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Original Submission

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September 8, 2014

GRN 000541

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OFFICE OF
FOOD ADDITIVE SAFETY

BY FEDERAL EXPRESS

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

Re: GRAS Notification for Citrus Fiber

Dear Sirs:

On behalf of our client, Ceamsa Polígono Industrial As Gándaras s/n Spain, we are hereby submitting the enclosed GRAS Notification for citrus fiber to be used as a food ingredient when used in the applications and under the conditions of use described herein. In compliance with 21 C.F.R. §170.36 (b) (proposed), we are enclosing an original and four copies of this notice.

Should you have any questions regarding this Notice, please do not hesitate to contact me.

Sincerely,

(b) (6)

Mark L. Itzkoff

GRAS EXEMPTION CLAIM

I. Claim of GRAS Status

A. Claim of Exemption from the Requirement for Premarket Approval Requirements Pursuant to Proposed 21 CFR § 170.36(c)(1):

Ceamsa, Spain has determined that Citrus Fiber is Generally Recognized As Safe (GRAS), consistent with Section 201(s) of the *Federal Food, Drug, and Cosmetic Act.* This determination is based on scientific procedures as described in the following sections, under the conditions of its intended use in selected food. Therefore, the use of Citrus Fiber is exempt from the requirement of premarket approval.

Signed:

(b) (6) [redacted]

29/8 2014.

Karen Laustsen — Date

Director R&D and
Technical Customer Service

Ceamsa Polígono Industrial As Gándaras s/n Spain

COMPAÑÍA ESPAÑOLA DE ALGAS MARINAS, S.A.
Polig. Ind.
Las Gándaras
Tel.: 986 344 089
PORRIÑO

B. Name and Address of Notifier:

Ceamsa
Polígono Industrial As Gándaras s/n
36418Porriño-Pontevedra
Spain

Phone: +34986344089
Fax: +34986336621
www.ceamsa.com

C. Common or usual name of the notified substance:

Citrus fiber, citrus pulp, Ceamfiber™. In addition to Ceamfiber brand name, Ceamsa may develop additional trade names for its range of citrus fiber products. At present the citrus fiber products will be marketed under the trade names Ceamfiber 7000, Ceamfiber 7000F and Ceamfiber 7000SF.

D. Conditions of use:

The citrus fiber is intended for use as a moisture retention agent, flavor enhancing agent, or as a processing aid in baked goods, pastas, salad dressings, confectionery, processed cheese spreads, frozen food entrees, and comminuted and whole muscle meat and poultry products at a maximum level of 5%; and as a flavor enhancer in non-carbonated beverages and fruit drinks; as seasoning in brine and in comminuted and whole muscle meat and poultry products, and as an ingredient in salads, sauces, meats, fillings, dips, baked goods, dairy products, fruit- and vegetable-based products, and pizza products at a maximum level of 5%. In some instances, the citrus fiber products may be supplied in combination with other permissible food ingredients.

The intended use levels of citrus fiber products and the food categories to which Citrus Food products will be added are same as those described for citrus flour in GRN 154 and GRN 487. Further, citrus fiber will be used in place of the Citrus Flour that was the subject of GRNs 154 and 487. Thus, the use of citrus fiber will not result in an increase in the dietary intake of dietary fiber, the main component of both citrus fiber and Citrus Flour. Given that the two ingredients will be used in the same applications at the same concentrations, one can rely upon the intake assessments described in GRN 487 to determine the estimated daily intake (EDI) of citrus fiber. In GRN 487, the estimated mean and 90^{th} percentile intake of Citrus Flour was calculated to be 23.4 g/day (0.4 g/kg bw/day) and 39.5 g/day (0.8 g/kg bw/ day), respectively. As the total fiber content of the citrus fiber products is 86.5%, the estimated mean and 90^{th} percentile fiber intake from the intended uses will be 20.24 and 34.17 g/day, respectively.

Table I
Proposed Food Uses, Use Levels and Technical Effects of citrus fiber products

Food Categories	Intended Use Levels	Technical Effects
Baked goods, pasta, salad dressing, confectionery, processed cheese spreads, frozen food entrees	Up to 5%	Moisture retention
Non-carbonated beverages, fruit drinks	Up to 2%	Flavor enhancer
Processed meat and poultry products	Up to 3%	Moisture retention and seasoning brine and solutions
Salad, sauces, meats, fillings, dips, bakery, dairy, fruit and vegetable based products, and pizza products	Up to 1%	Processing aid

E. Self-limiting levels of use:

Citrus fiber has self-limiting levels of use due to the high water-retention capacity of the products. When used above the self-limiting levels of use there is a loss of desirable eating qualities and processability.

F. Technical effects

Ceamsa's citrus fiber displays excellent water binding and fat binding properties. Technical food uses include use as a moisture retention agent, fat binding agent and processing aid.

G. Basis for the GRAS Determination

In accordance with 21 CFR 170.30 (proposed), Ceamsa has determined, based on scientific procedures that citrus fiber is Generally Recognized As Safe (GRAS) for the applications detailed in Table 1. A comprehensive search of the scientific literature was utilized for this determination. There exists sufficient qualitative and quantitative scientific evidence, including human and animal data, to determine that the proposed use of citrus fiber is safe. Citrus or orange derived product, primarily containing fiber, has been the subject of two GRAS notifications (GRN 154, GRN 487). In response to these GRAS notices, FDA did not question the conclusions that the use of dried orange pulp and citrus flour products is GRAS under the conditions of use described in the notices. In the most recent GRAS notice (GRN 487), citrus flour products were derived from juice cells, peels, rag or segment membranes, and cores from mandarin oranges (excluding bitter oranges), lemons, limes, grapefruits, and tangerines.

The citrus fiber described in this Notice is similar to the subject of GRN 487 GRAS (citrus flour), both substances are primarily dietary fiber. However, the percentage of soluble and insoluble fibers is different. In GRN 487, the total dietary fiber is approximately 75% with about 50% each of soluble and insoluble fiber. The subject of the present GRAS determination contains 86.5% total dietary fiber of which 85% is insoluble fiber. From safety point of view, both soluble and insoluble fibers are not digested in the human gastrointestinal track; soluble fiber is fermented by bacteria in the digestive tract, insoluble fiber is not fermented. Insoluble fiber is excreted from human gastrointestinal track, without any absorption. The safety determination of citrus fiber for the present GRAS assessment is based on the totality of the available scientific evidence that includes human observations, and preclinical and clinical studies. Based on the available information, the estimated daily intake of citrus fiber, if ingested daily over a lifetime, is considered safe.

H. Availability of Information

The data and information that serve as the basis for this GRAS Notification will be sent to the U.S. Food and Drug Administration (FDA) upon request, or will be available for review and copying at the offices of notifier. Should the FDA have any questions or additional information requests regarding this notification, Ceamsa will supply the data and information.

II. Detailed Information About the Identity of the Notified Substance:

(a) Common or usual name

Citrus fiber, citrus pulp

(b) Product description

Ceamsa's dried citrus fiber products derived from citrus fruit peels contains carbohydrates, fiber (primarily insoluble), ash and small amounts of protein and fat. A summary of the fiber types present in citrus fiber is provided in Table II.1, below.

Table II.1

Fiber types identification

PARAMETER	RESULT	UNITS	REFERENCE METHOD
Cellulose	66.95	%	Calculation
Hemicellulose	14.32	%	Calculation
Neutral detergent fiber	95.05	%	Van Soest
Acid detergent fiber	80.73	%	Van Soest
Acid detergent lignin	13.16	%	Van Soest

Pectin	168	mg/kg	HPLC
Neutral detergent fiber (NDF): hemicellulose, cellulose, lignin, cutin Acid detergent fiber (ADF): cellulose, lignin, cutin Acid detergent lignin (ADL): lignin, cutin			

The citrus fiber may be blended with other suitable ingredients, *e.g.*, xanthan gum, and provided to food processors as a blended product.

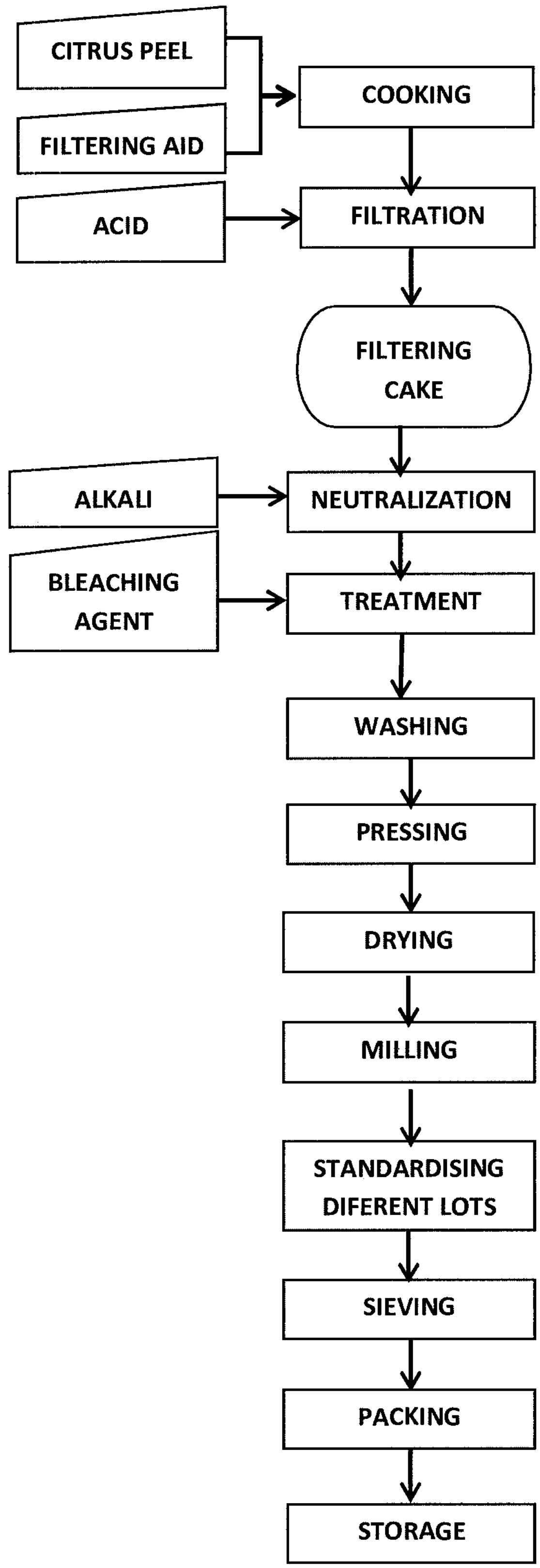
Xanthan gum is approved for use as a stabilizer, emulsifier, thickener, suspending agent, bodying agent or foam emulsifier under 21CFR §172.695. The amount of xanthan gum in foods resulting from addition of the Citrus Fiber product would be comparable to that affirmed as GRAS by FDA. At present, Citrus Fiber products e.g., Ceamfiber 7000, Ceamfiber 7000F and Ceamfiber 7000SF will be supplied to customers as either a powder or in blends with xanthan gum or other cleared food additives.

(c) Method of manufacture

The manufacture of citrus fiber products begins with the citrus peel, including lemon and lime peel, from the citrus processing operation. The peel is collected in a surge tank and mixed with water and food grade acid. The mixture is then cooked at 70°C for 6 hours with agitation. Cellulose (filtering aid) is added to the mixture in the cooking tank. The mixture is filtered using a vacuum filter to separate the soluble fiber portion for pectin processing. The insoluble fiber (filtered cake) is passed through a second filter and then transferred to a tank with fresh 80°C water. The insoluble fiber is subjected to neutralization and activation with sodium hydroxide. A bleaching agent is added and the mixture is agitated for 2 hours while holding the temperature at 80°C. The mixture is then subjected to 0.032% sodium hypochlorite with water three times while pressing the product after each wash and then pumped into a drying system. The drying system reduces the moisture content of the pulp down to 10% moisture so that it is shelf stable under ambient condition. From the dryer, the product is collected in a surge hopper where it is stored until it is ground. The dried product is then milled and sieved to the desired particle size (Ceamfiber 7000, 90% below 350 microns, Ceamfiber 7000F, 90% below 200 microns, Ceamfiber 7000SF, 90% below 75 microns) after which it goes through a metal detector and then packaged in 20KG poly-lined paper bags. The product is labeled Ceamfiber 7000, Ceamfiber 7000F or Ceamfiber 7000SF.

Processing aids used in the manufacturing process are all of food-grade quality as specified in the 8th Edition of Food Chemicals Codex. Ceamsa utilizes a HACCP-controlled manufacturing process. Citrus fiber products are manufactured according to current Good Manufacturing Practices.

Figure 1: Schematic overview of the manufacturing process for Ceamfiber 7000



(d) Characteristic properties

The product is a light beige powder, odorless and tasteless. The specifications for Ceamfiber 7000, Ceamfiber 7000F and Ceamfiber 7000SF are listed in section F.

(e) Any content of potential human toxicants

None

(f) Specifications for Ceamfiber, citrus fiber products

Typical food grade specifications of citrus fiber products (Ceamfiber 7000, Ceamfiber 7000F and Ceamfiber 7000SF) are summarized below. The only difference between the products is the particle size.

CEAMFIBER 7000

PHYSICAL/CHEMICAL SPECIFICATIONS	
Water absorption by centrifugation	**: Min. 8 (MA-703)**
Limits (% in ready product):	
Protein	**2.0%**
Fat	**<5.0%**
Ash	**≤3.0%**
Total Dietary fibre	**86.0 ± 3.0%**
As soluble fibre	*≤8.0%*
Moisture	**9.0%**

OTHER CHARACTERISTICS	
pH	: 7 – 9 (1.0% solution).
Loss on drying	: Not more than 12 %.
Particle size	: Free-flowing powder, 90 % below 350 microns (45 US mesh, DIN 18) (MA-72).
Total plate count	: Max. 10.000 cfu/g.
Mould and yeast	: Max. 500 cfu/g.
Pathogenic bacteria	: Negative by tests. **(E.Coli, Salmonella spp.)**
Heavy Metals	: < 20 ppm
As	: < 3 ppm
Pb	: < 5 ppm
Hg	: < 1 ppm
Cd	: < 1 ppm
Zn	: < 25 ppm
Cu + Zn :	<50 ppm

CEAM FIBER 7000F

PHYSICAL/CHEMICAL SPECIFICATIONS

Water absorption by centrifugation : Min. 4 (MA-703)

Limits (% in ready product):	
Protein	**2.0%**
Fat	**<5.0%**
Ash	**≤3.0%**
Total Dietary fibre	**86.0 ± 3.0%**
As soluble fibre	*≤8.0%*
Moisture	**9.0%**

OTHER CHARACTERISTICS

pH : 7 – 9 (1.0% solution).
Loss on drying : Not more than 12 %.
Particle size : Free-flowing powder, 90 % below 200 microns (70 US mesh, DIN 28) (MA-72).

Total plate count : Max. 10.000 cfu/g.
Mould and yeast : Max. 500 cfu/g.
Pathogenic bacteria : Negative by tests.
(E.Coli, Salmonella spp.)
Heavy Metals : < 20 ppm
As : < 3 ppm
Pb : < 5 ppm
Hg : < 1 ppm
Cd : < 1 ppm
Zn : < 25 ppm
Cu + Zn : <50 ppm

CEAMFIBER 7000SF

PHYSICAL/CHEMICAL SPECIFICATIONS

Water absorption by centrifugation : Min. 4 (MA-703)

Limits (% in ready product):	
Protein	**2.0%**
Fat	**<5.0%**
Ash	**≤3.0%**
Total Dietary fibre	**86.0 ± 3.0%**
As soluble fibre	*≤8.0%*
Moisture	**9.0%**

OTHER CHARACTERISTICS

pH : 7 – 9 (1.0% solution).
Loss on drying : Not more than 12 %.
Particle size : Free-flowing powder, 90 % below 75 microns (200 US mesh, DIN 78) (MA-72).

Total plate count : Max. 10.000 cfu/g.
Mould and yeast : Max. 500 cfu/g.
Pathogenic bacteria : Negative by tests.
(E.Coli, Salmonella spp.)
Heavy Metals : < 20 ppm
As : < 3 ppm
Pb : < 5 ppm
Hg : < 1 ppm
Cd : < 1 ppm
Zn : < 25 ppm
Cu + Zn : <50 ppm

Analysis of 3 non-consecutive lots of Citrus Fiber demonstrates that the manufacturing process as described in Section II C produces a consistent product which is in compliance with the product specifications. The analytical results from the testing of 3 lots of Citrus Fiber is presented below in Table II.2, below. The full analytical reports are attached in Appendix I.

Table II.2

Results of Tests on Individual Lots

Parameter	Limit	[redacted]	[redacted]	[redacted]
Moisture	$\leq$ 9.0%	5.78 %	5.14 %	5.18 %
Protein	$\leq$ 2.0%	0.31	0.60	0.33
Total Fat	$\leq$ 0.5%	4.40	3.64	3.26
Ash	$\leq$ 2.0%	2.05	2.49	2.21
Total Dietary Fiber	$\leq$ 86.5%	87.68	83.36	86.79
Sol. Fiber	$\leq$ 1.5%	6.53	6.52	3.49
Insol. Fiber	$\leq$ 85.0 %	81.15	76.84	83.30

Table II.3 presents the results of testing of 3 lots of citrus fiber for aflatoxin, heavy metals and pesticide residues. The full reports are included in Appendix III.

Table II.3

Aflatoxin, Heavy Metals and Pesticide Residue

PARAMETER	RESULT	UNITS	REFERENCE METHOD
AFLATOXIN B1	<1	µg/kg	ELISA
AFLATOXIN B2	<1	µg/kg	ELISA
AFLATOXIN G1	<1	µg/kg	ELISA
AFLATOXIN G2	<1	µg/kg	ELISA
ARSENIC	<0.10	mg/kg	Digestion. ICP.
COPPER	0.48	mg/kg	Digestion. ICP.
CADMIUM	<0.050	mg/kg	Digestion. ICP.

LEAD	<0.050	mg/kg	Digestion. ICP.
MERCURY	<0.0030	mg/kg	Digestion. AAS.
ZINC	<0,50	mg/kg	Digestion. ICP.
ORGANOCHLORIDE PESTICIDES	Not detected	mg/kg	CG/MS

Samples from lots (b) (4) [redacted] were also tested for active microorganisms. No active microorganisms were detected. The results of the testing are summarized in Table II.4, below:

<u>Analytical Limits</u>

Total plate count: Max. 10.000 cfu/g.
Mould and yeast: Max. 500 cfu/g.
Pathogenic bacteria: Negative by tests.
(E.Coli, Salmonella spp.)

Table II.4

Testing for Active Mocroorganisms

Ceamfibre 7000 (specifications)	pH (7-9)	Water absorption by centrifugation (min 8)	Total plate count (UFC/g) <10.000	Mould and yeast (UFC/g)<500	Pathogenic bacteria (E.coli, Salmonella spp.): absence
7000 PT-44577	7.9	8	200	20	Absence
7000F PT-42486	8.5	7.5	200	20	Absence
7000F PT-44160	7.9	7	100	20	Absence
7000SF PT-41889	8.9	7.5	300	15	Absence

(g) Information on any self-limiting levels of use

The use of citrus fiber is self-limiting levels due to the high water-retention capacity of the products. When used above the self-limiting levels of use there is a loss of desirable eating qualities and processability.

(h) Probable consumption of citrus fiber

As shown in Table 1, Ceamsa's citrus fiber products will be used in foods at levels up to 5%. Use levels in processed meat and poultry products will range from 0.1 to 3%.

(i) Use in meat, poultry and egg products

The intended uses of citrus fiber include use as a processing aid in meat and poultry products. Attached in Appendix II are reports of the effectiveness of citrus fiber when used as a moisture retention agent in comminuted meat and injected hams.

An additional intended use of citrus fiber is in liquid, frozen, and dried whole egg products destined for use in egg containing products such as baked good. In these applications citrus fiber is added to improve binding and to stabilize emulsions formed with the processed eggs, *e.g.*, as an agent to assist with whipping.

III. Summary of the Basis for the Notifier's Determination that citrus fiber is GRAS

A comprehensive search of the scientific literature for safety and toxicity information on citrus fiber and other related fibers through June 2014 was conducted and was utilized for this review. Based on a critical evaluation of the pertinent data and information summarized here, Ceamsa has determined through scientific procedures that the addition of citrus fiber products meeting the specification cited above and manufactured according to current Good Manufacturing Practice to the foods listed above, when not otherwise precluded by a Standard of Identity, is Generally Recognized As Safe (GRAS).

In coming to its conclusion that citrus fiber product is GRAS, Ceamsa relied upon the findings that neither citrus fiber product nor any of its constituents pose any toxicological hazards or safety concerns at the intended use levels, as well as on published safety studies and other articles relating to the safety of the product. Other qualified and competent scientists, reviewing the same publicly available toxicological and safety information, would reach the same conclusion.

For example, Citrus Flour products derived from juice cells, peels, rag or segment membranes, and cores from mandarin oranges (excluding bitter oranges), lemons, limes, grapefruits, and tangerines were the subject of GRAS notification GRN 487 to the FDA for use as a food ingredient. The safety and other relevant information described in GRN 487 was considered in evaluating the GRAS status of Ceamsa's proposed use of citrus fiber are hereby incorporated by reference into this document.

A synopsis of the pertinent information is presented below.

IV. Basis for a Conclusion that citrus fiber product is GRAS for its Intended Use

TABLE OF CONTENTS

1. INTRODUCTION

A comprehensive search of the scientific literature for safety and toxicity information on citrus fiber and other related fibers was conducted through June 2014 by Ceamsa, Spain to determine the Generally Recognized As Safe (GRAS) status of citrus fiber products, derived from citrus fruits, including lemon and lime peel, for its intended use as a moisture retention agent, a flavor enhancing agent, and a processing aid in foods.

1.1. Background

In general, complex carbohydrates and lignin that cannot be digested or absorbed in the small intestine, and that can be partially or completely fermented in the large intestine, are called dietary fibers. Fibers are obtained from a great variety of raw materials, mainly processing by-products. The main characteristics of the commercial fibers products that are the subject of this Notice are: total dietary fibers above 85% with insoluble dietary fiber greater than 80%, moisture below 9%, a content of lipids and proteins with a low caloric value, and with a neutral flavor and taste.

The addition of plant fibers to food contributes to water retaining properties and to the viscosity of the product. In a recent article, Vergara (2013) summarized several potential food uses and benefits of citrus fiber. Compared to most other fibers, citrus fibers have better quality due to the presence of associated bioactive compounds, such as flavonoids, polyphenols and carotene (Lario et al., 2004; Vergara, 2013). Additionally citrus fiber product from citrus peel presents a neutral pH which expands the application possibilities to a wider range of food applications, where a natural and neutral flavor is important. Given its technological and other properties, Ceamsa intends to use standardized citrus fiber as a moisture retention agent, a flavor enhancing agent, and a processing aid in selected food products.

1.2. Description, Manufacturing and Specifications

Citrus fiber products (Ceamfiber 7000, Ceamfiber 7000F and Ceamfiber 7000SF), are light beige, odorless and tasteless powders, which are dietary fiber concentrates derived primarily from lemon/lime peel. Typical food grade specifications and compositional analysis of citrus fiber manufactured by Ceamsa are summarized in Section II.F. Analytical results from three non-consecutive batches suggest that the product consistently meets the standard specifications. citrus fiber products are manufactured (Section II.C) according to current Good Manufacturing Practices. Ceamsa utilizes a HACCP-controlled manufacturing process and rigorously tests its final production batches to verify adherence to quality control specifications. The products meet the regulatory prescribed minimum values for heavy metals, pesticide residue and bioburden (cfu). These values are extremely low and far below the requirements.

1.3. History of Occurrence and Use

Oranges and lemons can be traced back to the ancient Middle East. In the classical Indian language Sanskrit, the orange and lemon were called "Nagrunga" and "Nimbu" and their nectar was used both as a drink and for therapeutic purposes. Arabs called oranges "Naranji" while the Romans called them "Arancium." Since ancient times citrus fruit has been cultivated in an ever-widening area around the world. The best-known examples of citrus fruits are the oranges, lemons, grapefruit, and limes. Citrus is a common term and genus (Citrus) of flowering plants in the rue family, Rutaceae. The genus is commercially important as many species are cultivated for their fruit, which is eaten fresh, pressed for juice, or preserved in marmalades, jams, jellies and pickles.

The available information indicates that consumption of citrus fruits is beneficial to human health (Baghurst 2003; McIndoo 2012). Citrus fruits have been reported to contain several bioactive compounds such as phenolics, flavonoids, limonoids, carotenoids, sterols and ascorbic acid that have been claimed to be responsible for various health promoting properties. The high levels of antioxidants, such as vitamin C and flavonoids in citrus fruits, provide protection against free radicals and oxidative stress (Jayaprakasha et al., 2008).

According to the U.S. Department of Agriculture (USDA) citrus fruits include grapefruits, oranges, lemons and limes. These fruits grow in warm climates but are available fresh across the country when other fresh fruits are out of season. Citrus fruits have long been valued as part of a nutritious and tasty diet. Because of their pectin content and water binding capacity, citrus peel has been used for years in preparing food products such as jams, jellies, dry beverage powders, low-calories foods, salad dressings, and yogurt (Braddock, 1983; Nelson, 1979).

1.3.1. Intended Uses and Estimated Daily Intake

Ceamsa intends to market citrus fiber products for use in baked goods, pastas, salad dressings, confectionery, processed cheese spreads, frozen food entrees, and comminuted and whole muscle meat and poultry products at a maximum level of 5%; in non-carbonated beverages and fruit drinks; in brine for use in comminuted and whole muscle meat and poultry products, and in salads, sauces, meats, fillings, dips, baked goods, dairy products, fruit- and vegetable-based products, and pizza products at a maximum level of 5%. The intended use levels of citrus fiber products and the food categories to which it will be added are the same as those described in GRN 154 and GRN 487. As Ceamsa intends to use its citrus fiber in the same foods and at the same use levels of addition as described in GRN 154 and GRN 487, estimates of possible daily intake from the proposed use levels were adapted from GRN 487 (Fiberstar, 2013)

In GRN 487, the estimated intake of Citrus Flour from all proposed food uses was reported as 23.4 mg/day (0.4 mg/kg bw/day) and 39.5 mg/day (0.8 mg/kg bw/day) at the mean and 90th percentile, respectively (Fiberstar, 2013). As the total fiber content of citrus fiber products is 86.5, the estimated mean and 90^{th} percentile fiber intake from the intended uses will be 20.24 and 34.17 g/day, respectively.

2. SAFETY OF CITRUS PRODUCT

2.1. Common Knowledge of Safe Use

There is long history of human consumption of citrus fruits and products derived from these fruits. For centuries, citrus fruits have been used for their juices. Citrus fruits such as oranges, grapefruits, tangerines, and clementines, are generally eaten fresh. More acidic citrus, such as lemons and limes, are not generally eaten on their own. The juices of these fruits are used in the preparation of popular beverages such as lemonade or limeade. Lemons and limes are also used as garnishes or in cooked dishes. Their juice is used as an ingredient in a variety of dishes. Lemon peel is used in pickling. Because of its popular lemony flavor, dried lemon peel has a history of uses in culinary, confectionery and cosmetic applications. Citrus fruit peel like lemon, tangerines can be dried, powdered, and stored for future usage. Citrus fruit rind and oil is generally very bitter, especially when cooked, and so is often combined with sugar. Marmalade, a condiment derived from cooked orange and lemon, can be especially bitter, but is usually sweetened to cut the bitterness and produce a jam-like result. Citrus peel tea has been studied for its health benefits.

A variety of citrus species are sold and consumed throughout the United States. The USDA Fact Book listed the annual per capita United States citrus fruit consumption to be 23.4 pounds (USDA 2002). Among the citrus fruit producers around the world, the United States is the second largest with over $20 billion in retail sales (Patil et al., 2006).

In accordance with 21 CFR 182.20, 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 Act. The relevant citrus species from which GRAS products are derived are described in below table. Additionally, 21 CFR 101.78 permits the health claims for fruits and vegetables and cancer. As per this regulation, oranges are considered a food low in fat and a good source of fiber and vitamin C. Furthermore, Orange peel (CAS No. 9777070-86-2), grapefruit essence (CA No.: 977091-54-5 and 977091-55-6), grapefruit extract (CAS No.: 090045-43-5), lemon peel granules (CAs No.: 977001-83-4), and citrus peel extracts (CAS No.: 977038-62-2) are listed in the FDA inventory of Everything Added to Food in the United States (EAFUS) (FDA, 2008).

Citrus derived essential oils, oleoresins (solvent-free), and natural extractives (including distillates) that are GRAS (21CFR 182.20)	
Common Name	**Botanical name of Citrus source**
Bergamot (bergamot orange)	*Citrus aurantium* L. subsp. bergamia Wright et Arn.
Citrus peels	*Citrus* spp.
Curacao orange peel (orange, bitter peel)	*Citrus aurantium* L.
Grapefruit	*Citrus paradisi* Macf.
Lemon	*Citrus limon* (L.) Burm. f.
Lemon peel	*Citrus limon* (L.) Burm. f.

Lime	*Citrus aurantifolia* Swingl
Mandarin	*Citrus reticulata* Blanco.
Naringin	*Citrus paradisi* Macf.
Neroli, bigarade	*Citrus aurantium* L.
Orange, bitter, flowers	*Citrus aurantium* L.
Orange, bitter, peel	*Citrus aurantium* L.
Orange leaf	*Citrus sinensis* (L.) Osbeck.
Orange, sweet	*Citrus sinensis* (L.) Osbeck.
Orange, sweet, flowers	*Citrus sinensis* (L.) Osbeck.
Orange, sweet, peel	*Citrus sinensis* (L.) Osbeck.
Petitgrain	*Citrus aurantium* L.
Petitgrain lemon	*Citrus limon* (L.) Burm. f.
Petitgrain mandarin or tangerine	*Citrus reticulata* Blanco.
Tangerine	*Citrus reticulata* Blanco.

It is commonly recognized that dietary fiber is an important component of a healthful diet. In general, nutritionists recommend a diet high in fiber (20-35 g fiber/day, or 10-13 g/1,000 kilocalories). The Nutrition Facts panel required under 21 C.F.R. §101.9 provides a good reference, stating as a goal 25 g dietary fiber for a 2,000 kilocalorie/day diet, or 30 g dietary fiber for a 2,500 kilocalorie/day diet. According to the National Center for Health Statistics, consumers average only 14-15 g fiber intake/day, far below moderate levels of dietary fiber. FDA recognizes the importance of fiber in the diet by requiring that fiber occupy a prominent position on the Nutrition Facts panel on food labels.

The food sources of dietary fiber include legumes, nuts, whole grains, bran products, fruits (including citrus fruits), and non-starchy vegetables. All plant-based foods contain mixtures of soluble and insoluble fiber. There is consistent evidence from clinical trials that fiber-rich diets are associated with significant reductions in cardiovascular disease risk. Given this evidence, the Food and Nutrition Board of the Institute of Medicine established its first recommended intake levels for fiber in 2001 (IOM, 2002). For adults ($\leq$ 50 years of age), the adequate intake recommendation for total fiber is 38 g/day for men and 25 g/day for women. For adults ($\geq$ 50 years of age), the recommendation is 30 g/day for men and 21 g/day for women. The daily reference value for dietary fiber is 25 g (for a 2000 calorie diet) [21 CFR 101.9(c)]. Dietary fiber intakes in the U.S. average from 16-18 g/day for men and 12-14 g/day for women, which are well below recommended intake levels (IOM, 2002). The available information demonstrates that there is common knowledge of the health benefits associated with the consumption of the fiber. The available information also suggests that citrus fruits and fruit preparations, including its fiber, are commonly consumed from diet and there are no reported adverse effects from its consumption as a food.

2.2. Similarity with other GRAS products

The subject of the present GRAS assessment, citrus fiber product is similar to the subject of a recent GRAS notice (GRN 487) for Citrus Flour products. Ceamsa recognizes that there are manufacturing differences but the final products are substantially similar. In order to show similarity and differences between these two products, the specifications (typical composition) of citrus fiber product are compared with citrus flour products in the below table.

Comparison of Specifications (composition) of citrus fiber and Citrus Flour (GRN 487)

Parameters	citrus fiber	Citrus Flour (GRN 487)
Total dietary fiber	86.5%	73.4%
Soluble fiber	1.5%	36.0%
Insoluble	85.0%	37.4%
Fat	0.5%	1.04%
Protein	2.0%	7.47%
Moisture	9.0%	6.84%
Ash	2.0%	2.44%
pH	7.0 – 9.0	5.5 – 7.5

The data presented in above table show that dietary fibers are the major components of both Citrus Flour products (GRN 487) and citrus fiber products. However, these two products differ in the percentage of soluble and insoluble fibers. The total dietary fiber in Citrus Flour products is 7.4%, of which 36% is soluble fiber and 37.4% is insoluble fiber. The subject of present GRAS determination, citrus fiber product contains 86.5% total dietary fiber of which 1.5% is soluble fiber and 85% is insoluble fiber. As described in the above table, other parameters are somewhat similar. From safety perspective, these other parameters are unlikely to be of any concern. With regard to the differences in soluble and insoluble fiber, from safety point of view, both soluble and insoluble fibers are not digested in the human gastrointestinal track. As described below, soluble fiber is fermented by bacteria in the digestive tract, while insoluble fiber is not fermented and is excreted in feces without any absorption. Given the lack of metabolism and absorption, insoluble fiber is unlikely to cause any adverse effects. Thus the higher level of insoluble fiber will not affect the safety assessment for citrus fiber and the safety information and GRAS assessment of Citrus Flour products described in GRN 487 are relevant to the present GRAS assessment of citrus fiber products.

Additionally, the available information from the FDA's GRAS inventory[1] website confirms that multiple fiber ingredients derived from other plants or grains are recognized as GRAS for their intended uses in specific food products. The fiber ingredients that received "no questions" letters from the FDA include: Barley Fiber – Cargill Inc., GRN 207; Carrot Fiber – Wm. Bolthouse Farms, GRN 116; Oat Hull Fiber – Grain Millers, Inc., GRN 261; Orange Pulp

[1] Available at: http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing&displayAll=true

– Fiberstar citrus fiber, Citri-Fi, GRN 154; Potato Fiber-Rettenmaier & Sohne, Vitacel® GRN 310; Oat Hull Fiber, J. Rettenmaier USA LP, GRN 342; Barley Fiber, Cargill Incorporated, GRN 344; Oat Hull Fiber, Z-Trim Holding Inc, GRN 366; Corn Hull Fiber, Z-Trim Holding Inc, GRN 368; Rice Bran Fiber, CJ America Inc., GRN 373; Rice Hull Fiber, Ribus Inc., GRN 426; Corn Hull Fiber, Z-Trim Holding Inc, GRN 427; Sugar Beet Fiber, Nordic Sugar A/S, GRN 430; and the above described GRN 487- Dried Citrus Pulp from Fiberstar Inc. In these GRAS notices, the safety of insoluble fiber was also considered. The "no question" letters issued by FDA in response to the GRAS Notices for these different types of dietary fiber suggest that the agency is comfortable with the use of dietary fiber.

2.3. Safety Studies of Citrus and Other Fibers

Given the safe history of consumption of citrus fruit and products derived from it as food and the available scientific literature on the effects of citrus and its fiber in animals and humans, the safety of citrus fiber consumption is not in question. No adverse effects have been reported from the consumption of citrus fiber. Hence, none of the standard basic or screening toxicology studies in laboratory animals are available in the scientific literature for citrus fiber. There are a few studies in the literature where citrus fiber was fed to animals; however, it is important to note that the focus of these studies was not safety endpoints. A thorough search and review of the published scientific literature did not reveal evidence of any adverse effects associated with consumption of citrus fiber. In few studies, effects of citrus fiber have been investigated and these studies are briefly described in the following section.

In a case-control study, Hakim et al. (2000) attempted to determine the usual citrus consumption patterns of an older Southwestern population in Arizona and then evaluated how the citrus consumption varied with history of squamous cell carcinoma (SCC) of the skin. In this Arizona population, 64.3% and 74.5% of the respondents reported weekly consumption of citrus fruits and citrus juices, respectively. Orange juice (78.5%), oranges (74.3%), and grapefruit (65.3%) were the predominant varieties of citrus consumed. Peel consumption was not uncommon, with 34.7% of all subjects reporting citrus peel use. No association between the overall consumption of citrus fruits or citrus juices and skin SCC was noted. However, the most striking result was the protection purported to result from citrus peel consumption. Moreover, there was a dose-response relationship between higher citrus peel in the diet and degree of risk lowering. The results of this study show that peel consumption is not uncommon and may have a potential protective effect in relation to skin SCC.

Reddy et al. (1981) investigated the effect of dietary wheat bran and dehydrated citrus fiber on carcinogenesis of the colon and small intestine in male F344 rats. In this study, weanling rats were fed semi-purified diets containing 5% fat and 15% wheat bran or citrus fiber. The daily intake of citrus fiber was approximately 2.4 g/day or approximately 8 g/kg bw/day assuming a F344 rat weighs 300 g based on feed intake measurements taken during week 10. Starting at 7 weeks of age, all animals, except vehicle-treated controls, received weekly subcutaneous injections of 8 mg azoxymethane (AOM)/kg body weight for 10 weeks. The AOM- or vehicle-treated groups were autopsied 20 weeks after the last injection of AOM. As compared to the animals fed the control diet and treated with AOM, the animals fed the wheat bran or citrus fiber diet and treated with AOM had a lower incidence (number of animals with tumors) and multiplicity (number of tumors/tumor-bearing animal) of colon tumors and tumors of the small intestine. The number of adenomas but not the number of adenocarcinomas was reduced in rats fed the citrus pulp diet. The results of this study indicate that diets containing wheat bran and citrus fiber reduced the risk of intestinal cancer.

In an animal model of atherosclerosis, forty white New Zealand male rabbits (10/group) were fed hypercholesterolemic diet for two months. While the first group was considered as the hypercholesterolemic control, groups 2 and 3 (intervention groups) received 5 ml/day lime juice and 1 g/day dried lime peel powder, respectively. Group 4 was fed a normal diet (normal control). 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. The aorta and coronary arteries were studied for the presence of fatty streaks. When compared to hypercholesterolemic control group, the plasma total antioxidant capacity was significantly increased in rabbits supplemented with lime juice and peel. The presence of fatty streaks in coronary arteries and aorta of the intervention groups was significantly decreased compared to the hypercholesterolemic control group. The investigators noted that lime peel was more effective than lime juice.

In an *in vitro* study, Sunvold *et al.* (1995) evaluated the influence of gastrointestinal tract microflora from several species on fiber fermentation characteristics. Fibrous substrates, such as cellulose, beet pulp, citrus pulp, and citrus pectin were incubated for 6, 12, 24, and 48 hours with inoculum or ruminal fluid from cattle or feces from dogs, cats, pigs, horses, or humans. Based on the pooled data across species, the investigators reported that substrate organic matter disappearance and short chain fatty acids (SCFA) production ranked from least to greatest in the following order: cellulose < beet pulp < citrus pulp < citrus pectin. It should be noted that citrus pectin contains soluble fiber, while citrus pulp contains both soluble and insoluble fiber.

In another *in vitro* study, Bosch et al. (2008) assessed fermentation kinetics and end product profiles of 16 dietary fibers for dog foods using canine fecal inoculum. In this study, gas production, fermentation kinetics, and end product profiles at 8 and 72 hours of incubation for citrus pectin and other fibers was compared. The investigators reported that citrus pectin and pea fiber showed a similar low Rmax (maximal rate of gas production), but the time at which this occurred was later compared with sugar beet fiber, sugar beet pulp, soy fiber, and wheat middlings. It should be noted that citrus pectin contains soluble fiber.

Both soluble and insoluble fibers are not digested in the human gastrointestinal track. Soluble fiber absorbs water to become a gelatinous, viscous substance and is fermented by bacteria in the digestive tract. Insoluble fiber has bulking action and is not fermented (Anderson *et al.*, 2009), therefore insoluble fiber is not absorbed into the bloodstream. Instead of being used for energy, insoluble fiber is excreted from human gastrointestinal track. Insoluble fiber promotes regular bowel movement and prevents constipation.

2.4. Dietary Fiber & Nutrients

The available studies on the effect of fiber on fat-soluble vitamin absorption are inconsistent. Compared to fat-soluble vitamins, the effect of fiber on absorption of water-soluble vitamins is even less understood. Available evidence does not suggest that increased fiber consumption in general is likely to significantly affect mal-absorption of vitamins and minerals (also see Section 2.2.3.). It is known that fat-soluble vitamins are absorbed similar to triacylglycerol. Due to the ability of certain dietary fibers to delay absorption of triacylglycerol, it has been proposed that fiber intake may alter absorption of fat-soluble vitamins. Studies of the effect of fiber consumption on vitamin A absorption were contradictory with studies indicating that wheat bran consumption may either increase (Rattan *et al.*, 1981) or decrease (Wahal *et al.*, 1986) serum vitamin A levels. Limited information is available with regards to the effects of consumption of specific fibers on the absorption of other fat soluble vitamins. In one study published as an abstract, consumption of citrus pectin fiber had no negative effect on the utilization of vitamin B_6 in humans (Miller *et al.*, 1980). Additional details of this study were not available.

The available evidence is not sufficient to draw conclusions concerning the effects of particular fiber types (including citrus fibers) or fiber mixtures on mineral absorption. Although the possibility that fiber consumption could impair mineral status has been raised, it has been argued persuasively by Gordon *et al.* (1995) that evidence to support this contention is lacking. Overall, there is no compelling evidence that consumption of fibers adversely impairs the absorption of vitamins or essential minerals in adequately nourished populations. Furthermore, there is a long history of consumption of fiber-rich foods without any major reports on vitamin-mineral mal-absorption resulting from high fiber intake, therefore it seems unlikely that one would observe any significant effects from the estimated increase in fiber intakes from citrus fiber products containing foods.

2.5. Allerginicity

Citrus fruits are reported to cause occasional allergic reactions, but citrus fruits are not among the most commonly allergenic foods. Allergy to oranges or other citrus fruits has been scarcely investigated (Lopez-Torrejon et al., 2005). Orange allergy is often associated with pollinosis and sensitization to other plants (Lopez-Torrejon et al., 2005) due to a phenomenon of cross-reactivity, whereby the pollen would be the cause of a sensitization by the respiratory way that could predispose to allergy towards foods that contain homologous proteins to those in sensitizing pollen. In another study, Iorio et al. (2013) reported that citrus allergens shared high percentage identity values with other clinically relevant species (i.e. *Triticum aestivum, Malus domestica*), confirming the possible cross-allergenicity citrus/grasses and citrus/apple. In GRN

487, it is mentioned that Citrus Flour products are not "likely to pose any allergenic risk even to few citrus allergic consumers in the population" (Fiberstar, 2013).

Ceamsa acknowledges that citrus fiber products do not contain any of eight foods (Milk, Egg, Fish, Crustacean shellfish, Tree nuts, Peanuts, Soybeans, Wheat) considered to be major food allergens under the U.S. Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

2.6. Dietary Fiber Adverse Effects Reported by IOM

The Institute of Medicine (IOM, 2002) has not established a tolerable upper intake level (UL) for dietary or functional fiber. Some of the fibers such as guar gum, inulin and oligofructose, fructooligosaccharides, polydextrose, resistant starch, and psyllium have been found to cause gastrointestinal distress, including abdominal cramping, bloating, gas, and diarrhea (IOM, 2002). Available evidence also indicates that abrupt increase in the intake of dietary fiber in some people may result in abdominal cramping, bloating or gas. These symptoms can be minimized or avoided by increasing intake of fiber-rich foods gradually and increasing fluid intake to ~2 liters/day. It has been reported that addition of cereal fiber to meals may decrease the absorption of iron, zinc, calcium, and magnesium during the same meal. However, available evidence indicates that phytate present in the cereal fiber rather than the fiber itself may be responsible for the decreased absorption. In general, dietary fiber as part of a balanced diet has not been found to adversely affect the calcium, magnesium, iron, or zinc status of healthy people at recommended intake levels (IOM, 2002).

3. SUMMARY

Citrus fruits have long been valued as part of a nutritious and tasty diet. Citrus fruits and in turn its fiber enjoys a long history of consumption as a food around the world and in the United States. The available information indicates that citrus fiber based ingredients have been around as long as citrus fruits have been harvested. A high daily intake of food sources rich in fiber has been claimed to possess several health benefits. The addition of insoluble dietary citrus fibers in food products contributes to water retaining properties and to the viscosity of the product. Additionally, insoluble citrus fibers can help consumers to meet the health recommendations of dietary fiber reducing the high deficit existing in its consumption.

citrus fiber products is derived from citrus fruits, including lemons and limes, manufactured under the highest standards of food purity, is safe for its intended uses. Ceamsa utilizes a HACCP-controlled manufacturing process and rigorously tests its final production batches to verify adherence to quality control specifications. The manufacturing process and the processing aids used in the production of citrus fiber products are similar to those commonly used in food industry, and the final product meets appropriate food grade specifications. Ceamsa intends to use citrus fiber products as a moisture retention agent, a flavor enhancing agent, or as a processing aid in a variety of food categories. The intended use levels and food categories are same as those described in GRN 487 and GRN 154. Ceamsa estimates that its intended uses of citrus fiber products will result in the estimated mean and 90th percentile intake of citrus fiber products of 23.4 g/day (0.4 g/kg bw/day) and 39.5 g/day (0.8 g/kg bw/day), respectively. The estimated mean and 90th percentile fiber intake from the intended uses will be 20.24 and 34.17 g/day, respectively.

There is common knowledge of human consumption of citrus fruits and its preparation, including the fiber portion. Among different food sources of dietary fiber, fruits (including citrus fruits) are also recognized as an important contributor. All plant-based foods contain mixtures of soluble and insoluble fiber. The IOM recommended intake levels for total dietary fibers ranges from 21 to 38 g/day, while the current dietary fiber intake of 12-18 g/person in the U.S. is well below recommended levels. The daily reference value for dietary fiber for a 2000 calorie diet is 25 g (21 CFR 101.9(d)). The 90th percentile intake of 34.17 g fiber/day from the citrus fiber products uses is similar to the recommended daily intake of dietary fiber. While the intended uses of citrus fiber products may add to the background daily intake of dietary fiber, the available information indicates that it is unlikely to lead to adverse effects. These estimates are based on levels of consumption that comply with dietary fiber source claims which are considered safe as little to no adverse effects have been observed or reported.

The totality of available evidence from dietary consumption of citrus fruits and its preparations for centuries, current intake of dietary fiber, and animal and human studies suggest that consumption of citrus fiber from the intended uses of citrus fiber products for use as a moisture retention agent in baked goods, pastas, salad dressings, confectionery, processed cheese spreads, frozen food entrees, and comminuted and whole muscle meat and poultry products at a maximum level of 5%; and, as a flavor enhancer in non-carbonated beverages and fruit drinks; as seasoning in brine and in comminuted and whole muscle meat and poultry products, and as an ingredient in salads, sauces, meats, fillings, dips, baked goods, dairy products, fruit- and vegetable-based products, and pizza products at a maximum level of 5%, is safe. On the basis of both scientific procedures[2] corroborated by history of exposure from natural dietary sources, Ceamsa considers the consumption of citrus fiber products as an added food ingredient to be safe.

[2] 21 CFR §170.3 Definitions. (h) Scientific procedures include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance.

4. CONCLUSION

Based on the information provided above and the fact that the constituents of citrus fiber are essentially the same as found in citrus fruits and its preparations and are also similar to other dietary fibers, and will be handled metabolically similar to fiber derived from other sources, Ceasma has determined that citrus fiber is safe for the intended applications and that scientific experts, generally, would recognize them to be as safe and as acceptable as other dietary fibers. Further, Ceamsa believe that there are no significant questions regarding the safety of citrus fiber that would require additional safety studies. In light of the data and discussion presented above, Ceamsa respectfully concludes that based on scientific procedures citrus fiber products meeting the specifications cited above, and when used as a moisture retention agent, a flavor enhancing agent, or as a processing aid in selected food categories as described in this GRAS dossier and when not otherwise precluded by Standards of Identity is GRAS.

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Appendix I

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BUREAU VERITAS Certification

ANALYSIS REPORT

N°: 4765/14

LAB REFERENCE: 140814LB21

CLIENT: COMPAÑIA ESPAÑOLA DE ALGAS MARINAS S.A.
P.I. Las Gándaras
36418 Porriño (Spain)

SAMPLE TYPE: Solid powdered sample.

SAMPLE ID: (b) (6) [redacted]

VOLUME: 100 gr. aprox.

DATE RECEIVED: 14/08/2014

BEGINNING: 18/08/2014

END: 29/08/2014

ANALYTICAL RESULTS

ANALYTE	RESULT	UNITS	METHOD
Energy	221	Kcal/100 g	Calculation
Moisture	5,14	%	Gravimetric
Protein	0,60	%	Kjeldahl
Total Fat	3,64	%	Acid hydrolysis/gravimetric
Ash	2,49	%	Gravimetric
Carbohydrate	4,77	%	Calculation
Total dietary fiber	83,36	%	Enzimatic/gravimetric
Insoluble dietary fiber	76,84	%	Enzimatic/gravimetric
Soluble dietary fiber	6,52	%	Calculation

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The laboratory declares that the results relate only to the sample.

(b) (6) [redacted]

Date of report,

Vigo, August 29th 2014

Clara Vieto
Technical Director

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ANALYSIS REPORT

N°: 4766/14

LAB REFERENCE: 140814LB22

CLIENT: COMPAÑIA ESPAÑOLA DE ALGAS MARINAS S.A.
P.I. Las Gándaras
36418 Porriño (Spain)

SAMPLE TYPE: Solid powdered sample.

SAMPLE ID: (b) (6) [redacted]

VOLUME: 100 gr. aprox.

DATE RECEIVED: 14/08/2014

BEGINNING: 18/08/2014

END: 29/08/2014

ANALYTICAL RESULTS

ANALYTE	RESULT	UNITS	METHOD
Energy	213	Kcal/100 g	Calculation
Moisture	5,18	%	Gravimetric
Protein	0,33	%	Kjeldahl
Total Fat	3,26	%	Acid hydrolysis/gravimetric
Ash	2,21	%	Gravimetric
Carbohydrate	2,23	%	Calculation
Total dietary fiber	86,79	%	Enzimatic/gravimetric
Insoluble dietary fiber	83,30	%	Enzimatic/gravimetric
Soluble dietary fiber	3,49	%	Calculation

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Date of report,

Vigo, August 29th 2014

(b) (6) [redacted]

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ANALYSIS REPORT

N°: 4767/14

LAB REFERENCE: 140814LB23

CLIENT: COMPAÑIA ESPAÑOLA DE ALGAS MARINAS S.A.
P.I. Las Gándaras
36418 Porriño (Spain)

SAMPLE TYPE: Solid powdered sample.

SAMPLE ID: (b) (6) [redacted]

VOLUME: 100 gr. aprox.

DATE RECEIVED: 14/08/2014

BEGINNING: 18/08/2014

END: 29/08/2014

ANALYTICAL RESULTS

ANALYTE	RESULT	UNITS	METHOD
Energy	217	Kcal/100 g	Calculation
Moisture	5,78	%	Gravimetric
Protein	0,31	%	Kjeldahl
Total Fat	4,40	%	Acid hydrolysis/gravimetric
Ash	2,05	%	Gravimetric
Carbohydrate	<0,10	%	Calculation
Total dietary fiber	87,68	%	Enzimatic/gravimetric
Insoluble dietary fiber	81,15	%	Enzimatic/gravimetric
Soluble dietary fiber	6,53	%	Calculation

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The laboratory declares that the results relate only to the sample.

(b) (6) [redacted]

Date of report,

Clara Vieto
Technical Director

Vigo, August 29th 2014

Appendix II

Technical Report

Use of citrus fiber as a functional ingredient in comminuted meat products

for

Ceamsa

by

PHD Technologies LLC
3234 Bayberry Road
Ames, IA 50014

July, 2014

Use of citrus fiber as a functional ingredient in comminuted meat products

Introduction

Meat processors have the option of adding binders and water to meat (meat extension) as an economical way to increase yield without changing the nutritional properties while reducing costs. Meat extension is a practical choice for schools, the military and other food service venues (Ellis, 2004). Starches, gums and proteins are common binders in meat extension. Many carbohydrates have the ability to boost the total fiber content when added to meat (Wade, 2004). Fibers are in many ways believed to be functional in that they are associated with a decrease in blood cholesterol levels, and a decrease in blood glucose and insulin response. Fibers also add bulk to the diet contributing little caloric value. Citrus fiber produced from citrus peel presents a neutral pH and neutral flavor making the ingredient favorable for use in meat products (Cruces, 2013).

Objectives

The objectives of this study were to evaluate the quality characteristics of standard of identity beef frankfurters containing 0%-3.5% citrus fiber.

Materials and Methods

Fresh beef 80's (with 20% fat) and beef 50's (with 50% fat) were obtained from Amend Packing Company, 410 SE 18th St, Des Moines, IA. Ceamfiber 7000 (citrus fiber) was obtained from Ceamsa (Polígono Industrial As Gándaras s/n, 36418 Porriño – Pontevedra, Spain). Five treatments were formulated as shown in Table 1. The lean beef (with 20% fat) was chopped in a bowl chopper (Kramer and Grebe model VSM65, GmbH & Co. KG, Wallau/Lahn, Germany) with salt, sodium phosphate, sodium nitrite, sodium erythorbate and half the water to 4.4°C (40°F), then the fat beef (with 50% fat), water, Ceamfiber 7000 and the other dry ingredients were added. Chopping was continued until the batter reached 18°C (64.4°F). Meat batters were then stuffed (Model RS 1000/65, Risco Brevetti, Zane-vi-Italy) into 22 mm diameter cellulose casings (Devro Teepak Summerville, SC) and smoked in an Alkar single truck smokehouse (Alkar, Lodi, WI) to an internal temperature of 71°C (162°F) using the smokehouse process shown in Table 2. After cooking, frankfurters were chilled using a cold shower for 30 min. They were then stored in a cooler at 2°C (35.6°F) for 24 h., peeled and vacuum packaged (AG800, Sepp Haggenmuller KG, West Germany) in high oxygen barrier pouches (Cryovac Sealed Air Corp., Duncan, SC) and kept in a cooler at 2°C (35.6°F) for subsequent evaluation.

Evaluations

Cooked yield
For each individual treatment, product cooked yield was calculated by dividing the chilled product weight 24 h. after it came out of the smokehouse by the uncooked product weight (cooked product weight/uncooked product weight x100). Cooked yield, therefore, represented product weight losses that occurred primarily during thermal processing and chilling.

Purge
Purge was measured every 2 weeks up to 12 weeks after manufacturing of the frankfurters. For each treatment, packages containing approximately 190 g of frankfurters were weighed before vacuum packaging. The samples were then removed from the bag, and dried off with a paper towel and weighed. Purge was calculated as a percentage of the initial weight [(bag & product weight)-(bag weight)-(product weight)/(bag & product weight)-(bag weight)]. Two packages from each treatment were used for purge measurement during each testing period.

Instrumental texture evaluation
Texture was measured using a TA-XT2 Stable Microsystems Texture Analyzer equipped with a ½" diameter round probe. The product was heated inside the package by dipping the package in 90°C water for 5 min. (to eating temperature) before texture was measured. Texture was measured on 10 cross sectional pieces cut to 20 mm. The texture measurements were done by compressing cross sectional pieces to 30% of the height. Peak load was measured in grams/cm^3.

Instrumental color evaluation
Instrumental color determinations were made on the interior of the frankfurters sliced longitudinally by using a Hunter Lab DP - 9000 equipped with a D25 A Optical Sensor (Hunter Assoc. Laboratory Inc., Reston, VA). Standardization was done by using the white and black standard plate. Measurements were taken directly on the surface of several frankfurters cut longitudinally. Samples were measured for "L", "a" and "b" values. Mean value of a sample was obtained from 5 readings.

Results and Discussion

Table 1: Frankfurter formulation

	Control	1% Ceamfiber 7000	2% Ceamfiber 7000	3% Ceamfiber 7000	3.5% Ceamfiber 7000
Beef 80s	32.48%	32.48%	32.48%	32.48%	32.48%
Beef 50s	38.70%	38.70%	38.70%	38.70%	38.70%
Water	20.87%	20.87%	20.87%	20.87%	20.87%
Salt	2.00%	2.00%	2.00%	2.00%	2.00%
Corn Syrup	2.00%	2.00%	2.00%	2.00%	2.00%
Dextrose	1.00%	1.00%	1.00%	1.00%	1.00%
Sodium phosphate	0.40%	0.40%	0.40%	0.40%	0.40%
Sodium Erythorbate	0.039%	0.039%	0.039%	0.039%	0.039%
Ceamfiber 7000	**0.00%**	**1.00%**	**2.00%**	**3.00%**	**3.50%**
Flavoring	2.50%	2.50%	2.50%	2.50%	2.50%
Sodium Nitrite	0.011%	0.011%	0.011%	0.011%	0.011%
Total	100.00%	101.00%	102.00%	103.00%	103.50%

Frankfurters were formulated with increasing amounts of Ceamfiber 7000 ranging from 0% to 3.5%. The usage level of all other ingredient was held constant across all treatments.

Table 2: Frankfurter cook cycle

Step #	Step Type	Step Time	DB F.	WB F.	rH	IT F.	pH	Main Blower	Exhaust Fan	Humidity	Dampers	Shower On	Shower Off	Smk Gen Preheat time	Liq Smk On	Liq Smk Dwell	Idle After Step
1	Cook	00:05	110	100	70%	---	0.00	8	Off	Steam	Auto	---	---	---	---	---	Off
2	Cook	01:30	120	0	0%	---	0.00	8	On	Steam	Auto	---	---	---	---	---	Off
3	Smoke Cook	00:30	130	0	0%	---	0.00	10	Off	Steam	Closed	---	---	---	---	---	Off
4	Smoke Cook	00 30	150	125	48%	---	0.00	10	Off	Steam	Closed	---	---	---	---	---	Off
5	Cook	00:15	165	140	51%	---	0 00	8	Off	Steam	Auto	---	---	---	---	---	Off
6	Cook	00:01	175	165	78%	162	0 00	8	Off	Steam	Auto	---	---	---	---	---	Off
7	Cold Shower	00 30	50	0	0%	---	0.00	0	Off	Off	Auto	---	---	---	---	---	Off

The cook cycle utilized natural smoke followed by increased humidity and finished off with a cold shower.

Table 3: Cooked yield

	Cooked Yield (%)
Control	90.41
1% Ceamfiber 7000	90.86
2% Ceamfiber 7000	91.28
3% Ceamfiber 7000	92.08
3.5% Ceamfiber 7000	92.52

Table 4: Purge

	Week 2	Week 4	Week 6	Week 8	Week 10	Week 12
Control	1.96%	1.89%	1.69%	2.26%	2.58%	2.67%
1% Ceamfiber 7000	1.63%	1.64%	1.53%	1.90%	1.94%	1.91%
2% Ceamfiber 7000	1.28%	1.71%	1.30%	1.55%	1.88%	1.79%
3% Ceamfiber 7000	0.96%	1.54%	1.21%	1.77%	1.78%	1.75%
3.5% Ceamfiber 7000	0.68%	0.99%	0.97%	1.15%	1.34%	1.53%

Table 5: Texture

	Peak Force (g/cm^3)
Control	1436.67
1% Ceamfiber 7000	2010.08
2% Ceamfiber 7000	3042.63
3% Ceamfiber 7000	3432.00
3.5% Ceamfiber 7000	4394.91

Table 6: Interior color

	Interior color		
	L	a	b
Control	65.69	11.90	17.48
1% Ceamfiber 7000	63.26	11.68	17.76
2% Ceamfiber 7000	64.54	11.77	17.62
3% Ceamfiber 7000	66.02	12.77	17.90
3.5% Ceamfiber 7000	66.28	13.40	17.75

Conclusions

1. The cook yield for frankfurters containing Ceamfiber 7000 was significantly higher compared to the control.
2. After weeks 12 weeks of refrigerated storage, the purge was significantly lower when Ceamfiber 7000 was used at 1% and above compared to the control.
3. Hardness values were significantly higher for treatments containing Ceamfiber 7000 compared to the control. The firmness of the frankfurter increased as the level of Ceamfiber 7000 in the formulation increased.

4. Interior color values were not significantly different from the control for treatments with 1%, 2%, 3% and 3.5% Ceamfiber 7000.
5. Ceamfiber 7000 is a functional ingredient that can increase cook yield, reduce purge and improve texture without significantly changing the quality attributes in comminuted meat products.

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Technical Report

Use of citrus fiber as a functional ingredient in injected ham

for

Ceamsa

by

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Use of citrus fiber as a functional ingredient in injected ham

Introduction

High moisture hams are usually prepared by injecting and tumbling with the pickle (water, salt, water, phosphate, nitrite and other ingredients) for extraction of the salt soluble protein and the meat pieces are bound together by subsequent thermal processing. Binding of the ham muscle pieces results from gelation of salt-soluble extracted myofibrillar protein (McFarlane et al., 1977, Siegal and Schmidt, 1979). The binding among ham muscle pieces and retained water are together responsible for the final product texture.

The effect of adding salt and phosphate in water retention in processed meat are well known. However, the amount of water retained by using only these ingredients is often not satisfactory when high levels of pickle are added. The pickle (brine) dilutes the protein in the surface exudate of the meat and binding among meat pieces decreases and cooking purge increases (Acton, 1983). Hydrocolloid gelling agents such as citrus fiber can be added to hams as binding agents. The functionality of citrus fiber in meat products is related to its water binding and gelling properties. During processing of meat, citrus fiber is first dispersed in the brine solution, then introduced into the meat by injecting and massaging and is dissolved and distributed throughout the meat by thermal processing. During cooling of the cooked product, the citrus fiber binds the water and firms up the texture of the product.

Objectives

The objectives of this study were to evaluate the quality characteristics of 30% injected ham containing 0%-1% citrus fiber.

Materials and Methods

Fresh hams were obtained from a commercial processing plant in Iowa (JBS Swift, Marshalltown, IA). Ceamfiber 7000 SF (citrus fiber) was obtained from Ceamsa (Polígono Industrial As Gándaras s/n, 36418 Porriño – Pontevedra, Spain). Four treatments were formulated as shown in Table 1. Brines were prepared by dissolving sodium phosphate followed by salt, sodium erythorbate, sodium nitrite, dextrose and Citrus Fiber in 10C tap water. Ham muscles were injected to 30% of the green weight with the brine solution, then vacuum tumbled (Globus Laboratories Inc. South Hackensack, N.J., U.S.A.) continuously for 4 hours. After refrigeration overnight, the hams were stuffed into 4" diameter smoked casings (Kalle, USA). The stuffed hams were thermally in an Alkar single truck smokehouse (Alkar, Lodi, WI) to an internal temperature of 70°C (158°F). After cooking, the product was cold showered for 30 min. The cooked product was stored overnight in a cooler at 4°C (39.2°F). The hams were sliced into 0.75mm-thick or 25mm-thick slices by using a Hobart slicer (Model 1712 Hobart Manufacturing Co., Troy, Ohio, U.S.A.), placed in high oxygen barrier pouches (Cryovac Sealed Air Corp., Duncan, SC), vacuum sealed at 1kaPA by using a Multivac MG-2 packaging machine (Sepp Haegenmuller KG) and kept in a cooler at 2°C (35.6°F) for subsequent evaluation.

Evaluations

Cooked yield

For each individual treatment, product cooked yield was calculated by dividing the chilled product weight 24 h. after it came out of the smokehouse by the uncooked product weight (cooked product weight/uncooked product weight x100). Cooked yield, therefore, represented product weight losses that occurred primarily during thermal processing and chilling of the product.

Purge

Purge was measured every 2 weeks up to 12 weeks after manufacturing of the hams. For each treatment, individually packaged 0.75mm-thick ham slices were weighed, and the initial weight was recorded. The samples were then removed from the bag and dried with a paper towel and weighed again (final weight). Purge was calculated as a percentage of the initial weight [(bag & product weight)-(bag weight)-(product weight)/(bag & product weight)-(bag weight)]. Two packages from each treatment were used for purge measurement during each testing period.

Instrumental texture evaluation

Texture was measured on the surface of the 25mm-thick ham slices using a TA-XT2 Stable Microsystems Texture Analyzer equipped with a ½" diameter round probe. Texture was measured on the surface of 10 ham samples per treatment. The texture measurements were done by compressing the ham slices to 30% of the height. Peak load was measured in grams/cm^3.

Instrumental color evaluation

Instrumental color determinations were made on the surface of the sliced ham by using a Hunter Lab DP - 9000 equipped with a D25 A Optical Sensor (Hunter Assoc. Laboratory Inc., Reston, VA). Standardization was done by using the white and black standard plate. Measurements were taken directly on the surface of the sliced product in 5 different locations. Samples were measured for "L", "a" and "b" values. Mean value of a sample was obtained from 5 readings.

Results and Discussion

Table 1: Brine formulation

Brine Formulation 0.6

Ingredient	Control				0.50%				0.75%				1.00%			
	%	60 lb brine	g	ppm	%	60 lb brine	g	ppm	%	60 lb brine	g	ppm	%	60 lb brine	g	ppm
Water	82.89	49.74	22580.51		80.73	48.44	21990.76		79.64	47.79	21695.21		78.56	47.14	21399.65	
Salt	8.65	5.19	2356.26		8.65	5.19	2356.26		8.65	5.19	2356.26		8.65	5.19	2356.26	
Dextrose	6.50	3.90	1770.60		6.50	3.90	1770.60		6.50	3.90	1770.60		6.50	3.90	1770.60	
Sodium phosphate	1.72	1.03	468.53		1.72	1.03	468.53		1.72	1.03	468.53		1.72	1.03	468.53	
Ceamfiber 7000 SF	0.00	0.00	0.00		2.17	1.30	589.75		3.25	1.95	885.30		4.34	2.60	1180.85	
Sodium Erythorbate	0.18	0.11	49.94		0.18	0.11	49.94		0.18	0.11	49.94		0.18	0.11	49.94	
Sodium Nitrite	0.05	0.03	14.16		0.05	0.03	14.16		0.05	0.03	14.16		0.05	0.03	14.16	
Total	100.00	60.00	27240.00		100.00	60.00	27240.00		100.00	60.00	27240.00		100.00	60.00	27240.00	

	Control	0.50%	0.75%	1.00%
Green Weight	8.01	8.28	8.35	10.11
Pumped Weight (Threoretical)	10.41	10.76	10.85	13.14
Pumped Weight 1 (Actual)	10.41	9.84	9.55	11.22
Pumped Weight 2 (Actual)		10.76	10.91	12.50
Pumped Weight 3 (Actual)				13.32
Drained/Added Weight (Actual)	10.41	10.76	10.85	13.14
Brine Temp (F)	33.90	17.50	37.20	16.60

454 g/lb

Finished Product Formulation

Ingredient	Control				0.50%				0.75%				1.00%			
	%	lbs	grams	ppm	%	lbs	grams	ppm	%	lbs	grams	ppm	%	lbs	grams	ppm
Boneless Picnics	76.92	8.01	3636.54		76.92	8.01	3636.54		76.92	8.01	3636.54		76.92	8.01	3636.54	
Water	19.13	1.99	904.35		18.63	1.94	880.73		18.38	1.91	868.89		18.13	1.89	857.06	
Salt	2.00	0.21	94.37		2.00	0.21	94.37		2.00	0.21	94.37		2.00	0.21	94.37	
Dextrose	1.50	0.16	70.91		1.50	0.16	70.91		1.50	0.16	70.91		1.50	0.16	70.91	
Sodium phosphate	0.40	0.04	18.76		0.40	0.04	18.76		0.40	0.04	18.76		0.40	0.04	18.76	
Ceamfiber 7000 SF	**0.00**	**0.00**	**0.00**		**0.50**	**0.05**	**23.62**		**0.75**	**0.08**	**35.46**		**1.00**	**0.10**	**47.29**	
Sodium Erythorbate	0.04	0.00	2.00	[redacted]	0.04	0.00	2.00	[redacted]	0.04	0.00	2.00	[redacted]	0.04	0.00	2.00	[redacted]
Sodium Nitrite	0.01	0.00	0.57	[redacted]	0.01	0.00	0.57	[redacted]	0.01	0.00	0.57	[redacted]	0.01	0.00	0.57	[redacted]
Total	100.00	10.41	4727.50		100.00	10.41	4727.50		100.00	10.41	4727.50		100.00	10.41	4727.50	

Hams were formulated with increasing amounts of Ceamfiber 7000 SF ranging from 0% to 1%.

Table 2: Cooked yield

Control	88.00%
0.5% Ceamfiber 7000 SF	89.66%
0.75% Ceamfiber 7000 SF	90.88%
1% Ceamfiber 7000 SF	91.31%

Cooked yield for all treatments based on the starting meat weight after brine addition ranged from 88 – 91.31%. The measured weight loss occurred primarily during thermal processing and chilling. Product weight loss due to left-over exudate in the tumbler was negligible. Addition of 0.5% Ceamfiber 7000 SF and higher resulted in higher yields compared to the control. There was an increase in cook yield as the level of Ceamfiber 7000SF in the product increased.

Table 3: Purge

	Week 2	Week 4	Week 6	Week 8	Week 10	Week 12
Control	5.85	6.23	6.79	6.85	6.80	6.84
0.5% Ceamfiber 7000 SF	4.68	5.25	4.76	4.80	5.11	4.93
0.75% Ceamfiber 7000 SF	3.56	4.12	4.56	4.87	4.85	4.77
1% Ceamfiber 7000 SF	2.74	3.26	3.30	3.37	3.42	3.76

An objective method of measuring free water is purge measurement. The higher the purge, greater is the free water content. As the level of Ceamfiber 7000SF increased, the amount of purge decreased. The highest purge values were seen in the control and the lowest was seen in the treatment with 1% Ceamfiber 7000SF.

Table 4: Texture

	Peak Force g/cm3
Control	2520.46
0.5% Ceamfiber 7000 SF	2628.37
0.75% Ceamfiber 7000 SF	2957.89
1% Ceamfiber 7000 SF	3467.98

The result of the instrumental texture analysis shows that there was increased firmness in the ham as the level of Ceamfiber 7000SF in the formulation increased. The control had the lowest Peak Force values while the highest Peak Force values were seen in the treatment containing 1% Ceamfiber 7000SF.

Table 5: Interior color

	L	a	b
Control	70.46	8.77	9.66
0.5% Ceamsa 7000 SF	66.96	9.51	9.35
0.75% Ceamsa 7000 SF	66.89	9.42	10.09
1% Ceamsa 7000 SF	69.39	9.07	9.97

Addition of Ceamfiber 7000SF did not seem to affect instrumental measurements of color in any of the treatments as there was no particular trend. The L, a and b values were not different for any of the treatments evaluated compared to the control.

Conclusions

1. The cook yield for hams containing Ceamfiber 7000 SF was significantly higher compared to the control. The cook yields increased as the level of Ceamfiber 7000SF in the formulation increased.

2. After 12 weeks of refrigerated storage, the purge was significantly lower when Ceamfiber 7000SF was used at 0.5% and above compared to the control.

3. Hardness values were significantly higher for treatments containing Ceamfiber 7000SF compared to the control. The firmness of the hams increased as the level of Ceamfiber 7000SF in the formulation increased.

4. Interior color values were not significantly different from the control for treatments with 0.5%, 0.75% and 1% Ceamfiber 7000SF.

5. Ceamfiber 7000SF is a functional ingredient that can increase cook yield, reduce purge and improve texture without significantly changing the quality attributes in whole muscle meat products.

References

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Appendix III

Report 0752/14. 7000. PT-44577

PARAMETER	RESULT	UNITS	LIMIT [1]	REFERENCE METHOD
AFLATOXINE B1	<1	µg/Kg		ELISA
AFLATOXINE B2	<1	µg/Kg		ELISA
AFLATOXINE G1	<1	µg/Kg		ELISA
AFLATOXINE G2	<1	µg/Kg		ELISA
ARSENIC	<0,10	mg/kg		Digestion. ICP
COPPER	0,48	mg/Kg		Digestion. ICP
CADMIUM	<0,050	mg/Kg		Digestion. ICP
LEAD	<0,050	mg/Kg		Digestion. ICP
MERCURY	<0,0030	mg/kg		Digestion. ICP
ZINC	<0,50	mg/Kg		Digestion. ICP
ORGANOCHLORINATED PESTICIDES	Not detected	mg/kg		CG/MS

(1) REFERENCES:

COMMENTS :

DATE:

Technical Director

(b) (6)

Vigo, 19th February 2014

María Silva Iglesias

Lic. en Química.Colegiada nº 1861

Report 2769/13. 7000. PT-41363

PARAMETER	RESULT	UNITS	LIMIT [1]	REFERENCE METHOD
AFLATOXINE B1	<1	µg/Kg		ELISA
AFLATOXINE B2	<1	µg/Kg		ELISA
AFLATOXINE G1	<1	µg/Kg		ELISA
AFLATOXINE G2	<1	µg/Kg		ELISA
ARSENIC	<0,10	mg/kg		Digestion. ICP
COPPER	0,23	mg/Kg		Digestion. ICP
CADMIUM	<0,050	mg/Kg		Digestion. ICP
LEAD	<0,050	mg/Kg		Digestion. ICP
MERCURY	0,0060	mg/kg		Digestion. ICP
ZINC	0,52	mg/Kg		Digestion. ICP
ORGANOCHLORINATED PESTICIDES	Not detected	mg/kg		CG/MS

(1) REFERENCES:

COMMENTS :

DATE:

Vigo, 10th May 2013

Technical Director

(b) (6)

María Silva Iglesias

Lic. en Química.Colegiada nº 1861

Report 2769/13. 7000. PT-41363

PARAMETER	RESULT	UNITS	LIMIT [1]	REFERENCE METHOD
AFLATOXINE B1	<1	µg/Kg		ELISA
AFLATOXINE B2	<1	µg/Kg		ELISA
AFLATOXINE G1	<1	µg/Kg		ELISA
AFLATOXINE G2	<1	µg/Kg		ELISA
ARSENIC	<0,10	mg/kg		Digestion. ICP
COPPER	0,14	mg/Kg		Digestion. ICP
CADMIUM	<0,050	mg/Kg		Digestion. ICP
LEAD	<0,050	mg/Kg		Digestion. ICP
MERCURY	<0,0030	mg/kg		Digestion. ICP
ZINC	<0.50	mg/Kg		Digestion. ICP
ORGANOCHLORINATED PESTICIDES	Not detected	mg/kg		CG/MS

(1) REFERENCES:

COMMENTS :

DATE:

Vigo, 10th October 2013

Technical Director

(b) (6)

María Silva Iglesias

Lic. en Química.Colegiada nº 1861

Submission End