatballs with cream or white sauce*
27143000	Chicken or turkey with cream sauce*
27146200	Chicken or turkey with cheese sauce*
27211500	Beef and potatoes with cheese sauce*
27212050	Beef and macaroni with cheese sauce*
27212300	Beef and noodles with cream or white sauce*

Food Code	Food Description
27213600	Beef and rice with cheese sauce*
27220170	Sausage and rice with cheese sauce*
27220520	Ham or pork and potatoes with cheese sauce*
27242300	Chicken or turkey and noodles with cream or white sauce*
27242310	Chicken or turkey and noodles with cheese sauce*
27243300	Chicken or turkey and rice with cream sauce*
27250126	Shrimp and noodles with cream or white sauce*
27250130	Shrimp and noodles with cheese sauce*
27250610	Tuna noodle casserole with cream or white sauce*
27311610	Beef, potatoes, and vegetables including carrots, broccoli, and/or dark-green leafy; cream sauce, white sauce, or mushroom sauce*
27311620	Beef, potatoes, and vegetables excluding carrots, broccoli, and dark-green leafy; cream sauce, white sauce, or mushroom sauce*
27311635	Beef, potatoes, and vegetables including carrots, broccoli, and/or dark-green leafy; cheese sauce*
27311640	Beef, potatoes, and vegetables excluding carrots, broccoli, and dark-green leafy; cheese sauce*
27315340	Beef, rice, and vegetables excluding carrots, broccoli, and dark-green leafy; cheese sauce*
27341035	Chicken or turkey, potatoes, and vegetables including carrots, broccoli, and/or dark-green leafy; cream sauce, white sauce, or mushroom sauce*
27341040	Chicken or turkey, potatoes, and vegetables excluding carrots, broccoli, and dark-green leafy; cream sauce, white sauce, or mushroom sauce*
27341045	Chicken or turkey, potatoes, and vegetables including carrots, broccoli, and/or dark-green leafy; cheese sauce*
27341050	Chicken or turkey, potatoes, and vegetables excluding carrots, broccoli, and dark-green leafy; cheese sauce*
27343470	Chicken or turkey, noodles, and vegetables including carrots, broccoli, and/or dark-green leafy; cream sauce, white sauce, or mushroom sauce*
27343480	Chicken or turkey, noodles, and vegetables excluding carrots, broccoli, and/or dark-green leafy; cream sauce, white sauce, or mushroom sauce*
27343950	Chicken or turkey, noodles, and vegetables including carrots, broccoli, and/or dark-green leafy; cheese sauce*
27345410	Chicken or turkey, rice, and vegetables including carrots, broccoli, and/or dark-green leafy; cream sauce, white sauce, or mushroom sauce*
27345420	Chicken or turkey, rice, and vegetables excluding carrots, broccoli, and dark-green leafy; cream sauce, white sauce, or mushroom sauce*
27345440	Chicken or turkey, rice, and vegetables including carrots, broccoli, and/or dark-green leafy; cheese sauce*
27345450	Chicken or turkey, rice, and vegetables excluding carrots, broccoli, and dark-green leafy; cheese sauce*
27350080	Tuna noodle casserole with vegetables, cream or white sauce*
27443110	Chicken or turkey a la king with vegetables including carrots, broccoli, and/or dark-green leafy; no potatoes, cream, white, or soup-based sauce*
27443120	Chicken or turkey a la king with vegetables excluding carrorts, broccoli, and dark-green leafy; no potatoes, cream, white, or soup-based sauce*
27446400	Chicken or turkey and vegetables including carrots, broccoli, and/or dark-green leafy; no potatoes, cheese sauce*

Food Code	Food Description
28141610	Chicken and vegetables in cream or white sauce, diet frozen meal*
28143080	Chicken with noodles and cheese sauce, diet frozen meal*
28143170	Chicken in cream sauce with noodles and vegetable, frozen meal*
28144100	Chicken and vegetable entree with noodles and cream sauce, frozen meal*
58131120	Ravioli, NS as to filling, with cream sauce*
58131330	Ravioli, meat-filled, with cream sauce*
58131535	Ravioli, cheese-filled, with cream sauce*
58131600	Ravioli, cheese and spinach-filled, with cream sauce*
58134660	Tortellini, cheese-filled, with cream sauce*
58145110	Macaroni or noodles with cheese*
58145111	Macaroni or noodles with cheese, from restaurant*
58145112	Macaroni or noodles with cheese, made from packaged mix*
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*
58145120	Macaroni or noodles with cheese and tuna*
58145135	Macaroni or noodles with cheese and meat*
58145136	Macaroni or noodles with cheese and meat, prepared from Hamburger Helper mix*
58145140	Macaroni or noodles with cheese and tomato*
58145160	Macaroni or noodles with cheese and frankfurters or hot dogs*
58145170	Macaroni or noodles with cheese and egg*
58145190	Macaroni or noodles with cheese and chicken or turkey*
58145300	Macaroni or noodles with cheese, whole grain*
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*
58146401	Pasta with cream sauce and meat, restaurant*
58146402	Pasta with cream sauce and meat, home recipe*
58146403	Pasta with cream sauce and meat, ready-to-heat*
58146411	Pasta with cream sauce, meat, and added vegetables, restaurant*
58146412	Pasta with cream sauce, meat, and added vegetables, home recipe*
58146413	Pasta with cream sauce, meat, and added vegetables, ready-to-heat*
58146421	Pasta with cream sauce and poultry, restaurant*
58146422	Pasta with cream sauce and poultry, home recipe*
58146423	Pasta with cream sauce and poultry, ready-to-heat*
58146431	Pasta with cream sauce, poultry, and added vegetables, restaurant*
58146432	Pasta with cream sauce, poultry, and added vegetables, home recipe*
58146433	Pasta with cream sauce, poultry, and added vegetables, ready-to-heat*
58146441	Pasta with cream sauce and seafood, restaurant*

Food Code	Food Description
58146442	Pasta with cream sauce and seafood, home recipe*
58146443	Pasta with cream sauce and seafood, ready-to-heat*
58146451	Pasta with cream sauce, seafood, and added vegetables, restaurant*
58146452	Pasta with cream sauce, seafood, and added vegetables, home recipe*
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*
58146702	Pasta, whole grain, with cream sauce and meat, home recipe*
58146713	Pasta, whole grain, with cream sauce, meat, and added vegetables, ready-to-heat*
58146722	Pasta, whole grain, with cream sauce and poultry, home recipe*
58146723	Pasta, whole grain, with cream sauce and poultry, ready-to-heat*
58146732	Pasta, whole grain, with cream sauce, poultry, and added vegetables, home recipe*
58146733	Pasta, whole grain, with cream sauce, poultry, and added vegetables, ready-to-heat*
58146741	Pasta, whole grain, with cream sauce and seafood, restaurant*
58147330	Macaroni or noodles, creamed, with cheese*
58147340	Macaroni or noodles, creamed, with cheese and tuna*
58164500	Rice, white, with cheese and/or cream based sauce, NS as to fat*
58164510	Rice, white, with cheese and/or cream based sauce, no added fat*
58164520	Rice, white, with cheese and/or cream based sauce, fat added*
58164800	Rice, brown, with cheese and/or cream based sauce, NS as to fat*
58164820	Rice, brown, with cheese and/or cream based sauce, fat added*
58165000	Rice, white, with vegetables, cheese and/or cream based sauce, NS as to fat*
58165010	Rice, white, with vegetables, cheese and/or cream based sauce, no added fat*
58165020	Rice, white, with vegetables, cheese and/or cream based sauce, fat added*
58165400	Rice, brown, with vegetables, cheese and/or cream based sauce, NS as to fat*
58165420	Rice, brown, with vegetables, cheese and/or cream based sauce, fat added*
58302000	Macaroni and cheese, diet frozen meal*
58303100	Rice, with broccoli, cheese sauce, frozen side dish*
58305250	Pasta with vegetable and cheese sauce, diet frozen meal*
72125230	Spinach, creamed*
72125231	Spinach, from fresh, creamed*
72125232	Spinach, from frozen, creamed*
72125250	Spinach, cooked, NS as to form, with cheese sauce*
72125253	Spinach, cooked, from canned, with cheese sauce*
72125260	Spinach and cheese casserole*
72201230	Broccoli, cooked, NS as to form, with cheese sauce*
72201231	Broccoli, cooked, from fresh, with cheese sauce*
72201232	Broccoli, cooked, from frozen, with cheese sauce*
72201250	Broccoli, cooked, NS as to form, with cream sauce*
72201252	Broccoli, cooked, from frozen, with cream sauce*
73102230	Carrots, cooked, NS as to form, creamed*

Food Code	Food Description
73102231	Carrots, cooked, from fresh, creamed*
75216153	Corn, creamed*
75340160	Vegetable and pasta combinations with cream or cheese sauce, broccoli, pasta, carrots, corn, zucchini, peppers, cauliflower, peas, etc., cooked*
75401010	Asparagus, NS as to form, creamed or with cheese sauce*
75401011	Asparagus, from fresh, creamed or with cheese sauce*
75403010	Beans, string, green, NS as to form, creamed or with cheese sauce*
75403011	Beans, string, green, from fresh, creamed or with cheese sauce*
75403012	Beans, string, green, from frozen, creamed or with cheese sauce*
75403013	Beans, string, green, from canned, creamed or with cheese sauce*
75409010	Cauliflower, NS as to form, creamed*
75409011	Cauliflower, from fresh, creamed*
75411032	Corn, cooked, from frozen, with cream sauce, made with milk*
75414010	Mushrooms, NS as to form, creamed*
75414011	Mushrooms, from fresh, creamed*
75414013	Mushrooms, from canned, creamed*
75415010	Onions, NS as to form, creamed*
75417010	Peas, NS as to form, creamed*
75417012	Peas, from frozen, creamed*
75418040	Squash, summer, casserole, with cheese sauce*
75440500	Vegetable combinations, including carrots, broccoli, and/or dark-green leafy; cooked, with cheese sauce*
75440510	Vegetable combinations, excluding carrots, broccoli, and dark-green leafy; cooked, with cheese sauce*
75450500	Vegetable combination, including carrots, broccoli, and/or dark-green leafy; cooked, with cream sauce*
75450510	Vegetable combination, excluding carrots, broccoli, and dark-green leafy; cooked, with cream sauce*
89901010	Cream sauce, for use with vegetables
89901020	Cheese sauce, for use with vegetables

Egg Products

Egg Substitutes

33000990	Egg substitute, omelet, scrambled, or fried, NS as to fat added in cooking*
33001010	Egg substitute, omelet, scrambled, or fried, fat added*
33001020	Egg substitute, omelet, scrambled, or fried, made with butter*
33001040	Egg substitute, omelet, scrambled, or fried, made with cooking spray*
33001050	Egg substitute, omelet, scrambled, or fried, no added fat*
33001200	Egg substitute, vegetable flavored, omelet, scrambled, or fried, fat added in cooking*
33001210	Egg substitute, vegetable flavored, omelet, scrambled, or fried, fat not added in cooking*
33401000	Egg substitute, omelet, scrambled, or fried, with cheese*
33401020	Egg substitute, omelet, scrambled, or fried, with cheese, NS as to fat added in cooking*
33401100	Egg substitute, omelet, scrambled, or fried, with meat*
33401200	Egg substitute, omelet, scrambled, or fried, with vegetables*

Food Code	Food Description
33401300	Egg substitute, omelet, scrambled, or fried, with cheese and meat*
33401310	Egg substitute, omelet, scrambled, or fried, with cheese and meat, fat not added in cooking*
33401400	Egg substitute, omelet, scrambled, or fried, with cheese and vegetables*
33401500	Egg substitute, omelet, scrambled, or fried, with meat and vegetables*
33401600	Egg substitute, omelet, scrambled, or fried, with cheese, meat, and vegetables*

* Only the proportion of the food mixture corresponding to food uses of bovine-identical β-lactoglobulin was included in the analysis.
** Powdered, not reconstituted powders were adjusted to the amount of prepared/reconstituted beverage.

From: Sylvester, Brian
To: Hice, Stephanie
Subject: [EXTERNAL] RE: GRN 001056 - Questions for Notifier
Date: Wednesday, October 12, 2022 11:58:26 AM
Attachments: image002.png
image003.png
image004.png
image005.png
image006.png
image021.png
Remilk Letter Responding to FDA"s 9.27.22 Questions re GRN 001056.docx
GRN 001056 - 1.10 Signature and name and title of the person signing this GRAS notice.docx

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Dear Dr. Hice,

I append Remilk's responses to the questions and comments attached to your email dated September 27, 2022. Please let us know if you have any further questions or if there is anything else we can do to help reach a satisfactory and prompt conclusion to your review of GRN 001056.

Best,

Brian

Brian P. Sylvester
Pronouns: He/Him/His

Covington & Burling LLP
One CityCenter, 850 Tenth Street, NW
Washington, DC 20001-4956
T +1 202 662-5988 | bsylvester@cov.com
www.cov.com

COVINGTON

From: Hice, Stephanie <Stephanie.Hice@fda.hhs.gov>
Sent: Tuesday, September 27, 2022 3:13 PM
To: Sylvester, Brian <BSylvester@cov.com>
Subject: GRN 001056 - Questions for Notifier

[EXTERNAL]
Dear Mr. Sylvester,

During our review of GRAS Notice No. 001056, we noted additional questions that need to be addressed and are attached to this email.

We respectfully request a response within **10 business days**. If you are unable to complete the

response within that time frame, please contact me to discuss further options. Please do not include any confidential information in your response.

If you have questions or need further clarification, please feel free to contact me. Thank you in advance for your attention to our comments.

Sincerely,

Stiffy Hice

Stephanie (Stiffy) Hice, Ph.D. (they/them/their)
Regulatory Review Scientist & Microbiology Reviewer

Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
stephanie.hice@fda.hhs.gov

Pronouns: They-Them-Their (what is this?)

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October 12, 2022

Dr. Stiffy Hice
Regulatory Review Scientist & Microbiology Reviewer
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5001 Campus Dr.
College Park, Maryland 20740

Re: Notifier's Responses to FDA's Questions Regarding GRN 001056

Dear Dr. Hice:

We are writing to respond to the questions and comments attached to your email dated September 27, 2022. Please find below Remilk's responses to your team's questions. We first set forth the FDA question, followed by Remilk's response.

Regulatory

1. In section 1.10, the notifier does not provide the name, and title of the person signing the GRAS notice (page 7). For the administrative record, please provide an updated signature page, including the missing items.

   Response:

   Please find attached an updated signature page, including the name and title of the person signing the GRAS notice.

2. On page 8, the notifier states "*P. pastoris* was reclassified in 1995 into a new phylogenetically distinct genus, *Komagataella*, and identified based on 26S rRNA sequencing data as *K. phaffii*", and on page 24, the notifier states "*P. pastoris* was re-classified in 1995 to the genus *Komagataella* following phylogenetic analysis of gene sequences". The corresponding citation describing this reclassification (listed below) was published in 2005. For the administrative record, please provide a statement that corrects the date listed in the notice.

   Kurtzman, C. (2005). Description of *Komagataella phaffii* sp. nov. and the transfer of *Pichia pseudopastoris* to the methylotrophic yeast genus *Komagataella*. International Journal of Systematic and Evolutionary Microbiology, 55, 973-976. doi: 10.1099/ijs.0.63491-0

Response:

In 1995, new insights generated by sequencing of ribosomal RNA caused all *P. pastoris* strains to be moved to a new genus, *Komagataella* (Yamada et al., 1995), and later separated into two species (Kurtzman, 2005): *Komagataella pastoris* and *K. phaffii*.

Cited:. Bernauer L, Radkohl A, Lehmayer LGK, Emmerstorfer-Augustin A. Komagataella phaffii as Emerging Model Organism in Fundamental Research. Front Microbiol. 2021 Jan 11.

3. On page 26, the notifier states "We incorporate by reference the relevant safety data on P. pastoris in the notices listed below" but does not identify or summarize the relevant information from each GRAS notice. As each GRAS notice stands on its own, for the administrative record, please briefly summarize the information incorporated by reference from the GRAS notices listed in Table 6.

Response:

Please see the updated Table 6:

Table 6: Summary of GRAS Notices for Substances Produced Using P. Pastoris Fermentation

Notifier	GRN No.	Notified Substance	Use	Relevant safety data
Diversa Corporation (Diversa)	204	Phospholipase C enzyme preparation from *Pichia pastoris* expressing a heterologous phospholipase C gene	As an enzyme in degumming vegetable oils for food use.	• Diversa relies on scientific review articles in support of its view that the safety of the production organism is the prime consideration in assessing the safety of its enzyme preparation. Diversa cites the following information to support the safe use of *P. pastoris* as a source of food ingredients: (1) ATCC classifies *P. pastoris* as Biosafety Level 1, indicating that it does not cause disease in healthy humans, (2) *P. pastoris* complies with OECD criteria for Good Industrial Large Scale Practice; (3) it has been used for the production of many proteins including proteins for pharmaceutical use; and (4) it has been reviewed for use in animal feed.
Impossible Foods	737	Soy leghemoglobin preparation from a strain of *Pichia pastoris*	For use at levels up to 0.8% soybean leghemoglobin protein to optimize flavor in ground beef	• Impossible Foods describes *P. pastoris* as a non-pathogenic, non-toxigenic, and well-characterized yeast with a history of safe use in the food industry. • Impossible Foods sequenced the *P. pastoris* production strain genome, verifying the

Notifier	GRN No.	Notified Substance	Use	Relevant safety data
			analogue products intended to be cooked.	sequence of the inserted DNA and confirming the production strain does not contain antibiotic resistance genes. • Impossible Foods commissioned analyses of the 17 most abundant *P. pastoris* proteins using the sequence alignment-based method and found that the 17 analyzed *P. pastoris* proteins do not contain significant amino acid sequence homology to known or putative allergens or toxins. • Impossible Foods states that a literature search (of published literature) did not identify information that suggested allergic, toxic, or adverse health effects related to consumption of *P. pastoris* proteins.
Motif FoodWorks, Inc.	1001	Myoglobin preparation from a strain of *Pichia pastoris* expressing the myoglobin gene from *Bos taurus*	To impart flavor and aroma at levels up to 2% myoglobin in ground meat and poultry analogue products.	• Motif states that its *P. pastoris* production strain is a non-pathogenic, non-toxigenic, well-characterized methyltrophic yeast with a history of safe use in the food industry. • Motif states that the lack of toxigenicity of *P. pastoris* proteins has been discussed in the published literature. Motif reasons that, because its production strain is derived from a safe host strain lineage that is described in the published literature, the small concentrations of residual *P. pastoris* proteins present in the ingredient do not pose a safety concern in terms of toxicity or allergenicity.

4. In Table 6, the notifier lists three GRAS notices, where the subject of the notice was a substance produced by a strain of *K. phaffii*, that have been submitted to FDA and have received "no questions" letters (page 26). We evaluated GRN 000967 and responded in a letter dated September 9, 2021, stating that we had no questions at the time regarding the notifier's GRAS conclusion. For the administrative record, please briefly discuss GRN 000967 in the context of the notifier's safety conclusion.

   Response:

   Please see the table below:

Notifier	**GRN No.**	**Notified Substance**	**Use**	**Relevant safety data**
Clara Foods Co.	GRN 967	Non-Animal Soluble Egg White Protein produced by *Pichia pastoris*	Can be used as a replacement for plant and animal-derived proteins currently consumed in foods.	• Clara states that *K. phaffii* GSD-1209 is non-pathogenic and non-toxigenic, and is deposited in the strain collection of the American Type Culture Collection (ATCC) in Manassas, VA with the deposit designation GSD-1209. • Clara also confirms that the production organism does not contain any antibiotic-resistant genes. • Clara further states that the production organism does not contain vector plasmid sequences and, therefore, is not capable of DNA transfer to other organisms.

Chemistry and Microbiology

1. Please provide the CAS registry number for β-lactoglobulin produced by *K. phaffii* strain "yRMK-66".

   Response:

   9066-45-9

2. In section 6.1.1, the notifier describes the safety of the parental strain, *K. phaffii* strain CBS 7435 (pages 24-27). For the administrative record, please state whether the production strain, *K. phaffii* strain "yRMK-66", is non-pathogenic and non-toxigenic.

   Response:

   The production strain, *K. phaffii* strain "yRMK-66," is non-pathogenic and non-toxigenic. This is because (1) the parental strain is non-pathogenic and non-toxigenic, and (2) the introduced DNA encoding for beta-lactoglobulin (and the resulting beta-lactoglobulin protein) is non-pathogenic and non-toxigenic.

3. For the administrative record, please provide a brief description of the production strain including phenotypic characteristics (e.g., production of antimicrobials, production of secondary metabolites), and whether this poses a safety concern.

   Response:

   The notifier describes the production strain in sections 2.1.3 and 6.1.2 of the GRAS notice. Turning to phenotypic characteristics, the notifier confirms that neither the parental strain nor the yRMK-66 contain antimicrobial genes. Both strains produce common *Pichia* metabolites. *K. phaffii* and other yeasts are not known for producing antibiotics or toxic secondary metabolites.

   Yeasts, in general, are not known to make antibiotics (I. C. MacWilliams, 1959)[1] and the Phaff Yeast Culture Collection (UC Davis) holds over 7500 strains of yeast, none of which are known to produce antibiotics.[2]

   As discussed in section 6.1.1 of the GRAS notice, *P. pastoris* itself has been approved by FDA as a source of animal feed protein for use in broiler feed up to 10% of the total feed (FDA, 1993). As also discussed in section 6.1.1 of the GRAS notice -- per FDA's review in 1993 -- toxicity studies done in support of the above-referenced *P. pastoris*-approved animal feed (including a pathogenicity study in mice, an acute oral toxicity study in rats,

[1] MacWilliams, I. C. 1959. A survey of A survey of the antibiotic powers of yeasts. J. Gen. Microbiol. 21: 410-414.

[2] https://phaffcollection.ucdavis.edu/searchable-fields-strain-database#8.

a subacute oral toxicity study in rats, and a two-generation teratology study in rats) also demonstrated that *P. pastoris* is neither pathogenic nor toxigenic.

4. Please state whether *K. phaffii* strain "yRMK-66" has been deposited in a recognized culture collection and provide the deposit designation.

   Response:

   No. The proprietary strain has not been deposited in a culture collection.

5. Please state whether the genome of *K. phaffii* strain "yRMK-66" has been sequenced.

   Response:

   Yes, Remilk performed whole genome sequencing (WGS) for the *K. phaffii* strain "yRMK-66."

6. On page 27, the notifier describes the introduction cassette. Please clarify whether any other genes (apart from the β-lactoglobulin gene) are present on the cassette. If other genes are present, please provide the description of the genes (e.g., source, identity, function).

   Response:

   Yes. Two auxotrophic marker genes encoding *K. phaffii* ARG and HIS were inserted as complementation genes in the cassette. In terms of function, both ARG and HIS are complemented and thus do not carry any effect on the cell.

7. Please state whether the β-lactoglobulin donor gene is *de novo* synthesized. Additionally, please specify the copy number and whether all copies of the β-lactoglobulin gene are integrated into the genome in tandem.

   Response:

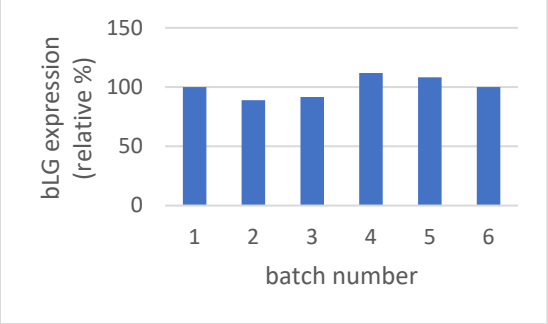
   Yes. The β-lactoglobulin donor gene is *de novo* synthesized.

   The strain contains 6 gene copies of β-lactoglobulin. The copies are not integrated in tandem.

8. On page 28, the notifier states, "β-lactoglobulin gene has been inserted into *Komagataella phaffii* genome and its integration stability was assessed by reverse transcription-quantitative PCR (RT-qPCR). Figure 4 below, displays confirmation of constant β-lactoglobulin gene copy levels over the course of three independent fermentation processes". For the administrative record, please briefly describe whether stability of β-lactoglobulin production is further assessed (e.g., generational stability).

   Response:

   The stability of β-lactoglobulin production is further assessed through a colorimetric quantification assay. Beta lactoglobulin production is measured for each production batch. The expression levels are similar between different batches, indicating that the β-lactoglobulin production is stable. The chart below shows the relative protein expression level at the end of fermentation for six consecutive batches.



9. For the administrative record, please state whether *K. phaffii* strain "yRMK-66" is capable of DNA transfer to other organisms.

   Response:

   No. The strain does not contain vector plasmid sequences and therefore is not capable of DNA transfer to other organisms.

10. For the administrative record, please briefly specify how the purity of *K. phaffii* strain "yRMK-66" is ensured.

    Response:

    The production strain master and working banks are prepared under sterile conditions (in biological hood) and tested for microbial purity by plating and observing the morphology of the resulting colonies.

11. In Table 2, based on the batch analyses, the notifier states that the specification for β-lactoglobulin purity is ≥ 80% of the total protein content (page 12). On page 28, the notifier further states "Residual *K. phaffii* proteins that were identified by the presence of at least two peptides with > 0.001% of the total protein content are listed in the LCMS/MS analysis report". Please confirm that the remaining balance of proteins present in the final article of commerce is only comprised of residual *K. phaffii* proteins and discuss whether these proteins pose a safety concern.

    Response:

    Yes, the remaining balance of proteins present in the final article of commerce is only comprised of residual *K. phaffii* proteins, which do not pose a safety concern.

    The notifier would like to first clarify that the specification of β-lactoglobulin purity at ≥ 80% does not represent the actual levels found in production. Instead, ≥ 80% represents the minimum amount that will meet our specifications. Indeed, as the agency pointed out, when we analyze the actual batch using LC-MS/MS, the analysis showed that β-lactoglobulin was the dominant protein with >99.4% of the total abundance of the identified proteins. Residual *K. phaffii* proteins that were identified by the presence of at least two peptides with > 0.001% of the total protein content are listed in the LC-MS/MS analysis report attached as Appendix 2.

    The notifier hereby confirms that the remaining balance of proteins present in the final article of commerce is only comprised of residual *K. phaffii* proteins. These *K. phaffii* proteins do not pose a safety concern. As discussed in Table 6 of the GRAS notice and in response to Questions 2 and 3, above, *K. phaffii* (previously known as *Pichia pastoris* or *P. pastoris*) has a long history of safe use in food production. The *P. pastoris* expression system has gained acceptance as an important host organism for the production of foreign proteins. *P. pastoris* has been safely used for the production of over 300 recombinant proteins since the mid-1980s and fulfills the criteria of several safety evaluations. In addition, FDA's GRAS Notice Inventory lists at least 4 successful notices involving use of *P. pastoris* that have received "no questions" letters from the FDA.

12. Please provide an updated literature search including the date (month and year) the literature search was performed and discuss the safety of *K. phaffii*.

    Response:

    An updated literature search was performed on October 3, 2022. The following papers issued during the last year are relevant for the safety of the different novel products produced using *K. phaffii*.

    1. *Safety and efficacy of the feed additive consisting of 6-phytase (produced by Komagataella phaffii CGMCC 7.19) (Nutrase P) for chickens for fattening, other poultry for fattening or reared for laying and ornamental birds (Nutrex N.V.).* EFSA J. 2022 Jun 7;20(6):e07343. doi: 10.2903/j.efsa.2022.7343. eCollection 2022 Jun.

EFSA was asked to deliver a scientific opinion on the safety and efficacy of 6-phytase produced by a genetically modified strain of *Komagataella phaffii* (CGMCC 7.19) (Nutrase P) for chickens for fattening, other poultry for fattening or reared for laying, and ornamental birds. The Panel concluded that the additive, in any formulations, does not pose any safety concern with regard to the production strain.

2. *Safety and efficacy of a feed additive consisting of endo-1,4-β-xylanase produced by Komagataella phaffii ATCC PTA-127053 (Xygest™ HT) for poultry (Kemin Europa N.V.).* EFSA J. 2022 Jul 21;20(7):e07439. doi: 10.2903/j.efsa.2022.7439. eCollection 2022 Jul.

   EFSA was asked to deliver a scientific opinion on the safety and efficacy of endo-1,4-β-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 (Xygest™ HT) as a zootechnical feed additive for poultry. The production strain is genetically modified. The Panel concluded that the additive does not pose any safety concern regarding the production strain.

3. *Safety and efficacy of a feed additive consisting of endo-1,4-β-xylanase produced by Komagataella phaffii DSM 33574 (Xylamax) for chickens and turkeys for fattening, chickens reared for laying/breeding, turkeys reared for breeding and minor poultry species for fattening or raised to the point of lay (BioResource international, Inc.).* EFSA J. 2022 Jul 25;20(7):e07428. doi: 10.2903/j.efsa.2022.7428. eCollection 2022 Jul.

   The EFSA Panel on Additives and Products of Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of the product containing endo-1,4-β-xylanase produced by *Komagataella phaffii* DSM 33574 (Xylamax) as a zootechnical additive in chickens for fattening, chickens reared for laying/breeding, turkeys for fattening, turkeys reared for breeding, and minor poultry species for fattening or raised to the point of lay. The production strain is genetically modified. The Panel concluded that the additive does not pose any safety concern regarding the production strain. Considering the production strain and the results obtained in the genotoxicity studies, the Panel concluded that the additive is safe for the consumers.

13. In Table 1, the notifier lists the following reference methods to establish the specifications for β-lactoglobulin: protein content (AOAC 968.06, AOAC 992.15, AOAC 984.13), moisture (AOAC 926.08, AOAC 925.09, AOAC 935.29), ash (AOAC 923.03, AOAC 942.05), fat (AOAC 989.05, AOAC 932.05, AOAC 986.25), and *Enterobacteriaceae* (AOAC 2003.01) (page 11). In Appendix 1, the listed reference methods for analyzing these components are different. For the administrative record, please clarify these discrepancies.

    Response: The notifier has updated Table 1, below, to include all the relevant methods. The listed reference methods noted in Table 1 are intended to capture potential variations that the notifier anticipates across labs in multiple jurisdictions. In other words, the methods noted in Table 1 represent the internationally recognized standards

for testing the enumerated elements and any lab's local method (and results generated therefrom) is expected to be consistent with the methods listed in Table 1.

Analysis	**Specification**	**Reference Method**
Protein (Dumas/Kjeldahl)	≥70 wt%	AOAC 968.06, AOAC 992.15, AOAC 984.13, AOAC 955.04, AOCS Ac 4-91
β-Lactoglobulin as % of Protein	≥80 %	HPLC
Moisture	≤7 wt%	AOAC 926.08, AOAC 925.09, AOAC 935.29, AOAC 925.45
Ash	≤4 wt%	AOAC 923.03, AOAC 942.05
Fat	≤4 wt%	AOAC 989.05, AOAC 932.05, AOAC 986.25, AOAC 945.48B
Total Carbohydrates	≤20 wt%	By difference
pH	5.0-7.5	AOAC 981.12, AOAC 945.27, AOAC 943.02
Arsenic	≤0.1 ppm	IPC/ICP-MS
Cadmium	≤0.1 ppm	IPC/ICP-MS
Lead	≤0.1 ppm	IPC/ICP-MS
Mercury	≤0.1 ppm	IPC/ICP-MS
Total Aerobic Count	≤10,000 CFU/g	AOAC 966.23, FDA BAM Chapter 3, CMMEF Chapter 8
Yeast	≤50 CFU/g	FDA BAM Chapter 18
Mold	≤50 CFU/g	FDA BAM Chapter 18
Enterobacteriaceae	≤10 CFU/g	AOAC 2003.01, ISO:21528, CMMEF Chapter 8

14. In Table 1, the notifier lists specifications for microorganisms, including *Enterobacteriaceae*, but does not provide specifications for notable foodborne pathogens, such as *Salmonella* serovars (page 11). On page 32, the notifier states that "Potential contaminants, such as … pathogenic microbes, are … absent (not detected)". While *Salmonella* is a member of the *Enterobacteriaceae* family, the referenced method used to enumerate *Enterobacteriaceae* is for the family, generally, and is not for a specific analysis of a particular pathogen (e.g., *Salmonella* serovars). For the administrative record, please clarify this discrepancy. Additionally, please clarify if further analysis is performed to identify the genera or species of any presumptive positive result from analysis of *Enterobacteriaceae*. If further analysis is not performed, please describe why analysis for *Enterobacteriaceae* is sufficient (and other methods employed during the manufacturing process to control for the presence of microorganisms).

Response:

Table 1 lists specifications for microorganisms, including *Enterobacteriaceae*. The test method noted for *Enterobacteriaceae* is meant to detect any foodborne pathogens comprising the *Enterobacteriaceae* family including, for example, *Salmonella*, and presence of *Enterobacteriaceae* in levels higher than the specifications (higher than the LOD of the method) would result in batch rejection. In practice, *Salmonella* is regularly tested at present during routine production. The notifier includes a full list of the foodborne pathogens Remilk now tests for under current specifications, and the table below supplements Table 1 of GRN 1056:

Parameter	Specification	Reference method
Salmonella	Absent in 25g	AOAC 2011.03, FDA BAM Chapter 5
Listeria Monocytogenes	Absent in 25g	AOAC 2004.02, ISO:11290
S.aureus	≤10 CFU/g	FDA BAM Chapter 12, ISO:6888

15. Please state whether all analytical methods used to analyze the batches for conformance with the stated specifications have been validated for that particular purpose.

Response:

All analytical methods used to analyze the batches for conformance with the stated specifications have been validated for that particular purpose.

Toxicology

1. Please confirm whether the amino acid sequence of the β-lactoglobulin from *K. phaffii* strain "yRMK-66" is 100% identical to the bovine β-lactoglobulin sequence with the UniProt accession number P02754, as this sequence was used in the allergenicity analysis. Alternatively, the notifier may provide the pairwise alignment data comparing their β-lactoglobulin sequence from *K. phaffii* strain "yRMK-66" with the bovine β-lactoglobulin sequence from the UniProt database (accession number P02754).

   Response:

   Confirmed. The sequence of the β-lactoglobulin from *K. phaffii* strain "yRMK-66" is 100% identical to the bovine β-lactoglobulin sequence with the UniProt accession number P02754.

* * *

We trust that this responds to your questions and comments. Please let us know if you have any further questions or if there is anything else we can do to help reach a satisfactory and prompt conclusion to your review of GRN 001056.

Sincerely,

Brian P. Sylvester

1.10. Signature and name and title of the person signing this GRAS notice:

Brian P. Sylvester
Special Counsel
Covington & Burling LLP

Date: March 4, 2022

From: Sylvester, Brian
To: Hice, Stephanie
Subject: [EXTERNAL] RE: GRN 001056 - Questions for Notifier
Date: Wednesday, November 30, 2022 10:29:03 AM
Attachments: image002.png
image003.png
image004.png
image005.png
image006.png
image021.png

Dear Dr. Hice,

Thank you for your email. I write on behalf of Remilk Ltd. to confirm that AOAC 932.06 corresponds to the analysis of fat in dried milk. This clarification amends Remilk's response to Question 13 in the Company's October 12, 2022 amendment to the notice.

Best,
Brian

Brian P. Sylvester
Pronouns: He/Him/His

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From: Hice, Stephanie <Stephanie.Hice@fda.hhs.gov>
Sent: Tuesday, November 29, 2022 8:42 AM
To: Sylvester, Brian <BSylvester@cov.com>
Subject: RE: GRN 001056 - Questions for Notifier

[EXTERNAL]
Dear Mr. Sylvester,

During our review of GRAS Notice No. 001056, we noted an additional question that needs to be addressed and is below:

In the October 12, 2022 amendment to the notice, in response to question 13, the notifier identifies AOAC 932.05 as one of the methods used for the analysis of fat. AOAC 932.05 corresponds to the analysis of citric acid in milk. We note that AOAC 932.06 corresponds to the analysis of fat in dried milk. For the administrative record, please clarify this discrepancy.

We respectfully request a response within **10 business days**. If you are unable to complete the response within that time frame, please contact me to discuss further options. Please do not include any confidential information in your response.

If you have questions or need further clarification, please feel free to contact me. Thank you in advance for your attention to our comment.

Sincerely,

Stiffy Hice

Stephanie (Stiffy) Hice, Ph.D. (they/them/their)
Regulatory Review Scientist & Microbiology Reviewer

Division of Food Ingredients
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Pronouns: They-Them-Their (what is this?)