GRAS Notification for Distarch Phosphate Modified Food Starch

Part 1 – Signed statements and certification

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

We submit this GRAS notification in accordance with 21 C.F.R. Part 170, Subpart E.

2. Name and address of the notifier

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USA

All communications on this matter are to be sent to Counsel for the Notifier

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3. Name of notified substance

Distarch phosphate modified food starch

Other common or usual names include: Food starch-modified, modified food starch, resistant starch, resistant food starch-modified, resistant modified food starch, distarch phosphate.

We will refer to Distarch Phosphate modified food starch as "DSP" throughout the document. DSP is sold under the brand name PenFibe® RS and/or Versafibe®.

4. Applicable conditions of use of the notified substance

(a) Foods in which the substance is to be used

The ingredient is to be used in bread, pancakes/waffles, nutrition bars, ready-to-eat (RTE) cereal, muffins, tortillas, pretzels, dry uncooked plain pasta, and meal

replacements excluding meat products, poultry products, and infant formula. These nine food categories are the most common use applications for this ingredient.

(b) Levels of use in such foods

DSP is to be used in the following food categories: bread, pancakes/waffles, nutrition bars, ready-to-eat (RTE) cereal, muffins, tortillas, pretzels, dry uncooked plain pasta, and meal replacements. The use of ingredient is limited by the level that can technically be added to a given food without jeopardizing its quality and consumer acceptability. Further, use is limited by the cost of the substance; food manufacturers will generally only use the amount necessary for it to contribute a meaningful amount of fiber per serving of the finished food product, which is 3.5 – 7.0 grams per serving or an average of 5 grams per serving. Use levels as a thickener or texturing agent may be similar to or lower than the fiber uses.

(c) Purpose for which the substance is used

The ingredient is used as a source of dietary fiber[1], and for other functional uses such as a thickener or texturizing agent.

(d) Description of the population expected to consume the substance

The population expected to consume the ingredient consists of members of the general population who consumer at least one of the products described above.

5. Basis for the GRAS determination

Keller and Heckman LLP, on behalf of Ingredion, hereby notifies the Agency of its determination that DSP is GRAS based on scientific procedures in accordance with 21 C.F.R. §170.30(a) and (b), and conforms to the guidance issued by the Food and Drug Administration (FDA) under 21 C.F.R. §170.36, 81 Fed. Reg. 54960 (Aug. 17, 2016). The GRAS determination has also been evaluated by experts qualified by scientific training and experience to assess the safety of DSP under the conditions of its intended use in food. The GRAS Expert Panel Report is available at Appendix III. It is respectfully submitted that this Notification establishes GRAS status for DSP for use in food based on the published safety data on DSP and other type 4 resistant starches.

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[1] We understand that as an isolated or synthetic non-digestible carbohydrate FDA will have to review whether the substance has a beneficial physiological effect on human health before it can be considered a dietary fiber under 21 C.F.R. §101.9(c)(6)(i). See 81 Fed. Reg. 33741 (May 27, 2016). Keller and Heckman on behalf of Ingredion has submitted comments in response to FDA's Scientific Review setting forth the beneficial physiological effects of distarch phosphate modified food starch.

6. Exclusion from premarket approval

The notified substance is not subject to the premarket approval requirements of the FD&C Act based on our conclusion that the notified substance is GRAS under the conditions of its intended use.

7. Availability of data and information

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

8. Applicability of FOIA exemptions

None of the data and information in Parts 2 through 7 of this GRAS Notification are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552.

9. Certification

We certify that, to the best of our knowledge, our GRAS notification is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information known to us and pertinent to the evaluation of the safety and GRAS status of the use of the substance.

(b) (6)

Name: Melvin S. Drozen
Title: Partner

5/11/17
Date: May 11, 2017

(b) (6)

Name: Evangelia C. Pelonis
Title: Partner

5/11/17
Date: May 11, 2017

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

1. Identity of the notified substance

(a) Chemical name

Chemical Name:	Distarch Phosphate
Synonyms:	Resistant Starch Type 4; RS4

(b) Chemical Abstracts Service (CAS) Registry Number

CAS No.: 55963-33-2

(c) Structural formula

Figure 1. Structural Formula for Starch

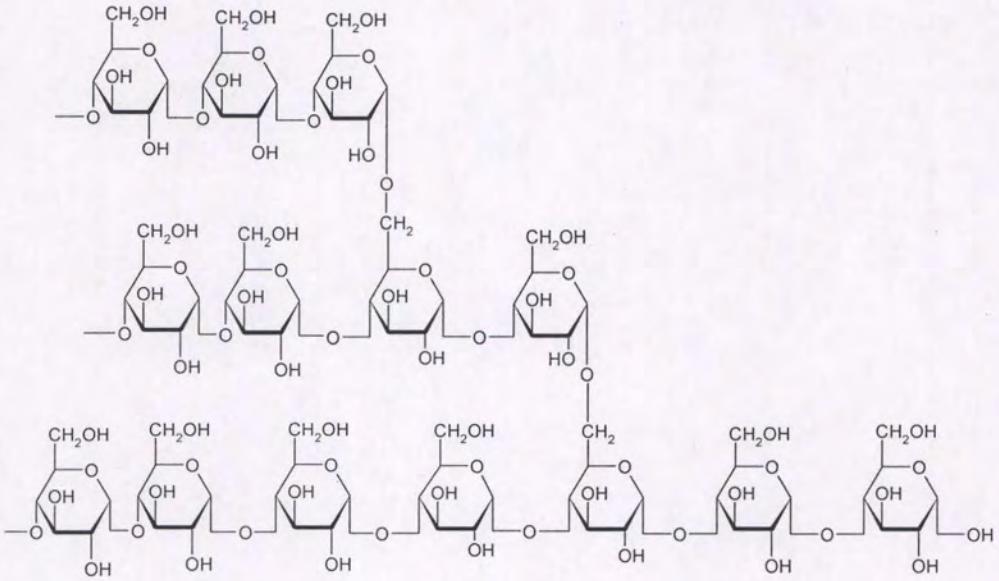
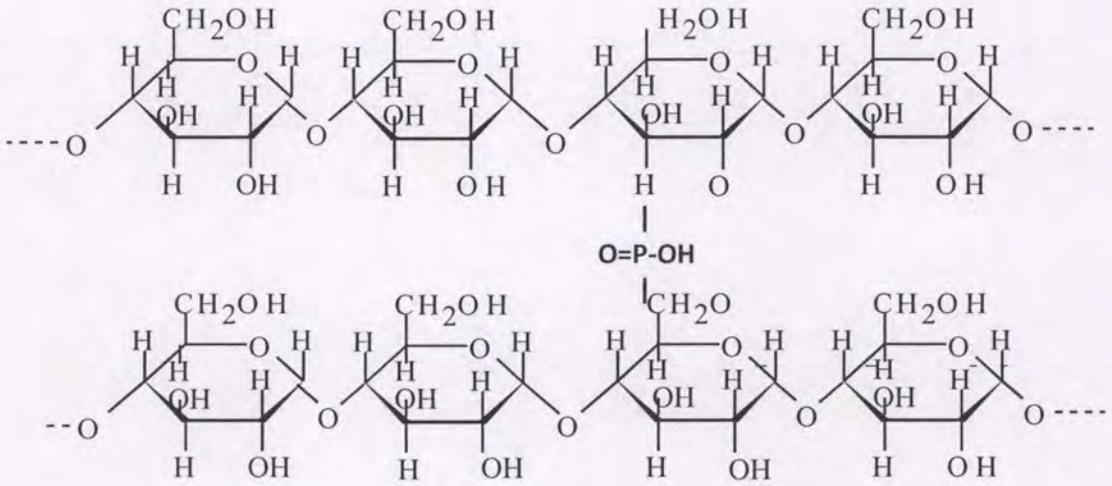


Figure 2. Structural Formula for Distarch Phosphate



(d) Characteristic properties

DSP is food starch that has been modified using phosphorus oxychloride ($POCl_3$). DSP is resistant to digestion, and is by chemical structure one of a class of phosphated starch products referred to as distarch phosphate, a form of starch that contains esterified phosphate crosslinks. Potato starch has the approximate composition: amylopectin 75-80%; amylose 20-25%; ash 0.35%; nitrogen, trace; and fat, practically none. Potato and wheat starch are unusual, relative to starch from other foods, in that they contain 0.06-0.10% phosphorus. Phosphorus is present as dihydrogen orthophosphate groups esterified to the amylopectin fraction.[2] DSP contains up to 0.5% total phosphorus resulting from the combination of additional phosphorylation with $POCl_3$, which is approximately 0.4%, plus the phosphorus naturally occurring in potato and wheat starch, which is approximately 0.1%.

DSP can be used to increase total dietary fiber of food products. It is bland in flavor and cannot be detected organoleptically in most applications. DSP contains at least 85% insoluble total dietary fiber analyzed on the dry solids basis (dsb). It contributes minimal viscosity to processed foods. Modification of the food starch results in crosslinking of starch polymers with phosphate groups and the presence of starch phosphate esters on the external surface of the starch granules.

Previous safety evaluations of DP products and phosphated DP, where additional monophosphate esters are added to the surface of the starch, have inferred the

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[2] Treadway, R. H. (1967). Manufacture of potato starch. R. L. Whistler and E. F. Paschall, eds. Starch: Chemistry and Technology, Vol. II, Academic Press, New York, at 87-101.

presence of phosphodiester crosslinks based on indirect evidence.[3] For example, crosslinking has a dramatic effect on the viscosity profile of starch. Starch that is susceptible to changes in viscosity after prolonged heating, high shear, or acidic conditions shows a stable viscosity profile over time once it is crosslinked. Crosslinked starch is sometimes referred to as "inhibited" starch because crosslinking inhibits swelling during cooking. Starch that is lightly crosslinked tends to show a peak viscosity that is actually higher than that of its native unmodified starch. The key benefits of crosslinking are stability and improved paste texture; the normally cohesive, gummy consistency associated with native waxy corn starch is eliminated, and a smooth, salve-like texture is produced. In general, as the level of crosslinking increases, the starch becomes more resistant to the changes generally associated with cooking and pasting.

More recently, Kasemsuwan and Jane reported direct evidence for phosphodiester bonds that crosslink starch after treatment with $POCl_3$ or sodium trimetaphosphate has been obtained using nuclear magnetic resonance.[4] The authors found that starch crosslinked with $POCl_3$ contained almost no detectable monophosphate esters, thus demonstrating the high selectivity of this reagent for producing only distarch phosphate.

(e) Any known toxicants that could be in the source

Microbiological controls are incorporated in the DSP manufacturing process to ensure that the substance is free of pathogenic or other objectionable organisms or unwanted microbial metabolites, and that DSP is otherwise suitable for its intended use. The production methods are consistent with current U.S. good manufacturing practices (cGMP) at 21 C.F.R. Part 110. The ingredient also does not contain more than 1 mg/kg lead consistent with the Food Chemicals Codex (FCC) monograph for Food Starch, Modified.

2. Description of method of manufacture

DSP is made from raw food starch such as potato, corn, tapioca, wheat or any other food grade starch source that is blended into a slurry and maintained at a temperature of 59-75°F. Sodium chloride or sodium sulfate is added to the slurry followed by the addition of sodium hydroxide until the pH of the slurry is 11.4-11.6. Treatment with up to 4.5% phosphorus oxychloride is added to the slurry while maintaining a pH of 11.4-11.6 by the addition of a sodium hydroxide solution. After the phosphorylation step is complete, the

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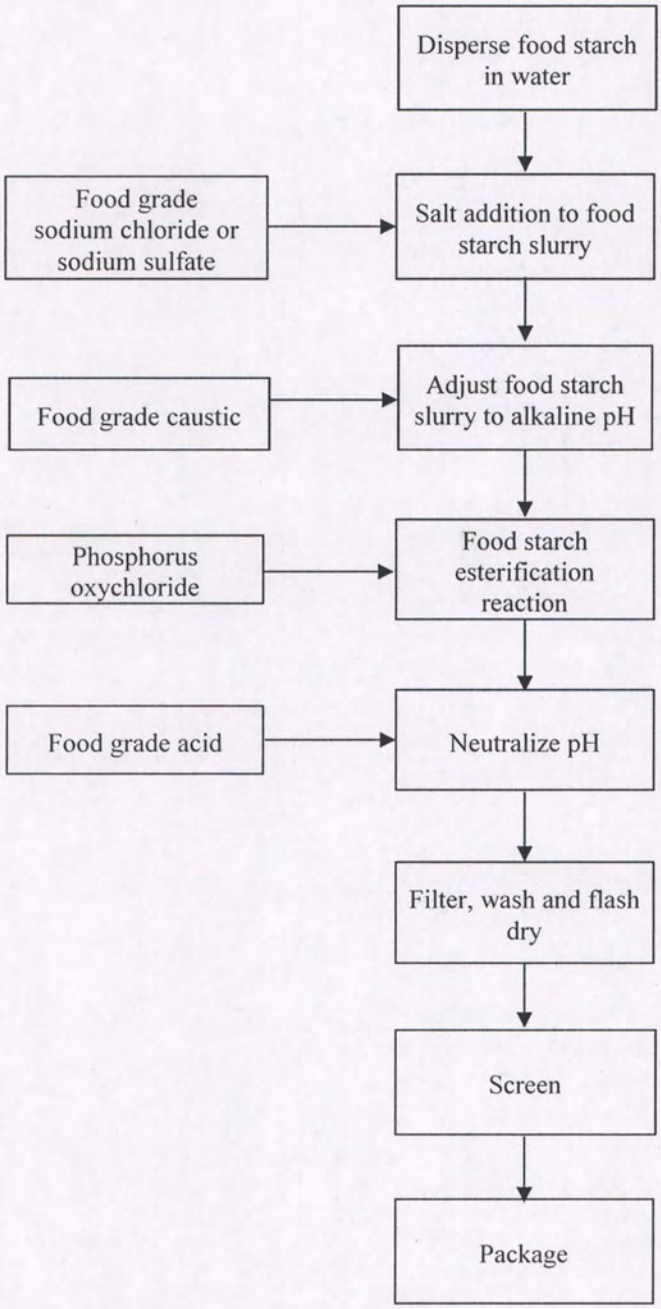
[3] SCOGS (1979). Evaluation of the Health Aspects of Starch and Modified Starches as Food Ingredients. Contract No. FDA 223-75-2004. Life Sciences Research Office, Federation of American Societies for Experimental Biology.

[4] Kasemsuwan, T. and Jane, J. J. (1994). Location of Amylose in Normal Starch Granules II and Locations of Phosphodiester Cross-Linking Revealed by Phosphorus-31 Nuclear Magnetic Resonance, Cereal Chemistry, 71 at 282-287.

pH is lowered to 5.5 with hydrochloric acid, sulfuric acid or other food grade acids. The starch is washed on a filter drum and flash dried to a moisture content of 10-13 percent. A typical flow chart for the manufacture of DSP is shown in Figure 3 below.

Figure 3. Distarch Phosphate Process Flow Diagram



3. Specifications for food-grade material

The specifications of DSP are provided in Table 1 below. Six non-consecutive lots of DSP were analyzed to confirm that the product is consistently produced; these results are reported in Table 2 below. DSP conforms to the finished ingredient specifications set forth in the Food Chemicals Codex (FCC) monograph for Food Starch, Modified.

Table 1. Specification for DSP Modified Food Starch

	Method	Typical Analysis
pH	Internal method	5.5-7.5
Moisture	Internal method	16% max
Phosphorus[5]	AOAC 2011.14	0.5% max
Particle size - % on U.S.S. 100	Internal method	2.0% max
Total Dietary Fiber	AOAC 991.43	85% min (dry solids basis)
Ash	Internal method	2.0% max
Total plate count	USP Chapter 61	10,000 cfu/g max
Yeast	USP Chapter 61	200 cfu/g max
Mold	USP Chapter 61	200 cfu/g max

[5] Not more than 0.40% phosphorus in the finished modified food starch as a result of the manufacturing process; there is an additional 0.10% naturally occurring phosphorus from the potato and wheat starch for a total maximum of 0.50% phosphorus.

Table 2. Analysis of Six Non-Consecutive Lots of DSP Modified Food Starch

	Specification	Lot No. A	Lot No. B	Lot No. C	Lot No. D	Lot No. E	Lot No. F
pH	5.5-7.5	7.17	6.97	7.11	6.93	7.01	6.92
Moisture[6] (%)	16% max	13.65	13.65	13.01	13.64	13.06	12.89
Bound Phosphorus(% dry basis)	0.5% max	0.50	0.50	0.50	0.50	0.44	0.47
Particle size (% on #100)	2% max	0.09	0.05	0.09	0.04	0.05	0.04
Total Dietary Fiber (%)	85% min	98.89	100	100	100	96.15	100
Ash (%)	2.0% max	1.64	1.72	1.70	1.96	1.58	1.80
Total plate count (cfu/g)	10000 cfu/g max	360	140	20	50	220	220
Yeast (cfu/g)	200 cfu/g max	10	10	<10	20	10	20
Mold (cfu/g)	200 cfu/g max	10	10	10	<10	10	10

Ingredion has also generated information on the composition of the DSP from six non-consecutive lots of product. This provides further information on the typical levels of fiber, phosphorus, moisture, ash, fat, protein and lead.

Table 3. Compositional Analysis of Six Non-Consecutive Lots of DSP Modified Food Starch

	Lot No. A	Lot No. B	Lot No. C	Lot No. D	Lot No. E	Lot No. F
Total Carbohydrate (dry basis)* by difference	84.62	84.55	85.19	84.32	85.27	85.23
Total Dietary Fiber (dry solids basis)**	98.89	100	100	100	96.15	100
Phosphorus (%)***	0.50	0.50	0.50	0.50	0.44	0.47
Moisture (%)	13.65	13.65	13.01	13.64	13.06	12.89
Ash (%)	1.64	1.72	1.70	1.96	1.58	1.80

Fat (%)	0.01	0.01	0.02	0.01	0.02	0.01
Protein (%)	0.08	0.07	0.08	0.07	0.07	0.07
Lead (mg/kg)****	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10

*Total composition of Distarch Phosphate accounted for by addition of percent moisture, ash (includes phosphorus & lead), fat and protein and carbohydrate (determined by percent difference from 100%).
**Total dietary fiber expressed as percent of total carbohydrate.
***Not more than 0.40% phosphorus in the finished modified food starch as a result of the manufacturing process; there is an additional 0.10% naturally occurring phosphorus from the potato and wheat starch for a total maximum of 0.50% phosphorus
****Lead is not included as a product specification, however, the lead analysis is based on data from audit testing.

4. Data and information bearing on physical or other technical effect

Ingredion has confirmed that DSP produced using up to 4.5% $POCl_3$ is highly resistant to digestion, based on the *in vitro* Englyst procedure. Further, the additional crosslinking of DSP created by using a higher level of $POCl_3$ treatment results in a significant decrease in the portion of the product that is digestible. Compared to product produced with 0.1% $POCl_3$ the quantity of starch in DSP that is not digestible is increased from 88% to 97%.

Ingredion evaluated the relative digestibility of uncooked, granular native, potato starch (PenPure® 10), modified potato starch (PenBind® 1381 and PenBind® 196),[6] and resistant potato starch (PenFibe® RS). As summarized in Table 4 below, PenPure® 10, PenBind® 1381 and PenBind® 196 showed similar *in vitro* digestion profiles. All three lots of PenFibe® RS showed similar *in vitro* digestion profiles to one another. *In vitro* glycemic response at 20 minutes was similar for the native and modified potato starches. *In vitro* glycemic response at 120 minutes was higher for the PenPure® 10 native potato starch, PenBind® 1381 and PenBind® 196 modified potato starches versus the PenFibe® RS.

Table 4. *In vitro* Digestion as Glucose Release for Penford Potato Starches by the Modified Englyst Method†

Ingredient	**Moisture** (%)	***In vitro* glycemic response** (%)			**Rapidly digested starch** (% db)	**Slowly digested starch** (% db)	**Resistant starch** (% db)
		20 min.	120 min.	240 min.			
PenPure® 10	12.4	3.1	12.0	26.0	3.1	8.8	88.1
PenBind® 1381	16.5	3.1	12.4	23.3	3.1	9.8	87.6
PenBind® 196	11.4	3.3	11.8	20.3	3.3	8.5	88.2

[6] PenBind® 196 and PenBind® 1381 are potato starch treated with phosphorus oxychloride within the treatment limitation of not more than 0.1% listed under 21 C.F.R. §172.892, food starch-modified.

PenFibe® RS	12.6	1.2	3.1	3.7	1.2	1.9	96.9
PenFibe® RS	9.9	0.6	3.2	6.6	0.6	2.6	96.8
PenFibe® RS	13.5	0.8	4.0	6.5	0.8	3.2	96.0

† Internal test measurement error for the Modified Englyst method is ±2 at T=20 and ±4 at T=120 and T=240 established for dent (native) corn starch (Melojel®). Percent dried basis is abbreviated % db.

The *in vitro* digestion study was performed on un-swollen, granular starches. Granular starch is the native form of starch as it is extracted from the source such as corn, or potato in this instance. The granular starch undergoes $POCl_3$ chemical treatment to produce a modified food starch. The unmodified, or native granular potato starch (PenPure® 10), lightly $POCl_3$ crosslinked modified potato starches (PenBind® 1381 and PenBind® 196), and PenFibe® RS samples were all exposed to enzyme digestion by the modified Englyst method. The digestion results show that all the granular starches tested have some degree of inherent resistance to digestion with the PenFibe® RS samples exhibiting the highest resistance. Food applications that utilize unmodified and modified food starches invariably undergo a heat processing as either a kill step or part of the preparation process, such as baking. Heat treatment intentionally causes granular unmodified and modified food starches to swell due to absorption of water from the food matrix resulting in a desired textural outcome. The PenPure® and PenBind® products would swell under typical food heating conditions to contribute viscosity or texture to the final food. PenFibe® RS would not swell to any appreciable extent under normal food processing conditions due to the extensive crosslinking. Thus PenFibe® RS is typically used for its fiber contribution. The heated, and swollen unmodified and modified potato starch granules are very susceptible to enzyme digestion. Thus, if the PenPure® and PenBind® starches were heated and cooled, and then exposed to the modified Englyst method, they would be almost completely digested with little resistant starch remaining. The PenFibe® RS would continue to resist enzyme digestion thereby retaining its fiber contribution to the finished food.

In summary, the data displayed in Table 4 above confirms that PenFibe® RS produced using up to 4.5% $POCl_3$ is highly resistant to digestion, based on the *in vitro* Englyst procedure. The additional crosslinking of DSP created by using a higher level of $POCl_3$ treatment results in a significant decrease in the portion of the product that is digestible. Compared to product produced with 0.1% $POCl_3$ the quantity of starch in DSP that is not digestible is increased from 88% to 97%.

Part 3 – Dietary exposure

Our estimate of an estimated daily intake (EDI) for DSP based on its use in nine food categories is 3.5 - 7.0 grams per serving or an average of 5 grams per serving. The nine food categories were selected as the most common use applications for this ingredient. The per user mean intake from these selected food categories is 9.06–18.1 g/day and the corresponding 90th percentile intake is 18.1–36.3 g/day.

The typical maximum level of use for DSP will be at a level that will support a nutrient content claim of "high" or "good source" of fiber on the label of the processed food product.[7] As displayed in Table 5 below, the use levels indicated (3.5 g–7.0 g per serving) will provide a daily intake of at least 2.8 grams or 5.6 grams per serving. These levels enable the finished product to qualify for a "high" or "good source" of fiber nutrient content claim. A "high," "excellent source of" or "rich in" fiber claim is permitted when the product contains 20 percent or more of the daily reference value (DRV) for fiber. The new DRV for fiber is 28 grams per day[8] so that product must contain at least 5.6 grams of fiber per reference amount customarily consumed (RACC) to make a "high fiber" claim. A "good source of," "contains" or "provides" fiber claim is permitted when the product contains 10 percent or more of the DRV for fiber. The DRV for fiber is 28 grams per day so that product must contain at least 2.8 grams of fiber per RACC to make a "good source of fiber" claim. We have assumed that 3.5 grams of DSP, which is 2.975 grams of dietary fiber, meets the requirements for a "good source" claim at 2.8 grams and that 7.0 grams of DSP, which is 5.95 grams dietary fiber, meets the requirements for a "high in fiber" claim at 5.6 grams dietary fiber.

Table 5. Proposed Foods Categories and Use Levels

Food Category	Serving Size (g)	DSP Use Level			
		Good Source (%)	High Fiber (%)	Good Source (g/serving)	High Fiber (g/serving)
Bread	50	7	14	3.5	7.0
Pancakes/Waffles	110	3.2	6.4		
Nutrition Bars	40	8.8	17.5		
Ready-to-eat (RTE) Cereal	15	23.3	46.7		
Muffins	110	3.2	6.4		
Tortillas	55	6.4	12.8		
Pretzels	30	11.7	23.3		
Pasta, plain (dry, uncooked)	55	6.4	12.8		
Meal replacement	240	1.45	2.9		

[7] 21 C.F.R. §101.54(b) and (c).

[8] 21 C.F.R. §101.9(c)(9). Please note that the old regulation cites the DRV for dietary fiber as 25 grams but the new regulation cites the DRV for dietary fiber as 28 grams. See 81 Fed. Reg. 33741 (May 27, 2016).

Exponent Inc. (Exponent) conducted an intake assessment to estimate the total daily intake of DSP based on its use in the above nine food categories, namely: bread, pancakes/waffles, nutrition bars, ready-to-eat (RTE) cereal, muffins, tortillas, pretzels, dry uncooked plain pasta, and meal replacements. The estimated daily intake (EDI) of DSP was based on food consumption data from the 2009-2012 National Health and Examination Survey (NHANES), and provided for the total U.S. population two years and older. Exponent generated consumption data on a "per capita" and "per user" basis. The "per capita" estimates refer to the consumption based on the entire population of interest whereas "per user" estimates refer to those who reported consuming any of the foods in a given food category in either of the survey days. Exponent generated the 2-day average EDIs of DSP on the per capita and per user basis at the mean and 90th percentile of consumption for the total U.S. population two years and older. The EDI when DSP is used at levels to achieve "good source" fiber claims in food is 9.06 g/day at the mean intake "per user" level and 18.1 g/day at the 90th percentile "per user" level. The EDI when DSP is used at levels to achieve "high" fiber claims in food is 18.1 g/day at the mean intake "per user" level and 36.3 g/day at the 90th percentile "per user" level. Exponent's full report is attached as Appendix V.

Part 4 – Self-limiting levels of use

DSP is proposed for use in food as a source of dietary fiber and for other functional uses such as a thickener or texturizing agent. The use of DSP as a food ingredient is limited by the level that can technically be added to a given food without jeopardizing its quality and consumer acceptability. Further, use is limited by the cost of DSP; food manufacturers will generally only use the amount of DSP necessary for it to contribute a meaningful amount of fiber per serving of the finished food product. Use levels as a thickener or texturing agent may be similar to or lower than the fiber uses.

Part 5 – Experience based on common use in food before 1958

The statutory basis for our GRAS notification is based on scientific procedures; thus, we do not include any evidence of a substantial history of consumption of the notified substance for food use by a significant number of consumers prior to 1958.

Part 6 – Narrative

This section provides documentation that DSP is safe and GRAS, based on published and unpublished studies and reviews by expert committees. Starches modified for use as food ingredients have been produced for use in food products since the 1950s and have been studied and evaluated several times since then. Modified food starch products have been used in infant foods since the early 1950s to provide uniform consistency.[9] The following brief narrative summarizes the current effects induced by modified starches and other poorly digested substances. References are provided more extensively in the following sections.

Food starch modified with the use of phosphorus oxychloride ($POCl_3$) is recognized as an approved food additive at 21 C.F.R. § 172.892. Section 172.892 sets forth the various treatments that can be used to modify starch including the esterification of starch by $POCl_3$ at up to 0.1%. There is also a Food Chemicals Codex (FCC) monograph for Food Starch-Modified that recognizes the use of 0.1% $POCl_3$ to produce distarch phosphate modified food starch. Ingredion would like to manufacture DSP with higher levels of $POCl_3$. Thus, we have reviewed Ingredion's DSP to confirm that it is generally recognized as safe (GRAS) when produced with this higher level of $POCl_3$. Modified food starch produced with 0.1% $POCl_3$ and 4.5% $POCl_3$ results in an end product that has levels of residual phosphorus below 0.4% and 0.5% for potato and wheat starches.[10] The level of residual phosphorus and not the treatment level of $POCl_3$ is the focus of modified food starch regulations in the EU, Codex/JECFA, China and Japan.

Ingredion's DSP is produced from potato starch, wheat starch or any other food grade starch source. Section 172.892 does not reference or limit the starch source, and the FCC monograph recognizes the production of modified food starch by treatment of "any of several grain- or root-based native starches (for example, corn, sorghum, wheat, potato, tapioca, and sago)."

As discussed further below, numerous expert committees including the European Food Safety Authority (EFSA), the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and the Scientific Committee for Food (SCF) have evaluated the safety of phosphated starches, and concluded that they are safe without any limitation on use. In 1979, the Select Committee on GRAS Substances (SCOGS) concluded that phosphated starches are safe but that unlimited use was not justified based on one report of adverse effects in the kidneys of rats; however, subsequent studies have concluded that these adverse effects are artifacts, and that the rats had similar issues when fed lactose (milk sugar) at high levels in the diet. Further, there are numerous toxicology studies available in the public scientific literature that are based on published toxicological studies of animals and humans to support the safety of phosphated starches, including the safety of type 4 resistant starches like DSP.

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[9] Filer, L.J. Jr. et al. (1971). Modified Food Starches for Use in Infant Foods. Nutr. Rev., 29(3): 55-59.

[10] Modified food starch produced with 0.1% POCl3 results in $\leq$ 0.4% residual phosphorus and modified food starch produced with 4.5% POCl3 results in residual phosphorus of $\leq$ 0.5%, 0.4% from the production process and 0.1% from naturally occurring phosphorus in the potato or wheat.

Early reviews by expert panels evaluated the safety of modified starches as a class.[11] The conclusions of safety for the use of modified starches in food based on early reviews have been confirmed by more recent reviews.[12] By the mid-1980s, a definitive model explaining the physiological effects (described as adaptive) reported for the class of cross-linked modified food starches had been developed and has not been challenged. Early studies performed at TNO laboratories in the Netherlands[13] supported by studies by Buttolph, Newberne, and colleagues[14] supported a model for induced physiological effects based on the osmotic effect of poorly digested starches fermented in the cecum, the initial portion of the large intestine. Other than the adaptive physiological effects engendered by osmotic changes in the cecum and colon, no adverse effects based on target organ toxicity have been reported for the class of cross-linked modified starches to which DSP belongs. The absence of challenges to this model in the current literature indicates that it is generally recognized as valid. It has been used to explain the physiological aspects of exposures to a variety of osmotically active substances, such as maltodextrins[15] and smaller molecular weight indigestible substances, such as sugar alcohols and synthetic sweeteners consumed in the diet.[16]

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[11] Second Report of the Scientific Committee for Food on Modified Food Starches, 13th Series; JECFA (1974). WHO Technical Report Series No. 539. JECFA (1982). Phosphated distarch phosphate: In Toxicological Evaluation of Certain Food Additives. 26th JECFA Session, Apr. 19-28, 1982, Rome. WHO Food Additives Series, No. 17. SCF (Scientific Committee for Food), 1982. Second report on modified starches. In: Food Science and Techniques. Commission of the European Communities (EEC), Scientific Committee for Food (SCF); Reports of the Scientific Committee for Food (13th Series), Brussels, Belgium, 7-9.

[12] 21 C.F.R. §172.892; EFSA (2010). Scientific Opinion on the safety of 'phosphated distarch phosphate' as a Novel Food ingredient. EFSA Journal 8(9) 1772. SCF (1982).

[13] de Groot, A.P., Til, H.P., Feron, V.J., Van der Meulle, H.C.D., Willems, M.I., (1974). Two-year feeding and multigeneration studies in rats on five chemically modified starches. Food and Cosmetics Toxicology, 12, 651-664. Leegwater, D.C., et al. (1974). The aetiology of caecal enlargement in the rat. Food Cosmet Toxicol., 12(5-6): 687-697.

[14] Newberne, P.M., Conner, M.W., Estes P. (1988). The influence of food additives and related materials on lower bowel structure and function. Toxicol Pathol.,16(2):184-197. Buttolph, M.L., Newberne P.M. (1980). Food Cosmet Toxicol., 18(4):357-62. Subchronic studies in rats fed octenyl succinate-modified food starch. Buttolph, M.L., Misa, T., and Newberne, P.M. (1981). Effects of caramel diets and other dietary manipulations on cecal enlargement, kidney pathology and hematology. Nutrition Reports International 23: 1043-1054.

[15] Yoshikawa, Y. (2013). Assessment of the safety of hydrogenated resistant maltodextrin: reverse mutation assay, acute and 90-day subchronic repeated oral toxicity in rats, and acute no-effect level for diarrhea in humans. J. Toxicol. Sci. 38(3): 459-470.

[16] Elia, M. and Cummings, J.H. (2007). Physiological aspects of energy metabolism and gastrointestinal effects of carbohydrates. European Journal of Clinical Nutrition, 61, S40-74. Grabitske, H.A. and Slavin, J.L. (2009). Gastrointestinal effects of low-digestible carbohydrates. Critical reviews in food science and nutrition, 49, 327-360. Lord, G.H., Newberne, P.M. (1990). Renal mineralization--a ubiquitous lesion in chronic rat studies. Food Chem. Toxicol. 28(6):449-455.

In brief, the model supported by published and unpublished reports, summarized below, indicates that modified starches, including distarch phosphates such as DSP and others in the class, contain some components that are digestible and some that are indigestible. The components that are digested and absorbed are the components of natural starch (glucose and a small amount of phosphate), and are absorbed without consequence. The undigested components pass through the small intestines into the cecum where colonic bacteria begin to degrade the resistant starches. The starches are broken down into osmotically active particles that cause retention of water in the colon accompanied by soft stools, diarrhea, enlargement of the cecum, and enhanced absorption of calcium. The effects are dose dependent.

Early reports of test animal studies of various modified starches indicated that in some cases calcium deposits were formed in the kidney (nephrocalcinosis), and higher than usual amounts of calcium appeared in the urine. Further investigations of these effects determined that enlargement of the cecum and increased permeability to calcium in the colon was a physiological adaptation that did not occur in the absence of excessive intakes. In fact, many substances common in the human diet, such as lactose, sugar alcohols, and synthetic sweeteners that are not easily broken down in the small intestine cause similar effects (see Newberne et al., 1990, in footnote 24). Recent studies with humans that ingested starches resistant to digestion have confirmed that intakes of up to 60 grams per day, as dietary fiber, were not accompanied by gastrointestinal effects resulting from osmotic activity of partially digested starch. Thus, according to the current model, there is reasonable expectation of no harm from the ingestion of modified starches, and no accompanying GI effects, at relatively high levels in the diet.

Because DSP is greater than 85% indigestible (see Table 1, page 8), it passes through the gastrointestinal (GI) tract essentially intact, and is unmodified until it reaches the colon where colonic bacteria ferment the starch into small osmotically active particles and then into small molecular weight organic acids. Because DSP is an insoluble fiber, the amount of fermentation in the colon is expected to be minimal and, therefore, osmotic effects due to partially digested fiber are expected to be minimal.[17] The 15% or smaller portion of DSP that is digested is potato starch and is absorbed and metabolized without consequence. Only the colonic fermentation products of the indigestible portion of DSP are potentially bioavailable. The products of fermentation of all resistant starches are small molecular weight acids, such as acetic, propionic, and butyric acids that are used as sources of metabolic energy and do not present a risk of harm to consumers. Many positive effects of resistant starches have been confirmed in the scientific literature.[18] Only one potentially adverse consequence of resistant starch fermentation has been documented: osmotic diarrhea and its accompanying secondary effects, including GI discomfort, soft stools, and potentially increased absorption of calcium at high levels of ingestion.

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[17] Dahl, W. J. et al. (2016). Resistant potato starch (RS4) influences laxation with phylum level changes in microbiota: a randomised trial in young adults. J. Funct. Foods. 23:1–11. Jha, R. and Berrocoso, J.D. (2015). Review: Dietary fiber utilization and its effects on physiological functions and gut health of swine. Animal, 9(9):1441-1452.

[18] Keenan, M.J. et al. (2015). Role of Resistant Starch in Improving Gut Health, Adiposity, and Insulin Resistance. Adv. Nutr., 6:198-205.

Reviews by expert committees have treated distarch phosphates as toxicologically equivalent to other cross-linked modified starches.[19] Consequently, toxicological studies performed with one type of phosphated starch may be used to infer conclusions with regard to other forms and the class as a whole. This view is supported by the published observations, and reviews by experts who have concluded that similar effects due to the osmotic activity of partially digested modified starches are observed for different types of modifications, including crosslinking and surface modifications. The modified starches cleared at 21 C.F.R. §172.892 for use as food additives and originally reviewed by SCOGS induced osmotic effects even though the degree of modification was smaller than resistant starches now used as dietary fiber. They also were reported in some cases to have similar amounts of total phosphorus. A higher degree of crosslinking simply results in a greater proportion of material that is transported to the cecum and colon. The published and unpublished literature clearly supports a physiological model that indicates that no adverse effects of resistant starches are expected as long as intakes are limited to amounts that preclude osmotic effects.

As explained more fully in the following sections on test animal and human exposures to modified starches, the safety evaluation and GRAS status of DSP in this notification rests on the publicly available data and information found in published peer reviewed studies of modified starches of limited digestibility, of all types, in conjunction with, and supported by, similar information on the safety of modified starches in unpublished reports, and as reviewed in the secondary literature by panels of experts qualified by training and experience to evaluate the safety of food ingredients. The weight of the available information in published and unpublished reports, including reviews of all available information on exposures to modified starches by expert panels indicates that no modified partially digestible starch product has induced an adverse effect directly in an organ or tissue when exposures occurred in test animals at levels as high as 60 mg/kg bw/day. In the studies reviewed below, we summarize data primarily for exposures to phosphate cross-linked starches with structures similar to that of DSP as the most relevant to the GRAS status of the product.

1. Animal Studies

In this section, we review the studies of modified starches crosslinked with phosphate. We focus primarily on published articles because they comprise the basis of the common knowledge element of our GRAS determination. In addition, some studies that were unpublished at the time of the expert panel reviews were later evaluated in virtually all expert panel evaluations of modified starches and most of the studies that were unpublished at the time of those reviews were subsequently published in the peer reviewed literature, often as compilations of separate studies on different types of modified starches (for example, de Groot et al. 1974). The animal studies reviewed here that form the basis of our GRAS determination are summarized in tabular form in Appendix I.

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[19] Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives. Modified Food Starch, available at, http://www.inchem.org/documents/jecfa/jeceval/jec_1663.htm

a. Acute Studies

The SCOGS report cited several acute exposures using distarch phosphate, a modified starch prepared through cross-linking with sodium trimetaphosphate or phosphorus oxychloride, using mice, rats, guinea pigs, rabbits and cats. All exposures indicated the absence of toxic effects. These exposures resulted in no deaths indicating that LD50s were greater than 19 g/kg bw for female mice, 35 g/kg bw for female rats, 18 g/kg bw for guinea pigs, 10 g/kg bw for rabbits, and 9 g/kg bw for cats.[20]

In another study, groups of eight Pitman-Moore miniature pigs three days of age were fed synthetic diets containing acid-modified waxy starch or distarch phosphate prepared by treatment of the acid-modified starch with 0.08 percent (dry weight basis) phosphorus oxychloride.[21] Starch provided 24 percent of the calories in the diet and each diet was fed for 25 days. Body weight gains were similar for test and control animals. The distarch phosphate diet had no statistically significant effects on organ weights expressed as a percentage of body weight. Serum cholesterol, triglyceride, calcium, phosphorus, alkaline phosphatase, urea nitrogen, total protein, albumin and globulin levels were similar for the exposed and control animals.

b. Long-term and Multigeneration Studies

Five chemically modified starches, acetylated distarch phosphate, acetylated diamylopectin phosphate, starch acetate, hydroxypropyl distarch glycerol and phosphated distarch phosphate, were fed to groups of 30 male and 30 female weanling CIVO (Wistar derived) rats at dietary levels of 0 (control), 5, 10 and 30% for 2 years and at one level, 10%, over three generations.[22] The dietary exposures resulted in approximate intakes of 2.5, 5.0, or 15.0 g/kg bw/day (2500, 5000, or 15000 mg/kg bw/day) for both males and females. No adverse effects were observed on mortality, food intake, hematology, blood biochemistry or urine composition. Each of the modified starches examined, except the phosphated distarch phosphate, slightly reduced body weights at the 30% level and caused distinct cecum enlargement at 10 and 30%. The microscopic structure of the cecum wall was normal. In comparison with the controls, the males fed the 30% level of any of the modified starches showed a slightly increased degree and incidence of focal hyperplasia of the renal papillary and pelvic epithelium, accompanied by calcified

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20 SCOGS (1979). Evaluation of the Health Aspects of Starch and Modified Starches as Food Ingredients. Contract No. FDA 223-75-2004. Life Sciences Research Office, Federation of American Societies for Experimental Biology, page 33. The studies were also cited in JECFA (1974). Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, WHO Tech. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53.

21 Anderson, T.A., Filer, Jr., L.J., Fomon, S.J., Andersen, D.W., Jensen, R. L., and Rogers, R.R. (1973). Effect of waxy corn starch modification on growth, serum biochemical values and body composition of Pitman-Moore miniature pigs. Food Cosmet. Toxicol. 11: 747-754.

22 de Groot, A.O., et al. (1974). Two-year feeding and multigeneration studies in rats on five chemically modified starches. Food Cosmet. Toxicol. 12:651- 663.

patches in the underlying tissue. The studies did not provide any indication of carcinogenicity. The authors concluded that the feeding of each of the modified starches at dietary levels up to 30% for 2 years and at a level of 10% over three generations did not result in any distinct effect of toxicological significance.

The same authors fed groups of 10 male and 20 female weanling Wistar derived rats a diet containing 10 percent (about 5 g/kg bw/day) hydroxypropyl distarch glycerol and 20 percent precooked potato starch for three generations. The test starch was potato starch which had been cross-linked with 0.1 percent epichlorohydrin and etherified with 5 percent propylene oxide. Rats were mated at weeks 12 and 20 after weaning. The second litter of each generation was used to produce the next generation. The F3b generation was kept for 3 weeks after weaning and then sacrificed for histopathological study. Implantation sites were counted in the parental, Flb, and F2b parents. Body weights did not differ among groups in successive generations and no treatment-related differences were observed in the test groups. No adverse effects were reported regarding resorption quotient, litter size, weight of pups, pre-weaning mortality or growth rate of pups. No gross or histological changes attributable to feeding the modified starch were reported.

The two-year exposure summarized above identified the only potentially adverse effect after feeding any modified starch product, deposition of calcium in the kidney and focal hyperplasia associated with the same sites. Table 6 below displays the incidence of the nephrocalcemic effect as compiled in the SCOGS report. Only rats fed the highest level of modified starch showed significant increases in the kidney lesion relative to controls.

Table 6. Incidence Kidney Lesions (as nephrocalcinosis) in Rats

Modified Starch Product	Control	2.5	5	15
		g/kg bw/day		
acetylated distarch phosphate	1/59	6/57	5/56	10/58
acetylated diamylopectin phosphate		6/55	5/56	4/56
hydroxypropyl distarch glycerol		2/58	0/59	7/56
phosphated distarch phosphate	1/57	4/57	0/58	10/57
starch acetate	3/58	1/57	3/57	4/57
Totals	5/174	19/284	13/586	35/284

The identification of the kidney lesion (deemed non-pathological in subsequent studies), in the studies performed at TNO Laboratories in the Netherlands, was found to be associated with calcium deposition (nephrocalcinosis), and increased levels of calcium in the urine initiated several investigations into the physiology of the effect. The explanation for the lesion as a physiological adaptation resulting from increased osmotic pressure in the cecum due to partially fermented starch was derived from previous observations on other types of dietary carbohydrates[23] and developed from the time of the

[23] See references in de Groot et al. (1974), page 657.

first published study in 1974 until a final review in 1990. For example, Leegwater et al. (1974) evaluated the relation of cecum size and osmotic effects by hydroxypropyl starch (degree of substitution 2.5%-10.6%), lactose, raw potato starch, polyethylene glycol 1000, or magnesium sulfate in male rats of ages varying from 4 weeks to 3 months in experiments lasting from 10 days to 3 months.[24] All of the test compounds induced cecum enlargement under the experimental conditions. Cecum enlarged by hydroxypropyl starch (degree of substitution 4.7%), lactose, or raw potato starch, returned to normal sizes within 4 weeks after the animals reverted to a control diet. The analytical data did not show a consistent relationship between cecum size and the percentages of dry matter, sodium, potassium, chloride or volatile fatty acids in the cecum contents. The osmotic values of the cecum contents of control and experimental groups were of the same order of magnitude. The authors postulated that the size of the rat caecum is controlled by the osmotic pressure of the cecum contents, irrespective of the nature or origin of the compounds contributing to this value, and the conclusion is drawn that cecum enlargement is a process of physiological adaptation.

In a second study of the physiological effects of modified starches, Fisher 344 rats were fed poorly digested octenyl succinate-modified food starch in a semi-purified diet from conception until they were killed 30 or 90 days after weaning.[25] Complete autopsies and histopathological evaluations showed that growth and hematology were unaffected, but that liver, kidney and cecum weights tended to increase with increasing concentrations of the modified starch. There were no consistent changes in serum chemistry values that could be attributed to starch intake. Female rats had higher concentrations of urinary magnesium and calcium than did male rats, and these higher mineral concentrations correlated with an increased incidence of renal calcium at the corticomedullary mineralization. The increase in mineralization occurred in both control and in octenyl succinate starch-treated female rats. Nephrocalcinosis specific to the pelvic region of the kidney was not observed in any of the rats. The authors concluded that no adverse effects were found that could be reported to feeding octenyl succinate starch to rats under the conditions of this study.

The above study was followed by an evaluation of kidney lesions induced by two modified starches crosslinked with phosphate or adipic acid added to the diets of Syrian Golden hamsters.[26] The incidence and severity of the lesion were dependent on the type and degree of modification of the starch and the magnesium content of the diet; increased dietary magnesium inhibited or prevented the morphologic expression of the lesion. This observation led to a series in the same publication of similar studies in rats where both the

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[24] Leegwater, D.C. et al. (1974). The aetiology of caecal enlargement in the rat. Food Cosmet. Toxicol., 12(5-6):687-97.

[25] Buttolph, M.L. and Newberne, P.M. (1980). Subchronic studies in rats fed octenyl succinate-modified food starch. Food Cosmet. Toxicol. 18(4):357-362.

[26] Buttolph, M.L. and Newberne, P.M. (1980). Modified food starch: effects on mineral availability in rats and hamsters. In Trace Substances in Environmental Health - XIV. Proc. Univ. Missouri's 14th Ann.l Conf. Trace Subst. Environ. Health. Univ. Missouri.

carbohydrate and dietary mineral content of the diets were varied. The renal lesion observed in these rats consisted of tubular mineralization at the corticomedullary junction and differed from the hamster lesion induced by similar starch products, and was more dependent on the calcium/phosphorus ratio and levels than the magnesium content or the type of modified food starch in the diet. The authors concluded that modified food starch ingestion increases the magnesium requirement of hamsters, but a more complex mineral-carbohydrate interaction is apparent in rats fed modified food starch.

In a review of the literature on the osmotic effects induced by modified food starches Newberne and colleagues discussed the evidence that food additives, drugs, and other chemicals are known to influence the lower gastrointestinal tract resulting in morphological alterations in the mucosa and other tissues, changes in absorption and excretion of nutrients, and, in some cases, injury to other organs and tissues as a secondary phenomenon.[27] In rats, hamsters, and dogs, there is increased absorption and urinary excretion of calcium, soft stools or diarrhea, and enlargement of the cecum. In the rat, hamster, and dog, renal lesions accompany the hypercalcemia and elevated excretion of calcium. These signs, symptoms, and lesions are typical of exposure to sugar alcohols (sorbitol, mannitol, xylitol, lactitol), lactose, caramel, some of the chemically modified food starches, and synthetic polydextrose. Soft stools and diarrhea, as well as cecum enlargement and variable hyperplasia of the colon mucosa, occur frequently when substances are absorbed incompletely in the small intestine and subjected to microbial metabolism in the cecum and colon. The remarkable cecum enlargement, mucosal hyperplasia, and when present, colonic mucosal hyperplasia, are reversible even when long-standing. Renal lesions are reversible only if exposure is of short duration, before significant mineralization and scarring has occurred.

Lord and Newberne (1990) further indicated that renal mineralization is a commonly encountered lesion in aged rats and its presence at times complicates the interpretation of data derived from chronic rat studies.[28] For example, the feeding of sucralose resulted in cecum enlargement and an increase in the incidence of renal mineralization and pelvic epithelial hyperplasia. Data on sucralose and other small molecular weight poorly digested substances, and the data on modified food starches, such as that discussed above, supports the view that cecum and renal changes occur frequently in response to feeding poorly absorbed osmotically active substances to rats. While increased calcium absorption and excretion appear to be important predisposing factors in the development of renal mineralization, the alterations in calcium metabolism are not in themselves pathognomonic (a sign or symptom specifically characteristic of a particular disease), as exemplified by the observation of MacKenzie et al. (1986) with sorbitol, that elevated

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[27] Newberne, P.M. et al. (1988). The influence of food additives and related materials on lower bowel structure and function. Toxicol. Path., 16(2): 184-197.

[28] Lord, G.H. and Newberne P.M. (1990). Renal mineralization: A ubiquitous lesion in chronic rat studies. Food Chem. Toxicol., 28(6): 449-455.

serum calcium did not result in an increase in the incidence of renal mineralization.[29] The weight of the evidence in the public literature indicates that the feeding of substances that are poorly absorbed and osmotically active to rodents, especially rats, initiates a series of events leading in some cases to an alteration in mineral disposition and to an increase in cecum intraluminal pressure. Increased cecum intraluminal pressure results from retention of water resulting in a compensatory distention of the organ and, in some cases, hyperplasia that is reversible. One manifestation of altered renal mineral disposition is an increase in urinary calcium excretion and the development of renal mineralization.

c. Conclusion with Regard to the Renal Lesions Reported

It is evident from the several publications in the peer reviewed scientific literature that the feeding of modified starches that are poorly absorbed and ultimately fermented in the proximal colon results in osmotic changes that result in increased water retention, softening of stools, diarrhea, and ultimately increased absorption of calcium. Increased absorption of calcium can result in accumulation in the kidney, and increased calcium excretion in the urine. These adaptive effects are observed after the ingestion of many poorly digested and osmotically active substances. In addition, the kidney effects reported are not specifically pathologic or hazardous because of their location in the kidney, and are reversible. Consequently, the several studies reviewed that address specific effects associated with modified starch ingestion indicates that such products are not reasonably considered hazardous nor do they pose a risk of harm to consumers ingesting either chemically modified starches or resistant starches added as dietary fiber to food products because GI effects do not occur at reasonable levels of intake.

d. Short-term Studies.

The studies below further support the safety and GRAS status of modified food starches including DSP. In a 90-day study groups of 25 male and 25 female Sprague-Dawley weanling rats were fed diets containing 0, 0.2%, 1.0%, or 5.0% (about 0, 0.2 0.8, or 4.0 g/kg bw/day) of distarch phosphate prepared by treating white milo starch with sodium trimetaphosphate.[30] Blood and urine analyses were performed at 45 and 90 days of exposure. Blood analyses were done individually on five males and five females of the highest dietary group. No abnormalities were reported in hematological parameters or urinalyses of the exposed animals. Body weight gains and organ-body weight ratios showed only a few, randomly distributed, intergroup differences, none of which were attributed to modified starch ingestion. Gross pathologic findings among test animals

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[29] MacKenzie, K.M. et al. (1986). Three-generation reproduction study of rats ingesting up to 10% sorbitol in the diet--and a brief review of the toxicological status of sorbitol. Food Chem. Toxicol., 24(3):191-200.

[30] As discussed in SCOGS (1979). Evaluation of the Health Aspects of Starch and Modified Starches as Food Ingredients. Contract No. FDA 223-75-2004. Life Sciences Research Office, Federation of American Societies for Experimental Biology. Pages 33-34.

were comparable to those reported among control animals and no adverse histopathologic changes attributed to the test starches were reported.[31]

In a 90-day study, groups of 10 male and 10 female rats received 0, 5%, 15%, or 45% (about 4, 12, or 36 g/ kg bw/day) of two types of distarch phosphate (0.085% or 0.128% esterified phosphate) in their diet. No abnormalities compared to controls were reported in regard to general appearance, behavior, mortality, food consumption, hematology, serum chemistry and urinalysis that could be attributed to the test starches. No diarrhea or increased cecum weights were reported. Gross and histopathologic examination revealed no abnormalities attributable to the distarch phosphate exposures.[32] In an 90-day study groups of three male and three female adult beagles were fed for a standard dog chow supplemented daily with 0.05, 0.25, or 1. 25 g/kg bw/day of distarch phosphate (trimetaphosphate-treated white milo starch) administered in gelatin capsules. Hematological studies and urinalyses were performed at the inception and conclusion of the feeding period and also after 45 days for the dogs fed the highest level of distarch phosphate. No significant abnormalities were reported. Mean body weight gains and organ-body weight ratios of the test animals did not differ significantly from the controls. Gross and histopathologic examination revealed no abnormalities attributable to the test substance.[33]

2. Human Studies

Dietary fiber is a macronutrient in the human diet. Consequently, consistent with Redbook requirements,[34] human studies cannot explicitly provide a basis for a safety evaluation of any ingredient but can provide supportive evidence of safety, provided that observations on the effects of the dietary component support the model of safety developed in test animals. Distarch Phosphate (DSP) is a type-4 resistant starch that has been rendered partially indigestible by chemical modification with $POCl_3$ or sodium trimetaphosphate (STMP); PenFibe® DSP is produced using only $POCl_3$. A third reagent, sodium tripolyphosphate (STPP), is used to make phosphated distarch phosphate (PDSP), which contains phosphate monoesters in addition to the cross-linking phosphodiesters. These chemical modifications produce a starch that is resistant to

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31 Kohn, F.E. et al. (1964). Subacute oral toxicity of phosphate starch code number 4822. Report of Industrial Bio-Test Laboratories, Inc., Northbrook, Ill. Reviewed by SCOGS (1979).

32 Til, H. P., van der Meulen, H. C. and de Groot, A. P. (1970). Report No. R 3303 of the Centraal Instituut voor Voedingsonderzoek, Zeist, Holland. As reported in WHO Food Addit. Ser. No. 5:345-349, 1974. Reviewed by SCOGS.

33 Cervenka, H. and Kay, J.H. (1963). Subacute oral toxicity of phosphate starch code number 4822: beagle dogs. Report of Industrial Bio-Test Laboratories, Inc., Northbrook, Ill. Reviewed by SCOGS (1979).

34 Redbook 2000. Guidance for Industry and Other Stakeholders Toxicological Principles for the Safety Assessment of Food Ingredients. Revised July 2007. Pages 195 and 208.

hydrolysis by digestive enzymes. Resistant starches of various types, including DSP, PDSP, and other type-4 chemically modified starches, have been studied in animals and humans. PenFibe® DSP has been evaluated in two human studies published in the peer reviewed scientific literature.[35] No adverse effects of any kind were reported in the two studies after the ingestion of 30 grams of PenFibe® DSP for 2 weeks (Dahl et al. 2016) or for two hours during the determination of the glycemic index (Haub et al. 2012).

A search of the literature for clinical trials in which human subjects were exposed to resistant starches recovered 11 studies in which healthy subjects or individuals with diabetes mellitus consumed up to 60 grams of resistant starch for various periods of time up to 12 weeks. These studies are cited and summarized in Appendix II. In addition to the two studies of PenFibe® DSP, one study exposed human subjects to 60 grams of phosphated distarch phosphate (PDSP) for four days without ill effect.[36] None of the human studies reported any adverse effects other than some discomfort at levels of exposure around 60 grams or larger in some of the individuals evaluated. In some publications the specific form of the resistant starch was not characterized in the clinical trials due to proprietary considerations. These clinical trials indicate that the non-digestibility of the starches is not expected to have any significant adverse effect, as the products pass directly through the gastrointestinal (GI) tract without change, until partial digestion by bacteria in the colon occurs. The safety of the type-4 and other resistant starches is evident from these studies, and is widely recognized by the absence of virtually any contraindications for intake for individuals regardless of their health status.

3. Studies on PenFibe® DSP

PenFibe® distarch phosphate was studied in a clinical trial in conjunction with five other type 4 resistant starches. Ten adult subjects consumed 30 grams of resistant starch at a single sitting.[37] All resistant starches were well tolerated with no adverse effects reported. This study was designed to determine the efficacy of two novel type-four resistant starches (RS4) on postprandial glycemia and ratings of fullness. Ten healthy young adult volunteers completed five interventions designed to determine the glycemic and satiety (fullness) effects of the starches consuming 38 g alone and when added to available carbohydrate. The dose of each resistant starch provided 30 g per treatment. The treatments were commercial resistant starch added to water, noncommercial resistant

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35 Dahl, W.J. et al. (2016). Resistant potato starch (RS4) influences laxation with phylum level changes in microbiota: a randomised trial in young adults J. Funct. Foods. Vol. 23: 1–11. Haub, M.D. et al. (2012). Novel Resistant Potato Starches on Glycemia and Satiety in Humans. J. Nutr. Metab., Vol. 2012: 1-4.

36 Pieters, J.J.L., W.A. vanStaveren, and B.G.A.M. Brinkhuis 1971. As reported in (1) EFSA Journal 2010; 8(9):1772 Scientific Opinion on the safety of 'phosphated distarch phosphate' as a Novel Food ingredient. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). (2) WHO Food Addit. Ser. No. 5:372-375, (1974).

37 Haub, M.D. et al. (2012). Novel resistant potato starches on glycemia and satiety in humans. J. Nutr. Metab., Vol. 2012, pages 1-4.

starch added to water, dextrose solution, dextrose mixed with Distarch Phosphate starch, and dextrose added to noncommercial starch. Blood glucose was measured in the fasted state and following the randomly assigned treatments at 30, 45, 60, 90, and 120 minutes post-consumption. A visual analog scale was used to determine fullness at each time point. There were no differences in the glucose incremental areas under the curve for treatments that included dextrose. The Distarch Phosphate treatments had decreased areas for glucose. There were no treatment differences for satiety. No indications of adverse effects were reported.

A 6-week randomised, double-blinded crossover intervention study was conducted during the spring of 2014.[38] The objective was to study the effects of resistant potato starches on gastrointestinal (GI) function and microbiota in healthy individuals. In a 6-week, double-blind, cross-over study, participants (N = 57, 21 male, 36 female healthy adults were randomised to consume 30 g fibre per day from one of three chemically modified resistant potato starches: RS4-A, soluble and viscous, RS4-B, soluble non-viscous; Distarch Phosphate (PenFibe® RS) RS4-C, insoluble, non-viscous, or a control starch in fruit-flavoured beverages (Kool-Aid®, Kraft Foods Inc.). Two beverages a day, each containing 15 g/serving of fibre were provided for two-week periods separated by a one-week washout. The Kool-Aid® vehicles provided 168 kcal/day. Beverages were consumed for 2 weeks with a 1-week washout between crossovers. Stools were analysed by qPCR and 16S rRNA sequencing. Stool frequency and the self-reported Bristol Stool Form Scale (BSFS) increased only with RS4-B, the soluble non-viscous starch. GI symptoms were minimal with slight increases in flatulence with all interventions. There were no changes in *Lactobacillus* or *Bifidobacteria* spp. However, RS4-B decreased Firmicutes species and the Firmicutes to Bacteriodetes ratio. Resistant potato starches vary in their effects on GI function which may be related to shifts in intestinal microbiota.

4. Reviews and Secondary Literature

Cross-linked starch phosphate products, such as Distarch Phosphate, have been extensively reviewed for safe use in food products. Expert committees for the specific review of phosphated starches were convened by EFSA (2010),[39] JECFA (1969, 1973, 1982),[40] SCF (the Scientific Committee for Food, 1976, 1982),[41] and SCOGS (1979).[42]

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[38] Dahl, W. J. et al. (2016). Resistant potato starch (RS4) influences laxation with phylum level changes in microbiota: a randomized trial in young adults. J. Funct. Foods. 2:1–11.

[39] EFSA Journal 2010; 8(9):1772 Scientific Opinion on the safety of 'phosphated distarch phosphate' as a Novel Food ingredient. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA).

[40] JECFA (1982). Phosphated distarch phosphate: In Toxicological Evaluation of Certain Food Additives. 26th JECFA Session, Apr. 19-28, 1982, Rome. WHO Food Additives Series, No. 17. See summary evaluations of distarch phosphates at http://www.inchem.org/documents/jecfa/jeceval/jec_674.htm; JECFA (1974). Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, WHO Tech. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53; JECFA (1969). Phosphated distarch phosphate: In

When sufficient data and reports were available to these expert committees, they concluded without exception that the available information justified the safe use of phosphated starches without limitation, except for the review by SCOGS. SCOGS concluded that unlimited use of phosphated starches was not justified, based on a single report that adverse effects in the kidney were found after the feeding of rats with phosphated distarch phosphate (PDP) for two years at a dietary level of 30%.[43] Subsequent studies of the same class of phosphated starches concluded that the kidney effects were artifacts.[44] Similar effects were reported when rats were fed lactose (milk sugar) at high levels in the diet. Reviews of phosphated starches subsequent to the findings of Hodgkinson et al. (1982) by EFSA (2010), JECFA (1982), and SCF (1982) concluded that the rat was a particularly sensitive species. Slow degradation of carbohydrates in the upper intestine led to the formation of absorbable breakdown products in the lower intestine, which was associated with enhanced calcium absorption leading to the kidney observations. The expert committees agreed that the findings were peculiar for the rat, and had little relevance for the safety assessment of modified starches for humans.[45]

The conclusions of the expert committees noted above, after resolution of the kidney findings, were based on the identical studies reviewed by SCOGS and other newer evaluations. In total, the conclusions that phosphated starches are safe for use in foods

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Thirteenth report of the Joint FAO/WHO Expert Committee on Food Additives, FAO Nutrition Meetings Report Series. The earlier reviews by JECFA (1969) concluded that insufficient data were available for a complete review.

41 SCF (Scientific Committee for Food), 1982. Second report on modified starches (Opinion expressed 12 June 1981). In: Food Science and Techniques. Commission of the European Communities (EEC), Scientific Committee for Food (SCF); Reports of the Scientific Committee for Food (13th Series), Brussels, Belgium, 7-9. The earlier reviews by SCF (1976) concluded that insufficient data were available for a complete review.

42 SCOGS (1979). Evaluation of the Health Aspects of Starch and Modified Starches as Food Ingredients. Contract No. FDA 223-75-2004. Life Sciences Research Office, Federation of American Societies for Experimental Biology.

43 Unpublished studies cited by SCOGS as: (1) de Knecht-van Eekelen, A., Til, H.P., Willems, M. I., de Groot, A.P. 1971. Chronic (2-Year) feeding study in albino rats with phosphated distarch phosphate (a chemically modified starch). Report No. R 3392. Centraal Instituut voor Voedingsonderzoek; Zeist, Holland. Cited In: JECFA, 1982. (2) Feuillet, X. 1975. Urolithiase chez les rats OFA traites par les amidons modifies de Roquette. Report No. 750802. Centre de Recherche et d'Elevage des Oncins. Submitted to Federation of American Societies for Experimental Biology, Bethesda, Md., by National Starch and Chemical Corporation, Bridgewater, N. J.

44 Hodgkinson, A., Davis, D., Fourman, J., Robertson, W.G., Roe, F.J.A. (1982). Comparison of the effects of lactose and of two chemically modified waxy maize starches on mineral metabolism in the rat. Food Chem. Toxicol., Vol. 20(4):371-382.

45 See the discussion in EFSA Journal 2010; 8(9):1772. Scientific Opinion on the safety of 'phosphated distarch phosphate' as a Novel Food ingredient; pages 12-13.

without limitation were based on studies using repeated dose designs and that used dietary exposures as high as 30% in the diet. Many of the studies were not initially published and were performed by TNO Laboratories in Holland, a widely known and respected laboratory. Subsequently, the five pivotal studies done at TNO and reviewed by virtually all expert committees were published in a single report.[46] A comprehensive list of all studies on phosphated starches that were reviewed by the expert committees is provided in Appendix IV.

5. Residual Phosphorus

We have also evaluated the residual level of phosphorus in the ingredient and confirmed that it does not contribute meaningful amounts of phosphorus in the human diet. The Food and Nutrition Board of the Institute of Medicine has set an upper level for phosphorus of 4.0 g/day for adults (IoM, 1997).[47] A panel of experts in the UK on Vitamins and Minerals established a guidance level for the supplemental intake of phosphorus of 250 mg/day, equivalent to 4.2 mg/kg bw in a 60 kg adult, which was expected not to produce adverse effects.[48] An EFSA report estimated the dietary intakes of phosphorus in European countries to be on average 1000 to 1500 milligrams per person per day, ranging up to about 2600 mg/day.[49] EFSA concluded that the available data indicated that healthy individuals can tolerate phosphorus (as phosphate) intakes up to at least 3000 mg/person per day without adverse systemic effects. Obviously, very high levels of phosphorus in the diet are required for adequate human nutrition and very high levels are well tolerated without adverse effects. The amount of available phosphorus in PenFibe® RS is very low, as a large fraction of the phosphorus is unavailable in the stable crosslinks that make the starch resistant to digestion. Even if all of the phosphorus in the resistant starch were available, the exposure would be in the range of 0.02 g/day from one serving of food that contains 5 grams of DSP or 0.14 g/day

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46 de Groot, A.O., et al. (1974). Two-year feeding and multigeneration studies in rats on five chemically modified starches. Food Cosmet. Toxicol. 12:651- 663.

47 IOM (Institute of Medicine), 1997. Phosphorus. In: Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride. National Academy of Sciences, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine (IOM). National Academy Press (NAP); Washington, DC.

48 EVM (Expert Group on Vitamins and Minerals), 2003. Safe Upper Levels for Vitamins and Minerals: Report of the Expert Group on Vitamins and Minerals. Food Standards Agency (FSA), Expert Group on Vitamins and Minerals (EVM), London, UK.

49 EFSA (European Food Safety Authority), 2005. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Phosphorus. The EFSA Journal, 233, 1-19.

based on the 90th percentile per user estimated daily intake of 36.3 g/day, which are a small fraction of the level of phosphorus tolerable in the human diet.[50]

6. Conclusion

Based on the foregoing discussion, we conclude that the proposed use of Distarch Phosphate as a source of dietary fiber and as a functional ingredient such as a thickener or texturizing agent in processed foods is GRAS. Information and data on the toxicology and other relevant properties of modified starch products in the same class of resistant starch as Distarch Phosphate are available in the public scientific literature and are based on published and unpublished toxicological studies of animals and humans. This class of modified starch products has been reviewed extensively by expert committees qualified by education and training to evaluate the safety of such products that have independently concluded that products such as Distarch Phospahte require is GRAS for use as a direct ingredient in food products.

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[50] For one serving of 5 g DSP the worst case exposure to phosphorus is 0.02 g/day (5 g DSP /day x 0.4 g P / 100 g DSP = 0.02 g P/day). For the 90th percentile per user EDI of DSP the worst case exposure to phosphorus is 0.14 g/day (36.3 g/day x 0.4 g P / 100 g DSP = 0.14 g P/day).

Part 7 – List of supporting data and information

Below is a list of Appendices that are referenced in the GRAS notice:

Appendix I	Table of Published Animal Studies of Modified Starches
Appendix II	Table of Human Studies of Resistant Starches
Appendix III	GRAS Expert Panel Report
Appendix IV	References
Appendix V	Exponent Estimated Daily Intake of Distarch Phosphate in the U.S. Population

APPENDIX I:
TABLE OF PUBLISHED ANIMAL STUDIES OF MODIFIED STARCHES

Pub. Year	Authors/Journal	Title	Type of Starch/Focus
1973	**Anderson**, T.A., L.J. Filer, Jr., S.J. Fomon, D.W. Andersen, R. L. Jensen, and R.R. Rogers. Food Cosmet. Toxicol. 11: 747-754.	Effect of waxy corn starch modification on growth, serum biochemical values and body composition of Pitman-Moore miniature pigs	Four groups eight miniature pigs were weaned at 3 days of age and then fed for 25 days on formula diets identical except for the type of carbohydrate. The diets contained thin-boiling waxy corn starch or one of three chemical modifications of this starch (distarch phosphate, distarch phosphate and hydroxypropylated distarch glycerol).
Summary Results	No statistically significant treatment-related effects were observed on growth, biochemical values of blood or serum, or carcass or liver composition.		
Pub. Year	**Authors/Journal**	**Title**	**Type of Starch/Focus**
1974	**de Groot**, A.P., Til, H.P., Feron, V.J., Van der Meulle, H.C.D., Willems, M.I. Food and Cosmet. Toxicol. 12: 651-664.	Two-year feeding and multigeneration studies in rats on five chemically modified starches.	Five chemically modified starches, acetylated distarch phosphate; acetylated diamylopectin phosphate; starch acetate, hydroxypropyl distarch glycerol; 32ccompany distarch phosphate were fed to rats at dietary levels of 0, 5, 10 and 30% for 2 years and at one level, 10%, over three generations.
Summary Results	2-yr study: no adverse effects were observed on mortality, food intake, hematology, blood biochemistry or urine composition. Each of the modified starches examined, except the 32ccompany distarch phosphate, slightly reduced body weights at the 30% level and caused distinct caecal enlargement at 10 and 30%; the microscopic structure of the		

	cecal wall was normal. Males fed the 30% of any modified starch had a slightly increased degree and incidence of focal hyperplasia of the renal papillary and pelvic epithelium, with calcified patches in the underlying tissue. There was no indication of carcinogenicity. Multigeneration study: no effect on fertility, on lactation performance or on embryonic or pre-weaning mortality. Extensive microscopic examination of the F3b-generation rats failed to reveal any changes attributable to treatment. Conclusion: modified starches at dietary levels up to 30% for 2 years and at a level of 10% over three generations did not result in any distinct effect of toxicological significance.		
Pub. Year	**Authors/Journal**	**Title**	**Type of Starch/Focus**
1974	**Leegwater D.C.**, de Groot, A.P., van Kalmthout-Kuyper M. Food Cosmet Toxicol. 1974 Oct;12(5-6):687-97.	The aetiology of caecal enlargement in the rat.	The effect of hydroxypropyl starches (2.5%-10.6%) lactose, raw potato starch, polyethylene glycol 1000 or magnesium sulfate on cecum size was studied in male rats of ages varying from 4 weeks to 3 months for 10 days to 3 months.
Summary Results	All the test compounds induced caecal enlargement under the experimental conditions and returned to normal sizes within 4 weeks after the animals reverted to a control diet. The analytical data did not show a consistent relationship between cecum size and the percentages of dry matter, sodium, potassium, chloride or volatile fatty acids in the cecum contents. The osmotic values of the cecum contents of control and experimental groups were of the same order of magnitude. The authors postulated that the size of the rat caecum is controlled by the osmotic value of the cecum contents, irrespective of the nature or origin of the ingested compounds and is a process of physiological adaptation.		
Pub. Year	**Authors/Journal**	**Title**	**Type of Starch/Focus**
1982	**Hodgkinson**, A., Davis, D., Fourman, J., Robertson, W.G., Roe, F.J.A. Food Chem. Toxicol. 20(4): 371-382.	Comparison of the effects of lactose and of two chemically modified waxy maize starches on mineral metabolism in the rat.	Diets containing 30% waxy maize starch, lactose monohydrate, acetylated distarch phosphate, or acetylated distarch adipate were fed to weanling female Specified Pathogen-Free Sprague–Dawley rats for 1 year and to similar 9-month-old rats for 34 wk.

Summary Results	Behavior and general health were unaffected by the different diets and there were no diet-related differences in food consumption. The body weight of 9-month-old rats receiving lactose was lower than that of the controls receiving starch. The animals receiving the modified starches were slightly but not significantly heavier than the controls at the end of both experiments. The main treatment-related changes in rats on the three test diets were (1) caecal enlargement, (2) increased urinary excretion of calcium, (3) increased renal calcification as measured by chemical analysis of renal tissue obtained at autopsy and, (4) increased medullary and pelvic nephrocalcinosis as assessed histopathologically. Acetylated distarch adipate had a slightly greater effect on the above parameters than acetylated distarch phosphate but both modified starches had less effect than lactose. The calcium content of the kidneys increased with age, even in the animals receiving the control diet		
Pub. Year	**Authors/Journal**	**Title**	**Type of Starch/Focus**
1980	**Buttolph**, M.L. and Newberne, P.M. Food Cosmet. Toxicol. 18: 357-362	Subchronic Studies in Rats Fed Octenyl Succinate-Modified Food Starch.	Fischer 344 rats were fed octenyl succinate-modified food starch in a semi-purified diet from conception until they were killed 30 or 90 days after weaning.
Summary Results	First study to relate modified starch intake with cecal enlargement and calcium and magnesium imbalances. No adverse effects associated with feeding octenyl succinate starch occurred in rats under the conditions of this study. Complete autopsies and histopathological evaluations showed that growth and hematology were unaffected. Liver, kidney and cecal weights tended to increase with increasing concentrations of dietary octenyl succinate starch. There were no consistent changes in serum chemistry values that could be associated with octenyl succinate starch intake. Female rats had higher concentrations of urinary magnesium and calcium than did male rats, and these higher mineral concentrations correlated with an increased incidence of renal cortico-medullary mineralization. The increase in mineralization of the cortico-medullary junction occurred in both control and in octenyl succinate starch-treated female rats. Pelvic nephrocalcinosis was not observed in any of the rats.		

Pub. Year	Authors/Journal	Title	Type of Starch/Focus
1980	**Maria Lynn Buttolph** and Paul M. Newberne Trace Substances in Environmental Health – XIV. Proc. Univ. Missouri's 14th Ann.l Conf. Trace Subst. Environ. Health. Univ. Missouri.	Modified Food Starch: Effects on Mineral Availability in Rats and Hamsters	This study examined the impact of modified food starches on mineral status. A series of metabolic and histologic studies were performed. In the first experiment, hamsters were fed diets with different magnesium levels and types of modified food starches: one level of acetylated distarch phosphate and two levels of hydroxypropyl distarch phosphate. The second experiment, with rats, manipulated the calcium/phosphorus ratios and levels in diets containing different types and levels of the same modified food starch in the first experiment.
Summary Results	Modified food starch ingestion increases the Mg requirement of hamsters, but a more complex mineral-carbohydrate interaction is apparent in rats fed modified food starch. Selected modified food starches added to the diets of Syrian Golden hamsters were associated with a renal lesion consisting of tubular dilation and cortical scarring. The incidence and severity of the lesion were dependent on the type and degree of modification of the starch and the magnesium content of the diet; increased dietary Mg inhibited or prevented the morphologic expression of the lesion. This observation led to a series of similar studies in rats where both the carbohydrate and dietary mineral content of the diets were varied. The renal lesion observed in these rats was tubular mineralization. This lesion differed from the hamster lesion and was more dependent on the calcium phosphorus ratio and levels than Mg content or the type of modified food starch in the diet.		
Pub. Year	**Authors/Journal**	**Title**	**Type of Starch/Focus**
1988	**Newberne**, P.M., Conner, M.W., Estes, P. Toxicologic Pathology. 16(2): 184-197	The Influence of Food Additives and Related Materials on Lower Bowel Structure and Function	This paper reviews the safety of lactose, modified food starches, sugar alcohols, and polydextrose when used as dietary ingredients. These substances cause changes in the lower gastrointestinal tract, specifically the part of the colon called the cecum. Some of the GI effects are

			induced secondary effects expressed as mineral imbalances that can under certain circumstances cause changes in the kidneys and adrenal glands. The paper provides a rationale for the secondary effects in the kidney and adrenals by osmotically active substances generated by the above ingredients based on the totality of evidence in the scientific literature.
Summary Results	Morphological and functional anomalies of the kidney and adrenal glands are associated with cecal enlargement, osmotic diarrhea, and occur secondary to these physical effects induced by high exposures. Food additives, drugs, and other chemicals are known to influence the lower gastrointestinal tract under certain conditions resulting in morphological changes in the mucosa and other tissues, altered absorption and excretion of nutrients, and, in some cases, injury to other organs and tissues as a secondary phenomenon. In rats, hamsters, and dogs, there is cecal enlargement, increased absorption and urinary excretion of calcium, soft stools, and diarrhea. In the rat, hamster, and dog renal lesions were found in addition to hypercalcemia and elevated excretion of calcium. These effects are typical of exposure to sugar alcohols (sorbitol, mannitol, xylitol, lactitol), lactose, caramel, some of the chemically modified food starches, and polydextrose. Soft stools and diarrhea, as well as cecal enlargement and variable hyperplasia of the colon mucosa, occur frequently when substances are absorbed incompletely in the small intestine and subjected to microbial metabolism in the cecum and colon. The remarkable cecal enlargement, mucosal hyperplasia and, when present, colonic mucosal hyperplasia are reversible, even when long-standing. Renal lesions are reversible if exposure is of short duration, before significant mineralization and scarring has occurred.		

APPENDIX II:
TABLE OF HUMAN STUDIES OF RESISTANT STARCHES

Year	Authors/Journal	Title	Type of Starch/Focus	Summary Results
	STUDIES USING DISTARCH PHOSPHATE OR PHOSPHATED DISTARCH PHOSPHATE TYPE 4 RESISTANT STARCHES			
(1) 2016	Dahl, W.J. et al. (2016). J.Funct. Foods. Vol. 23: 1–11.	Resistant potato starch (RS4) influences laxation with phylum level changes in microbiota: a randomised trial in young adults.	Intervention: 30 g of fiber per day for 2 weeks. RS4-A, PenFibe® RS, hydroxypropyl starch, soluble with high viscosity; RS4-B, PenFibe® RO – 177; hydroxypropyl starch, enzyme hydrolysed, soluble with low viscosity; RS4-C (**PenFibe® RS**; insoluble with low viscosity.	Stools were analysed by qPCR and 16S rRNA sequencing. Stool frequency and form increased only with RS4-B. GI symptoms were minimal with slight increases in flatulence with all interventions. There were no changes in *Lactobacillus* or *Bifidobacteria* spp. RS4-B decreased Firmicutes and the Firmicutes-Bacteriodetes ratio. RS4 resistant potato starches vary in their effects on GI function and may be related to shifts in intestinal microbiota.
(2) 2012	Haub, M.D. et al. Novel Resistant Potato Starches on Glycemia and Satiety in Humans. J. Nutr. Metab.,	Novel Resistant Potato Starches on Glycemia and Satiety in Humans	**PenFibe® Resistant Starch**, Cross-linked potato starch treated with 4.5% $POCL_3$. Interventions with	There were no differences in the glucose incremental areas under the curve (iAUC) for PF+ and PR+

	Vol. 2012: 1-4.		30 g of dietary fiber per day in 38 g of starch with or without glucose measured blood glucose for 2 hours. PF = PenFibe® RS, PR = noncommercial RS, + indicates RS+dextrose (DEX), – indicates RS + water.	compared with DEX. The PF−and PR− treatments had decreased iAUCs for glucose compared with DEX, PF+, and PR+. There were no treatment differences for satiety. The dose (38 g) of starches did not to alter glucose responses when added to 50 g of dextrose and caused no effects on blood glucose levels.
(3) 1971	Pieters, J.J.L., W.A. vanStaveren, and B.G.A.M. Brinkhuis 1971. As reported in (1) EFSA Journal 2010; 8(9):1772 Scientific Opinion on the safety of 'phosphated distarch phosphate' as a Novel Food ingredient. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). (2) WHO Food Addit. Ser. No. 5:372-375, (1974).	Report No. R 3433 of the Centraal Instituut voor Voedingsonderzoek.	Ten volunteers consumed 60 g of phosphated distarch phosphate (PDSP) or one of 4 other RS4 starches for 4 days. Over a period of 6 weeks the subjects consumed 60 g/day of one particular starch on 4 consecutive days each week, including.	The summary report of this study indicates that no adverse effects were reported, the frequency of feces, fecal water, and lactic acid excretion were not affected. The modified starches were well tolerated, although the observations were not separately provided for each of the five kinds of modified starches tested.
(4) 2014	Nichenametla, S.N., Weidauer, L.A., et al. Mol. Nutr. Food Res. 58(6) 1365-1369.	Resistant starch type 4-enriched diet lowered blood cholesterols and improved body composition in a	Blinded exchange of RS4-enriched flour (30% RS4) with control flour on multiple metabolic	A small but significant 1% increase in fat-free mass was observed in all participants combined.

		double blind controlled cross-over intervention.	syndrome endpoints. The RS4 starch was identified as Fibersym®, phosphated distarch phosphate and the amount consumed was not given.	Flour containing 30% PDSP was provided for normal cooking uses. No significant effect of RS4 was observed for glycemic variables and blood pressures. RS4 intake improved dyslipidemia.
	STUDIES USING RESISTANT STARCHES OTHER THAN TYPE 4			
(5) 2013	Wutzke, K.D., and Scholübbers, D. Isotopes Environ Health Stud. 49(4):464-470.	The metabolic effect of resistant starch and yoghurt on the renal and fecal nitrogen and ammonia excretion in humans as measured by lactose-15N-ureide (LU).	Intervention: 2 g RS1 potato starch and 10.5 g RS2 pea starch for 20 days in 190 g of Lactobacillus acidophilus yoghurt.	The intervention significantly lowered the colonic amount and renal excretion of toxic 15NH3 and shifted ammonia excretion from urinary to fecal when using 15N-LU as a xenobiotic marker.
(6) 2012	Maki, K.C., et al. J. Nutr. 142(4):717-723.	Resistant starch from high-amylose maize increases insulin sensitivity in overweight and obese men.	High amylose starch, type RS2, was consumed in obese patients at 15 g/d or 30 g/d for 4 weeks in a double blind crossover trial.	Insulin resistance was improved in males but not in females. Reported adverse events were not different in treated and controls. Most adverse events were mild and not related to consumption of the study product (RS2 starch).

(7) 2010	Johnston, K.L., et al. Diabet Med. 27(4):391-397.	Resistant starch improves insulin sensitivity in metabolic syndrome.	High amylose starch, type RS2, was consumed healthy subjects at 30 g/d for 12 weeks in a single blind placebo controlled trial.	Resistant starch consumption did not significantly affect body weight, fat storage in muscle, liver or visceral depots. There was no change with RS feeding on vascular function or markers of inflammation. Insulin sensitivity improved relative to placebo group.
(8) 2010	Penn-Marshall, M., et al. J Med Food. 2010 Aug;13(4):999-1004. Erratum in: J Med Food. 13(5):1286.	African Americans may have to consume more than 12 grams a day of resistant starch to lower their risk for type 2 diabetes.	A 14-week, double-blind, crossover design study was conducted with African American male and female subjects at risk for type 2 DM. All subjects consumed bread containing 12 g of added high amylose maize RS2 or control bread for 6 weeks, separated by a 2-week washout period.	Mean homeostasis model assessment of insulin resistance decreased to normal values (>2.5) at the end of the 14-week study, although there were no significant treatment effects positive or negative.
(9) 2009	Maki, K.C., et al. Int. J. Food Sci. Nutr. 2009;60 Suppl. 4:296-305.	Beneficial effects of resistant starch on laxation in healthy adults.	25 g RS3 or wheat bran were consumed for 14 days, then crossed over to the opposite treatment after a 7-day washout. A double-blind crossover design evaluated the effects of a type 3 resistant starch (RS3) versus wheat bran on	Daily fecal output increased with RS3 intake and with WB. No differences in bowel habits were observed. Fecal consistency ratings were increased with WB but unchanged with RS. Safety evaluations were monitored

			fecal weight, freq., and consistency in healthy adults following a 14-day baseline period when 14 subjects consumed low fiber test products.	in all subjects who provided informed consent and received at least one dose of product during the baseline period. No indication of intolerance for either RS3 or WB were found.
(10) 2007	Storey, D., et al. Eur J Clin Nutr. 61(11):1262-70.	Gastrointestinal responses following acute and medium term intake of retrograded resistant maltodextrins, classified as type 3 resistant starch.	GI responses of young adults following consumption of 0–60 g increments of retrograded resistant maltodextrin (RS3) to define the maximum non-effective dose (MNED). Part 2 determined whether a gradual increase in the daily dose of retrograded resistant RS3 to 10 g above the MNED was tolerated. Part 1 was a randomized double-blind placebo-controlled crossover study of 1 day exposures. Part 2 was longitudinal for 21 days. Forty-one healthy adult volunteers aged 18–24 years participated.	Consumption of up to 60 g RS3 was tolerated by most individuals with no evidence of any significant dose dependent increase in symptoms or the occurrence of multiple GI symptoms. A mild laxative effect when consuming > 60 g R3 is suggested. There was no change in GI responses following consumption of increasing doses of R3 over 21 days.
(11) 1995	de Roos, N., et al. Eur J Clin Nutr. 49(7):532-41.	Resistant starch has little effect on appetite, food	For 4 weeks 24 healthy males consumed either	Consumption of 30 g/day RS2 and RS3 had little

		intake and insulin secretion of healthy young men.	glucose, high-amylase corn starch (RS2), or extruded and retrograded high-amylase corn starch (RS3) in a cross-over, single-blind, randomized and balanced design. Each type of supplement was consumed for a week. In the first week each subject consumed the glucose supplement. The RS2 and RS3 supplements provided 30 g RS/day. At the end of weeks 2, 3 and 4, subjects rated their appetite each whole hour on a visual analogue scale. Food intake was assessed and C-peptide excretion in urine as a measure for 24-h insulin secretion.	influence on appetite and food intake, but RS3 reduced the insulin secretion. No adverse effects were reported.

APPENDIX III

EXPERT PANEL REPORT

The Generally Recognized as Safe (GRAS) Status of the Proposed Uses of Distarch Phosphate Modified Food Starch

19 April 2017

We, an independent panel of experts, qualified by scientific training and national and international experience to evaluate the safety of food and food ingredients (the "Expert Panel"), were specially convened by Keller and Heckman LLP, on behalf of their client, Ingredion Incorporated, to evaluate the safety and "Generally Recognized As Safe" ("GRAS") status of the proposed uses of Distarch Phosphate (DSP) modified food starch made using approximately 4.5% phosphorus oxychloride ($POCl_3$), which exceeds the 0.1% treatment level set forth in the food starch-modified regulation (21 C.F.R. §172.892). Modified food starch produced with 0.1% $POCl_3$ and 4.5% $POCl_3$ results in modified food starch with levels of residual phosphorus below 0.5%. The Expert Panel critically evaluated relevant data on Ingredion's DSP. Following its critical evaluation of all the information submitted and other information deemed appropriate, the Expert Panel unanimously concluded that the proposed uses of Ingredion's DSP, manufactured consistent with current good manufacturing practice (cGMP) and meeting appropriate food-grade specifications presented in the GRAS Notification, are safe and suitable, and GRAS based on scientific procedures.

Ingredion's DSP is intended for use in bread, pancakes/waffles, nutrition bars, ready-to-eat (RTE) cereal, muffins, tortillas, pretzels, dry uncooked plain pasta, and meal replacements to contribute enough dietary fiber to support a "good source of fiber" claim (10% of the 28 gram daily value of dietary fiber, which is 2.8 grams) or an "excellent source of fiber" claim (20% of the 28 gram daily value for dietary fiber, which is 5.6 grams). DSP will be used as a source of dietary fiber and as a functional ingredient such as a thickener or texturizing agent.

Modified food starch is an approved food additive as described at 21 C.F.R. § 172.892. Section 172.892 sets forth the various treatments that can be used to modify the starch including the esterification of starch by phosphorus oxychloride (POCl3); however, the level of POCl3 to be used is limited to 0.1% whereas Ingredion is interested in using 4.5% Thus, Ingredion's product technically falls outside the scope of the food additive regulation, and must be reviewed to determine if it is generally recognized as safe so that it can be lawfully used as an ingredient in food.

The Expert Panel critically evaluated the GRAS Notification prepared by Keller and Heckman LLP, that summarized the characteristics, manufacturing process, proposed uses, digestibility (including resistance to digestion, based on the in vitro Englyst procedure), safety studies applicable to Ingredion's DSP, and other information deemed appropriate.

The Expert Panel also critically evaluated reports of expert committees including the European Food Safety Authority (EFSA), the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and the Scientific Committee for Food (SCF) who evaluated the safety of phosphated starches and concluded that they are safe without any limitation on use. In 1979, the Select Committee on GRAS Substances (SCOGS) concluded that phosphated starches are safe but that unlimited use was not justified based on one report of adverse effects in the kidneys of rats. Subsequent studies demonstrated that these adverse effects are not relevant to human safety. It was also reported that similar renal effects occurred in rats fed lactose and other non-digestible ingredients at high dietary levels. Further, there are numerous published animal and human safety/toxicity studies that support the safety of phosphated starches. These findings are corroborated by unpublished studies. Published animal studies on modified starches and human studies on resistant starches are summarized in the Appendices to the GRAS Notification. These animal studies include: (1) acute studies in mice, rats, guinea pigs, rabbits and cats; (2) a long term multi-generational chronic study in rats; and (3) multigeneration reproductive and developmental studies. The human studies that support the safety of type 4 resistant starches like DSP are also summarized in the Appendices to the GRAS Notification.

The Expert Panel considered the residual phosphorus that is present in the DSP and concluded that the amount of bioavailable phosphorus in the DSP is very low. If all of the phosphorus in the resistant starch were bioavailable, the total amount would result in a small fraction of the level of phosphorus that is tolerable in the human diet (0.02 g/day from one serving of food that contains 5 grams of DSP or 0.14 g/day based on the 90^{th} percentile per user estimated daily intake of 36.3 g/day, which is well below the upper level of 4.0 g/day phosphorus that is established by the Food and Nutrition Board of the Institute of Medicine).

Conclusion

Following its independent and critical evaluation of the GRAS Notification prepared by Keller and Heckman LLP and other materials deemed appropriate, the Expert Panel convened by telephone, and independently, jointly, and unanimously concluded that the proposed uses in bread, pancakes/waffles, nutrition bars, ready-to-eat (RTE) cereal, muffins, tortillas, pretzels, dry uncooked plain pasta, and meal replacements that may typically provide up to 5.6 grams of dietary fiber in a serving of food where of Ingredion's Distarch Phosphate modified food starch, manufactured consistent with current good manufacturing practice (cGMP) and meeting appropriate food-grade specifications presented in the Keller and Heckman GRAS Notification, are safe and suitable.

The Expert Panel further unanimously concluded that Ingredion's Distarch Phosphate modified food starch, manufactured consistent with current good manufacturing practice (cGMP) and meeting appropriate food-grade specifications presented in the Keller and Heckman GRAS Notification, that is proposed for use in bread, pancakes/waffles, nutrition bars, ready-to-eat (RTE) cereal, muffins, tortillas, pretzels, dry uncooked plain pasta, and meal replacements at 3.5-7.0 grams per serving , is Generally Regarded As Safe (GRAS) based on scientific procedures.

It is the opinion of this Expert Panel that other qualified experts would concur with these conclusions.

(b) (6)

Date: 19 April 2017

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APPENDIX IV: REFERNCES

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APPENDIX V: ESTIMATED DAILY INTAKE OF DISTARCH PHOSPHATE IN THE U.S. POPULATION

Exponent®

Center for Chemical Regulation and Food Safety

ESTIMATED DAILY INTAKE OF DISTARCH PHOSPHATE IN THE U.S. POPULATION

ESTIMATED DAILY INTAKE OF DISTARCH PHOSPHATE IN THE U.S. POPULATION

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List of Acronyms

DHHS	Department of Health and Human Services
DSP	Distarch Phosphate
EDI	Estimated Daily Intake
FARE®	Foods and Residues Evaluation Program
FNDDS	Food and Nutrient Database for Dietary Studies
NCHS	National Center for Health Statistics
NHANES	National Health and Nutrition Examination Survey
RTE	Ready-to-Eat
USDA	U.S. Department of Agriculture
WWEIA	What We Eat in America

Introduction

At the request of Keller and Heckman LLP (Keller and Heckman), Exponent Inc. (Exponent) conducted an intake assessment to estimate the total daily intake of distarch phosphate (DSP) proposed for use in nine food categories. The estimated daily intake (EDI) of DSP was based on food consumption data from the 2009-2012 National Health and Examination Survey (NHANES) and provided for the total U.S. population two years (y) and older. The data and methods used to conduct the intake assessment and results are summarized in this report.

Data and Methods

Proposed Use and Levels

DSP is proposed for use in nine food categories including bread, pancake/waffles, nutrition bars, ready-to-eat (RTE) cereals, muffins, tortillas, pretzels, dry pasta, and meal replacement beverages. The proposed use levels of DSP are 3.5 and 7.0 g/serving so that the finished food product qualifies for a "good source" and "high" fiber claim, respectively. The one exception was for the pasta category for which the use level of DSP is based on the level in dry, uncooked pasta. Table 1 lists the proposed use food categories as well as the corresponding serving size amount and use level of DSP (expressed as % and g/serving) for each food type.

Table 1. Proposed Food Uses

Food Category	Serving Size (g)	DSP Use Level			
		Good Source (%)	High Fiber (%)	Good Source (g/serving)	High Fiber (g/serving)
Bread	50	7	14	3.5	7.0
Pancakes/Waffles	110	3.2	6.4		
Nutrition Bars	40	8.8	17.5		
Ready-to-eat (RTE) Cereal	15	23.3	46.7		
Muffins	110	3.2	6.4		
Tortillas	55	6.4	12.8		
Pretzels	30	11.7	23.3		
Pasta, plain (dry, uncooked)	55	6.4	12.8		
Meal Replacement	240	1.45	2.9		

Consumption Data

Estimated food consumption was based on food consumption records collected in the WWEIA component of NHANES conducted in 2009-2010 and 2011-2012 (NHANES 2009-2012). The NHANES is a continuous survey that uses a complex multistage probability sample designed to be representative of the civilian U.S. population (NCHS 2012, 2014). The NHANES datasets provide nationally representative nutrition and health data and prevalence estimates for nutrition and health status measures in the United States. 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 U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS). DHHS is responsible for the sample design and data collection, and USDA is responsible for the survey's dietary data collection methodology, maintenance of the databases used to code and process the data, and data review and processing. A total of 16,011 individuals in the survey period 2009-2012 provided 2 complete days of dietary recalls.

Analysis

Using the NHANES consumption data, Exponent estimated the 2-day average consumption of nine food categories for the total U.S. population two years and older and four U.S. sub-groups on a "per capita" and "per user" basis. In the 2-day average consumption analysis, "per capita" estimates refer to the consumption based on the entire population of interest whereas "per user" estimates refer to those who reported consuming any of the foods in a given food category on either of the survey days. Thus, if a participant reported consuming the food on day 1 but not on day 2, they would be considered a "user" and their 2-day average consumption is the amount they reported consumed on day 1 divided by 2. The analysis was limited to individuals who provided two complete and reliable dietary recalls as determined by NCHS. The 2-day average consumption by each individual was estimated using Exponent's Foods and Residues Evaluation Program (FARE® version 11.2) software. Exponent uses the statistically weighted values from the survey in its analyses to derive consumption estimates that are representative of the U.S. population.

Consumption data in the NHANES survey are reported on an "as consumed basis". That is, if a survey participant consumed an apple pie, the consumption amount reported in the survey for that subject would be for the amount of pie consumed, and not for the ingredients (flour, butter, apples, sugar, etc.) used to make that pie. For the following food categories, Exponent utilized the Food and Nutrient Database for Dietary Studies (FNDDS) developed by the U.S. Department of Agriculture (USDA), that translates the food as consumed into its corresponding ingredients (and gram amounts) or recipes:

- Bread

- Tortillas
- Pasta, dry

Identification of the weight of ingredients in foods allowed for the estimation of the food categories (listed above) that can be consumed as is or as a component in a food (i.e., bread component in a cheese sandwich, tortilla component in a wrap sandwich, and dry pasta component in mixed dishes or soups). Exponent applied FNDDS version 2011-2012 recipes (which corresponds to dietary consumption for NHANES 2011-2012) (USDA 2014) to process dietary recall data reported in NHANES 2009-2012 and FNDDS version 5.0 recipes (which corresponds to dietary consumption for NHANES 2009-2010) (USDA 2012) for foods that were only reported consumed in NHANES 2009-2010.

Other food selection approaches are summarized below by food product:

- Pasta: While the USDA recipes were relied upon to identify the weight of dry pasta in foods, cooked pasta was also identified to capture potential intake of DSP resulting from the use of dry pasta in cooking. The DSP use level for cooked pasta is the same as the other proposed food categories (3.5 and 7.0 g/serving for the "good source" and "high" fiber claim, respectively). Based on the cooked pasta serving size of 140 grams, the corresponding DSP use level is 2.5 and 5.0% for the "high" and "good source" of fiber claim, respectively.
- Meal replacement beverages: Non-reconstituted meal replacement codes were reconstituted to the amount of beverage consumed based on recipes and/or product labels corresponding to the beverage.

NHANES foods corresponding to all other food categories were identified based on the food description of the NHANES food. The list of all NHANES food codes (and their descriptions) included in the analysis can be found in Appendix I.

Results

The 2-day average EDIs of DSP on the *per capita* and *per user* basis at the mean and the 90th percentile of consumption for the total U.S. population 2+ y are provided in Table 2.

Table 2. Two day average estimated daily intake of DSP resulting in a "good source" of fiber and "high" fiber claim by the U.S. population 2 years and older (g/day); NHANES 2009-2012

			"Good Source" of Fiber Claim				"High" Fiber Claim			
			Per Capita		Per User		Per Capita		Per User	
Food Category	N*	% User	Mean	90th Percentile	Mean	90th Percentile	Mean	90th Percentile	Mean	90th Percentile
			---- g/day ----				---- g/day ----			
Bread	11,806	80	3.19	7.18	4.01	7.73	6.38	14.3	7.94	15.4
Nutrition Bars	210	2.5	0.07	0	2.95	5.50	0.15	0	5.87	10.9
RTE Cereal	6,140	40	3.31	10.7	8.37	15.5	6.63	21.5	16.8	31.0
Tortillas	4,184	26	0.94	3.21	3.62	7.59	1.89	6.43	7.24	15.2
Pretzels	937	8.1	0.17	0	2.07	4.25	0.33	0	4.13	8.46
Pasta	4,425	30	0.63	2.24	2.09	4.30	1.25	4.49	4.18	8.60
Pancakes/Waffles	1,669	10	0.16	0.23	1.59	2.59	0.32	0.46	3.17	5.17
Muffins	607	5	0.10	0.	2.05	3.63	0.20	0	4.11	7.26
Meal Replacement	327	2	0.10	0	4.14	8.41	0.20	0	8.28	16.8
Total	**14,276**	**96**	**8.7**	**17.8**	**9.06**	**18.1**	**17.4**	**35.6**	**18.1**	**36.3**

* Unweighted number of users; %user, *per capita* and *per user* estimates for NHANES derived using the statistical weights provided by the NCHS.

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Appendix I. Food Codes Included In Analysis

Food Category	Food code	Food Description
Bread	13210110	Pudding, bread*
	13210180	Pudding, Mexican bread (Capirotada)*
	14640000	Cheese sandwich*
	14640100	Cheese sandwich, grilled*
	27500050	Sandwich, NFS*
	27510110	Beef barbecue sandwich or Sloppy Joe, on bun*
	27510130	Beef barbecue submarine sandwich, on bun*
	27510210	Cheeseburger, plain, on bun*
	27510230	Cheeseburger, with mayonnaise or salad dressing, and tomato and/or catsup, on bun*
	27510250	Cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing, on bun*
	27510260	Cheeseburger, 1/4 lb meat, with mushrooms in sauce, on bun*
	27510280	Double cheeseburger (2 patties), with mayonnaise or salad dressing, on bun*
	27510300	Double cheeseburger (2 patties), with mayonnaise or salad dressing, on double-decker bun*
	27510310	Cheeseburger with tomato and/or catsup, on bun*
	27510311	Cheeseburger, 1 oz meat, plain, on miniature bun*
	27510320	Cheeseburger, 1/4 lb meat, with tomato and/or catsup, on bun*
	27510330	Double cheeseburger (2 patties), with tomato and/or catsup, on bun*
	27510340	Double cheeseburger (2 patties), with mayonnaise or salad dressing and tomatoes and/or catsup, on bun*
	27510350	Cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing, and tomato and/or catsup, on bun*
	27510355	Cheeseburger, 1/3 lb meat, with mayonnaise or salad dressing, tomato and/or catsup on bun*
	27510360	Bacon cheeseburger, with mayonnaise or salad dressing, tomato and/or catsup, on bun*
	27510370	Double cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing, on bun*
	27510375	Double cheeseburger (2 patties, 1/4 lb meat each), with tomato and/or catsup, on bun*
	27510380	Triple cheeseburger (3 patties, 1/4 lb meat each), with mayonnaise or salad dressing and tomatoes and/or catsup, on bun*
	27510385	Double bacon cheeseburger (2 patties), with tomato and/or catsup, on bun*
	27510390	Double bacon cheeseburger (2 patties, 1/4 lb meat each), on bun*
	27510400	Bacon cheeseburger, 1/4 lb meat, with tomato and/or catsup, on bun*
	27510425	Double bacon cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing, on bun*
	27510430	Double bacon cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing, and tomato and/or catsup, on bun*
	27510435	Double bacon cheeseburger (2 patties,1/3 lb meat each), with mayonnaise or salad dressing, on bun*
	27510440	Bacon cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing, and tomato and/or catsup, on bun*
	27510445	Bacon cheeseburger, 1/3 lb meat, with tomato and/or catsup, on bun*
	27510480	Cheeseburger (hamburger with cheese sauce), 1/4 lb meat, with grilled

Food Category	Food code	Food Description
		onions, on rye bun*
	27510500	Hamburger, plain, on bun*
	27510510	Hamburger, with tomato and/or catsup, on bun*
	27510520	Hamburger, with mayonnaise or salad dressing, and tomato and/or catsup, on bun*
	27510540	Double hamburger (2 patties), with tomato and/or catsup, on bun*
	27510560	Hamburger, 1/4 lb meat, with mayonnaise or salad dressing, and tomato and/or catsup, on bun*
	27510570	Hamburger, 2-1/2 oz meat, with mayonnaise or salad dressing and tomatoes, on bun*
	27510600	Hamburger, 1 oz meat, plain, on miniature bun*
	27510610	Hamburger, 1 oz meat, with tomato and/or catsup, on miniature bun*
	27510620	Hamburger, 1/4 lb meat, with tomato and/or catsup, on bun*
	27510670	Double hamburger (2 patties), with mayonnaise or salad dressing and tomatoes, on bun*
	27510680	Double hamburger (2 patties, 1/4 lb meat each), with tomato and/or catsup, on bun*
	27510690	Double hamburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing and tomatoes and/or catsup, on double-decker bun*
	27510700	Meatball and spaghetti sauce submarine sandwich*
	27510950	Reuben sandwich (corned beef sandwich with sauerkraut and cheese), with spread*
	27511010	Pastrami sandwich*
	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*
	27513060	Roast beef sandwich with bacon and cheese sauce*
	27513070	Roast beef submarine sandwich, on roll, au jus*
	27515020	Steak and cheese submarine sandwich, with lettuce and tomato*
	27515050	Fajita-style beef sandwich with cheese, on pita bread, with lettuce and tomato*
	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*
	27520130	Bacon, chicken, and tomato club sandwich, with lettuce 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*
	27520165	Bacon, chicken fillet (breaded, fried), and tomato club with lettuce and spread*
	27520166	Bacon, chicken fillet (breaded, fried), and tomato club sandwich with cheese, lettuce and spread*
	27520300	Ham sandwich, with spread*
	27520320	Ham and cheese sandwich, with lettuce and spread*
	27520370	Hot ham and cheese sandwich, on bun*
	27520390	Ham and cheese submarine sandwich, with lettuce, tomato and spread*
	27520410	Cuban sandwich, (Sandwich cubano), with spread*
	27520500	Pork sandwich, on white roll, with onions, dill pickles and barbecue sauce*

Food Category	Food code	Food Description
	27520510	Pork barbecue sandwich or Sloppy Joe, on bun*
	27520520	Pork sandwich*
	27540110	Chicken sandwich, with spread*
	27540111	Chicken sandwich, with cheese and spread*
	27540120	Chicken salad or chicken spread sandwich*
	27540130	Chicken barbecue sandwich*
	27540140	Chicken fillet (breaded, fried) sandwich*
	27540150	Chicken fillet (breaded, fried) sandwich with lettuce, tomato and spread*
	27540170	Chicken patty sandwich, miniature, with spread*
	27540190	Chicken patty sandwich, with lettuce and spread*
	27540200	Fajita-style chicken sandwich with cheese, on pita bread, with lettuce and tomato*
	27540230	Chicken patty sandwich with cheese, on wheat bun, with lettuce, tomato 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*
	27540250	Chicken fillet, broiled, sandwich with cheese, on whole wheat roll, with lettuce, tomato and non-mayonnaise type spread*
	27540260	Chicken fillet, broiled, sandwich, on oat bran bun, with lettuce, tomato, spread*
	27540270	Chicken fillet, broiled, sandwich, with lettuce, tomato, and non-mayonnaise type spread*
	27540280	Chicken fillet, broiled, sandwich with cheese, on bun, with lettuce, tomato and spread*
	27540290	Chicken submarine sandwich, with lettuce, tomato, and spread*
	27540291	Chicken submarine sandwich, with cheese, lettuce, tomato, and spread*
	27540310	Turkey sandwich, with spread*
	27540350	Turkey 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*
	27550000	Fish sandwich, on bun, with spread*
	27550100	Fish sandwich, on bun, with cheese and spread*
	27550720	Tuna salad sandwich*
	27550750	Tuna salad submarine sandwich, with lettuce and tomato*
	27550751	Tuna salad submarine sandwich, with cheese, lettuce and tomato*
	27560340	Frankfurter or hot dog, with catsup and/or mustard, on bun*
	27560350	Pig in a blanket (frankfurter or hot dog wrapped in dough)*
	27560400	Chicken frankfurter or hot dog, plain, on bun*
	27560500	Pepperoni and salami submarine sandwich, with lettuce, tomato, and spread*
	27560710	Sausage sandwich*
	27560910	Cold cut submarine sandwich, with cheese, lettuce, tomato, and spread*
	27564000	Frankfurter or hot dog sandwich, NFS, plain, on bun*
	27564010	Frankfurter or hot dog sandwich, NFS, plain, on white bread*
	27564020	Frankfurter or hot dog sandwich, NFS, plain, on wheat bread*
	27564060	Frankfurter or hot dog sandwich, beef, plain,on bun*
	27564070	Frankfurter or hot dog sandwich, beef, plain, on white bread*
	27564080	Frankfurter or hot dog sandwich, beef, plain, on wheat bread*

Food Category	Food code	Food Description
	27564090	Frankfurter or hot dog sandwich, beef, plain, on whole wheat bread, NS as to 100%*
	27564100	Frankfurter or hot dog sandwich, beef, plain, on whole grain white bread*
	27564120	Frankfurter or hot dog sandwich, beef and pork, plain, on 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, NS as to 100%*
	27564180	Frankfurter or hot dog sandwich, meat and poultry, plain, on 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, NS as to 100%*
	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 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, NS as to 100%*
	27564300	Frankfurter or hot dog sandwich, reduced fat or light, plain, on bun*
	27564310	Frankfurter or hot dog sandwich, reduced fat or light, plain, on white bread*
	27564360	Frankfurter or hot dog sandwich, fat free, plain, on bun*
	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 bun*
	27564450	Frankfurter or hot dog sandwich, with chili, on white bread*
	27564460	Frankfurter or hot dog sandwich, with chili, on wheat bread*
	27564500	Frankfurter or hot dog sandwich, with vegetarian chili, on bun*
	27564510	Frankfurter or hot dog sandwich, with vegetarian chili, on white bread*
	27570310	Hors d'oeuvres, with spread*
	32201000	Fried egg sandwich*
	32202000	Egg, cheese, ham, and bacon on bun*
	32202035	Egg, extra cheese (2 slices), and extra sausage (2 patties) on bun*
	42301010	Peanut butter sandwich*
	42302010	Peanut butter and jelly sandwich*
	51000100	Bread, NS as to major flour
	51000110	Bread, NS as to major flour, toasted
	51000200	Roll, NS as to major flour
	51000300	Roll, hard, NS as to major flour
	51101000	Bread, white
	51101010	Bread, white, toasted
	51102010	Bread, white with whole wheat swirl
	51102020	Bread, white with whole wheat swirl, toasted
	51105010	Bread, Cuban
	51105040	Bread, Cuban, toasted
	51107010	Bread, French or Vienna
	51107040	Bread, French or Vienna, toasted
	51108100	Naan, Indian flatbread

Food Category	Food code	Food Description
	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
	51119010	Bread, egg, Challah
	51122000	Bread, reduced calorie and/or high fiber, white or NFS
	51122010	Bread, reduced calorie and/or high fiber, white or NFS, toasted
	51122100	Bread, reduced calorie and/or high fiber, white or NFS, with fruit and/or nuts*
	51123020	Bread, high protein, toasted
	51127010	Bread, potato
	51127020	Bread, potato, toasted
	51129010	Bread, raisin
	51129020	Bread, raisin, toasted
	51133010	Bread, sour dough
	51133020	Bread, sour dough, toasted
	51136000	Bruschetta*
	51150000	Roll, white, soft
	51150100	Roll, white, soft, toasted
	51152000	Roll, white, soft, reduced calorie and/or high fiber
	51153000	Roll, white, hard
	51154550	Roll, egg bread
	51154600	Roll, cheese
	51155000	Roll, French or Vienna
	51156500	Roll, garlic
	51157000	Roll, hoagie, submarine
	51158100	Roll, Mexican, bolillo
	51159000	Roll, sour dough
	51160000	Roll, sweet, no frosting*
	51161250	Roll, sweet, no topping, Mexican (Pan Dulce)*
	51161270	Roll, sweet, sugar topping, Mexican (Pan Dulce)*
	51161280	Roll, sweet, with raisins and icing, Mexican (Pan Dulce)*
	51201010	Bread, whole wheat, 100%
	51201020	Bread, whole wheat, 100%, toasted
	51201110	Bread, whole wheat, 100%, with raisins*
	51201150	Bread, pita, whole wheat, 100%
	51207010	Bread, sprouted wheat
	51207020	Bread, sprouted wheat, toasted
	51220000	Roll, whole wheat, 100%
	51300050	Bread, whole grain white
	51300060	Bread, whole grain white, toasted
	51300110	Bread, whole wheat, NS as to 100%
	51300120	Bread, whole wheat, NS as to 100%, toasted
	51300140	Bread, whole wheat, NS as to 100%, made from home recipe or purchased at bakery
	51300150	Bread, whole wheat, NS as to 100%, made from home recipe or purchased at bakery, toasted

Food Category	Food code	Food Description
	51300175	Bread, chappatti or roti (Indian bread), wheat
	51300185	Bread, paratha, (Indian flat bread), wheat
	51301010	Bread, wheat or cracked wheat
	51301020	Bread, wheat or cracked wheat, toasted
	51301510	Bread, wheat or cracked wheat, reduced calorie and/or high fiber
	51301520	Bread, wheat or cracked wheat, reduced calorie and/or high fiber, toasted
	51301540	Bread, French or Vienna, whole wheat, NS as to 100%
	51301550	Bread, French or Vienna, whole wheat, NS as to 100%, toasted
	51301600	Bread, pita, whole wheat, NS as to 100%
	51301620	Bread, pita, wheat or cracked wheat
	51301630	Bread, pita, wheat or cracked wheat, toasted
	51302010	Bread, wheat bran
	51302050	Bread, wheat bran, with raisins*
	51320010	Roll, wheat or cracked wheat
	51320500	Roll, whole wheat, NS as to 100%
	51320510	Roll, whole wheat, NS as to 100%, toasted
	51401010	Bread, rye
	51401020	Bread, rye, toasted
	51401030	Bread, marble rye and pumpernickel
	51404010	Bread, pumpernickel
	51404020	Bread, pumpernickel, toasted
	51407010	Bread, black
	51407020	Bread, black, toasted
	51420000	Roll, rye
	51421000	Roll, pumpernickel
	51501010	Bread, oatmeal
	51501020	Bread, oatmeal, toasted
	51501040	Bread, oat bran
	51501050	Bread, oat bran, toasted
	51503000	Muffin, English, oat bran
	51601010	Bread, multigrain, toasted
	51601020	Bread, multigrain
	51602010	Bread, multigrain, reduced calorie and/or high fiber
	51620000	Roll, multigrain
	51806010	Bread, rice
	51808000	Bread, low gluten
	51808010	Bread, low gluten, toasted
	53415100	Crisp, apple, apple dessert*
	55301000	French toast, plain*
	58127500	Vegetable submarine sandwich, with fat free spread*
	75608100	Onion soup, French*
Pancakes/Waffles	55101000	Pancakes, plain
	55101010	Pancakes, reduced calorie, high fiber
	55101015	Pancakes, plain, reduced fat
	55101020	Pancakes, plain, fat free
	55103000	Pancakes, with fruit
	55103100	Pancakes, with chocolate chips
	55105000	Pancakes, buckwheat
	55105100	Pancakes, cornmeal
	55105200	Pancakes, whole wheat
	55105205	Pancakes, whole wheat, reduced fat

Food Category	Food code	Food Description
	55105210	Pancakes, whole wheat, fat free
	55201000	Waffle, plain
	55202000	Waffle, wheat, bran, or multigrain
	55203000	Waffle, fruit
	55203500	Waffle, nut and honey
	55203600	Waffle, chocolate chip
	55204000	Waffle, cornmeal
	55205000	Waffle, 100% whole wheat or 100% whole grain
	55206000	Waffle, oat bran
	55207000	Waffle, multi-bran
	55211000	Waffle, plain, fat free
	55211050	Waffle, plain, lowfat
	55212000	Waffle, whole wheat, lowfat
	58310310	Pancakes and sausage (frozen meal)*
Nutrition Bars	41435110	High protein bar, candy-like, soy and milk base
	41435120	Zone Perfect Classic Crunch nutrition bar
	41435300	Balance Original Bar
	41435500	Clif Bar
	41435700	South Beach Living High Protein Cereal Bar
	41435710	South Beach Living Meal Replacement Bar
	53540800	Kashi GOLEAN Chewy Bars
	53540802	Kashi TLC Chewy Granola Bar
	53540806	Kashi TLC Crunchy Granola Bar
	53541200	Meal replacement bar
	53541300	Slim Fast Original Meal Bar
	53544450	PowerBar (fortified high energy bar)
	53710800	Kashi GOLEAN Chewy Bars
	53710802	Kashi TLC Chewy Granola Bar
	53710804	Kashi GOLEAN Crunchy Bars
	53710806	Kashi TLC Crunchy Granola Bar
	53720100	Balance Original Bar
	53720200	Clif Bar
	53720300	PowerBar
	53720400	Slim Fast Original Meal Bar
	53720500	Snickers Marathon Protein bar
	53720600	South Beach Living Meal Bar
	53720610	South Beach Living High Protein Bar
	53720700	Tiger's Milk bar
	53720800	Zone Perfect Classic Crunch nutrition bar
	53729000	Nutrition bar or meal replacement bar, NFS
	91780010	Snickers Marathon Energy bar
	91781010	Snickers Marathon Protein bar
RTE Cereal	57000000	Cereal, NFS
	57000050	Kashi cereal, NS as to ready to eat or cooked
	57000100	Oat cereal, NFS
	57100100	Cereal, ready-to-eat, NFS
	57100500	Character cereals, TV or movie, Kellogg's
	57101000	All-Bran
	57101020	All-Bran with Extra Fiber
	57102000	Alpen
	57103000	Alpha-Bits

Food Category	Food code	Food Description
	57103050	Amaranth Flakes
	57103100	Apple Cinnamon Cheerios
	57104000	Apple Jacks
	57106050	Banana Nut Crunch Cereal (Post)
	57106060	Banana Nut Cheerios
	57106100	Basic 4
	57106250	Berry Berry Kix
	57106260	Berry Burst Cheerios
	57106530	Blueberry Morning, Post
	57107000	Booberry
	57110000	All-Bran Bran Buds, Kellogg's (formerly Bran Buds)
	57117000	Cap'n Crunch
	57119000	Cap'n Crunch's Crunch Berries
	57120000	Cap'n Crunch's Peanut Butter Crunch
	57123000	Cheerios
	57124000	Chex cereal, NFS
	57124050	Chex Cinnamon
	57124100	Chocolate Cheerios
	57124200	Chocolate flavored frosted puffed corn cereal
	57124300	Chocolate Lucky Charms
	57125000	Cinnamon Toast Crunch
	57125010	Cinnamon Toast Crunch Reduced Sugar
	57125900	Honey Nut Clusters (formerly called Clusters)
	57126000	Cocoa Krispies
	57127000	Cocoa Pebbles
	57128000	Cocoa Puffs
	57128005	Cocoa Puffs, reduced sugar
	57128880	Complete Oat Bran Flakes, Kellogg's (formerly Common Sense Oat Bran, plain)
	57130000	Cookie-Crisp
	57131000	Crunchy Corn Bran, Quaker
	57132000	Corn Chex
	57134000	Corn flakes, NFS
	57134090	Corn flakes, low sodium
	57135000	Corn flakes, Kellogg's
	57137000	Corn Puffs
	57138000	Total Corn Flakes
	57139000	Count Chocula
	57143000	Cracklin' Oat Bran
	57143500	Cranberry Almond Crunch, Post
	57144000	Crisp Crunch
	57148000	Crispix
	57148500	Crispy Brown Rice Cereal
	57151000	Crispy Rice
	57201800	Disney cereals, Kellogg's
	57201900	Dora the Explorer Cereal
	57206700	Fiber One
	57206705	Fiber One Caramel Delight
	57206710	Fiber One Honey Clusters
	57206715	Fiber One Raisin Bran Clusters
	57206800	Fiber 7 Flakes, Health Valley

Food Category	Food code	Food Description
	57207000	Bran Flakes, NFS (formerly 40% Bran Flakes, NFS)
	57208000	All-Bran Complete Wheat Flakes, Kellogg's
	57209000	Natural Bran Flakes, Post (formerly called 40% Bran Flakes, Post)
	57211000	Frankenberry
	57212100	French Toast Crunch, General Mills
	57213000	Froot Loops
	57213850	Frosted Cheerios
	57214000	Frosted Mini-Wheats
	57214100	Frosted Wheat Bites
	57218000	Frosted Rice Krispies, Kellogg's
	57219000	Fruit & Fibre (fiber), NFS
	57221000	Fruit & Fibre (fiber) with dates, raisins, and walnuts
	57221650	Fruit Harvest cereal, Kellogg's
	57221700	Fruit Rings, NFS
	57221800	Fruit Whirls
	57221810	Fruity Cheerios
	57223000	Fruity Pebbles
	57224000	Golden Grahams
	57227000	Granola, NFS
	57228000	Granola, homemade
	57229000	Granola, lowfat, Kellogg's
	57229500	Granola with Raisins, lowfat, Kellogg's
	57230000	Grape-Nuts
	57231000	Grape-Nuts Flakes
	57231200	Great Grains, Raisin, Date, and Pecan Whole Grain Cereal, Post
	57231250	Great Grains Double Pecan Whole Grain Cereal, Post
	57237100	Honey Bunches of Oats Honey Roasted Cereal
	57237200	Honey Bunches of Oats with Vanilla Clusters, Post
	57237300	Honey Bunches of Oats with Almonds, Post
	57237310	Honey Bunches of Oats with Pecan Bunches
	57237900	Honey Bunches of Oats Just Bunches
	57238000	Honeycomb, plain
	57239100	Honey Crunch Corn Flakes, Kellogg's
	57240100	Honey Nut Chex
	57241000	Honey Nut Cheerios
	57241200	Honey Nut Shredded Wheat, Post
	57243000	Honey Smacks, Kellogg's (formerly Smacks; Honey Smacks)
	57301100	Kaboom
	57301500	Kashi, Puffed
	57301505	Kashi Autumn Wheat
	57301510	Kashi GOLEAN
	57301511	Kashi GOLEAN Crunch
	57301512	Kashi GOLEAN Crunch Honey Almond Flax
	57301520	Kashi Good Friends
	57301530	Kashi Heart to Heart Honey Toasted Oat
	57301535	Kashi Heart to Heart Oat Flakes and Blueberry Clusters
	57301540	Kashi Honey Sunshine
	57302100	King Vitaman
	57303100	Kix
	57303105	Honey Kix
	57304100	Life (plain and cinnamon)

Food Category	Food code	Food Description
	57305100	Lucky Charms
	57305150	Frosted oat cereal with marshmallows
	57305160	Malt-O-Meal Blueberry Muffin Tops
	57305165	Malt-O-Meal Cinnamon Toasters
	57305170	Malt-O-Meal Coco-Roos
	57305174	Malt-O-Meal Colossal Crunch
	57305175	Malt-O-Meal Cocoa Dyno-Bites
	57305180	Malt-O-Meal Corn Bursts
	57305200	Malt-O-Meal Crispy Rice
	57305210	Malt-O-Meal Frosted Flakes
	57305300	Malt-O-Meal Fruity Dyno-Bites
	57305500	Malt-O-Meal Honey and Nut Toasty O's
	57305600	Malt-O-Meal Marshmallow Mateys
	57306100	Malt-O-Meal Puffed Rice
	57306120	Malt-O-Meal Puffed Wheat
	57306130	Malt-O-Meal Raisin Bran
	57306500	Malt-O-Meal Golden Puffs (formerly Sugar Puffs)
	57306700	Malt-O-Meal Toasted Oat Cereal
	57306800	Malt-O-meal Tootie Fruities
	57307010	Maple Pecan Crunch Cereal, Post
	57307150	Marshmallow Safari, Quaker
	57307500	Millet, puffed
	57307600	Mini-Swirlz Cinnamon Bun Cereal, Kellogg's
	57308150	Mueslix cereal, NFS
	57308190	Muesli, dried fruit and nuts (formerly Muesli with raisins, dates, and almonds)
	57308300	Multi Bran Chex
	57308400	MultiGrain Cheerios
	57309100	Nature Valley Granola, with fruit and nuts
	57316300	Oat Bran Flakes, Health Valley
	57316380	Oat Cluster Cheerios Crunch
	57316450	Oatmeal Crisp with Almonds
	57316500	Oatmeal Crisp, Raisin (formerly Oatmeal Raisin Crisp)
	57316710	Oh's, Honey Graham
	57319000	100% Natural Cereal, plain, Quaker
	57319500	Sun Country 100% Natural Granola, with Almonds
	57320500	100 % Natural Cereal, with oats, honey and raisins, Quaker
	57321700	Optimum, Nature's Path
	57321800	Optimum Slim, Nature's Path
	57321900	Organic Flax Plus, Nature's Path
	57322500	Oreo O's cereal, Post
	57325000	Product 19
	57326000	Puffins Cereal
	57327450	Quaker Oat Bran Cereal
	57327500	Quaker Oatmeal Squares (formerly Quaker Oat Squares)
	57328000	Quisp
	57329000	Raisin bran, NFS
	57330000	Raisin Bran, Kellogg's
	57330010	Raisin Bran Crunch, Kellogg's
	57331000	Raisin Bran, Post
	57332050	Raisin Bran, Total

Food Category	Food code	Food Description
	57332100	Raisin Nut Bran
	57335550	Reese's Peanut Butter Puffs cereal
	57336000	Rice Chex
	57337000	Rice Flakes, NFS
	57339000	Rice Krispies, Kellogg's
	57339100	Rice Krispies with Real Strawberries, Kellogg's
	57339500	Rice Krispies Treats Cereal, Kellogg's
	57340000	Rice, puffed
	57341000	Shredded Wheat'N Bran
	57341200	Smart Start Strong Heart Antioxidants Cereal, Kellogg's
	57342010	Smorz, Kellogg's
	57344000	Special K
	57344001	Special K Blueberry
	57344005	Special K Chocolatey Delight
	57344007	Special K Low Fat Granola
	57344010	Special K Red Berries
	57344015	Special K Fruit & Yogurt
	57344020	Special K Vanilla Almond
	57344025	Special K Cinnamon Pecan, Kellogg's
	57346500	Oatmeal Honey Nut Heaven, Quaker (formerly Toasted Oatmeal, Honey Nut)
	57347000	Corn Pops
	57348000	Frosted corn flakes, NFS
	57349000	Frosted Flakes, Kellogg's
	57349020	Reduced Sugar Frosted Flakes Cereal, Kellogg's
	57355000	Golden Crisp (Formerly called Super Golden Crisp)
	57401100	Toasted oat cereal
	57403100	Toasties, Post
	57404100	Malt-O-Meal Toasty O's
	57404200	Malt-O-Meal Apple and Cinnamon Toasty O's
	57406100	Total
	57406105	Total Cranberry Crunch
	57407100	Trix
	57407110	Trix, reduced sugar
	57408100	Uncle Sam Cereal (formerly Uncle Sam's Hi Fiber Cereal)
	57409100	Waffle Crisp, Post
	57410000	Weetabix Whole Wheat Cereal
	57411000	Wheat Chex
	57416000	Wheat, puffed, plain
	57416010	Wheat, puffed, presweetened with sugar
	57417000	Shredded Wheat, 100%
	57418000	Wheaties
	57419000	Yogurt Burst Cheerios
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
	52302100	Muffin, fruit, fat free, cholesterol free
	52302500	Muffin, chocolate chip
	52302600	Muffin, chocolate

Food Category	Food code	Food Description
	52302610	Muffin, chocolate, lowfat
	52303010	Muffin, whole wheat
	52304000	Muffin, whole grain
	52304010	Muffin, wheat bran
	52304040	Muffin, bran with fruit, lowfat
	52304100	Muffin, oatmeal
	52304150	Muffin, oat bran
	52304200	Muffin, oat bran with fruit and/or nuts
	52306010	Muffin, plain
	52306300	Muffin, cheese
	52306500	Muffin, pumpkin
	52306550	Muffin, zucchini
	52306700	Muffin, carrot
	52307120	Muffin, multigrain, with fruit
Tortillas	27146160	Chicken with mole sauce*
	27500200	Wrap sandwich, filled with meat, poultry, or fish, vegetables, and cheese*
	27500300	Wrap sandwich, filled with meat, poultry, or fish, and vegetables*
	27517000	Wrap sandwich filled with beef patty, cheese and spread and/or sauce*
	27517010	Wrap sandwich filled with beef patty, cheese, tomato and/or catsup, and spread and/or sauce*
	27540210	Wrap sandwich filled with chicken strips (breaded, fried), cheese, lettuce, and spread*
	27540300	Wrap sandwich filled with chicken strips (broiled), cheese, lettuce, and spread*
	28522000	Mole poblano (sauce)*
	32105180	Huevos rancheros*
	52215000	Tortilla, NFS
	52215100	Tortilla, corn
	52215200	Tortilla, flour (wheat)
	52215260	Tortilla, whole wheat
	52215350	Taco shell, flour
	53452500	Pastry, mainly flour and water, fried*
	58100000	Burrito, taco, or quesadilla with egg*
	58100005	Burrito, taco, or quesadilla with egg and potato*
	58100010	Burrito, taco, or quesadilla with egg and breakfast meat*
	58100013	Burrito, taco, or quesadilla with egg and breakfast meat, from fast food*
	58100015	Burrito, taco, or quesadilla with egg, potato, and breakfast meat*
	58100020	Burrito, taco, or quesadilla with egg, beans, and breakfast meat*
	58100100	Burrito with meat*
	58100110	Burrito with beef and beans*
	58100120	Burrito with meat and beans*
	58100125	Burrito with meat and beans, from fast food*
	58100130	Burrito with beef and cheese, no beans*
	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*
	58100150	Burrito with beef and potato, no beans*
	58100155	Burrito with beef, rice, and cheese*
	58100160	Burrito with meat, beans, and rice*
	58100165	Burrito with meat, beans, rice, and sour cream*
	58100180	Burrito with pork and beans*

Food Category	Food code	Food Description
	58100200	Burrito with chicken*
	58100210	Burrito with chicken and beans*
	58100220	Burrito with chicken, beans, and cheese*
	58100230	Burrito with chicken and cheese*
	58100235	Burrito with chicken and sour cream*
	58100240	Burrito with chicken, NFS*
	58100245	Burrito with chicken, beans, and sour cream*
	58100250	Burrito with chicken, rice, and cheese*
	58100255	Burrito with chicken, beans, and rice*
	58100260	Burrito with chicken, beans, rice, and sour cream*
	58100300	Burrito with beans and rice, meatless*
	58100310	Burrito with beans, meatless*
	58100320	Burrito with beans and cheese, meatless*
	58100325	Burrito with beans, meatless, from fast food*
	58100330	Burrito with beans, rice, and sour cream, meatless*
	58100340	Burrito with eggs, sausage, cheese and vegetables*
	58100350	Burrito with eggs and cheese, no beans*
	58100360	Chilaquiles, tortilla casserole with salsa, cheese, and egg*
	58100370	Chilaquiles, tortilla casserole with salsa and cheese, no egg*
	58100410	Burrito with beef, cheese, and sour cream*
	58100520	Enchilada with meat and beans, red-chile or enchilada sauce*
	58100525	Enchilada with meat and beans, green-chile or enchilada sauce*
	58100530	Enchilada with meat, red-chile or enchilada sauce*
	58100535	Enchilada with meat, green-chile or enchilada sauce*
	58100600	Enchilada with chicken, tomato-based sauce*
	58100620	Enchilada with chicken and beans, red-chile or enchilada sauce*
	58100625	Enchilada with chicken and beans, green-chile or enchilada sauce*
	58100630	Enchilada with chicken, red-chile or enchilada sauce*
	58100635	Enchilada with chicken, green-chile or enchilada sauce*
	58100710	Enchilada with beans, meatless*
	58100720	Enchilada with beans, meatless, red-chile or enchilada sauce*
	58100725	Enchilada with beans, green-chile or enchilada sauce*
	58100800	Enchilada, just cheese, meatless, no beans, red-chile or enchilada sauce*
	58100805	Enchilada, just cheese, meatless, no beans, green-chile or enchilada sauce*
	58101240	Flauta with chicken*
	58101300	Taco or tostada with beef, cheese and lettuce*
	58101310	Taco or tostada with beef, lettuce, tomato and salsa*
	58101320	Taco or tostada with meat*
	58101323	Taco or tostada with meat, from fast food*
	58101325	Taco or tostada with meat and sour cream*
	58101345	Soft taco with meat*
	58101347	Soft taco with meat, from fast food*
	58101350	Soft taco with meat and sour cream*
	58101357	Soft taco with meat and sour cream, from fast food*
	58101400	Soft taco with beef, cheese, and lettuce*
	58101450	Soft taco with chicken*
	58101457	Soft taco with chicken, from fast food*
	58101460	Soft taco with chicken and sour cream*
	58101510	Taco or tostada with chicken or turkey, lettuce, tomato and salsa*
	58101520	Taco or tostada with chicken*

Food Category	Food code	Food Description
	58101525	Taco or tostada with chicken and sour cream*
	58101530	Soft taco with beef, cheese, lettuce, tomato and salsa*
	58101540	Taco or tostada with fish*
	58101555	Soft taco with fish*
	58101600	Soft taco with bean, cheese, and lettuce*
	58101610	Soft taco with beans*
	58101615	Soft taco with beans and sour cream*
	58101620	Soft taco with meat and beans*
	58101625	Soft taco with chicken and beans*
	58101630	Soft taco with meat, beans, and sour cream*
	58101635	Soft taco with chicken, beans, and sour cream*
	58101710	Taco or tostada with beans, meatless, with lettuce, tomato and salsa*
	58101720	Taco or tostada with beans*
	58101725	Taco or tostada with beans and sour cream*
	58101730	Taco or tostada with meat and beans*
	58101733	Taco or tostada with meat and beans, from fast food*
	58101735	Taco or tostada with chicken and beans*
	58101740	Soft taco with egg and potato*
	58101745	Taco or tostada with meat, beans, and sour cream*
	58101750	Taco or tostada with chicken, beans, and sour cream*
	58101930	Taco or tostada salad with meat*
	58101935	Taco or tostada salad with chicken*
	58101940	Taco or tostada salad, meatless*
	58101945	Taco or tostada salad with meat and sour cream*
	58101950	Taco or tostada salad with chicken and sour cream*
	58101955	Taco or tostada salad, meatless with sour cream*
	58104260	Gordita, sope, or chalupa with beans*
	58104270	Gordita, sope, or chalupa with beans and sour cream*
	58104280	Gordita, sope, or chalupa with meat and sour cream*
	58104290	Gordita, sope, or chalupa with meat*
	58104320	Gordita, sope, or chalupa with chicken and sour cream*
	58104340	Gordita, sope, or chalupa with chicken*
	58104500	Chimichanga with meat*
	58104510	Chimichanga with beef, cheese, lettuce and tomato*
	58104520	Chimichanga, meatless*
	58104530	Chimichanga with chicken*
	58104535	Chimichanga with meat and sour cream*
	58104550	Chimichanga with chicken and sour cream*
	58104710	Quesadilla, just cheese, meatless*
	58104720	Quesadilla, just cheese, from fast food*
	58104730	Quesadilla with meat*
	58104740	Quesadilla with chicken*
	58104745	Quesadilla with chicken, from fast food*
	58104750	Quesadilla with vegetables*
	58104760	Quesadilla with vegetables and meat*
	58104770	Quesadilla with vegetables and chicken*
	58104800	Taquito or flauta with cheese*
	58104820	Taquito or flauta with meat*
	58104825	Taquito or flauta with meat and cheese*
	58104830	Taquito or flauta with chicken*
	58104835	Taquito or flauta with chicken and cheese*

Food Category	Food code	Food Description
	58104905	Taquito or flauta with egg and breakfast meat*
	58105000	Fajita with chicken and vegetables*
	58105050	Fajita with meat and vegetables*
	58105075	Fajita with vegetables*
	58200100	Wrap sandwich, filled with meat, poultry, or fish, vegetables, and rice*
	58306010	Beef enchilada dinner, NFS (frozen meal)*
	58306020	Beef enchilada, chili gravy, rice, refried beans (frozen meal)*
	58306070	Cheese enchilada (frozen meal)*
	58306100	Chicken enchilada (diet frozen meal)*
	58421080	Sopa de tortilla, Mexican style tortilla soup, home recipe*
	54402200	Salty snack mixture, mostly corn or cornmeal based, with pretzels, without nuts*
Pretzels		
	54408000	Pretzels, NFS
	54408010	Pretzels, hard
	54408030	Pretzel, hard, unsalted
	54408070	Pretzel, hard, multigrain
	54408200	Pretzel, hard, chocolate-coated
	54408250	Pretzel, yogurt-covered
	54408300	Pretzels, cheese-filled
	54420010	Multigrain mixture, pretzels, cereal and/or crackers, nuts*
	54420200	Multigrain mixture, bread sticks, sesame nuggets, pretzels, rye chips*
Pasta, plain (dry and cooked)	27212000	Beef and noodles, no sauce (mixture)*
	27212050	Beef and macaroni with cheese sauce (mixture)*
	27212100	Beef and noodles with tomato-based sauce (mixture)*
	27212120	Chili con carne with beans and macaroni*
	27212150	Beef goulash with noodles*
	27212200	Beef and noodles with gravy (mixture)*
	27212300	Beef and noodles with cream or white sauce (mixture)*
	27212350	Beef stroganoff with noodles*
	27220020	Ham and noodles with cream or white sauce (mixture)*
	27220190	Sausage and noodles with cream or white sauce (mixture)*
	27220210	Ham and noodles, no sauce (mixture)*
	27242000	Chicken or turkey and noodles, no sauce (mixture)*
	27242200	Chicken or turkey and noodles with gravy (mixture)*
	27242250	Chicken or turkey and noodles with (mushroom) soup (mixture)*
	27242300	Chicken or turkey and noodles with cream or white sauce (mixture)*
	27242310	Chicken or turkey and noodles with cheese sauce (mixture)*
	27242350	Chicken or turkey tetrazzini*
	27242400	Chicken or turkey and noodles, tomato-based sauce (mixture)*
	27250120	Shrimp and noodles, no sauce (mixture)*
	27250122	Shrimp and noodles with gravy (mixture)*
	27250124	Shrimp and noodles with (mushroom) soup (mixture)*
	27250126	Shrimp and noodles with cream or white sauce (mixture)*
	27250130	Shrimp and noodles with cheese sauce (mixture)*
	27250132	Shrimp and noodles with tomato sauce (mixture)*
	27250610	Tuna noodle casserole with cream or white sauce*
	27250630	Tuna noodle casserole with (mushroom) soup*
	27250900	Fish and noodles with (mushroom) soup*
	27250950	Shellfish mixture and noodles, tomato-based sauce (mixture)*
	27313010	Beef, noodles, and vegetables (including carrots, broccoli, and/or dark-

Food Category	Food code	Food Description
		green leafy), no sauce (mixture)*
	27313020	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
	27313210	Beef, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
	27313220	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
	27313320	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), (mushroom) soup (mixture)*
	27313410	Beef, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
	27313420	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
	27320025	Ham or pork, noodles and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
	27320027	Ham or pork, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
	27320030	Ham or pork, noodles and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
	27320070	Ham or pork, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
	27320080	Sausage, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce*
	27320090	Sausage, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce*
	27336310	Venison/deer, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
	27343010	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
	27343020	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
	27343410	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
	27343420	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
	27343470	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
	27343480	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and/or dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
	27343510	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
	27343520	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
	27343950	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), cheese sauce (mixture)*
	27343960	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
	27350080	Tuna noodle casserole with vegetables, cream or white sauce*
	27350090	Fish, noodles, and vegetables (including carrots, broccoli, and/or dark green

Food Category	Food code	Food Description
		leafy), cheese sauce (mixture)*
	27350100	Fish, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
	27350410	Tuna noodle casserole with vegetables and (mushroom) soup*
	27360010	Goulash, NFS*
	28310320	Beef noodle soup, Puerto Rican style (Sopa de carne y fideos)*
	28315120	Beef vegetable soup with noodles, stew type, chunky style*
	28315160	Italian Wedding Soup*
	28320120	Pork vegetable soup with noodles, stew type, chunky style*
	28320140	Ham, noodle, and vegetable soup, Puerto Rican style*
	28331110	Lamb, pasta, and vegetable soup, Puerto Rican style*
	28340220	Chicken soup with noodles and potatoes, Puerto Rican style*
	28340590	Chicken or turkey corn soup with noodles, home recipe*
	41601060	Bean soup, with macaroni and meat*
	56101000	Macaroni, cooked, NS as to fat added in cooking*
	56101010	Macaroni, cooked, fat not added in cooking*
	56101030	Macaroni, cooked, fat added in cooking*
	56102000	Macaroni, whole wheat, cooked, NS as to fat added in cooking*
	56102010	Macaroni, whole wheat, cooked, fat not added in cooking*
	56102020	Macaroni, whole wheat, cooked, fat added in cooking*
	56103010	Macaroni, cooked, spinach, fat not added in cooking*
	56104010	Macaroni, cooked, vegetable, fat not added in cooking*
	56104020	Macaroni, cooked, vegetable, fat added in cooking*
	56112000	Noodles, cooked, NS as to fat added in cooking*
	56112010	Noodles, cooked, fat not added in cooking*
	56112030	Noodles, cooked, fat added in cooking*
	56113000	Noodles, cooked, whole wheat, NS as to fat added in cooking*
	56113010	Noodles, cooked, whole wheat, fat not added in cooking*
	56113990	Noodles, cooked, spinach, NS as to fat added in cooking*
	56114000	Noodles, cooked, spinach, fat not added in cooking*
	56114020	Noodles, cooked, spinach, fat added in cooking*
	56130000	Spaghetti, cooked, NS as to fat added in cooking*
	56130010	Spaghetti, cooked, fat not added in cooking*
	56131000	Spaghetti, cooked, fat added in cooking*
	56132990	Spaghetti, cooked, whole wheat, NS as to fat added in cooking*
	56133000	Spaghetti, cooked, whole wheat, fat not added in cooking*
	56133010	Spaghetti, cooked, whole wheat, fat added in cooking*
	58130011	Lasagna with meat*
	58130020	Lasagna with meat and spinach*
	58130140	Lasagna with chicken or turkey*
	58130150	Lasagna, with chicken or turkey, and spinach*
	58130310	Lasagna, meatless*
	58130320	Lasagna, meatless, with vegetables*
	58131100	Ravioli, NS as to filling, no sauce*
	58131110	Ravioli, NS as to filling, with tomato sauce*
	58131120	Ravioli, NS as to filling, with cream sauce*
	58131310	Ravioli, meat-filled, no sauce*
	58131320	Ravioli, meat-filled, with tomato sauce or meat sauce*
	58131330	Ravioli, meat-filled, with cream sauce*
	58131510	Ravioli, cheese-filled, no sauce*
	58131520	Ravioli, cheese-filled, with tomato sauce*

Food Category	Food code	Food Description
	58131530	Ravioli, cheese-filled, with meat sauce*
	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*
	58132110	Spaghetti with tomato sauce, meatless*
	58132310	Spaghetti with tomato sauce and meatballs or spaghetti with meat sauce or spaghetti with meat sauce and meatballs*
	58132340	Spaghetti with tomato sauce and vegetables*
	58132350	Spaghetti with tomato sauce, meatless, whole wheat noodles*
	58132360	Spaghetti with tomato sauce and meatballs, whole wheat noodles or spaghetti with meat sauce, whole wheat noodles or spaghetti with meat sauce and meatballs, whole wheat noodles*
	58132450	Spaghetti with tomato sauce, meatless, made with spinach noodles*
	58132460	Spaghetti with tomato sauce and meatballs made with spinach noodles, or spaghetti with meat sauce made with spinach noodles, or spaghetti with meat sauce and meatballs made with spinach noodles*
	58132710	Spaghetti with tomato sauce and frankfurters or hot dogs*
	58132800	Spaghetti with clam sauce, NS as to red or white*
	58132820	Spaghetti with white clam sauce*
	58132910	Spaghetti with tomato sauce and poultry*
	58133110	Manicotti, cheese-filled, no sauce*
	58133120	Manicotti, cheese-filled, with tomato sauce, meatless*
	58133130	Manicotti, cheese-filled, with meat sauce*
	58133140	Manicotti, vegetable- and cheese-filled, with tomato sauce, meatless*
	58134110	Stuffed shells, cheese-filled, no sauce*
	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*
	58134210	Stuffed shells, with chicken, with tomato sauce*
	58134610	Tortellini, meat-filled, with tomato sauce*
	58134620	Tortellini, cheese-filled, meatless, with tomato sauce*
	58134640	Tortellini, cheese-filled, meatless, with vinaigrette dressing*
	58134650	Tortellini, meat-filled, no sauce*
	58134660	Tortellini, cheese-filled, with cream sauce*
	58134680	Tortellini, cheese-filled, no sauce*
	58134710	Tortellini, spinach-filled, with tomato sauce*
	58134720	Tortellini, spinach-filled, no sauce*
	58145110	Macaroni or noodles with cheese*
	58145115	Macaroni or noodles with cheese, from boxed mix with already prepared cheese sauce*
	58146100	Pasta with tomato sauce, meatless*
	58146110	Pasta with meat sauce*
	58146120	Pasta with cheese and meat sauce*
	58146130	Pasta with carbonara sauce*
	58146150	Pasta with cheese and tomato sauce, meatless*
	58146160	Pasta with vegetables, no sauce or dressing*
	58146300	Pasta, whole wheat, with meat sauce*
	58147100	Pasta with pesto sauce*
	58147110	Macaroni or noodles with beans or lentils and tomato sauce*
	58147310	Macaroni, creamed*

Food Category	Food code	Food Description
	58147330	Macaroni or noodles, creamed, with cheese*
	58147340	Macaroni or noodles, creamed, with cheese and tuna*
	58147350	Macaroni, creamed, with vegetables*
	58147510	Flavored pasta*
	58148110	Macaroni or pasta salad, made with mayonnaise*
	58148111	Macaroni or pasta salad, made with light mayonnaise*
	58148112	Macaroni or pasta salad, made with mayonnaise-type salad dressing*
	58148114	Macaroni or pasta salad, made with Italian dressing*
	58148115	Macaroni or pasta salad, made with light Italian dressing*
	58148116	Macaroni or pasta salad, made with 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*
	58148180	Macaroni or pasta salad with cheese*
	58148550	Macaroni or pasta salad with meat*
	58149110	Noodle pudding*
	58149160	Noodle pudding, with milk*
	58402100	Beef noodle soup, home recipe*
	58403040	Chicken or turkey noodle soup, home recipe*
	58403100	Noodle and potato soup, Puerto Rican style*
	58406020	Turkey noodle soup, home recipe*
	58421010	Sopa Seca de Fideo, Mexican style, made with dry noodles, home recipe*
	58421020	Sopa de Fideo Aguada, Mexican style noodle soup, home recipe*
	58450300	Noodle soup, made with milk*
	71802010	Macaroni and potato soup*
	72202010	Broccoli casserole (broccoli, noodles, and cream sauce)*
	75340160	Vegetable and pasta combinations with cream or cheese sauce (broccoli, pasta, carrots, corn, zucchini, peppers, cauliflower, peas, etc.), cooked*
	75460700	Vegetable combinations (including carrots, broccoli, and/or dark-green leafy), cooked, with pasta*
	75460710	Vegetable combinations (excluding carrots, broccoli, and dark-green leafy), cooked, with pasta*
	75649150	Vegetable noodle soup, home recipe*
	75651000	Minestrone soup, home recipe*
	75652040	Vegetable beef soup with noodles or pasta, home recipe*
Meal Replacement	11612000	Instant breakfast, powder, milk added
	11623000	Meal supplement or replacement, commercially prepared, ready-to-drink
	11641000	Meal supplement or replacement, milk-based, high protein, liquid
	11641020	Meal replacement or supplement, milk based, ready-to-drink
	11830800	Instant breakfast, powder, not reconstituted**
	11830810	Instant breakfast, powder, sweetened with low calorie sweetener, not reconstituted**
	11830900	Protein supplement, milk-based, powdered, not reconstituted**
	11830940	Meal replacement, high protein, milk based, fruit juice mixable formula, powdered, not reconstituted**
	11830970	Meal replacement, protein type, milk-based, powdered, not reconstituted**
	11830990	Nutrient supplement, milk-based, powdered, not reconstituted**
	11831500	Nutrient supplement, milk-based, high protein, powdered, not

Food Category	Food code	Food Description
		reconstituted**
	11832000	Meal replacement, protein type, milk- and soy-based, powdered, not reconstituted**
	11836000	Protein supplement, milk-based, Muscle Milk, powdered, not reconstituted**
	11836100	Protein supplement, milk-based, Muscle Milk Light, powdered, not reconstituted**
	41430200	Meal replacement or supplement, soy- and milk-base, powder, reconstituted with water
	41430310	Protein diet powder with soy and casein**
	41440010	Ensure liquid nutrition
	41440020	Ensure with fiber, liquid
	41440050	Ensure Plus liquid nutrition
	41440100	Meal replacement or supplement, liquid, soy-based
	95101000	Boost, nutritional drink, ready-to-drink
	95101010	Boost Plus, nutritional drink, ready-to-drink
	95102000	Carnation Instant Breakfast, nutritional drink, regular, ready-to-drink
	95103000	Ensure, nutritional shake, ready-to-drink
	95103010	Ensure Plus, nutritional shake, ready-to-drink
	95104000	Glucerna, nutritional shake, ready-to-drink
	95105000	Kellogg's Special K Protein Shake
	95106000	Muscle Milk, ready-to-drink
	95106010	Muscle Milk, light, ready-to-drink
	95110000	Slim Fast Shake, meal replacement, regular, ready-to-drink
	95110020	Slim Fast Shake, meal replacement, high protein, ready-to-drink
	95120000	Nutritional drink or meal replacement, ready-to-drink, NFS
	95120010	Nutritional drink or meal replacement, high protein, ready-to-drink, NFS
	95120020	Nutritional drink or meal replacement, high protein, light, ready-to-drink, NFS
	95120050	Nutritional drink or meal replacement, liquid, soy-based
	95201000	Carnation Instant Breakfast, nutritional drink mix, regular, powder**
	95201010	Carnation Instant Breakfast, nutritional drink mix, sugar free, powder**
	95201500	Herbalife, nutritional shake mix, high protein, powder**
	95202000	Muscle Milk, regular, powder**
	95202010	Muscle Milk, light, powder**
	95210000	Slim Fast Shake Mix, powder**
	95210020	Slim Fast Shake Mix, high protein, powder**
	95220000	Nutritional drink mix or meal replacement, powder, NFS**
	95220010	Nutritional drink mix or meal replacement, high protein, powder, NFS**

* Only the ingredient proportion corresponding to the food group was included in the analysis.
**Amount of non-reconstituted meal replacements were reconstituted to the amount of beverage consumed based on recipes and/or product labels corresponding to the beverage.