GRAS Notice (GRN) No. 596
http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm

ORIGINAL SUBMISSION

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THE UNIVERSITY OF BRITISH COLUMBIA

August 9, 2015

Dr. Leah Rosenfeld
Consumer Safety Officer
Division of Biotechnology and GRAS Notice Review
Office of Food Additive Safety
U.S. Food and Drug Administration
Tel: 240-402-1386
Email:Leah.Rosenfeld@fda.hhs.gov

Dear Dr. Rosenfeld

Attached please find our revised GRAS notice for breadfruit. We are very grateful for all of the comments and suggestions from your team. We have incorporated all of the information and it has improved our application considerably.

Thank you for all of your help and we are happy to provide additional information as needed.

Kind Regards,

(b) (6) [redacted]

Susan J. Murch, PhD
Professor & Canada Research Chair
Chemistry Department, Room 350, Fipke Centre
3247 University Way, University of British Columbia
Kelowna, British Columbia, Canada, V1V 1V7
Tel: 250-807-9566

596

a place of mind GRN 000596

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OFFICE OF
FOOD ADDITIVE SAFETY

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Dear Dr. Rosenfeld

The enclosed DVD is virus free by Sophos Endpoint Security and Control.

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GRAS EXEMPTION CLAIM

The PlantSMART Labs at the University of British Columbia (UBC), hereby notifies the U.S. Food and Drug Administration that the uses of breadfruit (*Artocarpus altilis* Parkinson (Fos) and hybrids) flours described below are exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because PlantSMART has determined that such uses are generally recognized as safe (GRAS). PlantSMART made this GRAS determination based on scientific procedures, a comprehensive search of the scientific literature, meta-analysis of the scientific nutritional literature and government databases as well as laboratory testing to establish safety and a lack of toxicity. These findings are described in the following sections, and the evaluation accurately reflects the conditions of the intended use of this substance in foods.

1.1 Name and Address of Notifier

PlantSMART Labs
University of British Columbia
Kelowna, British Columbia, Canada, V1V 1V7

Contact Name: Susan J. Murch
Professor & Canada Research Chair
Chemistry, Room 350 Fipke Centre
3247 University Way
Telephone: (250) 807-9566
e-mail: susan.murch@ubc.ca

As the notifier, PlantSMART, University of British Columbia accepts responsibility for the GRAS determination that has been made for breadfruit (*Artocarpus altilis* and hybrids) flours as described in the subject notification; consequently breadfruit flour described herein is exempt from pre-market approval requirements for food ingredients.

1.2 Name of GRAS Substance

The tropical tree species *Artocarpus altilis* Parkinson (Fos) and hybrids of *Artocarpus altilis* x *Artocarpus mariannensis* are most commonly known as breadfruit in English or ‘ulu’ in the Pacific but may also be known as: árbol de pan, fruta de pan, pan, panapen, (Spanish), arbre à pain, fruit à pain (French), beta (Vanuatu), bia, bulo, nimbalu (Solomon Islands), blèfoutou, yovotévi (Bénin), brotfruchtbaum (German), broodvrucht, broodboom (Dutch), cow, panbwa, pain bois, frutapan, and fruta de pan (Caribbean), fruta pao, pao de massa (Portuguese), kapiak (Papua New Guinea), kuru (Cook Islands), lemai, lemae (Guam, Mariana Islands), mazapan (Guatemala, Honduras), meduu (Palau), mei, mai (Federated States of Micronesia, Kiribati, Marshall Islands, Marquesas, Tonga, Tuvalu), mos (Kosrae), rata del (Sri Lanka), rimas

(Philippines), shelisheli (Tanzania), sukun (Indonesia, Malaysia), ‘ulu (Hawai‘i, Samoa, Rotuma, Tuvalu), ‘uru (Society Islands), uto, buco (Fiji). Breadfruit has a long traditional use as fresh food but dried and ground breadfruit will be sold as a food ingredient. The common name for dried, ground breadfruit will be “breadfruit flour”.

1.3 Conditions of Use

Breadfruit will be dried and ground into a milled product intended for use as an ingredient in various baked goods, breads, cereals, porridges, and pasta products. Breadfruit could also be used as a gluten-free substitute for other flours breads and snack foods.

1.4 Basis for GRAS Determination

The GRAS determination for the intended uses of breadfruit flour is based on scientific procedures as described under 2 1 CFR§170.30. Information provided includes comprehensive searches of the literature through May 2015 conducted by PlantSMART served as the basis for preparation of a monograph summarizing the totality of the available information germane to determining the safety of the intended uses of breadfruit flour.

Detailed analysis of the composition of macronutrients, micronutrients, and anti-nutritional factors demonstrated that breadfruit flour is similar to other commonly consumed flours. A comprehensive search and meta-analysis of the nutritional data was conducted along with compilation of scientific literature and government databases as well as laboratory testing of as well as studies of digestibility and responses in cell culture experiments.

It may be concluded that breadfruit flour is safe under the intended conditions of use because the total exposure to breadfruit flour and its constituents resulting from these uses is well within levels shown to be safe by both current levels of consumption of other flours, which are compositionally very similar to breadfruit flour and the long history of use of fresh breadfruit by human populations. The estimated intakes of breadfruit flour, even for the highest users, are below the level shown to have no adverse effects or nutritional hazards, based on nutritional composition comparisons and human use.

Therefore, the intended uses of breadfruit flour are determined to be safe and GRAS. Determination of the safety and GRAS status of breadfruit flour for direct addition to food under their intended conditions of use was made through evaluation of the scientific literature. Therefore, breadfruit flour is GRAS by scientific procedures under the conditions of use described.

1.5 Availability of Information

The data and information that serve as the basis for this GRAS notification will be sent to the US Food and Drug Administration (FDA) upon request or will be available for review and copying at reasonable times at the offices of the PlantSMART, University of British Columbia.

Notice to US Food and Drug Administration that the Use of Breadfruit (*Artocarpus altilis* and *A. altilis*×*A. mariannensis*) Flour is Generally Recognized As Safe

Submitted by the Notifier:

Plant Secondary Metabolite Analytical Research Team (PlantSMART) Labs
University of British Columbia
Kelowna, British Columbia, Canada, V1V 1V7

Prepared by

Susan J. Murch, PhD
Department of Chemistry
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Tel: 250-807-9566
e-mail: susan.murch@ubc.ca

Table of Contents

Tables:

I. GENERAL INFORMATION

1.1. Submission Type

This is a new submission.

1.2. Electronic Files

All files are free from computer viruses as verified by Sophos Endpoint Security and Control.

1.3. Date of Most Recent Meeting with FDA

teleconference with the following FDA team members on Monday, June 08th, 2015

Leah Rosenfeld	Consumer Safety Officer
Susan Carlson	Supervisory Consumer Safety Officer
Jeremy Mihalov	Chemist
Michael DiNovi	Chemistry Supervisor
Rebecca Danam	Toxicologist
Kotaro Kaneko	Toxicologist
Jason Aungst	Acting Toxicology Supervisor
Renata Kolanos	Chemistry fellow
Stephanie McCracken	Toxicology fellow

1.4. Correspondence with FDA

e-mail and telephone correspondence with Dr. Leah Rosenfeld beginning May 8th, 2015

e-mail correspondence with Dr. Frederick Fry Jr. beginning May 13th, 2015

e-mail and telephone correspondence with Dr. Leah Rosenfeld on July 22nd, 2015

II. INFORMATION ABOUT THE NOTIFIER

2.1. Notifier

PlantSMART Labs

2.2. Contact Person:

Susan J. Murch, PhD
Department of Chemistry, University of British Columbia
3247 University Way, Kelowna, British Columbia, Canada, V1V 1V7
Tel: 250-807-9566: e-mail: susan.murch@ubc.ca

2.3. Agent or Attorney Authorized to Act on Behalf of the Notifier

None.

III. GENERAL ADMINISTRATIVE INFORMATION

3.1. Common or Usual Name of the Notified Substance

The common name of the substance of this notification is breadfruit flour. Commonly used synonyms include "ulu", "uru", "lemai", "mei" and "fruta de pan". The substance is marketed under a variety of product and trade names including: Mango Valley Co-op (Jamaica), Signa-Haiti (Haiti), Carmeta's (Jamaica), Farine de Uru (Tahiti), Samoa Pure (Samoa) and others. The scientific name of the species is *Artocarpus altilis*, (diploid or triploid) and *A. altilis*×*A. mariannensis* (triploid hybrid). Flour is made from the fresh fruit by harvest, peeling, coring, slicing, air or oven drying and grinding as shown below. Appendix A contains a business plan for development of a breadfruit flour industry in the USA.

Photos from top left. Fresh breadfruit harvested from the tree. Peeled breadfruit cut in half. Sliced breadfruit. Dried and ground slices.

3.2. Format of Submission

TBD

3.3. Mode of Transmission

TBD

3.4. Information Already in Files

None

3.5.Statutory Basis of Claim of GRAS Status: GRAS Exemption Claim

PlantSMART has determined that breadfruit (*Artocarpus altilis* and *A. altilis*×*A. mariannensis*) flour is Generally Recognized as Safe (GRAS) for its intended use, consistent with section 201(s) of the Federal Food, Drug and Cosmetic Act. This determination has been made based on scientific procedures, published data and long history of human use of fresh fruit. Therefore the use of breadfruit flour, for its intended purpose is exempt from the requirement of pre-market approval.

3.6. Confidential Information

Information contained in Appendix C is currently in the publication process and embargoed until publication.

3.7. Redacted Copy of Information

None.

IV. INTENDED USE

4.1. Basis for GRAS Determination

In accordance with 21 CFR 170.30, the basis for determining breadfruit flour as Generally Recognized As Safe (GRAS) is scientific procedures and a comprehensive search and meta-analysis of the scientific literature and government databases as well as laboratory testing.

4.2. History of Consumption

The history of human consumption of breadfruit as a staple crop of the Pacific extends at least 3,000 years. Traditional cultivated varieties were bred by individuals, families and communities and carried by canoe from Papua New Guinea throughout Oceana. Traditional cultivars of breadfruit were brought to Hawaii with the canoe peoples sometime between 1000 and 1200 A.D.

European collections of breadfruit began with the Spanish and the Dutch East India Company during the 17th century. In the late 1700s, several governments and individuals engaged in widespread dissemination of the breadfruit to regions outside of Oceania (Barrau, 1976; Ragone, 1997; Smith et al., 1992). In 1769, Joseph Banks traveling with Captain James Cook to Tahiti recognized the potential of breadfruit and observed the following (Banks 1962):

> "In the article of food these happy people may almost be said to be exempt from the curse of our forefather; scarcely can it be said that they earn their bread with the sweat of their brow when their cheifest sustenance Bread fruit is procurd with no more trouble than that of climbing a tree and pulling it down. Not that the trees grow here spontaneously but if a man should in the course of his life time plant 10 such trees, which if well done might take the labor of an hour or thereabouts, he would as compleatly fulfull his duty to his own as well as future generations as we natives of less temperate climates can do by toiling in the cold of winter to sew and in the heat of summer to reap the annual produce of our soil, which when once gatherd into the barn must be again resowd and re-reapd as often as the Colds of winter or the heats of Summer return to make such labor disagreable." (The Endeavour Journal of Joseph Banks, August 14th 1769)

In August 1787, Banks successfully persuaded the King to invest in an expedition to collect breadfruit and transplant it to the Caribbean as a reliable food source for sugar plantations. Responsibility for the expedition was placed under the leadership of Lieutenant William Bligh RN and the HMS Bounty sailed from England in December 1787. The Bounty collected 1,015 breadfruit trees but all were lost in the famous mutiny at sea in 1789. Determined to transport breadfruit from East to West, Sir Joseph Banks ordered Bligh to commence two additional voyages that successfully transplanted 668 breadfruit trees from Tahiti to Jamaica and St. Vincent in 1793 and 1796 (Powell, 1977).

Breadfruit is commonly used as a staple food in Polynesia and Micronesia, and as a supplementary staple in most of Melanesia (Fosberg, 1960; Lim, 2012; Ragone, 2009). A single breadfruit tree produces >400 kg of fresh fruit (Liu et al., 2014). Edible portions of breadfruit for human consumption include immature and ripe fruit, seeds, young leaves, and ripe blossoms.

Breadfruit is consumed raw, boiled, roasted, baked, or fried. Preservation of the fruit can be achieved through sun-drying or in pits (Lim, 2012; Ragone 2009; Jones et al., 2013). A summary of common dishes made from breadfruit fruit commonly eaten in tropical regions are listed in Table 1 (Morton, 1987; Lim, 2012; Ragone, 2009; Meilleur et al., 2004).

Table 1 Examples of Breadfruit fruit Based Dishes in Human Diet

Region	**Common Dishes Made from Breadfruit**
Bahamas	Breadfruit soup made from under-ripe fruit
Barbados	Breadfruit chips made from overripe or soft fruit
	Combined with wheat for bread making
Brazil	Combined with wheat for bread making
Ceylon	Breadfruit dipped in a salt solution
Dominican Republic	Breadfruit bread "*buen pan*"
Philippines	Cooked fruit in coconut and sugar
Grenada	*"oil down"* by cooking breadfruit, meat, coconut milk, and dasheen leaves
Guam	Breadfruit paste soaked in water
Hawaii	Boiled under-ripe fruits with butter and sugar, or salt and pepper
	Breadfruit chowder made from cooking breadfruit with vegetables, bacon, and milk
	Substitution for taro in *poi*, "*poi ulu"*
Jamaica	Breadfruit flour-based porridge

Region	Common Dishes Made from Breadfruit
Malaysia	Fry sliced firm-ripe breadfruit in syrup or plam sugar
Micronesia	Made into a paste by fermenting breadfruit in banana leaf-lined boxes
	Breadfruit soaked and beaten in the sea
New Hebrides	Fermented breadfruit
Polynesia	Fermented or baked breadfruit in a native oven
Puerto Rico	"*pana*" or "*panen,*" cooked breadfruit with olive oil, onions, and saturated *bacalao* (salted cod fish)
Samoa	"*masi,*" fermented breadfruit with banana and *Heliconia* leaves to make a paste, which is cooked with coconut cream
Solomon Islands	Fruit roasted in an underground oven (*imu*)
Trinidad	Breadfruit chips made from overripe or soft fruit
	"*oil down,*" cooked breadfruit, meat, coconut milk and dasheen leaves
Tobago	"*oil down,*" cooked breadfruit, meat, coconut milk and dasheen leaves

4.3. Current Production, Uses and Significance in the World

Breadfruit is one of 35 crop species identified in the International Treaty on Plant Genetic Resources for Food and Agriculture as an underutilized crop with the potential to improve food security and interdependence (FAO, 2009). Table 2 summarizes the breadfruit production in the

United States based on the Agricultural Censuses Report conducted by the U.S. Department of Agriculture in 2007 (USDA, 2007).

Table 2 Breadfruit Production in 2007 Agricultural Censuses Report Conducted by the U.S. Department of Agriculture

Regions	**Virgin Islands**	**Northern Mariana Islands**	**Guam Island**	**American Samoa**
Year	2007	2007	2007	2008
Number of farms	54	42	14	4,828
Number of non-bearing trees	35	46	61	NA
Number of bearing trees	280	216	258	NA
Pounds harvested for sale	10,713	4,774	9,650	252,375
Pounds harvested for consumption	NA	NA	NA	3,140,728

In the past, breadfruit was mainly produced in Hawaii, Puerto Rico, the Marianas Islands and American Samoa for local use and the commercialization of breadfruit was impossible due to difficulties in propagation (Murch et al., 2008a&b; Ragone 2009). In 2008, we reported the development of *in vitro* propagation methods for clonal propagation of breadfruit trees in a sterile, controlled environment (Murch et al., 2008a & b; Shi et al., 2007). This advancement lead to development of a horticultural industry for mass propagation and distribution of the trees to tropical countries in projects designed to increase food security (www.globalbreadfruit.com). To date, there have been more than 60,000 trees planted in 32 countries across the world and it has been estimated that the trees planted to date will provide a staple nutritious food source for 250,000 people for the next 50-70 years.

4.4. Conditions of Intended Use in Food

The development of a commercial flour from dried breadfruit is a recent development with a long history of use. In 1830, a specimen of dried breadfruit "flour" from Mauritius Botanical Garden was deposited in the economic botany collections at Kew Gardens, UK (specimen number 42794). Several researchers have reported different methods of processing breadfruit to produce a flour or porridge (Arcelay and Graham, 1984; George et al., 2007; Wootton and Tumaalii, 1984). Breadfruit flour can be stored for months at room temperature with little loss in quality (Sharon and Usha, 2006), is easily shipped to global markets, and can be incorporated into a variety of regional recipes including stiff porridges (Mayaki et al., 2003), extruded products (McHugh et al., 2007), breads (Ayodele and Oginni, 2002; Esuoso and Bamiro, 1995; Nochera and Caldwell, 1992), cakes (Ayodele and Oginni, 2002), pancakes (Ayodele and Oginni, 2002) and biscuits (Nnam and Nwokocha, 2003; Olaoye et al., 2007; Omobuwajo, 2003). Compositional data on breadfruit flour is summarized in the following sections.

4.5. Discussion of Information Inconsistent with GRAS Determination

There is one study in the literature to suggest that adverse events are associated with the consumption of breadfruit. Grant et al., (1995) investigated feeding a powdered extract made from *Artocarpus* seeds to 4 male Hooded Lister rats. The paper identified the seeds as representing the species *A. altilis* seeds obtained from a tree at the Mayaguez Institute of Tropical Agriculture (MITA, Puerto Rico). However, the GRIN (Germplasm Resources Information Network) database provided by the U.S. Department of Agriculture, shows that the only *A. altilis* cultivar that might possibly produce seeds was not received until 2005. In 1990s, Puerto Rico had only seedless *A. altilis*, derived from the British and French introductions in late 18th century. MITA did have collections of the seeded species *A. camansi* brought by the French in the late 18th century, and it is possible that the species was misidentified in the paper. It is most likely that Grant et al., (1995) are actually describing an extract prepared from *A. camansi* (breadnut, photo on left) rather than *A. altilis* (breadfruit, photo on right).

Several other factors call into question the results published by Grant et al., (1995). First, only 4 rats were fed the diet and post-mortem details are not provided. It is possible that these rats died of causes entirely unrelated to the diet. The diet seems to have been formulated with an uncooked powdered extract while seeds are traditionally boiled and eaten like peanuts or cashews. Finally, it appears that the goals of the study were to investigate potential plant toxicity to wild animals rather than human use.

A second study is cited in the FDA database as evidence of toxicity of breadfruit *Artocarpus altilis*. Fletcher, (1971) conducted an ethnobotanical study on Guam and reported traditional knowledge of the use of the male inflorescences (flowers) as a treatment for conjunctivitis. Left side is a photo of 2 male inflorescences. The male inflorescences are not used in the production of flour from breadfruit. However, it is unlikely that these flowers are acutely toxic since they are cooked, soaked in coconut milk, candied and sold as traditional children's treats in many Pacific Island markets.

4.6. FDA Poisonous Plants Database

Correspondence with the FDA Poisonous Plants database administrator (May 13, 2015) indicates:

"The Poisonous plant database is/was a compendium of reports, mostly in older print literature and monographs, where toxicity has been reported or suspected. When you search on a plant name, the system presents references to that information as they existed in print. Many of the references refer to potential animal toxicity. The information in the database is bibliographic and does not directly discus degree of toxicity or hazard. There are no plans to update this database as more recent bibliographic information is easier to access."

This is the disclaimer that accompanies the database:

The Poisonous Plant database provides access to references in the scientific literature (primarily print literature through about 2007) describing studies and reports of the toxic properties and effects of plants and plant parts.

The information in this database is intended only for scientific exchange. It has not been approved by the United States Food and Drug Administration for publication nor does it have any official status. The information is continually increasing and being modified; it is neither error-free nor comprehensive. Information herein is in the public domain. Any copyrighted or privately owned material inadvertently included will be removed as soon as possible.

Therefore, while the inclusion of breadfruit in the database may be unsupported by the science, there is no mechanism to change the record.

V. IDENTITY OF SUBSTANCE AND PRODUCTION

5.1. Species Description

5.1.1. Botanical Description

The common name 'breadfruit' refers to *A. altilis*, which can be triploid (3n=2x=~84) and producing no seeds or diploid (2n=2x=~56) and producing few to several seeds (Ragone, 2001). Some of the cultivated varieties of breadfruit are interspecific hybrids of *A. altilis* × *A. mariannensis* (Fosberg, 1960; Zerega et al., 2004, 2005). Early generation hybrids produce fruits that most closely resemble its *A. mariannensis* parent while later generation hybrids more closely resemble *A. altilis* and are seedless. Several thousand cultivated varieties of breadfruit are known across the Pacific tropical islands and the fruit has been used as a staple food source for about 3,000 years. The hierarchical classification of breadfruit is shown in Table 3. Breadfruit is a moderately large evergreen tree generally growing 15 to 20 m, but sometimes reaching over 30 m tall (Niering, 1963; Ragone, 1997, 2006). Breadfruit trees are monoecious, with both male and female inflorescences in the same tree. The inflorescences are comprised of about 1500-2000 individual florets connected to the receptacle.

Table 3 Classification of Breadfruit (Artocarpus altilis and Artocarpus altilis× A. mariannensis).

Rank	**Scientific Name and Common Name**
Kingdom	Plantae – Plants
Subkingdom	Tracheobionta – Vascular plants
Superdivision	Spermatophyta – Seed plants

Rank	**Scientific Name and Common Name**
Division	Magnoliophyta – Flowering plants
Class	Magnoliopsida – Dicotyledons
Subclass	Hamamelididae
Order	Urticales
Family	Moraceae – Mulberry family
Genus	*Artocarpus* J.R. Forst. & G. Forst. – Breadfruit
Species	*Artocarpus altilis* (Parkinson) Fosberg – Breadfruit *Artocarpus mariannensis* Trécul– Artocarpus

5.1.2. Fruit

The shape of the fruits is irregular but the texture is generally flattened or rounded pebbly. The advanced hybrids have a similar texture and shape to the early generation hybrids, but the size of the fruit is relatively larger and the fruit is seedless (Jones et al., 2013). The general fruit size is 12 cm×16 cm and the fruit weight ranges from 1 to 2 kg. Some cultivars can produce fruit weighing up to 6 kg (Ragone, 1997, 2006; Zerega et al., 2005). During the mature process, the outside fruit skin turns from light green to yellow and the inside flesh becomes creamy white to yellow.

5.2. Characterization of Flour

The subject of this GRAS determination, breadfruit (*Artocarpus altilis* and *Artocarpus altilis*× *A. mariannensis*) flour, is a yellow to off-white powder without any characteristic taste or odor. Table 4 summarizes the general characteristics of breadfruit flour.

Table 4 General Descriptive Characteristics of Breadfruit Flour (Artocarpus altilis and Artocarpus altilis× A. mariannensis)

Parameter	**Description**
Botanical source	*Artocarpus altilis, A. altilis× A. mariannensis*
Synonym of source	Breadfruit, ulu, uru, mei, lamei, fruta de pan
Plant part used	Fruit (seeds removed, peel removed)
Synonyms of part used	Flesh
Appearance	Powder
Color	Yellow to off-white
Odor	No odor / sometimes slight green tea
Taste	Bland
Storage	Shelf
Shelf life	1-2 years

5.3. Nutritional Composition

We have identified 41 reports detailing the nutritional profile of breadfruit food cultivars *A. altilis* or hybrids of *A. altilis*× *A. mariannensis* using the Web of Science™ and Google Scholar™ search engines, as well as government databases and regional reports (Turi et al., 2015). For all nutritional parameters reviewed, data were converted to common units as an amount per 100 g fresh fruit (Tables 5-8). In instances where individual values were unavailable within a category, theoretical values were extrapolated from the available data and identified in the corresponding tables (Tables 5-8). Table 9 presents an amino acid profile of breadfruit from our previously published study of HPLC (high performance liquid chromatography) based amino acid analysis across 49 breadfruit cultivars (41 *A. altilis* and 8 hybrids) (Liu et al., 2015). Minimum and maximum values for the exposure to breadfruit flour in a standard diet are included later in the application.

Table 5 Minimum and Maximum Reported Values for Breadfruit (Artocarpus altilis and *Artocarpus altilis × A. mariannensis) Proximate Analyses*

Proximate Analysis						
Nutrient	**Fresh (100g)**		**Cooked (100g)**		**Flour (100g)**	
	Min	Max	Min	Max	Min	Max
Ash (%)	0.8	4.6	NA	NA	0.8	6.7
Moisture (%)	19	83	53.2	83.6	2.5	21
Dry matter (%)	17	80.9	16.4	46.8	79	97.5
Energy (Kcal)	102	310	80	160.9	279.8	378
Total Carbohydrates (g)	14.3	70.1	18.1	37	50	88
Lipid (g)	0.1	4.5	0.1	4.9	0.5	11.8
Protein (g)	0.07	5.2	0.6	11.4	1.9	18.7

Crude Fiber (g)	0.9	4.9	1.8	7.4	0.8	15.3
Insoluble Fiber (g)	3.1*	25.6*	2.4	20	7.5*	62.3*
Soluble Fiber (g)	0.20	0.2	NA	7.2	0.2*	11.4*

Values marked with * are extrapolated and based on the calculated average dry weight for breadfruit (fresh = 37.55%, baked = 29.35%, flour = 91.40%). NA represents not available.

Table 6 Minimum and Maximum Starch and Sugar Contents of Breadfruit (Artocarpus altilis and *Artocarpus altilis* × *A. mariannensis)*

Starch Analysis						
Nutrient	**Fresh (g/100g)**		**Cooked (g/100g)**		**Flour (g/100g)**	
	Min	Max	Min	Max	Min	Max
Total Starch	15.5	28.4	NA	NA	42.6	75.7
Fructose	NA	0.16	NA	NA	4.3	13.6
Glucose	0.18	0.44	NA	NA	6.5	11.3
Sucrose	0.25	0.62	NA	NA	NA	16.4
Total Sugars	NA	NA	NA	NA	2.8	26.8
Total Reducing Sugars	NA	NA	NA	NA	2.7	22.5

NA represents data not available

Table 7 Reported Minimum and Maximum Carotenoid and Vitamin Content for Breadfruit (Artocarpus altilis and *A. altilis × A. mariannensis)*

Carotenoids and Vitamins						
Nutrient	**Fresh (100g)**		**Cooked (100g)**		**Flour (100g)**	
	Min	Max	Min	Max	Min	Max
Total carotenoids (µg)	NA	3769	NA	1260	NA	6549
alpha carotene (µg)	NA	260	NA	142	NA	537.5
β carotene (µg)	NA	3410	NA	868	NA	5501.7
β cryptoxanthin (µg)	NA	3.3	NA	10.6	NA	20.5
Lutein (µg)	NA	690	NA	759	NA	2021.6
Lycopene (µg)	NA	48.7	NA	25.9	NA	99.6
Zeaxanthin (µg)	NA	60	NA	70	NA	182
Folic acid (µg)	NA	1.3	NA	1.0	NA	3.1
Vitamin B1 (mg)	0.12	0.28	0.09	0.14	0.29	0.6
Vitamin B2 (mg)	0.05	0.1	0.02	0.06	0.16	0.4
Vitamin B3 (mg)	0.84	1.7	0.64	1.4	2.30	4.4
Vitamin C (mg)	16.20	21	1.60	12.1	NA	22.7

NA represents not available.

Table 8 Reported Minimum and Maximum Mineral Content for Breadfruit (Artocarpus altilis and *Artocarpus altilis × A. mariannensis)*

Minerals						
Nutrient	**Fresh (100g)**		**Cooked (100g)**		**Flour (100g)**	
	Min	Max	Min	Max	Min	Max
Boron (mg)	0.5	0.5	0.4	0.4	1.3	1.3
Calcium (mg)	18	54	10	30	5	800
Chlorine (mg)	NA	2	NA	1.6	NA	4.9
Cobalt (µg)	NA	1.1	NA	0.9	NA	2.70
Copper (mg)	0.08	0.3	0.45	0.5	0.1	4.95
Iron (mg)	0.26	52	NA	1.1	0.5	12
Magnesium (mg)	20	70	14	30	9.9	200
Manganese (mg)	0.04	0.3	0.1	0.3	0.1	2.
Nickel (mg)	NA	0.08	NA	0.06	NA	0.19
Phosphorus (mg)	7	116	18	41	73.7	1920
Potassium (mg)	289	2390	240	522	66.9	2830
Sodium (mg)	3	27	2	70	1.90	597
Sulfur	20	31	15.6	24.2	48.7	75.5
Zinc (mg)	0.09	0.53	NA	0.13	0.13	3

NA represents not indicated.

Table 9 Amino Acid Profile of Breadfruit Protein (Liu et al., 2015 and unpublished results)

Amino Acid	***Artocarpus altilis***				***Artocarpus altilis* × *A. mariannensis***			
mg/g protein	Average	Max	Min	SE	Average	Max	Min	SE
Ala	18.61	38.44	8.04	1.13	24.75	41.38	16.56	3.37
Arg	15.92	37.17	6.50	1.09	18.58	27.66	12.03	2.14
Asn	45.12	113.81	15.89	3.64	46.89	89.08	21.85	8.98
Asp	36.96	105.78	12.95	3.10	40.28	83.21	16.71	8.07
Glu	31.19	82.03	8.87	2.47	32.87	54.33	15.49	5.43
Gly	12.29	31.44	4.44	0.86	13.79	21.85	10.26	1.62
Pro	4.97	12.62	2.03	0.39	5.62	8.88	4.07	0.69
Ser	14.09	36.40	5.16	1.08	19.78	31.83	11.98	2.61
His*	10.05	25.44	3.27	0.77	10.71	16.27	7.17	1.35
Ile*	33.45	79.69	14.61	2.19	39.80	59.97	26.47	4.78
Leu*	62.43	169.31	25.75	4.47	71.75	109.22	50.01	8.93
Lys*	17.34	39.52	7.34	1.14	19.67	30.76	12.16	2.62
Met*	2.85	7.70	0.75	0.22	3.82	6.29	2.45	0.61
Phe*	57.26	145.29	23.67	3.96	61.51	90.73	43.51	7.16
Thr*	14.40	37.04	5.10	1.07	14.69	23.12	8.46	1.87
Trp*	2.68	36.44	0.54	0.90	1.68	2.83	0.49	0.29
Tyr*	1.43	6.83	0.00	0.25	2.45	4.66	0.97	0.61
Val*	27.40	61.99	11.51	1.84	32.66	51.51	22.43	4.05

*represent essential amino acid or conditionally essential amino acid, lysine (lys), leucine (leu), threonine (thr), tryptophan (trp), histidine (his), isoleucine (ile), valine (val), phenylalanine (phe), tyrosine (tyr), and methionine (met)

5.4. Anti-nutritional Composition

Table 10 presents major anti-nutrients detected in breadfruit based on literature review using the Web of Science™ and Google Scholar™ search engines (Appiah et al., 2012; Famurewa et al., 2015; Ijarotimi and Aroge, 2005; Oulaï et al., 2014).

Enzyme inhibitors, such as α-amylase inhibitor and trypsin inhibitors are commonly found in raw cereals and legumes (Thompson, 1993). For example, in wheat, α-amylase inhibitor activity is 2.66×10^5 AIU/100g, and trypsin inhibitor activity is 0.47×10^5 TIU/100g (Abdel-Aal et al., 2011). Enzyme inhibitors are considered as anti-nutrients due to their inhibition of digestive enzymes. Despite their resistance to digestion, enzyme inhibitors are found to have some beneficial health impacts such as lowering blood glucose, reducing plasma cholesterol and triacylglycerol and treating breast cancer (Slavin et al., 1999). In breadfruit, trypsin inhibitor activity is not detected and α-amylase inhibitor activity is much lower (482 AIU/100g) compared to wheat. Due to the nature of the protein, the structure of these inhibitors is normally destroyed during the cooking/heating process (Thompson 1993).

Phenolic compounds, including tannins, catechin, gallic acid, and benzoic acid, are commonly found in bran layers of cereal grains, especially the bran layers of the whole grain, which has a total phenolic compound content of 764 mg/100g (Sidhu and Kabir, 2007; Thompson, 1993). Phenolic compounds can cause depression in food/feed intake, formation of less digestible protein complexes, and inhibition of digestive enzymes. However, phenolic compounds can be beneficial for humans since they can prevent accumulation of reactive oxygen species that cause cellular damage (Slavin, 2004). Breadfruit has a maximum total phenolic compounds of 408 mg/100g, which is much lower than whole grains, and similar to wheat germ (349 mg/100g) (Velioglu et al., 1998).

Oxalate is the major component of kidney stones in humans. It is widely disturbed in nuts, grains, legumes, and vegetables. In grain flours, the total oxalate content can range from 37-269 mg/100g, and in nuts, the number increases to 42-469 mg/100g (Chai and Liebman, 2005; Siener et al., 2006). Breadfruit has an oxalate content between 100-192 mg/100g in the flour. The cooking process typically results in a dramatic reduction of oxalate content (Siener et al., 2006). Therefore, the exposure to oxalate in breadfruit is in the same range as most other plant-based foods.

Phytic acid, and its salt phytate, can be found in the cotyledon of legumes, oilseeds, and the bran of cereal grains, at a range from 10 to 6000 mg/100g (Sidhu and Kabir 2007; Thompson 1993). These are considered as anti-nutrients because they can chelate mineral elements in the body, but researchers have found that phytate can also reduce blood glucose, and reduce plasma cholesterol and triacylglycerols (Jenab and Thompson, 2002; Schlemmer et al, 2009; Kumar et al, 2010). The maximum phytate content found in breadfruit is 1269 mg/100g. As many other anti-nutrients, the cooking process can reduce the phytate content. Cooked breadfruit has a maximum phytate content of about 58 mg/100g. Therefore, the exposure to phytate in a breadfruit diet is lower than exposure from brown rice or oatmeal and within the same range as most other plant-based foods.

Lignin is a very important part of the plant cell wall. It is classified as a major component of fiber by the American Association of Cereal Chemists (AACC) in 2001 and makes up about 4% of corn and about 4.4% of wheat bran. The amount of lignin in breadfruit is not different from other grains at 4.3%. Lignin is resistant to human digestion, but researchers showed that lignin can protect humans against colon cancer (Sidhu and Kabir, 2007).

Other anti-nutrients such as saponin and lectin are not detected in breadfruit flour or cooked breadfruit.

Table 10 Reported Maximum and Minimum Anti-nutrients for Breadfruit (Artocarpus altilis and Artocarpus altilis mariannensis).

Anti-nutrients	Flour (100g)		Reference	Cooked (100g)		
	Min	Max		Min	Ma	
α-amylase inhibitor activity (AIU)	Not detected	482	Ijarotimi and Aroge, 2005	118	333	
Trypsin inhibitor (TIU)	Not detected	Not detected	Ijarotimi and Aroge, 2005	No data available	No d availa	
Total phenolic compounds (mg)	Not detected	408.73	Oulaï et al., 2014	223.61	321.	
-Tannin (mg)	1	4.3	Appiah et al., 2012; Famurewa et al., 2015; Oulaï et al., 2014	2.2	4.02	
-Catechin (mg)	Not detected	51.07	Oulaï et al., 2014	33.83	40.96	
-Gallic acid (mg)	Not detected	102.99	Oulaï et al., 2014	47.02	89.78	
-Benzoic acid (mg)	Not detected	66.97	Oulaï et al., 2014	43.15	60.92	
Total oxalate (mg)	100	192	Famurewa et al., 2015	No data available	No d availa	
Phytate (mg)	63.4	1269	Famurewa et al., 2015; Oulaï et al., 2014	36.2	58.33	
Lignin (mg)	0	4320	Oulaï et al., 2014	3100	4050	

5.5. Manufacturing Process

To date, commercial facilities for manufacture of breadfruit flour have not been established in the USA. In Jamaica, Haiti and other tropical countries, small scale farmers and local business people are starting cottage-scale industries for flour production. The most common small scale method for manufacturing breadfruit flour is in Appendix B.

The recommended methods for production of flour from breadfruit are:

Step 1: Harvest – Breadfruit are collected at 7 days prior to ripe, drain to remove latex from the fruit, peel the fruits within 24 hours from harvest and remove the core.

Step 2: Slicing – Breadfruit are sliced to less than 0.5 inch (1 cm) sections.

Step 3: Dehydrating – Breadfruit slices are dried the chopped fruits to less than 35% moisture content in less than 2 hours in a secured/screened environment (solar heater or mechanical dry air heater), then to less than 10% moisture content within 24 hours. The drying temperature never exceeds 140F (or 60C), whether use solar (140F is the high end for solar heat, 135F is more common) or conventional dry air (the oven temperature set at 140F, and the breadfruit material max at 135F).

Step 4: The dried breadfruit granules are then packed in air-tight bags to a centrally located flour mill to grind to pass 80 mesh and this is the finished flour made from breadfruits. The flour will be held for QC testing on residual moisture, microbial counts and heavy metal content, if any.

5.6. Summary of Technical Evidence of Safety

The basis of this GRAS notification is scientific procedures and publications. Breadfruit has been consumed for centuries and is among the staple foods of Oceania. Brought to the Americas by early explorers, breadfruit was adopted into the diet in many parts of the Caribbean, Central and South America and tropical Africa. We along with many other scientists have conducted a range of scientific researches to evaluate the health impacts of breadfruit and we have found no evidence of toxicity. We have conducted tests of digestibility, gut function, immune-stimulation and the potential for food-related allergies and we have found no evidence that would suggest concern. We have demonstrated variability between cultivars with respect to specific nutrients and processing capacity but these are not outside of the normal range that is acceptable for human consumption.

5.6.1. Digestibility Study of Breadfruit

The digestion process was divided by mouth digestion, stomach digestion and intestinal digestion. Mouth digestion was mimicked by mixing cooked breadfruit or wheat flour with artificial saliva at pH 6-7 in 37 °C for 5 min. The stomach digestion was mimicked by mixing the previous solution with pepsin solution at pH 2-4 in 37 °C for 2 hours. The intestinal digestion was mimicked by mixing the previous solution with pancreatic solution and bile solution at pH 7.5 for 2 hours at 37 °C. The digestion samples were adjusted to pH 7.5 and centrifuged. The supernatants were stored for further analysis. Table 11 presents the chemicals and enzymes used in multi-stage digestion model for digesting breadfruit, as well as wheat.

The protein content was measured at two time points; before digestion started and after the entire digestion process was completed; using two orthogonal methods (bicinchoninic acid assay and modified Lowry assay).

Table 12 summarizes the protein digestibility of breadfruit and wheat, based on our data (embargoed until publication; details of methods in Appendix C). Breadfruit flour had an average protein digestibility of 87%-89% as compared to wheat with an average protein digestibility of 71%-79%. Breadfruit protein was 10-25% easier to digest than wheat protein.

Multi-stage enzyme digestion flow chart:

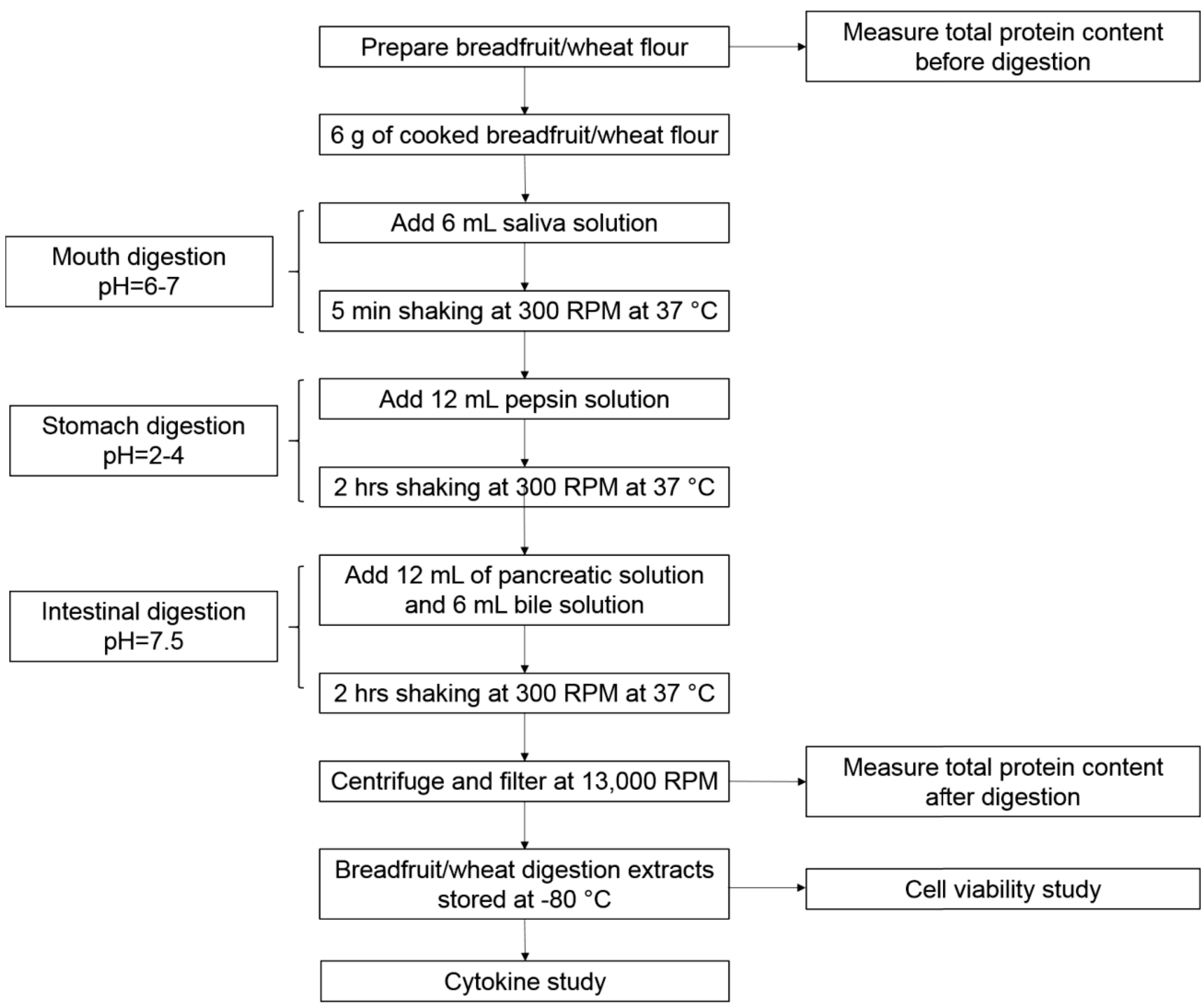

Table 11 Composition of Saliva Solution, Pepsin Solution, Pancreatic Solution and Bile Solution Used to Mimic Human Digestion.

Saliva Solution		**Pepsin Solution**		**Pancreatic Solution**		**Bile Solution**	
Item	g/l	Item	g/l	Item	g/l	Item	g/l
KCl	1.792	NaCl	5.500	NaCl	0.168	NaCl	10.518
KSCN	0.400	NaH_2PO_4	0.533	$NaHCO_3$	0.081	$NaHCO_3$	11.570
NaH_2PO_4	1.776	KCl	1.649	KH_2PO_4	0.002	KCl	0.753
Na_2SO_4	1.140	$CaCl_2·2H_2O$	0.799	KCl	0.014	Urea	0.500
NaCl	0.600	NH_4Cl	0.612	$MgCl_2$	0.001	$CaCl_2·2H_2O$	0.444
$NaHCO_3$	3.388	Urea	0.170	Urea	0.200	BSA	3.600
Urea	0.400	BSA	2.000	$CaCl_2·2H_2O$	0.400	Bile	60.000
α-amylase	0.002	Pepsin	5.000	BSA	2.000		
				Pancreatin	18.000		

BSA represents bovine serum albumin.

Table 12 Protein Digestibility of Boiled Wheat and Breadfruit Flour Using A Multi-Stage Enzyme Digestion Model

Protein Assay	**mg/g flour weight**	**Wheat flour**			**Breadfruit Flour**		
		Before digestion	After digestion	Digestibility	Before digestion	After digestion	Digestibility
Bicinchon-inic acid	Mean	37.89	10.96	71%*a*	44.65	5.11	89%*b*
	SEM	1.50	0.73	2%	3.21	0.66	1%
Modified Lowry	Mean	52.22	10.93	79%*a*	63.17	7.93	87%*a*
	SEM	2.50	7.24	15%	3.12	4.01	8%

Means with the same letter are not significantly different based on 2 sample t test at the alpha level of 0.05.

5.6.2. Cytotoxicity and Immunogenicity Studies of Breadfruit

The goal of this section is to understand the impact of digested breadfruit on human intestinal health based on two factors. The first one is morphology of the intestinal cells which indicates the cytotoxicity of breadfruit. The other one is the cytokine response of the intestinal cells to breadfruit which indicates the immunogenicity of breadfruit. Digested wheat is used as a reference for the comparison and better understanding of the results. Complete details about the methods and results can be found in the attached documents (embargoed until publication; Appendix C)

The breadfruit and wheat flour were digested in a multi-stage enzyme digestion model, as described in Section 5.6.1. Briefly, the breadfruit and wheat flour were digested through mouth, stomach, and intestinal digestions with specific enzymes and buffers that resembles the human digestion process. After the 3 steps digestion, digested samples were centrifuged and the supernatants were used for the cytotoxicity and immunogenicity study. A subculture of human epithelial colorectal adenocarcinoma (Caco-2) cells was obtained from the American Type Culture (ATCC® HTB-37™) and cultured using the established protocols.

For cytotoxicity determination, the digested breadfruit or wheat was mixed with standard Caco-2 growth media for 4 hours at four different concentrations (1%, 5%, 10%, and 50%). The live and dead cells were counted using trypan blue staining based on manufacturer's procedure.

Table 13 summarizes the potential for cytotoxicity of wheat and breadfruit digestions by assessing the cell viability of Caco-2 cells across a range of concentrations of digestion extracts. A treatment of 1% digested breadfruit, similar to wheat, did not alter Caco-2 cell viability suggesting breadfruit is not toxic to the intestinal epithelium. At 5%, 10%, 50% concentrations, there was a higher percentage of live cells remaining in breadfruit digestion treated group than wheat digestion treated group, indicating that breadfruit has a more positive impact on cell viability than wheat.

Table 13 Human Epithelial Colorectal Adenocarcinoma (Caco-2) Cell Viability after 4 Hours of Treatment of Wheat or Breadfruit Digestions in Various Concentrations.

Treatment Concentration	**Wheat Digestion**		**Breadfruit Digestion**	
	Cell viability	SEM	Cell viability	SEM
0%	99.80%	0.20%	99.80%	0.20%
1%	98.50%	1.50%	98.70%	0.80%
5%	66.30%	4.50%	75.20%	5.40%
10%	10.9%	4.90%	34.7%	3.40%
50%	1.69%	12.30%	7.32%	1.69%

For immunogenicity determination, 1% digested breadfruit or wheat was added into Caco-2 growth media for 24 hours without further stimulation and the expression of 8 major cytokines were quantified using quantitative polymerase chain reaction (qPCR) technology. This experiment was repeated another 3 times with 3 different stimulations: LPS (lipopolysaccharide) stimulation, IL-1β (interleukin 1 beta) stimulation, and LPS+IL 1β stimulation, to assess the impact of stimulation on Caco-2 response to breadfruit.

Table 14 summarizes the cytokine response of Caco-2 cells to breadfruit and wheat digestion under these conditions using qPCR. Caco-2 cells showed very similar cytokine response to breadfruit as wheat. Out of the 32 cases studied, only 4 cases showed significant differences between wheat and breadfruit treatment, which indicates that, as wheat, breadfruit is non-toxic to human intestinal cells.

Breadfruit digestion induced a higher expression of MCP-1 in non-stimulated cells. MCP-1 is a chemokine that regulates the migration and infiltration of monocytes, memory T lymphocytes and natural killer cells (Deshmane et al., 2009). When Caco-2 cells were challenged by LPS, breadfruit digestion induced iNOS, unlike the wheat digestion. LPS is an endotoxin found in Gram-negative bacteria. The early response to bacterial infection found in epithelium includes the upregulated expression and production of iNOS and NO (Kim et al., 1998; Witthöft et al., 1998; Klampfer 2011). However, Caco-2 cells alone has shown to be unable to respond to LPS stimulation. Thus, the induced iNOS expression of breadfruit could be a result of productive immune defensive responses of the epithelial cells.

The other two major differences between wheat and breadfruit treated groups is the production of IL 6, in which breadfruit induced a lower IL 6 production. IL 6 can act as a pro-and anti-inflammatory cytokine in the immune response depending on its pathway (Waldner et al., 2014). The classic-signalling is the anti-inflammatory pathway, however it requires a special protein receptor that is not found in most cells. The other pathway, trans-signalling pathway, is the pro-inflammatory pathway and it is often linked with cancer initiating processes (Becker et al., 2004a&b). The fact that breadfruit did not induce IL-6 production, indicates a lower likelihood of adverse gut reaction.

The overall conclusion of the immunogenicity study is that breadfruit induce a very similar cytokine response on human intestinal epithelial cells as wheat with some important differences. The similarity of the cytokine response between breadfruit and wheat shows that breadfruit is nontoxic to human intestinal cells as is wheat. The differences indicate that digested breadfruit may induce a more positive impact on intestinal cells in host defense response to pathogenic stimulation, compared to digested wheat.

Table 14 Cytokine *Response of Caco-2 Cells to Wheat and Breadfruit Digestions after 24 Hours of Treatment under Different Simulations.*

Function	**Cytokines**	**Non-stressed**	**Stressed**		
		Non-stimulated	LPS stimulated	IL 1β stimulated	IL 1β+LPS stimulated
Anti-inflammatory	IL 4	No significant difference	No significant difference	No significant difference	No significant difference
	IL 10	No significant difference	No significant difference	No significant difference	No significant difference
Pro-inflammatory	iNOS	No significant difference	Breadfruit digestion induced	No significant difference	No significant difference

Function	**Cytokines**	**Non-stressed**	**Stressed**		
		Non-stimulated	LPS stimulated	IL 1β stimulated	IL 1β+LPS stimulated
			significant increase than wheat digestion		
	TNF α	No significant difference	No significant difference	No significant difference	No significant difference
	IFN γ	No significant difference	No significant difference	No significant difference	No significant difference
	IL 6	No significant difference	No significant difference	Wheat digestion induced significant increase than breadfruit digestion	Wheat digestion induced significant increase than breadfruit digestion
Chemokines	MCP-1	Breadfruit digestion induced significant increase than wheat digestion	No significant difference	No significant difference	No significant difference

Function	Cytokines	Non-stressed	Stressed		
		Non-stimulated	LPS stimulated	IL 1β stimulated	IL 1β+LPS stimulated
	IL 8	No significant difference	No significant difference	No significant difference	No significant difference

LPS (lipopolysaccharide), IL-1β (interleukin 1 beta), IL-4 (interleukin 4), IL-10 (interleukin 10), TNF α (tumor necrosis factor alpha), IFN γ (interferon gamma), IL-6 (interleukin 6), iNOS (inducible nitric oxide synthase), MCP-1 (monocyte chemoattractant protein-1) and IL-8 (interleukin 8).

5.6.3. Human Studies Related to Breadfruit

The human studies related to breadfruit are summarized in Table 15. Human studies related to breadfruit mainly focused on the glycaemic index (GI) measurement. Widanagamager et al., (2009) Ramdath et al., (2004), and Bahado-Singh et al., (2006) showed that breadfruit had a low glycaemic index value compared to many common staples such as wheat, cassava, yam and potatoes. Researchers concluded that submitting breadfruit into the diet will potential bring health benefits (Bahado-Singh et al., 2006; Turi et al., 2015). None of the human studies reported any discomfort or death after consuming breadfruit.

Table 15 Human Studies Related to Breadfruit

Reference	**Study Type**	**Study Length**	**Study Size**	**Age**	**Diet Preparation**	**Control**	**Impact**
Glycaemic Index Measurement							
Widanagamage et al., 2009	Randomized and control	1 day	10 volunteers including both sexes (from a pool of 27 males and females)	20-30 years	Boiled breadfruit (*A. altilis/A. communis*) fruit	White bread	Breadfruit had a lo than wheat flour *ro pittu*, olu-milk rice bread
Ramdath et al., 2004	Randomized and controlled in clinical studies	1 day	8 normal volunteers (4 female and 4 male)	25.4 (SEM 1.5)	Boiled breadfruit (*A. altilis*) fruit	White bread	Breadfruit had a lo than cassava, cook sadhu *roti* and whi

Bahado-Singh et al., 2006	Randomized	1 day	10 healthy volunteers (age and sex matched)	18-40	Roasted and boiled breadfruit (*A. altilis*) fruit	100 GI glucose	Boiled breadfruit ha glycaemic index th yam, negro yam. L yam, sweet yam, swe potato, dasheen, co and ripe plantain. Roasted breadfruit glycaemic index th yam, negro yam. L yam, sweet yam, a
Sensory Evaluation							
Ragone and Cavaletto, 2006	Randomized blind test	Taste testing	10 volunteers	NA	Steamed breadfruit (*A. altilis*) and hybrid (*Artocarpus altilis* × *A. mariannensis*) fruit	NA	Breadfruit generall of aroma intensity The color ranged f The texture was no and relatively firm

NA represents that the information was not provided in the article.

5.7. Estimated Daily Intake and the Intended Uses

Breadfruit flour is intended for use as an ingredient in all food categories where standards of identity allow. It is intended to be used most frequently as a gluten-free alternative to wheat flour. In the United States, daily average consumption of refined grains was 5.78 ounce for male and female over the age of 2 from 2009 to 2010 (USDA, 2015). Table 16 summarizes the percentage of essential nutrients provided by consumption of 5.78 ounce of breadfruit based on the Food and Drug Administration's food labeling guidelines on different nutrients on a caloric intake of 2,000 calories for adults and children of four or more years of age (FDA, 2013). The 90^{th} percentile intake estimate is used by OFAS (Office of Food Additive Safety) in FDA's center to estimates to present long-term or lifetime average daily intake estimates or high level consumers of specific foods (FDA, 2006). Table 17 summarizes the percentage of essential nutrients provided by consumption of 11.65 ounce of breadfruit (estimate-90^{th} percentile intake) for high level consumers. Table 18 summarizes the essential amino acid content provided by consumption of 5.78 ounce of breadfruit, compared to the daily requirement of essential amino acid intake for preschool kids and adults per kg body weight based on a World Health Organization report (WHO, 2007). Table 19 summarizes the essential amino acid content provided by 11.65 ounce breadfruit (estimate-90^{th} percentile intake).

Table 16 Percent Daily of Recommended Daily Intake of Essential Nutrients Provided by Consumption of 5.78 Ounce of Breadfruit Based on a Caloric Intake of 2,000 Calories for Adults and Children Four or More Years of Age as Described by the FDA (2013)

Recommended Daily Values Provided by 5.78 Ounce of Breadfruit							
Nutrient	Daily Value	**Fresh**		**Cooked**		**Flour**	
		Min	Max	Min	Max	Min	Max
Energy (Kcal)	2000	8%	25%	7%	13%	23%	31%
Total Carbohydrates (g)	300	8%	38%	10%	20%	27%	48%
Lipid (g)	65	0%	11%	0%	12%	1%	30%
Protein (g)	50	0%	17%	2%	37%	6%	61%
Crude Fiber (g)	25	6%	32%	12%	48%	5%	100%
Folate	400	0%	0%	0%	0%	0%	1%
Vitamin B1 (mg)	1.5	13%	31%	10%	15%	31%	61%
Vitamin B2 (mg)	1.7	5%	10%	2%	5%	15%	38%
Vitamin B3 (mg)	20	7%	14%	5%	11%	19%	36%
Vitamin C (mg)	60	44%	57%	4%	33%	0%	62%
Calcium (mg)	1000	3%	9%	2%	5%	1%	131%
Copper (mg)	2	7%	20%	37%	37%	8%	406%
Iron (mg)	18	2%	473%	0%	10%	5%	109%
Magnesium (mg)	400	8%	29%	6%	12%	4%	82%
Manganese (mg)	2	3%	27%	7%	25%	6%	215%
Phosphorus (mg)	1000	1%	19%	3%	7%	12%	315%
Potassium (mg)	3500	14%	112%	11%	24%	3%	133%

Recommended Daily Values Provided by 5.78 Ounce of Breadfruit							
Nutrient	Daily Value	**Fresh**		**Cooked**		**Flour**	
		Min	Max	Min	Max	Min	Max
Sodium (mg)	2400	0%	2%	0%	5%	0%	41%
Zinc (mg)	15	1%	6%	0%	1%	1%	32%

Table 17 Percent Daily of Recommended Daily Intake of Essential Nutrients Provided by Consumption of 11.56 Ounce of Breadfruit (Estimate 90th Percentile Intake) Based on a Caloric Intake of 2,000 Calories for Adults and Children Four or More Years of Age as Described by the FDA (2013)

Recommended Daily Values Provided by 11.56 Ounce of Breadfruit (Estimate 90th Percentile Intake)							
Nutrient	Daily Value	**Fresh**		**Cooked**		**Flour**	
		Min	Max	Min	Max	Min	Max
Energy (Kcal)	2000	17%	51%	13%	26%	46%	62%
Total Carbohydrates (g)	300	16%	77%	20%	40%	55%	96%
Lipid (g)	65	1%	23%	0%	25%	2%	60%
Protein (g)	50	0%	34%	4%	75%	12%	123%
Crude Fiber (g)	25	12%	64%	24%	97%	11%	201%
Folate	400	0%	1%	0%	1%	0%	3%
Vitamin B1 (mg)	1.5	26%	61%	20%	30%	63%	122%
Vitamin B2 (mg)	1.7	10%	19%	4%	11%	31%	75%
Vitamin B3 (mg)	20	14%	28%	10%	23%	38%	72%
Vitamin C (mg)	60	88%	115%	9%	66%	0%	124%
Calcium (mg)	1000	6%	18%	3%	10%	2%	262%

Recommended Daily Values Provided by 11.56 Ounce of Breadfruit (Estimate 90th Percentile Intake)							
Nutrient	Daily Value	**Fresh**		**Cooked**		**Flour**	
		Min	Max	Min	Max	Min	Max
Copper (mg)	2	13%	41%	74%	74%	16%	811%
Iron (mg)	18	5%	947%	0%	20%	10%	219%
Magnesium (mg)	400	16%	57%	11%	25%	8%	164%
Manganese (mg)	2	7%	54%	15%	49%	13%	431%
Phosphorus (mg)	1000	2%	38%	6%	13%	24%	629%
Potassium (mg)	3500	27%	224%	23%	49%	6%	265%
Sodium (mg)	2400	0%	4%	0%	10%	0%	82%
Zinc (mg)	15	2%	11%	0%	3%	3%	65%

Table 18 Recommended Daily Intake of Essential Amino Acid Provided by Consumption of Breadfruit (Liu et al unpublished results)

Recommended Daily Requirements Provided by 5.78 Ounce of Breadfruit						
Essential Amino Acid	per kg preschool child	per kg adult	**Fresh**		**Flour**	
			Min	Max	Min	
His (mg)	0	10	16	115	28	
Ile (mg)	27	20	64	321	102	
Leu (mg)	54	39	115	580	193	
Lys (mg)	45	30	29	161	52	
Met+Cys (mg)	22	15	3	29	7	
Phe+Tyr (mg)	40	25	98	544	164	
Thr (mg)	23	15	25	152	41	
Trp (mg)	6	4	2	157	3	
Val (mg)	36	26	51	261	85	

Daily requirements listed are from the World Health Organization (WHO, 2007). Lysine (lys), leucine (leu), thre tryptophan (trp), histidine (his), isoleucine (ile), valine (val), phenylalanine (phe), tyrosine (tyr), and methionine

Table 19 Recommended Daily Intake of Essential Amino Acid Provided by Consumption of Breadfruit (Liu et al., unpublished results)

Recommended Daily Requirements Provided by 11.56 Ounce of Breadfruit (Estimate 90th Percentile Inta						
Essential Amino Acid	per kg preschool child	per kg adult	**Fresh**		**Flour**	
			Min	Max	Min	
His (mg)	0	10	33	229	56	
Ile (mg)	27	20	128	642	203	
Leu (mg)	54	39	229	1160	387	
Lys (mg)	45	30	59	321	105	
Met+Cys (mg)	22	15	7	59	13	
Phe+Tyr (mg)	40	25	197	1088	328	
Thr (mg)	23	15	49	305	82	
Trp (mg)	6	4	3	315	7	
Val (mg)	36	26	102	521	170	

Daily requirements listed are from the World Health Organization (WHO, 2007). Lysine (lys), leucine (leu), thre tryptophan (trp), histidine (his), isoleucine (ile), valine (val), phenylalanine (phe), tyrosine (tyr), and methionine

5.8. General Recognition

The information that provided the basis of this GRAS determination by scientific procedures is available in the public domain. All published studies and citations to pertinent government regulations are cited in the reference section of this notification.

VI. DISCUSSION AND CONCLUSIONS

The data and information presented in this report support the safety of using breadfruit (*Artocarpus altilis* and *A. altilis*×*A. mariannensis*) as an ingredient in all food categories for human consumption. Breadfruit has been used as a staple in the Pacific Island for over 3000 years, and has been prepared and consumed in different ways including raw, boiled, roasted, baked, or fried. It has been used in different food products such as stiff porridges, extruded products, breads, cakes, pancakes, and biscuits.

Breadfruit provides a source of macronutrients, such as carbohydrates, protein, and fat, as well as micronutrients, including minerals, carotenoids, and vitamins. Breadfruit also contains all the essential amino acids that are required by humans. A digestibility study of breadfruit showed that breadfruit protein is easier to digest than wheat protein. One 5.78 ounce consumption of breadfruit can provide most of the daily requirements of fiber, minerals, and vitamins recommended by FDA. On the basis of the novel food safety assessment guidelines, it is clear that the estimated intake of breadfruit, even for the highest users, are below the level shown to have no adverse effects or nutritional hazards. The anti-nutrients found in breadfruit are below the levels present in other grains and below the level that will have any adverse effects or nutritional hazards.

Information that is inconsistent with GRAS determination on breadfruit safety for human consumption has been discussed. The results of rat death from consumption of breadfruit in the Grant et al., (1995) study should be considered inaccurate due to the small sample size of 4 and likely misidentification of the breadfruit species used. The safety of breadfruit consumption is assessed by the cytotoxicity and immunogenicity studies on human intestinal cells. Breadfruit is non-toxic to human intestinal epithelial cells and breadfruit has a more positive impact on intestinal heath than wheat. No incident of discomfort, health issue or death was reported in any of the human studies involving breadfruit consumption.

Based upon the entirety of the available scientific data, published research articles, and government database reported and summarized in this document, it is concluded that breadfruit (*Artocarpus altilis* and *A. altilis*×*A. mariannensis*) would be generally recognized as safe for consumption in its intended uses in food.

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IGIA BREIFING PAPER: UNIVERSITY OF HAWAII PACIFIC BUSINESS CENTER PROGRAM

PACIFIC GLUTEN FREE BREADFRUIT FLOUR REGIONAL INDUSTRY DEVELOPMENT INITIATIVE

This briefing report is submitted by Dr. Tusi Avegalio, Director of the Pacific Business Center Program (PBCP) and Executive Director of the Honolulu Minority Business Enterprise Center (HMBEC) both located at the Shidler College of Business Administration, University of Hawaii- Manoa campus. Both programs serve under UH Vice President John Morton, who is the Principle Investigator. PBCP is supported by the US Department of Commerce Economic Development Administration (EDA), Western Regional Office based in Seattle, Washington. PBCP is the largest EDA University Center program in the nation, serving Hawaii and the US Affiliated Island Governments of the Pacific. The PBCP and HMBEC are winners of six national, three US regional and one State award in the past ten years for their project management, technical assistance and leadership in the Pacific region. The following report briefly encapsulates two years of developing the Pacific Regional Breadfruit Initiative and the feasibility of making it a reality within three years.

Introduction

Commercialization of Ulu at an industrial scale for export has not occurred anywhere in the world, yet. With the discovery that Ulu is gluten free, the opportunity to develop and refine existing practices will provide major economic development, food security and sustainability benefits wherever it can be supported. Breadfruit is gluten-free and has been dehydrated and processed successfully into a flour in Samoa, Philippines and Jamaica. However, efforts to expand the processing to a sufficiently industrialized scale for the introduction of breadfruit flour in the U.S. market as a GF food product have been unsuccessful. Actually, it has not been tried. Another compelling reason is that growing time from planting to harvest conventionally took seven plus years for the tree to mature.

Breadfruit Propagation for Mass Cultivation

Breadfruit has never been commercialized on a significant scale because the breadfruit tree, unlike the coconut tree, has proven difficult to mass-produce. A technique to mass-produce breadfruit plantlets from breadfruit plant tissue from the Maʻafala, a variety of breadfruit that is indigenous to Samoa and is common throughout the Pacific, was developed by research led by Dr. Susan Murch. Thousands of breadfruit plantlets can be produced in the lab and shipped to farmers anywhere in the world where breadfruit can be grown. A compelling aspect of the propagated ulu plantlets that significantly enhances commercialization is the plant to harvest time cycle is cut in half. Propagated trees fruit within two and a half to three years vs. the traditionally cultivated trees that take seven or more. Dr. Susan Murch's research is ongoing and in partnership with Dr. Diane Ragone, Director of the Breadfruit Institute, National Tropical Botanical Garden on Kauai. Dr. Murch's work is virtually unknown to the distributors of gluten free products.

Hawaii: Main Pacific Hub for Breadfruit Flour Manufacturing and Export

Several American Affiliated Pacific Islands are strategically located to serve as sub regional hubs receiving dried breadfruit shipped from Micronesia, Polynesian and Melanesia. Hawaii can become the main Pacific regional manufacturing and export hub with key US Territories as transshipment spokes for ulu grown and dried from Micronesia, Polynesia and Melanesia. Likewise, production and transshipment infrastructure constructed in the Marianas will be the link to Japan and Asian markets. CH Robinson, a leading national and international food distributor estimates that 150 to 200,000 tons of regular (non GF) flour is moved every week. To meet market demand for gluten free flour, a reliable production flow of a minimum of 100,000 tons per week will be essential. Engaging collaboratively with Oceania as a production source assures production supply no single pacific entity can meet on its own.

Hawaii, and other Pacific Islands have land that could be turned into breadfruit food forestry orchards that can support a gluten free breadfruit flour industry. These breadfruit trees could also provide food security in the case of natural disaster. Pacific Islands are aware of the work of Dr. Susan Murch in Canada and the rapidly growing demand for gluten-free products in the U.S., even so far as to include their endorsement of the proposed development at the recent Micronesia Chief Executives Summit on Saipan (December 4-6, 2013).

The two Samoas' Summit which was held on December 5, 2012, brought together all of the pieces that are essential to developing a breadfruit flour industry – market demand; distribution networks; manufacturing expertise; export infrastructure; agricultural technology; agricultural land base – with the realization that a collaborative regional initiative can harness the collective potential and begin to create the partnerships essential for establishing a regional Pacific breadfruit flour industry. The ramifications for employment opportunities for local residents, familiar with the tree and its cultivation are significant. As tuna, a pelagic marine species is impacted by the growing radioactive run off plume that is alarming in its size and drifting towards Hawaii and the west coast from Fukushima, and fish stocks being depleted without meaningful conservation, agriculturally based economic development utilizing the synthesis of modern science and traditional wisdom centered around the breadfruit, is not only a more viable and healthy alternate to the tuna industry, it is safer and more sustainable.

University of Hawaii Pacific Business Center Breadfruit R/D Team of Experts

For this project the PBCP assembled an all-star team of experts: Dr. Diane Ragone, Director of the Breadfruit Institute on Kauai; Dr. Susan Murch from the University of British Columbia; Craig Elevitch of Agroforestry Net and M. Kalani Souza from Olohana Foundation in Hawaii and representing the National Disaster Preparedness Training Center (NDPTC) on matters of food security; Dr. Alvin Huang at the College of Tropical Agriculture at the University of Hawaii; Dr. Fadi Aramouni and Dr. Jeff Gwirtz at the Food Sciences and International Grains Programs at Kansas State University; and Sean Nelsen, Director of Business Management, Food Source/C.H. Robinson, one of the world's largest third party logistics (3PL) providers, with 2012 gross revenues of $11.2 billion. FoodSource is based in Monterey California.

US Market Demand

In the U.S. the demand for gluten-free (GF) food and beverage products has increased astronomically since 2008, going from $1.54 billion to an estimated $3.31 billion in 2012 by Gluten Free Foods and Beverages Market: Trends and Developments in the U.S. 4th ed. There is also a more recent (2014) estimate of $10.5 Billion in 2013 to projections for the category of $15 billion in annual sales in 2016 according to Mintel, a market research company. The largest part of this market is baked goods and snacks that substitute GF flour for wheat flour. A gluten free beer has also hit the market and gaining in popularity. Local breweries may want to investigate that potential.

The major distributors of GF products in the U.S. know very little about breadfruit and its' potential as a source of GF flour. Sean Nelsen, representing FoodSource C.H. Robinson, one of the largest logistics and distribution companies for food products in the U.S., featured the GF market and distribution strategies and potential growth demand for the GF products in American Samoa (12/2012), where the first of two regional breadfruit summits were held initiated by PBCP in collaboration with the host governments. Having SubWay and Trader Joe's as two of their clients speaks to the Company's expansive reach and support of the health food movement in the U.S. Breadfruit flour developments in the Pacific have yet to be introduced into the US

Market and strategic marketing plans are being developed concurrently with continued Ulu food research and processing to flour.

Other Commercial Benefits: The sap from the Ulu is very high in organic latex, which the commodities market lists as $1,000.00 per gallon. The organic chemical content of the Ulu flower is nearly 60% more effective than the leading synthetic based insecticide. Studies by scientists at the USDA Agricultural Research Service (ARS) and Canada's University of British Columbia identified three compounds of the plant that repel mosquitoes more effectively than the leading commercial insecticide. The Deployed War-Fighter Protection Research Program, which develops and improves methods to protect our U.S. military personnel against insects that transmit diseases such as malaria, yellow fever and dengue fever are now aware of the breadfruit flower. The anticipated demand for a commercialized product is compelling. The health benefits are equally astonishing. Breadfruit is not only gluten free; its vitamin A is one of the highest among plants or fruits. This is significant in that Vitamin A deficiency (VAD) is one of the most common and devastating micro-nutrient deficiencies in the world and is especially common in tropical developing nations. With obesity epidemic, particularly in the US Affiliated Pacific States, breadfruit consumption replacing imported staples and sugar-laden foods, i.e., rice, confections, bread, etc. can curve the upward spiral of diabetes, heart disease and hypertension endemic in the region. Breadfruit is high in complex carbohydrates, low in fat, and cholesterol and gluten free. It has a moderate glycemic index (blood sugar shock) compared to white potato, white rice, white bread, and taro.

Tapping the Scientific, Research and Technical Expertise of the US University EDA (Economic Development Administration) network

The EDA National University Center program links the top university technical and scientific expertise in the nation providing state of the art technology, research, engineering and scientific know-how to support the growth and strength of American Economic development and initiatives that include the American Affiliated Island Governments of the Pacific. Two examples are the linkage to Kansas State University, that specializes in flour processes and technology for the US Department of Agriculture and major food production manufacturers in the US and the need to design requisite food engineering and technologies for breadfruit and other agricultural products of the Pacific.

There will be a need to design a production facility that is appropriately scaled (and scalable) for the volume of production required that takes advantage of the most economical, efficient technology and production equipment that is currently available and is appropriate for Hawaii. This production model would include applications of recent advances in solar technology that will allow tons of breadfruit to be dried continuously as well as economically at the farm level without the use of conventional sources of electricity. PBCP will work with Professor Jeff Gwirtz of the Advanced Manufacturing Institute (AMI) and the International Grains Program (IGP) at Kansas State University who is a national and internationally known expert in the field.

Partnership for Mutual Benefit: Building on Kinship, Cultural Ties and Existing Strengths

The agricultural land available for increasing the production of breadfruit is insufficient for supporting a new breadfruit industry at the national and international scale. A regional industry strategy will more than support the demand with key sub regional hubs linked to Hawaii. Consequently, partnering with its' Pacific Island neighbor, brings to the table substantial agricultural land capacity in support of the breadfruit initiative.

Sharing the Benefits with Individual Families, Villages, Pacific Island Neighbors and Caribbean Islands.

As a compelling form of Community Based Economic Development, the old copra drying and collection model may be an excellent method for the average family and village to earn a supplemental income from collecting and drying of Ulu for district collectors to weigh and purchase on the spot. Families can earn as much as they want depending on market value and cost per lb. of dried breadfruit. Considering the spiraling demand for gluten free food products, this income source can be significant. The significance of traditional food forest agro forestry cross cropping and multi tiered planting vs. mono cropping has been validated by agro forestry experts and research. It maximizes land use and environmental balance while minimizing disturbance to traditional island farming and culturally based life. Community based economic development also assures benefits are shared broadly among the village and community residents along coastal and inland areas.

US Territories in the Caribbean. As much of the research, experimentation and applications of breadfruit cultivation and propagation work has been done on islands in the Pacific where the breadfruit originated, the work and results can be transferred easily to the US Territories in the Caribbean and elsewhere where the breadfruit can grow and thieve. The template from the Pacific can benefit human society globally to feed the hungry, improve health, restore environmental stability, generate economic benefit and promote peace. It is more then a fruit; it is a gift of life.

Much of the research testing and design work will have been done by a process no single community entity can afford, yet the benefits from linking to a regional breadfruit development industry would jump start many island communities that can support the developed model. The model addresses transferability and scalability of the manufacturing and processing model for easy community access and use. The broader island community benefit will encourage communities to form clusters to share a community-processing model.

Like spokes on a wheel, this model is linked to the central commercialization processing and manufacturing center for each island for export and shipping that can be consolidated in American Samoa in the south pacific, Phonphei (FSM) in the Central Pacific and the Marianas in the far east Pacific, all linked to the shipping and distribution hub in Hawaii for manufacturing and export to multiple destinations on the west coast. This is just a concept model discussion, but one that is viable given the looming demand for gluten free foods in the US market. As each jurisdiction develops in this systems approach, expertise will facilitate local capacity to move it towards greater self-sufficiency to engage markets at its discretion. For now, all regions and governments need to work together collaboratively to move the regional breadfruit initiative forward. We can sail with the wind or turn into the wind and reach for shores yet untouched.

Feasibility Study/Business Plan

To attract private investment and to demonstrate that breadfruit production is both profitable and is supported by market demand, there needs to be a document that brings together all of the supply, production costs and market demand projections in a business plan with a full set of financials that an investor can analyze and verify.

The PBCP has done numerous successful business plans for products produced and sold from Hawaii and Pacific island states. In 2005-2006, PBCP managed the successful start-up of a candlenut oil factory in East Timor. The project was funded by USAID and was recognized by the University Economic Development Association as a Project of the Year. Further analysis and research is needed to move the initiative forward as current work has focused on aligning the research and commercialization aspects together. Its not there yet, but is feasible to launch with support within three years.

Premature Business Planning Precautions: Breadfruit can be used in so many different ways (gluten free flour for breads, crackers, chips, noodles; as a supplement for high protein drinks; as a source of latex; as a source of insect repellant, etc.). Project partner C.H. Robinson, a $10 billion global food distributor based in California, whose client list includes – SubWay, Carl's Jr., Trader Joe's and Walmart – has encouraged the project team to identify the most marketable breadfruit products for them to show to their clients (ex: Subway is looking for a gluten free bun for a gluten free sandwich).

Prematurely locking breadfruit into the wrong product form could add years to it successfully entering the market. Coconuts, for instance, were not commercial until they were turned into oil (via copra) and made into high-end premium soap for the European market in the second half of the 19th century. Kukui nuts were not commercially viable as an export product until they were turned into a skin moisturizer that is used throughout the cosmetics industry.

Mahalo:

PBCP has initiated the breadfruit initiative for over two years, often with limited or shared resources to achieve the current level of development. PBCP looks forward to collaborating with Territorial, State, Higher Education and Community organizations interested in the development of Ulu in the Pacific. It is conceivable that a local breadfruit industry in any or all of the territories can be fully operational within three years given the resources to operationalize and support the initiative in the realization of that goal. Mahalo Dr. Tusi

Contact Information:

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Guide to Producing and Packaging Breadfruit Flour

TREES THAT FEED FOUNDATION

Steps in Producing Breadfruit Flour

- Harvest fruit at the right stage
- Remove stem and drain latex
- Store in cool water until processing begins
- Cut into pieces, and shred or slice thin with shr or mandolin (peeling not necessary)
- Dry the shreds; must completely dry within 24 hour
- Grind into flour
- Store in airtight, waterproof packages
- Keep all equipment spotless and clean

More details on next few pages

Harvest the Fruit "Fit"

- Not too green but not overripe
- Pick the fruit when you see some white la the skin

- Cut out the stem, invert the fruit, drain out e latex

Cut up and Shred the Fruit

- Wash off the fruit thoroughly
- Cut the fruit into chunks for shredding or slicing
  - Peeling the skin is optional
- Shred finely; recommend 3/16” (or 4 mm) shr





Use smaller or larger equipment, depending on capacity needed. Phot Right: manual mandolin, $50; Dynacoupe shredder, $150; Nemco slicer/shredder, $200; food processor, about $400; Hobart shredder (needs motor, about $800).

Dry the Shreds (or Slices)

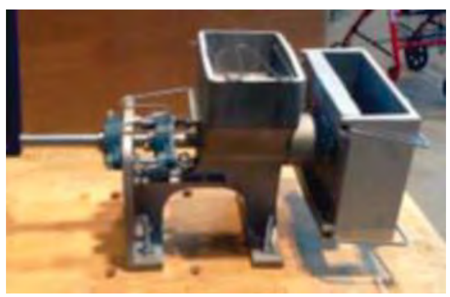
- Critical stage: dry quickly (within 24 hours) to avoid mould
- Shreds will be wet, avoid clumping
  - Spread out on a clean surface, preferably mesh
- Need plenty of air flow
  - Preferably warm, dry air; direct sunlight not necessary
  - Keep dust, insects away

When fully dry, the shreds (or slices) will snap between your finger can be safely stored for months, if they are airtight and moisture pr

Commercial driers are good, if electricity is convenient; TTFF is developing solar dryers, in cooperation with Northwestern University.

Grind into a Fine Flour

- Shreds must be completely dry, otherwise grinders/mills will clog
- Manual grinding is very heavy work…use electric other power if possible
- Keep equipment very clean—clean daily



Use smaller or larger equipment, depending on capacity needed. Photos Left to Right: Victorio manual or electric, $150; Compatible Technology Omega, $400 plus motor; Nutrimill, electric, $250; Pleasan Valley Stone Mill, 60 pounds/hour, $2,500.

Package and Distribute

- Use food safe packages, 1 to 5 pounds of flour per package
- Keep clean
- Weigh accurately
- Add labels

Nutrition Facts
Serving Size 1 cup (100g)

Amount Per Serving	
Calories 348	
	% Daily Values*
Total Fat 1.7g	**3%**
Saturated Fat 0g	**0%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Potassium 1170mg	**33%**
Sodium 10mg	**0%**
Total Carbohydrate 76g	**25%**
Dietary Fiber 4g	**16%**
Sugars 0g	
Protein 4g	**8%**

Vitamin C 18.3%	•	Calcium 7.8%
Iron 22.2%	•	Thiamin 20%
Riboflavin 18.8%	•	Niacin 16.5%
Phosphorus 15%	•	Magnesium 25.3%
Zinc 4.5%	•	Copper 20%
Manganese 25%		

*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs.

	Calories	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2400mg	2400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Design your own label, print on Avery label stock. Include your contact in
You will need gloves, knives, scale, cleaning brushes, poly food safe bags, dus
shields, food safe shelves, food safe storage containers

Breadfruit Flour Recipes

- Breadfruit flour is gluten free, it works a bit different from wheat flour
- You can make pancakes, flatbreads, cookies, fritters, pizelles, flan, ice cream, and more. Here's our favorite…

Breadfruit Banana Cake

½ cup butter, melted
1 cup sugar
2 eggs
1 tsp vanilla extract
½ tsp nutmeg
½ teaspoon cinnamon
1 ½ cups breadfruit flour
1 tsp salt
1 tsp baking soda
1 tsp baking powder
½ cup milk
Juice of 1 lime
3 medium mashed bananas

Preheat oven to 350 degrees. Grease cake pan or loaf pan In large bowl, stir together the melted butter and sugar. Mix the milk, lime juice and bananas and fold into the batter.

Combine flour, baking soda, baking powder, salt and spices mix well. Add to the batter. Spread evenly into cake pan

Bake at 350 degrees for 40 minutes or until a toothpick inserted into the center comes out clean. Cool for 10 minutes cool completely.

Guide to Producing and Packaging Breadfruit Flour

For more information, visit
www.treesthatfeed.org
Or www.facebook.com/treesthatfeed

Contact us at treesthatfeed@aol.com
Telephone +1.312.933.0241

Highlights:

- Breadfruit protein has a higher protein digestibility than wheat protein according BCA and modified Lowry methods using *in vitro* digestion model.
- A treatment of 1% digested breadfruit on human epithelial colon cells (Caco-2 cells), similar to wheat, did not alter cell viability suggesting breadfruit is not toxic to the intestinal epithelium.
- Digested breadfruit had a more positive impact on Caco-2 cell viability than digested wheat.
- Digested breadfruit induced a very similar cytokine response on Caco-2 cells as digested wheat.

Bonnette, Richard

From: Murch, Susan <susan.murch@ubc.ca>
Sent: Friday, August 28, 2015 2:01 PM
To: Bonnette, Richard
Cc: Rosenfeld, Leah
Subject: RE: Submission to U.S. FDA GRAS Notification program for uses of breadfruit in food

Dear Richard

My apologies. I am sorry I missed this. I will sign and date a page as you suggest and get it into the courier today.

Susan

--
Susan J. Murch
Professor & Canada Research Chair
Chemistry, Room 350 Fipke Centre
University of British Columbia
3247 University Way
Kelowna, British Columbia, Canada, V1V 1V7
web: http://chem.ok.ubc.ca/faculty/murch.html

From: Bonnette, Richard [Richard.Bonnette@fda.hhs.gov]
Sent: Friday, August 28, 2015 7:19 AM
To: Murch, Susan
Cc: Rosenfeld, Leah
Subject: Submission to U.S. FDA GRAS Notification program for uses of breadfruit in food

Dr. Murch,
As part of a prefiling review of the submission that you provided to FDA on behalf of PlantSMART, I noticed that we need a minor administrative detail taken care of before we can file the submission as a GRAS notice. I see that you have a GRAS exemption claim included on the second page of the submission (just after the cover letter), but that it is unsigned and not dated (required as part of proposed 170.35 (c)(1)). This is one of those administrative details that we tend to be a little picky about. Probably the easiest way to remedy this is to send us a cover letter (one hard copy is fine) that repeats the exemption claim from the second page with a signature and a date below the claim . You can send this to my attention and the notice will be ready for filing as soon as I get it.

If you have any questions, please let me know.

Thanks,
Richard

Richard E. Bonnette
Consumer Safety Officer
Division of Biotechnology and GRAS Notice Review
Office of Food Additive Safety
U.S. FDA, Center for Food Safety and Applied Nutrition

(240)402 1235
Richard.Bonnette@fda.hhs.gov

a place of mind
THE UNIVERSITY OF BRITISH COLUMBIA

August 28, 2015

Richard E. Bonnette
Consumer Safety Officer
Division of Biotechnology and GRAS Notice Review
Office of Food Additive Safety
U.S. FDA, Center for Food Safety and Applied Nutrition

Dear Dr. Bonnette

Attached please find our Notice to US Food and Drug Administration that the Use of Breadfruit (Artocarpus altilis and A. altilis×A. mariannensis) Flour is Generally Recognized As Safe.

GRAS EXEMPTION CLAIM

The PlantSMART Labs at the University of British Columbia (UBC), hereby notifies the U.S. Food and Drug Administration that the uses of breadfruit (*Artocarpus altilis* Parkinson (Fos) and hybrids) flours described below are exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because PlantSMART has determined that such uses are generally recognized as safe (GRAS). PlantSMART made this GRAS determination based on scientific procedures, a comprehensive search of the scientific literature, meta-analysis of the scientific nutritional literature and government databases as well as laboratory testing to establish safety and a lack of toxicity. These findings are described in the following sections, and the evaluation accurately reflects the conditions of the intended use of this substance in foods.

Name and Address of Notifier

PlantSMART Labs
University of British Columbia
Kelowna, British Columbia, Canada, V1V 1V7

Contact Name: Susan J. Murch
Professor & Canada Research Chair
Chemistry, Room 350 Fipke Centre
3247 University Way
Telephone: (250) 807-9566
e-mail: susan.murch@ubc.ca

As the notifier, PlantSMART, University of British Columbia accepts responsibility for the GRAS determination that has been made for breadfruit (Artocarpus altilis and hybrids) flours as described in the subject notification; consequently breadfruit flour described herein is exempt from pre-market approval requirements for food ingredients.

Name of GRAS Substance

The tropical tree species Artocarpus altilis Parkinson (Fos) and hybrids of Artocarpus altilis x Artocarpus mariannensis are most commonly known as breadfruit in English or 'ulu' in the Pacific but may also be known as: árbol de pan, fruta de pan, pan, panapen, (Spanish), arbre à pain, fruit à pain (French), beta (Vanuatu), bia, bulo, nimbalu (Solomon Islands), blèfoutou, yovotévi (Bénin), brotfruchtbaum (German), broodvrucht, broodboom (Dutch), cow, panbwa, pain bois, frutapan, and fruta de pan (Caribbean), fruta pao, pao de massa (Portuguese), kapiak (Papua New Guinea), kuru (Cook Islands), lemai, lemae (Guam, Mariana Islands), mazapan (Guatemala, Honduras), meduu (Palau), mei, mai (Federated States of Micronesia, Kiribati, Marshall Islands, Marquesas, Tonga, Tuvalu), mos (Kosrae), rata del (Sri Lanka), rimas (Philippines), shelisheli (Tanzania), sukun (Indonesia, Malaysia), 'ulu (Hawai'i, Samoa, Rotuma, Tuvalu), 'uru (Society Islands), uto, buco (Fiji). Breadfruit has a long traditional use as fresh food but dried and ground breadfruit will be sold as a food ingredient. The common name for dried, ground breadfruit will be "breadfruit flour".

Conditions of Use

Breadfruit will be dried and ground into a milled product intended for use as an ingredient in various baked goods, breads, cereals, porridges, and pasta products. Breadfruit could also be used as a gluten-free substitute for other flours breads and snack foods.

Basis for GRAS Determination

The GRAS determination for the intended uses of breadfruit flour is based on scientific procedures as described under 2 1 CFR§170.30. Information provided includes comprehensive searches of the literature through May 2015 conducted by PlantSMART served as the basis for preparation of a monograph summarizing the totality of the available information germane to determining the safety of the intended uses of breadfruit flour.

Detailed analysis of the composition of macronutrients, micronutrients, and anti-nutritional factors demonstrated that breadfruit flour is similar to other commonly consumed flours. A comprehensive search and meta-analysis of the nutritional data was conducted along with compilation of scientific literature and government databases as well as laboratory testing of as well as studies of digestibility and responses in cell culture experiments.

It may be concluded that breadfruit flour is safe under the intended conditions of use because the total exposure to breadfruit flour and its constituents resulting from these uses is well within levels shown to be safe by both current levels of consumption of other flours, which are compositionally very similar to breadfruit flour and the long history of use of fresh breadfruit by human populations. The estimated intakes of breadfruit flour, even for the highest users, are below the level shown to have no adverse effects or nutritional hazards, based on nutritional composition comparisons and human use.

Therefore, the intended uses of breadfruit flour are determined to be safe and GRAS. Determination of the safety and GRAS status of breadfruit flour for direct addition to food under their intended conditions of use was made through evaluation of the scientific literature. Therefore, breadfruit flour is GRAS by scientific procedures under the conditions of use described.

1.5 Availability of Information

The data and information that serve as the basis for this GRAS notification will be sent to the US Food and Drug Administration (FDA) upon request or will be available for review and copying at reasonable times at the offices of the PlantSMART, University of British Columbia.

Kind Regards,

Susan J. Murch, PhD
Professor & Canada Research Chair
Chemistry Department, Room 350, Fipke Centre
3247 University Way, University of British Columbia
Kelowna, British Columbia, Canada, V1V 1V7
Tel: 250-807-9566

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SUBMISSION END