ORIGINAL SUBMISSION

GRN 000599

ToxStrategies

Innovative solutions
Sound science

September 3, 2015

Richard E. Bonnette, M.S.
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Subject: GRAS Notification – Citrus Fiber (CitriTex® citrus fiber)

Dear Mr. Bonnette:

In response to your email of August 25, 2015 and our recent telephone conversation, I am resubmitting the Citrus fiber GRAS Notification on behalf of Cargill, Incorporated. ToxStrategies, Inc. (its agent) is submitting, for FDA review, Form 3667 and three copies of the GRAS notification as required. We have removed all redactions or reference to confidential business information that existed in the previously submitted documents. The enclosed document provides notice of a claim that the food ingredient, CitriTex® citrus fiber described in the enclosed notification is exempt from the premarket approval requirement of the Federal Food, Drug, and Cosmetic Act because it has been determined to be generally recognized as safe (GRAS), based on scientific procedures, for addition to select foods as a texturizer and moisture retention agent.

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

Sincerely,

(b) (6)

Don Schmitt, M.P.H.
Senior Managing Scientist

RECEIVED
SEP 4 2015
OFFICE OF
FOOD ADDITIVE SAFETY

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

GENERALLY RECOGNIZED AS SAFE *(GRAS)* NOTICE

Form Approved: OMB No. 0910-0342; Expiration Date: 02/29/2016
(See last page for OMB Statement)

FDA USE ONLY

GRN NUMBER	DATE OF RECEIPT
ESTIMATED DAILY INTAKE	INTENDED USE FOR INTERNET
NAME FOR INTERNET	
KEYWORDS	

RECEIVED
SEP 4 2015
OFFICE OF
FOOD ADDITIVE SAFETY

Transmit completed form and attachments electronically via the Electronic Submission Gateway *(see instructions)*; OR Transmit completed form and attachments in paper format or on physical media to: Office of Food Additive Safety *(HFS-200)*, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835.

PART I – INTRODUCTORY INFORMATION ABOUT THE SUBMISSION

1. Type of Submission *(Check one)*

☒ New ☐ Amendment to GRN No. _____ ☐ Supplement to GRN No. _____

2. ☐ All electronic files included in this submission have been checked and found to be virus free. *(Check box to verify)*

3a. For New Submissions Only: Most recent presubmission meeting *(if any)* with FDA on the subject substance *(yyyy/mm/dd)*: _____

3b. For Amendments or Supplements: Is your amendment or supplement submitted in response to a communication from FDA? *(Check one)* ☐ Yes ☐ No If yes, enter the date of communication *(yyyy/mm/dd)*: _____

PART II – INFORMATION ABOUT THE NOTIFIER

1a. Notifier

Name of Contact Person	Position
Ms. Witty Brathwaite	Senior Scientist

Company *(if applicable)*: Cargill, Incorporated

Mailing Address *(number and street)*: 15407 McGinty Road West

City	State or Province	Zip Code/Postal Code	Country
Wayzata	Minnesota	55391	United States of America

Telephone Number	Fax Number	E-Mail Address
647-464-8081		Witty_Brathwaite@cargill.com

1b. Agent or Attorney *(if applicable)*

Name of Contact Person	Position
Donald F. Schmitt	Senior Managing Scientist

Company *(if applicable)*: ToxStrategies, Inc.

Mailing Address *(number and street)*: 739 Thornapple Drive

City	State or Province	Zip Code/Postal Code	Country
Naperville	Illinois	60540	United States of America

Telephone Number	Fax Number	E-Mail Address
630-352-0303		dschmitt@toxstrategies.com

000003

PART III – GENERAL ADMINISTRATIVE INFORMATION

1. Name of Substance

Citrus fiber

2. Submission Format: *(Check appropriate box(es))*

☐ Electronic Submission Gateway

☐ Electronic files on physical media with paper signature page

☒ Paper

If applicable give number and type of physical media

3. For paper submissions only:

Number of volumes 1

Total number of pages 128

4. Does this submission incorporate any information in FDA's files by reference? *(Check one)*

☒ Yes *(Proceed to Item 5)* ☐ No *(Proceed to Item 6)*

5. The submission incorporates by reference information from a previous submission to FDA as indicated below *(Check all that apply)*

☒ a) GRAS Notice No. GRN 487

☐ b) GRAS Affirmation Petition No. GRP

☐ c) Food Additive Petition No. FAP

☐ d) Food Master File No. FMF

☐ e) Other or Additional *(describe or enter information as above)* GRNs 541, 154, 525, 478, 430, 427, 373, 344, 342, 310, 261, 213

6. Statutory basis for determination of GRAS status *(Check one)*

☒ Scientific Procedures *(21 CFR 170.30(b))* ☐ Experience based on common use in food *(21 CFR 170.30(c))*

7. Does the submission (including information that you are incorporating by reference) contain information that you view as trade secret or as confidential commercial or financial information?

☐ Yes *(Proceed to Item 8)*

☒ No *(Proceed to Part IV)*

8. Have you designated information in your submission that you view as trade secret or as confidential commercial or financial information *(Check all that apply)*

☐ Yes, see attached Designation of Confidential Information

☐ Yes, information is designated at the place where it occurs in the submission

☐ No

9. Have you attached a redacted copy of some or all of the submission? *(Check one)*

☐ Yes, a redacted copy of the complete submission

☐ Yes, a redacted copy of part(s) of the submission

☐ No

PART IV – INTENDED USE

1. Describe the intended use of the notified substance including the foods in which the substance will be used, the levels of use in such foods, the purpose for which the substance will be used, and any special population that will consume the substance *(e.g., when a substance would be an ingredient in infant formula, identify infants as a special population).*

CitriTex® citrus fiber is intended for use as a texturizer and moisture retention agent in select foods. Cargill intends to use citrus fiber (CitriTex® citrus fiber) as a texturizer and moisture retention agent in yogurt, low-fat mayonnaise, ice cream, ice pops and sorbet (use levels not to exceed 4%), and processed meat and poultry products (use levels not to exceed 5%), in accordance with current good manufacturing practices (cGMP). The amount used will not exceed the amount reasonably required to accomplish its intended technical effect.

2. Does the intended use of the notified substance include any use in meat, meat food product, poultry product, or egg product? *(Check one)*

☒ Yes ☐ No

PART V – IDENTITY

1. Information about the Identity of the Substance

	Name of Substance[1]	Registry Used *(CAS, EC)*	Registry No.[2]	Biological Source *(if applicable)*	Substance Category *(FOR FDA USE ONLY)*
1	citrus fiber (cellulose, hemicellulose, and pectin)			lemon, lime, and orange peels	
2					
3					

[1] Include chemical name or common name. Put synonyms *(whether chemical name, other scientific name, or common name)* for each respective item (1 - 3) in Item 3 of Part V *(synonyms)*

[2] Registry used e.g., CAS *(Chemical Abstracts Service)* and EC *(Refers to Enzyme Commission of the International Union of Biochemistry (IUB), now carried out by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology (IUBMB))*

2. Description

Provide additional information to identify the notified substance*(s)*, which may include chemical formula*(s)*, empirical formula*(s)*, structural formula*(s)*, quantitative composition, characteristic properties *(such as molecular weight(s))*, and general composition of the substance. For substances from biological sources, you should include scientific information sufficient to identify the source *(e.g., genus, species, variety, strain, part of a plant source (such as roots or leaves), and organ or tissue of an animal source)*, and include any known toxicants that could be in the source.

Citrus fiber is manufactured to meet the specifications on page 13 in Table 2.

3. Synonyms

Provide as available or relevant:

1	CitriTex® citrus fiber
2	
3	

PART VI – OTHER ELEMENTS IN YOUR GRAS NOTICE

(check list to help ensure your submission is complete – check all that apply)

- ☒ Any additional information about identity not covered in Part V of this form
- ☒ Method of Manufacture
- ☒ Specifications for food-grade material
- ☒ Information about dietary exposure
- ☒ Information about any self-limiting levels of use *(which may include a statement that the intended use of the notified substance is not-self-limiting)*
- ☐ Use in food before 1958 *(which may include a statement that there is no information about use of the notified substance in food prior to 1958)*
- ☒ Comprehensive discussion of the basis for the determination of GRAS status
- ☒ Bibliography

Other Information

Did you include any other information that you want FDA to consider in evaluating your GRAS notice?

☒ Yes ☐ No

Did you include this other information in the list of attachments?

☒ Yes ☐ No

PART VII – SIGNATURE

1. The undersigned is informing FDA that Cargill, Incorporated *(name of notifier)*

has concluded that the intended use(s) of Citrus fiber *(name of notified substance)*

described on this form, as discussed in the attached notice, is (are) exempt from the premarket approval requirements of section 409 of the Federal Food, Drug, and Cosmetic Act because the intended use(s) is (are) generally recognized as safe.

2. ☒ Cargill, Incorporated *(name of notifier)* agrees to make the data and information that are the basis for the determination of GRAS status available to FDA if FDA asks to see them.

Cargill, Incorporated *(name of notifier)* agrees to allow FDA to review and copy these data and information during customary business hours at the following location if FDA asks to do so.

15407 McGinty Road West, Wayzata, MN 55391 *(address of notifier or other location)*

Cargill, Incorporated *(name of notifier)* agrees to send these data and information to FDA if FDA asks to do so.

OR

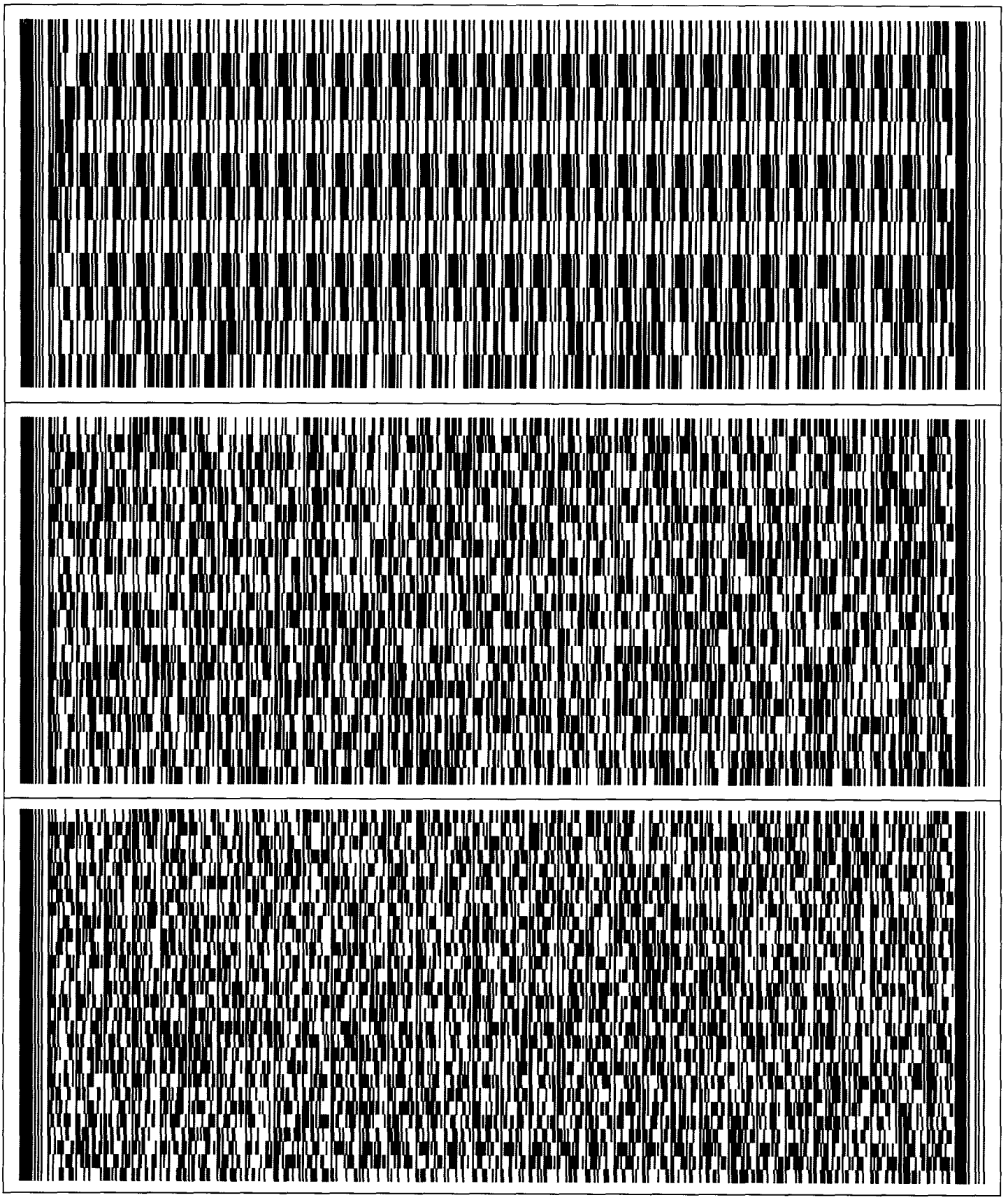
☐ The complete record that supports the determination of GRAS status is available to FDA in the submitted notice and in GRP No. ---------- *(GRAS Affirmation Petition No.)*

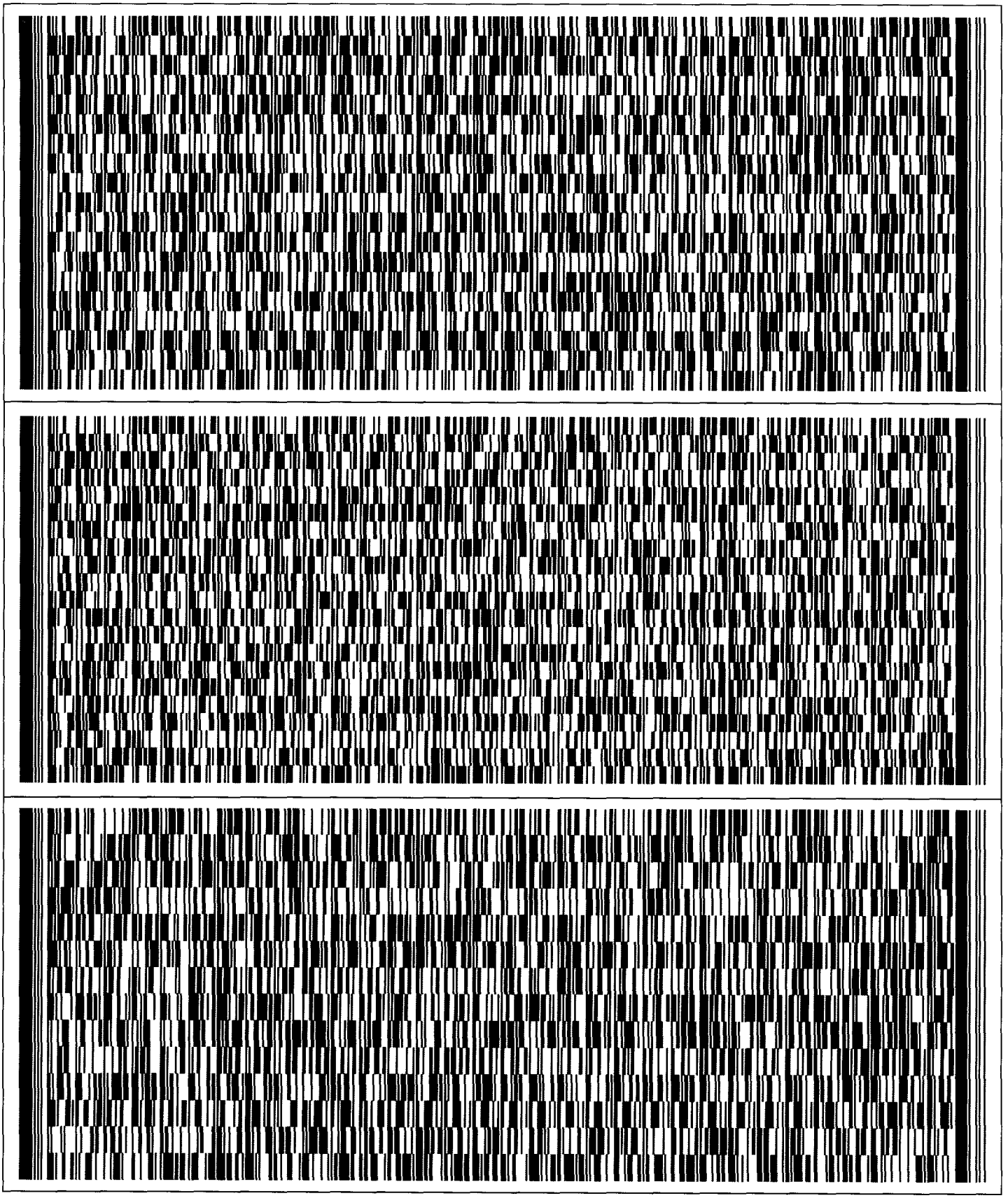
3. Signature of Responsible Official, Agent, or Attorney	Printed Name and Title	Date (mm/dd/yyyy)
[redacted]	Donald F. Schmitt, Senior Managing Scientist	09/03/2015

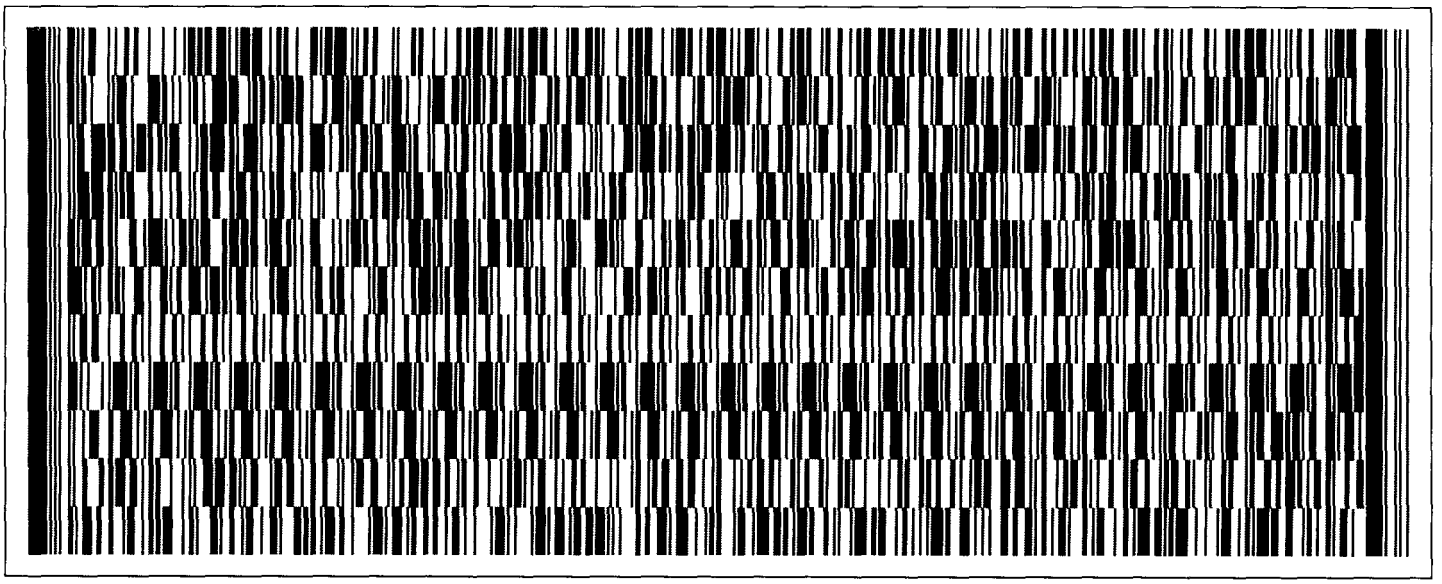
PART VIII – LIST OF ATTACHMENTS

List your attached files or documents containing your submission, forms, amendments or supplements, and other pertinent information. Clearly identify the attachment with appropriate descriptive file names (or titles for paper documents), preferably as suggested in the guidance associated with this form. Number your attachments consecutively. When submitting paper documents, enter the inclusive page numbers of each portion of the document below.

Attachment Number	Attachment Name	Folder Location (select from menu) (Page Number(s) for paper Copy Only)
	Appendix A - Certificates of Analysis - Characterization	pp. 45 - 60
	Appendix B - Additional Analytical Testing Data - Pesticides, Mycotoxins	pp. 61 - 80
	Appendix C - Stability Testing Results	pp. 81 - 82
	Appendix D - Intake Assessment Report	pp. 83 - 116
	Exhibit 1 - Report of the Expert Panel	pp. 117 - 128







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GRAS Determination of Citrus Fiber for Use in Food

JUNE 22, 2015

ToxStrategies

Innovative solutions
Sound science

GRAS Determination of Citrus Fiber for Use in Food

SUBMITTED BY:

Cargill, Incorporated
15407 McGinty Road West
Wayzata, MN 55391

SUBMITTED TO:

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

CONTACT FOR TECHNICAL OR OTHER INFORMATION

Donald F. Schmitt, MPH
ToxStrategies, Inc.
739 Thornapple Drive
Naperville, IL 60540

JUNE 22, 2015

Table of Contents

List of Acronyms

ACF	aberrant crypt foci
ADI	acceptable daily intake
ADME	absorption, distribution, metabolism, and excretion
AOM	azoxymethane
BLAM	Baupte Laboratoire Analyses Methodes
bw	body weight
C	centigrade
cGMP	current Good Manufacturing Practice
CAS	Chemical Abstracts Service
CF	citrus fiber
CFR	Code of Federal Regulations
cfu	colony forming units
COA	certificate of analysis
DMAB	3,2'-dimethyl-4-aminobiphenyl
DNA	deoxyribonucleic acid
DPPH	1,1-diphenyl-2-picryl hydrazyl radical
ds	dry substance of the spent peels
DV	daily value
EDI	estimated daily intake
FDA	Food and Drug Administration
FD&C	Food, Drug and Cosmetic
FFDCA	Federal Food, Drug, and Cosmetic Act
FRF	fiber-rich fractions
FSIS	Food Safety and Inspection Service
g	gram
GI	gastrointestinal
GRAS	Generally Recognized as Safe
GRN	Generally Recognized as Safe Notification
H_2O_2	hydrogen peroxide
HNO_3	nitric acid
IC50	half minimal inhibitory concentration
IgE	immunoglobulin E
IOM	Institute of Medicine
IPA	isopropyl alcohol
JECFA	Joint FAO/WHO Expert Committee on Food Additives
kg	kilogram
LSRO	Life Sciences Research Organization
mg	milligram
min	minute
mM	millimolar
mmol	millimole
MTCCA	1-methyl-1,2,3,4-tetrahydro-β-carboline-3-carboxylic acid
Na_2CO_3	sodium carbonate
$NaHSO_3$	sodium bisulfite

NHANES	National Health and Nutrition Examination Survey
OR	odds ratio
Pb	lead
PCB	polychlorinated biphenyl
PLA2	phospholipase A2
ppm	parts per million
s.c.	subcutaneous
RT-PCR	reverse transcription polymerase chain reaction
SCC	squamous cell carcinoma
SCF	Scientific Committee on Food
SCFA	short chain fatty acids
SCOGS	Scientific Committee on GRAS Substances
SD	standard deviation
µm	micrometer
US	United States
USDA	United States Department of Agriculture
w/w	weight/weight
yrs	years

1.0. GRAS Exemption Claim

A. Name and Address of Notifier

Cargill, Incorporated (Cargill), through its agent ToxStrategies, Inc., hereby notifies the U.S. Food and Drug Administration (FDA) that the use of citrus fiber (CitriTex® citrus fiber) described below and which meets the specifications described herein is exempt from pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act because Cargill has determined that such use is Generally Recognized as Safe (GRAS) through scientific procedures.

(b) (6) [redacted] 09/03/15

Donald F. Schmitt, M.P.H. Date
Senior Managing Scientist
ToxStrategies, Inc.
Agent for Cargill

B. Name of GRAS Substance

The name of the substance that is the subject of this GRAS determination is citrus fiber (CitriTex® citrus fiber). Cargill's citrus fiber is a food ingredient composed of citrus fiber (cellulose, hemicellulose, and pectin) from lemon, lime, and orange peels and is blended with sucrose to standardize functional properties.

C. Intended Use in Food

CitriTex® citrus fiber is intended for use as a texturizer and moisture retention agent in select foods. Cargill intends to use citrus fiber (CitriTex® citrus fiber) as a texturizer and moisture retention agent in yogurt, low-fat mayonnaise, ice cream, ice pops and sorbet, and processed meat and poultry products, in accordance with current good manufacturing practices (cGMP). The amount used will not exceed the amount reasonably required to accomplish its intended technical effect.

D. Basis for GRAS Determination

This assessment documents the evidence of the safety and the GRAS status of the proposed uses of Cargill's citrus fiber product (CitriTex® citrus fiber). It consists of an evaluation of the safety and the GRAS status of the proposed uses of this ingredient, and the conclusion by a panel of experts (Expert Panel) qualified by scientific training and experience to evaluate the safety of substances added to food that the proposed uses of Cargill's citrus fiber ingredient are safe and GRAS as determined by scientific procedures.

Cargill's GRAS determination for the intended use of CitriTex® citrus fiber is based on

scientific procedures as described under 21 CFR § 170.30(b). The intended use of the citrus fiber product has been determined to be safe and GRAS, and the safety of intake exposure under the proposed conditions of use is based on knowledge and information that is both publicly available and widely accepted by experts qualified by scientific training and experience to evaluate the safety of substances in food. The publicly available safety data combined with the widely disseminated knowledge concerning the chemistry of citrus fiber and other vegetable/grain fiber sources and the long history of approval/use of such ingredients provide a sufficient basis for an assessment of the safety of CitriTex® citrus fiber for the uses proposed herein.

To date, the U.S. FDA has reviewed/is reviewing three GRAS Notifications (GRNs) for similar citrus fiber products (GRN Nos. 154, 487, 541). Extensive published information and data on citrus fiber were submitted as part of these notifications. GRN numbers 154 (dried orange pulp) and 487 (dried citrus pulp) received "no questions" letters from the FDA, while GRN No. 541 (insoluble fiber from citrus peel) is still currently under review by FDA. Cargill considers the information and data described in these fiber-related GRAS notifications as applicable and supportive of the present GRAS self-determination. No recent studies raising any new safety concerns have appeared in the published literature subsequent to these existing evaluations. Furthermore, numerous fiber ingredients from other plants or grains that also include cellulose and hemicellulose components, are recognized as GRAS for their intended uses in specific foods and have received "no questions" letters from the FDA. In addition to containing reviews of the published safety information, the GRNs included expert panel reports that reviewed and discussed in detail the metabolism, toxicology, and human health and safety data for citrus fiber and other plant-derived fiber. Based on these GRAS notifications, FDA currently permits the use of fiber preparations from a variety of plant-based sources at the use levels indicated in the notifications.

There is common knowledge of a long history of human consumption of citrus fruits and products derived from these fruits. Citrus fruits have been consumed for thousands of years. In the absence of product-specific toxicological studies, the safety of Cargill's citrus fiber ingredient for the proposed uses in select food products that include processed meat and poultry products can be established based in part on the historical consumption of citrus fruits and citrus fibers through their natural occurrence in citrus fruits. Citrus fiber-based ingredients have been used in the food industry for a long time (e.g., orange peel in marmalade). Fiber from the edible portions of oranges (e.g., pectin, pulp, juice sacs, segment membranes) is used in a variety of food products. Pectin, the fiber fraction of cell wall material, is important for gelling and moisture binding of baked products, dairy, sweet spreads, and beverages and is recognized as GRAS (184.1588; use levels in food not to exceed cGMP). The albedo part of citrus peel is an abundant source of dietary fibers, including hemicelluloses, pectin, and cellulose. Cellulose, hemicellulose, and/or pectin are common components of grains and fruits and grain- and fruit-based food ingredients such as citrus fiber. In addition, various forms of cellulose are common food ingredients recognized by the FDA as multipurpose additives permitted for direct addition to foods [(e.g., ethyl cellulose (§ 172.868), hydroxypropyl cellulose (§ 172.870), methyl ethyl cellulose (§ 172.872)].

Fruits contain many biologically active substances, which have been proposed to have various health benefits. These substances include dietary fiber, carotenoids, vitamin C, folic acid, selenium, potassium, and many phytochemicals. In particular, nutrients in citrus fruits and their juices have been shown to promote health and protect against chronic disease. Increased dietary intake of fruits and vegetables is associated with a decreased risk of common human cancers, including breast, lung, colon, and prostate.

Consumption of dietary fiber leads to many health benefits, including lower risk of obesity, hypertension, coronary heart disease, stroke, diabetes, and various gastrointestinal (GI) diseases. Total fiber intake influences several metabolic functions, including fat metabolism and absorption of nutrients and carbohydrates.

Insoluble materials that are rich in fiber have been shown to have beneficial effects, such as reduction of glucose absorption, slowing of glucose adsorption and starch digestion, and control of postprandial serum glucose levels. Citrus peel contains large amounts of insoluble fiber-rich fractions (FRFs) including insoluble dietary fiber (main fraction), water-insoluble solid and alcohol-insoluble solid, which are primarily composed of cellulose and pectic substances.

Importantly, studies of citrus fruits and citrus fiber sources in humans and/or animals have demonstrated its safety as well as beneficial effects. Safety studies of dietary fiber sources including citrus fiber, vegetable/grain-based fiber, and cellulose and modified cellulose ingredients have been conducted at current levels of fiber consumption and above. *In vivo* and *in vitro* human and animal studies utilizing citrus fruits and their components (e.g., cellulose, hemicellulose) were reviewed and both their safety and/or potential health benefits summarized. Several studies of cellulose and its derivatives in different species, following oral and non-oral routes of exposure, have been published and summarized in GRAS notifications for cellulose-related ingredients and/or vegetable/grain fiber sources. The toxicological data on cellulose and modified celluloses include acute toxicity studies, subchronic toxicity studies, carcinogenicity and genotoxicity studies, as well as reproductive and developmental toxicity studies. No significant adverse effects associated with dietary fiber, cellulose, modified cellulose, or citrus fiber consumption were reported in the published literature.

Adequate intake recommendations for adults ($\leq$ 50 years of age) are 38 g total dietary fiber/day for men and 25 g total dietary fiber/day for women (IOM, 2005). For adults greater than 50 years of age, the Institute of Medicine (IOM) recommends 30 g/day and 21 g/day for men and women, respectively. It is notable that most Americans need to increase their intake of dietary fiber. The daily value (DV) for dietary fiber is 25 g for a 2000 calorie diet per 21 CFR § 101.9(d).

To date, FDA has reviewed extensive published information and data as part of GRAS notifications for citrus fiber and other vegetable/grain-based fiber sources and subsequently issued "no question letters" [e.g., GRN No. 154 (dried orange pulp); GRN No. 487 (dried citrus pulp); GRN No. 116 (carrot fiber); GRN No. 207 (barley fiber);

GRN No. 261 (oat hull fiber); GRN No. 310 (potato fiber); GRN No. 342 (oat hull fiber); GRN No. 344 (barley fiber); GRN No. 373 (rice bran fiber); GRN No. 427 (corn hull fiber); GRN No. 430 (sugar beet fiber); GRN No. 525 (pea fiber)]. No recent studies raising any new safety concerns concerning citrus fiber or plant-based fiber ingredients and their addition to processed foods have appeared in the published literature subsequent to these evaluations.

Given that CitriTex® citrus fiber meets the proposed specifications contained herein, the safe use of citrus fiber is justified by scientific procedures. In addition, the publicly available scientific literature is sufficient to support the safety and GRAS status of the proposed citrus fiber product. Therefore, since this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

Determination of the safety and GRAS status of citrus fiber that is the subject of this self-determination has been made through the deliberations of an Expert Panel convened by Cargill and comprised of James R. Coughlin, Ph.D., Carol A. Knight, Ph.D., and I. Glenn Sipes, Ph.D., who reviewed a dossier prepared by ToxStrategies as well as other information available to them. These individuals are qualified by scientific training and experience to evaluate the safety of food and food ingredients. They individually and collectively critically reviewed and evaluated published data and information pertinent to the safety of citrus fiber, and unanimously concluded that the intended use of citrus fiber in food, produced consistent with cGMP and meeting appropriate specifications as delineated herein, is "generally recognized as safe" ("GRAS") based on scientific procedures.

E. Availability of Information

The data and information that serve as the basis for this GRAS determination, as well any information that has become available since the GRAS determination, will be sent to the FDA upon request, or are available for the FDA's review and copying at reasonable times from ToxStrategies, Inc., Naperville, IL.

2.0 Introduction

Cargill, Incorporated (Cargill) intends to use citrus fiber (CitriTex® citrus fiber) as a texturizer and moisture retention agent in yogurt, low-fat mayonnaise, ice cream, ice pops and sorbet, and processed meat and poultry products, in accordance with current good manufacturing practices (cGMP). In accordance with Section 201(s) of the United States (U.S.) Federal Food, Drug, and Cosmetic Act (FFDCA) § 409, a panel of independent scientific experts (Expert Panel), qualified by scientific training and relevant experience to evaluate the safety and Generally Recognized As Safe (GRAS) status of the proposed uses of food/feed ingredients, was convened to evaluate the proposed use of Cargill's citrus fiber in foods. This document summarizes information that may be used to determine whether there is reasonable certainty that no harm will result from the intended use of citrus fiber, and that such use would be GRAS. It includes data pertaining to the safety of citrus fruits and citrus fibers obtained from comprehensive literature searches of databases including MEDLINE, TOXLINE, and PubMed, as well as other published sources by ToxStrategies, Inc. (ToxStrategies) through May 2015. Analytical data and other information that were deemed pertinent to the safety of Cargill's citrus fiber product, under the conditions of intended use, were also considered and summarized herein. Finally, this report documents the conclusion by the Expert Panel that the proposed uses of Cargill's citrus fiber ingredient are safe and suitable, and GRAS by scientific procedures.

3.0 Description of Substance

A. Identity

Cargill's citrus fiber is a food ingredient composed of citrus fiber (cellulose, hemicellulose, and pectin) from lemon, lime, and orange peels and is blended with sucrose to standardize functional properties. It is intended for use as a texturizer and moisture retention agent in select foods.

B. Common Name

The proposed common name for this product is citrus fiber.

C. Trade Name

The trade name of Cargill's citrus fiber product is CitriTex® citrus fiber.

D. Manufacturing Process

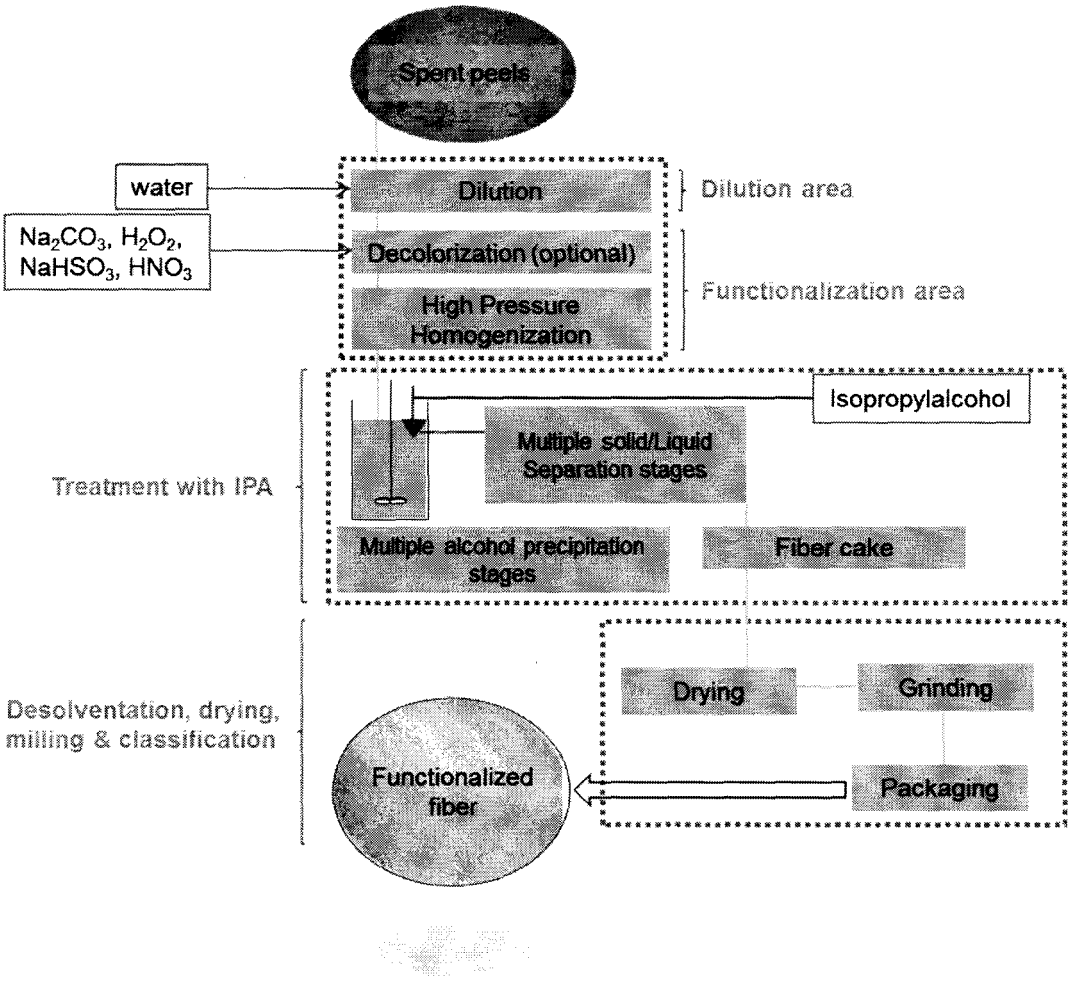
Cargill's citrus fiber product that is the subject of this GRAS self-determination is derived from lemon, lime, and orange peels. It is manufactured following cGMP for food in accordance with Title 21 of the U.S. Code of Federal Regulations (CFR) Part 110, utilizing raw materials and processing aids that are appropriate for use in foods. A flow

diagram of Cargill's manufacturing process precedes the narrative description below (Figure 1) and results in a product in compliance with Cargill's product specifications.

The main raw materials for the citrus fiber production line are the partially de-pectinized peels (named spent peels), which provide spent peels to the citrus fiber production line. Processing aids employed in the production of the citrus fiber ingredient are summarized in Table 1.

The individual steps of the manufacturing process are described in more detail below.

Figure 1. Manufacturing Process Flow Diagram for Citrus Fiber



Spent peels are transferred from the pectin manufacturing site to the spent peels buffer tank. The first step in the manufacturing process (conducted in the dilution tank) is to hydrate the spent peels and reduce the dry substance of the spent peels (ds) to ≤6%. Seeds and other large materials are removed from the hydrated peels and discarded.

The next step in the manufacturing process results in a functional (i.e., optimized) spent peel fibers product. Sodium bisulfite ($NaHSO_3$) is used in the functionalization step to remove residual H_2O_2 from the process stream. The remaining concentration of bisulfite is <10 ppm. The specific process in this functionalization step depends on the final application of the citrus fiber product (less colored product desired). Decolorization is considered an optional processing step. The spent peels are then activated in two steps: wet milling and high-pressure homogenization. The spent peels are first processed in a colloid mill where all fiber material is wet milled to reduce the particle size below 300µm. This stream is then further processed in a high-pressure homogenizer where the fibers in the spent peels are micronized, modifying their structure and substantially increasing their surface area.

The homogenized fibers then enter an isopropyl alcohol (IPA) precipitation step where the fibers are first precipitated and then re-dissolved/precipitated multiple times with IPA. The precipitation/re-dissolving is carried out in three steps in three continuously stirred tanks.

The citrus fibers are then conveyed into a desolventizing vessel. Sucrose is added before the desolventizing step. The mixing time in the conveyer is sufficient to dissolve the sucrose into the available liquid (IPA/water). The solids are then heated directly and indirectly in order to reduce the IPA content of the solids. Once the IPA is removed from the solids, they are transferred into a dryer in order to reduce the water content of the final product.

The solid dried product is then milled and classified to ensure that product particle size is <250µm (greater than 90% of particles), in accordance with product specifications. From the mill, the product is then transferred to the packaging area where it is packaged to meet final customer requirements.

Reagents/processing aids used in the manufacture of citrus fiber are listed in Table 1 below and are all commonly used in food additive/ingredient manufacturing processes.

Table 1. Reagents/Processing Aids - Citrus Fiber (CitriTex® citrus fiber)

Reagent/Processing Aid	*CAS Number*	*Optional*	*21 CFR Citation(s); FSIS*
Sodium carbonate	497-19-8	x	155; 163; 184.1742; 173.310; FSIS Directive 7120.1
Hydrogen peroxide	7722-84-1	x	173.356; 173.315; 178.1005; 178.1010; 184.1366; FSIS Directive 7120.1
Nitric acid	7697-37-2	x	175.105; 176.170; 178.1010

Catalase*	9001-05-2	x	GRN 89; FSIS Directive 7120.1
Sodium bisulfite	7631-90-5	x	182.3739; 176.170
Isopropyl alcohol	67-63-0		172.560; 173.240; 173.340; 176.200; 178.1010

* catalase employed to neutralize remaining hydrogen peroxide.

E. Product Specifications

The proposed food grade specifications for Cargill's CitriTex® citrus fiber product are presented in Table 2. CitriTex® citrus fiber occurs as a fine, creamy white-colored powder. The typical dietary fiber content (cellulose, hemicellulose, and pectin) of CitriTex® citrus fiber is a minimum of 50% on a dry matter basis. The majority of the dietary fiber content of CitriTex® citrus fiber (approximately 80%) is insoluble fiber. Flavonoids are only present at very low levels. As flavonoids are water soluble, they are removed in the water phase of the pectin extraction of the peels. A small amount of flavonoids stays in the water entrapped in the spent peels cake before further processing. However, during the processing of the activated fibers, three separate precipitation and washing steps essentially remove all the flavonoids. Analytical results from three non-consecutive lots of citrus fiber (pilot plant production) are provided in Appendix A. A comparison of these lots to the specifications below can be found in Table 3.

Table 2. Proposed Specifications for CitriTex® citrus fiber

Parameter (Assay Method)	Specification
Physical Characteristics	
Appearance (Visual)	Creamy, white-colored powder
Granulometry (AM U1 01 H03*)	Particles >250μm; ≤10%
pH (22 PA pH measurement Rev0*)	1% solution, ≤5.0
Viscosity (R-01 MS*)	3% solution, ≥400Pa
Color (HunterLab Spectrophotometer CM-5 CPF rev*)	≥75 (L-value)
Odor + Taste (Sensory analysis)	Neutral to slightly citrus
Chemical Characteristics	
Loss on drying (20 PA Dry Matter Content Rev0)	≤10%
Dietary fiber (AOAC 991.43)	≥50%
Sucrose (CAM-S-20-Rev02*)	Typical, 25-40%
Isopropyl alcohol (05 CPG Rev0)	≤0.3%
Methanol (05 CPG Rev0)	≤ 0.03%
Fat (81 ISO6492)	≤0.5%
Ash (01 PA Rev1)	≤5.0%

Heavy Metals	
Lead (LFGB L00.00-19/3)	≤1 ppm
Arsenic (Adapted from NF EN 13805)	≤2 ppm
Cobalt (ISO 17294-5-E29)	≤10 ppm
Chromium (Adapted from NF EN ISO 11885)	≤10 ppm
Nickel (Adapted from NF EN ISO 11885)	≤10 ppm
Copper (Adapted from NF EN ISO 11885)	≤10 ppm
Microbiological Analyses	
Total plate count (BLAM 3010)	≤1000 cfu/g
Yeasts + Molds (BLAM 3020)	≤100 cfu/g
Salmonella (BLAM 3303)	cfu/25g; Absent
E. coli (BLAM 3315)	cfu/g; Absent

*Cargill internal method

Table 3. Analytical Results for 3 Non-Consecutive Lots of CitriTex® citrus fiber

Specification		Lot No. OP9670	Lot No. OP9677	Lot No. OP9858
Appearance	Creamy, white-colored powder	Pass	Pass	Pass
Granulometry	Particles >250μm, ≤10%	2.0	0.15	0.3
pH	1% solution, ≤5.0	3.84	3.93	3.71
Viscosity	3% solution, ≥400Pa	543	614	770
Color	≥75 (L-value)	84.0	85.0	86.4
Odor + Taste	Neutral to slightly citrus	Pass	Pass	Pass
Loss on drying	≤10%	6.5	7.0	5.5
Dietary fiber	≥50%	65.1	67.9	58.67
Sucrose	Typical 25-40%	37.5	37.3	37.5
Isopropanol	≤0.3%	0.027	0.03	0.084
Methanol	≤0.03%	<0.01	<0.01	< 0.01
Fat	≤ 0.5%	<0.3	<0.3	<0.3
Ash	≤5.0%	1.32	1.66	2.51

Heavy Metals				
Lead	≤1 ppm	0.6	0.6	0.75
Arsenic	≤2 ppm	< 0.1	<0.1	< 0.1
Cobalt	≤10 ppm	< 0.1	<0.2	< 0.1
Chromium	≤10 ppm	0.4	0.4	1.8
Nickel	≤10 ppm	2.9	2.9	0.7
Copper	≤10 ppm	4.8	6.8	4.0
Microbiological Analyses				
Total plate count	≤1000 cfu/g	< 100	400	<100
Yeasts + Molds	≤100 cfu/g	Y< 10; M < 40	Y< 20; M = 60	Y< 20; M < 20
Salmonella	cfu/25g; Absent	Absent	Absent	Absent
E.coli	cfu/g; Absent	Absent	Absent	Absent

It should be noted that numerous other analyses of the final product are conducted but are not included in the product specifications (e.g., other physical/chemical properties, trace component analyses including additional heavy metals, pesticides, mycotoxins, furanocoumarins, polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, and dioxin-like polychlorinated biphenyls (PCBs)). Analytical results for additional select nutritional parameters and potential contaminants are provided in Tables 4 - 5. In summary, the analytical results from non-consecutive lots of citrus fiber confirm that the finished product meets the analytical specifications and confirms the lack of impurities/contaminants (e.g., heavy metals, pesticides, mycotoxins, furanocoumarins, polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, and dioxin-like polychlorinated biphenyls (PCBs)). Results of these additional analyses are included in the certificates of analysis (COAs) found in Appendices A and B.

Table 4. Select Nutritional Data for 3 Non-Consecutive Lots of CitriTex® citrus fiber

Parameter (%)	OP9591	OP9608	OP9677
Protein	2.92	3.56	3.66
Sucrose	35.9	28.3	37.3
Cellulose	33.1	34.0	26.4
Hemicellulose	15.2	20.5	28.1
Pectin	10.7	10.0	13.4

Table 5. Select Residual Contaminants Data for 3 Non-Consecutive Lots of CitriTex® citrus fiber

Parameter (ppb)	OP9591	OP9608	OP9677
Aflatoxins B1/B2/G1/G2	Sum <0.5	Sum <0.5	Sum <0.5
Ochratoxin A	<0.2	<0.2	<0.5
Patulin	<20	<20	<20

The analytical (physical, chemical, and microbiological) results for citrus fiber summarized in the above tables and included in the COAs in Appendix A confirm that the finished product meets the proposed analytical specifications and demonstrates the consistency of production.

F. Stability Data for Citrus Fiber

The citrus fiber product meets Cargill's proposed analytical specifications. Stability testing with respect to microbial contamination was conducted on three non-consecutive batches of citrus fiber. Samples were stored at ambient temperature for 12, 17, or 18 months and analyzed for the presence of potential microbiological contaminants as defined in the product specifications. After a 12- to 18-month storage period, each of the three lots of citrus fiber exhibited a similar microbiological profile as newly manufactured product and demonstrated the absence of microbial contamination over time, and thus the microbiological stability of the product. In addition, a low-fat mayonnaise test product containing the proposed citrus fiber ingredient has been evaluated over a 24-week period and the stability of the citrus fiber was demonstrated. Stability testing results can be found in Appendix C.

Based on the stability data for this product, recommended shelf-life and storage conditions for Cargill's CitriTex® citrus fiber are as follows: 12 months after production date stored under cool, dry conditions in original packaging until use.

4.0 History of Use/Regulatory Approval of Citrus Fiber and Other Fruit/Vegetable Fiber Sources

There is common knowledge of a long history of human consumption of citrus fruits and products derived from these fruits. Citrus fruits have been consumed for thousands of years. For example, a book from 1821 entitled *Culinary Chemistry* includes a recipe for orange marmalade (Accum, 1821, as cited in GRN 154). The first record of orange trees being planted in San Bernardino, CA dates back to 1857. Several citrus fairs were held in the area during the 1880s and 1890s. Lemons and limes, also grown in the county, were on display during the fairs (National Orange Show, 2015). The Seasonal Chef website (2015) includes *Five Orange Recipes from Yesteryear*, which were published in 1928 in conjunction with the San Bernardino festival. One of these recipes includes grated orange and lemon rind among the ingredients.

Pectin, a main component of citrus fruit fiber, is considered to be a safe and versatile material derived from natural sources (May, 1990). About 90% of pectin is sold as conventional high-methoxyl pectins, which are extracted from citrus peel or apple pomace. These are historically used as gelling agents in high-sugar solid jellies and jams (Nelson, 1979). Additional uses of pectin include fruit products for the food industry, soft drinks, desserts, dairy products, and pharmaceuticals (May, 1990).

Several important by-products are produced by citrus juice industries, which are primarily used for animal feeds and pectin. Notably, due to their high fiber content, these by-products can be used as a beneficial source of dietary fiber. Residue from citrus fruits makes up half of the original amount of whole fruit, with peels (flavedo and albedo) comprising almost one-fourth of the whole fruit mass (Lario *et al.*, 2004). Essential oils, obtained from the sacs of citrus fruit peel, are safely used by the food industry to flavor foods and drinks (Okwu, 2008).

Citrus fiber-based ingredients are commonly used in the food industry. Fiber from the edible portions of oranges (e.g., pectin, pulp, juice sacs, segment membranes) is used in a variety of food products. Pectin, a main component of citrus fruit fiber, is important for gelling and moisture binding of baked products, dairy, sweet spreads and beverages. The albedo (white portion) part of citrus peel is an abundant source of dietary fibers including hemicelluloses, pectin and cellulose. Miller (2011) conducted a study to evaluate whether citrus peel fiber could be used in bread production to increase bread yield via increasing the water content. In the study, flour was replaced by citrus peel fiber (2.5%) or pectin (0.23%). Citrus peel fiber increased water absorption by a greater extent than pectin. Citrus peel fiber strengthened the dough and increased loaf weight, which effectively increased bread yield (Miller, 2011). The study demonstrated that citrus peel can be processed to produce a functional, nutritious dietary fiber (Miller, 2011). In summary, humans throughout history have consumed fruit and grain fibers, which consist of cellulose, hemicellulose, and/or pectin.

Adequate fiber intake recommendations for adults ($\leq$ 50 years of age) are 38 g total dietary fiber/day for men and 25 g total dietary fiber/day for women (IOM, 2005). For adults greater than 50 years of age, the Institute of Medicine (IOM) recommends 30 g/day and 21 g/day for

men and women, respectively. Other guidelines also note that most Americans need to increase their intake of dietary fiber (HHS/USDA, 2015). The daily value (DV) for dietary fiber is 25 g for a 2000 calorie diet per Title 21 of the United States Code of Federal Regulations (CFR) § 101.9(d).

Essential oils, oleoresins (solvent-free), and natural extractives (including distillates) derived from citrus species are deemed to be GRAS for their intended use, within the meaning of Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The relevant sources and citrus species from which these essential oils, oleoresins, and extractives GRAS products are derived include bergamot, curacao orange peel, grapefruit, lemon/lemon peel, lime, mandarin, naringin, bigarade neroli, oranges (several species), petigrain, and tangerine (21 CFR § 182.20). Additionally, 21 CFR § 101.78 permits health claims for fruits and vegetables related to cancer.

To date, the U.S. Food and Drug Administration (FDA) has reviewed/is reviewing three GRAS Notifications for similar citrus fiber products (GRN Nos. 154, 487, 541). Extensive published information and data on citrus fiber were submitted as part of these notifications. GRAS notification numbers (GRNs) 154 (dried orange pulp) and 487 (dried citrus pulp) received "no questions" letters from the FDA, while GRN No. 541 (insoluble fiber from citrus peel) is still currently under review by FDA. Cargill considers the information and data described in these fiber-related GRAS notifications as applicable and supportive of the present GRAS self-determination. No recent studies raising any new safety concerns have appeared in the published literature subsequent to these existing evaluations.

Furthermore, numerous fiber ingredients from other plants or grains that also include cellulose and hemicellulose components are recognized as GRAS for their intended uses in specific foods (Table 6). The following fiber ingredients have received "no questions" letters from the FDA.

Table 6. Fiber GRAS Notifications*

GRN No.	Fiber Substance	Date of Closure
116	Carrot fiber	Mar. 20, 2003
207	Barley fiber	Dec. 19, 2006
261	Oat hull fiber	Feb. 3, 2009
310	Potato fiber	June 10, 2010
342	Oat hull fiber	Dec. 23, 2010
344	Barley fiber	May 23, 2011
373	Rice bran fiber	Aug 19, 2011
427	Corn hull fiber	Sep. 12, 2012
430	Sugar beet fiber	Mar. 6, 2013
525	Pea fiber	Sep. 25, 2014

*http://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&sort=GRN_No&order=DESC&startrow=1&type=basic&search=

In addition, various forms of cellulose are recognized by the FDA as multipurpose additives permitted for direct addition to foods [(e.g., ethyl cellulose (21 CFR § 172.868), hydroxypropyl cellulose (21 CFR § 172.870), methyl ethyl cellulose (21 CFR § 172.872)].

Cargill cites suitability data (moisture retention agent) for the use of similar citrus fiber products in processed meat and poultry products (GRN Nos. 154 and 487). The United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) Directive 7120.1 stated that FSIS determined that citrus fiber is suitable for the proposed uses (see FSIS Directive 7120.1, Safe and Suitable Ingredients in the Production of Meat, Poultry, and Egg Products (August 13, 2013; GRN 487, pp. 214-216).

5.0 Intended Use and Estimated Daily Intake (EDI)

Purpose

As previously mentioned, Cargill's citrus fiber product derived from lemon, lime, and orange peels is proposed for use as a texturizer and moisture retention agent.

Food Uses

The intended uses of CitriTex® citrus fiber include in yogurt, low-fat mayonnaise, ice cream, ice pops and sorbet, and processed meat and poultry products.

Levels of Use

CitriTex® citrus fiber will be used in low-fat mayonnaise, ice cream, ice pops, and sorbet at levels not to exceed 4%. The use level in processed meat and poultry products will not exceed 5%. The intended uses of CitriTex® citrus fiber will substitute for other current citrus and dietary fiber sources in these foods.

Estimated Exposure

The 2-day average intake of citrus fiber was estimated by ToxStrategies (ToxStrategies, 2015; See Appendix D) for the US population 2+ years of age using the National Health and Examination Survey (NHANES) conducted in 2009-2010 and 2011-2012. The estimated daily intakes (EDI) of citrus fiber were calculated on a *per capita* and *per user* basis in units of g/day and g/kg bw/day. It should be noted that the estimated intake values presented below are for CitriTex® citrus fiber, not citrus fiber alone. CitriTex® citrus fiber is approximately 60-70% fiber (insoluble/soluble), with the remainder being sucrose. The intake estimates are summarized in Tables 7 - 9.

Table 7. Estimated Daily Intakes (EDI; g/day) of Individual Proposed Uses of CitriTex® citrus fiber

Food Category	Number of Users	Percent Users	EDI Per User (g/day)		EDI Per Capita (g/day)	
			Mean	90th Percentile	Mean	90th Percentile
US Population, Ages 2+						
Ice cream, ice pop, sherbet, and sorbet	4564	30.6	3.09	6.27	0.97	3.46
Low fat mayonnaise	627	4.2	0.39	0.88	0.02	< 0.01
Processed meat and poultry products	11532	77.3	5.15	6.63	4.01	6.03
Yogurt	2735	18.3	3.71	7.35	0.74	3.40
Total *	**13015**	**87.3**	**6.40**	**9.76**	**5.64**	**9.36**
US Population, Ages 2-5						
Ice cream, ice pop, sherbet, and sorbet	535	37.3	1.97	3.89	0.78	2.40
Low fat mayonnaise	35	2.4	0.08	0.16	< 0.01	< 0.01
Processed meat and poultry products	1141	79.6	5.23	5.18	4.31	4.68
Yogurt	430	30.0	3.53	7.23	1.15	4.51
Total *	**1322**	**92.2**	**6.60**	**8.29**	**6.20**	**8.10**
US Population, Ages 6-18						
Ice cream, ice pop, sherbet, and sorbet	1434	37.1	3.05	6.09	1.15	3.89
Low fat mayonnaise	113	2.9	0.34	0.63	0.01	< 0.01
Processed meat and poultry products	3282	84.9	6.36	6.72	5.41	6.23
Yogurt	674	17.4	3.11	5.85	0.57	2.45
Total *	**3553**	**91.9**	**7.62**	**9.75**	**7.04**	**9.43**
US Population, Ages 19+						
Ice cream, ice pop, sherbet, and sorbet	2595	27.0	3.22	6.53	0.94	3.38
Low fat mayonnaise	479	5.0	0.40	0.93	0.02	< 0.01
Processed meat and poultry products	7109	74.0	4.82	6.77	3.66	6.06
Yogurt	1631	17.0	3.87	7.39	0.74	3.40
Total *	**8140**	**84.7**	**6.07**	**9.87**	**5.27**	**9.44**

* Total values refer to consumers of any of the four proposed food categories.

Table 8. Estimated Daily Intakes (EDI; g/kg BW/day) of Individual Proposed Uses of CitriTex® citrus fiber

Food Category	Number of Users**	EDI Per User (g/kg BW/day)		EDI Per Capita (g/kg BW/day)	
		Mean	90th Percentile	Mean	90th Percentile
US Population, Ages 2+					
Ice cream, ice pop, sherbet, and sorbet	4522	0.05	0.11	0.02	0.06
Low fat mayonnaise	620	0.01	0.01	< 0.01	< 0.01
Processed meat and poultry products	11431	0.09	0.11	0.07	0.10
Yogurt	2703	0.07	0.15	0.01	0.05
Total *	**12897**	**0.11**	**0.18**	**0.10**	**0.16**
US Population, Ages 2-5					
Ice cream, ice pop, sherbet, and sorbet	530	0.11	0.21	0.05	0.13
Low fat mayonnaise	35	0.01	0.01	< 0.01	< 0.01
Processed meat and poultry products	1128	0.33	0.30	0.27	0.26
Yogurt	424	0.22	0.44	0.07	0.25
Total *	**1308**	**0.41**	**0.48**	**0.39**	**0.46**
US Population, Ages 6-18					
Ice cream, ice pop, sherbet, and sorbet	1419	0.07	0.15	0.03	0.09
Low fat mayonnaise	111	0.01	0.01	< 0.01	< 0.01
Processed meat and poultry products	3260	0.14	0.15	0.12	0.14
Yogurt	668	0.08	0.17	0.02	0.06
Total *	**3526**	**0.17**	**0.25**	**0.16**	**0.25**
US Population, Ages 19+					
Ice cream, ice pop, sherbet, and sorbet	2573	0.04	0.08	0.01	0.04
Low fat mayonnaise	474	0.01	0.01	< 0.01	< 0.01
Processed meat and poultry products	7043	0.06	0.08	0.05	0.07
Yogurt	1611	0.05	0.11	0.01	0.04
Total *	**8063**	**0.08**	**0.13**	**0.07**	**0.12**

* Total values refer to consumers of any of the four proposed food categories.

** Body weight was not reported for ~1% of survey participants. Users with incomplete body weight data were excluded from this analysis.

Table 9. Estimated Daily Intakes (EDI) from All Proposed Uses of CitriTex® citrus fiber

	Per Capita		Per User	
Citrus Fiber	**Mean**	**90th Percentile**	**Mean**	**90th Percentile**
Proposed food uses (low-fat mayonnaise, ice cream, ice pops, and sorbet, processed meat and poultry products)				
g/day	5.64	9.36	6.40	9.76
g/kg bw/day	0.10	0.16	0.11	0.18

GRN No. 487 (2013) for Fiberstar's dried citrus pulp product estimated the *per user* daily intake of citrus fiber from many additional proposed food uses for the US population 2+ years of age to be 23.4 g/day (0.4 g/kg bw/day) and 39.5 g/day (0.8 g/kg bw/day) at the mean and 90th percentile, respectively. GRN No. 541 for Ceamsa's product (insoluble fiber from citrus peel) reported a *per user* daily intake of fiber, also from many additional proposed food uses, for the US population 2+ years of age to be 20.24 g/day and 34.17 g/day at the mean and 90th percentile, respectively. Both of these recent GRAS notifications provided estimates of fiber intake much higher than that from the proposed uses of CitriTex® citrus fiber.

GRN No. 487 (2013) for Fiberstar's dried citrus pulp product also estimated the background exposure to citrus fiber based on the total dietary fiber content in orange and other citrus-based foods and beverages. The *per user* mean and 90th percentile background intake of citrus fiber was estimated to be 0.7 g/day (0.01 g/kg bw/day) and 1.6 g/day (0.03 g/kg bw/day), respectively for the US population 2+ years of age (GRN 487, 2013). Therefore, taking into account the additional intake estimated from the proposed uses of CitriTex® citrus fiber (Table 9), the estimated *per user* mean and 90th percentile cumulative exposure to citrus fiber is 7.1 g/day (0.12 g/kg bw/day) and 11.36 g/day (0.21 g/kg bw/day), respectively for the US population 2+ years of age. The full exposure report generated by ToxStrategies can be found in Appendix D.

Self-limiting use

The use of citrus fiber as proposed is considered to be self-limiting for technological reasons such as product thickness/texture.

6.0 Safety

A. Introduction

In the absence of product-specific toxicological studies, the safety of Cargill's citrus fiber ingredient for the proposed uses in select food products that include processed meat and poultry products can be established based in part on the historical consumption of citrus fruits and citrus fibers through their natural occurrence in citrus fruits. Citrus fiber-based ingredients have been used in the food industry for a long time (e.g., orange peel in marmalade). Fiber from the edible portions of oranges (e.g., pectin, pulp, juice sacs, segment membranes) is used in a variety of food products. Pectin, the fiber fraction of cell wall material, is important for gelling and moisture binding of baked products, dairy, sweet spreads, and beverages and is recognized as GRAS (184.1588; use levels in food not to exceed current Good Manufacturing Practice). The albedo part of citrus peel is an abundant source of dietary fibers, including hemicelluloses, pectin, and cellulose. Cellulose, hemicellulose, and/or pectin are common components of grains and fruits and grain- and fruit-based food ingredients such as citrus fiber. In addition, various forms of cellulose are common food ingredients, recognized by the FDA as multipurpose additives permitted for direct addition to foods (e.g., ethyl cellulose (§ 172.868), hydroxypropyl cellulose (§ 172.870), methyl ethyl cellulose (§ 172.872).

B. Safety Data

This section provides a brief summary of *in vivo* and *in vitro* human and animal studies utilizing citrus fruits and their components (e.g., cellulose, hemicellulose) to evaluate safety and/or potential benefits to health. Several studies of cellulose and its derivatives in different species following oral and non-oral routes have been published. The toxicological data on modified celluloses include acute toxicity, subchronic and chronic toxicity and genotoxicity as well as reproductive and developmental toxicity and can be found in a number of reviews. No adverse effects associated with citrus fiber were reported in the published literature.

1. Dietary Fiber

Dietary fibers generally consist of lignin and complex carbohydrates that can be partially or completely fermented in the large intestine and cannot be absorbed or digested in the small intestine. Insoluble fibers (e.g., lignin, cellulose, hemicellulose) generally pass intact through the intestines. On the other hand, soluble fibers (pectin, beta-glucans, gums, mucilages, and some hemicellulose) are completely fermented by intestinal microflora in the colon (Vergara *et al.*, 2013; Williams and Bollella, 1995). Soluble fibers are found in fruits, vegetables, and some grains such as oats and barley. Soluble fiber is metabolized in the colon, and to a lesser extent in the small intestine, by the enzymatic action of anaerobic bacteria. Soluble fiber increases stool size moderately, delays intestinal transit time, gastric emptying, and glucose absorption, and decreases serum cholesterol. Insoluble fiber is not metabolized significantly by intestinal flora. Insoluble fiber significantly increases fecal bulk, decreases intestinal transit time, delays glucose absorption, and slows down the hydrolysis of starch (Williams and Bollella,

1995). It should be noted that the majority of the dietary fiber content of CitriTex® citrus fiber is insoluble fiber (approximately 80%).

A Joint FAO/WHO Expert Committee on Food Additives (JECFA) Consultation Report (FAO/WHO; 1997) addressed the physiological effects of dietary fiber and stated that it is well established that dietary fiber reaches the large intestine and is fermented by the colonic microflora resulting in the production of short chain fatty acids (SCFA), hydrogen, carbon dioxide and biomass. Furthermore, the fermentative process dominates human large bowel function and allows for energy to be obtained from carbohydrates not digested in the small bowel, through absorption of SCFA.

As described above, the major effects of dietary fiber occur in the colon. Both soluble and insoluble dietary fiber interacts with the microflora, and the colonic mucosa and muscle to produce several possible effects. The actions of an individual fiber source depend to a large extent on its fermentability. The least fermentable fibers (insoluble fiber such as cellulose) are the most likely to increase stool output. Soluble fiber, which is highly fermentable, is unlikely to have much effect on stool output but will affect bacterial fermentation products in the proximal colon (FAO/WHO, 1997).

Purified dietary fibers may also reduce acutely the absorption of some vitamins and minerals by binding or entrapping them in the small intestinal lumen. However, there is little evidence that population groups (including children) consuming nutritionally adequate diets rich in high fiber foods, such as vegetarians, have any problems with vitamin or mineral deficiencies (FAO/WHO, 1997; Williams and Bollella, 1995).

Williams and Bollella (1995) reviewed the scientific literature related to the safety of consumption of high fiber diets in children. They concluded that a small loss of energy, protein, and fat may occur with a high intake of dietary fiber. However, the small loss of energy was unlikely to be significant to children consuming adequate levels of major nutrients. They proposed that even with a doubling of the current dietary fiber intake, there is unlikely to be an adverse effect on serum vitamin and mineral concentrations in healthy US children consuming a balanced diet containing adequate levels of nutrients. In addition, they reported that even though studies linking dietary fiber with increased intestinal gas and stomach distress are lacking, fiber supplements have been shown to reduce the symptoms of chronic recurrent stomach pain in childhood.

Consumption of dietary fiber also may lead to many health benefits, including lower risk of obesity, hypertension, coronary heart disease, stroke, diabetes, and various GI diseases. Total fiber intake influences several metabolic functions, including fat metabolism and absorption of nutrients and carbohydrates. In both non-diabetics and diabetics, increased soluble fiber intake improves insulin sensitivity and glycemia. Increasing fiber intake lowers serum cholesterol levels and blood pressure. In obese individuals, fiber supplementation increases weight loss. Increased fiber consumption benefits a number of GI disorders including: constipation, hemorrhoids, diverticulitis, duodenal ulcer, and gastroesophageal reflux disease. Insoluble fiber, such as that from citrus peel, helps promote regular bowel movements, aiding in prevention of constipation.

Fiber intake appears to protect against breast, colon, and gastric cancers. Prebiotic fibers may increase immune function; dietary fiber benefits are similar for children and adults (Anderson *et al.*, 2009; Lario *et al.*, 2004; Vergara *et al.*, 2013; Willams and Bollella, 1995).

Cellulose and modified cellulose study reviews

Naturally occurring cellulose is the major carbohydrate of green plants, and thus, is a regular component of the normal human diet. Cellulose, a major component of citrus fiber, as well as modified forms of cellulose (i.e., carboxymethyl cellulose, hydroxpropylmethyl cellulose, methylcellulose, and sodium carboxymethyl cellulose) have been recognized as GRAS substances since 1973 (LSRO, 1973). The committee that evaluated the health aspects of cellulose and cellulose derivatives as food ingredients concluded:

> "There is no evidence in the available information on pure and regenerated cellulose, including microcrystalline cellulose, that demonstrates or suggests reasonable grounds to suspect, a hazard to the public where they are used at levels that are now current, or that might reasonably be expected in the future."

JECFA established a group acceptable daily intake (ADI) of "not specified" for cellulose and modified celluloses at its thirty-fifth meeting (JECFA, 1989). The modified celluloses included ethyl cellulose, ethyl hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, methyl ethyl cellulose, and sodium carboxymethyl cellulose; cross-linked sodium carboxymethyl cellulose was added at the fifty-ninth meeting in 2002 (JECFA, 2002). The toxicological monograph for the JECFA evaluation concluded that modified celluloses as a group are of very low toxicity. Thus, the JECFA review and evaluation supported a general interpretation of the toxicological properties of modified celluloses as reflective of the non-absorption of the ingredients and, hence, their general non-bioavailability.

The safety of naturally occurring cellulose and cellulose derivatives is very well established and supported by the scientific community. GRN Nos. 213 (2006; pp. 25 - 30) and 478 (2013; Tables 6 and 9) reviewed and provided summary tables of relevant preclinical and clinical studies of cellulose and modified cellulose ingredients. The preclinical studies included absorption, distribution, metabolism, and excretion (ADME), acute and repeated-dose studies (up to eight months) in various species, chronic toxicity and carcinogenicity studies, mutagenicity studies, and reproductive and developmental toxicity studies. Dietary concentrations ranged from 1- 50%, all without reported significant adverse effects in the treated animals. Carcinogenicity studies (dietary concentrations of 1 - 20%) of hydroxypropylmethyl cellulose, methyl cellulose, and methyl ethyl cellulose did not produce any evidence of a carcinogenic effect. Mutagenicity studies conducted with the modified cellulose ingredients have also been negative or without mutagenic effect. Several chronic toxicity, carcinogenicity, and

reproductive toxicity studies were summarized by Anderson *et al.* (1992) and are presented below.

A purified cellulose derivative, methylcellulose, was administered to Sprague-Dawley rats in a 2-year feeding study at concentrations of 0, 1, and 5% in the diet. Study results indicated no evidence of differences in spontaneous disease rates or neoplasia from the ingestion of methylcellulose (McCollister *et al.*, 1973, as cited in Anderson *et al*, 1992). Anastasia *et al.* (1990, as cited in Anderson *et al.*, 1992) compared a Purina Chow diet to two semi-purified diets containing 3% purified cellulose (Celluflour) (approximately 1.2 g cellulose/kg bw/day). The diets were fed *ad libitum* to groups of 50 rats per sex with scheduled sacrifices at 3, 6, 12 and 22 months. The semi-purified diets resulted in greater total weight gain with lower relative organ weights (g/100 g bw) as absolute organ weights were higher in cellulose-fed groups. Histopathology differences were limited to enhanced kidney mineralization in semi-purified diet females and to diffused perinuclear hepatocyte vacuolization in the semi-purified diet males. The authors stated that both of the findings were previously reported in rats ingesting semi-purified diets and were not considered significantly related to exogenous cellulose consumption. The percentage incidence of neoplasms and specific neoplasm types did not differ significantly between the chow diet and either of the cellulose-containing diets. The authors concluded that the semi-purified diets containing exogenous cellulose did not significantly alter the health of the rats.

The Scientific Committee on GRAS Substances (SCOGS) GRAS report (LSRO, 1973) concluded that exogenous cellulose did not induce adverse reproductive effects, based on a three-generation reproductive study in rats using purified cellulose at a 30% level in the diet (Anonymous, 1972, as cited in Anderson *et al.*, 1992). Reproduction in both rats and mice has been compared in animals ingesting an open formula, cereal-based diet (NIH-07) and a semi-purified diet (AIN-76) containing 5% exogenous cellulose (Bieri *et al.*, 1977, as cited in Anderson *et al.*, 1992). In rats bred twice and mice bred continuously, reproductive performance was comparable in terms of pups per litter, pup survival and pup growth. Teratogenic effects were not observed and growth rates in both species for up to 18 weeks after weaning were unaffected. It was concluded that 5% exogenous cellulose ingestion did not adversely influence either reproduction or growth and development in rats or mice.

Several growth studies employing dietary levels of exogenous cellulose up to 20% by weight did not retard growth in adult rats (Hove and King, 1979; Gordon, 1990, as cited in Anderson *et al.*, 1992). In another growth study of rat pups, the effects of exogenous cellulose (Avicel-PH) at 0, 5, 10 and 20% in the diet were studied on carcass composition in rat pups after 28 days of ad libitum ingestion. The pups ingesting the 10 and 20% cellulose diets did not increase food consumption to compensate for the caloric dilution and gained less weight (Sundaravalli *et al.*, 1971, as cited in Anderson *et al.*, 1992). In another study by Wojcik and Delorme (1983, as cited in Anderson et al., 1992), 4.8, 9.1, 16.7, and 28.6% exogenous cellulose was added to the diet for 4 weeks and crude protein quality was varied. At the highest dose, consumption of the cellulose containing diet decreased carcass fat due to lower caloric intake, but all other differences were dependent

upon protein quality and not the cellulose content.

It has also been demonstrated that high-calorie, high-quality protein components can compensate for caloric dilution to confirm the lack of toxicity with exogenous cellulose. Feeding of 40% exogenous cellulose in isocaloric, isonitrogenous diets did not affect growth when compared to a diet with 5% cellulose (Anderson *et al.*, 1987, as cited in Anderson *et al.*, 1992). In another study, the growth of rat pups was only slightly decreased by ingestion of a low-carbohydrate diet containing 41% cellulose (Solka Floe) introduced at parturition to their dams and then to the pups for 10 weeks after weaning Anderson *et al.*, 1988, as cited in Anderson *et al.*, 1992). Based on these dietary studies, Anderson et al. (1992) concluded that ingestion of extremely high doses of cellulose has no apparent adverse effect on pup growth and development in either mice or rats.

Clinical studies with cellulose and modified cellulose ingredients (dosages of 14 - 25 g/day for 1 -12 weeks) have been conducted without reported adverse effects related to cellulose consumption (Table 9; GRN 478, 2013).

Epidemiologic and Human Studies Evaluating Dietary Fiber

Wahal and co-workers (1986) evaluated the impact of wheat bran on serum vitamin A levels in 20 healthy volunteers living in India over a 6-week study. It was found that adding wheat bran containing 14.2 g fiber to a standard diet (containing 20,000 units of vitamin A) substantially decreased serum vitamin A levels within 1 week, and this trend persisted over 3 weeks. The authors concluded that bran in the wheat flour, which is prominent in the diets of people living in North India, might contribute to the vitamin A deficiency typically observed in this area. No other adverse effects were noted (Wahal *et al.*, 1986).

Three groups of healthy subjects were recruited for a study (Rattan *et al.*, 1981) in the Tel Aviv area: 1) 68 individuals regularly adding ≥2 tablespoons bran (7.1 – 31.9 g/day) to their diet for at least 6 months; 2) 43 controls not consuming additional bran; and 3) 20 vegetarians (8 of them consuming additional bran) who consumed very high amounts of fiber for many years. Mean serum levels of vitamin A, zinc, magnesium, iron, total iron binding capacity, phosphorus, calcium, alkaline phosphatase, and cholesterol were within the normal range for all three groups. There was no correlation between the amount of bran ingested and the blood level of nutrients and no adverse effects related to dietary fiber consumption were noted. The authors concluded that moderate or even very high fiber consumption over a long period of time does not result in nutrient or mineral deficiencies in a western type population (Rattan *et al.*, 1981).

2. Citrus Fiber

Animal Studies Evaluating Citrus Peel Fiber

Reddy and Mori (1981a,b) evaluated the impact of dehydrated citrus fiber (from orange peel) and wheat bran on small intestinal and colon carcinogenesis induced by 3,2'-dimethyl-4-aminobiphenyl (DMAB) in male F344 rats. Weanling rats consumed diets

containing alphacel (5%), alphacel (5%) and wheat bran (15%), or alphacel (5%) and citrus fiber (15%). At 7 weeks, non-control animals received subcutaneous (s.c.) injections of 50 mg DMAB/kg once per week for 20 weeks. All animals were weighed weekly up to 20 weeks and then once every 2 weeks. For metabolic balance studies, vehicle-treated rats fed various diets were transferred to individual metabolism cages and food consumption measured for 7 days after an adjustment period of 3 days. Feces were collected for 4 days. Animals that were dying or moribund were necropsied. Surviving animals were autopsied as scheduled. All organs were examined grossly and histologically for the number and types of tumors. Treated rats consuming the citrus fiber diet developed fewer small intestinal tumors than did animals on the control diet; the number of adenocarcinomas was decreased in rats fed the citrus fiber diet. In addition, no adverse effects were noted in the control group rats that received 15% citrus fiber in their diets for 27 weeks. The daily intake of citrus fiber was approximately 2.4 g/day or approximately or approximately 8 g/kg bw/day based on a 300 g rat and feed intake measurements (week 10). It was concluded that the study demonstrated that diets containing citrus peel fiber decrease the risk for intestinal cancer induced by DMAB (Reddy and Mori, 1981a).

Iwata *et al.* (2012) evaluated the bifidogenic and hypolipidemic potentials of dietary fiber from the Mikan (Japanese mandarin orange: *Citrus unshiu*) albedo. In an *in vitro* study, albedo soluble dietary fiber inhibited enzymatic degradation of triolein by pancreatic lipase. Male Wistar-Hannover GALAS rats were given a control diet (5% cellulose) or 4% cellulose with 1% albedo total dietary fiber for 4 weeks. Treated animals had significantly increased fecal lipid excretion, decreased serum triacylglycerol concentrations, and no changes in serum concentrations of total cholesterol, phospholipid, or hepatic lipid content (triacylglycerol, total cholesterol, and phospholipid). Treated rats had an increased number of beneficial bifidobacteria in the cecum. This study showed that albedo total dietary fiber consumption reduced serum triacylglycerol concentrations (due to the increased lipid excretion into the feces via inhibition of pancreatic lipase) and increased levels of bifidobacteria in the rat cecum (Iwata *et al.*, 2012).

3. Citrus Fruits

Fruits contain many biologically active substances, which have been proposed to have various health benefits. These substances include dietary fiber, carotenoids, vitamin C, folic acid, selenium, potassium, and many phytochemicals. In particular, nutrients in citrus fruits and their juices have been shown to promote health and protect against chronic disease. Increased dietary intake of fruits and vegetables is associated with a decreased risk of common human cancers, including breast, lung, colon, and prostate. Citrus fruits also have anti-inflammatory and antiviral activities, ability to inhibit platelet aggregation, and beneficial effects on capillary fragility and macular degeneration (Beecher, 2003; Neuhouser, 2004; Okwu, 2008).

Insoluble materials that are rich in fiber have been shown to have beneficial effects, such as reduction of glucose absorption, slowing of glucose adsorption and starch digestion, and control of postprandial serum glucose levels. Citrus peel contains large amounts of

insoluble FRFs including insoluble dietary fiber (main fraction), water-insoluble solid and alcohol-insoluble solid, which are primarily composed of cellulose and pectic substances (Chau *et al.*, 2003a,b).

Fiber influences colonic fermentation and stool production (Vergara, 2013). Fruit fibers, in particular, have beneficial quality due to colonic fermentability, low caloric count, high soluble and total fiber content, and positive functional properties (oil and water holding capacities). Of the citrus fruits, lemon is the most beneficial fiber for dietary benefit for cardiovascular and other diseases (Lario *et al.*, 2004). In an evaluation conducted by Lario *et al.* (2004), high dietary fiber lemon powder from lemon (Fino *cv*) by-products was found to have desirable physicochemical characteristics to be used in food formulations (e.g., bakery dairy, meat products) and favorable microbial and functional quality (Lario *et al.*, 2004).

Dhiman *et al.* (2011) evaluated the heavy metal and mineral ion content of *Citrus sinensis* (sweet orange) peel, which is often used for medicinal purposes. The peel was dried and digested using a wet digestion method, and aluminum, arsenic, cadmium, copper, mercury, selenium, zinc, calcium, and magnesium concentrations were measured via atomic absorption spectrophotometry. The metal and mineral content was found to be low when compared with the limits prescribed by various authorities (e.g., World Health Organization, American Public Health Association, International Center for Materials Research). In conclusion, the tested sweet orange peel was found to meet appropriate safety standards for heavy metals (Dhiman *et al.*, 2011).

Epidemiologic and Human Studies of Citrus Fruits

Hakim and co-workers (2000) performed a case-control study evaluating the typical citrus consumption patterns of an older population from Arizona and studied how history of squamous cell carcinoma (SCC) of the skin varied with citrus consumption. A total of 470 (242 SCC cases and 228 controls) participants ≥30 years of age completed the dietary citrus questionnaire for a final response of 86.7%. Of the respondents, 74.5% reported weekly consumption of citrus juices and 64.3% reported weekly consumption of citrus fruits; primarily orange juice, oranges and grapefruit. Nearly 35% of participants reported citrus peel consumption and no adverse effects related to its consumption were reported. No association was found between the overall citrus fruits or juice consumption and skin SCC. However, citrus peel consumption appeared to offer protection against SCC (odds ratio [OR] = 0.66, 95% CI=0.45–0.95), and the protection was dose-dependent. The authors attributed the protective effect to *d*-limonene present in the peel (Hakim *et al.*, 2000).

In a similar case-control study using the same population as Hakim *et al.* (2000), Hakim and Harris (2001) evaluated the relationships between citrus peel intake or black tea consumption and SCC of the skin. Controls were more likely than were cases to report citrus peel consumption (OR = 0.67). After adjustment for iced and hot tea consumption, ORs associated with citrus peel use were 0.69 and 0.55, respectively. The authors concluded that both citrus peel and strong, hot black tea intake potentially have

independent protective effects against SCC of the skin. No adverse effects related to citrus peel intake were reported (Hakim and Harris, 2001).

Miller *et al.* (1980) evaluated the effect of citrus pectin on vitamin B6 (B6) bioavailability in 8 men, ages 20-27 yrs. After a 4-day adaptation period, Group 1 consumed the constant basal diet supplemented with 15 g pectin during the first 18-day period, followed by no pectin for 18 days then pectin again for the final 18 days. Group 2 was administered, in order, no pectin, pectin, then no pectin diets for 18 days per treatment. In 5 subjects, pectin consistently increased fecal B6, but had no impact on any other B6 parameters. No treatment-related adverse effects were noted. The authors suggested that pectin may promote intestinal synthesis of B6 which is not available to the host (Miller *et al.*, 1980).

In Vivo Animal Studies of Citrus Fruits

Boshtam *et al.* (2013) evaluated the effects of key lime (*Citrus aurantifolia* [Christm]) juice and peel on atherosclerosis progression and antioxidant activity in rabbits that were administered a hypercholesterolemic diet. Forty male white New Zealand rabbits were randomly allocated to four groups, three of which consumed a hypercholesterolemic diet for two months. The first group served as the hypercholesterolemic control; Groups 2 and 3 received 5 mL/day lime juice and 1 g/day dried lime peel powder, respectively. Group 4 consumed a normal diet. Before and after the study, weight was measured and a fasting blood specimen was taken from the rabbits. Serum lipids analyses and antioxidant activity evaluations were then performed. No treatment-related signs of toxicity were reported. The rabbits' aorta and coronary arteries were separated and the presence of fatty streaks was studied. The presence of fatty streaks in the aorta and coronary arteries of the lime juice and lime peel groups (juice (0.2 ± 0.001) [grade: mean ± SD]; peel (0.0 ± 0.00)) was significantly reduced compared to that of the hypercholesterolemic diet group (1.2 ± 0.04) ($p < 0.001$). Relative to the normal diet, the hypercholesterolemic diet group total antioxidant capacity was reduced approximately 25%, but the total antioxidant capacity change was significantly increased in rabbits supplemented with lime peel (approximately 8%) and juice (approximately 16%) ($p = 0.011$). Lime peel was more effective in reducing the grade of fatty streaks, while the juice caused greater changes in serum antioxidant capacity. This difference indicated that lime juice and peel may contain different types of flavonoids. The authors concluded that *C. aurantifolia* juice and peel increase plasma antioxidant capacity in rabbits, and can therefore possibly decelerate or even prevent atherogenesis (Boshtam *et al.*, 2013).

In an *in vivo* study in sheep, Callaway *et al.* (2011a,b) showed that inclusion of orange peel products in the diet reduced *Salmonella typhimurium* populations in the gut of animals who were experimentally inoculated with the bacteria. Significant decreases in cecum bacteria occurred in animals consuming 10% dried orange pellet and fresh orange peel mixture for 10 days before inoculation. No treatment-related adverse effects were reported beyond palatability issues at the higher dietary concentration of 20%.

In Vitro Studies of Citrus Fruits

Citrus fruits decrease the mutagenicity of known mutagens and the risk of stomach cancer (Higashimoto *et al.*, 1998). Previous data have shown that the mutagenicity of 1-methyl-1,2,3,4-tetrahydro- β -carboline-3-carboxylic acid (MTCCA), a mutagen precursor in soy sauce treated with nitrite, is significantly increased when it was treated with nitrite in the presence of alcohols. Higashimoto and co-workers (1998) demonstrated that the mutagenicity of MTCCA (treated with 50 mM nitrite at pH 3, 37° C for 60 min in the presence of 7.5% ethanol) was decreased by the addition of citrus fruits lemon (*Citrus limon*), yuzu (*C. junos*) and sudachi (*C. sudachi*). The mutagenicity-reducing activity of the outer, colored portions of citrus peel was significantly higher than that of the juices. Among the citrus fruit constituents, dietary fibers pectin and lignin demonstrated strong antimutagenic activity, indicating that the mixed fractions of these components including pectin, lignin, *d*-limonene, ascorbic acid, citric acid, naringin, and hesperidin decrease the mutagenicity of MTCCA in the presence of nitrite and ethanol. Some citrus fruits including lemon, yuzu, and sudachi are consumed along with soy sauce in the Japanese menu as refreshing flavors. The authors concluded that citrus fruits might bring additional health benefits if they prevent the development of mutagens in the stomach during a meal (Higashimoto *et al.*, 1998).

In an *in vitro* study, Chau *et al.* (2003b) isolated FRFs from the peel of *Citrus sinensis* L. cv. Liucheng (Liucheng sweet orange). The authors demonstrated that the three FRFs could effectively slow glucose diffusion, adsorb glucose, and inhibit R-amylase activity. The potential hypoglycemic effects of these fractions suggest that they could be added as low-calorie bulk ingredients in high-fiber foods to modulate blood glucose level and reduce calories (Chau *et al.*, 2003a,b).

4. Human Tolerance /Allergenicity

Citrus fruits are not listed among the major food allergens by FDA (www.fda.gov/Food/ResourcesForYou/Consumers/ucm079311.htm). While allergic reactions to citrus juice or fruits are uncommon, citrus fruits have been linked to allergenic reactions in sensitive adults. A Chinese study indicates that allergenicity is not due to the juice itself, but orange seeds contain potent allergens capable of causing sensitivity. Other studies have linked allergic reactions with preservatives present in some juices. The potential allergenicity of citrus had led to speculation as to whether it might be involved in asthma. However, studies have shown that a diet low in vitamin C (found in citrus) is linked with a higher risk of asthma (Baghurst, 2003).

Iorio *et al.* (2013) discuss previous studies, which have shown evidence of citrus allergy. In a group of 100 adults suffering from oral allergy syndrome as a typical display of allergy to oranges, 17% reported adverse food reactions after consuming oranges. An English study of 67 asthmatic children compared parental perception of food allergy to a test for multiple food-specific immunoglobulin E (IgE) antibodies; oranges were suggested in 15% of patients. Additional studies reported mild local reactions from orange-dependent anaphylaxis induced by exercise after consuming oranges (Iorio *et al.*, 2013).

Allergy to citrus fruits is often associated with sensitization to other plants and pollinosis (hay fever) due to cross-reactivity (Iorio *et al.*, 2013; López-Torrejón *et al.*, 2005). Iorio and co-workers (2013) examined the cross-reactivity between citrus and the major allergenic fruits/pollens and evaluated the sensitization frequency to citrus fruits in a population with hay fever. Study participants included 72 children and young adults (22 females, 50 males); mean age 12.3 years (range 6–22 years). In the volunteers, 39% exhibited sensitivity to citrus, and all of these individuals had a positive response to the prick-to-prick test, indicating an IgE-mediated mechanism. Reverse transcription polymerase chain reaction (RT-PCR) experiments revealed that citrus allergens shared similar identities with other clinically relevant species (i.e., *Malus domestica* [apple], *Triticum aestivum* [wheat]), confirming the possible cross-allergenicity between citrus/apple and citrus/grasses. In this experiment, two phospholipase A2 isoforms (PLA2 α and β) were found both in Triticum pollens and citrus. As the PLA2 enzyme is capable of producing pro-inflammatory factors, it may participate in activation of the allergenic cascade of inflammatory reactions. The authors concluded that this study confirms citrus fruit sensitization and shows that clementine and orange allergy is not a rare condition in patients who are sensitized to pollen. It is believed that allergy to oranges can occur primarily through local symptoms (e.g., erythema and oral allergy syndrome) unlike other food allergies, which are characterized by more generalized symptoms such as abdominal pain, diarrhea, and vomiting (Iorio *et al.*, 2013).

López-Torrejón *et al.* (2005) evaluated 23 patients who had an orange allergy. Using skin prick tests, reactivity to Cit s 2 (natural orange profilin, a potential orange allergen) was analyzed. Reactivity to Cit s 2 was also evaluated *in vitro* by specific IgE determination in individual sera and enzyme-linked immunosorbent assay-inhibition assays, and IgE immunodetection. The purified allergen inhibited approximately 50% of the IgE binding to an extract of orange pulp. An unexpectedly high reactivity to Cit s 2 occurred *in vitro* (87% of sera from volunteers with orange allergy had IgE specific to Cit s 2) as well as *in vivo* (78% of positive skin prick test responses). Profilin seems to be present mainly in orange pulp. The authors concluded that, unlike other profilins of plant food origin, orange profilin Cit s 2 is a highly prevalent, major allergen.

However, it should be noted that GRN 487 (2013) for a similar citrus fiber product (dried citrus pulp) contains an expert opinion letter from Steve L. Taylor, Ph.D. that states that,

> "citrus fruits are reported to cause occasional allergic reactions, but citrus fruits are not among the most commonly allergenic foods. Allergic reactions to citrus fruits are both rare and typically mild. Furthermore, no reports exist of allergic reactions to citrus pulp or fiber; the few reports involve reactions to the fruit and not the pulp. The protein contents of these citrus fiber products are appreciable (approximately 10%), but the usage level of this ingredient in typical formulations is comparatively low. For these reasons, I do not believe that these citrus fiber products are likely to pose any allergenic risk even to the few citrus-allergic consumers in the population."

It should be noted that the protein content of the proposed citrus fiber ingredient is <4%.

C. Safety Data Summary

There is common knowledge of a long history of human consumption of citrus fruits and products derived from these fruits. Citrus fiber-based ingredients have been used in the food industry for a long time (e.g., orange peel in marmalade). Fiber from the edible portions of oranges (e.g., pectin, pulp, juice sacs, segment membranes) is used in a variety of food products. Pectin, the fiber fraction of cell wall material, is important for gelling and moisture binding of baked products, dairy, sweet spreads, and beverages and is recognized as GRAS (21 CFR § 184.1588; use levels in food not to exceed current Good Manufacturing Practice). The albedo part of citrus peel is an abundant source of dietary fibers, including hemicelluloses, pectin, and cellulose. Cellulose, hemicellulose, and/or pectin are common components of grains and fruits and grain- and fruit-based food ingredients such as citrus fiber. In addition, various forms of cellulose are common food ingredients, recognized by the FDA as multipurpose additives permitted for direct addition to foods [e.g., ethyl cellulose (21 CFR § 172.868), hydroxypropyl cellulose (21 CFR § 172.870), methyl ethyl cellulose (21 CFR § 172.872)]. The intended uses of CitriTex® citrus fiber will substitute for other current citrus and dietary fiber sources in the proposed foods (see Section 5.0).

Fruits contain many biologically active substances, which have been proposed to have various health benefits. These substances include dietary fiber, carotenoids, vitamin C, folic acid, selenium, potassium, and many phytochemicals. In particular, nutrients in citrus fruits and their juices have been shown to promote health and protect against chronic disease. Increased dietary intake of fruits and vegetables is associated with a decreased risk of common human cancers, including breast, lung, colon, and prostate.

Consumption of dietary fiber leads to many health benefits, including lower risk of obesity, hypertension, coronary heart disease, stroke, diabetes, and various GI diseases. Total fiber intake influences several metabolic functions, including fat metabolism and absorption of nutrients and carbohydrates.

Insoluble materials that are rich in fiber have been shown to have beneficial effects, such as reduction of glucose absorption, slowing of glucose adsorption and starch digestion, and control of postprandial serum glucose levels. Citrus peel contains large amounts of insoluble FRFs including insoluble dietary fiber (main fraction), water-insoluble solid and alcohol-insoluble solid, which are primarily composed of cellulose and pectic substances (Chau *et al.*, 2003a,b).

Importantly, studies of citrus fruits and citrus fiber sources in humans and/or animals have demonstrated its safety as well as beneficial effects. Safety studies of dietary fiber sources including citrus fiber, vegetable/grain-based fiber, and cellulose and modified cellulose ingredients have been conducted at current levels of fiber consumption and

above. *In vivo* and *in vitro* human and animal studies utilizing citrus fruits and their components (e.g., cellulose, hemicellulose) were reviewed and both their safety and/or potential health benefits summarized. Several studies of cellulose and its derivatives in different species, following oral and non-oral routes, have been published and summarized in GRAS notifications for cellulose-related ingredients and/or vegetable/grain fiber sources. The toxicological data on cellulose and modified celluloses include acute toxicity studies, subchronic toxicity studies, carcinogenicity and genotoxicity studies, as well as reproductive and developmental toxicity studies. No significant adverse effects associated with dietary fiber, cellulose, modified cellulose, or citrus fiber consumption were reported in the published literature.

Citrus fruits are not listed among the major food allergens by FDA (www.fda.gov/Food/ResourcesForYou/Consumers/ucm079311.htm). While allergic reactions to citrus juice or fruits are uncommon, citrus fruits have been linked to allergenic reactions in sensitive adults. Allergy to citrus fruits is often associated with sensitization to other plants and pollinosis (hay fever) due to cross-reactivity (Iorio *et al.*, 2013; López-Torrejón *et al.*, 2005). However, GRN 487 (2013) for a similar citrus fiber product (dried citrus pulp) contains an expert opinion letter from Steve L. Taylor, Ph.D. that states "the citrus fiber products are not likely to pose any allergenic risk even to the few citrus-allergic consumers in the population. Additionally, if these citrus fiber products are labeled as recommended, the presence of a citrus-based ingredient would be readily identifiable on the ingredient statement and individuals with allergies to citrus fruits would likely avoid the product."

7.0 Basis for the GRAS Determination

A. Introduction

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

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

These criteria are applied in the analysis below to determine whether the use of citrus fiber for use in food for human consumption is GRAS based upon scientific procedures. All data used in this GRAS determination are publicly available and generally known, and therefore meet the "general recognition" standard under the FD&C Act.

B. Safety Determination

The subject of this GRAS determination is the use of citrus fiber from lemon, lime, and orange peels as a texturizer and moisture retention agent in select foods for human consumption. There is common knowledge of a long history of human consumption of citrus fruits and products derived from these fruits. Citrus fruits have been consumed for thousands of years. Citrus fiber-based ingredients have been used in the food industry for some time. Fiber from the edible portions of oranges (e.g., pectin, pulp, juice sacs, segment membranes) is used in a variety of processed food products.

Consumption of dietary fiber leads to many health benefits, including lower risk of obesity, hypertension, coronary heart disease, stroke, diabetes, and various GI diseases. Total fiber intake influences several metabolic functions, including fat metabolism and absorption of nutrients and carbohydrates.

The *per user* mean and 90th percentile intake of citrus fiber was estimated to be 6.40 g/day (0.11 g/kg bw/day) and 9.76 g/day (0.18 g/kg bw/day), respectively, for the US population 2+ years of age (Table 9). The *per user* mean and 90th percentile background intake of citrus fiber has been estimated to be 0.7 g/day (0.01 g/kg bw/day) and 1.6 g/day (0.03 g/kg bw/day), respectively for the US population 2+ years of age (GRN 487, 2013). Therefore, the estimated *per user* cumulative mean and 90th percentile exposure to citrus fiber is 7.1 g/day (0.12 g/kg bw/day) and 11.36 g/day (0.21 g/kg bw/day), respectively for the US population 2+ years of age.

The safety section describes human safety studies of citrus fiber as well as other GRAS-notified citrus-based products currently added to processed foods. Recent GRNs (Nos. 491 and 541) provided higher estimates of exposure to their citrus-based fiber products than for CitriTex® citrus fiber. For example, the *per user* mean and 90th percentile intake of these citrus fiber products were estimated to range from 20.2 - 23.4 g/day and 34.2-39.5 g/day), respectively, for the US population 2+ years of age, compared to 6.4 and 9.76 g/day for CitriTex® citrus fiber. Studies of citrus fruits and citrus fiber sources in humans and/or animals have demonstrated its beneficial effects as well as safety. Safety studies of other fiber sources (e.g., cellulose, modified celluloses, vegetable/grain-based fiber) have also demonstrated a lack of toxicity at high levels of consumption.

Citrus fruits are not listed among the major food allergens by FDA. While allergic reactions to citrus juice or fruits are uncommon, citrus fruits have been linked to allergenic reactions in sensitive adults. Allergy to citrus fruits is often associated with sensitization to other plants and pollinosis (hay fever) due to cross-reactivity. If the food product containing the citrus fiber ingredient is labeled as containing citrus fiber, the presence of a citrus-based ingredient would be readily identifiable on the ingredient statement and individuals who wish to avoid citrus-based ingredients would be able to identify its presence.

C. General Recognition of the Safety of Citrus Fiber

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

- The citrus fiber that is the subject of this notification is composed of fiber from the peels of lemons, limes, and oranges. The citrus fiber product is manufactured consistent with current Good Manufacturing Practice (cGMP) for food (21 CFR Part 110). The raw materials and processing aids used in the manufacturing process are food grade and/or approved for use as in food.

- There is common knowledge of a long history of human consumption of citrus fruits and citrus fiber. Numerous food products containing citrus fiber and/or fiber derived from other fruits, vegetables, and grains are marketed in the U.S. and around the world, and citrus fiber has become a desirable ingredient for addition to a variety of food products as a texturizing and moisture retention agent

as well as a source of dietary fiber.

- Safety studies of dietary fiber sources including citrus fiber, vegetable/grain-based fiber, and cellulose and modified cellulose ingredients have been conducted at current levels of fiber consumption and above. *In vivo* and *in vitro* human and animal studies utilizing citrus fruits and their components (e.g., cellulose, hemicellulose) were reviewed and both their safety and/or potential health benefits summarized. Several studies of cellulose and its derivatives in different species, following oral and non-oral routes of exposure, have been published and summarized in GRAS notifications for cellulose-related ingredients and/or vegetable/grain fiber sources. The toxicological data on cellulose and modified celluloses include acute toxicity studies, subchronic toxicity studies, carcinogenicity and genotoxicity studies, as well as reproductive and developmental toxicity studies. No significant adverse effects associated with dietary fiber, cellulose, modified cellulose, or citrus fiber consumption were reported in the published literature. In addition, a number of studies of citrus fruits and citrus fiber sources in humans and/or animals have demonstrated a number of beneficial effects as well as safety.

- Adequate fiber intake recommendations for adults ($\leq$ 50 years of age) are 38 g total dietary fiber/day for men and 25 g total dietary fiber/day for women (IOM, 2005). For adults greater than 50 years of age, the Institute of Medicine (IOM) recommends 30 g/day and 21 g/day for men and women, respectively. It is notable that most Americans need to increase their intake of dietary fiber. The daily value (DV) for dietary fiber is 25 g for a 2000 calorie diet per 21 CFR § 101.9(d). The intended uses of CitriTex® citrus fiber will provide an alternative to other current citrus and dietary fiber sources, at a *per user* mean level of 6.40 g CitriTex® citrus fiber/day.

- To date, FDA has reviewed extensive published information and data as part of GRAS notifications for citrus fiber and other vegetable/grain-based fiber sources and subsequently issued "no question letters" [e.g., GRN No. 154 (dried orange pulp); GRN No. 487 (dried citrus pulp); GRN No. 116 (carrot fiber); GRN No. 207 (barley fiber); GRN No. 261 (oat hull fiber); GRN No. 310 (potato fiber); GRN No. 342 (oat hull fiber); GRN No. 344 (barley fiber); GRN No. 373 (rice bran fiber); GRN No. 427 (corn hull fiber); GRN No. 430 (sugar beet fiber); GRN No. 525 (pea fiber)].

- The publicly available scientific literature on the consumption and safety of dietary fiber (vegetable/grain-based fiber), citrus fiber, and cellulose and modified cellulose ingredients in animal studies as well as clinical studies in humans, is sufficient to support the safety and GRAS status of the proposed citrus fiber product.

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

Determination of the safety and GRAS status of citrus fiber that is the subject of this self-determination has been made through the deliberations of an Expert Panel convened by Cargill and comprised of James R. Coughlin, Ph.D., Carol A. Knight, Ph.D., and I. Glenn Sipes, Ph.D. These individuals are qualified by scientific training and experience to evaluate the safety of substances intended to be added to foods. They have critically reviewed and evaluated the publicly available information summarized in this document and have individually and collectively concluded that citrus fiber, produced consistent with GMP and meeting the specifications described herein, is safe under its intended conditions of use. The Panel further unanimously concludes that these uses of citrus fiber are GRAS based on scientific procedures, and that other experts qualified to assess the safety of foods and food additives would concur with these conclusions. The Panel's GRAS opinion is included as Exhibit 1 to this document.

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

Cargill is not aware of any information that would be inconsistent with a finding that the proposed use of citrus fiber in food for human consumption meeting appropriate specifications, and used according to GMP, is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

8.0 References

Anderson RL, Owens JW, Timms CW. 1992. The toxicity of purified cellulose in studies with laboratory animals. Cancer Letters 63:83-92.

Anderson JW, Baird P, Davis RH Jr, Ferreri S, Knudtson M, Koraym A, Waters V, Williams CL. 2009. Health benefits of dietary fiber. Nutr Rev 67(4):188-205. doi: 10.1111/j.1753-4887.2009.00189.x.

Baghurst, K. 2003. The Health Benefits of Citrus Fruits. CSIRO Health Sciences & Nutrition, Project Number CT02057, Horticultural Australia Ltd.

Beecher GR. 2003. Overview of dietary flavonoids: nomenclature, occurrence and intake. J Nutr 133(10):3248S-3254S.

Boshtam M, Asgary S, Moshtaghian J, Naderi G, Jafari-Dinani N. 2013. Impacts of fresh lime juice and peel on atherosclerosis progression in an animal model. ARYA Atheroscler 9(6):357-362.

Callaway TR, Carroll JA, Arthington JD, Edrington TS, Anderson RC, Rossman ML, Carr MA, Genovese KJ, Ricke SC, Crandall P, Nisbet DJ. 2011a. Orange peel products can reduce Salmonella populations in ruminants. Foodborne Pathog Dis 8(10):1071-1075. doi: 10.1089/fpd.2011.0867. Epub 2011 Jun 8.

Callaway TR, Carroll JA, Arthington JD, Edrington TS, Rossman ML, Carr MA, Krueger NA, Ricke SC, Crandall P, Nisbet DJ. 2011b. *Escherichia coli* O157:H7 populations in ruminants can be reduced by orange peel product feeding. J Food Prot 74(11):1917-1921. doi: 10.4315/0362-028X.JFP-11-234.

Chau CF and Huang YL. 2003a. Comparison of the chemical composition and physicochemical properties of different fibers prepared from the peel of *Citrus sinensis* L. Cv. Liucheng. J Agric Food Chem 51(9):2615-2618.

Chau CF, Huang YL, Lee MH. 2003b. In vitro hypoglycemic effects of different insoluble fiber-rich fractions prepared from the peel of *Citrus sinensis* L. cv. Liucheng. J Agric Food Chem 22:51(22):6623-6626.

Dhiman A, Nanda A, Ahmad S. 2011. Metal analysis in citrus sinensis fruit peel and psidium guajava leaf. Toxicol Int 18(2):163-7. doi: 10.4103/0971-6580.84271.

FAO/WHO. 1997. Carbohydrates in human nutrition. FAO Food and Nutrition Paper - 66. April.

GRN 541. 2014. GRAS Notification for Insoluble Fiber from Citrus Peel. Submitted by OFW Law for Ceamsa Poligono Industrial As Gándaras s/n Spain. September 8.

GRN 525. 2014. GRAS Notification for Pea Fiber. Submitted by Fuji Oil Company Limited. June 30.

GRN 487. 2013. GRAS Notification for Dried Citrus Pulp. Submitted by Hyman, Phelps & McNamara, P.C. for Fiberstar Inc. September 5.

GRN 478. 2013. GRAS Notification for Rice Hull Fiber. Submitted by SunOpta Ingredients Group. July 30.

GRN 430. 2012. GRAS Notification for Sugar Beet Fiber. Submitted by Nordic Sugar A/S. May 15.

GRN 427. 2012. GRAS Notification for Corn Hull Fiber. Submitted by Z Trim Holdings. March 21.

GRN 373. 2011. GRAS Notification for Rice Bran Fiber. Submitted by CJ America, Inc. February 28.

GRN 344. 2010. GRAS Notification for Barley Fiber. Submitted by Cargill, Incorporated. May 23.

GRN 342. 2010. GRAS Notification for Oat Hull Fiber. Submitted by J Rettenmaier USA LP. May 27.

GRN 310. 2009. GRAS Notification for Potato Fiber. Submitted by J Rettenmaier USA LP. December 24.

GRN 261. 2008. GRAS Notification for Oat Hull Fiber. Submitted by Grain Millers, Inc. September 22.

GRN 213. 2006. GRAS Notification for Hydroxypropyl methylcellulose - expanded substitution pattern (HPMC-ESP). Submitted by The Dow Chemical Company, September 27.

GRN 207. 2006. GRAS Notification for Barley Fiber. Submitted by Cargill, Inc. June 23.

GRN 154. 2004. GRAS Notification for Dried Orange Pulp. Submitted by Hyman, Phelps & McNamara, P.C. for Fiberstar Inc. June 21.

GRN 116. 2002. GRAS Notification for Carrot Fiber. Submitted by Wm. Bolthouse Farms, Inc. October 3.

Hakim IA and Harris RB. 2001. Joint effects of citrus peel use and black tea intake on the risk of squamous cell carcinoma of the skin. BMC Dermatol 1:3. doi:10.1186/1471-5945-1-3.

Hakim IA, Harris RB, Ritenbaugh C. 2000. Citrus peel use is associated with reduced risk of squamous cell carcinoma of the skin. Nutr Cancer 37(2):161-168.

U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA). 2015. Dietary Guidelines for Americans. http://www.health.gov/dietaryguidelines/2015.asp.

Higashimoto M, Yamato H, Kinouchi T, Ohnishi Y. 1998. Inhibitory effects of citrus fruits on the mutagenicity of 1-methyl-1,2,3,4-tetrahydro-beta-carboline-3-carboxylic acid treated with nitrite in the presence of ethanol. Mutat Res. 415(3):219-226.

Institute of Medicine (IOM) of the National Academies. 2005. Dietary, Functional and Total Fiber. Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids Washington DC. National Academies Press.

Iorio RA, Del Duca S, Calamelli E, Pula C, Lodolini M, Scamardella F, Pession A, Ricci G. 2013. Citrus allergy from pollen to clinical symptoms. PLoS One 8(1):e53680. doi: 10.1371/journal.pone.0053680. Epub 2013 Jan 4.

Iwata E, Hotta H, Goto M. 2012. Hypolipidemic and bifidogenic potentials in the dietary fiber prepared from Mikan (Japanese mandarin orange: Citrus unshiu) albedo. J Nutr Sci Vitaminol (Tokyo) 58(3):175-180.

Joint FAO/WHO Expert Committee on Food Additives (JECFA). 1989. Modified celluloses. TRS 789-JECFA-35/24.

Joint FAO/WHO Expert Committee on Food Additives (JECFA). 2002. Modified celluloses. TRS 913-JECFA-59/9.

Lario Y, Sendra E, Garica-Pérez J, Fuentes C, Sayas-Barberá E, Fernández-López J, Pérez-Alvarez JA. 2004. Preparation of high dietary fiber powder from lemon juice by-products. Innov. Food Sci Emerg Tech 5(1):113–117.

Life Sciences Research Organization. 1973. Select Committee on GRAS Substances (SCOGS) Opinion: Cellulose, Microcrystalline Cellulose. Report No. 25.

López-Torrejón G, Ibáñez MD, Ahrazem O, Sánchez-Monge R, Sastre J, Lombardero M, Barber D, Salcedo G. 2005. Isolation, cloning and allergenic reactivity of natural profilin Cit s 2, a major orange allergen. Allergy 60(11):1424-1429.

May CD. 1990. Industrial pectins: Sources, production and applications. Carbohyd. Polym 12(1):79–99.

Miller LT, Shultz TD, Leklem JE. 1980. Influence of citrus pectin on the bioavailability of vitamin B6 in men. P Fed Am Soc Exp Biol Vol. 39. Abstract No. 2796.

Miller RA. 2011. Increased yield of bread containing citrus peel fiber. Cereal Chem 88(2):174–178.

National Orange Show. 2015. Fair History. http://nosevents.com/fair-history/

Nelson FF. 1979. Newer applications for pectin. Food Product Development 13(2):36-38.

Neuhouser ML. 2004. Dietary flavonoids and cancer risk: evidence from human population studies. Nutr Cancer 50(1):1-7.

Nigg HN, Nordby HE, Beier RC, Dillman A, Macias C, Hansen RC. 1993. Phototoxic coumarins in limes. Food Chem Toxicol 31(5):331-335.

Okwu DE. 2008. Citrus fruits: A rich source of phytochemicals and their roles in human health: A review. Int. J. Chem. Sci.: 6(2), 451-471.

Rattan J, Levin N, Graff E, Weizer N, Gilat T. 1981. A high-fiber diet does not cause mineral and nutrient deficiencies. J Clin Gastroenterol. 3(4):389-393.

Reddy BS, Mori H. 1981a. Effect of dietary wheat bran and dehydrated citrus fiber on 3,2'-dimethyl-4-aminobiphenyl-induced intestinal carcinogenesis in F344 rats. Carcinogenesis 2(1):21-25.

Reddy BS, Mori H, Nicolais M. 1981b. Effect of dietary wheat bran and dehydrated citrus fiber on azoxymethane-induced intestinal carcinogenesis in Fischer 344 rats. J Natl Cancer Inst 66(3):553-557.

Seasonal Chef. 2015. Five Orange Recipes from Yesteryear. Available at http://www.seasonalchef.com/preserves17.htm

Vergara TC. 2013. Insoluble dietary citrus fibers. Food Market Technol Key No. 81334, p. 14-18.

Wahal PK, Singh R, Kishore B, Prakash V, Maheshwari BB, Gujral VK, Jain BB. 1986. Effect of high fibre intake on serum vitamin A levels. J Assoc Phys India 34(4):269-70.

Williams CL and Bollella M. 1995. Is a high-fiber diet safe for children? Pediatrics 96:1014-1019.

9.0 Appendices

Appendix A. Certificates of Analysis – Characterization

Trial identification

Trial number: Lot No. **OP9677**

Chemical properties

	Method	Unit	Result
Fat	Gravimetry ISO 6492 *(Cargill Provimi)*	%	<0.3
Moisture	20 PA Rev 0 *(Cargill PPD)*	%	7.0
pH	22 PA Rev 0 *(Cargill PPD)*		3.93
Dietary fiber (∑ cellulose, hemi-cellulose & pectin)	AOAC 991.43 *(Eurofins)*	%	67.9
Pectin	24 PA Rev0 *(Cargill PPD)*	%	13.4
Cellulose	13 PA Rev 0 *(Cargill PPD)*	%	26.4
Hemi-cellulose (calculated)		%	28.1
Sugars	adapted from CAM-S-20C Rev02 *(Cargill Vilv. R&D)*	%	37.3
DE	AM-U1-01-D.04 v 1.3 *(Cargill PPD FP)*	%	49.9
GalA	AM-U1-01-D.04 v 1.3 *(Cargill PPD FP)*	%	14.8
Ca^{++}	06 PA Rev 1 *(Cargill PPD)*	%	0.2
Mg^{++}	06 PA Rev 1 *(Cargill PPD)*	%	0.005
Na^{+}	06 PA Rev 1 *(Cargill PPD)*	%	0.3
Nitrates	05 COLOR Rev 0 *(Cargill PPD)*	%	<0.015
Nitrites	07 COLOR Rev0 *(Cargill PPD)*	%	<0.0005
Isopropanol	05 CPG Rev 0 *(Cargill PPD)*	%	0.03
Methanol	05 CPG Rev 0 *(Cargill PPD)*	%	0.0054
Ash (550°C)	01 PA Rev 1 *(Cargill PPD)*	%	1.66

Trace components

	Method	Unit	Result
As	adapted from EN13805 (*Eurofins*)	mg/kg	<0.1
Cu	adapted from NF EN ISO 11885 (*Eurofins*)	mg/kg	6.8
Cd	adapted from EN 14084 & EN13805 (*Eurofins*)	mg/kg	<0.01
Fe	17 PA Rev 0 (*Cargill PPD*)	mg/kg	31
Co	EN ISO 17294-2-E29 (*Eurofins*)	mg/kg	<0.2
Cr	adapted from NF EN ISO 11885 (*Eurofins*)	mg/kg	0.40
Ni	adapted from NF EN ISO 11885 (*Eurofins*)	mg/kg	2.9
Heavy metals [Total (as Pb)]	USP231 (*CHELAB*)	mg/kg	<20

Additional analysis

	Method	Unit	Result
K^+	06 PA Rev 1 (*Cargill PPD*)	%	0.01
Pb	adapted from EN 14084 & EN13805 (*Eurofins*)	mg/kg	0.6
Hg	§64 LFGB L00.00-19/4 (*Eurofins*)	mg/kg	<0.005
Proteins	02 PA Rev 1 (*Cargill PPD*)	%	2.66
Ethanol	05 CPG Rev 0 (*Cargill PPD*)	%	<0.0015
Aflatoxins B1/B2/G1/G2	internal adapted from EN 14123 (*Eurofins*)	µg/kg	Sum <0.5
Ochratoxin A	internal adapted from EN 14132 (*Eurofins*)	µg/kg	<0.5
Patulin	Internal method, LC-MS/MS (*Eurofins*)	µg/kg	<20
Ash 900°C	ISO3593 (*Cargill PPD*)	%	1.10
Particle size: D4,3	Malvern_2000_PSD_CPF_Rev0 (*Cargill Vilv. R&D*)	µm	132

Particle size: d3,2	Malvern_2000_PSD_CPF_Rev0 *(Cargill Vilv. R&D)*	µm	71
Particle size: D (10)	Malvern_2000_PSD_CPF_Rev0 *(Cargill Vilv. R&D)*	µm	35
Particle size: D (50)	Malvern_2000_PSD_CPF_Rev0 *(Cargill Vilv. R&D)*	µm	112
Particle size: D (90)	Malvern_2000_PSD_CPF_Rev0 *(Cargill Vilv. R&D)*	µm	260
Granulometry >250µm	AM-U1-01-H 03 *(Cargill PPD-FP)*	%	0.15
Viscosity (3% solution)	R-01MS *(Cargill Vilv. R&D)*	Pa	614
Appearance	–		Creamy-white powder
Color (L-value)	HunterLab_Spectrophotometer_CM-5_CPF_rev0 *(Cargill Vilv. R&D)*		85.0
Odour + taste	–		Neutral to slightly citrus

Microbiological analysis

	Method	**Unit**	**Result**
Aerobic Plate Count	BLAM 3010 *(Cargill Quality)*	cfu/g	400
Yeast	BLAM 3020 *(Cargill Quality)*	cfu/g	<20
Molds	BLAM 3020 *(Cargill Quality)*	cfu/g	60
Coliforms	BLAM 3315 *(Cargill Quality)*	cfu/g	Absence in 5g
E. Coli	BLAM 3315 *(Cargill Quality)*	cfu/g	Absence in 5g
Enterobacteriaceae	BLAM 3081 *(Cargill Quality)*	cfu/g	<10
Lactic Acid Bacteria	NF ISO 15214 *(Eurofins)*	cfu/g	<10
Coagulase Positive Staphylococci	BLAM 3310 *(Cargill Quality)*	cfu/g	Absence in 1g
Bacillus cereus	NF EN ISO 7932 *(Eurofins)*	cfu/g	<5
Salmonella	BLAM 3303 *(Cargill Quality)*	cfu/g	Absence in 10g
Clostridium perfringens	NF EN ISO 7937 *(Eurofins)*	cfu/g	<10
Listeria monocytogenes	BLAM 3342 *(Cargill Quality)*	cfu/g	Absence in 10g

(Cargill PPD) = measured by the Product & Process Development Department of Cargill in Baupte (France)
(Cargill Quality) = measured by the Quality Department of Cargill in Baupte (France)
(Eurofins) = measured by Eurofins Analytics France (Nantes)
(CHELAB) = measured by CHELAB France
(Cargill Vilv. R&D) = measured by R&D Centre Vilvoorde (Belgium)
(Cargill PPD FP) = measured by the Product & Process Development Department of Cargill in Malchin (Germany)

Trial identification

Trial number: Lot No. **OP9670**

Chemical properties

	Method	Unit	Result
Fat	Gravimetry ISO 6492 *(Cargill Provimi)*	%	<0.3
Moisture	20 PA Rev 0 *(Cargill PPD)*	%	6.5
pH	22 PA Rev 0 *(Cargill PPD)*		3.84
Dietary fiber (∑ cellulose, hemi-cellulose & pectin)	AOAC 991.43 *(Eurofins)*	%	65.1
Sugars	adapted from CAM--S-20C Rev02 *(Cargill Vilv. R&D)*	%	37.5
Isopropanol	05 CPG Rev 0 *(Cargill PPD)*	%	0.027
Methanol	05 CPG Rev 0 *(Cargill PPD)*	%	<0.01
Ash (550°C)	01 PA Rev 1 *(Cargill PPD)*	%	1.32

Trace components

	Method	Unit	Result
As	analog §64 LFGB L00.00-19/3 *(Eurofins)*	mg/kg	<0.1
Cu	adapted from NF EN ISO 11885 *(Eurofins)*	mg/kg	4.8
Co	EN ISO 17294-2-E29 *(Eurofins)*	mg/kg	<0.1
Cr	adapted from NF EN ISO 11885 *(Eurofins)*	mg/kg	0.4
Ni	adapted from NF EN ISO 11885 *(Eurofins)*	mg/kg	2.9
Pb	§64 LFGB L00.00-19/3 *(Eurofins)*	mg/kg	0.6

Additional analysis

	Method	Unit	Result
Granulometry >250µm	AM-U1-01-H 03 *(Cargill PPD-FP)*	%	2.0
Viscosity (3% solution)	R-01MS *(Cargill Vilv. R&D)*	Pa	543

Appearance	_		Creamy-white powder
Color (L-value)	HunterLab_Spectrophotometer_CM-5_CPF_rev0 *(Cargill Vilv. R&D)*		84.0
Odour + taste	_		Neutral to slightly citrus

Microbiological analysis

	Method	Unit	Result
Aerobic Plate Count	XP V08-034 *(Eurofins)*	cfu/g	<100
Yeast	NF V 08-059 *(Eurofins)*	cfu/g	<10
Molds	NF V 08-059 *(Eurofins)*	cfu/g	<40
E. Coli	ISO 16649-2 (Eurofins)	cfu/g	Absence
Salmonella	SOL 37/01-06/13 *(Eurofins)*	cfu/25g	Absence

(Cargill PPD) = measured by the Product & Process Development Department of Cargill in Baupte (France)
(Cargill Quality) = measured by the Quality Department of Cargill in Baupte (France)
(Eurofins) = measured by Eurofins Analytics France (Nantes)
(CHELAB) = measured by CHELAB France
(Cargill Vilv. R&D) = measured by R&D centre Vilvoorde (Belgium)
(Cargill PPD FP) = measured by the Product & Process Development Department of Cargill in Malchin (Germany)

Trial identification

Trial number: Lot No. **OP9858**

Chemical properties

	Method	Unit	Result
Fat	Gravimetry ISO 6492 *(Cargill Provimi)*	%	<0.3
Moisture	20 PA Rev 0 *(Cargill PPD)*	%	5.5
pH	22 PA Rev 0 *(Cargill PPD)*		3.71
Dietary fiber (∑ cellulose, hemi-cellulose & pectin)	AOAC 991.43 *(Eurofins)*	%	58.67
Sugars	adapted from CAM--S-20C Rev02 *(Cargill Vilv. R&D)*	%	37.5
Isopropanol	05 CPG Rev 0 *(Cargill PPD)*	%	0.084
Methanol	05 CPG Rev 0 *(Cargill PPD)*	%	<0.01
Ash (550°C)	01 PA Rev 1 *(Cargill PPD)*	%	2.51

Trace components

	Method	Unit	Result
As	analog §64 LFGB L00.00-19/3 *(Eurofins)*	mg/kg	<0.1
Cu	adapted from NF EN ISO 11885 *(Eurofins)*	mg/kg	4.0
Co	EN ISO 17294-2-E29 *(Eurofins)*	mg/kg	<0.1
Cr	adapted from NF EN ISO 11885 *(Eurofins)*	mg/kg	1.8
Ni	adapted from NF EN ISO 11885 *(Eurofins)*	mg/kg	0.7
Pb	§64 LFGB L00.00-19/3 *(Eurofins)*	mg/kg	0.75

Additional analysis

	Method	Unit	Result
Granulometry >250µm	AM-U1-01-H 03 *(Cargill PPD-FP)*	%	0.3

Viscosity (3% solution)	R-01MS *(Cargill Vilv. R&D)*	Pa	770
Appearance	–		Creamy-white powder
Color (L-value)	HunterLab_Spectrophotometer_CM-5_CPF_rev0 *(Cargill Vilv. R&D)*		86.4
Odour + taste	–		Neutral to slightly citrus

Microbiological analysis

	Method	**Unit**	**Result**
Aerobic Plate Count	XP V08-034 *(Eurofins)*	cfu/g	<100
Yeast	NF V 08-059 *(Eurofins)*	cfu/g	<20
Molds	NF V 08-059 *(Eurofins)*	cfu/g	<20
E. Coli	ISO 16649-2 *(Eurofins)*	cfu/g	Absence
Salmonella	SOL 37/01-06/13 *(Eurofins)*	cfu/25g	Absence

(Cargill PPD) = measured by the Product & Process Development Department of Cargill in Baupte (France)
(Cargill Quality) = measured by the Quality Department of Cargill in Baupte (France)
(Eurofins) = measured by Eurofins Analytics France (Nantes)
(CHELAB) = measured by CHELAB France
(Cargill Vilv. R&D) = measured by R&D centre Vilvoorde (Belgium)
(Cargill PPD FP) = measured by the Product & Process Development Department of Cargill in Malchin (Germany)

Trial identification

Trial number: Lot No. **OP9591**

Chemical properties

	Method	Unit	Result
Fat	Gravimetry ISO 6492 *(Cargill Provimi)*	%	<0.3
Moisture	20 PA Rev 0 *(Cargill PPD)*	%	6.5
pH	22 PA Rev 0 *(Cargill PPD)*		4.35
Dietary fiber (∑ cellulose, hemi-cellulose & pectin)	AOAC 991.43 *(Eurofins)*	%	59.0
Pectin	24 PA Rev 0 *(Cargill PPD)*	%	10.7
Cellulose	13 PA Rev 0 *(Cargill PPD)*	%	33.1
Hemi-cellulose (calculated)		%	15.2
Sugars	adapted from CAM--S-20C Rev02 *(Cargill Vilv. R&D)*	%	35.9
DE	AM-U1-01-D.04 v 1.3 *(Cargill PPD FP)*	%	49.1
GalA	AM-U1-01-D.04 v 1.3 *(Cargill PPD FP)*	%	12.1
Ca^{++}	06 PA Rev 1 *(Cargill PPD)*	%	0.36
Mg^{++}	06 PA Rev 1 *(Cargill PPD)*	%	0.004
Na^{+}	06 PA Rev 1 *(Cargill PPD)*	%	0.31
Nitrates	05 COLOR Rev 0 *(Cargill PPD)*	%	0.036
Nitrites	07 COLOR Rev 0 *(Cargill PPD)*	%	<0.0005
Isopropanol	05 CPG Rev 0 *(Cargill PPD)*	%	0.072
Methanol	05 CPG Rev 0 *(Cargill PPD)*	%	0.006
Ash (550°C)	01 PA Rev 1 *(Cargill PPD)*	%	2.06

Trace components

	Method	Unit	Result
As	analog §64 LFGB L00.00-19/3 (*Eurofins*)	mg/kg	<0.1
Cu	adapted from NF EN ISO 11885 (*Eurofins*)	mg/kg	5.1
Cd	(adapted from EN 14084 & EN13805) §64 LFGB L00.00-19/3 (*Eurofins*)	mg/kg	<0.01
Fe	17 PA Rev 0 *(Cargill PPD)*	mg/kg	12
Co	EN ISO 17294-2-E29 (*Eurofins*)	mg/kg	<0.1
Cr	adapted from NF EN ISO 11885 (*Eurofins*)	mg/kg	0.8
Ni	adapted from NF EN ISO 11885 (*Eurofins*)	mg/kg	3.1
Heavy metals [Total (as Pb)]	USP231 *(CHELAB)*	mg/kg	<20

Additional analysis

	Method	Unit	Result
K^+	06 PA Rev 1 *(Cargill PPD)*	%	0.03
Pb*	§64 LFGB L00.00-19/3 (*Eurofins*)	mg/kg	2.3
Hg	§64 LFGB L00.00-19/4 (*Eurofins*)	mg/kg	<0.005
Proteins	02 PA Rev 1 *(Cargill PPD)*	%	2.92
Ethanol	05 CPG Rev 0 *(Cargill PPD)*	%	0.014
Aflatoxins B1/B2/G1/G2	internal adapted from EN 14123 (*Eurofins*)	µg/kg	Sum <0.5
Ochratoxin A	internal adapted from EN 14132 (*Eurofins*)	µg/kg	<0.2
Patulin	Internal method, LC-MS/MS (*Eurofins*)	µg/kg	<20
Ash 900°C	ISO3593 *(Cargill PPD)*	%	0.41
Particle size: D4,3	Malvern_2000_PSD_CPF_Rev0 *(Cargill Vilv. R&D)*	µm	135.4
Particle size: d3,2	Malvern_2000_PSD_CPF_Rev0 *(Cargill Vilv. R&D)*	µm	73.4
Particle size: D (10)	Malvern_2000_PSD_CPF_Rev0	µm	36.5

	(Cargill Vilv. R&D)		
Particle size: D (50)	Malvern_2000_PSD_CPF_Rev0 *(Cargill Vilv. R&D)*	µm	114.3
Particle size: D (90)	Malvern_2000_PSD_CPF_Rev0 *(Cargill Vilv. R&D)*	µm	266.4
Granulometry >250µm	AM-U1-01-H 03 *(Cargill PPD-FP)*	%	0.35
Viscosity (3% solution)	R-01MS *(Cargill Vilv. R&D)*	Pa	818
Appearance	–		Creamy-white powder
Color (L-value)	HunterLab_Spectrophotometer_CM-5_CPF_rev0 *(Cargill Vilv. R&D)*		78.6
Odour + taste	–		Neutral to slightly citrus

Microbiological analysis

	Method	**Unit**	**Result**
Aerobic Plate Count	XP V08-034 *(Eurofins)*	cfu/g	<100
Yeast	NF V 08-059 *(Eurofins)*	cfu/g	<100
Molds	NF V 08-059 *(Eurofins)*	cfu/g	< 100
Coliforms	BLAM 3315 (Cargill Quality)	cfu/g	absence
E. Coli	BLAM 3315 (Cargill Quality)	cfu/g	absence
Enterobacteriaceae	NF V08-054 *(Eurofins)*	cfu/g	<10
Lactic Acid Bacteria	NF ISO 15214 *(Eurofins)*	cfu/g	<1000
Coagulase Positive Staphylococci	NF V 08-057-1 *(Eurofins)*	cfu/g	<100
Bacillus cereus	NF EN ISO 7932 *(Eurofins)*	cfu/g	<100
Salmonella	SOL 37/01-06/13 *(Eurofins)*	cfu/g	absence in 25g
Clostridium perfringens	NF EN ISO 7937 *(Eurofins)*	cfu/g	<10
Listeria monocytogenes	AES 10/03-09/00 *(Eurofins)*	cfu/g	absence in 25g

* While the Pb level for this batch did not meet the proposed specification (≤1 ppm), refinements of the pilot plant production of citrus fiber have been made to ensure that future commercial production will produce consistent citrus fiber product that meets the proposed citrus fiber specifications, including for residual Pb.

(Cargill PPD) = measured by the Product & Process Development Department of Cargill in Baupte (France)
(Cargill Quality) = measured by the Quality Department of Cargill in Baupte (France)
(Eurofins) = measured by Eurofins Analytics France (Nantes)
(CHELAB) = measured by CHELAB France
(Cargill Vilv. R&D) = measured by R&D centre Vilvoorde (Belgium)
(Cargill PPD FP) = measured by the Product & Process Development Department of Cargill in Malchin (Germany)

Trial identification

Trial number: Lot No. **OP9608**

Chemical properties

	Method	Unit	Result
Fat	Gravimetry ISO 6492 *(Cargill Provimi)*	%	<0.3
Moisture	20 PA Rev 0 *(Cargill PPD)*	%	4.8
pH	22 PA Rev 0 *(Cargill PPD)*		3.99
Dietary fiber (∑ cellulose, hemi-cellulose & pectin)	AOAC 991.43 *(Eurofins)*	%	64.5
Pectin	24 PA Rev 0 *(Cargill PPD)*	%	10.0
Cellulose	13 PA Rev 0 *(Cargill PPD)*	%	34.0
Hemi-cellulose (calculated)		%	20.5
Sugars	adapted from CAM-S-20C Rev02 *(Cargill Vilv. R&D)*	%	28.3
DE	AM-U1-01-D.04 v 1.3 *(Cargill PPD FP)*	%	38.6
GalA	AM-U1-01-D.04 v 1.3 *(Cargill PPD FP)*	%	13.6
Ca^{++}	06 PA Rev 1 *(Cargill PPD)*	%	0.42
Mg^{++}	06 PA Rev 1 *(Cargill PPD)*	%	0.02
Na^{+}	06 PA Rev 1 *(Cargill PPD)*	%	0.94
Nitrates	05 COLOR Rev 0 *(Cargill PPD)*	%	< 0.015
Nitrites	07 COLOR Rev 0 *(Cargill PPD)*	%	<0.0005
Isopropanol	05 CPG Rev 0 *(Cargill PPD)*	%	0.085
Methanol	05 CPG Rev 0 *(Cargill PPD)*	%	0.005
Ash (550°C)	01 PA Rev 1 *(Cargill PPD)*	%	4.81

Trace components

	Method	Unit	Result
As	adapted from EN13805 (*Eurofins*)	mg/kg	<0.1
Cu	adapted from NF EN ISO 11885 (*Eurofins*)	mg/kg	6.8
Cd	adapted from EN 14084 & EN13805 (*Eurofins*)	mg/kg	< 0.01
Fe	17 PA Rev 0 (*Cargill PPD*)	mg/kg	17
Co	EN ISO 17294-2-E29 (*Eurofins*)	mg/kg	<0.1
Cr	adapted from NF EN ISO 11885 (*Eurofins*)	mg/kg	0.7
Ni	adapted from NF EN ISO 11885 (*Eurofins*)	mg/kg	2.3
Heavy metals [Total (as Pb)]	USP231 (*CHELAB*)	mg/kg	<20

Additional analysis

	Method	Unit	Result
K^+	06 PA Rev 1 (*Cargill PPD*)	%	0.05
Pb*	adapted from EN 14084 & EN13805 (*Eurofins*)	mg/kg	2.46
Hg	§64 LFGB L00.00-19/4 (*Eurofins*)	mg/kg	<0.005
Proteins	02 PA Rev 1 (*Cargill PPD*)	%	3.56
Ethanol	05 CPG Rev 0 (*Cargill PPD*)	%	<0.0015
Aflatoxins B1/B2/G1/G2	internal adapted from EN 14123 (*Eurofins*)	µg/kg	Sum <0.5
Ochratoxin A	internal adapted from EN 14132 (*Eurofins*)	µg/kg	<0.2
Patulin	Internal method, LC-MS/MS (*Eurofins*)	µg/kg	<20
Ash 900°C	ISO3593 (*Cargill PPD*)	%	4.51
Particle size: D4,3	Malvern_2000_PSD_CPF_Rev0 (*Cargill Vilv. R&D*)	µm	232.7
Particle size: d3,2	Malvern_2000_PSD_CPF_Rev0 (*Cargill Vilv. R&D*)	µm	44.3
Particle size: D (10)	Malvern_2000_PSD_CPF_Rev0	µm	21.8

	(Cargill Vilv. R&D)		
Particle size: D (50)	Malvern_2000_PSD_CPF_Rev0 *(Cargill Vilv. R&D)*	µm	73.9
Particle size: D (90)	Malvern_2000_PSD_CPF_Rev0 *(Cargill Vilv. R&D)*	µm	936.9
Granulometry >250µm	AM-U1-01-H 03 *(Cargill PPD FP)*	%	2.54
Viscosity (3% solution)	R-01MS *(Cargill Vilv. R&D)*	Pa	630
Appearance	–		Creamy-white powder
Color (L-value)	HunterLab_spectrophotometer_CM-5_CPF_rev0 *(Cargill Vilv. R&D)*		89.5
Odour + taste	–		Neutral to slightly citrus

Microbiological analysis

	Method	**Unit**	**Result**
Aerobic Plate Count	BLAM 3010 *(Cargill Quality)*	cfu/g	200
Yeast	BLAM 3020 *(Cargill Quality)*	cfu/g	<20
Molds	BLAM 3020 *(Cargill Quality)*	cfu/g	20
Coliforms	BLAM 3315 *(Cargill Quality)*	cfu/g	absence
E. Coli	BLAM 3315 *(Cargill Quality)*	cfu/g	absence
Enterobacteriaceae	BLAM 3081 *(Cargill Quality)*	cfu/g	<10
Lactic Acid Bacteria	NF ISO 15214 *(Eurofins)*	cfu/g	<1000
Coagulase Positive Staphylococci	BLAM 3310 *(Cargill Quality)*	cfu/g	absence
Bacillus cereus	NF EN ISO 7932 *(Eurofins)*	cfu/g	<100
Salmonella	BLAM 3303 *(Cargill Quality)*	cfu/g	absence in 25g
Clostridium perfringens	NF EN ISO 7937 *(Eurofins)*	cfu/g	<10
Listeria monocytogenes	BLAM 3342 *(Cargill Quality)*	cfu/g	absence in 25g

* While the Pb level for this batch did not meet the proposed specification (≤1 ppm), refinements of the pilot plant production of citrus fiber have been made to ensure that future commercial production will produce consistent citrus fiber product that meets the proposed citrus fiber specifications, including for residual Pb.

(Cargill PPD) = measured by the Product & Process Development Department of Cargill in Baupte (France)
(Cargill Quality) = measured by the Quality Department of Cargill in Baupte (France)
(Eurofins) = measured by Eurofins Analytics France (Nantes)
(CHELAB) = measured by CHELAB France
(Cargill Vilv. R&D) = measured by R&D centre Vilvoorde (Belgium)
(Cargill PPD FP) = measured by the Product & Process Development Department of Cargill in Malchin (Germany)

Appendix B. Additional Analytical Testing Data – Pesticides, Mycotoxins

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WESSLING GmbH, Haynauer Str. 60, 12249 Berlin

Cargill Deutschland GmbH
Mr. Sandro Schwarz
An der Mühlentorweide 1
17139 Malchin

Test report No.:	**CBE15-001866-1**
Order No.:	CBE-00207-15
Business Unit:	food and feed analysis
Your contact:	S. Hoppe
Extension:	+49 30 77 507 424
fax:	+49 30 77 507 544
Email:	susann.hoppe @wessling.de
Date:	06.02.2015

Report

Analysis of food and feed

Your order: dated of January 13th, 2015

Sample information

Sample no.	15-004481-01-1
Designation	Proben-ID: F00000393-0114094812 Zitrustrester, entpektinisiert, 6.07.02 Ursprungsland: Mexiko Int. Bez.: Orangenschale 2014 Luise Dryfus Beprobter Standort: Cargill Deutschland GmbH, Werk Malchin F00000393, 72
Sampling	12.01.2015
Sampling by	Auftraggeber
Sampling by	Sandro Schwarz
Date of receipt	14.01.2015
Temperature on receipt	Raumtemperatur
Start of analysis	14.01.2015
End of analysis	30.01.2015

Test results

Microscopic tests

sample no.		15-004481-01-1
Animal components	OS	As far as was discernible using a light microscope, no particle derived from terrestrial animals and fish were detected in the submitted sample

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Test report No.:	**CBE15-001866-1**
Order No.:	CBE-00207-15
Date:	06.02.2015

Sample information

Sample no.	15-004481-01
Designation	Proben-ID: F00000393-0114094812 Zitrustrester, entpektinisiert, 6.07.02 Ursprungsland: Mexiko Int. Bez.: Orangenschale 2014 Luise Dryfus Beprobter Standort: Cargill Deutschland GmbH, Werk Malchin F00000393, 72
Sampling	12.01.2015
Sampling by	Auftraggeber
Sampling by	Sandro Schwarz
Date of receipt	14.01.2015
Temperature on receipt	Raumtemperatur
Start of analysis	14.01.2015
End of analysis	30.01.2015

Test results

Microbiological tests

sample no.	15-004481-01
Salmonella/25 g	**negativ**

sample no.		15-004481-01
Ochratoxin A	µg/kg 88% dm	2,1

Dioxane and furans (PCDD / PCDF)

sample no.		15-004481-01
2,3,7,8 TCDD	ng/kg 88% dm	<0,02
1,2,3,7,8 PeCDD	ng/kg 88% dm	<0,04
1,2,3,4,7,8 HxCDD	ng/kg 88% dm	<0,06
1,2,3,6,7,8 HxCDD	ng/kg 88% dm	<0,06
1,2,3,7,8,9 HxCDD	ng/kg 88% dm	<0,06
1,2,3,4,6,7,8 HpCDD	ng/kg 88% dm	<0,3
Octa CDD	ng/kg 88% dm	<1
2,3,7,8 TCDF	ng/kg 88% dm	<0,04
1,2,3,7,8 PeCDF	ng/kg 88% dm	<0,04
2,3,4,7,8 PeCDF	ng/kg 88% dm	<0,04
1,2,3,4,7,8 HxCDF	ng/kg 88% dm	<0,06
1,2,3,6,7,8 HxCDF	ng/kg 88% dm	<0,06
2,3,4,6,7,8 HxCDF	ng/kg 88% dm	<0,06
1,2,3,7,8,9 HxCDF	ng/kg 88% dm	<0,06
1,2,3,4,6,7,8 HpCDF	ng/kg 88% dm	<0,3
1,2,3,4,7,8,9 HpCDF	ng/kg 88% dm	<0,3
Octa CDF	ng/kg 88% dm	<1

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Test report No.:	CBE15-001866-1
Order No.:	CBE-00207-15
Date:	06.02.2015

Dioxin-like PCBs

sample no.		15-004481-01
PCB no. 77	ng/kg 88% dm	<2
PCB no. 81	ng/kg 88% dm	<1
PCB no. 126	ng/kg 88% dm	<0,25
PCB no. 169	ng/kg 88% dm	<1
PCB no. 105	ng/kg 88% dm	<10
PCB no. 114	ng/kg 88% dm	<20
PCB no. 118	ng/kg 88% dm	<40
PCB no. 123	ng/kg 88% dm	<2
PCB no. 156	ng/kg 88% dm	<4
PCB no. 157	ng/kg 88% dm	<2
PCB no. 167	ng/kg 88% dm	<4
PCB no. 189	ng/kg 88% dm	<4
PCB-TEQ (WHO 2005) incl. LOQ	ng/kg 88% dm	0,0581

Calculated values

sample no.		15-004481-01
TEQ (WHO 2005) incl. LOQ	ng/kg 88% dm	0,129
Sum of PCDD/F and dioxin. PCBs (TEQ) (WHO 2005) incl. LOQ	ng/kg 88% dm	0,187

Chemical Analysis

sample no. 15-004481-01

Polycyclic aromatic hydrocarbons (PAH)

sample no.		15-004481-01
Naphthalene	µg/kg OS	9,71
Acenaphthylene	µg/kg OS	<1
Acenaphthene	µg/kg OS	<1
Fluorene	µg/kg OS	<1
Phenanthrene	µg/kg OS	1,54
Anthracene	µg/kg OS	<1
Fluoranthene	µg/kg OS	1,27
Pyrene	µg/kg OS	<1
Benzo(a)anthracene	µg/kg OS	<1
Chrysene	µg/kg OS	1
Benzo(b)fluoranthene	µg/kg OS	<1
Benzo(k)fluoranthene	µg/kg OS	<1
Benzo(a)pyrene	µg/kg OS	<1
Dibenz(ah)anthracene	µg/kg OS	<1
Benzo(ghi)perylene	µg/kg OS	<1
Indeno(123-cd)pyrene	µg/kg OS	<1
Sum of presented PAH	µg/kg OS	13,5

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Test report No.:	CBE15-001866-1
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Date:	06.02.2015

Mycotoxines

sample no.		15-004481-01
Aflatoxin B1	µg/kg 88% dm	<0,25
Aflatoxin B2	µg/kg 88% dm	<0,25
Aflatoxin G1	µg/kg 88% dm	<0,25
Aflatoxin G2	µg/kg 88% dm	<0,25
OS_Aflatoxin B1	µg/kg 88% dm	<0,25
OS_Aflatoxin B2	µg/kg 88% dm	<0,25
OS_Aflatoxin G1	µg/kg 88% dm	<0,25
OS_Aflatoxin G2	µg/kg 88% dm	<0,25
Deoxynivalenol	µg/kg 88% dm	<40
Zearalenone (ZEA)	µg/kg 88% dm	<10

Pesticides

sample no.		15-004481-01
Carbendazim complete	mg/kg OS	0,024
Bifenthrin	mg/kg OS	0,048
Chlorpyrifos-ethyl	mg/kg OS	0,04
Cypermethrin	mg/kg OS	0,097
Dicofol (total)	mg/kg OS	0,019
Folpet	mg/kg OS	<0,01
Methidathion	mg/kg OS	0,016
Phosmet	mg/kg OS	0,025
Propargite	mg/kg OS	0,20
Tebuconazole	mg/kg OS	0,027
Trifloxystrobin	mg/kg OS	0,05
more Pesticides (GC)	OS	<LOQ
Dimethoate	mg/kg OS	0,018
Imidacloprid	mg/kg OS	0,01
Pyraclostrobin	mg/kg OS	0,054
more Pesticides (LC)	OS	<LOQ

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Test report No.:	CBE15-001886-1
Order No.:	CBE-00207-15
Date:	06.02.2015

Heavy Metals

sample no.		15-004481-01
Arsenic (As)	mg/kg 88% dm	<0,1
Lead (Pb)	mg/kg 88% dm	<0,1
Cadmium (Cd)	mg/kg 88% dm	<0,01
Mercury (Hg)	mg/kg 88% dm	<0,05

<, <LOQ: value below limit of quantification

The sample was analysed according to the pesticide lists 1 (GC) and 2 (LC) of "Pesticides-scope of active substances_ 5_1-EN".

Traces of Difenoconazol, Diflubenzuron, Hexythiazox, l-Cyhalothrin an Fenproparthrin has been found below LOQ

Shortcuts and Methods

Salmonella (ASU)	ASU L 00.00-20[A]	Produktanalytik Altenberge
Ochratoxin A	A. Theilmann, W. Weber. DLR 93 (1), 1997, S. 1-3[A]	Produktanalytik Altenberge
Polychlorinated dibenzodioxins in feed	EPA 1613 mod. in Verb. mit VO (EU) 709/2014[A]	Umweltanalytik Altenberge
Polychlorinated dibenzofuranes (PCDF) in feed	EPA 1613 mod. in Verb. mit VO (EU) 709/2014[A]	Umweltanalytik Altenberge
PCB basing analogy to dioxin	EPA 1613 mod. in Verb. mit VO (EU) 709/2014[A]	Umweltanalytik Altenberge
Calculated values	EPA 1613 mod. in Verb. mit VO (EU) 709/2014[A]	Umweltanalytik Altenberge
Humidity	VDLUFA Bd.III 3.1[A]	Produktanalytik Altenberge
Polycyclic aromatic hydrocarbons (PAH)	WES 027[A]	Umweltanalytik Bochum
Aflatoxins	VDLUFA Bd. III Kap. 16.1.4[A]	Produktanalytik Altenberge
Deoxynivalenol	VDLUFA Bd. III, Kap. 16.12.1[A]	Produktanalytik Altenberge
Zearalenon	WES 129[A]	Produktanalytik Altenberge
Benzimidazole fungicides	WES 220[A]	Produktanalytik Berlin
Pesticides (GC)	ASU L 00.00-115[A]	Produktanalytik Berlin
Pesticides (LC)	ASU L 00.00-115[A]	Produktanalytik Berlin
Metals/elements	EN ISO 36406 E29[A]	Umweltanalytik Altenberge
Mercury	EN 1483 (E12)[A]	Umweltanalytik Altenberge
Microscopic test	VO (EG) 51/2013 Anhang VI[A]	Produktanalytik Altenberge
88% dm	88 % dry matter	
OS	Original substance	

Assessment

Within the analysed sample, the following contaminants were determined:

- Ochratoxin A: 2.1 µg/kg 88 % dry matter, maximum limit (Futtermittelverordnung, in combination with directive 2002/32/EC): not determined, guidance value (commission recommendation 2006/576/EC): 0.25 mg/kg 88 % dry matter (feed materials - cereals and cereal products) resp.0.05 mg/kg 88 % dry matter (complementary and complete feedingstuffs for pigs)

- Sum of Dioxines (WHO-PCDD/F-TEQ inkl. BG): 0.129 ng/kg 88 % dry matter, maximum content (directive 2002/32/EC): 0.75 ng/kg 88 % dry matter (Feed materials of plant origin)

- Sum of Dioxines and dioxine-like PCB (WHO-PCDD/F-PCB-TEQ): 0.187 ng/kg 88 % dry matter, maximum content (directive 2002/32/EC): 1.25 ng/kg 88 % dry matter (Feed materials of plant origin)

- Sum of dioxne-like PCB (WHO-PCB-TEQ inkl. BG): 0.058 ng/kg 88 % dry matter, Action threshold (directive 2002/32/EC): 0.35 ng/kg 88 % dry matter (Feed materials of plant origin)

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Test report No.:	**CBE15-001866-1**
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Date:	06.02.2015

- PAK: sum (BaP-equivalents)*: 0.014 µg BAPEQ/kg OS; maximum limit (Futtermittelverordnung, in combination with directive 2002/32/EC): not determined; QS-guidance value: 50 µg/kg Fett, Action level: 15 µg/kg

*calculation according to RIKILT-report No. 2001.006

Furthermore, the following residues were determined:

- Bifenthrin: 0.048 mg/kg, processing factor: unknown, maximum residue limit (regulation 396/2005): 0.1 mg/kg (citrus fruits, fresh)

- Chlorpyrifos (-ethyl): 0.040 mg/kg, processing factor: unknown, maximum residue limit (regulation 396/2005): 0.3 mg/kg (oranges, fresh)

- Cypermethrin: 0.097 mg/kg, processing factor: unknown, maximum residue limit (regulation 396/2005): 2 mg/kg cypermethrin including other mixtures of constituent isomers (sum of isomers) (citrus fruits, fresh)

-- Dicofol: 0.019 mg/kg, processing factor: unknown, maximum residue limit (regulation 396/2005): 0.02 mg/kg (citrus fruits, fresh)

- Methidathion: 0.016 mg/kg, processing factor: unknown, maximum residue limit (regulation 396/2005): 0.02 mg/kg (citrus fruits, fresh)

- Phosmet: 0.20 mg/kg, processing factor: unknown, maximum residue limit (regulation 396/2005): 0.5 mg/kg (Phosmet and Phosmet-oxon, expressed as Phosmet) (citrus fruits, fresh)

- Propargit: 0.20 mg/kg, processing factor: unknown, maximum residue limit (regulation 396/2005): 3 mg/kg (citrus fruits, fresh)

- Tebuconazol: 0,027 mg/kg, , processing factor: unknown, maximum residue limit (regulation 396/2005): 0,9 mg/kg (Oranges, fresh)

- Trifloxystrobin: 0,050 mg/kg, processing factor: unknown, maximum residue limit (regulation 396/2005): 0,3 mg/kg (citrus fruits, fresh)

-- Dimethoat: 0,018 mg/kg, processing factor: unknown, maximum residue limit (regulation 396/2005): 0,02 mg/kg (sum of dimethoate and omethoate expressed as dimethoate) (citrus fruits, fresh)

-- Imidacloprid: 0,010 mg/kg, processing factor: unknown, maximum residue limit (regulation 396/2005): 1 mg/kg (citrus fruits, fresh)

- Pyraclostrobin: 0,054 mg/kg, processing factor: unknown, maximum residue limit (regulation 396/2005): 2 mg/kg (Oranges, fresh)

- Carbendazim: 0,024 mg/kg processing factor: unknown, maximum residue limit (regulation 396/2005): 0,2 mg/kg (sum of benomyl and carbendazim expressed as carbendazim) (Oranges, fresh)

With regard to the analysis carried out the sample corresponds to the legal regulations.

Furthermore we determined Phthalimid in the sample. Phthalimid is the main metabolite of the active substance Folpet but there could be other natural sources, too.

We recommend to find out the source of the Phthalimid-content.

***Key to furanocoumarin analytical results:**

Document	Sample code	Product
AR-13-JK-075710-02	A2212	Lemon peel
AR-13-JK-075711-02	A2613	Lemon peel
AR-13-JK-075712-02	LM2512	Lemon peel
AR-13-JK-075713-02	H7785	Fiber (HERBACEL)
AR-13-JK-075714-02	OP9526	Lemon peel fiber
AR-13-JK-075715-02	OP9522	Lemon peel fiber

eurofins | Wiertz-Eggert-Jörissen

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Cargill Deutschland GmbH
Cargill Texturizing Solutions
An der Mühlentorweide 1
17139 Malchin

Person in charge Mrs C. Klatte-Adiloğlu - 1713
Client support Mrs N. Tetzlaff - 1704

Report date 05.02.2015

Analytical report AR-13-JK-075710-02

This report replaces report number: AR-13-JK-075710-01

Sample Code 703-2013-00682043

Reference	Zitronenschale
Client sample code	A2212
Number	1
Amount	228,8 g
Reception temperature	room temperature
Ordered by	Cargill Deutschland GmbH
Submitted by	Herr Ivo Kohls
Sender	DPD
Reception date time	23.08.2013
Packaging	plastic bag
Start/end of analyses	23.08.2013 / 13.09.2013

TEST RESULTS

Physikalisch-chemische Untersuchung

JJ0BI Furocoumarine
Method : Interne Methode, LC-MS/MS
Subcontracted to a Eurofins laboratory accredited for this test.

5,7-Dimethoxycoumarin	<2,5	*	mg/kg
6,7-Dihydroxybergamottin	<2,5	*	mg/kg
7-Methoxycoumarin	<2,5	*	mg/kg
Byakangelicol	<2,5	*	mg/kg
Epoxybergamottin	<2,5	*	mg/kg
Oxypeucedanin	<2,5	*	mg/kg
8-Geranyloxypsoralen	<2,5	*	mg/kg
Angelicin	<2,5	*	mg/kg
Bergamottin	<2,5	*	mg/kg
Bergapten	<2,5	*	mg/kg
Imperatorin	<2,5	*	mg/kg
Isoimperatorin	<2,5	*	mg/kg
Isopimpinellin	<2,5	*	mg/kg
Psoralen	<2,5	*	mg/kg
Trioxalen	<2,5	*	mg/kg
Xanthotoxin	<2,5	*	mg/kg
6-Methylcoumarin (Toncarin)	<2,5	*	mg/kg

* = Below indicated quantification level

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Analytical report AR-13-JK-075710-02
Sample Code 703-2013-00682043

This report replaces report number: AR-13-JK-075710-01

Signature (b) (6)

Analytical Service Manager (Constanze Klatte-Adiloğlu)

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Cargill Deutschland GmbH
Cargill Texturizing Solutions
An der Mühlentorweide 1
17139 Malchin

Person in charge Mrs C. Klatte-Adiloğlu - 1713
Client support Mrs N. Tetzlaff - 1704

Report date 05.02.2015

Analytical report AR-13-JK-075711-02

This report replaces report number: AR-13-JK-075711-01

Sample Code 703-2013-00682044

Reference	Zitronenschale
Client sample code	A2613
Number	1
Amount	332,1 g
Reception temperature	room temperature
Ordered by	Cargill Deutschland GmbH
Submitted by	Herr Ivo Kohls
Sender	DPD
Reception date time	23.08.2013
Packaging	plastic bag
Start/end of analyses	23.08.2013 / 13.09.2013

TEST RESULTS

Physikalisch-chemische Untersuchung

JJ0BI **Furocoumarine**
Method : Interne Methode, LC-MS/MS
Subcontracted to a Eurofins laboratory accredited for this test.

5,7-Dimethoxycoumarin	<2,5	*	mg/kg
6,7-Dihydroxybergamottin	<2,5	*	mg/kg
7-Methoxycoumarin	<2,5	*	mg/kg
Byakangelicol	<2,5	*	mg/kg
Epoxybergamottin	<2,5	*	mg/kg
Oxypeucedanin	<2,5	*	mg/kg
8-Geranyloxypsoralen	<2,5	*	mg/kg
Angelicin	<2,5	*	mg/kg
Bergamottin	<2,5	*	mg/kg
Bergapten	<2,5	*	mg/kg
Imperatorin	<2,5	*	mg/kg
Isoimperatorin	<2,5	*	mg/kg
Isopimpinellin	<2,5	*	mg/kg
Psoralen	<2,5	*	mg/kg
Trioxalen	<2,5	*	mg/kg
Xanthotoxin	<2,5	*	mg/kg
6-Methylcoumarin (Toncarin)	<2,5	*	mg/kg

* = Below indicated quantification level

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Analytical report AR-13-JK-075711-02
Sample Code 703-2013-00682044

This report replaces report number: AR-13-JK-075711-01

Signature (b) (6)

Analytical Service Manager (Constanze Klatte-Adiloğlu)

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Person in charge Mrs C. Klatte-Adiloğlu - 171
Client support Mrs N. Tetzlaff - 170

Report date 05.02.201

Analytical report AR-13-JK-075712-02

This report replaces report number: AR-13-JK-075712-01

Sample Code 703-2013-00682045

Reference	Zitronenschale
Client sample code	LM2512
Number	1
Amount	297,2 g
Reception temperature	room temperature
Ordered by	Cargill Deutschland GmbH
Submitted by	Herr Ivo Kohls
Sender	DPD
Reception date time	23.08.2013
Packaging	plastic bag
Start/end of analyses	23.08.2013 / 13.09.2013

TEST RESULTS

Physikalisch-chemische Untersuchung

JJ0BI Furocoumarine

Method : Interne Methode, LC-MS/MS

Subcontracted to a Eurofins laboratory accredited for this test.

5,7-Dimethoxycoumarin	<2,5	*	mg/kg
6,7-Dihydroxybergamottin	<2,5	*	mg/kg
7-Methoxycoumarin	<2,5	*	mg/kg
Byakangelicol	<2,5	*	mg/kg
Epoxybergamottin	<2,5	*	mg/kg
Oxypeucedanin	<2,5	*	mg/kg
8-Geranyloxypsoralen	<2,5	*	mg/kg
Angelicin	<2,5	*	mg/kg
Bergamottin	<2,5	*	mg/kg
Bergapten	<2,5	*	mg/kg
Imperatorin	<2,5	*	mg/kg
Isoimperatorin	<2,5	*	mg/kg
Isopimpinellin	<2,5	*	mg/kg
Psoralen	<2,5	*	mg/kg
Trioxalen	<2,5	*	mg/kg
Xanthotoxin	<2,5	*	mg/kg
6-Methylcoumarin (Toncarin)	<2,5	*	mg/kg

* = Below indicated quantification level

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Analytical report AR-13-JK-075712-02
Sample Code 703-2013-00682045

This report replaces report number: AR-13-JK-075712-01

Signature (b) (6)

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Report date 05.02.2015

Analytical report AR-13-JK-075713-02

This report replaces report number: AR-13-JK-075713-01

Sample Code 703-2013-00682046

Reference	Zitronenfasern
Client sample code	H7785
Number	1
Amount	43,2 g
Reception temperature	room temperature
Ordered by	Cargill Deutschland GmbH
Submitted by	Herr Ivo Kohls
Sender	DPD
Reception date time	23.08.2013
Packaging	plastic container with screw closure
Start/end of analyses	23.08.2013 / 13.09.2013

TEST RESULTS

Physikalisch-chemische Untersuchung

JJ0BI Furocoumarine

Method : Interne Methode, LC-MS/MS

Subcontracted to a Eurofins laboratory accredited for this test.

5,7-Dimethoxycoumarin	<2,5	*	mg/kg
6,7-Dihydroxybergamottin	<2,5	*	mg/kg
7-Methoxycoumarin	<2,5	*	mg/kg
Byakangelicol	<2,5	*	mg/kg
Epoxybergamottin	<2,5	*	mg/kg
Oxypeucedanin	<2,5	*	mg/kg
8-Geranyloxypsoralen	<2,5	*	mg/kg
Angelicin	<2,5	*	mg/kg
Bergamottin	<2,5	*	mg/kg
Bergapten	<2,5	*	mg/kg
Imperatorin	<2,5	*	mg/kg
Isoimperatorin	<2,5	*	mg/kg
Isopimpinellin	<2,5	*	mg/kg
Psoralen	<2,5	*	mg/kg
Trioxalen	<2,5	*	mg/kg
Xanthotoxin	<2,5	*	mg/kg
6-Methylcoumarin (Toncarin)	<2,5	*	mg/kg

* = Below indicated quantification level

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Analytical report AR-13-JK-075713-02
Sample Code 703-2013-00682046

This report replaces report number: AR-13-JK-075713-01

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Report date 05.02.2015

Analytical report AR-13-JK-075714-02

This report replaces report number: AR-13-JK-075714-01

Sample Code 703-2013-00682047

Reference	Zitronenfasern
Client sample code	OP9526
Number	1
Amount	43,2 g
Reception temperature	room temperature
Ordered by	Cargill Deutschland GmbH
Submitted by	Herr Ivo Kohls
Sender	DPD
Reception date time	23.08.2013
Packaging	plastic container with screw closure
Start/end of analyses	23.08.2013 / 13.09.2013

TEST RESULTS

Physikalisch-chemische Untersuchung

JJ0BI Furocoumarine

Method : Interne Methode, LC-MS/MS

Subcontracted to a Eurofins laboratory accredited for this test.

5,7-Dimethoxycoumarin	<2,5	*	mg/kg
6,7-Dihydroxybergamottin	<2,5	*	mg/kg
7-Methoxycoumarin	<2,5	*	mg/kg
Byakangelicol	<2,5	*	mg/kg
Epoxybergamottin	<2,5	*	mg/kg
Oxypeucedanin	<2,5	*	mg/kg
8-Geranyloxypsoralen	<2,5	*	mg/kg
Angelicin	<2,5	*	mg/kg
Bergamottin	<2,5	*	mg/kg
Bergapten	<2,5	*	mg/kg
Imperatorin	<2,5	*	mg/kg
Isoimperatorin	<2,5	*	mg/kg
Isopimpinellin	<2,5	*	mg/kg
Psoralen	<2,5	*	mg/kg
Trioxalen	<2,5	*	mg/kg
Xanthotoxin	<2,5	*	mg/kg
6-Methylcoumarin (Toncarin)	<2,5	*	mg/kg

* = Below indicated quantification level

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Analytical report AR-13-JK-075714-02
Sample Code 703-2013-00682047

This report replaces report number: AR-13-JK-075714-01

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Report date 05.02.2015

Analytical report AR-13-JK-075715-02

This report replaces report number: AR-13-JK-075715-01

Sample Code 703-2013-00682048

Reference	Zitronenfasern
Client sample code	OP9522
Number	1
Amount	43,5 g
Reception temperature	room temperature
Ordered by	Cargill Deutschland GmbH
Submitted by	Herr Ivo Kohls
Sender	DPD
Reception date time	23.08.2013
Packaging	plastic container with screw closure
Start/end of analyses	23.08.2013 / 13.09.2013

TEST RESULTS

Physikalisch-chemische Untersuchung

JJ0BI Furocoumarine

Method : Interne Methode, LC-MS/MS

Subcontracted to a Eurofins laboratory accredited for this test.

5,7-Dimethoxycoumarin	<2,5	*	mg/kg
6,7-Dihydroxybergamottin	<2,5	*	mg/kg
7-Methoxycoumarin	<2,5	*	mg/kg
Byakangelicol	<2,5	*	mg/kg
Epoxybergamottin	<2,5	*	mg/kg
Oxypeucedanin	<2,5	*	mg/kg
8-Geranyloxypsoralen	<2,5	*	mg/kg
Angelicin	<2,5	*	mg/kg
Bergamottin	<2,5	*	mg/kg
Bergapten	<2,5	*	mg/kg
Imperatorin	<2,5	*	mg/kg
Isoimperatorin	<2,5	*	mg/kg
Isopimpinellin	<2,5	*	mg/kg
Psoralen	<2,5	*	mg/kg
Trioxalen	<2,5	*	mg/kg
Xanthotoxin	<2,5	*	mg/kg
6-Methylcoumarin (Toncarin)	<2,5	*	mg/kg

* = Below indicated quantification level

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Analytical report AR-13-JK-075715-02
Sample Code 703-2013-00682048

This report replaces report number: AR-13-JK-075715-01

Signature (b) (6) [redacted]

Analytical Service Manager (Constanze Klatte-Adiloğlu)

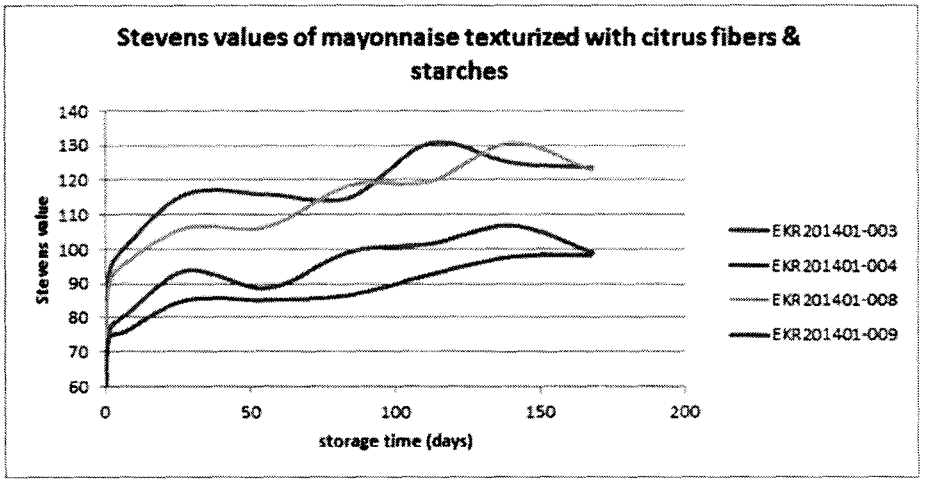
Appendix C. Stability Testing Results

		OP9591 production date: 18/11/2013	OP9608 production date: 16/12/2013	OP9677 production date: 19/05/2015
	Unit	*after 18 months: 11/05/2015*	*after 17 months: 11/05/2015*	*after 12 months: 11/05/2015*
		Eurofins: AR-15-AA-076434-01	Eurofins: AR-15-AA-076435-01	Eurofins: AR-15-AA-076436-01
Aerobic plate count	cfu/g	**<10**	**<10**	**<10**
Yeasts	cfu/g	**<10**	**<10**	**<10**
Molds	cfu/g	**<10**	**<10**	**<10**
Escherichia Coli	cfu/g	**<10**	**<10**	**<10**
Salmonella	cfu/g	**absence/25g**	**absence/25g**	**absence/25g**

Stability of citrus fibers in a final food product application.

While it is not possible to analyze the fibers themselves when in the final product, an indirect method employs measurement of the Stevens value of a low-fat mayonnaise product that has been formulated with Cargill's citrus fiber. This is a common measurement of "texture" in low-fat mayonnaise. If the citrus fibers are degraded, the Stevens value will drop quickly over time.

The following chart indicates that the texturizing activity of the citrus fibers remain unchanged over the storage test period of 24 weeks. While the Stevens values increase slightly, it occurs as a result of the starch present in the mayonnaise product. It should also be noted that it takes +/- 2 weeks before the mayonnaise (independent of the citrus fiber texturizer) is truly stabilized.



Appendix D. Intake Assessment Report

Estimated Daily Intake of Citrus Fiber

JUNE 17, 2015

ToxStrategies

Innovative solutions
Sound science

Estimated Daily Intake of Citrus Fiber

JUNE 17, 2015

PREPARED FOR:
Cargill, Inc.
Scientific & Regulatory Affairs
15497 McGinty Road West
Wayzata, MN 55391

PREPARED BY:
ToxStrategies, Inc.
9390 Research Blvd
Suite 100
Austin, Texas

Table of Contents

List of Tables

List of Acronyms and Abbreviations

ARS	Agricultural Research Service
CDC	Centers for Disease Control and Prevention
EDI	estimated daily intake
EPA	Environmental Protection Agency
FNDDS	Food and Nutrient Database for Dietary Studies
g/day	grams per day
g/kg BW/day	grams per kilogram body weight per day
NHANES	National Health and Nutrition Examination Survey
USDA	United States Department of Agriculture
WWEIA	What We Eat in America

1.0 Executive Summary

ToxStrategies, Inc. (ToxStrategies) has conducted an intake assessment to estimate the mean and 90th percentile daily intake of the ingredient citrus fiber based on its intended use in foods. This assessment included four proposed food categories for use of citrus fiber: yogurt; low fat mayonnaise; ice cream, ice pop, sherbet, and sorbet; and processed meat and poultry products. After analyzing dietary survey data from the National Health and Nutrition Examination Survey (NHANES), the *per user* mean and 90th percentile estimated daily intake (EDI) of citrus fiber for the US population ages 2 and over were determined to be 6.40 and 9.76 g/day (0.11 and 0.18 g/kg body weight/day), respectively. For the total US population ages 2 and over, the *per capita* mean and 90th percentile EDI were 5.64 and 9.36 g/day (0.10 and 0.16 g/kg body weight/day), respectively.

2.0 Data

To calculate the EDI of citrus fiber, information about its proposed uses in foods was combined with up-to-date, publicly available dietary intake survey data. Data sources are described in the following sections.

2.1 Proposed Uses and Use Levels of CitriTex® Citrus Fiber

Cargill, Inc. proposes to use citrus fiber, consisting of a mixture of lemon, lime, and orange powder with sucrose, in various food categories according to Table 1.

Table 1. Proposed uses and use levels of CitriTex® citrus fiber

Food Category	Proposed Technical Use of Citrus Fiber	Maximum Proposed Use Level (%)
Yogurt	Texturizer	4
Low fat mayonnaise	Texturizer	4
Ice cream, ice pop, sherbet, and sorbet	Moisture retention	4
Processed meat and poultry products	Moisture retention and in seasoning brine	5

2.2 Dietary Survey Data

Dietary survey data was obtained from What We Eat in America (WWEIA), the dietary interview portion of the National Health and Nutrition Examination Survey (NHANES). NHANES is carried out in two-year cycles by the Centers for Disease Control and Prevention (CDC) in order to characterize the general health and nutritional status of children and adults across the US. The two most recent biennials for which dietary intake data are available were included in this analysis (2009-2010, 2011-2012).

The first day of the WWEIA dietary questionnaire was administered in person, in conjunction with the participants' interviews and examinations for the other NHANES lifestyle and laboratory assessments. The second day of the survey was collected via a phone interview at some point three to ten days after the first survey day. Data collected during the dietary interview includes foods as consumed by the participant, encoded by a US Department of Agriculture (USDA) food code, and amount eaten.

Respondents who provided complete records for both days were designated reliable by WWEIA, and only those respondents were considered in this analysis (N = 8,405 in 2009-2010 and N = 7,605 in 2011-2012). A small percentage of participants (approximately 1%) did not provide body weight information and were therefore excluded from the statistics estimating intake on a per kilogram body weight basis.

2.3 Recipe Data

Recipe data were obtained from the Food and Nutritional Data for Dietary Studies (FNDDS), released by the Agricultural Research Service (ARS) of USDA as a companion to NHANES WWEIA. For each food, the most recent available recipe was applied (*i.e.*, foods reported in the 2009-2010 WWEIA survey were analyzed using recipes from the 2011-2012 release of FNDDS, if possible). As the contents of FNDDS are continually updated and refined, this method ensures that EDI estimates reflect the most up-to-date information about foods consumed in the US.

3.0 Methods

To estimate the intake of citrus fiber from its proposed uses, ToxStrategies performed the following steps:

- Step 1: Identified foods and their components to which citrus fiber may be applied
- Step 2: Calculated individual intake of citrus fiber for individual survey participants
- Step 3: Calculated population statistics estimating intake of citrus fiber

Details of each step are provided in the following sections.

3.1 Identification of Foods and Their Components to Which Citrus Fiber May Be Applied

To identify foods that are proposed to contain citrus fiber, ToxStrategies performed a thorough search of food codes reported in WWEIA. Food code descriptions from WWEIA and associated ingredients listed in FNDDS where queried for keywords pertaining to each proposed food category. The resulting list of relevant food codes was then refined based on the proposed technical uses of citrus fiber in each food category. Food codes retained for further analysis are listed in the appendix.

In some cases, citrus fiber would only be present in a subcomponent of a reported food (*e.g.*, ice cream as part of a sundae). Relevant proportions of each food were determined by reviewing the recipe for that food item from FNDDS, with further development by ToxStrategies. An asterisk

in Appendix 1 indicates that citrus fiber was only present in a subcomponent of that food item, *i.e.* the technical use of citrus fiber applied to less than 100% of the reported food.

3.2 Calculation of Individual Intake of Citrus Fiber for Individual Survey Participants

Only those respondents designated as reliable were included in this assessment.
Both days of the NHANES WWEIA dietary interviews from the 2009-2010 and 2011-2012 biennials were analyzed. Participants' consumption of the citrus fiber was averaged over the two response days, *i.e.* (Day1 consumption + Day2 consumption)/2. Raw consumption of citrus fiber was calculated using the grams of the relevant food consumed as reported in NHANES, multiplied by the proportion of the food that was relevant to the technical use of citrus fiber (see Section 3.1), multiplied by its maximum proposed use level. For example, for the food "13121100 Ice cream sundae, fruit topping, with whipped cream", the relevant proportion of that food for the food category "ice cream" was 0.53, and the use level was 0.04. Thus, for a survey participant who consumed 100g of this food, approximately 2.12g, or (100 * 0.53 * 0.04), of citrus fiber were consumed.

3.3 Calculation of Population Statistics Describing Citrus Fiber Estimated Daily Intake

To ensure that the most up-to-date data on consumption were used for this analysis, the two most recent NHANES biennials for which there are published dietary survey data available were used: 2009-2010 and 2011-2012. The dietary and sample weighting data from the two biennials were combined according to the NHANES analytic guidelines for combining surveys. From the combined dataset we estimated survey design weighted descriptive statistics for the population consumption per day. Population statistics were estimated using the survey package (Lumley, 2004) in the R 3.1.2 environment for statistical computing (R Core Team, 2015) using the appropriate adjustment to sampling weights for combining biennials, then incorporating survey sampling units and strata from the survey design to ensure that sub-populations and areas were correctly represented. Descriptive statistics (mean, 90^{th} percentile) were calculated for the subset of consumers of citrus fiber and for the entire population, and were broken down by age range and body weight adjustment. Values were provided by individual food category and for total consumption of all four food categories. Calculations of total consumption took into account that some foods were associated with more than one category (*i.e.,* frozen yogurt food codes belonged to both the yogurt and ice cream food categories, but were only counted once in the estimates of total consumption).

4.0 Results

Tables 2 and 3 below, respectively, present the EDI for citrus fiber in grams per day and grams per kilogram body weight per day for the following age groups in the US populations: 2 years and older, 2 to 5 years, 6 to 18 years, and 19 years and older. The "number of users" refers to the number of survey participants in a given age group who consumed a food item in given food category. The "percent users" is the percentage of citrus fiber users out of the total number of reliable survey participants (users and non-users) belonging to a given age group. "Total" values include users who consumed foods in any of the four proposed food categories.

Table 2. Estimated daily intake for CitriTex® citrus fiber (g/day)

Food Category	Number of Users	Percent Users	EDI *per User* (g/day)		EDI *per Capita* (g/day)	
			Mean	90th Percentile	Mean	90th Percentile
US Population, Ages 2+						
Ice cream, ice pop, sherbet, and sorbet	4564	30.6	3.09	6.27	0.97	3.46
Low fat mayonnaise	627	4.2	0.39	0.88	0.02	< 0.01
Processed meat and poultry products	11532	77.3	5.15	6.63	4.01	6.03
Yogurt	2735	18.3	3.71	7.35	0.74	3.40
Total *	**13015**	**87.3**	**6.40**	**9.76**	**5.64**	**9.36**
US Population, Ages 2-5						
Ice cream, ice pop, sherbet, and sorbet	535	37.3	1.97	3.89	0.78	2.40
Low fat mayonnaise	35	2.4	0.08	0.16	< 0.01	< 0.01
Processed meat and poultry products	1141	79.6	5.23	5.18	4.31	4.68
Yogurt	430	30.0	3.53	7.23	1.15	4.51
Total *	**1322**	**92.2**	**6.60**	**8.29**	**6.20**	**8.10**
US Population, Ages 6-18						
Ice cream, ice pop, sherbet, and sorbet	1434	37.1	3.05	6.09	1.15	3.89
Low fat mayonnaise	113	2.9	0.34	0.63	0.01	< 0.01
Processed meat and poultry products	3282	84.9	6.36	6.72	5.41	6.23
Yogurt	674	17.4	3.11	5.85	0.57	2.45
Total *	**3553**	**91.9**	**7.62**	**9.75**	**7.04**	**9.43**
US Population, Ages 19+						
Ice cream, ice pop, sherbet, and sorbet	2595	27.0	3.22	6.53	0.94	3.38
Low fat mayonnaise	479	5.0	0.40	0.93	0.02	< 0.01
Processed meat and poultry products	7109	74.0	4.82	6.77	3.66	6.06
Yogurt	1631	17.0	3.87	7.39	0.74	3.40
Total *	**8140**	**84.7**	**6.07**	**9.87**	**5.27**	**9.44**

* Total values refer to consumers of any of the four proposed food categories.

Table 3. Estimated daily intake for CitriTex® citrus fiber (g/kg BW/day)

Food Category	Number of Users**	EDI *per User* (g/kg BW/day)		EDI *per Capita* (g/kg BW/day)	
		Mean	90th Percentile	Mean	90th Percentile
US Population, Ages 2+					
Ice cream, ice pop, sherbet, and sorbet	4522	0.05	0.11	0.02	0.06
Low fat mayonnaise	620	0.01	0.01	< 0.01	< 0.01
Processed meat and poultry products	11431	0.09	0.11	0.07	0.10
Yogurt	2703	0.07	0.15	0.01	0.05
Total *	**12897**	**0.11**	**0.18**	**0.10**	**0.16**
US Population, Ages 2-5					
Ice cream, ice pop, sherbet, and sorbet	530	0.11	0.21	0.05	0.13
Low fat mayonnaise	35	0.01	0.01	< 0.01	< 0.01
Processed meat and poultry products	1128	0.33	0.30	0.27	0.26
Yogurt	424	0.22	0.44	0.07	0.25
Total *	**1308**	**0.41**	**0.48**	**0.39**	**0.46**
US Population, Ages 6-18					
Ice cream, ice pop, sherbet, and sorbet	1419	0.07	0.15	0.03	0.09
Low fat mayonnaise	111	0.01	0.01	< 0.01	< 0.01
Processed meat and poultry products	3260	0.14	0.15	0.12	0.14
Yogurt	668	0.08	0.17	0.02	0.06
Total *	**3526**	**0.17**	**0.25**	**0.16**	**0.25**
US Population, Ages 19+					
Ice cream, ice pop, sherbet, and sorbet	2573	0.04	0.08	0.01	0.04
Low fat mayonnaise	474	0.01	0.01	< 0.01	< 0.01
Processed meat and poultry products	7043	0.06	0.08	0.05	0.07
Yogurt	1611	0.05	0.11	0.01	0.04
Total *	**8063**	**0.08**	**0.13**	**0.07**	**0.12**

* Total values refer to consumers of any of the four proposed food categories.
** Body weight was not reported for ~1% of survey participants. Users with incomplete body weight data were excluded from this analysis.

5.0 References

Agricultural Research Service, United States Department of Agriculture (USDA). 2009-2010. Food and Nutrient Database for Dietary Studies. Available at: http://www.ars.usda.gov/Services/docs.htm?docid=12068. Last accessed April 1, 2015.

Agricultural Research Service, United States Department of Agriculture (USDA). 2011-2012. Food and Nutrient Database for Dietary Studies. Available at: http://www.ars.usda.gov/Services/docs.htm?docid=12068. Last accessed April 1, 2015.

Centers for Disease Control and Prevention (CDC). 2009-2010. National Health and Nutrition Examination Survey. Available at: http://wwwn.cdc.gov/nchs/nhanes/search/nhanes09_10.aspx. Last accessed April 1, 2015.

Centers for Disease Control and Prevention (CDC). 2011-2012. National Health and Nutrition Examination Survey. Available at: http://wwwn.cdc.gov/nchs/nhanes/search/nhanes11_12.aspx. Last accessed April 1, 2015.

Lumley, T. (2004). Analysis of complex survey samples. *Journal of Statistical Software*, *9*(1), 1-19.

R Core Team, (2015). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL http://www.R-project.org/.

Appendix: List of Food Codes

A.1 Food Codes for Ice Cream, Ice Pop, Sherbet, and Sorbet

Food Code	Description
11459990	Yogurt, frozen, NS as to flavor, NS as to type of milk
11460000	Yogurt, frozen, flavors other than chocolate, NS as to type of milk
11460100	Yogurt, frozen, chocolate, NS as to type of milk
11460150	Yogurt, frozen, NS as to flavor, lowfat milk
11460160	Yogurt, frozen, chocolate, lowfat milk
11460170	Yogurt, frozen, flavors other than chocolate, lowfat milk
11460190	Yogurt, frozen, NS as to flavor, nonfat milk
11460200	Yogurt, frozen, chocolate, nonfat milk
11460250	Yogurt, frozen, flavors other than chocolate, with sorbet or sorbet-coated *
11460300	Yogurt, frozen, flavors other than chocolate, nonfat milk
11460400	Yogurt, frozen, chocolate, nonfat milk, with low-calorie sweetener
11460410	Yogurt, frozen, flavors other than chocolate, nonfat milk, with low-calorie sweetener
11460420	Yogurt, frozen, NS as to flavor, whole milk
11460430	Yogurt, frozen, chocolate, whole milk
11460440	Yogurt, frozen, flavors other than chocolate, whole milk
11461000	Yogurt, frozen, chocolate-coated *
11461250	Yogurt, frozen, cone, chocolate *
11461260	Yogurt, frozen, cone, flavors other than chocolate *
11461270	Yogurt, frozen, cone, flavors other than chocolate, lowfat milk *
11461280	Yogurt, frozen, cone, chocolate, lowfat milk *
11541000	Milk shake, NS as to flavor or type *
11541100	Milk shake, homemade or fountain-type, NS as to flavor *
11541110	Milk shake, homemade or fountain-type, chocolate *
11541120	Milk shake, homemade or fountain-type, flavors other than chocolate *
11541500	Milk shake, made with skim milk, chocolate *
11541510	Milk shake, made with skim milk, flavors other than chocolate *
11542000	Carry-out milk shake, NS as to flavor *
11542100	Carry-out milk shake, chocolate *
11542200	Carry-out milk shake, flavors other than chocolate *
11553000	Fruit smoothie drink, made with fruit or fruit juice and dairy products *
13110000	Ice cream, NFS
13110100	Ice cream, regular, flavors other than chocolate
13110110	Ice cream, regular, chocolate
13110120	Ice cream, rich, flavors other than chocolate
13110130	Ice cream, rich, chocolate
13110140	Ice cream, rich, NS as to flavor
13110200	Ice cream, soft serve, flavors other than chocolate
13110210	Ice cream, soft serve, chocolate
13110220	Ice cream, soft serve, NS as to flavor
13110310	Ice cream, no sugar added, NS as to flavor
13110320	Ice cream, no sugar added, flavors other than chocolate
13110330	Ice cream, no sugar added, chocolate
13120050	Ice cream bar or stick, not chocolate covered or cake covered
13120100	Ice cream bar or stick, chocolate covered *
13120110	Ice cream bar or stick, chocolate or caramel covered, with nuts *
13120120	Ice cream bar or stick, rich chocolate ice cream, thick chocolate covering *
13120121	Ice cream bar or stick, rich ice cream, thick chocolate covering *
13120130	Ice cream bar or stick, rich ice cream, chocolate covered, with nuts *
13120140	Ice cream bar or stick, chocolate ice cream, chocolate covered *
13120300	Ice cream bar, cake covered *

13120310	Ice cream bar, stick or nugget, with crunch coating *
13120400	Ice cream bar or stick with fruit *
13120500	Ice cream sandwich *
13120550	Ice cream cookie sandwich *
13120700	Ice cream cone with nuts, flavors other than chocolate *
13120710	Ice cream cone, chocolate covered, with nuts, flavors other than chocolate *
13120720	Ice cream cone, chocolate covered or dipped, flavors other than chocolate *
13120730	Ice cream cone, no topping, flavors other than chocolate *
13120740	Ice cream cone, no topping, NS as to flavor *
13120750	Ice cream cone with nuts, chocolate ice cream *
13120760	Ice cream cone, chocolate covered or dipped, chocolate ice cream *
13120770	Ice cream cone, no topping, chocolate ice cream *
13120780	Ice cream cone, chocolate covered, with nuts, chocolate ice cream *
13120790	Ice cream sundae cone *
13121000	Ice cream sundae, NS as to topping, with whipped cream *
13121100	Ice cream sundae, fruit topping, with whipped cream *
13121200	Ice cream sundae, prepackaged type, flavors other than chocolate *
13121300	Ice cream sundae, chocolate or fudge topping, with whipped cream *
13121400	Ice cream sundae, not fruit or chocolate topping, with whipped cream *
13121500	Ice cream sundae, fudge topping, with cake, with whipped cream *
13122100	Ice cream pie, no crust *
13122500	Ice cream pie, with cookie crust, fudge topping, and whipped cream *
13126000	Ice cream, fried *
13127000	Dippin' Dots, flash frozen ice cream snacks, flavors other than chocolate
13127010	Dippin' Dots, flash frozen ice cream snacks, chocolate
13130100	Light ice cream, NS as to flavor (formerly ice milk)
13130300	Light ice cream, flavors other than chocolate (formerly ice milk)
13130310	Light ice cream, chocolate (formerly ice milk)
13130320	Light ice cream, no sugar added, NS as to flavor
13130330	Light ice cream, no sugar added, flavors other than chocolate
13130340	Light ice cream, no sugar added, chocolate
13130590	Light ice cream, soft serve, NS as to flavor (formerly ice milk)
13130600	Light ice cream, soft serve, flavors other than chocolate (formerly ice milk)
13130610	Light ice cream, soft serve, chocolate (formerly ice milk)
13130620	Light ice cream, soft serve cone, flavors other than chocolate (formerly ice milk) *
13130630	Light ice cream, soft serve cone, chocolate (formerly ice milk) *
13130640	Light ice cream, soft serve cone, NS as to flavor (formerly ice milk) *
13130700	Light ice cream, soft serve, blended with candy or cookies *
13135000	Ice cream sandwich, made with light ice cream, flavors other than chocolate *
13135010	Ice cream sandwich, made with light chocolate ice cream *
13136000	Ice cream sandwich, made with light, no sugar added ice cream *
13140100	Light ice cream, bar or stick, chocolate-coated (formerly ice milk) *
13140110	Light ice cream, bar or stick, chocolate covered, with nuts (formerly ice milk) *
13140450	Light ice cream, cone, NFS (formerly ice milk) *
13140500	Light ice cream, cone, flavors other than chocolate (formerly ice milk) *
13140550	Light ice cream, cone, chocolate (formerly ice milk) *
13140570	Light ice cream, no sugar added, cone, NS as to flavor *
13140575	Light ice cream, no sugar added, cone, flavors other than chocolate *
13140580	Light ice cream, no sugar added, cone, chocolate *
13140600	Light ice cream, sundae, soft serve, chocolate or fudge topping, with whipped cream (formerly ice milk) *
13140630	Light ice cream, sundae, soft serve, fruit topping, with whipped cream (formerly ice milk) *
13140650	Light ice cream, sundae, soft serve, not fruit or chocolate topping, with whipped cream (formerly ice milk) *

13140660	Light ice cream, sundae, soft serve, chocolate or fudge topping (without whipped cream) (formerly ice milk) *
13140670	Light ice cream, sundae, soft serve, fruit topping (without whipped cream) (formerly ice milk) *
13140680	Light ice cream, sundae, soft serve, not fruit or chocolate topping (without whipped cream) (formerly ice milk) *
13140700	Light ice cream, creamsicle or dreamsicle (formerly ice milk)
13140710	Light ice cream, creamsicle or dreamsicle, no sugar added *
13140900	Light ice cream, fudgesicle (formerly ice milk)
13142000	Milk dessert bar or stick, frozen, with coconut *
13150000	Sherbet, all flavors
13160150	Fat free ice cream, no sugar added, chocolate
13160160	Fat free ice cream, no sugar added, flavors other than chocolate
13160400	Fat free ice cream, flavors other than chocolate
13160410	Fat free ice cream, chocolate
13160420	Fat free ice cream, NS as to flavor
13161000	Milk dessert bar, frozen, made from lowfat milk
13161500	Milk dessert sandwich bar, frozen, made from lowfat milk *
13161520	Milk dessert sandwich bar, frozen, with low-calorie sweetener, made from lowfat milk *
13161600	Milk dessert bar, frozen, made from lowfat milk and low calorie sweetener
13161630	Light ice cream, bar or stick, with low-calorie sweetener, chocolate-coated (formerly ice milk) *
13170000	Baked Alaska *
53112000	Cake, ice cream and cake roll, chocolate *
53112100	Cake, ice cream and cake roll, not chocolate *
53112150	Cake, frozen yogurt and cake layer, not chocolate, with icing *
53112160	Cake, frozen yogurt and cake layer, chocolate, with icing *
53366000	Pie, yogurt, frozen *
53430300	Crepe, dessert type, ice cream-filled *
63420100	Fruit juice bar, frozen, orange flavor
63420110	Fruit juice bar, frozen, flavor other than orange
63420200	Fruit juice bar, frozen, sweetened with low calorie sweetener, flavors other than orange
63430100	Sorbet, fruit, noncitrus flavor
63430110	Sorbet, fruit, citrus flavor
63430500	Fruit juice bar with cream, frozen
91601000	Ice, fruit
91611000	Ice pop
91611050	Ice pop filled with ice cream, all flavor varieties
91611100	Ice pop, sweetened with low calorie sweetener
92510730	Fruit punch, made with soda, fruit juice, and sherbet or ice cream *

A.2 Food Codes for Low Fat Mayonnaise

Food Code	Description
83110010	Mayonnaise-type salad dressing, cholesterol-free
83203250	Mayonnaise-type salad dressing, fat-free
83204000	Mayonnaise, light
83204010	Mayonnaise, low-calorie or diet, low sodium
83204020	Mayonnaise, reduced calorie or diet, cholesterol-free
83204030	Mayonnaise, reduced fat, with olive oil
83204050	Mayonnaise-type salad dressing, light
83204060	Mayonnaise-type salad dressing, low-calorie or diet, cholesterol-free
83300700	Mayonnaise, fat free

27446225	Chicken or turkey salad, made with light mayonnaise *
27446235	Chicken or turkey salad, made with light mayonnaise-type salad dressing *
27446260	Chicken or turkey salad, made with any type of fat free dressing *
27450061	Tuna salad, made with light mayonnaise *
27450063	Tuna salad, made with light mayonnaise-type salad dressing *
27450068	Tuna salad, made with any type of fat free dressing *
32103015	Egg salad, made with light mayonnaise *
32103025	Egg salad, made with light mayonnaise-type salad dressing *
32103050	Egg Salad, made with any type of fat free dressing *
58148111	Macaroni or pasta salad, made with light mayonnaise *
58148113	Macaroni or pasta salad, made with light mayonnaise-type salad dressing *
58148118	Macaroni or pasta salad, made with any type of fat free dressing *
71601015	Potato salad with egg, made with light mayonnaise *
71601025	Potato salad with egg, made with light mayonnaise-type salad dressing *
71601050	Potato salad with egg, made with any type of fat free dressing *
71603015	Potato salad, made with light mayonnaise *
71603025	Potato salad, made with light mayonnaise-type salad dressing *
71603050	Potato salad, made with any type of fat free dressing *
75141040	Cabbage salad or coleslaw, made with any type of fat free dressing *
83107100	Mayonnaise, made with yogurt
83108000	Mayonnaise, imitation

A.3 Food Codes for Processed Meat and Poultry Products

Food Code	Description
14102110	Cheese, Brick, with salami *
14620320	Topping from meat pizza *
14620330	Topping from meat and vegetable pizza *
21002000	Beef, pickled
21401400	Beef, roast, canned
21416000	Corned beef, cooked, NS as to fat eaten
21416110	Corned beef, cooked, lean and fat eaten
21416120	Corned beef, cooked, lean only eaten
21416150	Corned beef, canned, ready-to-eat
21500100	Ground beef or patty, cooked, NS as to percent lean (formerly NS as to regular, lean, or extra lean)
21500200	Ground beef or patty, breaded, cooked *
21500300	Ground beef patty, cooked (for fast food sandwiches)
21601000	Beef, bacon, cooked
21601500	Beef, bacon, formed, lean meat added, cooked
21602000	Beef, dried, chipped, uncooked
21602010	Beef, dried, chipped, cooked in fat *
21602100	Beef jerky
21603000	Beef, pastrami (beef, smoked, spiced)
22001000	Pork, pickled, NS as to cut
22002000	Pork, ground or patty, cooked
22002100	Pork, ground or patty, breaded, cooked *
22002800	Pork jerky
22107000	Pork chop, smoked or cured, cooked, NS as to fat eaten
22107010	Pork chop, smoked or cured, cooked, lean and fat eaten
22107020	Pork chop, smoked or cured, cooked, lean only eaten
22300120	Ham, fried, NS as to fat eaten *
22300130	Ham, fried, lean and fat eaten *
22300140	Ham, fried, lean only eaten *

22300150	Ham, breaded or floured, fried, NS as to fat eaten *
22300160	Ham, breaded or floured, fried, lean and fat eaten *
22300170	Ham, breaded or floured, fried, lean only eaten *
22301000	Ham, fresh, cooked, NS as to fat eaten
22301110	Ham, fresh, cooked, lean and fat eaten
22301120	Ham, fresh, cooked, lean only eaten
22311000	Ham, smoked or cured, cooked, NS as to fat eaten
22311010	Ham, smoked or cured, cooked, lean and fat eaten
22311020	Ham, smoked or cured, cooked, lean only eaten
22311200	Ham, smoked or cured, low sodium, cooked, NS as to fat eaten
22311210	Ham, smoked or cured, low sodium, cooked, lean and fat eaten
22311220	Ham, smoked or cured, low sodium, cooked, lean only eaten
22311450	Ham, prosciutto
22311500	Ham, smoked or cured, canned, NS as to fat eaten
22311510	Ham, smoked or cured, canned, lean and fat eaten
22311520	Ham, smoked or cured, canned, lean only eaten
22321110	Ham, smoked or cured, ground patty
22421000	Pork roast, smoked or cured, cooked, NS as to fat eaten
22421010	Pork roast, smoked or cured, cooked, lean and fat eaten
22421020	Pork roast, smoked or cured, cooked, lean only eaten
22431000	Pork roll, cured, fried
22501010	Canadian bacon, cooked
22600100	Bacon, NS as to type of meat, cooked
22600200	Pork bacon, NS as to fresh, smoked or cured, cooked
22601000	Pork bacon, smoked or cured, cooked
22601040	Bacon or side pork, fresh, cooked
22602010	Pork bacon, smoked or cured, lower sodium
22605010	Pork bacon, formed, lean meat added, cooked
22621000	Salt pork, cooked
22707020	Pork, pig's feet, pickled
23132000	Lamb, ground or patty, cooked
23220010	Veal, ground or patty, cooked
23220020	Mock chicken legs, cooked *
23220030	Veal patty, breaded, cooked *
23321050	Venison/deer, cured
23321900	Venison/deer jerky
23322100	Deer bologna
23345100	Wild pig, smoked
24198570	Chicken, canned, meat only
24198690	Chicken patty, fillet, or tenders, breaded, cooked, from fast food / restaurant *
24198700	Chicken patty, fillet, or tenders, breaded, cooked *
24198710	Chicken patty with cheese, breaded, cooked *
24198730	Chicken nuggets, from fast food / restaurant *
24198740	Chicken nuggets *
24198770	Chicken nuggets, lowfat *
24201500	Turkey, light or dark meat, smoked, cooked, NS as to skin eaten
24201510	Turkey, light or dark meat, smoked, cooked, skin eaten
24201520	Turkey, light or dark meat, smoked, cooked, skin not eaten
24202120	Turkey, drumstick, smoked, cooked, skin eaten
24203120	Turkey, wing, smoked, cooked, skin eaten
24206000	Turkey, canned
24208000	Turkey, nuggets *
24208500	Turkey bacon, cooked
25112200	Liver paste or pate, chicken
25160110	Tongue, smoked, cured, or pickled, cooked

25210110	Frankfurter, wiener, or hot dog, NFS
25210120	Frankfurter or hot dog, breaded, baked *
25210150	Frankfurter or hot dog, cheese-filled *
25210160	Frankfurter or hot dog, bacon and cheese-filled
25210170	Frankfurter or hot dog, chili-filled *
25210210	Frankfurter or hot dog, beef
25210220	Frankfurter or hot dog, beef and pork
25210230	Frankfurter or hot dog, beef and pork, lowfat
25210240	Frankfurter or hot dog, beef and pork, reduced fat or light
25210250	Frankfurter or hot dog, meat and poultry, fat free
25210280	Frankfurter or hot dog, meat and poultry
25210290	Frankfurter or hot dog, meat and poultry, reduced fat or light
25210310	Frankfurter or hot dog, chicken
25210410	Frankfurter or hot dog, turkey
25210510	Frankfurter or hot dog, low salt
25210610	Frankfurter or hot dog, beef, lowfat
25210620	Frankfurter or hot dog, beef, reduced fat or light
25210700	Frankfurter or hot dog, meat & poultry, lowfat
25210750	Frankfurter or hot dog, reduced fat or light, NFS
25220010	Cold cut, NFS
25220100	Beef sausage, NFS
25220105	Beef sausage
25220106	Beef sausage, reduced fat
25220110	Beef sausage, brown and serve, links, cooked
25220120	Beef sausage, smoked, stick
25220130	Beef sausage, smoked
25220140	Beef sausage, fresh, bulk, patty or link, cooked
25220150	Beef sausage with cheese *
25220210	Blood sausage
25220310	Bockwurst
25220350	Bratwurst
25220360	Bratwurst, with cheese *
25220370	Bratwurst, beef, cooked
25220390	Bologna, beef, lowfat
25220400	Bologna, pork and beef
25220410	Bologna, NFS
25220420	Bologna, Lebanon
25220430	Bologna, beef
25220440	Bologna, turkey
25220450	Bologna ring, smoked
25220460	Bologna, pork
25220470	Bologna, beef, lower sodium
25220480	Bologna, chicken, beef, and pork
25220490	Bologna, with cheese *
25220500	Bologna, beef and pork, lowfat
25220510	Capicola
25220610	Cervelat, soft
25220650	Turkey or chicken and beef sausage
25220710	Chorizo
25220910	Head cheese
25221110	Knockwurst
25221210	Mortadella
25221250	Pepperoni
25221310	Polish sausage
25221350	Italian sausage

25221400	Sausage (not cold cut), NFS
25221405	Pork sausage
25221406	Pork sausage, reduced fat
25221410	Pork sausage, fresh, bulk, patty or link, cooked
25221420	Pork sausage, brown and serve, cooked
25221430	Pork sausage, country style, fresh, cooked
25221450	Pork sausage rice links
25221460	Pork and beef sausage
25221470	Pork and beef sausage, brown and serve, cooked
25221480	Mettwurst
25221500	Salami, NFS
25221510	Salami, soft, cooked
25221520	Salami, dry or hard
25221530	Salami, beef
25221610	Scrapple, cooked
25221650	Smoked link sausage, pork
25221660	Smoked link sausage, pork and beef
25221680	Smoked sausage, pork
25221710	Souse
25221810	Thuringer
25221830	Turkey or chicken sausage
25221840	Turkey breakfast sausage, bulk, patty or link, cooked
25221850	Turkey sausage, smoked
25221860	Turkey or chicken sausage, reduced fat
25221870	Turkey or chicken and pork sausage
25221880	Turkey or chicken, pork, and beef sausage, reduced fat
25221890	Turkey, pork, and beef sausage, lowfat, smoked
25221910	Vienna sausage, canned
25221950	Pickled sausage
25230110	Luncheon meat, NFS
25230210	Ham, sliced, prepackaged or deli, luncheon meat
25230220	Ham, sliced, low salt, prepackaged or deli, luncheon meat
25230230	Ham, sliced, extra lean, prepackaged or deli, luncheon meat
25230235	Ham, sliced, extra lean, lower sodium, prepackaged or deli, luncheon meat
25230310	Chicken or turkey loaf, prepackaged or deli, luncheon meat
25230410	Ham loaf, luncheon meat
25230430	Ham and cheese loaf
25230450	Honey loaf
25230510	Ham, luncheon meat, chopped, minced, pressed, spiced, not canned
25230520	Ham, luncheon meat, chopped, minced, pressed, spiced, lowfat, not canned
25230530	Ham and pork, luncheon meat, chopped, minced, pressed, spiced, canned
25230540	Ham, pork and chicken, luncheon meat, chopped, minced, pressed, spiced, canned
25230550	Ham, pork, and chicken, luncheon meat, chopped, minced, pressed, spiced, canned, reduced sodium
25230560	Liverwurst
25230610	Luncheon loaf (olive, pickle, or pimiento)
25230710	Sandwich loaf, luncheon meat
25230790	Turkey ham, sliced, extra lean, prepackaged or deli, luncheon meat
25230800	Turkey ham
25230810	Veal loaf
25230820	Turkey pastrami
25230840	Turkey salami
25230900	Turkey or chicken breast, prepackaged or deli, luncheon meat
25230905	Turkey or chicken breast, low salt, prepackaged or deli, luncheon meat
25231110	Beef, sliced, prepackaged or deli, luncheon meat

25231150	Corned beef, pressed
25240000	Meat spread or potted meat, NFS
25240110	Chicken salad spread
25240210	Ham, deviled or potted
25240220	Ham salad spread
25240310	Roast beef spread
25240320	Corned beef spread
27111500	Beef sloppy joe (no bun) *
27112010	Salisbury steak with gravy (mixture) *
27113200	Creamed chipped or dried beef *
27113300	Swedish meatballs with cream or white sauce (mixture) *
27118110	Meatballs, Puerto Rican style (Albondigas guisadas) *
27118120	Stewed seasoned ground beef, Puerto Rican style (Picadillo guisado, picadillo de carne) *
27118130	Stewed dried beef, Puerto Rican style (Tasajo guisado, carne cecina guisada) *
27118140	Stuffed pot roast, Puerto Rican style, NFS (assume with gravy and stuffing) *
27118180	Puerto Rican style beef stew, meat with gravy (potatoes reported separately) *
27120020	Ham or pork with gravy (mixture) *
27120030	Ham or pork with barbecue sauce (mixture) *
27120080	Ham stroganoff *
27120090	Ham or pork with (mushroom) soup (mixture) *
27120100	Ham or pork with tomato-based sauce (mixture) *
27120110	Sausage with tomato-based sauce (mixture) *
27120120	Sausage gravy *
27120150	Pork or ham with soy-based sauce (mixture) *
27120210	Frankfurter or hot dog, with chili, no bun *
27120250	Frankfurters or hot dogs with tomato-based sauce (mixture) *
27121010	Stewed pork, Puerto Rican style *
27133010	Stewed goat, Puerto Rican style (Cabrito en fricase, chilindron de chivo) *
27135150	Veal cordon bleu *
27146250	Chicken or turkey cordon bleu *
27148010	Stuffed chicken, drumstick or breast, Puerto Rican style (Muslo de pollo o pechuga rellena) *
27160100	Meatballs, NS as to type of meat, with sauce (mixture) *
27161010	Puerto Rican style meat loaf (Albondigon) *
27162050	Spaghetti sauce with combination of meats, homemade-style *
27211400	Corned beef hash *
27213120	Porcupine balls with tomato-based sauce (mixture) *
27213420	Porcupine balls with (mushroom) soup (mixture) *
27214100	Meat loaf made with beef *
27214110	Meat loaf made with beef, with tomato-based sauce *
27214300	Beef wellington *
27214500	Corned beef patty
27214600	Creamed dried beef on toast *
27218110	Puerto Rican style stuffed pot roast (larded meat) with potatoes (Carne mechada con papas boliche) *
27218210	Puerto Rican style beef stew with potatoes (Carne guisada con papas) *
27218310	Stewed corned beef, Puerto Rican style ("Corned beef" guisado) *
27220010	Meat loaf made with ham (not luncheon meat) *
27220020	Ham and noodles with cream or white sauce (mixture) *
27220030	Ham and rice with (mushroom) soup (mixture) *
27220050	Ham or pork with stuffing (mixture) *
27220080	Ham croquette *
27220120	Sausage and rice with tomato-based sauce (mixture) *
27220150	Sausage and rice with (mushroom) soup (mixture) *
27220170	Sausage and rice with cheese sauce (mixture) *

27220190	Sausage and noodles with cream or white sauce (mixture) *
27220210	Ham and noodles, no sauce (mixture) *
27220310	Ham or pork and rice, no sauce (mixture) *
27220510	Ham or pork and potatoes with gravy (mixture) *
27220520	Ham or pork and potatoes with cheese sauce (mixture) *
27221100	Stewed pig's feet, Puerto Rican style (Patitas de cerdo guisadas) *
27221110	Stuffed pork roast, Puerto Rican style *
27230010	Lamb or mutton loaf *
27235000	Meat loaf made with venison/deer *
27246300	Chicken or turkey cake, patty, or croquette *
27246500	Meat loaf made with chicken or turkey *
27246505	Meat loaf made with chicken or turkey, with tomato-based sauce *
27250270	Clams Casino *
27260010	Meat loaf, NS as to type of meat *
27260050	Meatballs, with breading, NS as to type of meat, with gravy *
27260080	Meat loaf made with beef and pork *
27260090	Meat loaf made with beef, veal and pork *
27260100	Meat loaf made with beef and pork, with tomato-based sauce *
27260500	Vienna sausages stewed with potatoes, Puerto Rican style (Salchichas guisadas) *
27311210	Corned beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture) *
27311220	Corned beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture) *
27320020	Ham pot pie *
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 *
27320120	Sausage, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture) *
27320130	Sausage, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture) *
27320410	Ham, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture) *
27320450	Ham, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture) *
27331150	Veal fricassee, Puerto Rican style (ternera en fricase) *
27348100	Chicken fricassee, Puerto Rican style (Fricase de pollo) *
27350020	Paella with seafood *
27350030	Seafood stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-base sauce *
27350310	Seafood stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-base sauce *
27360090	Paella, NFS *
27362000	Stewed tripe, Puerto Rican style, with potatoes (Mondongo) *
27363100	Jambalaya with meat and rice *
27411150	Beef rolls, stuffed with vegetables or meat mixture, tomato-based sauce *

27418310	Corned beef with tomato sauce and onion, Puerto Rican style (mixture) *
27420010	Cabbage with ham hocks (mixture) *
27420020	Ham or pork salad *
27420040	Frankfurters or hot dogs and sauerkraut (mixture) *
27420080	Greens with ham or pork (mixture) *
27420250	Ham and vegetables (including carrots, broccoli, and/or dark- green leafy (no potatoes)), no sauce (mixture) *
27420270	Ham and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), no sauce (mixture) *
27420450	Sausage and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), tomato-based sauce (mixture) *
27420460	Sausage and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), tomato-based sauce (mixture) *
27420470	Sausage and peppers, no sauce (mixture) *
27421010	Stuffed christophine, Puerto Rican style (Chayote relleno) *
27446315	Chicken or turkey garden salad with bacon and cheese (chicken and/or turkey, bacon, cheese, lettuce and/or greens, tomato and/or carrots, other vegetables), no dressing *
27446320	Chicken or turkey (breaded, fried) garden salad with bacon and cheese (chicken and/or turkey, bacon, cheese, lettuce and/or greens, tomato and/or carrots, other vegetables), no dressing *
27448020	Chicken or turkey fricassee, with sauce, no potatoes, Puerto Rican style (potatoes reported separately) *
27450250	Oysters Rockefeller *
27460490	Julienne salad (meat, cheese, eggs, vegetables), no dressing *
27460510	Antipasto with ham, fish, cheese, vegetables *
27461010	Stewed seasoned ground beef, Puerto Rican style (Picadillo para relleno) *
27500050	Sandwich, NFS *
27500100	Meat sandwich, NFS *
27510110	Beef barbecue sandwich or Sloppy Joe, on bun *
27510210	Cheeseburger, plain, on bun *
27510220	Cheeseburger, with mayonnaise or salad dressing, on bun *
27510230	Cheeseburger, with mayonnaise or salad dressing, and tomato and/or catsup, on bun *
27510240	Cheeseburger, 1/4 lb meat, plain, 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 *
27510265	Double cheeseburger, (2 patties, 1 oz each), plain, on miniature bun *
27510270	Double cheeseburger (2 patties), plain, on bun *
27510280	Double cheeseburger (2 patties), with mayonnaise or salad dressing, on bun *
27510290	Double cheeseburger (2 patties), plain, on double-decker 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 *
27510359	Cheeseburger, 1/3 lb meat, with mayonnaise or salad dressing, and mushrooms, 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 *
27510410	Chiliburger, on bun *
27510420	Taco burger, 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 *
27510450	Cheeseburger, 1/4 lb meat, with ham, on bun *
27510480	Cheeseburger (hamburger with cheese sauce), 1/4 lb meat, with grilled 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 *
27510530	Hamburger, 1/4 lb meat, plain, on bun *
27510540	Double hamburger (2 patties), with tomato and/or catsup, on bun *
27510550	Double hamburger (2 patties), with mayonnaise or salad dressing and tomatoes, on double-decker 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 *
27510590	Hamburger, with mayonnaise or salad dressing, 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 *
27510630	Hamburger, 1/4 lb meat, with mayonnaise or salad dressing, on bun *
27510650	Double hamburger (2 patties), plain, on bun *
27510660	Double hamburger (2 patties), with mayonnaise or salad dressing, 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 *
27510710	Pizzaburger (hamburger, cheese, sauce) on 1/2 bun *
27510720	Pizzaburger (hamburger, cheese, sauce) on whole bun *
27510910	Corned beef sandwich *
27510950	Reuben sandwich (corned beef sandwich with sauerkraut and cheese), with spread *
27511010	Pastrami sandwich *
27513060	Roast beef sandwich with bacon and cheese sauce *
27516010	Gyro sandwich (pita bread, beef, lamb, onion, condiments), with tomato and spread *
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 *
27518000	Wrap sandwich filled with beef patty, bacon, cheese, tomato and/or catsup, and spread and/or sauce *
27520110	Bacon sandwich, with spread *

27520120	Bacon and cheese sandwich, with 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 *
27520160	Bacon, chicken, and tomato club sandwich, on multigrain roll with lettuce and 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 *
27520170	Bacon on biscuit *
27520250	Ham on biscuit *
27520300	Ham sandwich, with spread *
27520310	Ham sandwich with lettuce and spread *
27520320	Ham and cheese sandwich, with lettuce and spread *
27520330	Ham and egg sandwich *
27520340	Ham salad sandwich *
27520350	Ham and cheese sandwich, with spread, grilled *
27520360	Ham and cheese sandwich, on bun, with lettuce and spread *
27520370	Hot ham and cheese sandwich, on bun *
27520380	Ham and cheese on English muffin *
27520390	Ham and cheese submarine sandwich, with lettuce, tomato and spread *
27520410	Cuban sandwich, (Sandwich cubano), with spread *
27520420	Midnight sandwich, (Media noche), with spread *
27520540	Ham and tomato club sandwich, with lettuce and spread *
27540170	Chicken patty sandwich, miniature, with spread *
27540180	Chicken patty sandwich or biscuit *
27540190	Chicken patty sandwich, with lettuce and spread *
27540230	Chicken patty sandwich with cheese, on wheat bun, with 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 *
27560000	Luncheon meat sandwich, NFS, with spread *
27560110	Bologna sandwich, with spread *
27560120	Bologna and cheese sandwich, with spread *
27560300	Corn dog (frankfurter or hot dog with cornbread coating) *
27560310	Corny dog, with chili, on bun *
27560320	Frankfurter or hot dog, plain, on bun *
27560330	Frankfurter or hot dog, with cheese, plain, on bun *
27560340	Frankfurter or hot dog, with catsup and/or mustard, on bun *
27560350	Pig in a blanket (frankfurter or hot dog wrapped in dough) *
27560360	Frankfurter or hot dog, with chili, on bun *
27560370	Frankfurter or hot dog with chili and cheese, on bun *
27560380	Pochito (frankfurter or hot dog and beef chili wrapped in tortilla) *
27560400	Chicken frankfurter or hot dog, plain, on bun *
27560410	Puerto Rican sandwich (Sandwich criollo) *
27560500	Pepperoni and salami submarine sandwich, with lettuce, tomato, and spread *
27560510	Salami sandwich, with spread *
27560650	Sausage on biscuit *
27560660	Sausage griddle cake sandwich *
27560670	Sausage and cheese on English muffin *
27560700	Sausage on biscuit, diet *
27560705	Sausage balls (made with biscuit mix and cheese) *
27560710	Sausage sandwich *
27560720	Sausage and spaghetti sauce sandwich *
27560910	Cold cut submarine sandwich, with cheese, lettuce, tomato, and spread *
27563010	Meat spread or potted meat sandwich *

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 *
27564030	Frankfurter or hot dog sandwich, NFS, plain, on whole wheat bread, NS as to 100% *
27564040	Frankfurter or hot dog sandwich, NFS, plain, on whole grain white bread *
27564050	Frankfurter or hot dog sandwich, NFS, plain, on multigrain 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 *
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 *
27564110	Frankfurter or hot dog sandwich, beef, plain, on multigrain 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% *
27564160	Frankfurter or hot dog sandwich, beef and pork, plain, on whole grain white bread *
27564170	Frankfurter or hot dog sandwich, beef and pork, plain, on multigrain bread *
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 *
27564230	Frankfurter or hot dog sandwich, meat and poultry, plain, on multigrain 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% *
27564280	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on whole grain white bread *
27564290	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on multigrain bread *
27564300	Frankfurter or hot dog sandwich, reduced fat or light, plain, on bun *
27564310	Frankfurter or hot dog sandwich, reduced fat or light, plain, on white bread *
27564320	Frankfurter or hot dog sandwich, reduced fat or light, plain, on wheat bread *
27564330	Frankfurter or hot dog sandwich, reduced fat or light, plain, on whole wheat bread, NS as to 100% *
27564340	Frankfurter or hot dog sandwich, reduced fat or light, plain, on whole grain white bread *
27564350	Frankfurter or hot dog sandwich, reduced fat or light, plain, on multigrain bread *
27564360	Frankfurter or hot dog sandwich, fat free, plain, on bun *
27564370	Frankfurter or hot dog sandwich, fat free, plain, on white bread *
27564380	Frankfurter or hot dog sandwich, fat free, plain, on wheat bread *
27564390	Frankfurter or hot dog sandwich, fat free, plain, on whole wheat bread, NS as to 100% *
27564400	Frankfurter or hot dog sandwich, fat free, plain, on whole grain white bread *
27564410	Frankfurter or hot dog sandwich, fat free, plain, on multigrain 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 *
27564470	Frankfurter or hot dog sandwich, with chili, on whole wheat bread, NS as to 100% *
27564480	Frankfurter or hot dog sandwich, with chili, on whole grain white bread *
27564490	Frankfurter or hot dog sandwich, with chili, on multi-grain bread *
27564500	Frankfurter or hot dog sandwich, with vegetarian chili, on bun *
27564510	Frankfurter or hot dog sandwich, with vegetarian chili, on white bread *

27564520	Frankfurter or hot dog sandwich, with vegetarian chili, on wheat bread *
27564530	Frankfurter or hot dog sandwich, with meatless chili, on whole wheat bread, NS as to 100% *
27564540	Frankfurter or hot dog sandwich, with vegetarian chili, on whole grain white bread *
27564550	Frankfurter or hot dog sandwich, with vegetarian chili, on multigrain bread *
27564560	Frankfurter or hot dog sandwich, meatless, on bun, with vegetarian chili *
27564570	Frankfurter or hot dog sandwich, meatless, on bread, with vegetarian chili *
28110300	Salisbury steak dinner, NFS (frozen meal) *
28110310	Salisbury steak with gravy, potatoes, vegetable (frozen meal) *
28110330	Salisbury steak with gravy, whipped potatoes, vegetable, dessert (frozen meal) *
28110340	Salisbury steak with gravy, potatoes, vegetable, soup or macaroni and cheese, dessert (frozen meal) *
28110350	Salisbury steak with gravy, potatoes, vegetable, dessert (frozen meal, large meat portion) *
28110370	Salisbury steak with gravy, macaroni and cheese, vegetable (frozen meal) *
28110380	Salisbury steak with gravy, macaroni and cheese (frozen meal) *
28110390	Salisbury steak, potatoes, vegetable, dessert (diet frozen meal) *
28110640	Meatballs, Swedish, in sauce, with noodles (frozen meal) *
28110660	Meatballs, Swedish, in gravy, with noodles (diet frozen meal) *
28111010	Corned beef hash with apple slices, vegetable (frozen meal) *
28113110	Salisbury steak, baked, with tomato sauce, vegetable (diet frozen meal) *
28120310	Pork with rice, vegetable, in soy-based sauce (diet frozen meal) *
28140720	Chicken patty, or nuggets, boneless, breaded, potatoes, vegetable (frozen meal) *
28140730	Chicken patty, breaded, with tomato sauce and cheese, fettuccine alfredo, vegetable (frozen meal) *
28140740	Chicken patty, or nuggets, boneless, breaded, with pasta and tomato sauce, fruit, dessert (frozen meal) *
28141050	Chicken patty parmigiana, breaded, with vegetable (diet frozen meal) *
28141630	Chicken cordon bleu with vegetable, rice (frozen meal) *
28160300	Meat loaf dinner, NFS (frozen meal) *
28160310	Meat loaf with potatoes, vegetable (frozen meal) *
28310230	Meatball soup, Mexican style, home recipe (Sopa de Albondigas) *
28315160	Italian Wedding Soup *
28320130	Ham, rice, and potato soup, Puerto Rican style *
28320140	Ham, noodle, and vegetable soup, Puerto Rican style *
28321130	Bacon soup, cream of, prepared with water *
28340210	Chicken rice soup, Puerto Rican style (Sopa de pollo con arroz) *
28340220	Chicken soup with noodles and potatoes, Puerto Rican style *
28340700	Bird's nest soup (chicken, ham, and noodles) *
28350050	Fish chowder *
28360210	Spanish vegetable soup, Puerto Rican style (Caldo gallego) *
32101500	Egg, Benedict *
32105030	Egg omelet or scrambled egg, with ham or bacon *
32105059	Egg omelet or scrambled egg, with ham or bacon, and dark-green vegetables *
32105060	Egg omelet or scrambled egg, with ham or bacon and vegetables other than dark-green *
32105080	Egg omelet or scrambled egg, with ham or bacon and cheese *
32105081	Egg omelet or scrambled egg, with ham or bacon, cheese, and dark-green vegetables *
32105082	Egg omelet or scrambled egg, with ham or bacon, cheese, and vegetables other than dark-green *
32105085	Egg omelet or scrambled egg, with ham or bacon, cheese, and tomatoes *
32105116	Egg omelet or scrambled egg, with sausage and dark-green vegetables *
32105117	Egg omelet or scrambled egg, with sausage, cheese, and dark-green vegetables *
32105118	Egg omelet or scrambled egg, with sausage and vegetables other than dark-green *
32105119	Egg omelet or scrambled egg, with sausage, cheese, and vegetables other than dark-green *

32105120	Egg omelet or scrambled egg, with sausage and mushrooms *
32105121	Egg omelet or scrambled egg, with sausage and cheese *
32105122	Egg omelet or scrambled egg, with sausage *
32105123	Egg omelet or scrambled egg, with sausage, cheese, and mushrooms *32105125 Egg omelet or scrambled egg, with hot dogs *
32105126	Egg omelet or scrambled egg, with hot dog and cheese *
32105160	Egg omelet or scrambled egg, with chorizo *
32105161	Egg omelet or scrambled egg, with chorizo and cheese *
32105190	Egg casserole with bread, cheese, milk and meat *
32105330	Scrambled eggs with jerked beef, Puerto Rican style (Revoltillo de tasajo) *
32110100	Eggs a la Malaguena, Puerto Rican style (Huevos a la Malaguena) *
32130200	Egg omelet or scrambled egg, with meat, made with margarine *
32130210	Egg omelet or scrambled egg, with meat, made with oil *
32130220	Egg omelet or scrambled egg, with meat, made with butter *
32130240	Egg omelet or scrambled egg, with meat, made with animal fat or meat drippings *
32130260	Egg omelet or scrambled egg, with meat, made with cooking spray *
32130270	Egg omelet or scrambled egg, with meat, made without fat *
32130300	Egg omelet or scrambled egg, with cheese and meat, made with margarine *
32130310	Egg omelet or scrambled egg, with cheese and meat, made with oil *
32130320	Egg omelet or scrambled egg, with cheese and meat, made with butter *
32130340	Egg omelet or scrambled egg, with cheese and meat, made with animal fat or meat drippings *
32130360	Egg omelet or scrambled egg, with cheese and meat, made with cooking spray *
32130370	Egg omelet or scrambled egg, with cheese and meat, made without fat * 32130800 Egg omelet or scrambled egg, with meat and tomatoes, fat added in cooking *
32130810	Egg omelet or scrambled egg, with meat and tomatoes, fat not added in cooking *
32130820	Egg omelet or scrambled egg, with meat and tomatoes, NS as to fat added in cooking *
32130830	Egg omelet or scrambled egg, with meat and dark-green vegetables, fat added in cooking *
32130840	Egg omelet or scrambled egg, with meat and dark-green vegetables, fat not added in cooking *
32130850	Egg omelet or scrambled egg, with meat and dark-green vegetables, NS as to fat added in cooking *
32130860	Egg omelet or scrambled egg, with meat, tomatoes, and dark-green vegetables, fat added in cooking *
32130870	Egg omelet or scrambled egg, with meat, tomatoes, and dark-green vegetables, fat not added in cooking *
32130880	Egg omelet or scrambled egg, with meat, tomatoes, and dark-green vegetables, NS as to fat added in cooking *
32130890	Egg omelet or scrambled egg, with meat and vegetables other than dark-green and/or tomatoes, fat added in cooking *
32130900	Egg omelet or scrambled egg, with meat and vegetables other than dark-green and/or tomatoes, fat not added in cooking *
32130910	Egg omelet or scrambled egg, with meat and vegetables other than dark-green and/or tomatoes, NS as to fat added in cooking *
32131000	Egg omelet or scrambled egg, with cheese, meat, and tomatoes, fat added in cooking *
32131010	Egg omelet or scrambled egg, with cheese, meat, and tomatoes, fat not added in cooking *
32131020	Egg omelet or scrambled egg, with cheese, meat, and tomatoes, NS as to fat added in cooking *
32131030	Egg omelet or scrambled egg, with cheese, meat, and dark-green vegetables, fat added in cooking *
32131040	Egg omelet or scrambled egg, with cheese, meat, and dark-green vegetables, fat not added in cooking *

32131050	Egg omelet or scrambled egg, with cheese, meat, and dark-green vegetables, NS as to fat added in cooking *
32131060	Egg omelet or scrambled egg, with cheese, meat, tomatoes, and dark-green vegetables, fat added in cooking *
32131070	Egg omelet or scrambled egg, with cheese, meat, tomatoes, and dark-green vegetables, fat not added in cooking *
32131080	Egg omelet or scrambled egg, with cheese, meat, tomatoes, and dark-green vegetables, NS as to fat added in cooking *
32131090	Egg omelet or scrambled egg, with cheese, meat, and vegetables other than dark-green and/or tomatoes, fat added in cooking *
32131100	Egg omelet or scrambled egg, with cheese, meat, and vegetables other than dark-green and/or tomatoes, fat not added in cooking *
32131110	Egg omelet or scrambled egg, with cheese, meat, and vegetables other than dark-green and/or tomatoes, NS as to fat added in cooking *
32202000	Egg, cheese, ham, and bacon on bun *
32202010	Egg, cheese, and ham on English muffin *
32202020	Egg, cheese, and ham on biscuit *
32202025	Egg, cheese and ham on bagel *
32202030	Egg, cheese, and sausage on English muffin *
32202035	Egg, extra cheese (2 slices), and extra sausage (2 patties) on bun *
32202050	Egg, cheese, and sausage on biscuit *
32202055	Egg, cheese, and sausage griddle cake sandwich *
32202060	Egg and sausage on biscuit *
32202070	Egg, cheese, and bacon on biscuit *
32202075	Egg, cheese, and bacon griddle cake sandwich *
32202080	Egg, cheese, and bacon on English muffin *
32202085	Egg, cheese and bacon on bagel *
32202090	Egg and bacon on biscuit *
32202110	Egg and ham on biscuit *
32202120	Egg, cheese and sausage on bagel *
32400200	Egg white, omelet, scrambled, or fried, with meat, fat added in cooking *
32400210	Egg white, omelet, scrambled, or fried, with meat, fat not added in cooking *
32400220	Egg white, omelet, scrambled, or fried, with meat, NS as to fat added in cooking *
32400400	Egg white, omelet, scrambled, or fried, with cheese and meat, fat added in cooking *
32400410	Egg white, omelet, scrambled, or fried, with cheese and meat, fat not added in cooking *
32400420	Egg white, omelet, scrambled, or fried, with cheese and meat, NS as to fat added in cooking *
32400600	Egg white, omelet, scrambled, or fried, with meat and vegetables, fat added in cooking *
32400610	Egg white, omelet, scrambled, or fried, with meat and vegetables, fat not added in cooking *
32400620	Egg white, omelet, scrambled, or fried, with meat and vegetables, NS as to fat added in cooking *
32400700	Egg white, omelet, scrambled, or fried, with cheese, meat, and vegetables, fat added in cooking *
32400710	Egg white, omelet, scrambled, or fried, with cheese, meat, and vegetables, fat not added in cooking *
32400720	Egg white, omelet, scrambled, or fried, with cheese, meat, and vegetables, NS as to fat added in cooking *
33401100	Egg substitute, omelet, scrambled, or fried, with meat, fat added in cooking *
33401110	Egg substitute, omelet, scrambled, or fried, with meat, fat not added in cooking *
33401120	Egg substitute, omelet, scrambled, or fried, with meat, NS as to fat added in cooking *
33401300	Egg substitute, omelet, scrambled, or fried, with cheese and meat, fat added in cooking *
33401310	Egg substitute, omelet, scrambled, or fried, with cheese and meat, fat not added in cooking *

33401320	Egg substitute, omelet, scrambled, or fried, with cheese and meat, NS as to fat added in cooking *
33401500	Egg substitute, omelet, scrambled, or fried, with meat and vegetables, fat added in cooking *
33401510	Egg substitute, omelet, scrambled, or fried, with meat and vegetables, fat not added in cooking *
33401520	Egg substitute, omelet, scrambled, or fried, with meat and vegetables, NS as to fat added in cooking *
33401600	Egg substitute, omelet, scrambled, or fried, with cheese, meat, and vegetables, fat added in cooking *
33401610	Egg substitute, omelet, scrambled, or fried, with cheese, meat, and vegetables, fat not added in cooking *
33401620	Egg substitute, omelet, scrambled, or fried, with cheese, meat, and vegetables, NS as to fat added in cooking *
35001000	Scrambled eggs, sausage, hash brown potatoes (frozen meal) *
35002000	Scrambled eggs, bacon, home fried potatoes (frozen meal) *
35003000	Scrambled eggs, sausage, pancakes (frozen meal) *
41201010	Baked beans, NFS *
41204020	Boston baked beans *
41205030	Refried beans with meat *
41208100	Beans, dry, cooked with pork *
41210090	Stewed beans with pork, tomatoes, and chili peppers, Mexican style (Frijoles a la charra) *
41210100	Stewed red beans, Puerto Rican style (Habichuelas coloradas guisadas) *
41210110	Stewed dry lima beans, Puerto Rican style *
41210120	Stewed white beans, Puerto Rican style *
41210150	Stewed pink beans with white potatoes and ham, Puerto Rican style *
41210160	Stewed pink beans with pig's feet, Puerto Rican style *
41210170	Stewed red beans with pig's feet, Puerto Rican style *
41210180	Stewed white beans with pig's feet, Puerto Rican style *
41210190	Stewed red beans with pig's feet and potatoes, Puerto Rican style *
41210200	Black beans, Cuban style (Habichuelas negras guisadas a la Cubana) *
41303500	Stewed green peas, Puerto Rican style *
41303550	Stewed green peas with pig's feet and potatoes, Puerto Rican style *
41304030	Peas, dry, cooked with pork *
41304130	Cowpeas, dry, cooked with pork *
41310100	Stewed pigeon peas, Puerto Rican style (Gandules guisados, Gandur, Gandules) *
41310150	Stewed chickpeas, Puerto Rican style *
41310160	Stewed chickpeas, with potatoes, Puerto Rican style *
41310200	Chickpeas stewed with pig's feet, Puerto Rican style (Garbanzos guisados con patitas de cerdo) *
41310210	Stewed chickpeas with Spanish sausages, Puerto Rican style (Garbanzos guisados con chorizos) *
41310220	Fried chickpeas with bacon, Puerto Rican style (Garbanzos fritos con tocineta) *
41502000	Beans and franks, frozen dinner *
41601010	Bean soup, NFS *
41601020	Bean with bacon or ham soup, canned or ready-to-serve *
41601040	Lima bean soup, home recipe, canned or ready-to-serve *
41601060	Bean soup, with macaroni and meat *
41601080	Pinto bean soup, home recipe, canned or ready-to-serve *
41601100	Portuguese bean soup, home recipe, canned or ready-to-serve *
41601110	Bean and ham soup, chunky style, canned or ready-to-serve *
41601120	Bean soup with vegetables, rice, and pork *
41601130	Bean soup, mixed beans, home recipe, canned or ready-to-serve *
41601140	Bean soup, home recipe *

41601160	Bean and ham soup, canned, reduced sodium, prepared with water or ready-to-serve *
41601180	Bean and ham soup, home recipe *
41602010	Pea and ham soup, chunky style, canned or ready-to-serve *
41602020	Garbanzo bean or chickpea soup, home recipe, canned or ready-to-serve *
41602030	Split pea and ham soup *
41602090	Split pea and ham soup, canned, reduced sodium, prepared with water or ready-to-serve *
41610100	White bean soup, Puerto Rican style (Sopon de habichuelas blancas) *
58100010	Burrito, taco, or quesadilla with egg and breakfast meat *
58100013	Burrito, taco, or quesadilla with egg and breakfast meat, from fast food *
58100015	Burrito, taco, or quesadilla with egg, potato, and breakfast meat *
58100017	Burrito, taco, or quesadilla with egg, potato, and breakfast meat, from fast food *
58100020	Burrito, taco, or quesadilla with egg, beans, and breakfast meat *
58100340	Burrito with eggs, sausage, cheese and vegetables *
58100560	Enchilada with ham and cheese, no beans *
58106500	Pizza with meat, prepared from frozen, thin crust *
58106505	Pizza with meat, prepared from frozen, thick crust *
58106540	Pizza with pepperoni, from restaurant or fast food, NS as to type of crust *
58106550	Pizza with pepperoni, from restaurant or fast food, thin crust *
58106555	Pizza with pepperoni, from restaurant or fast food, regular crust *
58106560	Pizza with pepperoni, from restaurant or fast food, thick crust *
58106565	Pizza with pepperoni, stuffed crust *
58106570	Pizza with pepperoni, from school lunch, thin crust *
58106580	Pizza with pepperoni, from school lunch, thick crust *
58106610	Pizza with meat other than pepperoni, from restaurant or fast food, NS as to type of crust *
58106620	Pizza with meat other than pepperoni, from restaurant or fast food, thin crust *
58106625	Pizza with meat other than pepperoni, from restaurant or fast food, regular crust *
58106630	Pizza with meat other than pepperoni, from restaurant or fast food, thick crust *
58106633	Pizza, with meat other than pepperoni, stuffed crust *
58106635	Pizza, with meat other than pepperoni, from school lunch, thin crust *
58106636	Pizza, with meat other than pepperoni, from school lunch, thick crust *
58106640	Pizza with extra meat, NS as to type of crust *
58106650	Pizza with extra meat, thin crust *
58106655	Pizza with extra meat, regular crust *
58106660	Pizza with extra meat, thick crust *
58106700	Pizza with meat and vegetables, prepared from frozen, thin crust *
58106705	Pizza with meat and vegetables, prepared from frozen, thick crust *
58106710	Pizza with meat and vegetables, NS as to type of crust *
58106720	Pizza with meat and vegetables, thin crust *
58106725	Pizza with meat and vegetables, regular crust *
58106730	Pizza with meat and vegetables, thick crust *
58106733	Pizza with extra meat and extra vegetables, prepared from frozen, thin crust *
58106734	Pizza with extra meat and extra vegetables, prepared from frozen, thick crust *
58106735	Pizza with extra meat and extra vegetables, NS as to type of crust *
58106736	Pizza with extra meat and extra vegetables, thin crust *
58106737	Pizza with extra meat and extra vegetables, thick crust *
58106738	Pizza with extra meat and extra vegetables, regular crust *
58106740	Pizza with meat and fruit, NS as to type of crust *
58106750	Pizza with meat and fruit, thin crust *
58106755	Pizza with meat and fruit, regular crust *
58106760	Pizza with meat and fruit, thick crust *
58106780	Pizza with meat and vegetables, prepared from frozen, lowfat, thin crust *
58107050	Pizza, no cheese, thin crust *
58107100	Pizza, no cheese, thick crust *
58108010	Calzone, with meat and cheese *

58108030	Panzerotti, with meat, vegetables, and cheese *
58108050	Pizza rolls *
58109010	Italian pie with meat *
58115210	Taco with crab meat, Puerto Rican style (Taco de jueye) *
58116210	Meat pie, Puerto Rican style (Pastelon de carne) *
58117510	Hayacas, Puerto Rican style (hominy, pork or ham, vegetables) *
58125110	Quiche with meat, poultry or fish *
58127210	Croissant sandwich, filled with ham and cheese *
58127270	Croissant sandwich with sausage and egg *
58127290	Croissant sandwich with bacon and egg *
58127310	Croissant sandwich with ham, egg, and cheese *
58127330	Croissant sandwich with sausage, egg, and cheese *
58127350	Croissant sandwich with bacon, egg, and cheese *
58128000	Biscuit with gravy *
58132310	Spaghetti with tomato sauce and meatballs or spaghetti with meat sauce or spaghetti with meat sauce and meatballs *
58132313	Pasta with tomato sauce and meat or meatballs, canned *
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 *
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 *
58132713	Pasta with tomato sauce and frankfurters or hot dogs, canned *
58134610	Tortellini, meat-filled, with tomato sauce *
58134613	Tortellini, meat-filled, with tomato sauce, canned *
58134650	Tortellini, meat-filled, no sauce *
58140110	Spaghetti with corned beef, Puerto Rican style *
58145150	Macaroni or noodles with cheese and pork or ham *
58145160	Macaroni or noodles with cheese and frankfurters or hot dogs *
58146130	Pasta with carbonara sauce *
58148550	Macaroni or pasta salad with meat *
58149210	Somen salad with noodles, lettuce, egg, fish, and pork *
58155110	Rice with chicken, Puerto Rican style (Arroz con Pollo) *
58155310	Paella, Valenciana style, with meat (Paella Valenciana) *
58155410	Soupy rice with chicken, Puerto Rican style (Asopao de pollo) *
58155510	Soupy rice mixture with chicken and potatoes, Puerto Rican style *
58155810	Stewed rice, Puerto Rican style (arroz guisado) *
58156110	Fried rice, Puerto Rican style (arroz frito) *
58156210	Rice with vienna sausage, Puerto Rican style (arroz con salchichas) *
58156310	Rice with Spanish sausage, Puerto Rican style *
58156510	Soupy rice from Puerto Rican style Asopao de Pollo (chicken parts reported separately) *
58156710	Rice with stewed beans, Puerto Rican style *
58160160	Hopping John (blackeye peas and rice) *
58304010	Spaghetti and meatballs dinner, NFS (frozen meal) *
58304020	Spaghetti and meatballs with tomato sauce, sliced apples, bread (frozen meal) *
58310110	Frozen breakfast, NFS (frozen meal) *
58310210	Sausage and french toast (frozen meal) *
58310310	Pancakes and sausage (frozen meal) *
58310410	Sausage rice links and whole wheat pancakes (frozen meal) *
58404100	Rice and potato soup, Puerto Rican style *
71106000	Stewed potatoes, Puerto Rican style (Papas guisadas) *
71301120	White potato, cooked, with ham and cheese *
71305110	White potato, scalloped, with ham *

71402505	White potato, french fries, with cheese and bacon *
71411000	White potato skins, with adhering flesh, fried, with cheese and bacon *
71508060	White potato, stuffed, baked, peel eaten, stuffed with bacon and cheese *
71508070	White potato, stuffed, baked, peel not eaten, stuffed with bacon and cheese *
71508120	White potato, stuffed with ham, broccoli and cheese sauce, baked, peel eaten *
71602010	Potato salad, German style *
71803010	Potato chowder *
74410110	Puerto Rican seasoning with ham *
74415110	Puerto Rican seasoning with ham and tomato sauce *
75140500	Broccoli salad with cauliflower, cheese, bacon bits, and dressing *
75144100	Lettuce, wilted, with bacon dressing *
75145000	Seven-layer salad (lettuce salad made with a combination of onion, celery, green pepper, peas, mayonnaise, cheese, eggs, and/or bacon) *
75148000	Cobb salad with dressing *
75148010	Cobb salad, no dressing *
75414020	Mushrooms, stuffed *
75656010	Vegetable soup, Spanish style, stew type *
77121010	Fried stuffed potatoes, Puerto Rican style (Rellenos de papas) *
77121110	Potato and ham fritters, Puerto Rican style (Frituras de papa y jamon) *
77205110	Ripe plantain fritters, Puerto Rican style (Pionono) *
77205610	Ripe plantain meat pie, Puerto Rican style (Pinon) *
77230210	Cassava Pasteles, Puerto Rican style (Pasteles de yuca) *
77230510	Cassava fritter stuffed with crab meat, Puerto Rican style (Empanada de yuca y jueyes) *
77250110	Stuffed tannier fritters, Puerto Rican style (Alcapurrias) *
77272010	Puerto Rican pasteles (Pasteles de masa) *
77513010	Spanish stew, Puerto Rican style (Cocido Espanol) *
77563010	Puerto Rican stew (Salcocho / Sancocho) *
83101500	Bacon dressing (hot) *
83101600	Bacon and tomato dressing *

A.4 Food Codes for Yogurt

Food Code	Description
11410000	Yogurt, NS as to type of milk or flavor
11411010	Yogurt, plain, NS as to type of milk
11411100	Yogurt, plain, whole milk
11411200	Yogurt, plain, lowfat milk
11411300	Yogurt, plain, nonfat milk
11420000	Yogurt, vanilla, lemon, or coffee flavor, NS as to type of milk
11421000	Yogurt, vanilla, lemon, or coffee flavor, whole milk
11422000	Yogurt, vanilla, lemon, maple, or coffee flavor, lowfat milk
11422100	Yogurt, vanilla, lemon, maple, or coffee flavor, lowfat milk, sweetened with low calorie sweetener
11423000	Yogurt, vanilla, lemon, maple, or coffee flavor, nonfat milk
11424000	Yogurt, vanilla, lemon, maple, or coffee flavor, nonfat milk, sweetened with low calorie sweetener
11425000	Yogurt, chocolate, NS as to type of milk
11426000	Yogurt, chocolate, whole milk
11427000	Yogurt, chocolate, nonfat milk
11430000	Yogurt, fruit variety, NS as to type of milk
11431000	Yogurt, fruit variety, whole milk
11432000	Yogurt, fruit variety, lowfat milk
11432500	Yogurt, fruit variety, lowfat milk, sweetened with low-calorie sweetener

11433000	Yogurt, fruit variety, nonfat milk
11433500	Yogurt, fruit variety, nonfat milk, sweetened with low-calorie sweetener
11444000	Yogurt, fruit and nuts, NS as to type of milk
11445000	Yogurt, fruit and nuts, lowfat milk
11446000	Fruit and lowfat yogurt parfait
11459990	Yogurt, frozen, NS as to flavor, NS as to type of milk
11460000	Yogurt, frozen, flavors other than chocolate, NS as to type of milk
11460100	Yogurt, frozen, chocolate, NS as to type of milk
11460150	Yogurt, frozen, NS as to flavor, lowfat milk
11460160	Yogurt, frozen, chocolate, lowfat milk
11460170	Yogurt, frozen, flavors other than chocolate, lowfat milk
11460190	Yogurt, frozen, NS as to flavor, nonfat milk
11460200	Yogurt, frozen, chocolate, nonfat milk
11460250	Yogurt, frozen, flavors other than chocolate, with sorbet or sorbet-coated *
11460300	Yogurt, frozen, flavors other than chocolate, nonfat milk
11460400	Yogurt, frozen, chocolate, nonfat milk, with low-calorie sweetener
11460410	Yogurt, frozen, flavors other than chocolate, nonfat milk, with low-calorie sweetener
11460420	Yogurt, frozen, NS as to flavor, whole milk
11460430	Yogurt, frozen, chocolate, whole milk
11460440	Yogurt, frozen, flavors other than chocolate, whole milk
11461000	Yogurt, frozen, chocolate-coated *
11461100	Yogurt, frozen, carob-coated *
11461200	Yogurt, frozen, sandwich *
11461250	Yogurt, frozen, cone, chocolate *
11461260	Yogurt, frozen, cone, flavors other than chocolate *
11461270	Yogurt, frozen, cone, flavors other than chocolate, lowfat milk *
11461280	Yogurt, frozen, cone, chocolate, lowfat milk *
11553000	Fruit smoothie drink, made with fruit or fruit juice and dairy products *
27116100	Beef curry *
27120160	Pork curry *
27130100	Lamb or mutton curry *
27146150	Chicken curry *
27150100	Shrimp curry *
27150320	Fish curry *
27213010	Biryani with meat *
27243100	Biryani with chicken *
27516010	Gyro sandwich (pita bread, beef, lamb, onion, condiments), with tomato and spread *
32101530	Egg curry *
51108100	Naan, Indian flatbread *
58124500	Pastry, filled with potatoes and peas, fried *
75440600	Vegetable curry *
53104580	Cheesecake -type dessert, made with yogurt, with fruit *
53112150	Cake, frozen yogurt and cake layer, not chocolate, with icing *
53112160	Cake, frozen yogurt and cake layer, chocolate, with icing *
53366000	Pie, yogurt, frozen *
53441210	Basbousa (semolina dessert dish) *
53540402	Kellogg's Nutri-Grain Yogurt Bar *
53540500	Breakfast bar, date, with yogurt coating *
53540902	Nature Valley Chewy Granola Bar with Yogurt Coating *
53544300	Granola bar, high fiber, coated with non-chocolate yogurt coating *
53710502	Kellogg's Nutri-Grain Yogurt Bar *
53710902	Nature Valley Chewy Granola Bar with Yogurt Coating *
53714300	Granola bar, high fiber, coated with non-chocolate yogurt coating *
53714510	Breakfast bar, date, with yogurt coating *
54408250	Pretzel, yogurt-covered *

54430010	Yogurt chips *
57344015	Special K Fruit & Yogurt *
57419000	Yogurt Burst Cheerios *
63401015	Apple and grape salad with yogurt and walnuts *
91701030	Almonds, yogurt-covered *
91708150	Yogurt covered fruit snacks candy, with added vitamin C *
91708160	Yogurt covered fruit snacks candy rolls, with high vitamin C *
81103041	Margarine-like spread, made with yogurt, stick, salted
81104011	Margarine-like spread, reduced calorie, about 40% fat, made with yogurt, tub, salted
83107100	Mayonnaise, made with yogurt *
83115000	Yogurt dressing *
91731150	Peanuts, yogurt covered *
91739600	Raisins, yogurt covered *

* Citrus fiber was present in a subcomponent of the food item. See section 3.1 of this report.

Exhibit I. Report of the Expert Panel

OPINION OF AN EXPERT PANEL ON THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF CITRUS FIBER FOR USE IN FOOD

Introduction

An independent panel of experts (Expert Panel), qualified by scientific training and experience to evaluate the safety of food and food ingredients, was requested by Cargill, Incorporated (Cargill) to determine the safety and Generally Recognized As Safe (GRAS) status of the use of CitriTex® citrus fiber in foods. Cargill intends to use CitriTex® citrus fiber as a texturizer and moisture retention agent in yogurt, low-fat mayonnaise, ice cream, ice pops and sorbet, and processed meat and poultry products, in accordance with current Good Manufacturing Practices (cGMP). The amount used will not exceed the amount reasonably required to accomplish its intended technical effect.

A safety review based on the existing scientific literature (through May 2015) on: (1) the safety of citrus fiber, (2) the safety of other plant-derived fiber ingredients, and (3) the specific properties of CitriTex® citrus fiber was conducted by ToxStrategies, Inc. (ToxStrategies) and is summarized in the attached dossier. The Expert Panel members reviewed the dossier prepared by ToxStrategies and other pertinent information and unanimously agreed to the conclusions described below.

Description

Cargill's citrus fiber is a food ingredient composed of citrus fiber (cellulose, hemicellulose, and pectin) from lemon, lime, and orange peels and is blended with sucrose to standardize functional properties. The trade name of Cargill's citrus fiber product is CitriTex® citrus fiber.

Manufacturing Process (Confidential Business Information)

Cargill's citrus fiber product is derived from lemon, lime, and orange peels. It is manufactured following cGMP for food in accordance with Title 21 of the U.S. Code of Federal Regulations (CFR) Part 110, utilizing raw materials and processing aids that are appropriate for use in foods. The main raw materials for the citrus fiber production line are the partially de-pectinized peels (named spent peels), which provide spent peels to the citrus fiber production line.

The first step in the manufacturing process (conducted in the dilution tank) is hydration of the spent peels and reduction of the dry substance of the spent peels. Seeds and other large materials are removed from the hydrated peels and discarded. The next step in the manufacturing process results in a functional (i.e., optimized) spent peel fibers product. Sodium bisulfite (NaHSO3) is used in the functionalization step to remove residual hydrogen peroxide (H_2O_2) from the process stream. The remaining concentration of bisulfite is <10 ppm. The specific process in the functionalization step depends on the final application of the citrus fiber product (bleached or non-bleached product desired).

Bleaching is considered an optional processing step. The bleached (or non-bleached) spent peels are then activated in two steps: wet milling and high-pressure homogenization, where the fibers in the spent peels are micronized, modifying their structure and substantially increasing their surface area. The homogenized fibers then enter an isopropyl alcohol (IPA) precipitation step where the fibers are first precipitated and then re-dissolved/precipitated twice with IPA. The citrus fibers are then conveyed into a desolventizing vessel and sucrose (solid or liquid) is added. The mixing time in the conveyer is sufficient to dissolve the sucrose into the available liquid (IPA/water). The solids are then heated directly and indirectly with steam in order to reduce the IPA content of the solids. Once the IPA is removed from the solids, they are transferred into a dryer in order to reduce the water content of the final product. The solid dried product is then milled and classified to ensure that product particle size is <250μm (greater than 90% of particles), in accordance with product specifications. From the mill, the product is then transferred to the packaging area where it is packaged to meet final customer requirements.

Analytical (chemical and microbiological) results for CitriTex® citrus fiber confirm that the finished product meets the proposed specifications as demonstrated by the consistency of production, the lack of impurities/contaminants (e.g., heavy metals, pesticides, microbiological toxins), and its stability over a 12-month period.

History of Use

There is common knowledge of a long history of human consumption of citrus fruits and products derived from these fruits. Citrus fruits have been consumed for thousands of years. In the absence of product-specific toxicological studies, the safety of Cargill's citrus fiber ingredient for the proposed uses in select food products (i.e., yogurt, low-fat mayonnaise, ice cream, ice pops and sorbet, and processed meat and poultry products) can be established based in part on the historical consumption of citrus fruits and citrus fibers through their natural occurrence in citrus fruits. Citrus fiber-based ingredients have been used in the food industry for a long time (e.g., orange peel in marmalade). Fiber from the edible portions of oranges (e.g., pectin, pulp, juice sacs, segment membranes) is used in a variety of food products. Pectin, the fiber fraction of cell wall material, is important for gelling and moisture binding of baked products, dairy, sweet spreads, and beverages and is recognized as GRAS (21 CFR § 184.1588; use levels in food not to exceed cGMP). The albedo part of citrus peel is an abundant source of dietary fibers, including hemicelluloses, pectin, and cellulose. Cellulose, hemicellulose, and/or pectin are common components of grains and fruits and grain- and fruit-based food ingredients such as citrus fiber. In addition, various forms of cellulose are common food ingredients, recognized by the FDA as multipurpose additives permitted for direct addition to foods [e.g., ethyl cellulose (21 CFR § 172.868), hydroxypropyl cellulose (21 CFR § 172.870), methyl ethyl cellulose (21 CFR § 172.872)].

Fruits contain many biologically active substances, which have been proposed to have various health benefits. These substances include dietary fiber, carotenoids, vitamin C, folic acid, selenium, potassium, and many phytochemicals. In particular, nutrients in

citrus fruits and their juices have been shown to promote health and protect against chronic disease. Increased dietary intake of fruits and vegetables is associated with a decreased risk of common human cancers, including breast, lung, colon, and prostate.

Consumption of dietary fiber leads to many health benefits, including lower risk of obesity, hypertension, coronary heart disease, stroke, diabetes, and various gastrointestinal (GI) diseases. Total fiber intake influences several metabolic functions, including fat metabolism and absorption of nutrients and carbohydrates.

Adequate fiber intake recommendations for adults (≤ 50 years of age) are 38 g total dietary fiber/day for men and 25 g total dietary fiber/day for women (IOM, 2015). For adults greater than 50 years of age, the Institute of Medicine (IOM) recommends 30 g/day and 21 g/day for men and women, respectively. It is notable that most Americans need to increase their intake of dietary fiber. The daily value (DV) for dietary fiber is 25 g for a 2000 calorie diet per 21 CFR § 101.9(d).

To date, FDA has reviewed extensive published information and data as part of GRAS notifications for citrus fiber and other vegetable/grain-based fiber sources and subsequently issued "no question letters" [e.g., GRN No. 154 (dried orange pulp); GRN No. 487 (dried citrus pulp); GRN No. 116 (carrot fiber); GRN No. 207 (barley fiber); GRN No. 261 (oat hull fiber); GRN No. 310 (potato fiber); GRN No. 342 (oat hull fiber); GRN No. 344 (barley fiber); GRN No. 373 (rice bran fiber); GRN No. 427 (corn hull fiber); GRN No. 430 (sugar beet fiber); GRN No. 525 (pea fiber)]. No recent studies raising any new safety concerns about citrus fiber or plant-based fiber ingredients and their addition to processed foods have appeared in the published literature subsequent to these evaluations.

Intended Use and Intake Assessment

The focus of this GRAS assessment is the use of citrus fiber in low-fat mayonnaise, ice cream, ice pops, and sorbet at levels not to exceed 4%. The use level in processed meat and poultry products will not exceed 5%. The intended uses of CitriTex® citrus fiber will substitute for other current citrus and dietary fiber sources in these foods without being additive to the diet.

The 2-day average intake of citrus fiber was estimated for the US population 2+ years of age using the National Health and Nutrition Examination Survey (NHANES) conducted in 2009-2010 and 2011-2012. The estimated daily intakes (EDI) of citrus fiber were calculated on a *per capita* and *per user* basis in units of g/day and g/kg bw/day. It should be noted that the estimated intake values presented below are for CitriTex® citrus fiber, not citrus fiber alone. CitriTex® citrus fiber is approximately 60-70% fiber (insoluble/soluble), with the remainder being sucrose. The *per user* mean and 90th percentile background intake of citrus fiber from the proposed food uses was estimated to be 6.40 g/day (0.11 g/kg bw/day) and 9.76 g/day (0.18 g/kg bw/day), respectively for the US population 2+ years of age.

GRN No. 487 (2013) for Fiberstar's dried citrus pulp product estimated the *per user* daily intake of citrus fiber from many additional proposed food uses for the US population 2+ years of age to be 23.4 g/day (0.4 g/kg bw/day) and 39.5 g/day (0.8 g/kg bw/day) at the mean and 90th percentile, respectively. GRN No. 541 for Ceamsa's product (insoluble fiber from citrus peel) reported a *per user* daily intake of fiber, also from many additional proposed food uses, for the US population 2+ years of age to be 20.24 g/day and 34.17 g/day at the mean and 90th percentile, respectively. Both of these recent GRAS notifications provided estimates of fiber intake much higher than that from the proposed uses of CitriTex® citrus fiber.

GRN No. 487 (2013) for Fiberstar's dried citrus pulp product also estimated the background exposure to citrus fiber based on the total dietary fiber content in orange and other citrus-based foods and beverages. The *per user* mean and 90th percentile background intake of citrus fiber was estimated to be 0.7 g/day (0.01 g/kg bw/day) and 1.6 g/day (0.03 g/kg bw/day), respectively for the US population 2+ years of age. Therefore, taking into account the additional intake estimated from the proposed uses of CitriTex® citrus fiber, the estimated *per user* mean and 90th percentile cumulative exposure to citrus fiber is 7.1 g/day (0.12 g/kg bw/day) and 11.36 g/day (0.21 g/kg bw/day), respectively for the US population 2+ years of age.

The use of citrus fiber as proposed is considered to be self-limiting for technological reasons such as product thickness/texture.

Safety Data

There is common knowledge of a long history of human consumption of whole citrus fruits and products derived from these fruits. Citrus fiber-based ingredients have been used in the food industry for a long time (e.g., orange peel in marmalade). Fiber from the edible portions of oranges (e.g., pectin, pulp, juice sacs, segment membranes) is used in a variety of food products. Pectin, the fiber fraction of cell wall material, is important for gelling and moisture binding of baked products, dairy, sweet spreads, and beverages and is recognized as GRAS (21 CFR § 184.1588; use levels in food not to exceed cGMP). The albedo part of citrus peel is an abundant source of dietary fibers, including hemicelluloses, pectin, and cellulose. Cellulose, hemicellulose, and/or pectin are common components of grains and fruits and grain- and fruit-based food ingredients such as citrus fiber. In addition, various forms of cellulose are common food ingredients, recognized by the FDA as multipurpose additives permitted for direct addition to foods [e.g., ethyl cellulose (21 CFR § 172.868), hydroxypropyl cellulose (21 CFR § 172.870), methyl ethyl cellulose (21 CFR § 172.872)]. As mentioned above, the intended uses of CitriTex® citrus fiber will substitute for other current citrus and dietary fiber sources in the proposed foods.

Importantly, studies of citrus fruits and citrus fiber sources in humans and/or animals have demonstrated its safety as well as beneficial effects. Safety studies of dietary fiber sources including citrus fiber, vegetable/grain-based fiber, and cellulose and modified cellulose ingredients have been conducted at current levels of fiber consumption and

above. *In vivo* and *in vitro* human and animal studies utilizing citrus fruits and their components (e.g., cellulose, hemicellulose) were reviewed and both their safety and/or potential health benefits summarized. Several studies of cellulose and its derivatives in different species, following oral and non-oral routes of exposure, have been published and summarized in GRAS notifications for cellulose-related ingredients and/or vegetable/grain fiber sources. The toxicological data on cellulose and modified celluloses include acute toxicity studies, subchronic toxicity studies, carcinogenicity and genotoxicity studies, as well as reproductive and developmental toxicity studies. No significant adverse effects associated with dietary fiber, cellulose, modified cellulose, or citrus fiber consumption were reported in the published literature.

Citrus fruits are not listed among the major food allergens by FDA (www.fda.gov/Food/ResourcesForYou/Consumers/ucm079311.htm). While allergic reactions to citrus juice or fruits are uncommon, citrus fruits have been linked to allergenic reactions in sensitive adults. Allergy to citrus fruits is often associated with sensitization to other plants and pollinosis (hay fever) due to cross-reactivity. However, GRN 487 (2013) for a similar citrus fiber product (dried citrus pulp) contains an expert opinion letter from Steve L. Taylor, Ph.D. that states "the citrus fiber products are not likely to pose any allergenic risk even to the few citrus-allergic consumers in the population. Additionally, if these citrus fiber products are labeled as recommended, the presence of a citrus-based ingredient would be readily identifiable on the ingredient statement and individuals with allergies to citrus fruits would likely avoid the product."

Fruits contain many biologically active substances, which have been proposed to have various health benefits. These substances include dietary fiber, carotenoids, vitamin C, folic acid, selenium, potassium, and many phytochemicals. In particular, nutrients in citrus fruits and their juices have been shown to promote health and protect against chronic disease. Increased dietary intake of fruits and vegetables is associated with a decreased risk of common human cancers, including breast, lung, colon, and prostate.

Consumption of dietary fiber leads to many health benefits, including lower risk of obesity, hypertension, coronary heart disease, stroke, diabetes, and various GI diseases. Total fiber intake influences several metabolic functions, including fat metabolism and absorption of nutrients and carbohydrates.

Insoluble materials that are rich in fiber have been shown to have beneficial effects, such as reduction of glucose absorption, slowing of glucose absorption and starch digestion, and control of postprandial serum glucose levels. Citrus peel contains large amounts of insoluble fiber-rich fractions (FRFs) including insoluble dietary fiber (main fraction), water-insoluble solid and alcohol-insoluble solid, which are primarily composed of cellulose and pectic substances.

General Recognition of the Safety of Citrus Fiber

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

- The citrus fiber that is the subject of this notification is composed of fiber from the peels of lemons, limes, and oranges. The citrus fiber product is manufactured consistent with cGMP for food (21 CFR Part 110). The raw materials and processing aides used in the manufacturing process are food grade and/or approved for use as in food.

- There is a common knowledge of a long history of human consumption of citrus fruits and citrus fiber. Numerous food products containing citrus fiber and/or fiber derived from other fruits, vegetables, and grains are marketed in the U.S. and around the world, and citrus fiber has become a desirable ingredient for addition to a variety of food products as a texturizing and moisture retention agent as well as a source of dietary fiber.

- Safety studies of dietary fiber sources including citrus fiber, vegetable/grain-based fiber, and cellulose and modified cellulose ingredients have been conducted at current levels of fiber consumption and above. *In vivo* and *in vitro* human and animal studies utilizing citrus fruits and their components (e.g., cellulose, hemicellulose) were reviewed and both their safety and/or potential health benefits summarized. Several studies of cellulose and its derivatives in different species, following oral and non-oral routes of exposure, have been published and summarized in GRAS notifications for cellulose-related ingredients and/or vegetable/grain fiber sources. The toxicological data on cellulose and modified celluloses include acute toxicity studies, subchronic toxicity studies, carcinogenicity and genotoxicity studies, as well as reproductive and developmental toxicity studies. No significant adverse effects associated with dietary fiber, cellulose, modified cellulose, or citrus fiber consumption were reported in the published literature. In addition, a number of studies of citrus fruits and citrus fiber sources in humans and/or animals have demonstrated a number of beneficial effects as well as safety.

- Adequate fiber intake recommendations for adults ($\leq$ 50 years of age) are 38 g total dietary fiber/day for men and 25 g total dietary fiber/day for women (IOM, 2005). For adults greater than 50 years of age, the IOM recommends 30 g/day and 21 g/day for men and women, respectively. It is notable that most Americans need to increase their intake of dietary fiber. The DV for dietary fiber is 25 g for a 2000 calorie diet per 21 CFR § 101.9(d). The intended uses of CitriTex® citrus fiber will provide an alternative to other current citrus and dietary fiber sources in the proposed foods, at a *per user* mean level of 6.40 g CitriTex® citrus fiber/day.

- To date, FDA has reviewed extensive published information and data as part of

GRAS notifications for citrus fiber and other vegetable/grain-based fiber sources and subsequently issued "no question letters" [e.g., GRN No. 154 (dried orange pulp); GRN No. 487 (dried citrus pulp); GRN No. 116 (carrot fiber); GRN No. 207 (barley fiber); GRN No. 261 (oat hull fiber); GRN No. 310 (potato fiber); GRN No. 342 (oat hull fiber); GRN No. 344 (barley fiber); GRN No. 373 (rice bran fiber); GRN No. 427 (corn hull fiber); GRN No. 430 (sugar beet fiber); GRN No. 525 (pea fiber)].

- The publicly available scientific literature on the consumption and safety of dietary fiber (vegetable/grain-based fiber), citrus fiber, and cellulose and modified cellulose ingredients in animal studies as well as clinical studies in humans, is sufficient to support the safety and GRAS status of the proposed citrus fiber product.

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

Conclusions of the Expert Panel

We, the undersigned members of the Expert Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use and safety of the CitriTex® citrus fiber product. We conclude that citrus fiber produced by Cargill under the conditions described in the attached dossier and meeting Cargill specifications is safe.

We further unanimously conclude that the intended use of citrus fiber in food, meeting the specifications described above, is Generally Recognized As Safe (GRAS) based on scientific procedures and that other experts qualified to assess the safety of foods and food additives would concur with these conclusions.

_____ _____

James R. Coughlin, PhD, CFS — Date
Consultant
Coughlin & Associates

_____ _____

Carol A. Knight, PhD — Date
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Knight International

_____ _____

I. Glenn Sipes, PhD, Fellow AAAS and ATS — Date
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(b) (6)

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SUBMISSION END