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OFFICE OF
FOOD ADDITIVE SAFETY

February 6, 2019

Dr. Paulette Gaynor
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740-3835

Subject: GRAS Notification – Rice Bran Extract

Dear Dr. Gaynor:

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

If you have any questions or require additional information, please do not hesitate to contact me at 919-797-9938, or rhenderson@toxstrategies.com. In addition, I will be your contact during the GRAS determination review process at FDA.

Sincerely,

[redacted]

Rayetta G. Henderson, Ph.D.
Managing Scientist

GRAS Determination of Rice Bran Extract for Use in Food

DECEMBER 12, 2018

ToxStrategies

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Sound science

GRAS Determination of Rice Bran Extract for Use in Food

SUBMITTED BY:

Florida Food Products, LLC
2231 W. CR 44
Eustis, FL 32726

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

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DECEMBER 12, 2018

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List of Acronyms

AOAC	Association of Official Agricultural Chemists
bw	body weight
CCP	critical control point
CFR	Code of Federal Regulations
cfu	colony-forming units
cGMP	current Good Manufacturing Practice
CIR	Cosmetic Ingredient Review
cv	cultivar
EDI	estimated daily intake
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FD&C	Federal Food, Drug, and Cosmetic Act
FGIS	Federal Grain Inspection Services
FNB	Food and Nutrition Board (US)
FSIS	Food Safety and Inspection Service
GIPSA	Grain Inspection, Packers and Stockyards Administration
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GRAS	Generally Recognized as Safe
GRN	GRAS Notification
HFD	high-fat diet
IOM	Institute of Medicine
LDL	low-density lipoprotein
NHANES	National Health and Nutrition Examination Survey
RDA	recommended daily allowance
RDI	reference daily intake
TPA	12-*O*-tetradecanoylphorbol-13-acetate
UL	tolerable upper intake level
U.S.C.	United States Code
USDA	U.S. Department of Agriculture
WWEIA	What We Eat in America

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

(1) GRAS Notice Submission

Florida Food Products, LLC (Florida Food), through its agent, ToxStrategies, Inc., hereby notifies the U.S. Food and Drug Administration (FDA) of the submission of a Generally Recognized as Safe (GRAS) notice for rice bran extract, and that the use of rice bran extract described below that meets the specifications described herein is exempt from pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act, because Florida Food has determined that such use is GRAS through scientific procedures.

(2) Name and Address

Florida Food Products, LLC
2231 W. CR 44
Eustis, FL 32726

(3) Name of Notified Substance

The name of the substance that is the subject of this GRAS determination is rice bran extract. The rice bran extract product is a water-soluble dried powder consisting of rice bran extract that is high in naturally occurring phosphates (5-7%) and is derived from *Oryza sativa*.

(4) Intended Use in Food

Florida Food proposes to use rice bran extract in specified processed meats at a maximum use level of 1.5% by weight. The intended use of the rice bran extract is as a moisture retention agent.[1] Specifically, the rice bran extract would be used as an alternative to other phosphates already commonly added to processed meats for the same functional purpose, such as sodium tripolyphosphate and tetrasodium pyrophosphate.

(5) Statutory Basis for GRAS Determination

Florida Food Products, LLC (Florida Food), through its agent, ToxStrategies, Inc., hereby notifies the FDA of the submission of a GRAS notice for rice bran extract, which meets the specifications described herein and has been determined to be GRAS through scientific procedures in accordance with § 170.30(a) and (b).

(6) Premarket Approval Statement

Florida Food further asserts that the use of rice bran extract in food, as described below, is exempt from the pre-market approval requirements of the Federal Food, Drug, and

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[1] Florida Food, LLC intends for rice bran extract to be placed on the U.S. Department of Agriculture's (USDA's) list of Safe and Suitable Ingredients Used in the Production of Meat, Poultry, And Egg Products, in the category of "moisture retention."

Cosmetic Act, based on a conclusion that the notified substance is GRAS under the conditions of its intended use.

(7) Availability of Information

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

(8) Data and Information Confidentiality Statement

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

(9) GRAS Notice Certification

To the best of our knowledge, the GRAS notice is a complete, representative, and balanced submission. Florida Food is not aware of any information that would be inconsistent with a finding that the proposed use of rice bran extract in food that meets appropriate specifications and is used according to current Good Manufacturing Practices (cGMP), is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

(10) Name/Position of Notifier

_______________________ December 12, 2018
Rayetta G. Henderson, PhD — Date
Assistant Practice Leader
Foods and Consumer Products
ToxStrategies, Inc.
Agent for Florida Food Products, LLC

(11) FSIS Statement

The intended use of the rice bran extract product does include processed meat products and therefore falls under joint FDA and US Department of Agriculture (USDA)/Food Safety and Inspection Service (FSIS) jurisdiction. Florida Food, LLC, intends for rice bran extract to be placed on the USDA's list of Safe and Suitable Ingredients Used in the Production of Meat, Poultry, And Egg Products (Safe and Suitable List) in the category of "moisture retention."

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

Identity

The rice bran extract product that is the subject of this GRAS determination is a water-soluble dried powder consisting of rice bran extract that is high in naturally occurring phosphates and is derived from *Oryza sativa*.

Common Names

Rice bran extract

Trade Name

The trade name of Florida Food's rice bran extract product is Veg Stable® 486.

Chemical/Structural Formulas

The rice bran extract product (Veg Stable® 486) is high in naturally occurring phosphate and consists primarily of carbohydrates, ash, and protein.

Rice Bran Extract Composition

The representative nutritional composition of the Veg Stable® 486 rice bran extract product can be found in Table 1 and Appendix A.

Table 1. Typical nutritional composition of Veg Stable® 486 rice bran extract

Nutrient	Veg Stable® 486 Rice Bran Extract
Calories (kcal/100g)	144
Protein (%)	7
Moisture (%)	10
Carbohydrates (%)	29
Dietary fiber (%)	5
Total sugars (%)	11
Ash (%)	54
Total starch (%)	6
Fat (%)	<0.2
pH	7-8
Phosphorus (%)	5.5
Sodium (%)	18.6

Manufacturing Process

The following is a description of the process employed in the manufacture of the Florida Food rice bran extract product. Veg Stable® 486 rice bran extract is derived from rice bran in compliance with current good manufacturing practices (cGMP). A flow diagram of the manufacturing process follows the narrative below (see Figure 1; rice bran extract manufacture, immediately below).

Rice Bran Extract 486

Batching: Rice Bran (RB), Soft water, Hydrochloric acid	
▼	
Batch Tank--Extraction	
▼	
Shaker Screen	▸ Spent RB waste
Centrifugation	▸ Separated solids waste
▼	
Microfiltration	
▼	
Ion Exchange	
▼	
Tank, pH adjust neutralization	◂ NaOH, 50%
▼	
Evaporator 1 (>50 brix)	
▼	
Cold wall tank1 or Cold wall tank2	
PASTEURIZER 1 or 2 (CCP1)	
▼	
CHILL	
TO DRYER	▸ QC evaluation
Vacuum Belt or Vacuum Tray Dryer	
▼	
Bulk Bag Filling	
▼	
Storage, Humidity-Controlled	▸ QC evaluation
▼	
TO GRIND & PACK	
Dump to Grinder/Grind	
▼	
Ingredient Addition/Standardize	
▼	
Filter/Screening (CCP2)	
Metal Detector	
▼	
Fill/Vacuum Package/Heat Seal	
Storage	▸ QC evaluation
Distribution	

Figure 1. Rice bran extract manufacturing process

The manufacture of rice bran extract involves the addition of hydrochloric acid (Table 2) and soft water to dehulled rice bran[2] to reach a specific pH. The mixture is then subjected to an extraction process that includes heat and agitation for a designated time period. Following the extraction process, the liquid extract is separated from insoluble solids by a combination of separation techniques, including screen filtration, centrifugation, and membrane filtration, to remove fine insoluble particulates. The liquid extract is then treated further using an ion exchange resin to chelate mineral ions. The liquid extract is then pH-adjusted using concentrated sodium hydroxide (Table 2). The pH-adjusted liquid extract is concentrated in solids by removing water using vacuum evaporation. The concentrated liquid extract is then stored at refrigeration temperatures until it is pasteurized to reduce microbial loads and meet microbial specifications. The concentrated liquid extract is dried in a vacuum belt dryer or a vacuum tray dryer to convert it to dry flakes. The dry flakes are stored in a humidity-controlled atmosphere until they are ground into a fine powder. An anticaking agent (silicon dioxide) (Table 2) is added to produce a free-flowing powder product, which is referred to as the final rice bran extract product. Sea salt is added to ensure the functionality is standardized based on concentration of phosphorous (variances in naturally occurring phosphorous/phosphate content are dependent upon the raw material). The final rice bran extract is passed through a metal detector to ensure absence of any metal particles before packaging in vacuum-sealed packages. The finished rice bran extract undergoes quality control tests to meet product specifications before being released for sale.

All reagents/processing aids are safe and suitable for use in production of the rice bran extract ingredient. They are commonly used in food ingredient manufacturing processes, as described in Table 2.

Table 2. Reagents/processing aids

Reagent/Processing Aid	CAS Number(s)	21 CFR Citation(s)
Hydrochloric acid	7647-01-0	21 CFR § 182.1057
Sodium hydroxide	1310-73-2	21 CFR § 184.1763
Silicon dioxide	7631-86-9	21 CFR § 172.480; 173.340; 182.90
Sea salt (sodium chloride)	7647-14-5	21 CFR § 182.1

The rice bran extract ingredient is manufactured in accordance with cGMP, including quality control (QC) checks at various stages of the production process.

Product Specifications

The specifications for the Veg Stable® 486 rice bran extract product are summarized in Table 3. Analytical results for three non-consecutive lots of the proposed rice bran extract are found in Table 4 and Appendix A. It should be noted that numerous other analyses of

[2] Dehulled rice bran is purchased from domestic rice milling companies.

the proposed rice bran extract product have been conducted but are not included in the product specifications (e.g., pesticides, vitamins, tocopherols). Results of some of the additional analyses are included in Table 5 and Appendix A.

The specification for total arsenic in Table 3 is <1 ppm, and all analyzed batches of the rice bran extract were found to be low and ranged from 0.383 to 0.546 ppm. Given a projected 90th percentile maximum intake of rice bran extract of approximately 0.89 – 1.26 g/d and applying the maximum of 0.546 ppm (546 μg/kg) as being present in the rice bran extract, the estimated daily total arsenic intake is approximately 0.486–0.688 μg/person/day, and the inorganic arsenic intake a small percentage of that estimate. Therefore, the intake of total and inorganic arsenic from the intended use of the rice bran extract is negligible and would not be expected to contribute to the background dietary intake of arsenic. In addition, inorganic arsenic is water soluble, and thus, the manufacturing process of the rice bran extract will remove most of the inorganic arsenic.

Table 3. Specifications for Veg Stable® 486 rice bran extract

Parameter	Specification	Analytical Methods
Appearance	Tan to brown free-flowing powder	Not applicable
Moisture (%)	≤12	AOAC 930.15; AOAC 925.10
pH (5% solution)	6.0–8.0	AOAC 981.12
Total phosphorus (%)	5-7	AOAC 965.17, AOAC 968.08
Heavy Metals		
Arsenic (ppm)	<1	AOAC 993.14
Cadmium (ppm)	<0.4	J. AOAC vol. 90 (2007) 844-856 (mod)
Lead (ppm)	<0.2	AOAC 993.14
Microbiological Contaminants		
Total plate count (cfu/g)	≤10,000	AOAC 966.23
Coliforms (cfu/g)	Negative	AOAC 991.14
Yeasts & molds (cfu/g)	≤100	AOAC 997.02
Aflatoxins (ppb)	<5	AOAC-RI 050901; USDA/GIPSA 2015-070
Fumonisins (ppm)	<0.3	FGIS 2018-1

Table 4. Analytical results for three non-consecutive lots of Veg Stable® 486 rice bran extract

		Batch Numbers		
Parameter	**Specifications**			
Moisture (%)	≤12	9.8	8.5	10
pH (5% solution)	6.0–8.0	7.23	7.58	7.60
Total phosphorus (%)	5–7	5.6	5.8	5.3
Arsenic (ppm)	<1	0.55	0.54	0.48
Total plate count (cfu/g)	≤10,000	1,000	2,000	1,800
Coliforms (cfu/g)	Negative	None detected	None detected	None detected
Yeasts (cfu/g)	≤100	<100	<100	<100
Molds (cfu/g)	≤100	<100	<100	<100

Table 5. Selected analytical results for residual contaminants in lots of Veg Stable® 486 rice bran extract

Elemental Analyses			
Cadmium (ppm)	<0.01	<0.01	<0.01
Lead (ppm)	<0.05	<0.05	<0.05
Mercury (ppm)	<0.025	<0.025	<0.025
Sodium (ppm)	162,300	185,200	177,700
Potassium (ppm)	27,690	10,240	29,550
Calcium (ppm)	336.8	691.1	486.2
Phosphorus (ppm)	56,450	57,760	52,930
Magnesium (ppm)	2,930	279.5	4,134
Iron (ppm)	155.9	139	151.2
Zinc (ppm)	9.333	1.639	31
Copper (ppm)	1.216	<1.0	2.723
Microbiological Analyses			
Escherichia coli (cfu/g)	<10	<10	<10
Aflatoxins (ppb)	<5.0	<5.0	<5.0
Fumonisins (ppm)	<0.3	<0.3	<0.3

In summary, the analytical results confirm that the proposed rice bran extract ingredient meets the analytical specifications and confirm that impurities/contaminants are not present at levels of toxicological concern.

Stability Data

Florida Food currently recommends that the product be kept in its original container and tightly sealed when not in use. The container should be stored in a cool, dry place at a temperature not exceeding 90°F.

Accelerated stability testing of the rice bran extract demonstrates that the active component, phosphate, remains stable over a 6-month period. In addition, there is little concern for potential microbiological contamination over time as stability data for six to nine months shows no increase in individual measurements and decreased total plate counts in all four lots analyzed. These data are presented in Appendix C.

§ 170.235 Part 3, Dietary Exposure

Purpose

Florida Food Products, LLC, is proposing to use rice bran extract in specific processed meats as a moisture retention agent. The rice bran extract would be used as an alternative to other phosphates already commonly added to processed meats for the same functional purpose, such as sodium tripolyphosphate and tetrasodium pyrophosphate. The addition of phosphate is not intended for nutritional purposes.

Food Uses

The rice bran extract is proposed as a moisture retention agent, at a maximum use level of 1.5% by weight in specific processed meat products. The types of processed meats include bacon, hot dogs (frankfurters), luncheon meats, sausages, hams, and corned beef.

Levels of Use

The proposed rice bran extract will be used at levels up to 1.5%.

Estimated Exposure

ToxStrategies, Inc. (ToxStrategies, 2018; included herein as Appendix B) conducted an intake assessment to estimate the mean and 90th percentile daily intake of the ingredient, rice bran extract, based on its intended use in foods. Two-day average intake data were obtained from the three most recent National Health and Nutrition Examination Survey (NHANES) biennials: 2009–2010, 2011–2012, and 2013–2014.
Based on a maximum use level of 1.5%, the *per-user* mean and 90th percentile estimated daily intake (EDI) of rice bran extract for the U.S. population ages 2 and older were determined to be 0.71 and 1.50 g/day (0.011 and 0.025 g/kg body weight/day), respectively. For the total U.S. population ages 2 and older, the *per capita* mean and 90th percentile EDI were 0.44 and 1.24 g/day (0.007 and 0.019 g/kg body weight/day), respectively. The intake estimates for all age groups are provided in Tables 6 and 7.

Table 6. Estimated daily intake of rice bran extract (g/day)

Age Group	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+	13133	60%	0.71	1.50	0.44	1.24
US Population, Ages 2–5	1179	60%	0.53	1.09	0.34	0.89
US Population, Ages 6–18	3532	61%	0.67	1.40	0.42	1.11
US Population, Ages 19+	8422	60%	0.73	1.59	0.45	1.26

Table 7. Estimated daily intake of rice bran extract (g/kg-bw/day)

Age Group	Number of Users	Percent 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+	13133	60%	0.011	0.025	0.007	0.019
US Population, Ages 2–5	1179	60%	0.031	0.064	0.020	0.054
US Population, Ages 6–18	3532	61%	0.015	0.033	0.010	0.026
US Population, Ages 19+	8422	60%	0.009	0.019	0.006	0.015

There are numerous studies in the public domain that utilize estimates of processed meat intake to better understand its potential association with such health outcomes as heart disease and certain cancers. However, it is difficult to rely solely on such publications for estimates of processed meat intake due to the conflicting consumption data that are reported across studies (Fehrenbach et al., 2016). These inconsistencies in intake estimates have been attributed to a number of factors, including the source of data and the definition of "processed meat." Therefore, to ensure that the present GRAS determination of rice bran extract reflects the most accurate estimates of consumption based on the proposed use of the product in specified processed meats, a novel intake assessment was conducted by ToxStrategies (Appendix B). It is worth noting, however, that the available data on trends in processed meat consumption demonstrate that intake is not expected to increase in the near future. For example, Rehm et al. (2016) found that consumption of processed meats (defined as frankfurters, sausage, luncheon meats [made from meat or poultry], and smoked/cured meats) did not change significantly in adults between 1999–2000 and 2011–2012 (p value for trend = 0.22). Consumption was found to decrease in children, with intake of processed meats (defined as frankfurters, sausages, luncheon meats, and other processed meat products) decreasing between 1989–1991 and 2009–2010 (p value <0.01) (Slining et al., 2013). These studies provide corroborative information demonstrating that the intake estimates presented above are likely conservative and are unlikely to change over time. Of note, rice bran is listed on USDA's Safe and Suitable List as a binder for various comminuted meat and poultry products, up to 3.5% of the product formulation (USDA, 2018). The rice bran extract product that is the subject of the current GRAS determination is intended to be used as an alternative to other phosphates already approved for use in foods (see summary in Part 6) and included on the Safe and Suitable List and is to be used in a similar manner and for the same technical reasons (i.e., moisture retention) as those other phosphates (USDA, 2018).

§ 170.240 Part 4, Self-Limiting Levels of Use

The rice bran extract ingredient is incorporated into specific food products at specified levels and is not intended to be used at levels above those specified in Part 3 above. In addition, the use of rice bran extract in foods is considered to be self-limiting for technological reasons, such as product texture and/or flavor profile, either of which could affect consumer acceptance.

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

While the source material for the extract, rice bran, is naturally found in various foods and has been commonly added to food for human consumption, the statutory basis for our conclusion of the GRAS status in the notice is based on scientific procedures and not common use in food.

§ 170.250 Part 6, GRAS Narrative

History of Use and Regulatory Approvals

Rice and its derivatives have a long history as a source of human food, with rice cultivation documented back to prehistoric times (Burlando and Cornara, 2014). At present, rice is produced on most continents, with leading rice-producing countries including the United States, Brazil, and various Asian countries (Childs and Skorbiansky, 2018). Rice serves as a dietary staple for more than half the global population (Burlando and Cornara, 2014; Henderson et al. 2012); the 2018–2019 global and US production forecasts for rice as a crop are 487.8 and 218.8 million tons, respectively (Childs and Skorbiansky, 2018). The average per capita rice consumption has been estimated at 56.9 kg/year globally, and as high as approximately 68.5 kg/year in developing countries (Kahlon, 2009). In the U.S., a more recent intake survey estimated 84% of adults (age 19+ years) to be rice consumers, with the majority consuming between 0.25 and 0.5 oz (equivalent) per day (Nicklas et al., 2014).
Once harvested, rice is hulled to generate brown rice; rice bran is a by-product of this milling process, which is the part between the husk and endosperm of rice (Burlando and Cornara, 2014; Andersen, 2006). Rice bran is considered to be nutritionally comparable to rice, and is a concentrated source of vitamins, minerals, flavones, and other phytonutrients that are also present in brown rice (Burlando and Cornara, 2014; Zarei et al., 2017). While rice bran historically has been used more in animal feed, rice bran is also processed for human foods. Rice bran contains an enzyme lipase that results in a short shelf-life of the unmodified product, rendering it inedible. However, beginning as early as 1985, stabilization processes have been developed to inactivate the lipase, enabling rice bran to be used more frequently in direct human food applications (FDA, 2011; Kahlon, 2009; Sharif et al., 2014; Zarei et al., 2017). According to Kahlon (2009), 63–76 million tons of rice bran are produced annually in the world. Rice bran can be altered further or processed to generate derivatives such as rice bran oil or rice bran fiber. As discussed in detail in Part 2, the rice bran extract that is the subject of the current GRAS determination is generated via a simple water-based extraction process from rice bran.

Thus, the starting material for the Florida Food rice bran extract is rice bran, which is considered GRAS as a substance of natural biological origin consumed prior to January 1, 1958 (i.e., according to prior sanction). Rice bran is currently used in many food applications, including in baked goods, cereals, crackers, pasta, beverages, and medical foods (FDA, 2011; Kahlon, 2009; Sharif et al., 2014; Zarei et al., 2017). In addition, as noted in FDA (2011; also cited in Kahlon, 2009), a rice bran drink has been provided to preschool children in Latin America via a partnership between the U.S. Department of Agriculture (USDA) and a nonprofit organization. Rice bran is also currently listed on the USDA's Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products as a binder for various comminuted meat and poultry products, up to 3.5% of the product formulation (USDA, 2018).

Safety

Safety Assessment of Rice Bran Extract

As noted above, rice bran can be further modified to generate derivatives such as rice bran oil and rice bran extract. For example, a GRAS notification (GRN 373; FDA, 2011) has been submitted for the use of rice bran fiber for general food use at concentrations consistent with current Good Manufacturing Practices. This GRN, determined through scientific procedures, stated that rice bran fiber should be considered GRAS, consistent with 21 CFR 170.30, which includes "distillates, isolates, extracts, and concentration of extracts of GRAS substances." In the submission to FDA (2011), GRN 373 stated the following regarding rice bran fiber:

> *In general, materials of natural biological origin that have no significant detrimental effect and no known health hazard are eligible for GRAS status. Rice bran fiber is of biological origin, and is a concentrated fiber mechanically isolated from defatted rice bran which has been safely consumed in the U.S. for over 100 years, without known detrimental effects.*

Together with the well-established safety of rice itself, and a review of animal and human studies demonstrating the health benefits of rice bran, rice bran fiber, and other cereal fibers, the GRN concluded rice bran fiber to be a safe source of fiber in foods. The FDA issued a "no questions letter" for this GRN.

In addition to GRN 373, extensive published information and data have been submitted to and reviewed by FDA as part of various GRNs for rice-related products. Table 8 provides a summary list of such GRAS notifications, all of which received "no objection" letters for their respective use(s) in food.

Table 8. GRAS Notifications relevant to the assessment of rice bran extract

GRAS Notification Number	Substance
720	Rice bran wax
609	Rice protein
478	Rice hull fiber
373	Rice bran fiber

The subject of the current GRAS determination, performed by scientific procedures, is a rice bran extract for use as a moisture retention agent in specific processed meats. Other rice bran extracts and related products have been reported to be used in human foods, cosmetics, and personal care products, and as nutritional supplements, for many years (Andersen, 2006). RIBUS, Inc., a manufacturer of various rice bran extract products, has concluded rice bran extracts to be GRAS for use in human foods on a self-determination (i.e., without notification to FDA) basis since 1992 (RIBUS, 2018).

Rice bran is GRAS as a substance of natural biological origin in accordance with 21 CFR 170.30. The rice bran extract that is the subject of the current GRAS determination employs only water, heat, and agitation in the extraction process, as described in Part 2, above. Hydrochloric acid is used to adjust pH, and silicon dioxide is used as an anti-caking agent, both of which are commonly used in food ingredient manufacturing processes, as described in Table 2 (Part 2). As such, the extraction process is not expected to introduce any new or potential constituents of concern relative to what is present in rice bran currently consumed widely as foodstuff.

As mentioned above, rice bran contains high levels of vitamins (B vitamins), minerals (calcium, magnesium, phosphorus), and naturally occurring antioxidants (tocopherols, oryzanol) (Sharif et al., 2014). The composition of rice bran has been shown to vary, depending on whether the rice bran has undergone a stabilization step. In general, the components of rice bran are reported to be: moisture (5%–9%), lipids/fat (12%–25%), protein (5%–16%), ash (6.5%–11%), carbohydrate (41%–51%), and fiber (6%–29%) (Moongngarm et al., 2012; Rafe et al., 2017; Sharma et al., 2004). The nutrient profile of the Florida Food rice bran extract is very similar to whole rice bran, with reported values of moisture (10%), protein (7%), and fiber (6%). As can be noted in Table 1 (Part 2; see also Appendix A), this dry extract has no quantifiable fat component but, rather, has an increased ash content relative to rice bran.

The chemical composition of rice bran extracts can vary based on their method of extraction. For example, Insuan et al. (2017; summarized in Part 6) demonstrated that the methanol extracts used in their study contained higher levels of total phenols, flavonoids, and phytic acid and very little vitamin E and γ-oryzanol. Conversely, the dichloromethane extracts tested in the same study had the inverse composition profile. A detailed analysis of the rice bran extract product demonstrates that the expected chemical constituents were identified (Appendix A). As expected, based on the intended use and specifications, the Florida Food extract was rich in phosphorus. Other major components include members of the vitamin B family and various minerals, such as sodium and potassium. Levels of some antioxidants were low or not detected, including γ-oryzanol and various tocopherols (vitamin E family). The safety of these components is discussed in more detail below in Part 6. As an extract of a GRAS substance, the Florida Food rice bran extract that is the subject of this GRAS determination can be considered GRAS, as the water-based extraction process does not give rise to any concerns regarding the potential safety of the product for human consumption.

This conclusion can be supported further by the nutrient and chemical profile of the rice bran extract, which is consistent with other rice- and rice bran-derived products readily available in the marketplace. The safety of rice bran and its constituents, the same as those present in the rice bran extract product, has been reviewed in numerous publications, focused primarily on their physiological benefits (e.g., Henderson et al., 2010; Kahlon, 2009; Zarei et al., 2017). These reviews include overviews of the extensive data set of mechanistic, animal, and human clinical studies on rice bran and rice bran derivatives. These are further supported by a recent study that identified more than 400 metabolites from the rice bran metabolome, most of which were correlated with known positive health effects in animals and humans (Zarei et al., 2017). The authors of GRN 373 for rice bran fiber also reviewed these types of studies on rice bran, noting that traditional toxicology studies did not exist, "because the basic safety of rice bran fiber from rice bran is not in question" (FDA, 2011).

The safe use of the Florida Food rice bran extract for human consumption is supported by the long history of use of rice and rice bran, including its derivatives, and available safety-related data specific to rice bran extracts.

Studies on Rice Bran Extract

For the present GRAS determination of rice bran extract, comprehensive literature searches were performed using the PubMed and Embase databases pertinent to its safe use. Because rice and rice bran are common components of the human diet, very few traditional toxicology studies of rice bran extract were identified in the public domain. As mentioned above, extensive clinical studies on rice and rice bran are available and have been reviewed elsewhere.

The studies below include those identified on any rice bran extract in the public domain. As noted above, the chemical composition of rice bran extracts can vary based on their method of extraction and analysis (Goufo and Trindade, 2014). Because the rice bran extract under assessment is a water extraction process, studies on other extract types can provide additional information when considered within such context.

Animal Studies

The acute oral toxicity of a rice bran extract was evaluated by Choi and colleagues (2013) following Good Laboratory Practices (GLP). Male and female Sprague Dawley rats were administered a supercritical CO_2 rice bran extract (*Oryza sativa* L.) at doses of 0, 2,500, 5,000, or 10,000 mg/kg-bw (5/sex/group); control animals received corn oil. Animals were necropsied following a 14-day observation period. No mortalities, effects on body weight, or observations at gross necropsy were noted following exposure to the rice bran extract. No treatment-related effects were reported; the "approximate lethal dose" was determined to be greater than 10,000 mg/kg-bw/day by the study authors.

There are a number of studies in animal models designed to evaluate the beneficial effects of rice bran extracts on various health conditions, including those associated with metabolic syndrome and other cardiovascular diseases. While these studies do not typically evaluate standard toxicological parameters, they do provide context related to the dose levels used in these studies. For example, in a study published by Parklak et al. (2017), male Sprague Dawley rats were exposed to a water-extract of rice bran at levels up to 4,410 mg/kg-bw/day in combination with a high-fat diet (HFD) for four weeks. The addition of rice bran extract was shown to attenuate many of the metabolic disturbances associated with an HFD, including a number of pancreatic parameters. Perez-Ternero et al. (2017) fed ApoE-/- mice with either a low-fat diet or an HFD, and then either supplemented or not with 1% or 5% rice bran enzymatic extract for 23 weeks. The rice bran extract was found to improve inflammation and hyperlipidemia in the mice fed an HFD. Similarly, Justo et al. (2016) reported that rice bran enzymatic extract (1% or 5%, in combination with an HFD) attenuated insulin resistance, dyslipidemia, and morphological and functional alterations associated with obesity in C57BL/6J mice. Insuan et al. (2017) investigated the mutagenic and anti-mutagenic potential of methanol and dichloromethane extracts of rice bran derived from *Oryza sativa* L., purple rice (cv.

Kum Doi Saket) and white rice (cv. RD6). Both extract types were negative for mutagenic effects in *Salmonella typhimurium* TA98 and TA100, with and without metabolic activation by S9 mix at all doses tested, ranging from 0.2 to 5.0 mg/plate. In addition, the rice bran extracts demonstrated antimutagenic activity against several indirectly acting mutagens, including aflatoxin B1, sodium azide, 2-amino-3,4-dimethylimidazo[4,5-f]quinoline, and benzo(a)pyrene. Of note, the methanol extracts contained higher levels of total phenols, flavonoids, and phytic acid, and very little vitamin E and γ-oryzanol; the dichloromethane extracts had the inverse composition profile.

While there are no traditional carcinogenicity studies with rice bran extract, its anti-cancer properties have been evaluated in a number of studies. For example, Hudson et al. (2000) demonstrated that brown rice bran extract (extracted with diethyl ether, ethyl acetate, and methanol) at 100 μ/mL reduced the number of viable cells, and reduced colony formation in human-derived breast (MDA MB 468 and HBL 100) and colon (human colon epithelial cell and SW 480) cell lines. Similar effects were seen when many of the rice bran constituents were tested individually, such as caffeic acid and ferulic acid. Yasukawa et al. (1998) published their findings of a study in which a methanol extract of rice bran, as well as several constituents thereof, inhibited 12-*O*-tetradecanoylphorbol-13-acetate (TPA)-induced inflammation in a two-stage mouse model for carcinogenesis. Phytic acid from a hexane-extracted rice bran was shown by Norhaizan et al. (2011) to inhibit growth of ovary, breast, and liver cancer cells *in vitro*.

Studies in Humans

Rice bran extract has been evaluated for its beneficial cardiovascular effects in two published human clinical trials. In the first trial, Ito et al. (2015) reported that exposure to a rice bran extract containing acylated steryl glucosides (FANCL-manufactured PSG®; no further description provided) led to significant improvement in markers of arteriosclerosis in subjects compared to controls, including low-density lipoprotein (LDL) cholesterol, non-high-density lipoprotein, abdominal circumference, and subcutaneous fat area. In this randomized, double-blind study, sixty obese Japanese men consumed a capsule of 30–50 mg/day of the rice bran extract or corn oil placebo for 12 weeks. The second study was a single-blind trial in post-menopausal Vietnamese women with high LDL cholesterol levels, published by Nhung et al (2016), which reported similar beneficial effects of rice bran extract, including reduced LDL cholesterol levels and reduced flow-mediated dilation. In this second study, women (30 per group) received capsules containing either corn oil placebo or a total of 50 mg pre-germinated rice bran extract containing acylated steryl glucosides (FANCL-manufactured PSG®) for six months. No adverse effects were reported in either of these clinical trials with rice bran extracts in which male and females consumed up to 50 mg/day for up to six months.

A third human study reported on the pharmacokinetics of a rice bran extract from a three-armed crossover trial (Calvo-Castro et al., 2018); the study was randomized but not blinded. Specifically, the study was designed to evaluate the relative bioavailability of three bioactives between food media: vitamin E, γ-oryzanol, and ferulic acid. After a 10-hour fast, subjects (6/sex/group) received either 10 g rice bran and 1 g heat-stabilized rice bran extract (from HEALTHTECH, Giza, Egypt) in oatmeal prepared with milk, or 2 g of rice bran extract followed by water.[3] Blood samples were collected 0 (before intake), 0.5, 1, 2, 4, 6, 8, and 24 h after ingestion of the rice bran extract. Urine was collected 0 (before intake), starting with the second daily urination, and in 6-hr periods (1–6, 6–12, and 12–24 hr) until the first morning urine of the following day. Parameters relevant for toxicological evaluation were not significantly affected by treatment, including blood glucose levels, lipid levels, and biomarkers of liver and kidney function. Some mild adverse events were reported (e.g., headache, fatigue) but were fully resolved without intervention. Regardless of food preparation, consumption of rice bran extract significantly increased the concentration of ferulic acid in plasma. No significant increases in vitamin E or γ-oryzanol levels were observed following rice bran extract intake.

Safety of the Components of the Rice Bran Extract

As would be expected given the source material being rice bran, the rice bran extract contains several minerals, including sodium, potassium, calcium, phosphorus, and magnesium. These are all commonly found in food and pose no toxicological concern or questions with regard to safety of the proposed product.

Of note, some antioxidant constituents of rice bran often associated with some extract types were analyzed for but determined not to be present in the Florida Food product. The first, γ-oryzanol is an antioxidant derived from the rice plant often found in some extracts. However, this constituent was not measured in any of the four lots above the limit of detection of 3.13 µg/mL (Appendix A). Similarly, the vitamin E profile was analyzed for but determined not to be present at appreciable levels. Of the five individual tocopherols measured, only two were found to be slightly above the limit of detection (0.1 mg/100 g), and only in one of the four lots.

The rice bran extract that is the subject of this GRAS determination contains multiple B vitamins, including biotin, niacin, thiamine (B1), riboflavin (B2), pantothenic acid (B5), pyridoxine (B6), and vitamin B12. B vitamins are found naturally in a variety of foods such as fish, pork, whole grains, legumes, and dairy products (IOM, 2006). The FDA provides reference daily intakes (RDIs) for B vitamins. Because these B vitamins are present in the rice bran extract, based on a 2,000-calorie diet, it is helpful to summarize these as shown in Table 9, along with the recommended daily allowance (RDA) from the U.S. Food and Nutrition Board, Institute of Medicine (IOM, 1998). While many of the B vitamins exhibit no adverse effects at high intake levels, the IOM has set tolerable upper intake levels (ULs) for two of those present in the rice bran extract. Niacin has a UL ranging from 10 mg/d in children 1-3 years to 35 mg/d in adults, which is based on flushing as a critical endpoint and applies only to synthetic forms obtained from supplements, fortified foods, or a combination of the two (IOM, 1998, 2006). Pyridoxine (B6) has a UL ranging from 30 mg/d in children 1–3 years to 100 mg/d in adults; however, IOM (1998) states that "no adverse effects have been associated with high intake of vitamin B6 from food sources." Rather, the UL for pyridoxine is based on sensory neuropathy associated with "high-dose" supplemental clinical uses. Based on an

[3] The publication refers to the test material as a "rice bran extract oil" in some places, but not in the formulation section.

EDI of 1.09–1.59 g rice bran extract/day in the 90th percentile user population (Part 2) rice bran extract, exposure to vitamin B6 of 33–48 μg/d would be expected to result from the proposed intended use in processed meats, which is well below the UL for vitamin B6.

Table 9. FDA reference daily intake (RDI) and recommended dietary allowance (RDA) for B vitamins relevant to the rice bran extract product[a]

Vitamin	RDI	RDA (women 19–50)	RDA (men 19–50)
Biotin	30 μg	30 μg[b]	30 μg[b]
Niacin	16 mg	14 mg	16 mg
Thiamine (B1)	1.2 mg	1.1 mg	1.2 mg
Riboflavin (B2)	1.3 mg	1.1 mg	1.3 mg
Pantothenic acid (B5)	No value	5 mg[b]	5 mg[b]
Pyridoxine (B6)	1.7 mg	1.3 mg	1.3 mg
Vitamin B12	2.4 mcg	2.4 μg	2.4 μg

a 21 CFR, Chapter I, Subchapter B, Part 101.9

b This value is an adequate intake (AI); no RDA has been set.

Phosphorus

Phosphorus is an essential nutrient involved in many physiological processes and is the main mineral constituent of the bones (EFSA, 2015). It is also widely found in foods as phosphates, found commonly in protein-rich foods such as dairy, meats, fish, and grains (FDA, 2009).

Florida Food proposes to use the rice bran extract as an alternative source of phosphates that are commonly added for moisture retention in specified processed meats, as described in Part 3. Food-grade phosphates have a long history of use in meat products to provide desired technical effects, such as pH alteration, buffer properties, water retention, texture improvement, or sensory benefits (Long et al., 2011). The intended use of the phosphate in the rice bran extract is to increase water-holding capacity (i.e., water retention), similar to the function of several of the most common phosphates most widely used currently in the marketplace, such as sodium tripolyphosphate and tetrasodium pyrophosphate (FAO, 1985; Long et al., 2011). The list of existing phosphates already approved in the U.S. and European Union for use in meat products is extensive. A summary of the most common phosphates is available in a review by Long and colleagues (2011). Many food phosphates are noted in the CFR as GRAS for multipurpose use, according to 21 CFR 182 (e.g., 182.1087, 182.1778, 182.1781, 182.1810, and 182.6789).

The highest content of phosphorus in rice is present in the bran, of which the most abundant form is phytic acid (63%–73% of total phosphorus); other forms include cellular and inorganic phosphorus (Goufo and Trinadade, 2014). The specifications for the rice bran extract product require a total phosphorus content of 5%–7%. As noted in Table 4 and Appendix A, the average phosphorus content of the four consecutive lots analyzed was 5.5%, the average phytic acid content of the lots was 14.95%.
The rice bran extract is intended to be used as an alternative to the existing food-grade sources of phosphates added to processed meats, and therefore, is not expected to increase the overall consumption of phosphate by individuals. However, for sake of completeness, the contribution of rice bran extract to the daily intake of dietary phosphorus was considered as part of the overall safety determination.

In the U.S., the phosphorus RDI for individuals 4+ years of age, based on a 2,000-calorie diet, is 1,250 mg/day (21 CFR, Chapter I, Subchapter B, Part 101.9; IOM, 2006). IOM (1998, 2006) has determined a UL ranging from 3 g/d in toddlers (1–3 years) to 4 g/d in adults based on levels associated with alterations in plasma phosphorus homeostasis. Of note, EFSA (2005, 2015) concluded that adverse effects observed in animal studies following excessive intake (e.g., hyperphosphatemia, secondary hyperparathyroidism, skeletal deformations, bone loss) have not been reported in human studies, except in individuals with end-stage renal disease. While no UL has been set for phosphorus in the EU, EFSA (2005) stated that normal, healthy individuals can tolerate phosphorus up to 3 g/d without adverse systemic effects. Of note, a relationship between hyperphosphatemia and advanced chronic kidney disease has been investigated. The authors of one such review paper suggest that patients with advanced renal failure should not exceed 1,000 mg/day of phosphate from food additives (Ritz et al., 2012).

Based on an EDI of 1.09–1.59 g rice bran extract/d in the 90th percentile user population (Part 2) of rice bran extract, an intake of phosphorus ranging from 60 to 88 mg/d would be expected to result from the proposed use in processed meats. This contribution is negligible relative to the estimated average intake of phosphorus from foods by adults of 1,000–2,000 mg/d (FDA, 2009). In addition, this level of intake does not warrant concern relative to the UL set by IOM (1998, 2006) and provides more than an adequate margin of safety even for individuals with advanced renal failure. Further, given that the rice bran extract is intended to be used as an alternative to other phosphate products already in use, it is not expected to add to the existing level of intake from food products.

Allergy

The potential for rice and its derivatives to cause sensitization and subsequent allergic reactions has been reviewed in detail by the Cosmetic Ingredient Review (CIR) Panel (Andersen, 2006). In its report, the CIR Panel provides an extensive review of available human and animal data relevant to an evaluation of the allergic potential of rice products, including rice bran and rice bran extracts. The data from available studies demonstrate that rice bran products were negative for sensitization in guinea pigs and rabbits, and in human clinical tests (Andersen, 2006). And while there are reported cases of allergic responses to various forms of rice in the literature, including asthma, contact urticaria, edema, rhinitis, and dermatitis, these were attributed to exposure to other forms of rice (whole rice, rice pollen, and rice flour); none was attributable directly to rice bran or rice bran extracts (Andersen, 2006; Burlando and Cornara, 2014). The CIR Panel considered rice, in general, to be nonallergenic, including rice bran protein, rice bran, and rice bran extracts. In addition, an up-to-date literature search conducted for the current GRAS determination did not identify any additional studies of relevance specific to rice bran extract.

Rice is not listed as one of eight major allergen groups by the FDA under the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II). A comprehensive assessment of rice and its derivatives conducted by CIR found there to be no potential for allergy outside of isolated instances of hypersensitivity to rice itself. In addition, GRN 609 concluded that even consumption of rice protein concentrate is unlikely to result in allergic reaction, which received no questions from FDA (FDA, 2015). Given that the rice bran extract that is the subject of the current GRAS determination contains very little protein (~7%, Table 1), the potential to cause allergy is very low at the levels of intended use. However, any potential concern for an allergic reaction in already sensitive individuals would be addressed, because the food product ingredient lists would state the presence of a rice-derived ingredient, and individuals who wish to avoid rice consumption for any reason would be able to identify the presence of a rice-derived ingredient.

Basis for the GRAS Determination

Introduction

The regulatory framework for determining whether a substance can be considered GRAS in accordance with section 201(s) (21 U.S.C. § 321(s)) of 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 rice bran extract in food for human consumption is GRAS based on 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.

Safety Determination

The Florida Food rice bran extract that is the subject of the current GRAS determination is proposed for use as a moisture retention agent in specific processed meats. The intended use of the rice bran extract is to increase water holding capacity, a function of several of the most common phosphates widely used currently in the marketplace, such as sodium tripolyphosphate and tetrasodium pyrophosphate (FAO, 1985; Long et al., 2011). Many food phosphates are noted in the CFR as GRAS for multipurpose use according to 21 CFR 182 (e.g., 182.1087, 182.1778, 182.1781, 182.1810, and 182.6789). The rice bran extract would be used as an alternative to these other phosphates already commonly added to processed meats.

Rice and its derivatives have a long history as a source of human food, and they serve as a dietary staple for more than half the global population (Burlando and Cornara, 2014; Henderson et al. 2012). In the US, a more recent intake survey estimated 84% of adults (age 19+ years) to be rice consumers, with the majority consuming between 0.25- and 0.5 oz (equivalent) per day (Nicklas et al., 2014). Rice bran is considered to be nutritionally comparable to rice, and is a concentrated source of vitamins, minerals, flavones, and other phytonutrients also present in brown rice (Burlando and Cornara, 2014; Zarei et al., 2017). The starting material for the subject of the current GRAS determination, rice bran, is considered GRAS as a substance of natural biological origin consumed prior to January 1, 1958 and is currently used in many food applications, including in baked goods, cereals, crackers, pasta, beverages, and medical foods (FDA, 2011; Kahlon, 2009; Sharif et al., 2013; Zarei et al., 2017). Rice bran is also currently listed on the USDA's Safe and Suitable List as a binder for various comminuted meat and poultry products (USDA, 2018).

GRAS-self-determination statements have been referenced in the public domain for rice bran extract since 1992 (RIBUS, 2018). Rice bran is GRAS as a substance of natural biological origin in accordance with 21 CFR 170.30. The rice bran extract that is the subject of the current GRAS determination employs only water, heat, and agitation in the extraction process, as described in Part 2. Hydrochloric acid is used to adjust pH, and silicon dioxide is used as an anti-caking agent, both of which are commonly used in food ingredient manufacturing processes, as described in Table 2 (Part 2). As such, the extraction process is not expected to introduce any new or potential constituents of concern relative to what is present in rice bran currently consumed widely as foodstuff.

The chemical constituents of the Florida Food rice bran extract are all commonly found in food and pose no toxicological concern or questions with regard to safety of the proposed product. Based on the EDI, the contribution of phosphorus from the rice bran extract was found to be negligible. Further, given that the rice bran extract is intended to be used as an alternative source of other phosphate products already in use, it is not expected to add to the already existing level of phosphate intake from food products. The available data on rice bran extracts in the published literature further corroborate these findings, with the various types of extracts demonstrating a lack of mutagenic potential in Ames assays, and anti-mutagenicity and anti-cancer properties in numerous other studies (Hudson et al., 2000; Insuan et al., 2017; Norhaizan et al., 2011; Yasukawa et al., 1998). Studies in animal models designed to evaluate the beneficial effects of rice bran extracts on various health conditions demonstrate that exposure to levels up to 4,410 mg/kg-bw/day for four weeks in rats do not result in adverse effects reported (Parklak et al., 2017). Similarly, several human clinical trials with rice bran extracts are available in which male or female adults consumed up to 50 mg rice bran extract/day for up to six months, with no adverse effects (Ito et al., 2015; Nhung et al., 2016).

The nutrient and analytical profiles of the Florida Food rice bran extract are very similar to that of whole rice bran. Therefore, safety-related information on rice bran and its constituents, the same as those present in the rice bran extract product, are directly relevant to the current GRAS determination and have been reviewed previously in numerous publications and shown to demonstrate the well-established safety of these foods (FDA, 2011; Henderson et al., 2012; Kahlon, 2009; Zarei et al., 2017). Finally, rice and its derivatives have been determined not to be allergenic outside of isolated instances of hypersensitivity to rice itself. However, any potential concern for an allergic reaction in already sensitive individuals would be addressed, because the food product ingredient lists would state the presence of a rice-derived ingredient, and individuals who wish to avoid rice consumption for any reason would be able to identify the presence of a rice-derived ingredient.

In conclusion, rice and its derivatives have a long history as a source of human food, and rice bran, which is the starting material of the rice bran extract product, is considered GRAS as a substance of natural biological origin. Therefore, the safety of rice and rice bran are well-established. The water-based extraction process does not give rise to any concerns regarding the potential safety of the rice bran extract product for human consumption. This conclusion is supported further by the nutrient and chemical profile of the rice bran extract, which is consistent with other rice- and rice bran-derived products that are readily available in the marketplace. The safe use of the Florida Food rice bran extract for human consumption is supported by the long history of use of rice and rice bran, including its derivatives, and available safety-related data specific to rice bran extracts.

General Recognition of the Safety of Rice Bran Extract

The intended use of rice bran extract 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 rice bran extract that is the subject of this notification is a water-soluble dried powder consisting of rice bran extract that is high in naturally occurring phosphates. The rice bran extract product is manufactured in a manner consistent with current cGMP for food (21 CFR Part 110). The raw materials and processing aids used in the manufacturing process are food grade and/or approved for use as in food.

- The intake of total and inorganic arsenic from the intended use of rice bran extract is negligible and would not be expected to contribute to the background dietary intake of arsenic. In addition, inorganic arsenic is water soluble, and thus, the manufacturing process of rice bran extract will remove most of the inorganic arsenic.

- Based on a maximum use level of 1.5%, the *per-user* mean and 90^{th} percentile EDI of rice bran extract for the U.S. population ages 2 and older were determined to be 0.71 and 1.50 g/day (0.011 and 0.025 g/kg body weight/day), respectively. The rice bran product is intended to be used as an alternative to other phosphates already approved for use in foods and included on the Safe and Suitable List and is to be used in a similar manner and for the same technical reasons.

- Rice and its derivatives have a long history as a source of human food and serves as a dietary staple for more than half the global population. Safety-related information on rice bran and its constituents, the same as those present in the rice bran extract product, have well-established safety profiles.

- The starting material, rice bran, is GRAS as a substance of natural biological origin in accordance with 21 CFR 170.30. The water extraction process for rice bran extract employed by Florida Food is not expected to introduce any new or potential constituents of concern relative to what is present in rice bran currently consumed widely as foodstuff. The Florida Food rice bran extract is very similar to whole rice bran, containing several vitamins and minerals commonly found in food and that pose no toxicological concern or questions with regard to safety of the proposed product.

- The intended use of the rice bran extract as a water retention agent, a function of several of the most commonly used phosphates currently in the marketplace. Given that the rice bran extract is intended to be used as an alternative source of other phosphate products already in use, it is not expected to add to the existing level of phosphorus intake from food products. In addition, the contribution of phosphorus from the rice bran extract is negligible.
- Available data on rice bran extracts in the public domain do not raise any questions with regard to their safe use in foods. Various types of extracts were shown to be nonmutagenic in Ames assays, and exhibited anti-mutagenicity and anti-cancer properties in numerous other studies. Human clinical trials and studies in animal models designed to evaluate the beneficial effects of rice bran extracts on various health conditions report a lack of adverse effects associated with consumption of rice bran extracts.
- The potential of rice bran extract to cause allergy is very low at the levels of intended use. However, any potential concern for an allergic reaction in already sensitive individuals would be addressed, because the food product ingredient lists would state the presence of a rice-derived ingredient.
- The body of publicly available scientific literature on the consumption and safety of rice bran and rice bran extract is sufficient to support the safety and GRAS status of the proposed rice bran extract product.

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

Determination of the safety and GRAS status of rice bran extract that is the subject of this self-determination has been made through the deliberations of an Expert Panel convened by Florida Food, LLC, and composed of Michael Carakostas, DVM, Ph.D.; Stanley M. Tarka, Jr., Ph.D.; and Thomas Vollmuth, 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 rice bran extract, produced in a manner consistent with GMP and meeting the specifications described herein, is safe under its intended conditions of use. The Panel further unanimously concluded that the use of rice bran extract is 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 Florida Food's opinion that other qualified scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. Florida Food has concluded that rice bran extract 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. Florida Food is not aware of any information that would be inconsistent with a finding that the proposed use of rice bran extract 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.

§ 170.250 Part 7, Supporting Data and Information

The following references are all generally available, unless otherwise noted. Appendix A and Exhibit 1 (analytical data for rice bran extract, signed Expert Panel report) are not generally available but are attached for reference.

References

Andersen, FA. 2006. Amended final report on the safety assessment of oryza sativa (rice) bran oil, oryza sativa (rice) germ oil, rice bran acid, oryza sativa (rice) bran wax, hydrogenated rice bran wax, oryza sativa (rice) bran extract, oryza sativa (rice) extract, oryza sativa (rice) germ powder, oryza sativa (rice) starch, oryza sativa (rice) bran, hydrolyzed rice bran extract, hydrolyzed rice bran protein, hydrolyzed rice extract, and hydrolyzed rice protein. Int J Toxicol 25(Suppl 2):91–120.

Burlando B, Cornara L. 2014. Therapeutic properties of rice constituents and derivatives (Oryza sativa L.): A review update. Trends Food Sci Technol 40(1):82–98.

Calvo-Castro LA, Sus N, Schiborr C, Bosy-Westphal A, Duran ML, Fesenmeyer D, Fesenmeyer G, Frank J. 2018. Pharmacokinetics of vitamin E, γ-oryzanol, and ferulic acid in healthy humans after the ingestion of a rice bran-enriched porridge prepared with water or with milk. Eur J Nutr: Jul 5.

Childs N, Skorbiansky SR. 2018. *Rice Outlook*, RCS-18J, U.S. Department of Agriculture, Economic Research Service, October 15, 2018. Accessed at: https://www.ers.usda.gov/webdocs/publications/90348/rcs-18j.pdf?v=2292.6.

Choi J-S, Moon W-S, Moon JN, Cheon EJ, Son SW, Kim J-W, Kim M-R. 2013. Cytotoxicity and single-dose oral toxicity testing for rice bran supercritical CO2 extract. Toxicol Environ Health Sci 5:215.

European Food Safety Authority (EFSA). 2005. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Phosphorus (Request N° EFSA-Q-2003-018). EFSA Journal 233:1–19.

European Food Safety Authority (EFSA). 2015. Scientific Opinion on Dietary Reference Values for phosphorus EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). EFSA Journal 13(7):4185.

Fehrenbach KS, Righter AC, Santo RE. 2016. A critical examination of the available data sources for estimating meat and protein consumption in the USA. Public Health Nutr 19(8):1358–1367.

Food and Agriculture Organization of the United Nations (FAO). 1985. Small-scale sausage production. FAO Animal Production and Health Paper 52, available at: http://www.fao.org/docrep/003/x6556e/X6556E00.htm#chPRE.

Food and Drug Administration (U.S. FDA). 2009. GRN No. 300. GRAS Notification for trisodium diphosphate. Prepared by Chemische Fabrik Budenheim KG.

Food and Drug Administration (U.S. FDA). 2011. GRN No. 373. GRAS Notification for Rice bran fiber. Prepared by CJ America, Inc.

Food and Drug Administration (U.S. FDA). 2015. GRN No. 609. GRAS Notification for Rice protein concentrate. Prepared by Axiom Foods.

Goufo P, Trindade H. 2014. Rice antioxidants: Phenolic acids, flavonoids, anthocyanins, proanthocyanidins, tocopherols, tocotrienols, γ-oryzanol, and phytic acid. Food Sci Nutr 2(2):75–104.

Henderson AJ, Ollila CA, Kumar A, Borresen EC, Raina K, Agarwal R, Ryan EP. 2012. Chemopreventive properties of dietary rice bran: current status and future prospects. Adv Nutr 3(5):643–53.

Hudson EA, Dinh PA, Kokubun T, Simmonds MS, Gescher A. 2000. Characterization of potentially chemopreventive phenols in extracts of brown rice that inhibit the growth of human breast and colon cancer cells. Cancer epidemiology, biomarkers & prevention: A publication of the American Association for Cancer Research, cosponsored by the American Society of Preventive Oncology. 9:(11):1163–1170.

Insuan O, Chariyakornkul A, Rungrote Y, Wongpoomchai R. 2017. Antimutagenic and antioxidant activities of Thai rice brans. J Cancer Prevent 22:89–97.

Institute of Medicine (IOM). 1998. Dietary reference intakes: Thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin, and choline. Food and Nutrition Board. Washington, DC: National Academy Press.

Institute of Medicine (IOM). 2006. Dietary Reference Intakes: The Essential Guide to Nutrient Requirements. Washington, DC: The National Academies Press. https://doi.org/10.17226/11537.

Ito Y, Nakashima Y, Matsuoka S. 2015. Rice bran extract containing acylated steryl glucoside fraction decreases elevated blood LDL cholesterol level in obese Japanese men. J Med Invest. 62:80–84.

Justo ML, Claro C, Zeyda M, Stulnig TM, Herrera MD, Rodríguez-Rodríguez R. 2016. Rice bran prevents high-fat diet-induced inflammation and macrophage content in adipose tissue. Europ J Nutr 55(6):2011–2019.

Kahlon TS. 2009. Rice bran: Production, composition, functionality, food applications and physiological benefits. In: Cho SS, Samuel P, Editors. Fiber Ingredients. Food Applications and Health Benefits. New York: CRC Press. Taylor & Francis Group, pp. 305–321.

Long NHBS, Gál R, Bunka F. 2011. Use of phosphates in meat products. Afric J Biotechnol 10(86):19874–19882.

Nhung BG, Tuyen LD, Linh VA, Anh ND, Nga TT, Thuc VT, et al. 2016. Rice bran extract reduces the risk of atherosclerosis in post-menopausal Vietnamese women. J Nutr Sci Vitaminol 62:295–302.

Nicklas T, O'Neil,C, Fulgoni V. 2014. Rice consumption is associated with better nutrient intake and diet quality in adults: National Health and Nutrition Examination Survey (NHANES) 2005-2010. Food Nutr Sci 5:525–532.

Norhaizan ME, Ng SK, Norashareena MS, Abdah MA. 2011. Antioxidant and cytotoxicity effect of rice bran phytic acid as an anticancer agent on ovarian, breast and liver cancer cell lines. Malaysian J Nutr 17:367–375.

Moongngarm A, Daomukda N, Khumpika S. 2012. Chemical compositions, phytochemicals, and antioxidant capacity of rice bran, rice bran layer, and rice germ. APCBEE Proc. 2:73–79.

Parklak W, Munkong N, Somnuk S, Somparn N, Naowaboot J, Yoysungnoen B, Lerdvuthisopon N. 2017. Rice bran water extract attenuates pancreatic abnormalities in high-fat diet-induced obese rats. Trop J Pharmaceut Res 16:819.

Perez-Ternero C, Claro C, Parrado J, Herrera MD, Alvarez de Sotomayor M. 2017. Rice bran enzymatic extract reduces atherosclerotic plaque development and steatosis in high-fat fed ApoE-/- mice. Nutrition (Burbank, Los Angeles County, Calif.) 37:22–29.
Rafe A, Sadeghian A, Hoseini-Yazdi SZ. 2017. Physicochemical, functional, and nutritional characteristics of stabilized rice bran form tarom cultivar. Food Sci Nutr 5:407–414.

Rehm CD, Peñalvo JL, Afshin A, Mozaffarian D. 2016. Dietary intake among US adults, 1999-2012. JAMA 315(23):2542–2553.

RIBUS, Inc. 2018. GRAS statement – Rice bran extract. Accessed at: https://ribus.com/wp-content/uploads/2017/12/RIBUS-GRAS-Status_Rice-Bran-Extract1_1_18.pdf.

Ritz E, Hahn K, Ketteler M, Kuhlmann MK, Mann J. 2012. Phosphate additives in food—a health risk. Dtsch Arztebl Int. 109(4): 49–55.

Sharif MK, Butt MS, Anjum FM, Khan SH. 2014. Rice bran: Aa novel functional ingredient. Crit Rev Food Sci Nutr 54(6):807–816.

Sharma HR, Chauhan GS, Agrawal K. 2004. Physico-chemical characteristics of rice bran processed by dry heating and extrusion cooking. Int J Food Properties 7:3:603–614.

Slining MM, Mathias KC, Popkin BM. 2013. Trends in food and beverage sources among US children and adolescents: 1989-2010. J Acad Nutr Diet 113(12):1683–1694.

ToxStrategies. 2018. Estimated daily intake of rice bran extract. ***Appendix B, this document.***

U.S. Department of Agriculture (USDA). 2018. FSIS Directive 7120.1, Revision 46, Safe and suitable ingredients used in the production of meat, poultry, and egg products, Mar 19, 2018.

Yasukawa K, Akihisa T, Kimura Y, Tamura T, Takido M. 1998. Inhibitory effect of cycloartenol ferulate, a component of rice bran, on tumor promotion in two-stage carcinogenesis in mouse skin. Biol Pharmaceut Bull 21:1072–1076.

Zarei I, Brown DG, Nealon NJ, Ryan EP. 2017. Rice bran metabolome contains amino acids, vitamins & cofactors, and phytochemicals with medicinal and nutritional properties. Rice (N Y) 10(1):24.

APPENDIX A

Analytical Results

Florida Food Rice Bran Extract Analytical Results for Four Consecutive Lots

Analytical Parameter	Units	[redacted]	[redacted]	[redacted]
pH (5% solution)		7.23	7.58	7.6
Moisture	%	9.84	8.52	10
Protein	%	7.78	7.53	8.28
Fat, Soxhlet	%	<0.2	<0.2	<0.2
Dietary Fiber, AOAC total	%	5.13	6.48	4.45
Ash, 600C	%	51.1	52.3	55.7
Total Starch	%	6.09	5.94	4.79
Carbohydrate by calculation	%	31.28	31.65	26
Calories	kcal/100g	156	157	137
Phytic acid, ion exchange	%	15.7	15.4	14.2
Sodium	ppm	162300	185200	177700
Potassium	ppm	27690	10240	29550
Calcium	ppm	336.8	691.1	486.2
Phosphorus	ppm	56450	57760	52930
Magnesium	ppm	2930	279.5	4134
Iron	ppm	155.9	139	151.2
Manganese	ppm	10.94	1.291	20.37
Zinc	ppm	9.333	1.639	31
Copper	ppm	1.216	<1.0	2.723
Mercury	ppm	<0.025	<0.025	<0.025
Lead	ppm	<0.05	<0.05	<0.05
Arsenic	ppm	0.546	0.54	0.479
Cadmium	ppm	<0.01	<0.01	<0.01
Diazinon	ppm	<0.01	<0.01	<0.01
Disulfoton	ppm	<0.01	<0.01	<0.01
Ethion	ppm	<0.01	<0.01	<0.01
Malathion	ppm	<0.01	<0.01	<0.01
Methyl Parathion	ppm	<0.01	<0.01	<0.01
Parathion	ppm	<0.01	<0.01	<0.01
Thimet	ppm	<0.01	<0.01	<0.01
Thiodan	ppm	<0.01	<0.01	<0.01
Trithion	ppm	<0.01	<0.01	<0.01
Heptachlor Epoxide	ppm	<0.01	<0.01	<0.01
Heptachlor	ppm	<0.01	<0.01	<0.01
DDE	ppm	<0.01	<0.01	<0.01
Lindane	ppm	<0.01	<0.01	<0.01
Endrin	ppm	<0.01	<0.01	<0.01
Mirex	ppm	<0.01	<0.01	<0.01
Alpha-BHC	ppm	<0.01	<0.01	<0.01
Delta-BHC	ppm	<0.01	<0.01	<0.01
Aldrin	ppm	<0.02	<0.02	<0.02
Dieldrin	ppm	<0.01	<0.01	<0.01
DDT	ppm	<0.01	<0.01	<0.01
Chlordane	ppm	<0.01	<0.01	<0.01
Methoxychlor	ppm	<0.01	<0.01	<0.01
Beta-BHC	ppm	<0.01	<0.01	<0.01
HCB	ppm	<0.01	<0.01	<0.01
PCB	ppm	<0.05	<0.05	<0.05
APC	cfu/g	1000	2000	1800

Florida Food Rice Bran Extract Analytical Results for Four Consecutive Lots

Analytical Parameter	Units			
Total Coliforms (Detection Limit >10 CFU/g)		None Detected	None Detected	None Detected
E. coli (Detection limit >10 CFU/g)		None Detected	None Detected	None Detected
Yeasts	cfg/g	<100	<100	<100
Molds	cfu/g	<100	<100	<100
Aflatoxins	ppb	<5.0	<5.0	<5.0
Fumonisins	ppm	<0.3	<0.3	<0.3
Biotin	mg/100g	0.0304	0.0425	0.0464
Gamma-Oryzanol	µg/ml	<3.13	<3.13	<3.13
Inositol	mg/100g	115	105	83.9
Niacin	mg/100g	72.3	74.5	71.1
Raffinose	g/kg	<0.5	<0.5	1.158
Stachyose	g/kg	<0.5	<0.5	<0.5
Verbascose	g/kg	<0.5	<0.5	<0.5
Folic acid	mg/100g	0.0214	0.0237	0.0189
Vitamin B12	µg/100g	<0.440	<0.440	<0.440
Vitamin B1 - Thiamine HCl	mg/100g	0.137	0.0188	0.012
Vitamin B2 - Riboflavin	mg/100g	0.57	0.49	0.779
Vitamin B5 - Pantothenic acid	mg/100g	5.09	3.78	2.32
Vitamin B6 - Pyridoxine	mg/100g	3.14	2.87	3.64
Alpha - Tocopherol	mg/100g	<0.1	<0.1	0.202
Beta - Tocopherol	mg/100g	<0.1	<0.1	<0.1
Gamma - Tocopherol	mg/100g	<0.1	<0.1	<0.1
Delta - Tocopherol	mg/100g	<0.1	<0.1	<0.1
Total Tocopherols	mg/100g	<0.1	<0.1	0.202

APPENDIX B

Intake Assessment Report

Estimated Daily Intake of Rice Bran Extract

OCTOBER 17, 2018

ToxStrategies

Innovative solutions
Sound science

Estimated Daily Intake of Rice Bran Extract

OCTOBER 17, 2018

PREPARED FOR:
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Acronyms

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

Executive Summary

ToxStrategies, Inc. (ToxStrategies), conducted an intake assessment to estimate the mean and 90th percentile daily intake of the ingredient, rice bran extract, based on its intended use in foods. This assessment included one proposed food category for use of rice bran extract: specific processed meat products. After analyzing 2009–2014 dietary survey data from the National Health and Nutrition Examination Survey (NHANES), the *per-user* mean and 90th percentile estimated daily intake (EDI) of rice bran extract for the U.S. population ages 2 and older were determined to be 0.71 and 1.50 g/day (0.011 and 0.025 g/kg body weight/day), respectively. For the total U.S. population ages 2 and older, the *per capita* mean and 90th percentile EDI were 0.44 and 1.24 g/day (0.007 and 0.019 g/kg body weight/day), respectively.

1 Data

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

1.1 Proposed Uses and Use Levels of Rice Bran Extract

Florida Food Products, LLC, proposes to use rice bran extract as a moisture retention agent (as an alternative to other phosphates already commonly added to processed meats for the same functional purpose), at a maximum use level of 1.5% by weight in specific processed meat products.

1.2 Dietary Survey Data

Dietary survey data were 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) to characterize the general health and nutritional status of children and adults across the U.S. The three most recent biennials for which dietary intake data are available were included in this analysis (2009–2010, 2011–2012, 2013–2014).

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 3–10 days after the first survey day. Data collected during the dietary interview include foods as consumed by the participant, encoded by a U.S. Department of Agriculture (USDA) food code, and amount eaten.

Respondents who provided complete records for both days were designated reliable by WWEIA. Only these reliable respondents who also had corresponding body-weight data were considered in this analysis (N = 8,293 in 2009–2010; N = 7,496 in 2011–2012; and N = 7,457 in 2013–2014).

1.3 Recipe Data

Recipe data for NHANES 2009–2012 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.

For NHANES 2013–2014, foods and recipes were not re-analyzed. There were relatively few food codes in NHANES 2013–2014 that did not exist in NHANES 2011–2012, and they represented minor changes in description. For these food codes, recipes were assumed to be the same as for the most similar item (in ToxStrategies' professional judgment) in FNDDS 2011–2012 and are marked with an asterisk in Appendix A. For example, the new food in WWEIA 2012–2014, "Frankfurter or hot dog sandwich, NFS, plain, on wheat bun," was assumed to obey the same recipe as the WWEIA 2011–2012 food, "Frankfurter or hot dog sandwich, NFS, plain, on bun."

2 Methods

To estimate the intake of rice bran extract based on its proposed use, ToxStrategies performed the following steps:

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

Details of each step are provided in the following sections.

2.1 Identification of Foods and Their Components to Which Rice Bran Extract May Be Applied

To identify foods that are proposed to contain rice bran extract, ToxStrategies performed a thorough search of food codes reported in WWEIA. Food code descriptions from WWEIA and associated ingredients listed in FNDDS were queried for key words pertaining to the proposed food category of specific processed meat products. The resulting list of relevant food codes was then refined based on the proposed technical use of rice bran extract. Food codes retained for further analysis are listed in the appendix.

In some cases, rice bran extract would be present in only a subcomponent of a reported food (e.g., in a bacon, lettuce, and tomato sandwich, rice bran extract would be present in only the bacon). Relevant proportions of each food were determined by reviewing the recipe for that food item from FNDDS, with further development by ToxStrategies.

Proportions listed as less than "1.00" in Appendix A indicate where rice bran extract was present in only a subcomponent of that food item (i.e., the technical use of rice bran extract applied to less than 100% of the reported food).

2.2 Calculation of Individual Intake of Rice Bran Extract for Individual Survey Participants

Only those respondents designated as reliable were included in this assessment.

For all three biennials (2009–2010, 2011–2012, and 2013–2014), both days of the NHANES WWEIA dietary interviews were analyzed. Participants' estimated consumption of rice bran extract was averaged over the two response days—i.e., (Day1 consumption + Day2 consumption)/2. Raw consumption of rice bran extract was calculated using the intake (in grams) of the relevant food as reported in NHANES, multiplied by the proportion of the food that was relevant to the technical use of rice bran extract (see Section 3.1), multiplied by its maximum proposed use level. For example, for the food, "27520150 Bacon, lettuce, and tomato sandwich with spread," the relevant proportion (by weight) of that food was 0.11, and the use level in that relevant proportion was 0.015. Thus, a survey participant who consumed 100 g of this food consumed approximately 0.165 g of rice bran extract, or (100 g food * 0.11 g relevant food/1 g food * 0.015 g rice bran extract/1 g relevant food).

2.3 Calculation of Population Statistics Describing Rice Bran Extract Estimated Daily Intake

To ensure that the most up-to-date data on consumption were used for this analysis, the three most recent NHANES biennials for which published dietary survey data are available were used: 2009–2010, 2011–2012, and 2013–2014. The dietary and sample weighting data from the three biennials were combined according to the NHANES analytic guidelines for combining surveys. From the combined data set, survey-design-weighted descriptive statistics were estimated for the population consumption per day. Population statistics were estimated using the "survey" package (version 3.32; Lumley, 2004) in the R environment for statistical computing (version 3.5.0; R Core Team, 2018) 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, 90th percentile) were calculated for the subset of consumers of rice bran extract and for the entire population, and were broken down by age range and body-weight adjustment.

3 Results

Tables 1 and 2 below, respectively, present the EDI for rice bran extract in grams per day and grams per kilogram body weight per day for the following age groups in the U.S. 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 the category of interest (specific processed meat products). The "percent users" is the percentage of rice bran extract users out of the total number of reliable survey participants (both users and non-users) belonging to a given age group.

Table 1. Estimated daily intake of rice bran extract (g/day)

			EDI per User (g/day)		EDI per Capita (g/day)	
Age Group	**Number of Users**	**Percent Users**	**Mean**	**90th Percentile**	**Mean**	**90th Percentile**
US Population, Ages 2+	13133	60%	0.71	1.50	0.44	1.24
US Population, Ages 2–5	1179	60%	0.53	1.09	0.34	0.89
US Population, Ages 6–18	3532	61%	0.67	1.40	0.42	1.11
US Population, Ages 19+	8422	60%	0.73	1.59	0.45	1.26

Table 2. Estimated daily intake of rice bran extract (g/kg-bw/day)

			EDI per User (g/kg-BW/day)		EDI per Capita (g/kg-BW/day)	
Age Group	**Number of Users**	**Percent Users**	**Mean**	**90th Percentile**	**Mean**	**90th Percentile**
US Population, Ages 2+	13133	60%	0.011	0.025	0.007	0.019
US Population, Ages 2–5	1179	60%	0.031	0.064	0.020	0.054
US Population, Ages 6–18	3532	61%	0.015	0.033	0.010	0.026
US Population, Ages 19+	8422	60%	0.009	0.019	0.006	0.015

4 References

Agricultural Research Service, United States Department of Agriculture (USDA). 2009–2010; 2011–2012; 2013–2014. Food and Nutrient Database for Dietary Studies. Available at: https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/fndds-download-databases/. Last accessed October 17, 2018.

Centers for Disease Control and Prevention (CDC). 2009–2010. National Health and Nutrition Examination Survey. Available at: https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx?BeginYear=2009. Last accessed October 17, 2018.

Centers for Disease Control and Prevention (CDC). 2011–2012. National Health and Nutrition Examination Survey. Available at: https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx?BeginYear=2011. Last accessed October 17, 2018.

Centers for Disease Control and Prevention (CDC). 2013–2014. National Health and Nutrition Examination Survey. Available at: https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx?BeginYear=2013. Last accessed October 17, 2018.

Lumley T. 2004. Analysis of complex survey samples. J Statistical Software 9(1):1–19.

R Core Team. 2018. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/.

APPENDIX A

List of Food Codes and Proportions

Table A-1. Food codes included in intake analysis with descriptions and relevant proportion as estimated by recipe analysis

NHANES cycle letters: F = 2009-2010; G = 2011-2012; H = 2013-2014. Food codes that appeared only in 2013-2014 have their NHANES cycle labeled as H*. Each H* food code is listed immediately following its most-similar non-H* food code. Each H* food code was assigned the same proportion as the closest preceding non-H* food code.

Food Code	NHANES Cycles	Description	Proportion
14620320	F, G, H	Topping from meat pizza	0.37
14620330	F, G, H	Topping from meat and vegetable pizza	0.29
21416000	F, G, H	Corned beef, cooked, NS as to fat eaten	1.00
21416110	F, G, H	Corned beef, cooked, lean and fat eaten	1.00
21416120	F, G, H	Corned beef, cooked, lean only eaten	1.00
21601000	F, G, H	Beef, bacon, cooked	1.00
21601010	H*	Beef, bacon, reduced sodium, cooked	1.00
21601500	F, G	Beef, bacon, formed, lean meat added, cooked	1.00
22300120	F, G, H	Ham, fried, NS as to fat eaten	0.95
22300130	F, G, H	Ham, fried, lean and fat eaten	0.95
22300140	F, G, H	Ham, fried, lean only eaten	0.95
22300150	F, G, H	Ham, breaded or floured, fried, NS as to fat eaten	0.83
22300160	F, G, H	Ham, breaded or floured, fried, lean and fat eaten	0.83
22300170	F, G, H	Ham, breaded or floured, fried, lean only eaten	0.83
22301000	F, G, H	Ham, fresh, cooked, NS as to fat eaten	1.00
22301110	F, G, H	Ham, fresh, cooked, lean and fat eaten	1.00
22301120	F, G, H	Ham, fresh, cooked, lean only eaten	1.00
22311000	F, G, H	Ham, smoked or cured, cooked, NS as to fat eaten	1.00
22311010	F, G, H	Ham, smoked or cured, cooked, lean and fat eaten	1.00
22311020	F, G, H	Ham, smoked or cured, cooked, lean only eaten	1.00
22311200	F, G	Ham, smoked or cured, low sodium, cooked, NS as to fat eaten	1.00

Food Code	NHANES Cycles	Description	Proportion
22311210	F, G	Ham, smoked or cured, low sodium, cooked, lean and fat eaten	1.00
22311220	F, G	Ham, smoked or cured, low sodium, cooked, lean only eaten	1.00
22311500	F, G, H	Ham, smoked or cured, canned, NS as to fat eaten	1.00
22311510	F, G, H	Ham, smoked or cured, canned, lean and fat eaten	1.00
22311520	F, G, H	Ham, smoked or cured, canned, lean only eaten	1.00
22321110	F, G, H	Ham, smoked or cured, ground patty	1.00
22431000	F, G, H	Pork roll, cured, fried	1.00
22501010	F, G, H	Canadian bacon, cooked	1.00
22600100	F, G, H	Bacon, NS as to type of meat, cooked	1.00
22600110	H*	Bacon, NS as to type of meat, reduced sodium, cooked	1.00
22600200	F, G, H	Pork bacon, NS as to fresh, smoked or cured, cooked	1.00
22600210	H*	Pork bacon, NS as to fresh, smoked or cured, reduced sodium, cooked	1.00
22601000	F, G, H	Pork bacon, smoked or cured, cooked	1.00
22601040	F, G, H	Bacon or side pork, fresh, cooked	1.00
22602010	F, G, H	Pork bacon, smoked or cured, lower sodium	1.00
22605010	F, G	Pork bacon, formed, lean meat added, cooked	1.00
24208500	F, G, H	Turkey bacon, cooked	1.00
24208510	H*	Turkey bacon, reduced sodium, cooked	1.00
25210110	F, G, H	Frankfurter, wiener, or hot dog, NFS	1.00
25210120	F	Frankfurter or hot dog, breaded, baked	0.87
25210150	F, G, H	Frankfurter or hot dog, cheese-filled	0.90
25210160	F	Frankfurter or hot dog, bacon and cheese-filled	1.00
25210170	F	Frankfurter or hot dog, chili-filled	0.71
25210210	F, G, H	Frankfurter or hot dog, beef	1.00
25210220	F, G, H	Frankfurter or hot dog, beef and pork	1.00

Food Code	NHANES Cycles	Description	Proportion
25210230	F	Frankfurter or hot dog, beef and pork, lowfat	1.00
25210240	G, H	Frankfurter or hot dog, beef and pork, reduced fat or light	1.00
25210250	F, G, H	Frankfurter or hot dog, meat and poultry, fat free	1.00
25210280	F, G, H	Frankfurter or hot dog, meat and poultry	1.00
25210290	G, H	Frankfurter or hot dog, meat and poultry, reduced fat or light	1.00
25210310	F, G, H	Frankfurter or hot dog, chicken	1.00
25210410	F, G, H	Frankfurter or hot dog, turkey	1.00
25210510	F	Frankfurter or hot dog, low salt	1.00
25210610	F	Frankfurter or hot dog, beef, lowfat	1.00
25210620	G, H	Frankfurter or hot dog, beef, reduced fat or light	1.00
25210700	F	Frankfurter or hot dog. meat & poultry, lowfat	1.00
25210750	G, H	Frankfurter or hot dog, reduced fat or light, NFS	1.00
25220010	F, G, H	Cold cut, NFS	1.00
25220100	F	Beef sausage, NFS	1.00
25220105	G, H	Beef sausage	1.00
25220106	G, H	Beef sausage, reduced fat	1.00
25220108	H*	Beef sausage, reduced sodium	1.00
25220110	F	Beef sausage, brown and serve, links, cooked	1.00
25220120	F	Beef sausage, smoked, stick	1.00
25220130	F	Beef sausage, smoked	1.00
25220140	F	Beef sausage, fresh, bulk, patty or link, cooked	1.00
25220150	F, G, H	Beef sausage with cheese	0.90
25220210	F, G, H	Blood sausage	1.00
25220310	F	Bockwurst	1.00
25220350	F, G, H	Bratwurst	1.00

Food Code	NHANES Cycles	Description	Proportion
25220360	F, G, H	Bratwurst, with cheese	0.90
25220370	F	Bratwurst, beef, cooked	1.00
25220390	F, G, H	Bologna, beef, lowfat	1.00
25220400	F, G, H	Bologna, pork and beef	1.00
25220410	F, G, H	Bologna, NFS	1.00
25220420	F, G, H	Bologna, Lebanon	1.00
25220430	F, G, H	Bologna, beef	1.00
25220440	F, G, H	Bologna, turkey	1.00
25220450	F, G, H	Bologna ring, smoked	1.00
25220460	F, G, H	Bologna, pork	1.00
25220470	F, G, H	Bologna, beef, lower sodium	1.00
25220480	F, G, H	Bologna, chicken, beef, and pork	1.00
25220490	F, G, H	Bologna, with cheese	0.90
25220500	F, G, H	Bologna, beef and pork, lowfat	1.00
25220510	F, G, H	Capicola	1.00
25220610	F	Cervelat, soft	1.00
25220650	F, G, H	Turkey or chicken and beef sausage	1.00
25221250	F, G, H	Pepperoni	1.00
25221310	F, G, H	Polish sausage	1.00
25221350	F, G, H	Italian sausage	1.00
25221400	F, G, H	Sausage (not cold cut), NFS	1.00
25221405	G, H	Pork sausage	1.00
25221406	G, H	Pork sausage, reduced fat	1.00
25221408	H*	Pork sausage, reduced sodium	1.00
25221410	F	Pork sausage, fresh, bulk, patty or link, cooked	1.00

Food Code	NHANES Cycles	Description	Proportion
25221420	F	Pork sausage, brown and serve, cooked	1.00
25221430	F	Pork sausage, country style, fresh, cooked	1.00
25221450	F, G, H	Pork sausage rice links	1.00
25221460	F, G, H	Pork and beef sausage	1.00
25221470	F	Pork and beef sausage, brown and serve, cooked	1.00
25221500	F, G, H	Salami, NFS	1.00
25221510	F, G, H	Salami, soft, cooked	1.00
25221520	F, G, H	Salami, dry or hard	1.00
25221530	F, G, H	Salami, beef	1.00
25221610	F, G, H	Scrapple, cooked	1.00
25221650	F	Smoked link sausage, pork	1.00
25221660	F	Smoked link sausage, pork and beef	1.00
25221680	F	Smoked sausage, pork	1.00
25221830	G, H	Turkey or chicken sausage	1.00
25221840	F	Turkey breakfast sausage, bulk, patty or link, cooked	1.00
25221850	F	Turkey sausage, smoked	1.00
25221855	H*	Turkey or chicken sausage, reduced sodium	1.00
25221860	F, G, H	Turkey or chicken sausage, reduced fat	1.00
25221870	F, G, H	Turkey or chicken and pork sausage	1.00
25221875	H*	Turkey or chicken, pork, and beef sausage, reduced sodium	1.00
25221880	F, G	Turkey or chicken, pork, and beef sausage, reduced fat	1.00
25221890	F	Turkey, pork, and beef sausage, lowfat, smoked	1.00
25230110	F, G, H	Luncheon meat, NFS	1.00
25230210	F, G, H	Ham, sliced, prepackaged or deli, luncheon meat	1.00
25230220	F, G, H	Ham, sliced, low salt, prepackaged or deli, luncheon meat	1.00

Food Code	NHANES Cycles	Description	Proportion
25230230	F, G, H	Ham, sliced, extra lean, prepackaged or deli, luncheon meat	1.00
25230235	G, H	Ham, sliced, extra lean, lower sodium, prepackaged or deli, luncheon meat	1.00
25230310	F, G, H	Chicken or turkey loaf, prepackaged or deli, luncheon meat	1.00
25230410	F, G, H	Ham loaf, luncheon meat	1.00
25230430	F, G, H	Ham and cheese loaf	1.00
25230450	F, G, H	Honey loaf	1.00
25230510	F, G, H	Ham, luncheon meat, chopped, minced, pressed, spiced, not canned	1.00
25230520	F, G, H	Ham, luncheon meat, chopped, minced, pressed, spiced, lowfat, not canned	1.00
25230610	F, G, H	Luncheon loaf (olive, pickle, or pimiento)	1.00
25230710	F, G, H	Sandwich loaf, luncheon meat	1.00
25230790	F, G, H	Turkey ham, sliced, extra lean, prepackaged or deli, luncheon meat	1.00
25230800	F, G, H	Turkey ham	1.00
25230820	F, G, H	Turkey pastrami	1.00
25230840	F, G, H	Turkey salami	1.00
25230900	F, G, H	Turkey or chicken breast, prepackaged or deli, luncheon meat	1.00
25230905	F, G, H	Turkey or chicken breast, low salt, prepackaged or deli, luncheon meat	1.00
25231110	F, G, H	Beef, sliced, prepackaged or deli, luncheon meat	1.00
27120020	F, G, H	Ham or pork with gravy (mixture)	0.49
27120030	F, G, H	Ham or pork with barbecue sauce (mixture)	0.70
27120080	F, G, H	Ham stroganoff	0.27
27120090	F, G, H	Ham or pork with (mushroom) soup (mixture)	0.49
27120100	F, G, H	Ham or pork with tomato-based sauce (mixture)	0.23
27120110	F, G, H	Sausage with tomato-based sauce (mixture)	0.29

Food Code	NHANES Cycles	Description	Proportion
27120120	F, G, H	Sausage gravy	0.18
27120150	F, G, H	Pork or ham with soy-based sauce (mixture)	0.46
27120210	F, G, H	Frankfurter or hot dog, with chili, no bun	0.47
27120250	F, G, H	Frankfurters or hot dogs with tomato-based sauce (mixture)	0.46
27220020	F, G, H	Ham and noodles with cream or white sauce (mixture)	0.26
27220030	F, G, H	Ham and rice with (mushroom) soup (mixture)	0.17
27220050	F, G, H	Ham or pork with stuffing (mixture)	0.35
27220080	F, G, H	Ham croquette	0.42
27220120	F, G, H	Sausage and rice with tomato-based sauce (mixture)	0.34
27220150	F, G, H	Sausage and rice with (mushroom) soup (mixture)	0.27
27220170	F, G, H	Sausage and rice with cheese sauce (mixture)	0.22
27220190	F, G, H	Sausage and noodles with cream or white sauce (mixture)	0.12
27220210	F, G, H	Ham and noodles, no sauce (mixture)	0.36
27220310	F, G, H	Ham or pork and rice, no sauce (mixture)	0.36
27220510	F, G, H	Ham or pork and potatoes with gravy (mixture)	0.14
27220520	F, G, H	Ham or pork and potatoes with cheese sauce (mixture)	0.18
27260500	F, G, H	Vienna sausages stewed with potatoes, Puerto Rican style (Salchichas guisadas)	0.23
27311210	F, G, H	Corned beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)	0.21
27311220	F, G, H	Corned beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)	0.24
27320020	F, G, H	Ham pot pie	0.18
27320025	G, H	Ham or pork, noodles and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)	0.23
27320027	G, H	Ham or pork, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)	0.24
27320030	F, G, H	Ham or pork, noodles and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)	0.14

Food Code	NHANES Cycles	Description	Proportion
27320070	F, G, H	Ham or pork, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)	0.16
27320080	F, G, H	Sausage, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce	0.29
27320090	F, G, H	Sausage, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce	0.29
27320120	F, G, H	Sausage, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)	0.16
27320130	F, G, H	Sausage, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)	0.16
27320410	F, G, H	Ham, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)	0.32
27320450	F, G, H	Ham, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)	0.45
27350020	F, G, H	Paella with seafood	0.01
27350030	F, G, H	Seafood stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-base sauce	0.02
27350310	F, G, H	Seafood stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-base sauce	0.02
27360090	F, G, H	Paella, NFS	0.04
27363100	F, G, H	Jambalaya with meat and rice	0.13
27418310	F, G, H	Corned beef with tomato sauce and onion, Puerto Rican style (mixture)	0.63
27420020	F, G, H	Ham or pork salad	0.52
27420040	F, G, H	Frankfurters or hot dogs and sauerkraut (mixture)	0.62
27420080	F, G, H	Greens with ham or pork (mixture)	0.13
27420250	F, G, H	Ham and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), no sauce (mixture)	0.49
27420270	F, G, H	Ham and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)). no sauce (mixture)	0.49
27420450	F, G, H	Sausage and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), tomato-based sauce (mixture)	0.40

Food Code	NHANES Cycles	Description	Proportion
27420460	F, G, H	Sausage and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), tomato-based sauce (mixture)	0.44
27420470	F, G, H	Sausage and peppers, no sauce (mixture)	0.76
27446315	F, G, H	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	0.04
27446320	F, G, H	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	0.04
27448020	F, G, H	Chicken or turkey fricassee, with sauce, no potatoes, Puerto Rican style (potatoes reported separately)	0.09
27460510	F, G, H	Antipasto with ham, fish, cheese, vegetables	0.20
27510910	F, G, H	Corned beef sandwich	0.40
27510950	F, G, H	Reuben sandwich (corned beef sandwich with sauerkraut and cheese), with spread	0.30
27511010	F, G, H	Pastrami sandwich	0.40
27513060	F, G, H	Roast beef sandwich with bacon and cheese sauce	0.13
27518000	G, H	Wrap sandwich filled with beef patty, bacon, cheese, tomato and/or catsup, and spread and/or sauce	0.41
27520110	F, G, H	Bacon sandwich, with spread	0.35
27520120	F, G, H	Bacon and cheese sandwich, with spread	0.06
27520130	F, G, H	Bacon, chicken, and tomato club sandwich, with lettuce and spread	0.08
27520135	F, G, H	Bacon, chicken, and tomato club sandwich, with cheese, lettuce and spread	0.08
27520140	F, G, H	Bacon and egg sandwich	0.12
27520150	F, G, H	Bacon, lettuce, and tomato sandwich with spread	0.11
27520155	H*	Bacon, lettuce, and tomato submarine sandwich, with spread	0.11
27520156	H*	Bacon, lettuce, tomato, and cheese submarine sandwich, with spread	0.11

Food Code	NHANES Cycles	Description	Proportion
27520160	F, G, H	Bacon, chicken, and tomato club sandwich, on multigrain roll with lettuce and spread	0.17
27520165	F, G, H	Bacon, chicken fillet (breaded, fried), and tomato club with lettuce and spread	0.05
27520166	F, G, H	Bacon, chicken fillet (breaded, fried), and tomato club sandwich with cheese, lettuce and spread	0.05
27520170	F, G, H	Bacon on biscuit	0.11
27520250	F, G, H	Ham on biscuit	0.11
27520300	F, G, H	Ham sandwich, with spread	0.47
27520310	F, G, H	Ham sandwich with lettuce and spread	0.45
27520320	F, G, H	Ham and cheese sandwich, with lettuce and spread	0.36
27520330	F, G, H	Ham and egg sandwich	0.22
27520340	F, G, H	Ham salad sandwich	0.36
27520350	F, G, H	Ham and cheese sandwich, with spread, grilled	0.41
27520360	F, G, H	Ham and cheese sandwich, on bun, with lettuce and spread	0.36
27520370	F, G, H	Hot ham and cheese sandwich, on bun	0.37
27520380	F, G, H	Ham and cheese on English muffin	0.30
27520390	F, G, H	Ham and cheese submarine sandwich, with lettuce, tomato and spread	0.33
27520410	F, G, H	Cuban sandwich, (Sandwich cubano), with spread	0.18
27520540	F, G, H	Ham and tomato club sandwich, with lettuce and spread	0.33
27541000	F, G, H	Turkey, ham, and roast beef club sandwich, with lettuce, tomato and spread	0.09
27541001	F, G, H	Turkey, ham, and roast beef club sandwich with cheese, lettuce, tomato, and spread	0.09
27560000	F, G, H	Luncheon meat sandwich, NFS, with spread	0.32
27560110	F, G, H	Bologna sandwich, with spread	0.32
27560120	F, G, H	Bologna and cheese sandwich, with spread	0.24
27560300	F, G, H	Corn dog (frankfurter or hot dog with cornbread coating)	0.67

Food Code	NHANES Cycles	Description	Proportion
27560310	F	Corny dog, with chili, on bun	0.28
27560320	F	Frankfurter or hot dog, plain, on bun	0.58
27560330	F	Frankfurter or hot dog, with cheese, plain, on bun	0.45
27560340	F	Frankfurter or hot dog, with catsup and/or mustard, on bun	0.51
27560350	F, G, H	Pig in a blanket (frankfurter or hot dog wrapped in dough)	0.67
27560360	F	Frankfurter or hot dog, with chili, on bun	0.35
27560370	F	Frankfurter or hot dog with chili and cheese, on bun	0.36
27560380	F	Pochito (frankfurter or hot dog and beef chili wrapped in tortilla)	0.46
27560400	F	Chicken frankfurter or hot dog, plain, on bun	0.58
27560410	F, G, H	Puerto Rican sandwich (Sandwich criollo)	0.10
27560650	F, G, H	Sausage on biscuit	0.50
27560660	F, G, H	Sausage griddle cake sandwich	0.50
27560670	F, G, H	Sausage and cheese on English muffin	0.30
27560700	F	Sausage on biscuit, diet	0.41
27560705	F, G, H	Sausage balls (made with biscuit mix and cheese)	0.23
27560710	F, G, H	Sausage sandwich	0.50
27560720	F, G, H	Sausage and spaghetti sauce sandwich	0.44
27560910	F, G, H	Cold cut submarine sandwich, with cheese, lettuce, tomato, and spread	0.33
27563010	F, G, H	Meat spread or potted meat sandwich	0.50
27564000	G, H	Frankfurter or hot dog sandwich, NFS, plain, on bun	0.58
27564001	H*	Frankfurter or hot dog sandwich, NFS, plain, on wheat bun	0.58
27564002	H*	Frankfurter or hot dog sandwich, NFS, plain, on whole wheat bun	0.58
27564003	H*	Frankfurter or hot dog sandwich, NFS, plain, on whole grain white bun	0.58

Food Code	NHANES Cycles	Description	Proportion
27564004	H*	Frankfurter or hot dog sandwich, NFS, plain, on multigrain bun	0.58
27564010	G, H	Frankfurter or hot dog sandwich, NFS, plain, on white bread	0.67
27564020	G, H	Frankfurter or hot dog sandwich, NFS, plain, on wheat bread	0.67
27564030	G, H	Frankfurter or hot dog sandwich, NFS, plain, on whole wheat bread, NS as to 100%	0.61
27564040	G, H	Frankfurter or hot dog sandwich, NFS, plain, on whole grain white bread	0.61
27564050	G, H	Frankfurter or hot dog sandwich, NFS, plain, on multigrain bread	0.61
27564060	G, H	Frankfurter or hot dog sandwich, beef, plain,on bun	0.58
27564061	H*	Frankfurter or hot dog sandwich, beef, plain, on wheat bun	0.58
27564062	H*	Frankfurter or hot dog sandwich, beef, plain, on whole wheat bun	0.58
27564063	H*	Frankfurter or hot dog sandwich, beef, plain, on whole grain white bun	0.58
27564064	H*	Frankfurter or hot dog sandwich, beef, plain, on multigrain bun	0.58
27564070	G, H	Frankfurter or hot dog sandwich, beef, plain, on white bread	0.67
27564080	G, H	Frankfurter or hot dog sandwich, beef, plain, on wheat bread	0.67
27564090	G, H	Frankfurter or hot dog sandwich, beef, plain, on whole wheat bread, NS as to 100%	0.61
27564100	G, H	Frankfurter or hot dog sandwich, beef, plain, on whole grain white bread	0.61
27564110	G, H	Frankfurter or hot dog sandwich, beef, plain, on multigrain bread	0.61
27564120	G, H	Frankfurter or hot dog sandwich, beef and pork, plain, on bun	0.58
27564121	H*	Frankfurter or hot dog sandwich, beef and pork, plain, on wheat bun	0.58
27564122	H*	Frankfurter or hot dog sandwich, beef and pork, plain, on whole wheat bun	0.58

Food Code	NHANES Cycles	Description	Proportion
27564123	H*	Frankfurter or hot dog sandwich, beef and pork, plain, on whole grain white bun	0.58
27564124	H*	Frankfurter or hot dog sandwich, beef and pork, plain, on multigrain bun	0.58
27564130	G, H	Frankfurter or hot dog sandwich, beef and pork, plain, on white bread	0.67
27564140	G, H	Frankfurter or hot dog sandwich, beef and pork, plain, on wheat bread	0.67
27564150	G, H	Frankfurter or hot dog sandwich, beef and pork, plain, on whole wheat bread, NS as to 100%	0.61
27564160	G, H	Frankfurter or hot dog sandwich, beef and pork, plain, on whole grain white bread	0.61
27564170	G, H	Frankfurter or hot dog sandwich, beef and pork, plain, on multigrain bread	0.61
27564180	G, H	Frankfurter or hot dog sandwich, meat and poultry, plain, on bun	0.58
27564181	H*	Frankfurter or hot dog sandwich, meat and poultry, plain, on wheat bun	0.58
27564182	H*	Frankfurter or hot dog sandwich, meat and poultry, plain, on whole wheat bun	0.58
27564183	H*	Frankfurter or hot dog sandwich, meat and poultry, plain, on whole grain white bun	0.58
27564184	H*	Frankfurter or hot dog sandwich, meat and poultry, plain, on multigrain bun	0.58
27564190	G, H	Frankfurter or hot dog sandwich, meat and poultry, plain, on white bread	0.67
27564200	G, H	Frankfurter or hot dog sandwich, meat and poultry, plain, on wheat bread	0.67
27564210	G, H	Frankfurter or hot dog sandwich, meat and poultry, plain, on whole wheat bread, NS as to 100%	0.61
27564220	G, H	Frankfurter or hot dog sandwich, meat and poultry, plain, on whole grain white bread	0.61
27564230	G, H	Frankfurter or hot dog sandwich, meat and poultry, plain, on multigrain bread	0.61

Food Code	NHANES Cycles	Description	Proportion
27564240	G, H	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on bun	0.58
27564241	H*	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on wheat bun	0.58
27564242	H*	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on whole wheat bun	0.58
27564243	H*	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on whole grain white bun	0.58
27564244	H*	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on multigrain bun	0.58
27564250	G, H	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on white bread	0.67
27564260	G, H	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on wheat bread	0.67
27564270	G, H	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on whole wheat bread, NS as to 100%	0.61
27564280	G, H	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on whole grain white bread	0.61
27564290	G, H	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on multigrain bread	0.61
27564300	G, H	Frankfurter or hot dog sandwich, reduced fat or light, plain, on bun	0.58
27564301	H*	Frankfurter or hot dog sandwich, reduced fat or light, plain, on wheat bun	0.58
27564302	H*	Frankfurter or hot dog sandwich, reduced fat or light, plain, on whole wheat bun	0.58
27564303	H*	Frankfurter or hot dog sandwich, reduced fat or light, plain, on whole grain white bun	0.58
27564304	H*	Frankfurter or hot dog sandwich, reduced fat or light, plain, on multigrain bun	0.58
27564310	G, H	Frankfurter or hot dog sandwich, reduced fat or light, plain, on white bread	0.67
27564320	G, H	Frankfurter or hot dog sandwich, reduced fat or light, plain, on wheat bread	0.67

Food Code	NHANES Cycles	Description	Proportion
27564330	G, H	Frankfurter or hot dog sandwich, reduced fat or light, plain, on whole wheat bread, NS as to 100%	0.61
27564340	G, H	Frankfurter or hot dog sandwich, reduced fat or light, plain, on whole grain white bread	0.61
27564350	G, H	Frankfurter or hot dog sandwich, reduced fat or light, plain, on multigrain bread	0.61
27564360	G, H	Frankfurter or hot dog sandwich, fat free, plain, on bun	0.58
27564361	H*	Frankfurter or hot dog sandwich, fat free, plain, on wheat bun	0.58
27564362	H*	Frankfurter or hot dog sandwich, fat free, plain, on whole wheat bun	0.58
27564363	H*	Frankfurter or hot dog sandwich, fat free, plain, on whole grain white bun	0.58
27564364	H*	Frankfurter or hot dog sandwich, fat free, plain, on multigrain bun	0.58
27564370	G, H	Frankfurter or hot dog sandwich, fat free, plain, on white bread	0.67
27564380	G, H	Frankfurter or hot dog sandwich, fat free, plain, on wheat bread	0.67
27564390	G, H	Frankfurter or hot dog sandwich, fat free, plain, on whole wheat bread, NS as to 100%	0.61
27564400	G, H	Frankfurter or hot dog sandwich, fat free, plain, on whole grain white bread	0.61
27564410	G, H	Frankfurter or hot dog sandwich, fat free, plain, on multigrain bread	0.61
27564440	G, H	Frankfurter or hot dog sandwich, with chili, on bun	0.35
27564441	H*	Frankfurter or hot dog sandwich, with chili, on wheat bun	0.35
27564442	H*	Frankfurter or hot dog sandwich, with chili, on whole wheat bun	0.35
27564443	H*	Frankfurter or hot dog sandwich, with chili, on whole grain white bun	0.35
27564444	H*	Frankfurter or hot dog sandwich, with chili, on multigrain bun	0.35
27564450	G, H	Frankfurter or hot dog sandwich, with chili, on white bread	0.38

Food Code	NHANES Cycles	Description	Proportion
27564460	G, H	Frankfurter or hot dog sandwich, with chili, on wheat bread	0.38
27564470	G, H	Frankfurter or hot dog sandwich, with chili, on whole wheat bread, NS as to 100%	0.36
27564480	G, H	Frankfurter or hot dog sandwich, with chili, on whole grain white bread	0.36
27564490	G, H	Frankfurter or hot dog sandwich, with chili, on multi-grain bread	0.36
27564500	G, H	Frankfurter or hot dog sandwich, with vegetarian chili, on bun	0.35
27564501	H*	Frankfurter or hot dog sandwich, with meatless chili, on wheat bun	0.35
27564502	H*	Frankfurter or hot dog sandwich, with meatless chili, on whole wheat bun	0.35
27564503	H*	Frankfurter or hot dog sandwich, with meatless chili, on whole grain white bun	0.35
27564504	H*	Frankfurter or hot dog sandwich, with meatless chili, on multigrain bun	0.35
27564510	G, H	Frankfurter or hot dog sandwich, with vegetarian chili, on white bread	0.38
27564520	G, H	Frankfurter or hot dog sandwich, with vegetarian chili, on wheat bread	0.38
27564530	G, H	Frankfurter or hot dog sandwich, with meatless chili, on whole wheat bread, NS as to 100%	0.36
27564540	G, H	Frankfurter or hot dog sandwich, with vegetarian chili, on whole grain white bread	0.36
27564550	G, H	Frankfurter or hot dog sandwich, with vegetarian chili, on multigrain bread	0.36
27564560	G, H	Frankfurter or hot dog sandwich, meatless, on bun, with vegetarian chili	0.40
27564570	G, H	Frankfurter or hot dog sandwich, meatless, on bread, with vegetarian chili	0.43
28110300	F, G, H	Salisbury steak dinner, NFS (frozen meal)	0.20
28111010	F	Corned beef hash with apple slices, vegetable (frozen meal)	0.20

Food Code	NHANES Cycles	Description	Proportion
28120310	F	Pork with rice, vegetable, in soy-based sauce (diet frozen meal)	0.22
28320140	F, G, H	Ham, noodle, and vegetable soup, Puerto Rican style	0.18
28321130	F, G, H	Bacon soup, cream of, prepared with water	0.10
28340700	F, G, H	Bird's nest soup (chicken, ham, and noodles)	0.10
32101500	F, G, H	Egg, Benedict	0.25
32105030	F	Egg omelet or scrambled egg, with ham or bacon	0.29
32105059	F	Egg omelet or scrambled egg, with ham or bacon, and dark-green vegetables	0.14
32105060	F	Egg omelet or scrambled egg, with ham or bacon and vegetables other than dark-green	0.15
32105080	F	Egg omelet or scrambled egg, with ham or bacon and cheese	0.15
32105081	F	Egg omelet or scrambled egg, with ham or bacon, cheese, and dark-green vegetables	0.12
32105082	F	Egg omelet or scrambled egg, with ham or bacon, cheese, and vegetables other than dark-green	0.12
32105085	F	Egg omelet or scrambled egg, with ham or bacon, cheese, and tomatoes	0.14
32105116	F	Egg omelet or scrambled egg, with sausage and dark-green vegetables	0.14
32105117	F	Egg omelet or scrambled egg, with sausage, cheese, and dark-green vegetables	0.12
32105118	F	Egg omelet or scrambled egg, with sausage and vegetables other than dark-green	0.14
32105119	F	Egg omelet or scrambled egg, with sausage, cheese, and vegetables other than dark-green	0.12
32105120	F	Egg omelet or scrambled egg, with sausage and mushrooms	0.16
32105121	F	Egg omelet or scrambled egg, with sausage and cheese	0.15
32105122	F	Egg omelet or scrambled egg, with sausage	0.17
32105123	F	Egg omelet or scrambled egg, with sausage, cheese, and mushrooms	0.13

Food Code	NHANES Cycles	Description	Proportion
32105125	F	Egg omelet or scrambled egg, with hot dogs	0.29
32105126	F	Egg omelet or scrambled egg, with hot dog and cheese	0.15
32105190	F, G, H	Egg casserole with bread, cheese, milk and meat	0.22
32130200	G, H	Egg omelet or scrambled egg, with meat, made with margarine	0.31
32130210	G, H	Egg omelet or scrambled egg, with meat, made with oil	0.31
32130220	G, H	Egg omelet or scrambled egg, with meat, made with butter	0.31
32130240	G, H	Egg omelet or scrambled egg, with meat, made with animal fat or meat drippings	0.31
32130260	G, H	Egg omelet or scrambled egg, with meat, made with cooking spray	0.32
32130270	G, H	Egg omelet or scrambled egg, with meat, made without fat	0.46
32130300	G, H	Egg omelet or scrambled egg, with cheese and meat, made with margarine	0.29
32130310	G, H	Egg omelet or scrambled egg, with cheese and meat, made with oil	0.29
32130320	G, H	Egg omelet or scrambled egg, with cheese and meat, made with butter	0.29
32130340	G, H	Egg omelet or scrambled egg, with cheese and meat, made with animal fat or meat drippings	0.29
32130360	G, H	Egg omelet or scrambled egg, with cheese and meat, made with cooking spray	0.30
32130370	G, H	Egg omelet or scrambled egg, with cheese and meat, made without fat	0.30
32130800	G, H	Egg omelet or scrambled egg, with meat and tomatoes, fat added in cooking	0.17
32130810	G, H	Egg omelet or scrambled egg, with meat and tomatoes, fat not added in cooking	0.17
32130820	G, H	Egg omelet or scrambled egg, with meat and tomatoes, NS as to fat added in cooking	0.17
32130830	G, H	Egg omelet or scrambled egg, with meat and dark-green vegetables, fat added in cooking	0.17

Food Code	NHANES Cycles	Description	Proportion
32130840	G, H	Egg omelet or scrambled egg, with meat and dark-green vegetables, fat not added in cooking	0.17
32130850	G, H	Egg omelet or scrambled egg, with meat and dark-green vegetables, NS as to fat added in cooking	0.17
32130860	G, H	Egg omelet or scrambled egg, with meat, tomatoes, and dark-green vegetables, fat added in cooking	0.16
32130870	G, H	Egg omelet or scrambled egg, with meat, tomatoes, and dark-green vegetables, fat not added in cooking	0.16
32130880	G, H	Egg omelet or scrambled egg, with meat, tomatoes, and dark-green vegetables, NS as to fat added in cooking	0.16
32130890	G, H	Egg omelet or scrambled egg, with meat and vegetables other than dark-green and/or tomatoes, fat added in cooking	0.19
32130900	G, H	Egg omelet or scrambled egg, with meat and vegetables other than dark-green and/or tomatoes, fat not added in cooking	0.21
32130910	G, H	Egg omelet or scrambled egg, with meat and vegetables other than dark-green and/or tomatoes, NS as to fat added in cooking	0.19
32131000	G, H	Egg omelet or scrambled egg, with cheese, meat, and tomatoes, fat added in cooking	0.16
32131010	G, H	Egg omelet or scrambled egg, with cheese, meat, and tomatoes, fat not added in cooking	0.16
32131020	G, H	Egg omelet or scrambled egg, with cheese, meat, and tomatoes, NS as to fat added in cooking	0.16
32131030	G, H	Egg omelet or scrambled egg, with cheese, meat, and dark-green vegetables, fat added in cooking	0.20
32131040	G, H	Egg omelet or scrambled egg, with cheese, meat, and dark-green vegetables, fat not added in cooking	0.20
32131050	G, H	Egg omelet or scrambled egg, with cheese, meat, and dark-green vegetables, NS as to fat added in cooking	0.20
32131060	G, H	Egg omelet or scrambled egg, with cheese, meat, tomatoes, and dark-green vegetables, fat added in cooking	0.19
32131070	G, H	Egg omelet or scrambled egg, with cheese, meat, tomatoes, and dark-green vegetables, fat not added in cooking	0.19
32131080	G, H	Egg omelet or scrambled egg, with cheese, meat, tomatoes, and dark-green vegetables, NS as to fat added in cooking	0.19

Food Code	NHANES Cycles	Description	Proportion
32131090	G, H	Egg omelet or scrambled egg, with cheese, meat, and vegetables other than dark-green and/or tomatoes, fat added in cooking	0.18
32131100	G, H	Egg omelet or scrambled egg, with cheese, meat, and vegetables other than dark-green and/or tomatoes, fat not added in cooking	0.19
32131110	G, H	Egg omelet or scrambled egg, with cheese, meat, and vegetables other than dark-green and/or tomatoes, NS as to fat added in cooking	0.18
32202000	F, G, H	Egg, cheese, ham, and bacon on bun	0.25
32202010	F, G, H	Egg, cheese, and ham on English muffin	0.25
32202020	F, G, H	Egg, cheese, and ham on biscuit	0.25
32202025	F, G, H	Egg, cheese and ham on bagel	0.08
32202030	F, G, H	Egg, cheese, and sausage on English muffin	0.21
32202034	H*	Egg, cheese, and sausage on bun	0.21
32202035	F, G, H	Egg, extra cheese (2 slices), and extra sausage (2 patties) on bun	0.43
32202050	F, G, H	Egg, cheese, and sausage on biscuit	0.21
32202055	F, G, H	Egg, cheese, and sausage griddle cake sandwich	0.21
32202060	F, G, H	Egg and sausage on biscuit	0.21
32202070	F, G, H	Egg, cheese, and bacon on biscuit	0.21
32202075	F, G, H	Egg, cheese, and bacon griddle cake sandwich	0.21
32202080	F, G, H	Egg, cheese, and bacon on English muffin	0.21
32202085	F, G, H	Egg, cheese and bacon on bagel	0.08
32202090	F, G, H	Egg and bacon on biscuit	0.21
32202110	F, G, H	Egg and ham on biscuit	0.21
32202120	F, G, H	Egg, cheese and sausage on bagel	0.08
32400200	G, H	Egg white, omelet, scrambled, or fried, with meat, fat added in cooking	0.37

Food Code	NHANES Cycles	Description	Proportion
32400210	G, H	Egg white, omelet, scrambled, or fried, with meat, fat not added in cooking	0.38
32400220	G, H	Egg white, omelet, scrambled, or fried, with meat, NS as to fat added in cooking	0.37
32400400	G, H	Egg white, omelet, scrambled, or fried, with cheese and meat, fat added in cooking	0.33
32400410	G, H	Egg white, omelet, scrambled, or fried, with cheese and meat, fat not added in cooking	0.35
32400420	G, H	Egg white, omelet, scrambled, or fried, with cheese and meat, NS as to fat added in cooking	0.33
32400600	G, H	Egg white, omelet, scrambled, or fried, with meat and vegetables, fat added in cooking	0.23
32400610	G, H	Egg white, omelet, scrambled, or fried, with meat and vegetables, fat not added in cooking	0.24
32400620	G, H	Egg white, omelet, scrambled, or fried, with meat and vegetables, NS as to fat added in cooking	0.23
32400700	G, H	Egg white, omelet, scrambled, or fried, with cheese, meat, and vegetables, fat added in cooking	0.21
32400710	G, H	Egg white, omelet, scrambled, or fried, with cheese, meat, and vegetables, fat not added in cooking	0.22
32400720	G, H	Egg white, omelet, scrambled, or fried, with cheese, meat, and vegetables, NS as to fat added in cooking	0.21
33401100	G, H	Egg substitute, omelet, scrambled, or fried, with meat, fat added in cooking	0.37
33401110	G, H	Egg substitute, omelet, scrambled, or fried, with meat, fat not added in cooking	0.38
33401120	G, H	Egg substitute, omelet, scrambled, or fried, with meat, NS as to fat added in cooking	0.37
33401300	G, H	Egg substitute, omelet, scrambled, or fried, with cheese and meat, fat added in cooking	0.33
33401310	G, H	Egg substitute, omelet, scrambled, or fried, with cheese and meat, fat not added in cooking	0.35
33401320	G, H	Egg substitute, omelet, scrambled, or fried, with cheese and meat, NS as to fat added in cooking	0.33

Food Code	NHANES Cycles	Description	Proportion
33401500	G, H	Egg substitute, omelet, scrambled, or fried, with meat and vegetables, fat added in cooking	0.23
33401510	G, H	Egg substitute, omelet, scrambled, or fried, with meat and vegetables, fat not added in cooking	0.24
33401520	G, H	Egg substitute, omelet, scrambled, or fried, with meat and vegetables, NS as to fat added in cooking	0.23
33401600	G, H	Egg substitute, omelet, scrambled, or fried, with cheese, meat, and vegetables, fat added in cooking	0.21
33401610	G, H	Egg substitute, omelet, scrambled, or fried, with cheese, meat, and vegetables, fat not added in cooking	0.22
33401620	G, H	Egg substitute, omelet, scrambled, or fried, with cheese, meat, and vegetables, NS as to fat added in cooking	0.21
35001000	F	Scrambled eggs, sausage, hash brown potatoes (frozen meal)	0.18
35002000	F	Scrambled eggs, bacon, home fried potatoes (frozen meal)	0.13
35003000	F	Scrambled eggs, sausage, pancakes (frozen meal)	0.11
41201010	F, G, H	Baked beans, NFS	0.05
41502000	F	Beans and franks, frozen dinner	0.10
41602030	F, G, H	Split pea and ham soup	0.20
41602090	F, G, H	Split pea and ham soup, canned, reduced sodium, prepared with water or ready-to-serve	0.20
58100010	G, H	Burrito, taco, or quesadilla with egg and breakfast meat	0.13
58100013	G, H	Burrito, taco, or quesadilla with egg and breakfast meat, from fast food	0.18
58100015	G, H	Burrito, taco, or quesadilla with egg, potato, and breakfast meat	0.12
58100017	G, H	Burrito, taco, or quesadilla with egg, potato, and breakfast meat, from fast food	0.17
58100020	G, H	Burrito, taco, or quesadilla with egg, beans, and breakfast meat	0.11
58100340	F	Burrito with eggs, sausage, cheese and vegetables	0.07
58100560	F	Enchilada with ham and cheese, no beans	0.15

Food Code	NHANES Cycles	Description	Proportion
58106500	F, G, H	Pizza with meat, prepared from frozen, thin crust	0.06
58106505	F, G, H	Pizza with meat, prepared from frozen, thick crust	0.08
58106610	F, G, H	Pizza with meat other than pepperoni, from restaurant or fast food, NS as to type of crust	0.08
58106620	F, G, H	Pizza with meat other than pepperoni, from restaurant or fast food, thin crust	0.06
58106625	F, G, H	Pizza with meat other than pepperoni, from restaurant or fast food, regular crust	0.08
58106630	F, G, H	Pizza with meat other than pepperoni, from restaurant or fast food, thick crust	0.08
58106633	G, H	Pizza, with meat other than pepperoni, stuffed crust	0.10
58106635	G, H	Pizza, with meat other than pepperoni, from school lunch, thin crust	0.09
58106636	G, H	Pizza, with meat other than pepperoni, from school lunch, thick crust	0.14
58106640	F, G, H	Pizza with extra meat, NS as to type of crust	0.10
58106650	F, G, H	Pizza with extra meat, thin crust	0.14
58106655	F, G, H	Pizza with extra meat, regular crust	0.10
58106660	F, G, H	Pizza with extra meat, thick crust	0.10
58106700	F, G, H	Pizza with meat and vegetables, prepared from frozen, thin crust	0.06
58106705	F, G, H	Pizza with meat and vegetables, prepared from frozen, thick crust	0.03
58106710	F, G, H	Pizza with meat and vegetables, NS as to type of crust	0.03
58106720	F, G, H	Pizza with meat and vegetables, thin crust	0.06
58106725	F, G, H	Pizza with meat and vegetables, regular crust	0.03
58106730	F, G, H	Pizza with meat and vegetables, thick crust	0.03
58106733	F	Pizza with extra meat and extra vegetables, prepared from frozen, thin crust	0.12
58106734	F	Pizza with extra meat and extra vegetables, prepared from frozen, thick crust	0.12

Food Code	NHANES Cycles	Description	Proportion
58106735	F, G, H	Pizza with extra meat and extra vegetables, NS as to type of crust	0.12
58106736	F, G, H	Pizza with extra meat and extra vegetables, thin crust	0.05
58106737	F, G, H	Pizza with extra meat and extra vegetables, thick crust	0.03
58106738	F, G, H	Pizza with extra meat and extra vegetables, regular crust	0.04
58106740	F, G, H	Pizza with meat and fruit, NS as to type of crust	0.12
58106750	F, G, H	Pizza with meat and fruit, thin crust	0.13
58106755	F, G, H	Pizza with meat and fruit, regular crust	0.10
58106760	F, G, H	Pizza with meat and fruit, thick crust	0.08
58106780	F	Pizza with meat and vegetables, prepared from frozen, lowfat, thin crust	0.11
58108010	F, G, H	Calzone, with meat and cheese	0.07
58108030	F	Panzerotti, with meat, vegetables, and cheese	0.10
58109010	F	Italian pie with meat	0.10
58117510	F, G, H	Hayacas, Puerto Rican style (hominy, pork or ham, vegetables)	0.03
58125110	F, G, H	Quiche with meat, poultry or fish	0.14
58127210	F, G, H	Croissant sandwich, filled with ham and cheese	0.25
58127270	F, G, H	Croissant sandwich with sausage and egg	0.28
58127290	F, G, H	Croissant sandwich with bacon and egg	0.11
58127310	F, G, H	Croissant sandwich with ham, egg, and cheese	0.20
58127330	F, G, H	Croissant sandwich with sausage, egg, and cheese	0.10
58127350	F, G, H	Croissant sandwich with bacon, egg, and cheese	0.10
58128000	F, G, H	Biscuit with gravy	0.12
58132713	F, G, H	Pasta with tomato sauce and frankfurters or hot dogs, canned	0.17
58145160	F, G, H	Macaroni or noodles with cheese and frankfurters or hot dogs	0.20
58146130	F, G, H	Pasta with carbonara sauce	0.03

Food Code	NHANES Cycles	Description	Proportion
58156210	F, G, H	Rice with vienna sausage, Puerto Rican style (arroz con salchichas)	0.22
58310210	F, G, H	Sausage and french toast (frozen meal)	0.27
58310310	F, G, H	Pancakes and sausage (frozen meal)	0.24
58310410	F	Sausage rice links and whole wheat pancakes (frozen meal)	0.42
71301120	F, G, H	White potato, cooked, with ham and cheese	0.08
71305110	F, G, H	White potato, scalloped, with ham	0.10
71402505	F, G, H	White potato, french fries, with cheese and bacon	0.04
71411000	F, G, H	White potato skins, with adhering flesh, fried, with cheese and bacon	0.11
71508060	F, G, H	White potato, stuffed, baked, peel eaten, stuffed with bacon and cheese	0.03
71508070	F, G, H	White potato, stuffed, baked, peel not eaten, stuffed with bacon and cheese	0.04
71508120	F, G, H	White potato, stuffed with ham, broccoli and cheese sauce, baked, peel eaten	0.12
71602010	F, G, H	Potato salad, German style	0.03
74410110	F, G, H	Puerto Rican seasoning with ham	0.13
74415110	F, G, H	Puerto Rican seasoning with ham and tomato sauce	0.26
75140500	F, G, H	Broccoli salad with cauliflower, cheese, bacon bits, and dressing	0.06
75144100	F, G, H	Lettuce, wilted, with bacon dressing	0.06
75145000	F, G, H	Seven-layer salad (lettuce salad made with a combination of onion, celery, green pepper, peas, mayonnaise, cheese, eggs, and/or bacon)	0.03
75148000	F	Cobb salad with dressing	0.03
75148010	G, H	Cobb salad, no dressing	0.02
83101500	F, G	Bacon dressing (hot)	0.12
83101600	F, G, H	Bacon and tomato dressing	0.12

APPENDIX C

Stability Testing Results

Florida Food Rice Bran Extract Stability Testing Results

First Test Date	4/27/18	4/10/18	2/26/18	5/17/18
Total Plate Count (cfu/g)	1000	2000	1800	600
Total Coliforms (cfu/g)	<10	<10	<10	<10
E. coli (cfu/g)	<10	<10	<10	<10
Yeasts (cfu/g)	<100	<100	<100	<100
Molds (cfu/g)	<100	<100	<100	<100
Second Test Date	11/28/18	11/28/18	11/28/18	11/28/18
Total Plate Count (cfu/g)	470	1300	50	80
Total Coliforms (cfu/g)	<10	<10	<10	<10
E. coli (cfu/g)	<10	<10	<10	<10
Yeasts (cfu/g)	<100	<100	<100	<100
Molds (cfu/g)	<100	<100	<100	<100
Storage Temperature (℃)	25	25	25	35
Time Between Tests (weeks)	31	33	39	28

EXHIBIT I

Report of the Expert Panel

OPINION OF AN EXPERT PANEL ON THE SAFETY AND GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF RICE BRAN EXTRACT 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 Florida Food Products, LLC (Florida Foods) to determine the safety and Generally Recognized as Safe (GRAS) status of the use of rice bran extract as an ingredient for use in food for human consumption. The intended use of the rice bran extract is as a moisture retention agent. Specifically, the rice bran extract would be used as an alternative to other phosphates already commonly added to processed meats for the same functional purpose, such as sodium tripolyphosphate and tetrasodium pyrophosphate. The rice bran extract product is manufactured in accordance with current Good Manufacturing Practice (cGMP) and meets the proposed specifications.

A detailed review based on the existing scientific literature (through October 2018) on the safety of rice bran extract was conducted by ToxStrategies, Inc. (ToxStrategies) and is summarized in the attached dossier. The Expert Panel members independently reviewed the dossier prepared by ToxStrategies and other pertinent information and convened on December 5, 2018 via teleconference. Based on their independent, critical evaluation of all of the available information and discussions during the December 5, 2018 teleconference, the Expert Panel unanimously concluded that the intended uses described herein for Florida Food's rice bran extract ingredient, meeting appropriate food-grade specifications as described in the supporting dossier (**GRAS Determination of Rice Bran Extract for Use in Food**) and manufactured according to cGMP, is safe, suitable, and GRAS based on scientific procedures. A summary of the basis for the Expert Panel's conclusion is provided below.

Summary and Basis for GRAS Determination

Description

The rice bran extract ingredient is a water-soluble dried powder consisting of rice bran extract that is high in naturally occurring phosphates (5-7%) and is derived from *Oryza sativa*.

Manufacturing Process

The manufacture of rice bran extract involves the addition of hydrochloric acid and soft water to dehulled rice bran to reach a specific pH. The mixture is then subjected to an extraction process that includes heat and agitation for a designated time period. Following the extraction process, the liquid extract is separated from insoluble solids by a combination of separation techniques, including screen filtration, centrifugation, and membrane filtration, to remove fine insoluble particulates. The liquid extract is then treated further using an ion exchange resin to chelate mineral ions. The liquid extract is then pH-adjusted using concentrated sodium hydroxide. The pH-adjusted liquid extract is concentrated in solids by removing water using vacuum evaporation. The concentrated liquid extract is then stored at refrigeration temperatures until it is pasteurized to reduce microbial loads and meet microbial specifications. The concentrated liquid extract is dried in a vacuum belt dryer or a vacuum tray dryer to convert it to dry flakes. The dry flakes are stored in a humidity-controlled atmosphere until they are ground into a fine powder. An anticaking agent (silicon dioxide) is added to produce a free-flowing powder product, which is referred to as the final rice bran extract product. Sea salt is added to ensure the functionality is standardized based on concentration of phosphorous (variances in naturally occurring phosphorous/phosphate content are dependent upon the raw material). The final rice bran extract is passed through a metal detector to ensure absence of any metal particles before packaging in vacuum-sealed packages. The finished rice bran extract undergoes quality control tests to meet product specifications before being released for sale. All reagents/processing aids are safe and suitable for use in production of the rice bran extract ingredient and are commonly used in food ingredient manufacturing processes.

Analytical (chemical and microbiological) results for the rice bran extract product confirm that the finished product meets the proposed analytical specifications as demonstrated by the consistency of production, the lack of impurities and contaminants (e.g., heavy metals, pesticides, mycotoxins, polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, and dioxin-like polychlorinated biphenyls), and its stability under accelerated stability conditions over a six- to nine-month period.

Intended Use and Intake Assessment

Florida Food proposes to use rice bran extract in specified processed meats at a maximum use level of 1.5% by weight. The intended use of the rice bran extract is as a moisture retention agent. The rice bran extract product is intended to be used as an alternative to other phosphates already approved for use in foods and included on the list of USDA Safe and Suitable Ingredients Used in the Production of Meat, Poultry, And Egg Products, in the category of "moisture retention. It is to be used in a similar manner and for the same technical reasons (i.e., moisture retention) as those other phosphates on this List (USDA, 2018).

An intake assessment to estimate the mean and 90th percentile daily intake of the ingredient, rice bran extract, based on its intended use in foods was conducted by ToxStrategies (2018). Two-day average intake data were obtained from the three most recent National Health and Nutrition Examination Survey (NHANES) biennials: 2009–2010, 2011–2012, and 2013–2014. Based on a maximum use level of 1.5%, the *per-user* mean and 90th percentile estimated daily intakes (EDIs) of rice bran extract for the U.S. population ages 2 and older were determined to be 0.71 and 1.50 g/day (0.011 and 0.025 g/kg body weight/day), respectively. For the total U.S. population ages 2 and older, the *per capita* mean and 90th percentile EDIs were 0.44 and 1.24 g/day (0.007 and 0.019 g/kg body weight/day), respectively.

In addition, the available data on trends in processed meat consumption demonstrate that intake is not expected to increase in the near future. For example, Rehm et al. (2016) found that consumption of processed meats (defined as frankfurters, sausage, luncheon meats [made from meat or poultry], and smoked/cured meats) did not change significantly in adults between 1999–2000 and 2011–2012 (p value for trend = 0.22). Consumption was found to decrease in children, with intake of processed meats (defined as frankfurters, sausages, luncheon meats, and other processed meat products) decreasing between 1989–1991 and 2009–2010 (p value <0.01) (Slining et al., 2013). These studies provide corroborative information demonstrating that the intake estimates presented above are likely conservative and are unlikely to change over time. Of note, rice bran is listed on USDA's Safe and Suitable List as a binder for various comminuted meat and poultry products, up to 3.5% of the product formulation (USDA, 2018).

History of Use

The intended use of the rice bran extract is to increase water holding capacity (i.e., water retention), a function of several of the most common phosphates widely used currently in the marketplace, such as sodium tripolyphosphate and tetrasodium pyrophosphate (FAO, 1985; Long et al., 2011). Many food phosphates are noted in the CFR as GRAS for multipurpose use according to 21 CFR §182 (e.g., §182.1087, §182.1778, §182.1781, §182.1810, and §182.6789).

Rice and its derivatives have a long history as a source of human food, and they serve as a dietary staple for more than half the global population (Burlando and Cornara, 2014; Henderson et al. 2012). In the US, a more recent intake survey estimated 84% of adults (age 19+ years) to be rice consumers, with the majority consuming between 0.25- and 0.5 oz (equivalent) per day (Nicklas et al., 2014). Rice bran is considered to be nutritionally comparable to rice, and is a concentrated source of vitamins, minerals, flavones, and other phytonutrients also present in brown rice (Burlando and Cornara, 2014; Zarei et al., 2017). The starting material for the subject of the current GRAS determination, rice bran, is considered GRAS as a substance of natural biological origin consumed prior to January 1, 1958 and is currently used in many food applications, including in baked goods, cereals, crackers, pasta, beverages, and medical foods (FDA, 2011; Kahlon, 2009; Sharif et al., 2013; Zarei et al., 2017). Rice bran is also currently listed on the USDA's Safe and Suitable List as a binder for various comminuted meat and poultry products (USDA, 2018).

Other rice bran extracts and related products have been reported to be used in human foods, cosmetics, and personal care products, and as nutritional supplements, for many years (Andersen, 2006). In addition, a brief self-GRAS statement has been available in the public domain since 1992 (RIBUS, 2018). The starting material, rice bran, is GRAS as a substance of natural biological origin in accordance with 21 CFR §170.30. The rice bran extract that is the subject of the current GRAS determination employs only water, heat, and agitation in the extraction process. Hydrochloric acid is used to adjust pH, and silicon dioxide is used as an anti-caking agent, both of which are commonly used in food ingredient manufacturing processes. As such, the extraction process is not expected to introduce any new or potential constituents of concern relative to what is present in rice bran currently consumed widely as a foodstuff.

Safety Data

The chemical constituents of the Florida Food rice bran extract are all commonly found in food and pose no toxicological concern or questions with regard to safety of the proposed product. Based on the EDI, the contribution of phosphorus from the rice bran extract was found to be negligible. Further, given that the rice bran extract is intended to be used as an alternative source of other phosphate products already in use, it is not expected to add to the already existing level of phosphate intake from food products.

The available data on rice bran extracts in the published literature further corroborate these findings, with the various types of extracts demonstrating a lack of mutagenic potential in Ames assays, and anti-mutagenicity and anti-cancer properties in numerous other studies (Hudson et al., 2000; Insuan et al., 2017; Norhaizan et al., 2011; Yasukawa et al., 1998). Studies in animal models designed to evaluate the beneficial effects of rice bran extracts on various health conditions demonstrate that exposure to levels up to 4,410 mg/kg-bw/day for four weeks in rats do not result in any adverse effects reported (Parklak et al., 2017). Similarly, several human clinical trials with rice bran extracts are available in which male or female adults consumed up to 50 mg rice bran extract/day for up to six months, with no adverse effects (Ito et al., 2015; Nhung et al., 2016).

The nutrient and analytical profiles of the Florida Food rice bran extract are very similar to that of whole rice bran. Therefore, safety-related information on rice bran and its constituents, the same as those present in the rice bran extract product, are directly relevant to the current GRAS determination and have been reviewed previously in numerous publications and shown to demonstrate the well-established safety of these foods (FDA, 2011; Henderson et al., 2012; Kahlon, 2009; Zarei et al., 2017). Finally, rice and its derivatives have been determined not to be allergenic outside of isolated instances of hypersensitivity to rice itself. However, any potential concern for an allergic reaction in already sensitive individuals would be addressed, because the food product ingredient lists would state the presence of a rice-derived ingredient, and individuals who wish to avoid rice consumption for any reason would be able to identify the presence of a rice-derived ingredient.

In conclusion, rice and its derivatives have a long history of use as a source of human food, and rice bran, which is the starting material of the rice bran extract product, is considered GRAS as a substance of natural biological origin. Therefore, the safety of rice and rice bran are well-established. The Florida Food rice bran extract can be considered GRAS as the water-based extraction process does not give rise to any concerns regarding the potential safety of the product for human consumption. The safe use of the Florida Food rice bran extract for human consumption is supported by the long history of use of rice and rice bran, including its derivatives, and available safety-related data specific to rice bran extracts. This conclusion is supported further by the nutrient and chemical profile of the rice bran extract, which is consistent with other rice- and rice bran-derived products that are readily available in the marketplace.

General Recognition of the Safety of Rice Bran Extract

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

- The rice bran extract that is the subject of this notification is a water-soluble dried powder consisting of rice bran extract that is high in naturally occurring phosphates. The rice bran extract product is manufactured in a manner consistent with current cGMP for food (21 CFR Part 110). The raw materials and processing aids used in the manufacturing process are food grade and/or approved for use as in food.
- The intake of total and inorganic arsenic from the intended use of rice bran extract is negligible and would not be expected to contribute to the background dietary intake of arsenic. In addition, inorganic arsenic is water soluble, and thus, the manufacturing process of rice bran extract will remove most of the inorganic arsenic.
- Based on a maximum use level of 1.5%, the *per-user* mean and 90th percentile EDIs of rice bran extract for the U.S. population ages 2 and older were determined to be 0.71 and 1.50 g/day (0.011 and 0.025 g/kg body weight/day), respectively. The rice bran product is intended to be used as an alternative to other phosphates already approved for use in foods and included on the Safe and Suitable List and is to be used in a similar manner and for the same technical reasons.
- Rice and its derivatives have a long history of use as a source of human food and serve as a dietary staple for more than half the global population. Safety-related information on rice bran and its constituents, the same as those present in the rice bran extract product, have well-established safety profiles.
- The starting material, rice bran, is GRAS as a substance of natural biological origin in accordance with 21 CFR §170.30. The water extraction process employed by Florida Food is not expected to introduce any new or potential constituents of concern relative to what is present in rice bran currently consumed widely as foodstuff. The Florida Food rice bran extract is very similar to whole rice bran, containing several vitamins and minerals commonly found in food and that pose no toxicological concern or questions with regard to safety of the proposed product.
- The intended use of the rice bran extract is for water retention, a function of several of the most commonly used phosphates currently in the marketplace. Given that the rice bran extract is intended to be used as an alternative source of other phosphate products already in use, it is not expected to add to the existing level of intake from food products. In addition, the contribution of phosphorus from the rice bran extract is negligible.
- Available data on rice bran extracts in the public domain do not raise any questions with regard to their safe use in foods. Various types of extracts were shown to be nonmutagenic in Ames assays, and exhibited anti-mutagenicity and anti-cancer properties in numerous other studies. Human clinical trials and studies in animal models designed to evaluate the beneficial effects of rice bran extracts on various health conditions report a lack of adverse effects associated with consumption of rice bran extracts.
- The potential of rice bran extract to cause allergy is very low at the levels of intended use. However, any potential concern for an allergic reaction in already sensitive individuals would be addressed, because the food product ingredient lists would state the presence of a rice-derived ingredient.

- The body of publicly available scientific literature on the consumption and safety of rice bran and rice bran extract is sufficient to support the safety and GRAS status of the proposed rice bran extract product.

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 Florida Food's rice bran extract product as described in the safety dossier titled **GRAS Determination of Rice Bran Extract for Use in Food**. We conclude that the rice bran extract ingredient produced under the conditions described in the attached dossier and meeting the proposed specifications is safe.

We further unanimously conclude that the intended use of the rice bran extract as a moisture retention agent in specific processed meats at a maximum level of 1.5%, produced from rice bran in a manner that is consistent with current Good Manufacturing Practice ("cGMP") and meeting the appropriate specifications as presented in the supporting dossier, is Generally Recognized as Safe (GRAS) based on scientific procedures.

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

______________________________ ______________

Michael Carakostas, DVM, PhD — Date
Consultant
MC Scientific Consulting LLC

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Stanley M. Tarka, Jr., PhD, F.A.T.S. — Date
Consultant
Tarka Group, Inc.

______________________________ ______________

Thomas Vollmuth, PhD — Date
Consultant
Vollmuth and Associates, LLC

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

[redacted]

Michael Carakostas, DVM, PhD
Consultant
MC Scientific Consulting LLC

12/14/18
Date

____
Stanley M. Tarka, Jr., PhD, F.A.T.S.
Consultant
Tarka Group, Inc.

____
Date

____
Thomas Vollmuth, PhD
Consultant
Vollmuth and Associates, LLC

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Date

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______________________________ ____________

Michael Carakostas, DVM, PhD — Date
Consultant
MC Scientific Consulting LLC

[redacted] — 15 December 2018

Stanley M. Tarka, Jr., PhD, F.A.T.S. — Date
Consultant
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Thomas Vollmuth, PhD — Date
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Michael Carakostas, DVM, PhD — Date
Consultant
MC Scientific Consulting LLC

______________________________ ____________

Stanley M. Tarka, Jr., PhD, F.A.T.S. — Date
Consultant
Tarka Group, Inc.

[redacted] 12/16/2018

Thomas Vollmuth, PhD — Date
Consultant
Vollmuth and Associates, LLC

References

Andersen, FA. 2006. Amended final report on the safety assessment of oryza sativa (rice) bran oil, oryza sativa (rice) germ oil, rice bran acid, oryza sativa (rice) bran wax, hydrogenated rice bran wax, oryza sativa (rice) bran extract, oryza sativa (rice) extract, oryza sativa (rice) germ powder, oryza sativa (rice) starch, oryza sativa (rice) bran, hydrolyzed rice bran extract, hydrolyzed rice bran protein, hydrolyzed rice extract, and hydrolyzed rice protein. Int J Toxicol 25(Suppl 2):91–120.

Burlando B, Cornara L. 2014. Therapeutic properties of rice constituents and derivatives (Oryza sativa L.): A review update. Trends Food Sci Technol 40(1):82–98.

Food and Agriculture Organization of the United Nations (FAO). 1985. Small-scale sausage production. FAO Animal Production and Health Paper 52, available at: http://www.fao.org/docrep/003/x6556e/X6556E00.htm#chPRE.

Food and Drug Administration (U.S. FDA). 2011. GRN No. 373. GRAS Notification for Rice Bran Fiber. Prepared by CJ America, Inc.

Henderson AJ, Ollila CA, Kumar A, Borresen EC, Raina K, Agarwal R, Ryan EP. 2012. Chemopreventive properties of dietary rice bran: current status and future prospects. Adv Nutr 3(5):643–53.

Ito Y, Nakashima Y, Matsuoka S. 2015. Rice bran extract containing acylated steryl glucoside fraction decreases elevated blood LDL cholesterol level in obese Japanese men. J Med Invest. 62:80–84.

Kahlon TS. 2009. Rice bran: Production, composition, functionality, food applications and physiological benefits. In: Cho SS, Samuel P, Editors. Fiber Ingredients. Food Applications and Health Benefits. New York: CRC Press. Taylor & Francis Group, pp. 305–321.

Hudson EA, Dinh PA, Kokubun T, Simmonds MS, Gescher A. 2000. Characterization of potentially chemopreventive phenols in extracts of brown rice that inhibit the growth of human breast and colon cancer cells. Cancer epidemiology, biomarkers & prevention: A publication of the American Association for Cancer Research, cosponsored by the American Society of Preventive Oncology. 9:(11):1163–1170.

Insuan O, Chariyakornkul A, Rungrote Y, Wongpoomchai R. 2017. Antimutagenic and antioxidant activities of Thai rice brans. J Cancer Prevent 22:89–97.

Long NHBS, Gál R, Bunka F. 2011. Use of phosphates in meat products. Afric J Biotechnol 10(86):19874–19882.

Nhung BG, Tuyen LD, Linh VA, Anh ND, Nga TT, Thuc VT, et al. 2016. Rice bran extract reduces the risk of atherosclerosis in post-menopausal Vietnamese women. J Nutr Sci Vitaminol 62:295–302.

Nicklas T, O'Neil,C, Fulgoni V. 2014. Rice consumption is associated with better nutrient intake and diet quality in adults: National Health and Nutrition Examination Survey (NHANES) 2005-2010. Food Nutr Sci 5:525–532.

Norhaizan ME, Ng SK, Norashareena MS, Abdah MA. 2011. Antioxidant and cytotoxicity effect of rice bran phytic acid as an anticancer agent on ovarian, breast and liver cancer cell lines. Malaysian J Nutr 17:367–375.

Parklak W, Munkong N, Somnuk S, Somparn N, Naowaboot J, Yoysungnoen B, Lerdvuthisopon N. 2017. Rice bran water extract attenuates pancreatic abnormalities in high-fat diet-induced obese rats. Trop J Pharmaceut Res 16:819.

Rehm CD, Peñalvo JL, Afshin A, Mozaffarian D. 2016. Dietary intake among US adults, 1999-2012. JAMA 315(23):2542–2553.

RIBUS, Inc. 2018. GRAS statement – Rice bran extract. Accessed at: https://ribus.com/wp-content/uploads/2017/12/RIBUS-GRAS-Status_Rice-Bran-Extract1_1_18.pdf.

Sharif MK, Butt MS, Anjum FM, Khan SH. 2014. Rice bran: Aa novel functional ingredient. Crit Rev Food Sci Nutr 54(6):807–816.

Slining MM, Mathias KC, Popkin BM. 2013. Trends in food and beverage sources among US children and adolescents: 1989-2010. J Acad Nutr Diet 113(12):1683–1694.

ToxStrategies. 2018. Estimated daily intake of rice bran extract. ***Appendix B, GRAS Determination of Rice Bran Extract for Use in Food.***

U.S. Department of Agriculture (USDA). 2018. FSIS Directive 7120.1, Revision 46, Safe and suitable ingredients used in the production of meat, poultry, and egg products, Mar 19, 2018.

Yasukawa K, Akihisa T, Kimura Y, Tamura T, Takido M. 1998. Inhibitory effect of cycloartenol ferulate, a component of rice bran, on tumor promotion in two-stage carcinogenesis in mouse skin. Biol Pharmaceut Bull 21:1072–1076.

Zarei I, Brown DG, Nealon NJ, Ryan EP. 2017. Rice bran metabolome contains amino acids, vitamins & cofactors, and phytochemicals with medicinal and nutritional properties. Rice (N Y) 10(1):24.

ToxStrategies

Innovative solutions
Sound science

September 25, 2019

Mr. Richard Bonnette, M.S.
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
U.S. Food and Drug Administration
Via electronic mail

Subject: GRAS Notification – Rice Bran Extract

Dear Mr. Bonnette:

In response to your original email correspondence on February 27, 2019, we are pleased to provide you with the attached report, which summarizes the available data supporting the efficacy/suitability of rice bran extract's technical function as a moisture retention agent in relevant processed meat products. This report is being provided on behalf of Florida Food Products, LLC, by ToxStrategies, Inc. (its agent) to be appended to the original generally recognized as safe (GRAS) submission package, dated February 6, 2019. The data presented herein reflect additional work performed based on feedback received by Dr. Jennifer Green of the United States Department of Agriculture (USDA) on May 14, 2019.

If you have any questions or require additional information, please do not hesitate to contact me at 919-797-9938, or rhenderson@toxstrategies.com.

Sincerely,

Rayetta G. Henderson, Ph.D.
Managing Scientist

Functionality of Rice Bran Extract in Meat Applications

Florida Food Products

September 20, 2019

Additional information for the GRAS Notification – Rice Bran Extract
Submitted to the US FDA dated February 6, 2019

Table of Contents

Summary

Rice bran extract manufactured by Florida Food Products, LLC (FFP) using a proprietary process was tested in various meat applications to demonstrate functionality compared to phosphate commonly added to processed meats for the same functional purpose. In the studies reported herein, phosphate was added in the form of sodium tripolyphosphate (STPP). Applications tested include ham, turkey breast, smoked sausage, beef hot dog, chicken breast, turkey sausage patty, beef sausage patty. Several key characteristics were tested including cook yield, purge, texture, slicing yield, and color, where applicable. An informal sensory evaluation was also conducted. Rice bran extract was tested at 0.5%, 1%, and/or 1.5% and dose response was demonstrated. Statistical analysis was done using z-test. Cooked yields in treatments containing rice bran extract were significantly higher in all applications compared to control treatments without phosphate, demonstrating increased water holding capacity of meat proteins with added rice bran extract. Purge in chicken breast was significantly reduced compared to control treatment. Slicing yields in ham and turkey breast were significantly higher with rice bran extract compared to control meats without phosphate and similar to treatments containing phosphate. Texture of ham with rice bran extract was similar to or better than the control and phosphate treatments. In the smoked sausage application, treatments containing rice bran extract were similar in texture to control and significantly lower than phosphate containing treatments. However, in turkey breast and hot dog applications, rice bran extract resulted in significantly higher hardness compared to control but similar to phosphate containing treatments. Color impact of rice bran extract was not adversely affected in applications, except for hot dogs where a and b values were lower than rest of the treatments. Informal sensory evaluation suggested a good flavor, appearance, and mouthfeel in all applications containing rice bran extract compared to control and phosphate, except in the smoked sausage application at 0.5% rice bran extract, which had insufficient texture. In conclusion, rice bran extract provided excellent functionality at 0.5 to 1.5% in various comminuted and whole muscle meat applications without any adverse effects on color, texture, taste, and overall appearance of products compared to a commonly used phosphate (as STPP) in meat processing.

Application Data

Ham

Ham was extended 20% by weight using a pickle. Pickle was made by dissolving sea salt, turbinado sugar, celery juice powder, acerola juice powder, vinegar powder, and one of three treatments – STPP (0.45%), rice bran extract (0.5, 1.0, or 1.5%), or nothing (control) – in water by mixing for 6 minutes at 30-36°F. Ham muscle was macerated and tumbled with brine under vacuum for 4 hours, followed by storing it overnight in a cooler at 34°F. Ham was then stuffed into prestuck fibrous casings of 4" diameter and cooked in a smokehouse to an internal temperature of 162°F. Cooked ham was stabilized as per United States Department of Agriculture (USDA) cooling guidelines. Ham was then sliced using a Bizerba slicer to 2 mm diameter thickness, vacuum packaged, and stored in cooler at 34°F. The pH of the pickle was measured for each treatment (Table 1). Cooked yield was calculated as well as slice yield. Slice yield was calculated based on the number of intact slices out of thirty slices. Color was measured on the surface of the sliced packaged ham at 4°C using a HunterLab XE Plus 45/0-L handheld device set at D65 light source and 10-degree observer standardized with bland and white standard plates. Packaging material is compensated for during instrument standardization by covering the black and white standard tiles with a Cryovac bag. Samples were measured for "L", "a", and "b" values.

Table 1. pH of pickle for each treatment

Treatment	pH
Control	5.58
Phosphate 0.45%	6.05
Rice bran extract 0.5%	5.75
Rice bran extract 1.0%	5.83
Rice bran extract 1.5%	6.05

Cooked yield (Figure 1) was significantly higher with the addition of rice bran extract compared to control. Cooked yield increased with increase in concentration of rice bran extract from 0.5% to 1.5%. This shows that the rice bran extract is functioning as intended by holding water in the ham. Each level of rice bran extract was significantly different from the control and each other.

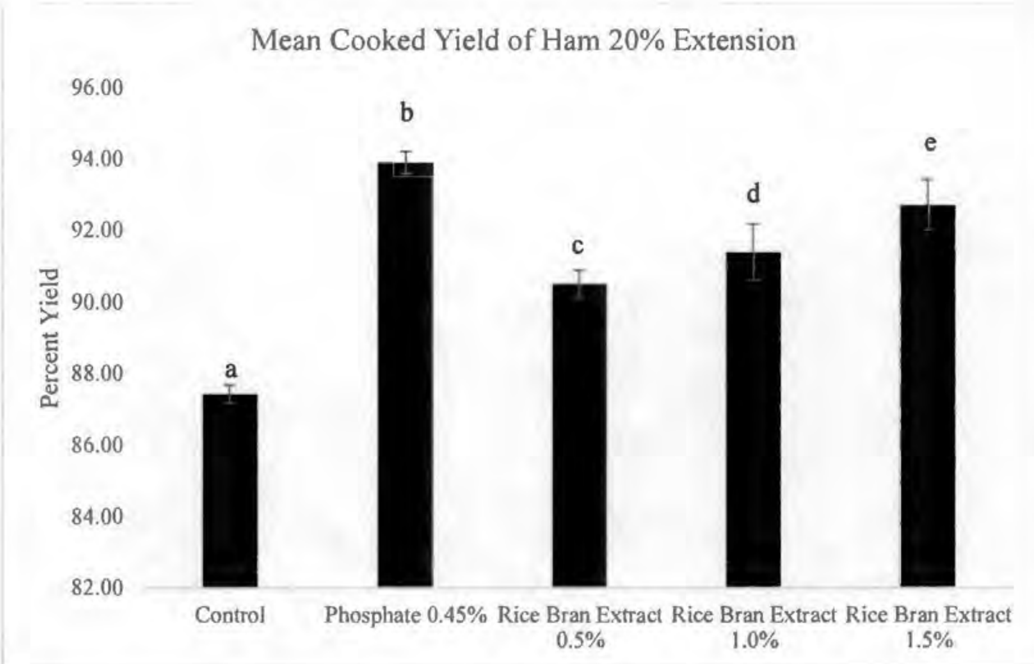

Figure 1. Mean cooked weight yield of ham. Different letters indicate significant difference between treatments ($p<0.05$).

Increase in rice bran extract concentration in ham was associated with a linear dose response in cooked yield as shown in Figure 2. This further illustrates the functionality of rice bran extract.

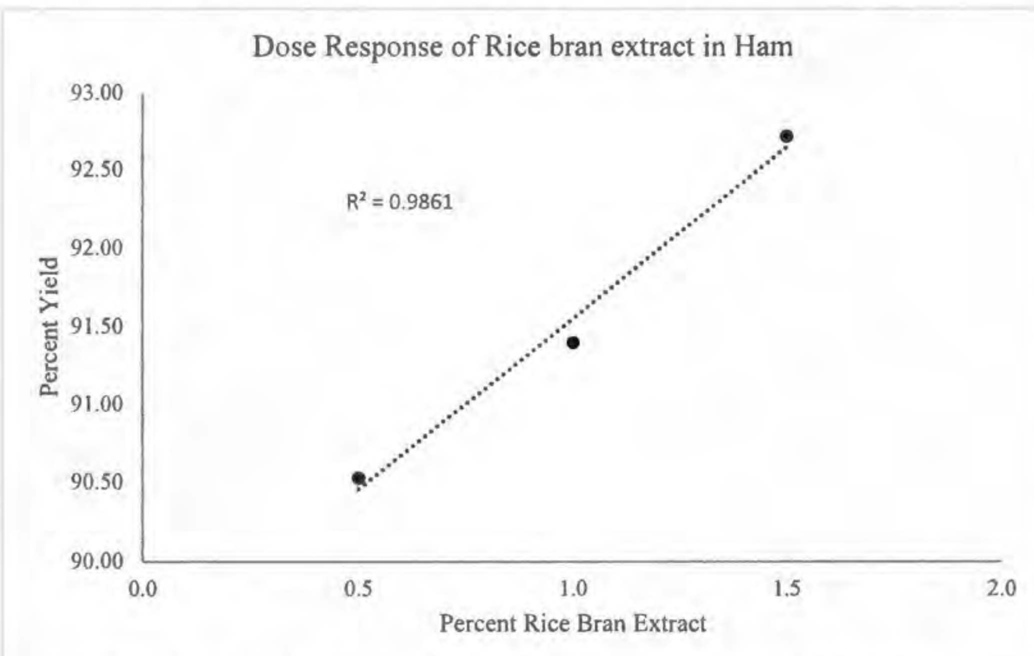

Figure 2. Dose response of rice bran extract and percent yield in ham

Mean slicing yield (Figure 3) for control was at 75% while the treatments containing phosphate (STPP) or rice bran extract significantly increased to 100% without any loss in slices, thus showing functionality in texture improvement.

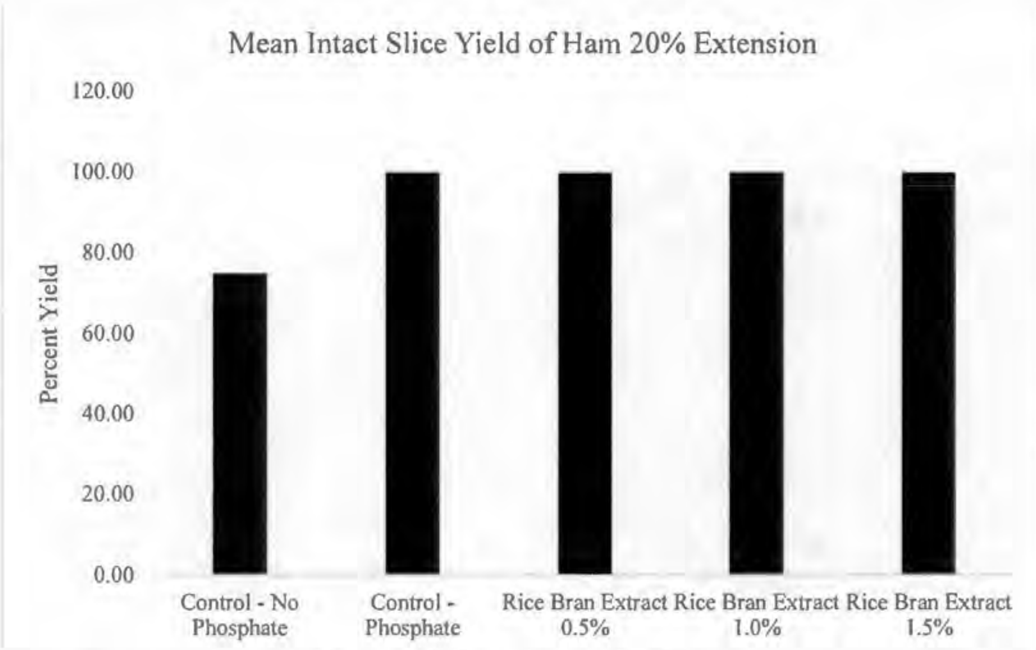

Figure 3. Mean slice yield of ham

The texture/hardness was measured by Texture Profile Analysis (TPA). TPA was performed on ham by compressing 20mm thick slices to 30% of the height using a 3" diameter flat probe. Pre-test and post-test speeds were set to 10 mm/s and test speed to 2 mm/s. Hardness is the peak load of the first compression. Figure 4 contains the mean hardness data for each treatment. While the hardness was similar across treatments, 0.5% and 1.5% (but not 1.0%) rice bran extract-containing treatments were significantly higher in hardness compared to control and phosphate treatments.

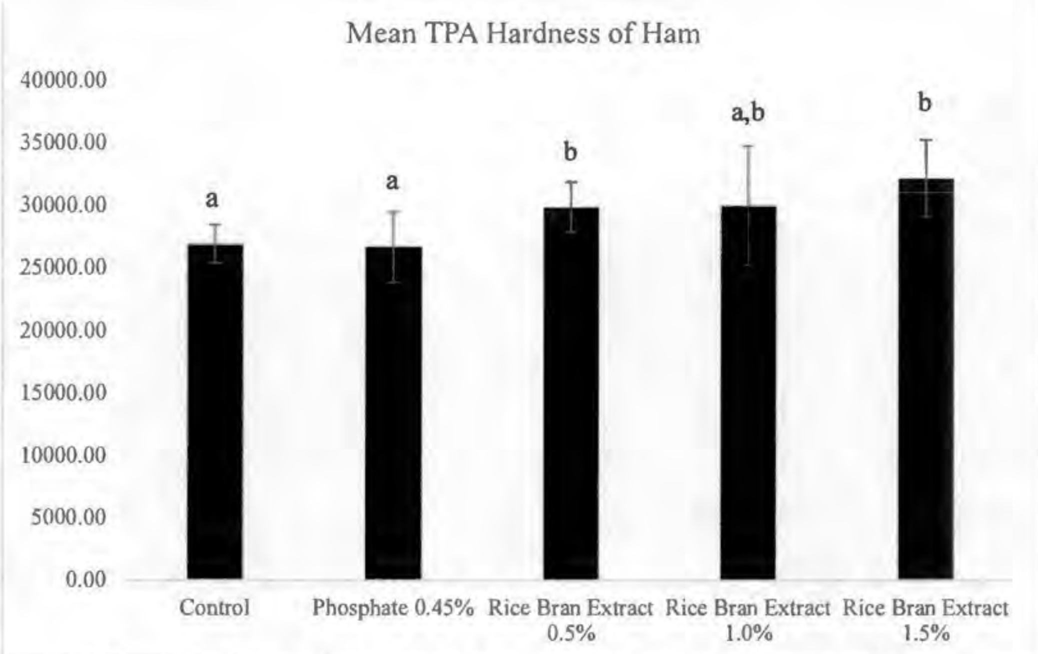

Figure 4. Mean hardness of ham. Different letters indicate significant difference between treatments ($p<0.05$).

The internal color of the ham was measured using the Hunter Lab color scale. Figures 5, 6, and 7 contain the means for each value. The internal color of ham treated with STPP and rice bran extract at 1.0% and 1.5% were darker than the control. The rice bran extract treated samples were similar in a-value to the control and STPP treatments. Rice bran extract at 0.5% and 1.5% were similar in b-value to the control and STPP treated hams. Rice bran extract at 1% was higher than 0.5% rice bran extract, control, and phosphate hams.

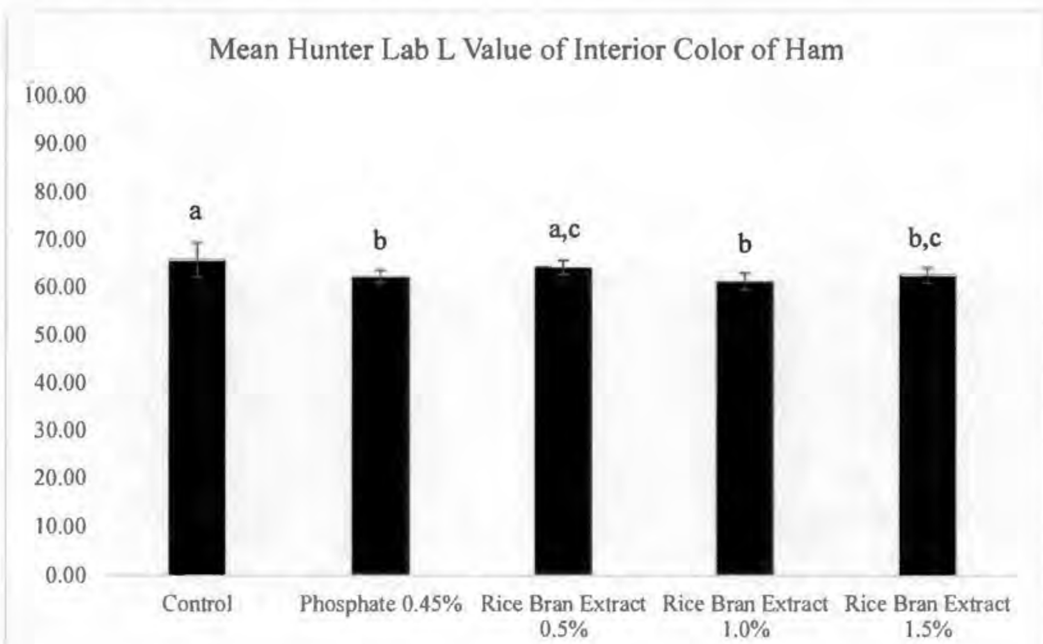

Figure 5. Internal L value of ham. Different letters indicate significant difference (p<0.05)

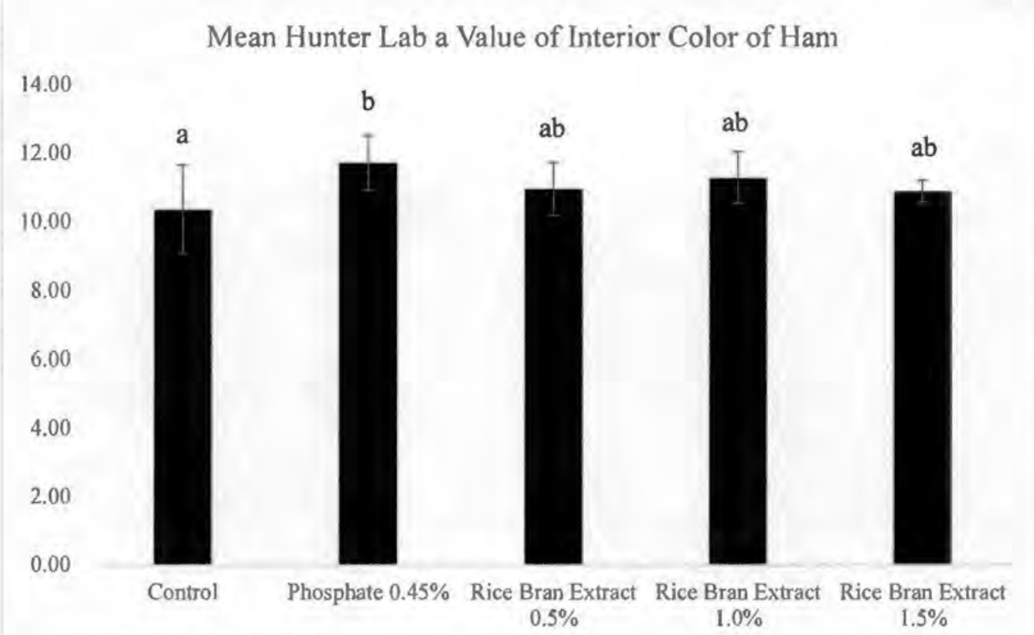

Figure 6. Internal a value of ham. Different letters indicate significant difference (p<0.05)

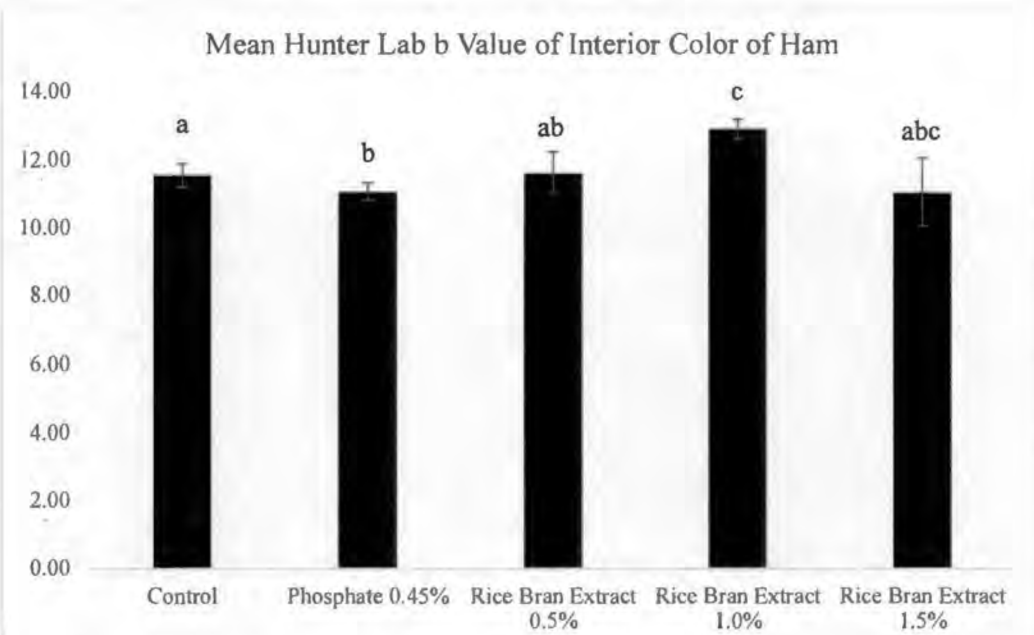

Figure 7. Internal b value of ham. Different letters indicate significant difference (p<0.05)

Sensory characteristics such as flavor, texture, and appearance were evaluated informally by lab personnel (not a trained sensory panel). Appearance was based on visual inspection of the product. Flavor and texture were evaluated by comparing the taste and mouthfeel of different treatments. Observations are reported in Table 2. All treatments were observed to be similar, with the rice bran extract 1.5% treatment perceived as too dry when compared to the others.

Table 2. Informal sensory evaluation

Treatment	Remarks
Control	Typical flavor and texture, appearance similar to all treatments
Phosphate 0.45%	Typical flavor and texture, appearance similar to all treatments
Rice Bran Extract 0.5%	Good flavor and texture, appearance similar to all treatments
Rice Bran Extract 1.0%	Typical flavor, firm texture, a bit dry, appearance similar to all treatments
Rice Bran Extract 1.5%	Typical flavor, very firm texture, a bit too dry, appearance similar to all treatments

Smoked Sausage

Smoked sausage (made from pork) was extended 15% by weight. Pork 70s (70% lean, 30% fat) and 50s (50% lean, 50% fat) were ground through a kidney plate then ½" plate. Pork 70s was mixed in paddle mixer slowly while adding salt, celery juice powder, acerola juice powder, either phosphate (STPP 0.45%), rice bran extract (0.5%, 1%, or 1.5%) or nothing (control), and held overnight. Flavor, turbinado sugar, vinegar powder, and Pork 50s were then added and reground through 1/8" plate. Mixture was then stuffed into 31 mm cellulose casings and cooked in smokehouse. Cooked sausage was stabilized following USDA Appendix B requirements. Casings were peeled, vacuum packaged, and refrigerated.

Figure 8 contains the data for cooked weight yield of the sausages. The control had the lowest yield and the STPP had the highest. Cooked yield among the rice bran extract treatments showed a significantly higher cooked yield compared to control, thus demonstrating functionality. Cooked yields were also significantly different between all treatments in the smoked sausage. The rice bran extract at 1.5% approached a similar weight yield as STPP, but was still significantly different ($p<0.05$).

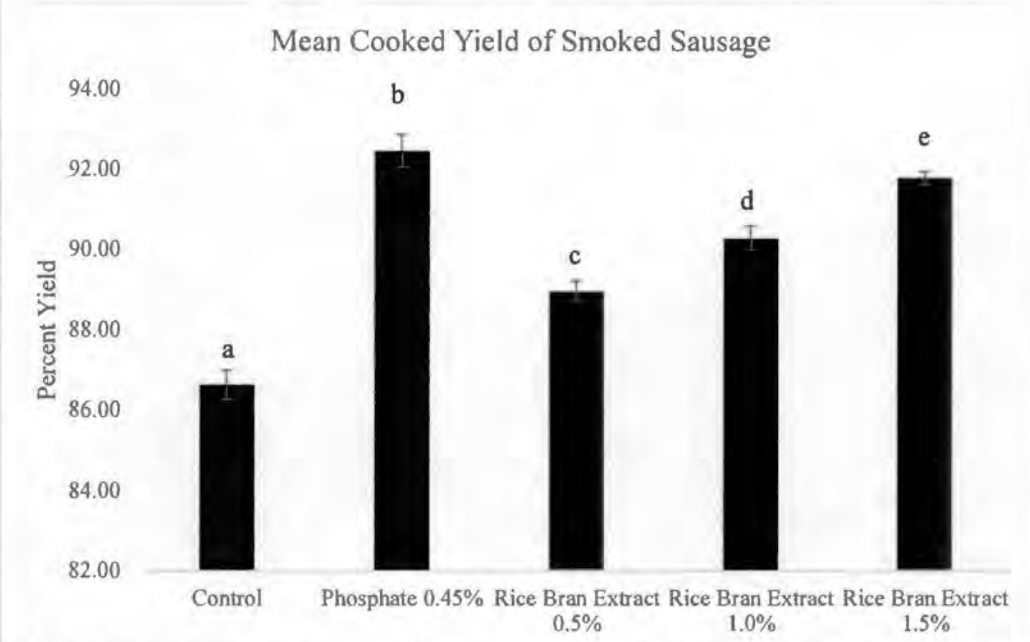

Figure 8. Mean cooked weight yield of smoked sausage. Different letters indicate significant difference between treatments ($p<0.05$).

Smoked sausage displayed a linear dose response among the rice bran extract treatments. This can be seen in Figure 9 below.

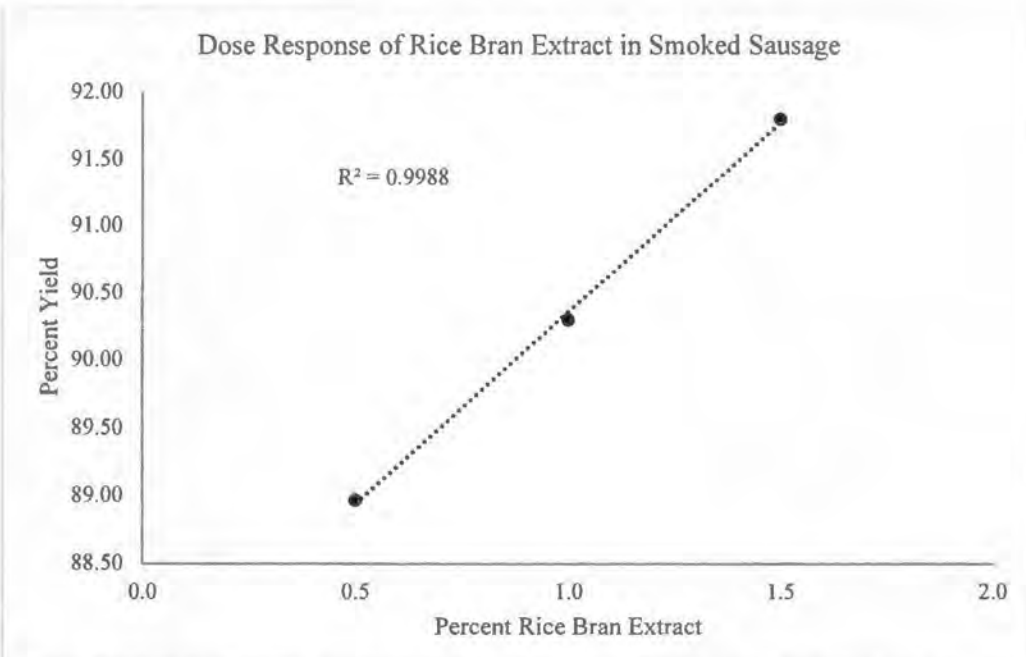

Figure 9. Dose response of rice bran extract and percent yield in smoked sausage

TPA was done on sausages heated on a roller grill on medium heat for 20 min. The preheated sausages were cut 20 mm height and compressed to 30% of the height using a 3" diameter flat probe Pre-test and post-test speeds set to 10 mm/s and test speed set to 2 mm/s. Hardness is the peak load of the first compression. Figure 10 contains the mean hardness data for each treatment. Hardness of rice bran extract treatments were similar to control but significantly lower than the phosphate-treated sausage. Hardness did not increase with increase in concentration of rice bran extract from 0.5% to 1.5%. However, sensory observations (Table 3) suggest that the texture improved with addition of rice bran extract, with 1.5% rice bran extract treatment perceived as having firmest texture.

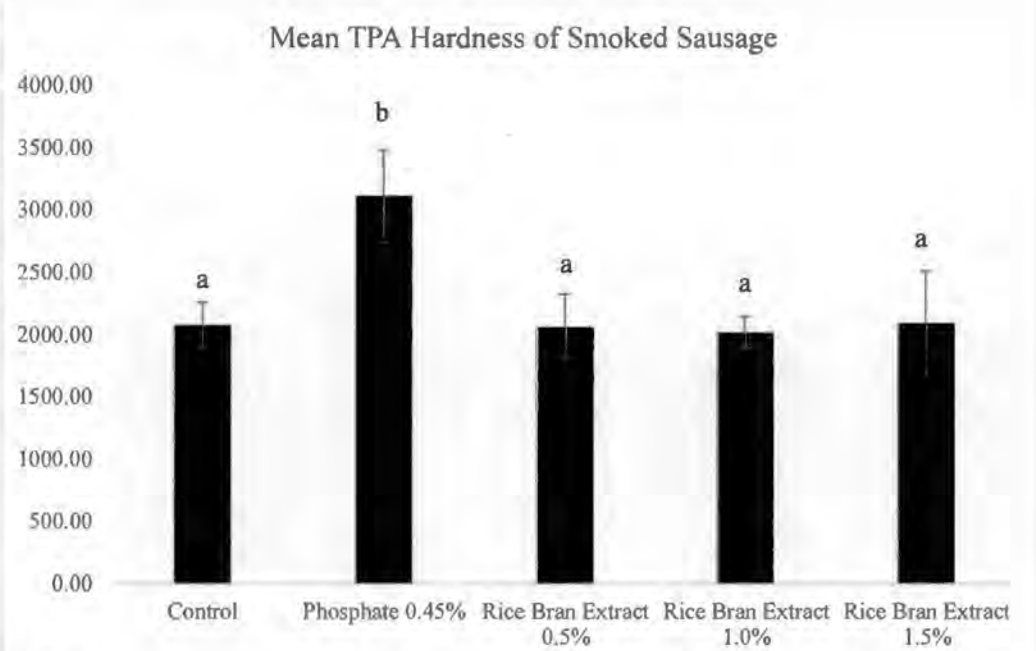

Figure 10. Mean hardness of smoked sausage. Different letters indicate significant difference ($p<0.05$)

Instrumental color determinations were made on the interior of the sausages sliced longitudinally by using a Hunter Lab XE Plus 45/)-L handheld device equipped with a D65 light source and a 10-degree observer. Standardization was done by using the white and black standard plates. Measurements were taken directly on the surface of sausages cut longitudinally. Samples were measured for "L", "a", "b" values. In general, the smoked sausage became slightly darker with the addition of STPP or rice bran extract. Figures 11, 12, and 13 show that the smoked sausage internal Lab values were relatively steady.

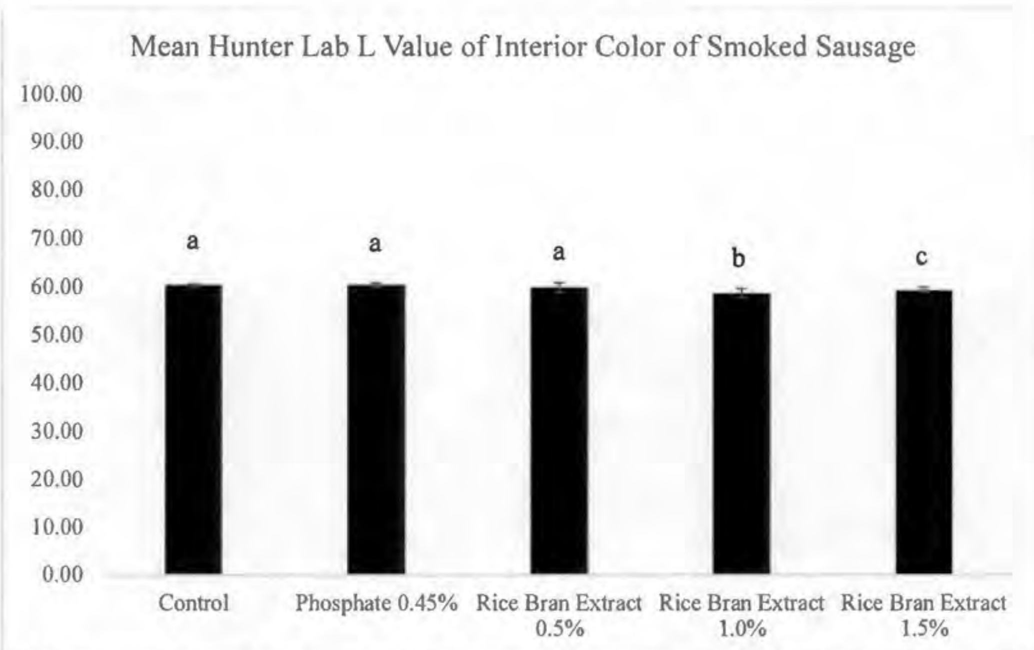

Figure 11. Internal L value of smoked sausage. Different letters indicate significant difference between treatments (p<0.05).

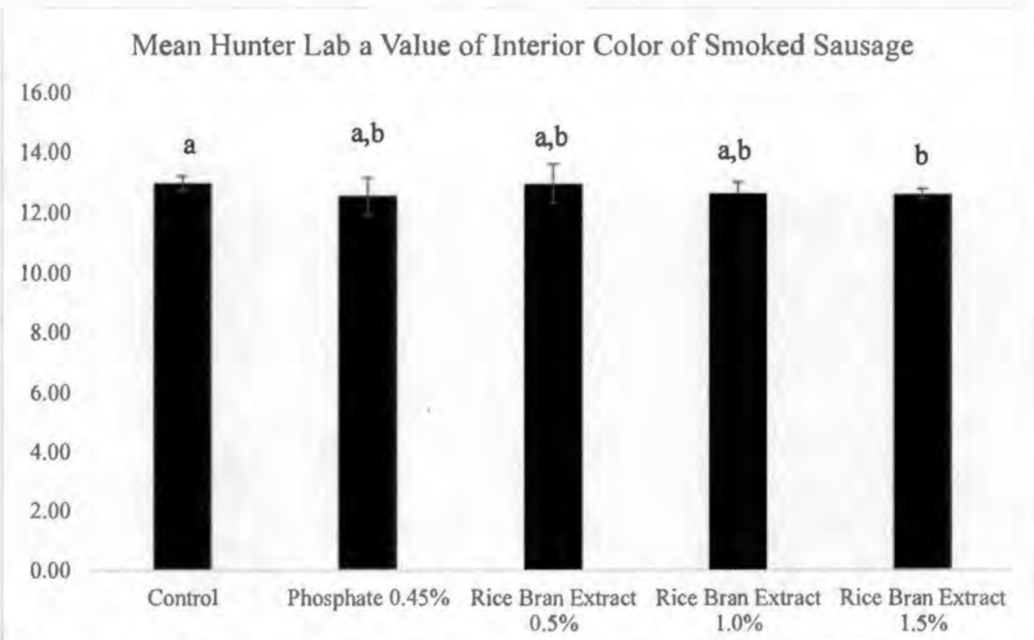

Figure 12. Internal a value of smoked sausage. Different letters indicate significant difference between treatments (p<0.05).

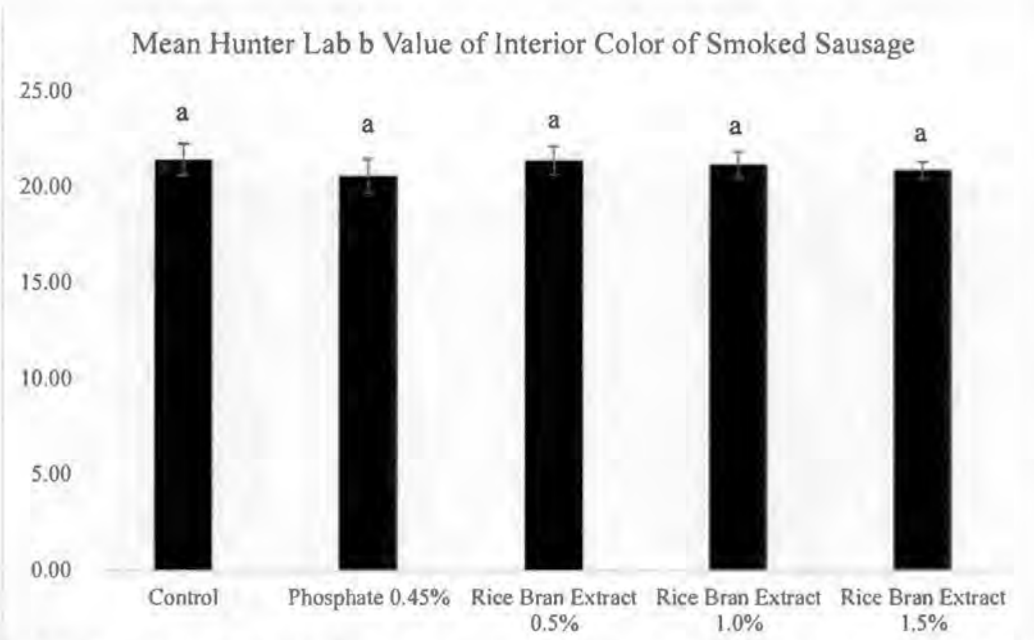

Figure 13. Internal b value of smoked sausage. Different letters indicate significant difference between treatments ($p<0.05$).

Sensory characteristics such as flavor, texture, and appearance were evaluated informally by lab personnel (not a trained sensory panel). Appearance was based on visual inspection of the product. Flavor and texture were evaluated by comparing the taste and mouthfeel of different treatments. Observations are reported in Table 3. Sensory evaluation found all treatments to be similar with regards to acceptable flavor. Texture of control sausage and 0.5% rice bran extract-treated sausage were perceived as loose/insufficient. However, texture increased with higher concentrations of rice bran extract. Sausage with 1.5% rice bran extract was perceived as having the firmest texture and similar to phosphate treatment. Sensory observations regarding texture/firmness were contrary to the hardness values reported in Figure 10.

Table 3. Informal sensory evaluation of smoked sausage

Treatment	Remarks
Control	Loose texture, exterior appearance rough, flavor acceptable
Phosphate 0.45%	Tighter texture, smooth and shiny exterior appearance, flavor acceptable
Rice Bran Extract 0.5%	Loose texture, exterior appearance rough, flavor acceptable
Rice Bran Extract 1.0%	Moderate texture, exterior appearance rough, flavor acceptable
Rice Bran Extract 1.5%	Firmest texture of all test treatments, exterior appearance smoother than all other test treatments but not as smooth as phosphate control, flavor acceptable

Turkey Breast

Turkey breast was injected with a pickle and extended 20% by weight. The pickle consisted of salt, carrageenan, turbinado sugar, celery juice powder, acerola juice powder, vinegar powder, turkey broth, antioxidant, and either STPP (0.45%), rice bran extract (0.5, 1.0, or 1.5%), or nothing (control), while maintaining a temperature <35°F. Turkey breast bone side was injected and macerated ½". Injected turkey breast was tumbled for 80 min at 12 rpm under vacuum. It was hand stuffed into fibrous casing and clipped. Stuffed turkey was racked and steam cooked to internal temperature of 160°F. Cooked turkey was stabilized following USDA requirements for an uncured product. Turkey was sliced, packaged, and refrigerated. Pickle pH is reported in Table 4 for each treatment. Cooked yield was calculated as well as slice yield. Slice yield was calculated based on the number of intact slices out of thirty slices.

Table 4. pH of pickle for each treatment

Treatment	pH
Control	7.10
Phosphate 0.45%	6.95
Rice Bran Extract 0.5%	6.57
Rice Bran Extract 1.0%	6.52
Rice Bran Extract 1.5%	6.47

Figure 14 shows that the rice bran extract performed better than the control in cooked weight yield. Rice bran extract in turkey showed a slight dose response, but, not as well as in the ham or smoked sausage. With the exception of 0.5% rice bran extract compared to 1% rice bran extract, all treatments were significantly different from each other ($p<0.05$).

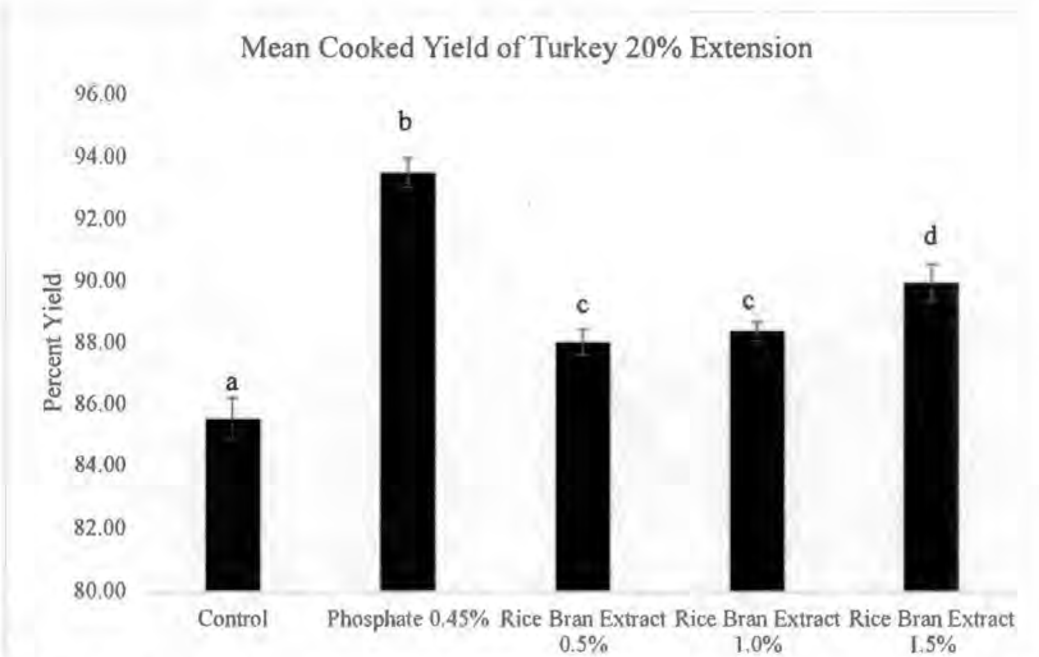

Figure 14. Mean cooked weight yield of turkey. Different letters indicate significant difference between treatments ($p<0.05$).

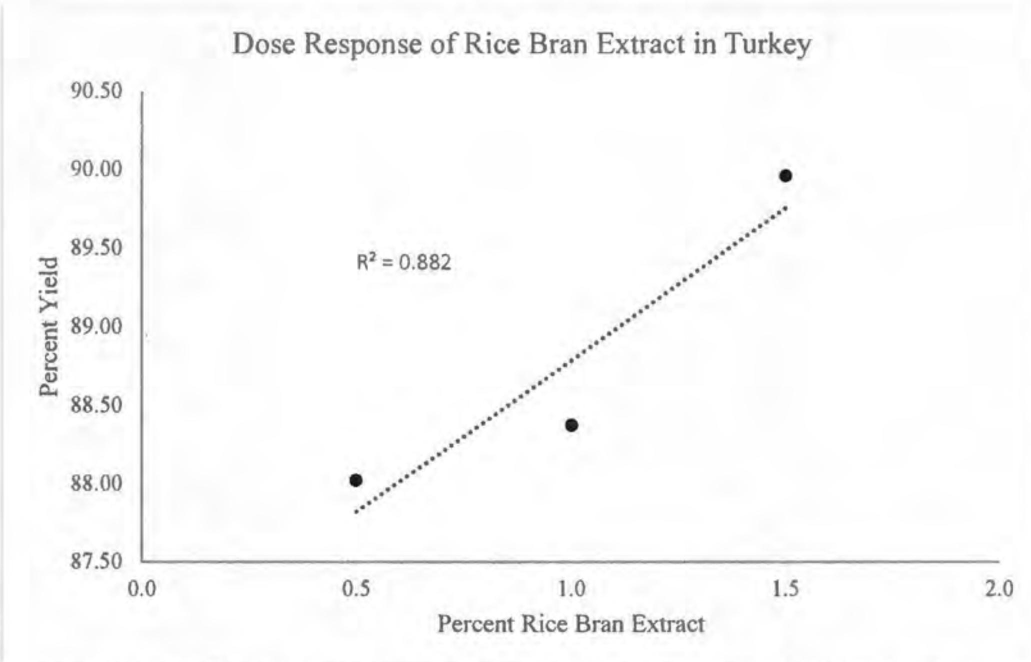

Figure 15. Dose response of rice bran extract and percent yield in turkey

Mean slicing yield (Figure 16) for control was at 25% while the treatments containing STPP or rice bran extract significantly increased to over 90% and up to 100%, thus showing functionality in texture improvement.

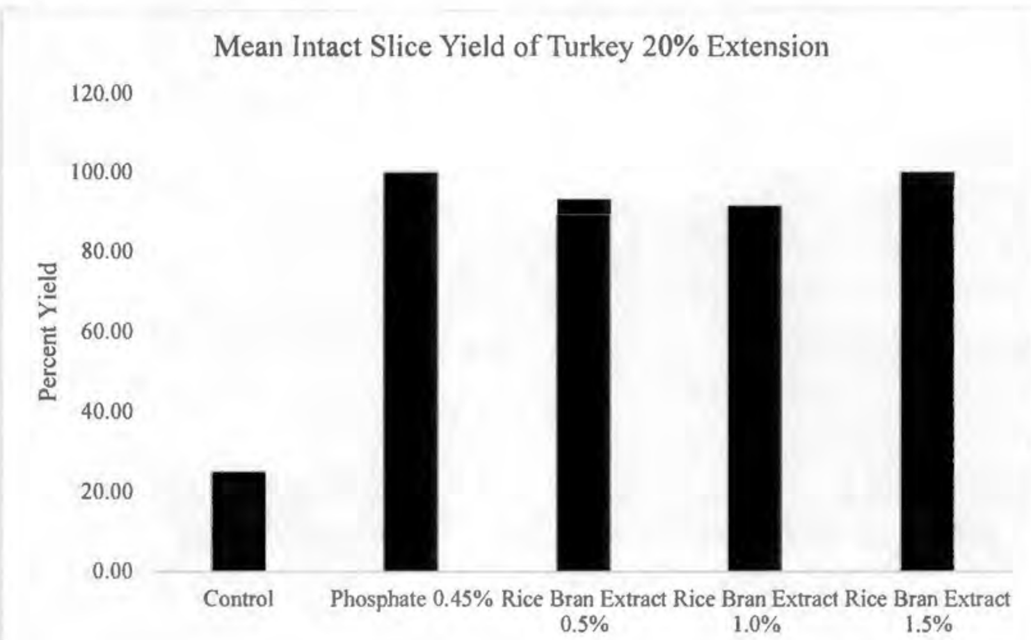

Figure 16. Slicing yield of turkey

The texture/hardness was measured by TPA. TPA was performed on turkey by compressing 20mm thick slices to 30% of the height using a 3" diameter flat probe. Pre-test and post-test speeds were set to 10 mm/s and test speed to 2 mm/s. Hardness is the peak load of the first compression. Figure 17 contains the mean hardness data and analysis for each treatment. The hardness for all rice bran extract treatments were similar or higher than both phosphate and control treatments suggesting good functionality of rice bran extract in binding turkey proteins.

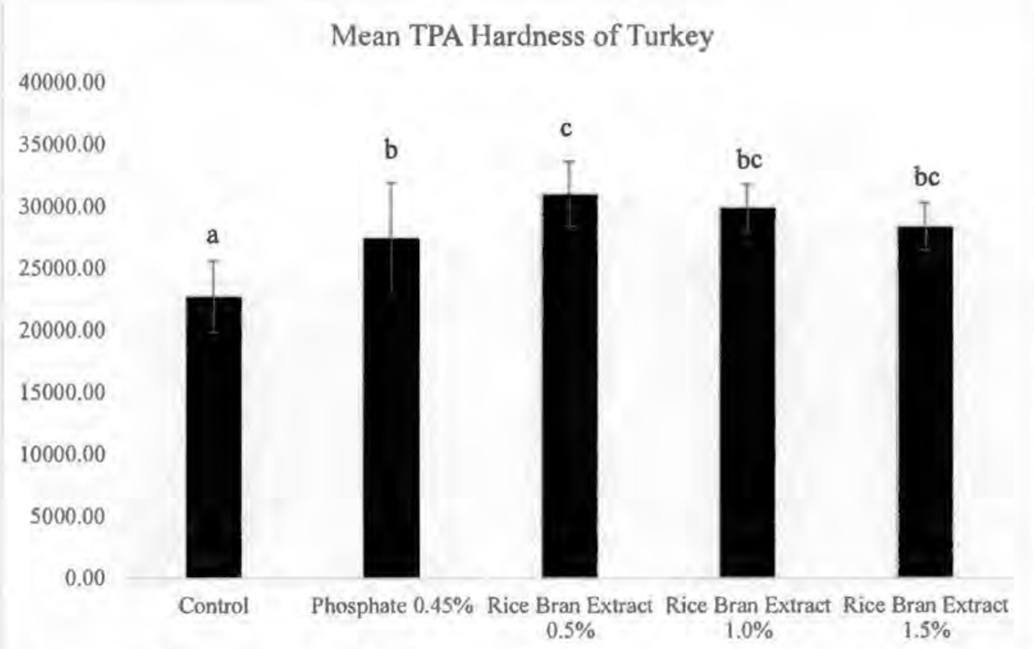

Figure 17. Mean hardness of turkey. Different letters indicate significant difference between treatments ($p<0.05$).

Color was measured on the surface of the sliced packaged turkey at 4°C using a HunterLab XE Plus 45/0-L handheld device set at D65 light source and 10-degree observer standardized with bland and white standard plates. Packaging material is compensated for during instrument standardization by covering the black and white standard tiles with a Cryovac bag. Samples were measured for "L", "a", and "b" values and reported in Figures 18, 19, and 20. In turkey, the L-value and b-value remained relatively steady between treatments. Addition of rice bran extract increased the a-value compared to control and phosphate.

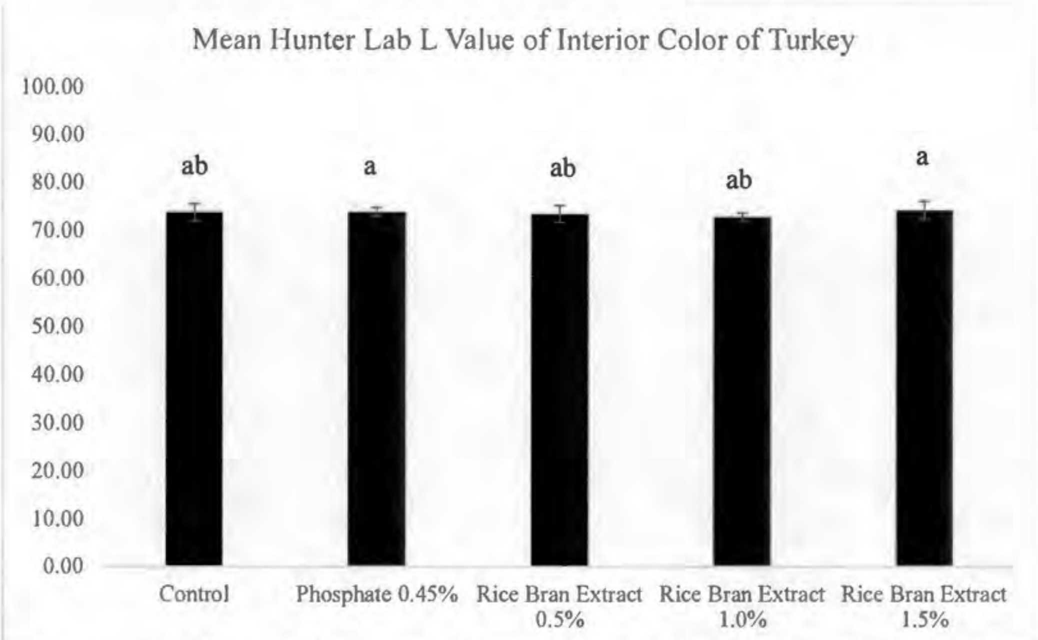

Figure 18. Internal L value of turkey. Different letters indicate significant difference between treatments ($p<0.05$).

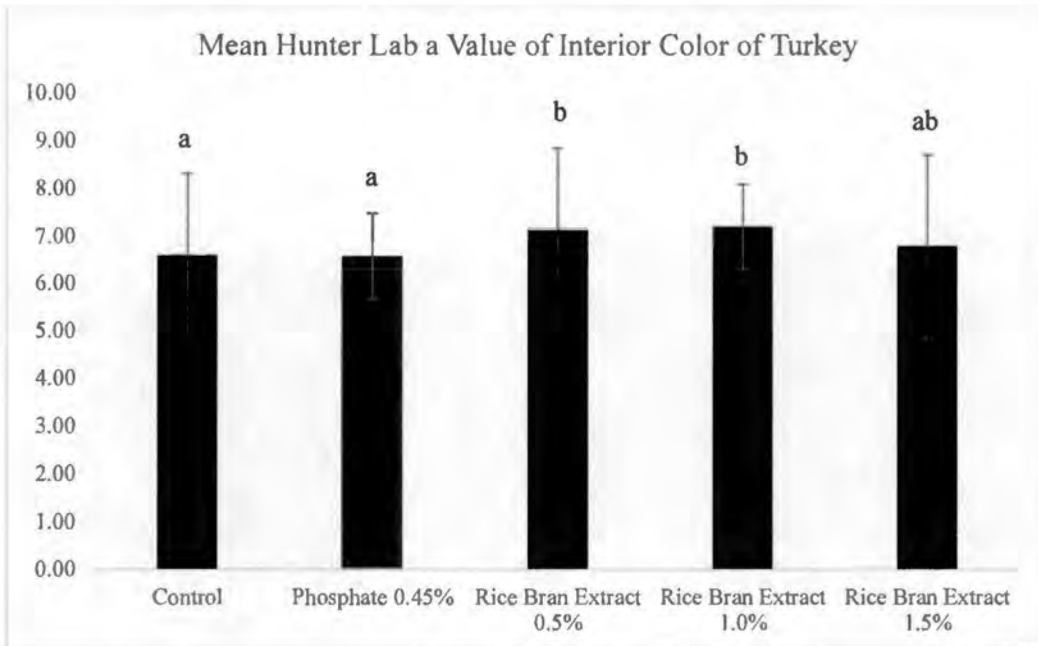

Figure 19. Internal a value of turkey. Different letters indicate significant difference between treatments ($p<0.05$).

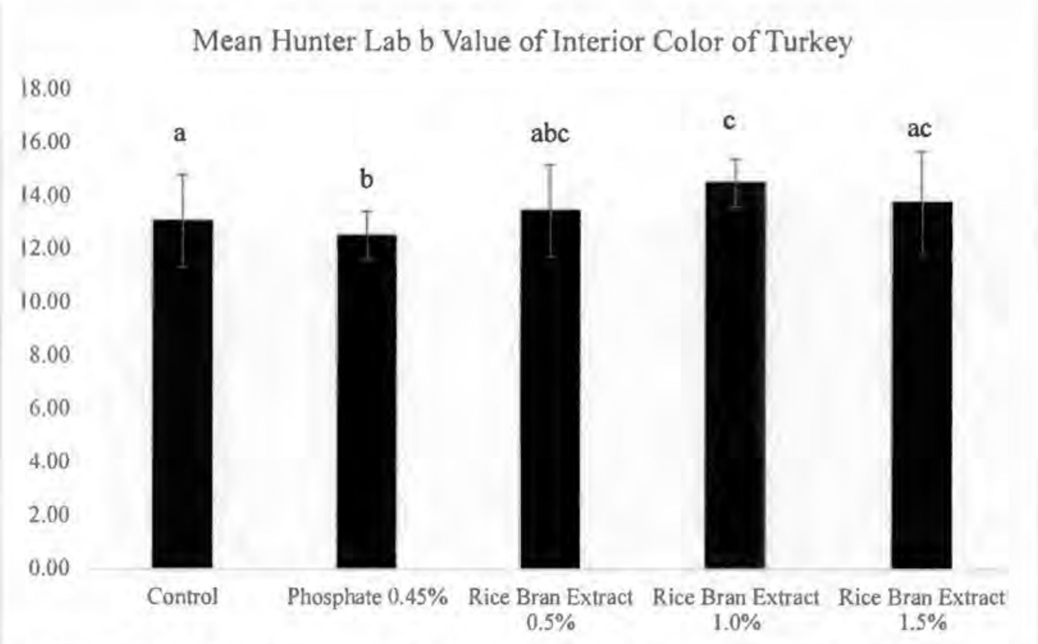

Figure 20. Internal b value of turkey. Different letters indicate significant difference between treatments ($p<0.05$).

Sensory characteristics such as flavor, texture, and appearance were evaluated informally by lab personnel (not a trained sensory panel). Appearance was based on visual inspection of the product. Flavor and texture were evaluated by comparing the taste and mouthfeel of different treatments. Observations are reported in Table 5. Evaluation found the rice bran extract similar to control or phosphate, with some noticeable dryness in the 1.5% rice bran extract treatment. The texture of the rice bran extract treatments was comparable to the STPP treatment and better than the control.

Table 5. Informal sensory evaluation of turkey

Treatment	Remarks
Control	Softest texture, typical flavor, appearance similar to all treatments
Phosphate 0.45%	Firmer texture than control, typical flavor, appearance similar to all treatments
Rice Bran Extract 0.5%	Firm texture, good flavor, appearance similar to all treatments
Rice Bran Extract 1.0%	Firm texture, a bit dry, good flavor, appearance similar to all treatments
Rice Bran Extract 1.5%	Firm texture, a little drier than other treatments, appearance similar to all treatments

Beef Hot Dogs

Beef 85s (85% lean, 15% fat) was passed through a kidney plate followed by a ½" plate. Beef 50s (50% lean, 50% fat) was also processed in the same manner. The beef 85s was mixed with salt, sodium nitrite, and ice/water. Either STPP (0.45%), rice bran extract (0.5%, 1.0%, or 1.5%), or nothing (control) was then added to the beef 85s. Samples were held overnight in the cooler. The next day the lean mixture was chopped in a bowl chopper. Then the beef 50s, mustard, spice, antimicrobial, and additional ice/water were added and an emulsion created. The emulsion was stuffed into cellulose casings. A standard cook program was used to cook and then cool the hotdogs, and the casings were removed. Hot dogs were placed in the cooler for storage.

The percent cooked weight yield of the hot dogs was calculated by dividing the pre-cooked weight by the cooked weight and multiplying by 100. The rice bran extract-treated hot dogs were significantly higher in weight yield than the control (Figure 21). The 1.0% and 1.5% rice bran extract treated hot dogs were as good as, or better than the STPP-treated hot dogs. In case of the 1.0% rice bran extract treatment, the weight yield was significantly higher than the STPP-treated hot dogs ($p<0.05$). The 1.5% rice bran extract-treated hot dogs had the same weight yield as STPP treated hot dogs.

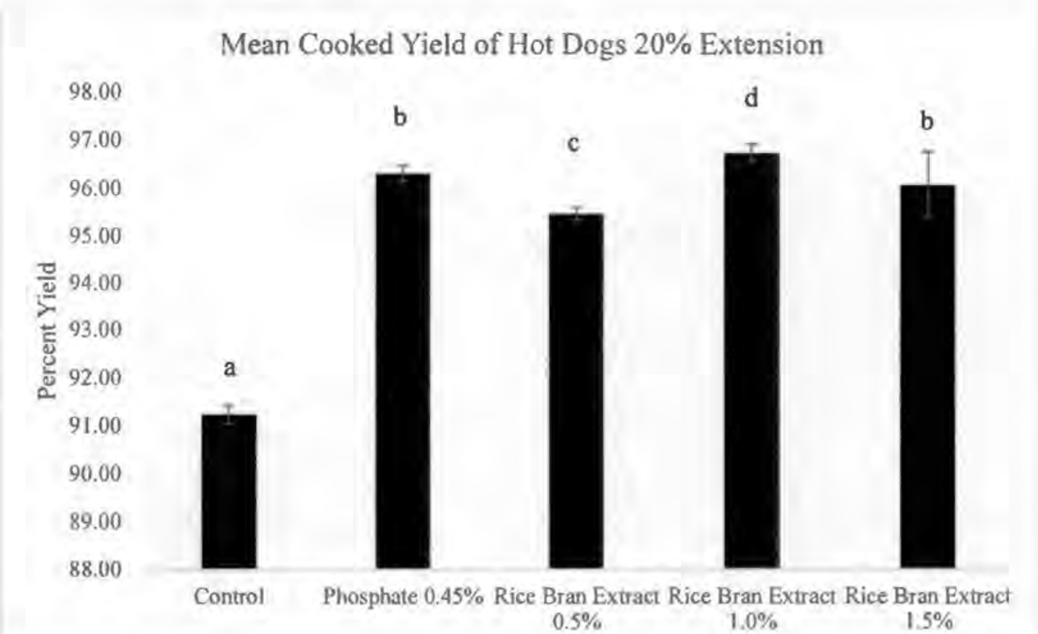

Figure 21. Cooked weight yield of hot dogs. Different letters indicate significant difference between treatments ($p<0.05$).

TPA was done on hot dogs heated on a roller grill on medium heat for 20 min. The preheated hot dogs were cut 20 mm height and compressed to 30% of the height using a 3" diameter flat probe Pre-test and post-test speeds set to 10 mm/s and test speed set to 2 mm/s. Hardness is the peak load of the first compression. Figure 22 contains the mean hardness data and analysis for each treatment. The hardness for all rice bran extract treatments and phosphate were different than the control. Within rice bran extract treatments there was no significant difference. There was no significant difference between the phosphate and rice bran extract at 1.5%.

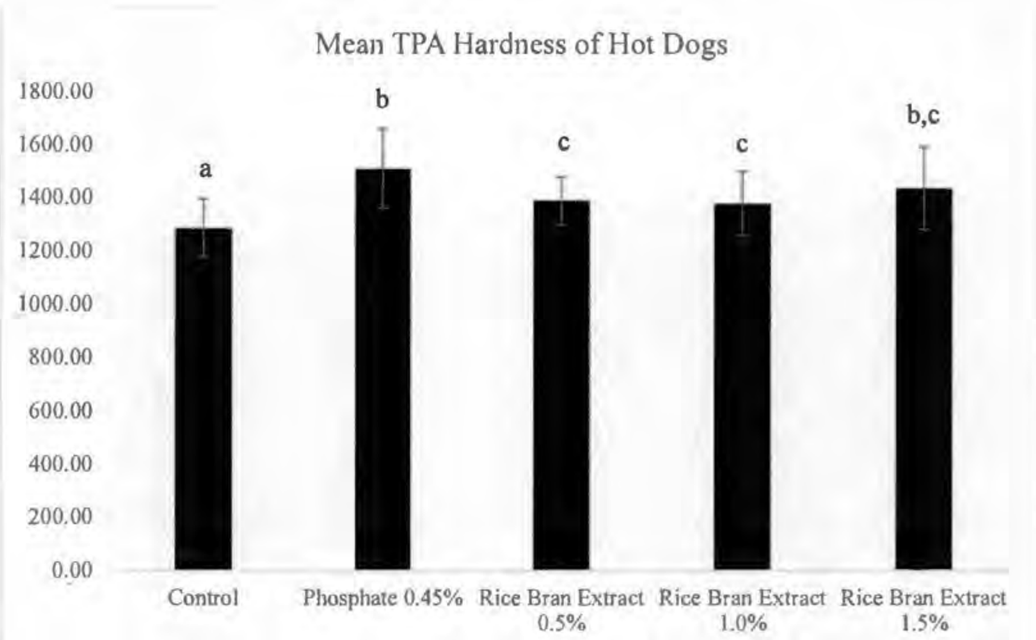

Figure 22. Hardness of hot dogs. Different letters indicate significant difference between treatments ($p<0.05$).

Instrumental color determinations were made on the interior of the hot dogs sliced longitudinally by using a HunterLab XE Plus 45/)-L handheld device equipped with a D65 light source and a 10-degree observer. Standardization was done by using the white and black standard plates. Measurements were taken directly on the surface of hot dogs cut longitudinally. Samples were measured for "L", "a", "b" values reported in Figures 23, 24, 25. In hot dogs the lightness remained relatively steady. The a-value decreased with an increase of rice bran extract.

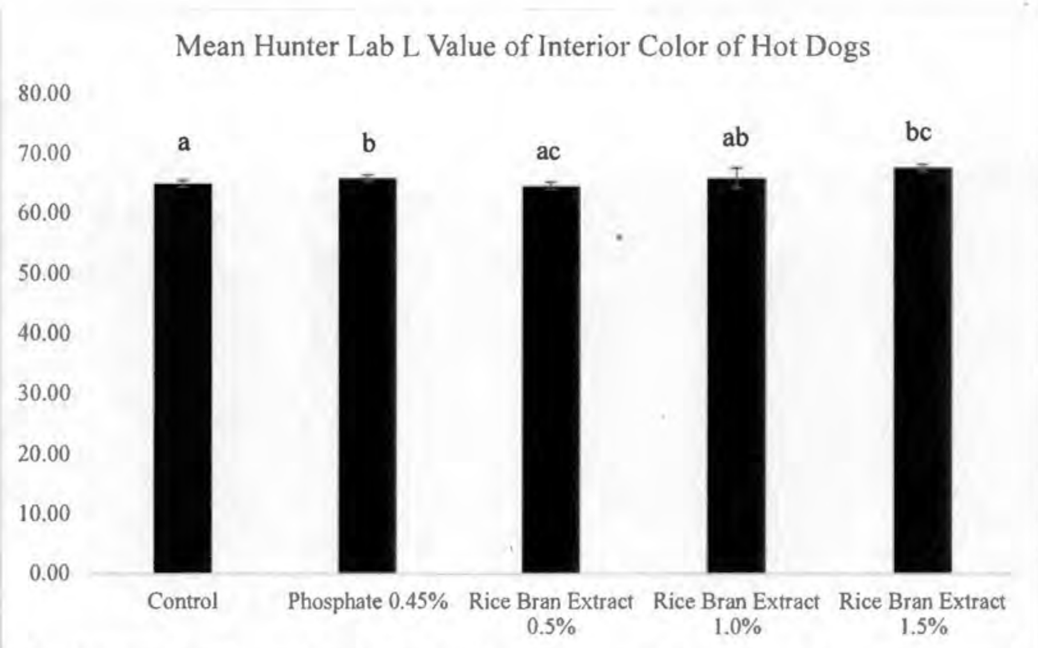

Figure 23. Internal L-value of hot dogs. Different letters indicate significant difference between treatments ($p<0.05$).

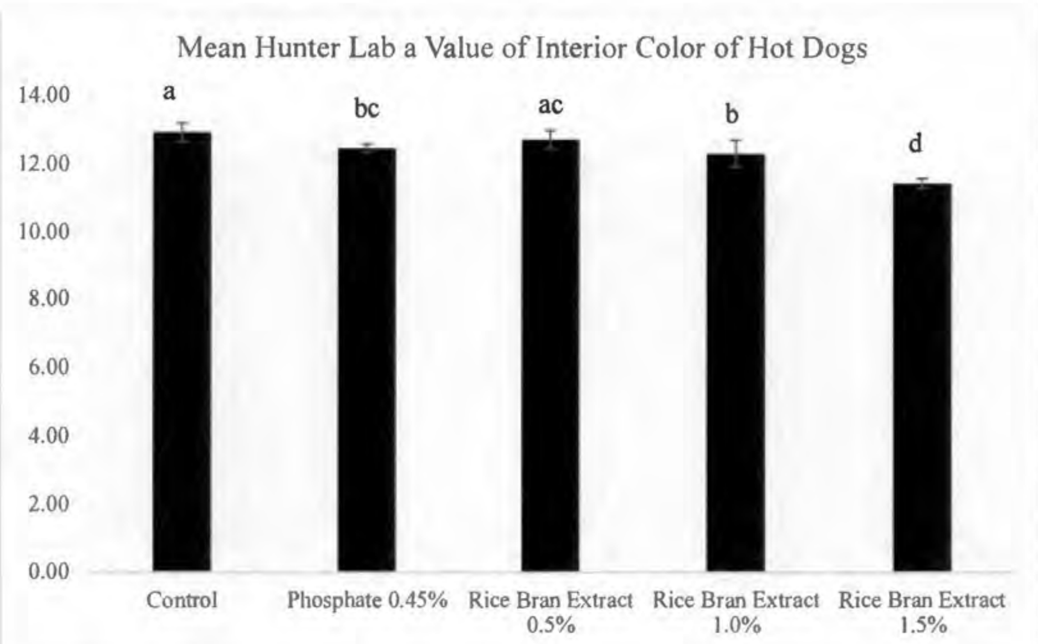

Figure 24. Internal a-value of hot dogs. Different letters indicate significant difference between treatments ($p<0.05$).

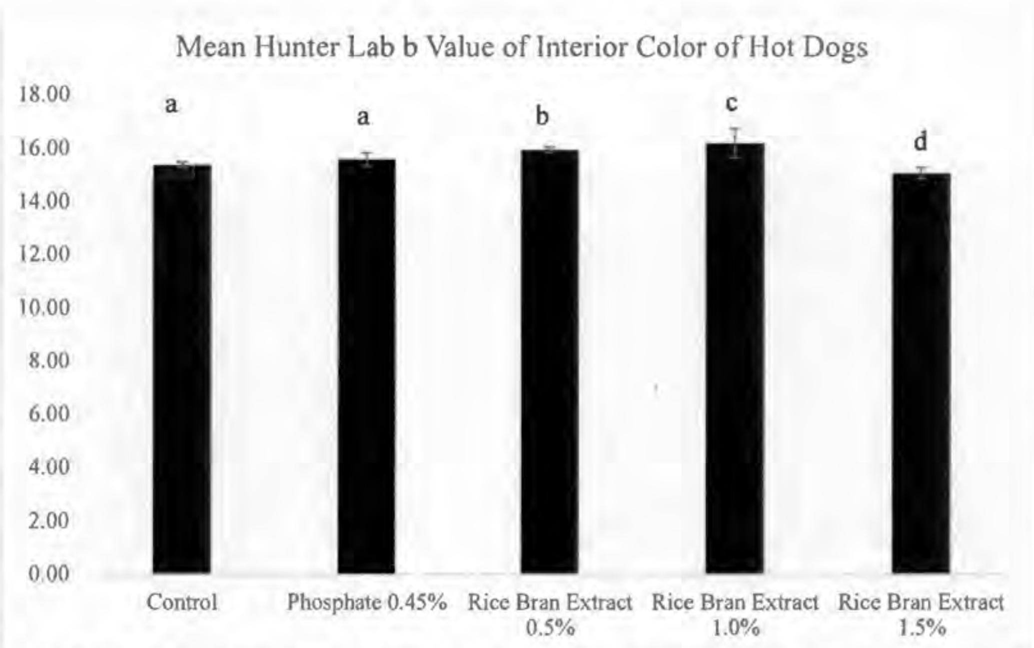

Figure 25. Internal b-value of hot dogs. Different letters indicate significant difference between treatments ($p<0.05$).

Chicken Breast

Chicken breasts free of any additives were locally sourced and exposed to one of three treatments – a control was injected with salt brine at 15% weight extension, rice bran extract at 1.0% by weight and 15% weight extension or STPP at 0.3% by weight and 15% weight extension. After injection, individual breasts were sealed in a plastic vacuum bag without applying vacuum. The bagged chicken was then tumbled for one hour in a vacuum tumbler at 0.4 Bar. Tumbled chicken was refrigerated overnight, until it was weighed and cooked to an internal temperature of 165 °F. The cooled, cooked chicken was weighed again. The ratio of cooked to raw weight was calculated and reported as cooked weight yield.

The yield of the rice bran extract-treated chicken (Figure 26) was equivalent to the weight yield of STPP-treated chicken. Both the STPP- and rice bran extract-treated breasts retained significantly more water than the control. The difference in means was analyzed by z-test. Figure 26 shows no significant difference between STPP and rice bran extract, while there was a significant difference between each of these and control.

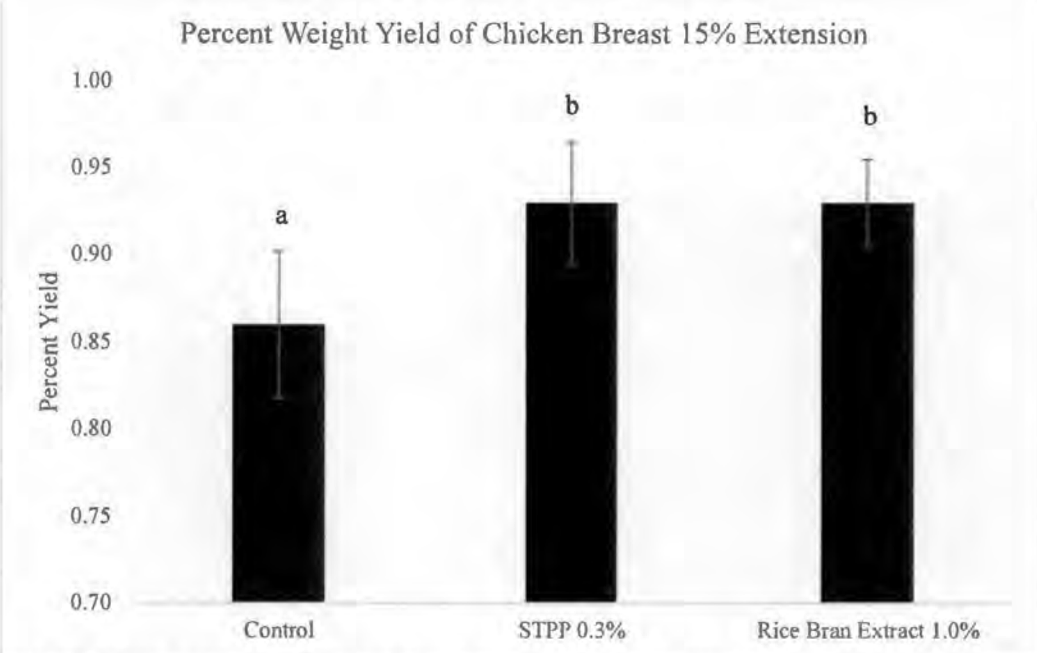

Figure 26. Mean cooked weight yield of injected chicken breasts. Different letters indicate significant difference between treatments ($p<0.05$).

Purge of injected breasts was also tested. The chicken was treated as described above. Prior to cooking, the entire package was weighed. The chicken was removed from the package, free water removed using a paper towel, and the chicken was reweighed. The packaging was dried and reweighed. The weight of the chicken and packaging was subtracted from the total weight and the difference was reported as purge. Purge was divided by the raw weight of chicken breast and a percentage was calculated.

Mean percent (%) purge (Figure 27) of raw chicken containing rice bran extract was similar to the STPP treatment. Again, both outperformed control treatment.

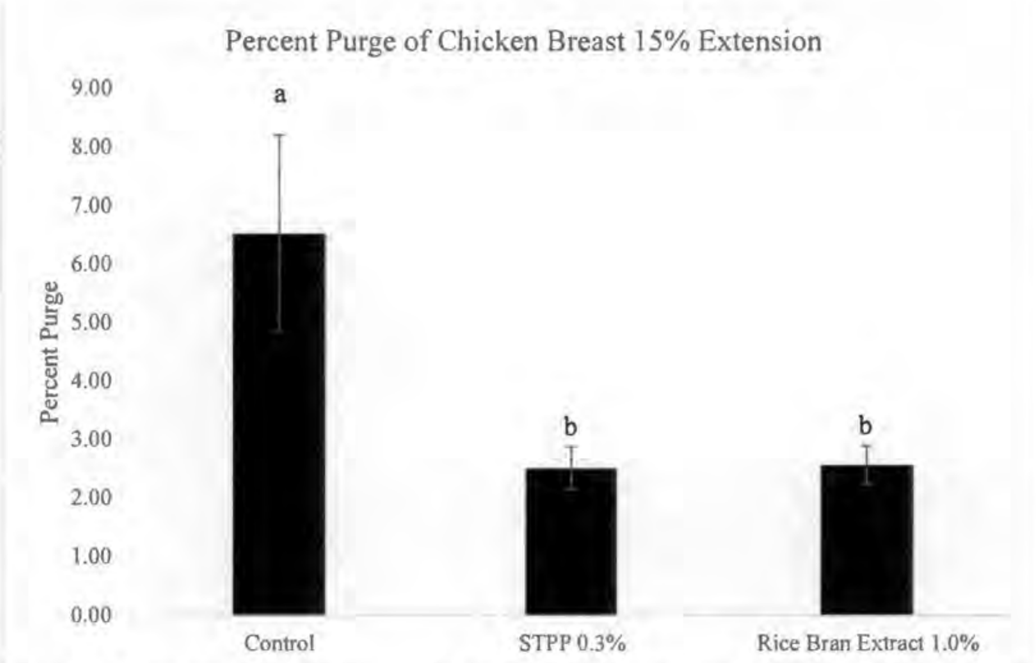

Figure 27. Mean percent (%) purge of chicken breast. Different letters indicate significant difference between treatments ($p<0.05$).

Turkey Sausage Patty

Turkey breasts were purchased and ground upon request at a local supermarket. The ground turkey was separated into three treatments: control (nothing added), STPP at 0.3%, or rice bran extract (1.5%). Salt brines were made with each treatment ingredient and mixed into the turkey sausage at 10% weight extension for four minutes. The turkey sausage was then formed into approximately 100 g patties and the weight recorded. The turkey sausage patties were cooked for 14 minutes at 400 °F. The turkey sausage patties were cooled to room temperature and weighed again. The cooked yield was calculated by dividing the cooked weight by the raw weight.

The results in Figure 28 show that the rice bran extract performed similarly to STPP in the treated turkey sausage. Both the STPP and rice bran extract treatments performed significantly better than the control.

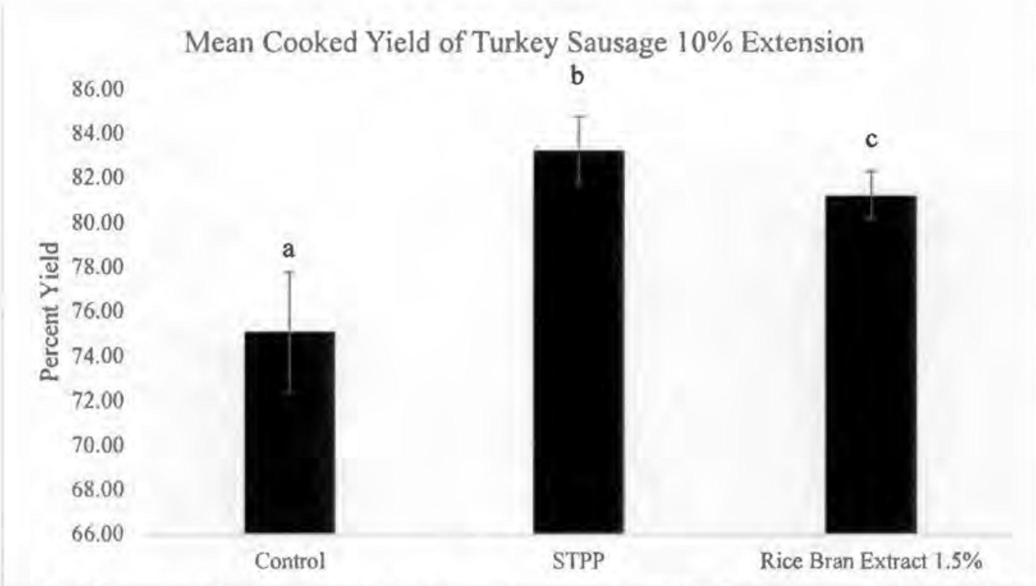

Figure 28. Mean cooked weight yield of turkey sausage. Different letters indicate significant difference between treatments ($p<0.05$).

Beef Sausage Patty

Chuck roasts were purchased and ground upon request at a local supermarket. The beef sausage was separated into three treatments: control (nothing added), STPP (0.3%), and rice bran extract (1.5%). Three tests at different weight extensions (10, 15, or 20%) were performed. Salt brines were made with each treatment ingredient and mixed into the beef sausage for four minutes. The beef sausage was then formed into approximately 100 g patties and the weight recorded. The beef sausage patties were cooked for 14 minutes at 400 °F. The beef sausage patties were cooled to room temperature and weighed again. The cooked yield was calculated by dividing the cooked weight by the raw weight.

The rice bran extract performed similarly to the STPP in beef sausage. At each extension level, both the STPP and rice bran extract treatments performed significantly ($p<0.05$) better than the control and were similar to each other (Figures 29, 30, and 31).

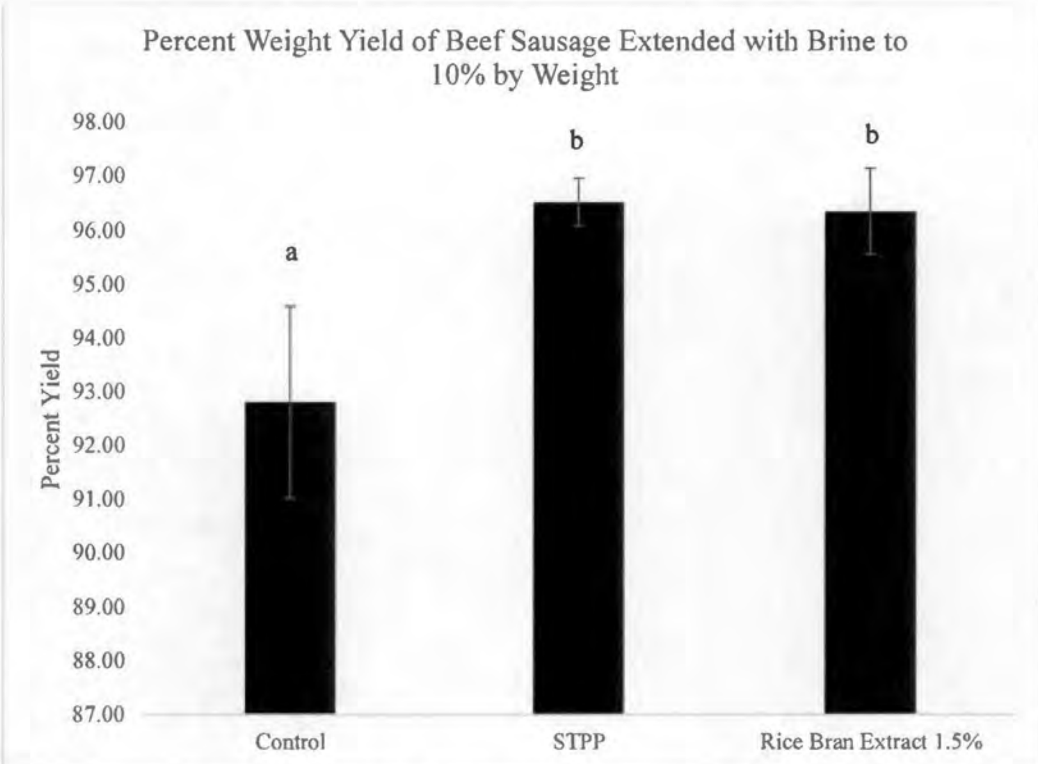

Figure 29. Mean cooked weight yield of beef sausage extended 10% by weight. Different letters indicate significant difference between treatments ($p<0.05$).

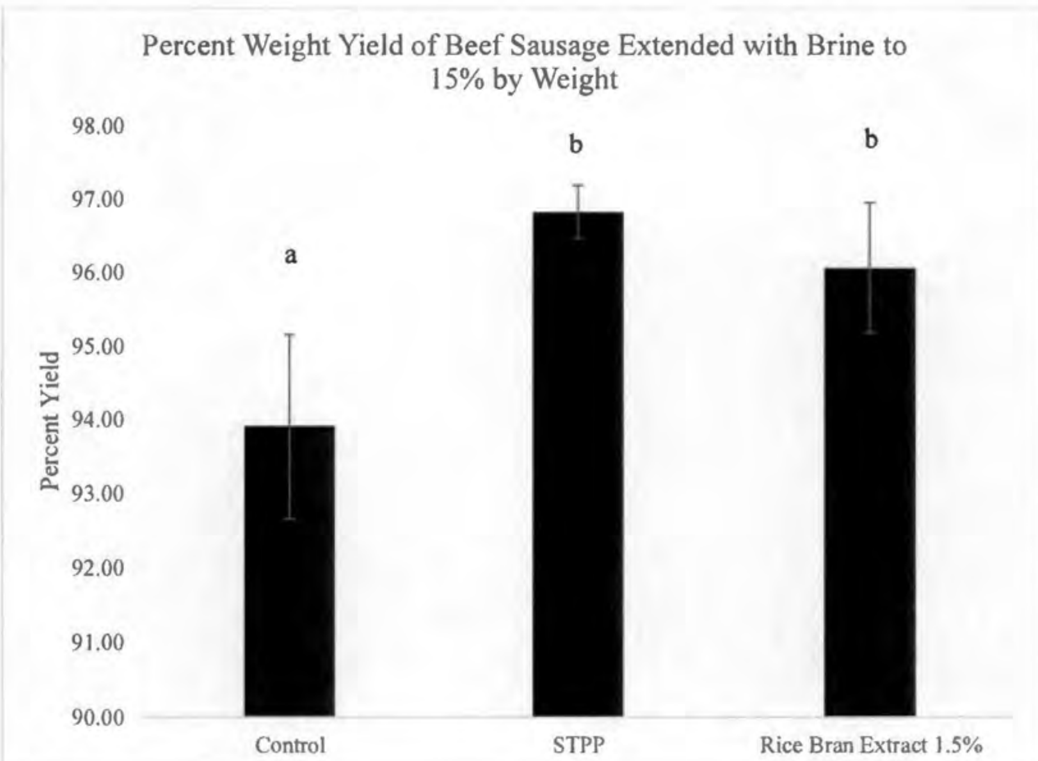

Figure 30. Mean cooked weight yield of beef sausage extended 15% by weight. Different letters indicate significant difference between treatments (p<0.05).

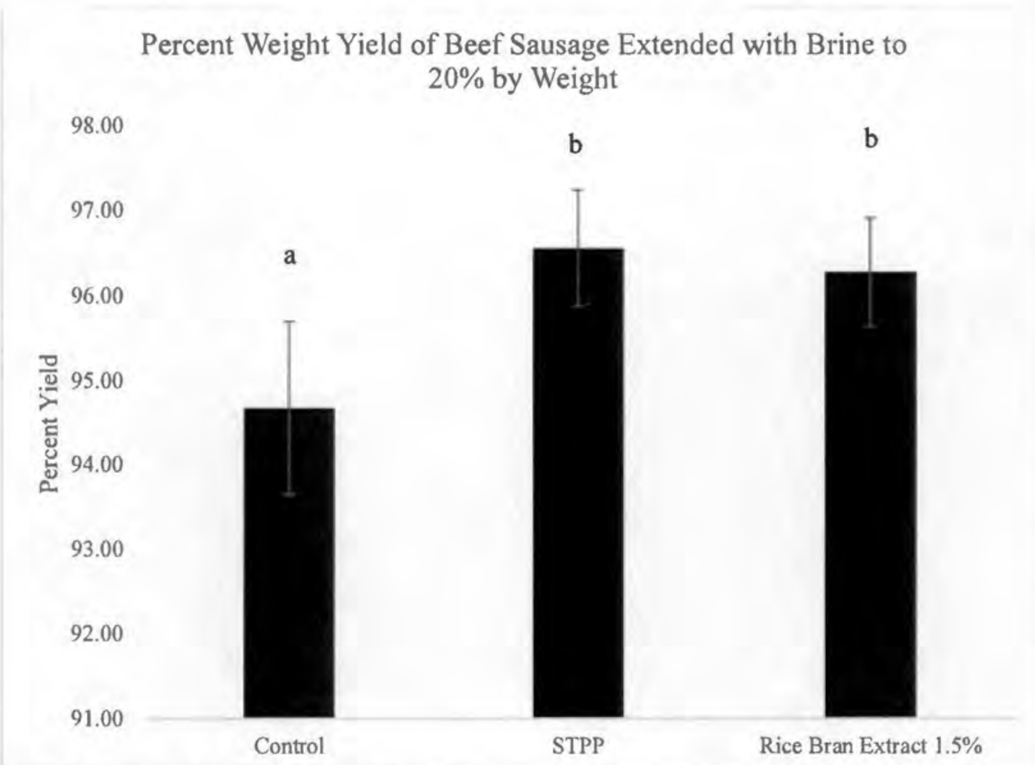

Figure 31. Mean cooked weight yield of beef sausage extended 20% by weight. Different letters indicate significant difference between treatments (p<0.05).

ToxStrategies

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December 19, 2019

Jason Downey, Ph.D.
Division of Food Ingredients
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
U.S. Food and Drug Administration

SUBJECT: GRN 884 Questions to the Notifer (dated December 16, 2019)

Dear Dr. Downey:

The attachment to this letter contains Florida Food, LLC's responses to the questions raised in FDA's letter of December 16, 2019. We believe these responses address the issues raised and provide clarification of both items

Please let me know if you have any further questions or needs with regard to GRN 884.

Sincerely,

Rayetta G. Henderson, Ph.D.
Managing Scientist

ToxStrategies, Inc., 1121 Military Cutoff Rd., Suite C, Box 352, Wilmington, NC 28405
Office (919) 797-9938 • www.toxstrategies.com

Responses to FDA's Questions to the Notifier of GRN 884

<u>FDA Request</u> 1. Please provide estmates of the daily dietary intake for cadmium, lead, and mercury resultng from the intended uses of the notified substance.

<u>Florida Food Response</u> 1. Estimates of the daily dietary intake for cadmium, lead, and mercury resulting from the intended use of the rice bran wax were determined as follows:

The specification for cadmium in Table 3 is <0.4 ppm, and all analyzed batches of the rice bran extract were found to be below the limit of detection (LOD) of 0.01 ppm. Given a projected 90th percentile maximum intake of rice bran extract of approximately 0.89 – 1.26 g/d and applying the maximum of 0.01 ppm (10 µg/kg) as being present in the rice bran extract, the estimated daily cadmium intake is approximately 0.009 – 0.013 µg/person/day.

The specification for lead in Table 3 is <0.2 ppm, and all analyzed batches of the rice bran extract were found to be below the LOD of 0.05 ppm. Given a projected 90th percentile maximum intake of rice bran extract of approximately 0.89 – 1.26 g/d and applying the maximum of 0.05 ppm (50 µg/kg) as being present in the rice bran extract, the estimated daily lead intake is approximately 0.045 – 0.063 µg/person/day

No specification has been set for mercury; however, all analyzed batches of the rice bran extract were found to be below the LOD of 0.025 ppm. Given a projected 90th percentile maximum intake of rice bran extract of approximately 0.89 – 1.26 g/d and applying the maximum of 0.025 ppm (25 µg/kg) as being present in the rice bran extract, the estimated daily mercury intake is approximately 0.022 – 0.032 µg/person/day.

<u>FDA Request</u> 2. On pages 11, 13, 26, and 28 and in Appendix A of the notice, the batch analyses are inconsistently described as "four consecutive lots" and "three non-consecutive lots". Please clarify whether data for a fourth lot are missing and whether the lots analyzed were manufactured consecutively or nonconsecutive.

<u>Florida Food Response</u> 2. The analytical data are presented from three non-consecutive lots of the rice bran extract. As such, the text on pages 11 and 13 ("three non-consecutive lots") is correct as written. The text on pages 26 and 28 ("four lots" or "four consecutive lots") and in Appendix A ("four consecutive lots") are incorrect and should read "three lots" or "three consecutive lots".