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ADDRESS: 123 ABC Street, USA	SUPERSEDES	08/31/2018

Selected Sections of a Food Safety Plan Teaching Example

Food Safety Plan for Breadfruit Flour

Reviewed by: Bran Floursome, Food Safety/QA Manager, PCQI Date: 8/31/2018

Approved by: *J. Knowitall*, Plant Manager Date: 9/1/2018

This food safety plan teaching example was developed by a group of academic subject matter experts assembled by the University of Guam as part of the Western Regional Center to Enhance Food Safety. This model is based on the draft models originally developed by the Southern Training, Education, Extension, Outreach, and Technical Assistance Center to Enhance Produce Safety at the University of Florida.

The information in this example is for training purposes only and does not represent any specific operation. Processing steps may have been omitted or combined to facilitate its use for class exercises. **It is not complete and contains both required and optional information.** Because development of a Food Safety Plan is site specific, it is highly unlikely that this plan can be used in a specific facility without significant modification. Conditions and specifications used (e.g., validation information) are for illustrative purposes only and may not represent actual process conditions.

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Company Overview

This example company is a small firm that makes a variety of breadfruit flour that may be single breadfruit flour or blends. They are assumed to be food ingredients because they may be used as ingredients for ready-to-eat products or in cooked products. Products include breadfruit flour, breadfruit cake mix (including wheat and milk protein), and breadfruit pancake mix (including wheat, milk, and egg proteins). The breadfruit cake mix and breadfruit pancake mix are blended in a separate room to prevent cross-contact issues. The only potential concern for allergen cross-contact is a filling.

Product is made 5 days a week in one 8 hour production shift, followed by 2 hours for sanitation. A sanitary facility program is in place, with dry cleaning procedures enforced in most production areas of the facility to minimize establishment of environmental pathogens. A separate wet-washing room is used for washing, drying, and sanitizing small equipment. Water is treated and tested per EPA requirements by the city. An integrated pest control program is also in place. The company follows guidance such as from the North American Miller's Association for production of safe and nutritious flour.

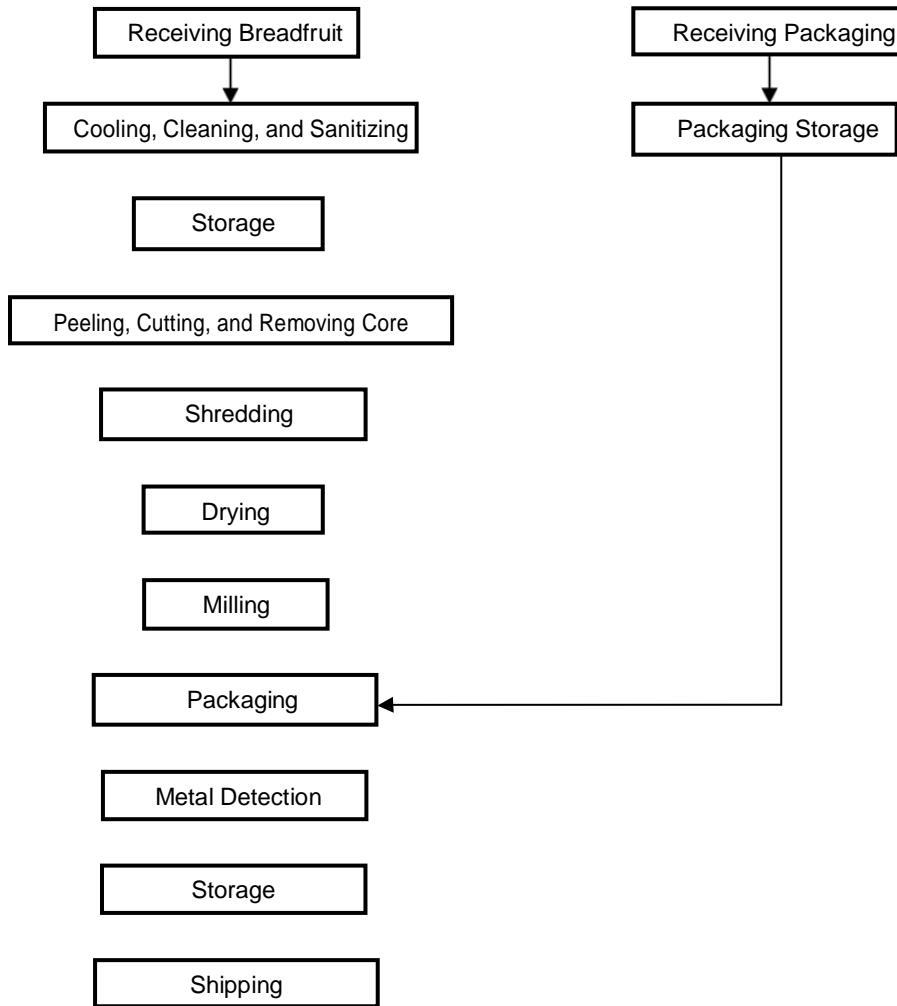
This Food Safety Plan covers production of breadfruit flour. Other products have separate Food Safety Plans

Product Description

Product Name(s)	Breadfruit Flour
Product Description, including Important Food Safety Characteristics	Dried milled breadfruit. This product is used as a food ingredient. The low water activity makes the product shelf stable. Processing involves shredding, drying, and milling. Sanitizing and hot-air drying eliminates pathogen in the product. Water activity ≤ 0.60
Ingredients	Breadfruit
Packaging Used	Food grade sealable polyethylene bag
Intended Use	The product is considered as a food ingredient
Intended Consumers	General public
Shelf Life	6 months at ambient
Labeling Instructions	None
Storage and Distribution	Ambient, temperature $\leq 82^{\circ}\text{F}$ and relative humidity $\leq 60\%$
Approved: Signature: <i>J. Knowitall</i> Print name: J. Knowitall	Date: 09/01/2018

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Flow Diagram



Verified by: _____ Date _____

NOTE: Several more steps are usually included in a real process. This process is for teaching-purposes only.

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Process Narrative

Breadfruit is supplied from local farmers that comply with national recognized food safety and quality systems. The fruit is stored according to food safety recommendations and the postharvest guide of breadfruit.

Receiving Breadfruit

Fresh breadfruit is delivered from approved suppliers as whole, firm-mature, and undamaged fruit. The postharvest handling and shipping should follow the Good Agricultural Practices (GAPs) and the postharvest guide of breadfruit to prevent fruit damage, decay, and contamination.

Receiving Packaging

Food grade polyethylene bags and food grade containers with lids are received in bulk shipment. Specifications require food grade material for packages that is compatible with flour or dried storage of food products.

Cooling, Cleaning, and Sanitizing

To slow the breadfruit ripening and extend the shelf life, the fruit is cooled by immersing in cold water or ice bath for 10-15 minutes to remove field heat. Then, breadfruit fruit is rinsed in clean water and gently brushed with a soft bristle brush to remove the dust, dirt, and other foreign materials. To reduce microbial contamination in the field and prevent cross contamination during cleaning, the breadfruit is sanitized in water with 150 ppm total chlorine for 1 minute then air-dried for storage.

Breadfruit Storage

Breadfruit is stored in a well-ventilated storage room with a temperature less than 24°C and relative humidity less than 60% for less than 2 days. The fruit are placed as a single layer in well-ventilated containers lined with paper to prevent the fruit bruise. Only mature and firm fruit will be used for processing breadfruit flour.

Packaging Storage

Food grade polyethylene bags and containers with lids are stored in dry ambient storage room segregated from ingredients and fresh breadfruit. The bags are stored in sealed containers to protect from contamination. Packaging is used First-In-First-Out.

Peeling, Cutting, Removing Core

First, remove the stem of breadfruit, and semi-automatically peel the fruit using electronic peeler or manually using a vegetable peeler or knife. Then, cut the fruit into quarters and remove the core with a knife. All the tools and utensils are cleaned, sanitized with 200 ppm chlorine solution, rinsed in clean water, and air-dried before use.

Shredding

Quartered breadfruit is cut into chunks then shredded with a food processor before drying. The fruit can also be cut into thin slices less than 0.64 cm (¼ inch) for drying.

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Drying

A single layer of shredded or sliced breadfruit are dried with a food dehydrator at 71°C (160°F) for 6-8 hours until breadfruit pieces are crispy with water activity less than 0.6.

Milling

The dried breadfruit is milled with sifter screens to a particle size that meets flour specifications for food application. Follow the instruction to operate the mills with right sifter screens. If the mill does not incorporate a sifting screen, the ground flour can be sieved with sieves at a size of 0.250–0.420 mm (Mesh No. 60-40) to meet the specifications.

Packaging

Breadfruit flour is filled and packaged in food grade polyethylene bag and labeled. The finished product is cased and coded with the appropriate lot and date.

Metal Detection

Finished breadfruit-flour product passes through an in line metal detector prior to packing. Rejected breadfruit flour is diverted prior to filling in packaging. All rejected flour is examined for the presence of metal.

Storage

Finished product is stored at the ambient temperature of 24 °C and the relative humidity of less than 60% until distributed.

Shipping

Product is shipped in clean and sanitary vehicles to customers.

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Hazard Analysis

Hazard identification (column 2) considers those that may be present in the food because the hazard occurs naturally, the hazard may be unintentionally introduced, or the hazard may be intentionally introduced for economic gain.

B = Biological hazards including bacteria, viruses, parasites, and environmental pathogens

C = Chemical hazards, including radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives

P = Physical hazards including potentially harmful extraneous matter that may cause choking, injury or other adverse health effects

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3 <i>Based on evaluation of severity and likelihood of occurrence</i>	(5) What preventive control measures(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Receiving Breadfruit	B Vegetative pathogens such as <i>Salmonella</i> and pathogenic <i>E. coli</i>	X		History of microbial contamination of vegetative pathogens on fruits and recall of flour	<i>Process Control:</i> Subsequent sanitizing and drying steps		X
	C Aflatoxin	X		Breadfruit has a history of potential contamination with aflatoxin from <i>Aspergillus</i>	<i>Supply Chain Control:</i> Verification of supplier. Certificates of Analysis for aflatoxin residues	X	
	P Foreign materials		X	Unavoidable foreign materials (dirt, insects) associated with the growing and harvesting environment are not physical hazards. The subsequent cleaning step will remove these foreign materials			
Cooling, Cleaning, and Sanitizing	B Vegetative pathogens such as <i>Salmonella</i> and pathogenic <i>E. coli</i>	X		Cross contamination may occur during cooling and cleaning. The growth of pathogens is not likely with short process time. Adding antimicrobials to the water (chlorine) reduces the chance of cross contamination.	<i>Process control:</i> Control of free chlorine in water	X	
	C Sanitizer		X	Sanitizer used to sanitize the surface of breadfruit will not affect finish product after removing the peels			
	P None						
Breadfruit Storage	B <i>Aspergillus</i>		X	Molds may exist in tropical environment. The growth of <i>Aspergillus</i> is controlled by relative humidity ($\leq 60\%$) and short storage time (≤ 2 days)			
	C None						
	P None						
Receiving Packaging	B None						
	C None						
	P None						

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(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3 <i>Based on evaluation of severity and likelihood of occurrence</i>	(5) What preventive control measures(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Packaging Storage	B None						
	C None						
	P None						
Peeling, Cutting, and Removing Core	B Environmental pathogens, such as <i>Listeria monocytogenes</i>	X		History of environmental contamination	<i>Sanitation Control:</i> Equipment and environmental sanitation	X	
	C None						
	P None						
Shredding	B Environmental pathogens, such as <i>Listeria monocytogenes</i>	X		History of environmental contamination	<i>Sanitation Control:</i> Equipment and environmental sanitation	X	
	C None						
	P Metal	X		Potential equipment failure at shredding step	<i>Process Control:</i> Subsequent metal detection		X
Drying	B Vegetative pathogens	X		Potential contamination of pathogens from raw fruit and environment. Hot-air dehydration eliminates vegetative pathogens.	<i>Process Control:</i> Heat treatment for pathogen reduction <i>Sanitation Control:</i> Zoning and sanitation	X	
	C None						
	P None						
Milling	B Environmental pathogens, such as <i>Listeria monocytogenes</i>	X		Post pasteurization contamination, cross contamination	<i>Sanitation Control:</i> Zoning and environmental sanitation	X	
	C None						
	P Metal			Equipment failure can potentially introduce metal	<i>Process Control:</i> Subsequent metal detection		X
Packaging	B Environmental pathogens, such as <i>Listeria monocytogenes</i>	X		Post pasteurization contamination, cross contamination	<i>Sanitation Control:</i> Zoning and environmental sanitation	X	
	C Undeclared Allergens	X		Potential contact of allergens during filling step from the breadfruit cake mix containing wheat and milk proteins and the breadfruit pancake mix containing wheat, milk, and egg proteins.	<i>Allergen Control:</i> Prevent allergen cross- contact and verify appropriate label used. <i>Sanitation Control:</i> Clean allergen from filler	X	
	P None						
Metal Detection	B None						
	C None						
	P Metal	X		Potential equipment failure at milling step	<i>Process Control:</i> Metal detection	X	
Storage	B None						
	C None						
	P None						
Shipping	B None						
	C None						
	P None						

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Process Preventive Controls

Process Control(s)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification Activities	Records
			What	How	Frequency	Who			
Cooling, Cleaning, and Sanitizing	Vegetative pathogens such as <i>Salmonella</i> and pathogenic <i>E. coli</i>	Free chlorine in sanitizing solution at end of batch run is ≥ 150 ppm, pH 7.5 maximum; Sanitizing time is 1 minute.	Sanitizing solution- Initial chlorine level in solution is ≥ 150 ppm and ≤ 200 ppm; sanitizing 1 minute.	Chlorine, pH test strips match color, and exposure time.	Each batch	Cleaning and sanitizing operator	If chlorine, pH level, or time is not correct, then 1) Adjust and conduct training as needed to prevent recurrence; 2) Segregate breadfruit to the last good check and reprocess; 3) Identify root cause and correct.	Daily review of sanitizing solution chlorine treatment log Perform accuracy check on both pH and chlorine strips for each new lot of strips with standard solution Review of corrective action log. Review of verification records	Breadfruit sanitizing log showing chlorine, pH values, and treatment time Corrective action records Validation report that shows chlorine wash solution is effective

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Process Control(s)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification Activities	Records
			What	How	Frequency	Who			
Drying	Vegetative pathogens such as <i>Salmonella</i> and pathogenic <i>E. coli</i>	X°F for Y ¹ minutes as a heat treatment for shredded breadfruit	Review time and temperature on recording chart to meet parameters listed under critical limits	Chart recorder	After initial temperature is reached, conduct continuous monitoring by visual check of recording instrument chart during each run	Breadfruit drying equipment operator	If parameters are not met then reprocess. Determine the root cause of processing failure and correct to prevent recurrence.	Calibrate equipment once per month QA manager or designee reviews and initials records daily Quarterly generic <i>E. coli</i> and <i>Salmonella</i> testing	Breadfruit Drying Processor Log Recording device calibration records Corrective actions Validation study by literatures or demonstrating that the time/temperature exposure for breadfruit is sufficient for a 5-log inactivation of pathogens Copy of report is in the plan.
Metal Detection	See Food Safety Plan in curriculum for an example for potential wording for metal detection. Parameters can vary depending on the product, packaging, detection system, etc.								

¹An actual plan would insert specific temperature and time. No specific numbers are used in this model to prevent misapplication of parameters that may not apply to a specific product.

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Allergen Preventive Controls

Allergen Cross-contact Prevention

Production Line Allergen Assessment

Product Name	Production Line	Intentional Allergens							
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)
Breadfruit flour	1								
Breadfruit cake mix	1		X		X				
Breadfruit pancake mix	1	X	X		X				

Scheduling Implications: Breadfruit cake mix in the product that contains a food allergen (milk and wheat and protein) and is run after the run of breadfruit flour. Breadfruit pancake mix in the product that contains food allergens (egg, milk, and wheat proteins) and is run at the end of the day. Dedicated filters are used for each product to minimize the risk of allergen cross-contact

Allergen Cleaning Implications: Dry cleaning procedures must be used in all production areas. The filler head is completely dismantled after the Breadfruit Pancake Mix product is run for through cleaning using alcohol wipes to ensure that there is no visible residue. Swabs have been taken to validate the effectiveness of this cleaning method to remove egg, milk, wheat protein to non-detectable levels on a routine basis. The cleaning crew is trained on this procedure, including its importance.

Allergen Label Verification Listing

Product	Allergen Statement	Label Number
Breadfruit Flour	Contains: none	BF123
Breadfruit cake mix	Contains: Milk, wheat	BCM456
Breadfruit pancake mix	Contains: Egg, milk, wheat	BPM789

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Sanitation Preventive Controls

Objective: To address 1) cleanliness of food contact surface and 2) prevention of allergen cross-contact.

Operation Table and Equipment Sanitation

Purpose: Cleaning and sanitizing of operation tables and equipment is important to reduce cross-contamination or recontamination with environmental pathogens that may impact product safety.

Frequency:

Cleaning: At lunch break, after breadfruit production, at the end of daily production.

Sanitizing: Before operation begin, at lunch break, after breadfruit production, at the end of daily production.

Who: Sanitation team member

Procedures:

Cleaning

1. Remove unused packaging material to an area at the end of the shift to prevent it from getting wet. Cover it during the lunch clean up.
2. Remove gross soil with a squeegee.
3. Wipe table and equipment surface with a clean cloth dipped in ABC cleaning solution (Y oz. per gallon)
4. Rinse table with clean water. Detergent remaining on the surface can inactivate the sanitizer.

Sanitizing:

1. Spray table and equipment surface with 200 ppm quaternary ammonium compounds (QUAT) solution, ensuring that entire surface is covered.
2. Allow surface to air dry, about 5 minutes. Contact time required per label – 1 minute.

Monitoring (at a frequency indicated above):

Inspect table and equipment for residual soil and cleanliness. Record on Daily Sanitation sheet.

Use test strip to measure the QUAT concentration BEFORE application. Record on Daily Sanitation sheet.

Correction:

If residual soil is observed on the table and equipment, re-clean, and sanitize. If QUAT is not at the proper concentration, make a new solution.

Records: Daily Sanitation Sheet

Verification: Supervisor reviews and signs Daily Sanitation Sheet within 7 working days.

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Hygienic Zoning/Environmental Monitoring

Purpose: Hygienic zoning in post-pathogen-destruction (drying) area is important to minimize the potential of re-contamination with environmental pathogens. The Flow Diagram highlights areas managed as zones and the basic plant layout. It illustrates primary pathogen control areas (sensitive areas), which are physically segregated from areas with raw material and packed finished-products.

Entry	Office	Break Room	Men's Locker Room	Women's Locker Room	Maintenance	Mechanical
Hall						
Shipping/Receiving	Cooling, Cleaning, Sanitation	Breadfruit storage	Peeling and Cutting	Drying and milling	Packaging and metal detection	Finished product storage
Hall						
Indicators	Non-GMP Area		Transition	Basic GMP	Primary pathogen control area-CONTROLLED ACCESS	

Frequency: During production and cleaning

Who: Employees and other individuals entering primary pathogen control area

Procedure: Employees entering the primary pathogen control area must (in the order listed):

1. Take a clean, blue smock from the rack outside the production area and put it on. Smocks must cover outer clothing that would be above the processing line.
2. Take blue shoe covers from the box by the entry and put them on over shoes.
3. Take a blue hairnet from the box by the entry and put it on. Ensure that all loose hair is captured. Men with facial hair should also apply beard nets.
4. Wash hands just before entering the area following the procedures posted by the sink. Apply a clean pair of gloves.
5. When exiting the room deposit smocks, shoe covers and hair nets in the receptacles provided. DO NOT reuse disposable items after entering uncontrolled areas.

Maintenance workers and visitors must follow the procedures above but use white foot covers and clean white smocks when entering this area. Traffic in this area is minimized during production.

Monitoring: The sanitation supervisor visually observes the presence of the properly smocked employee, before start up and after lunch break, and every 2 hours.

Corrections: Employee is instructed to gown properly

Records: Daily Hygienic Zoning Record, Environmental Monitoring Sampling Record and lab results.

Verification: Environmental monitoring for verification of sanitation preventive controls and records review within one week.

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Hygienic Zoning/Environmental Sanitation

Purpose: Cleaning and sanitizing of the floor and the table and equipment support (legs) in hygienic zoning area is important to prevent establishment of environmental pathogens.

Frequency: Daily after production

Who: Sanitation team member

Procedures:

Cleaning and sanitizing the table and equipment support structure

Cleaning is done in conjunction with cleaning of the table and equipment, following the same procedure, including table legs, and edges at the end of day.

Cleaning floors

NOTE: Separate tools are used for floors because of the potential for higher levels of contamination.

1. Remove gross soil with a squeegee
2. Mop floor using a washable mop head, using a clean mop each day
3. Rinse floor with clean water. Detergent remaining on the floor can inactivate the sanitizer.

Sanitizing

1. Apply QUAT sanitizer to floor at a 400-600 ppm concentration. Sanitizer solution may also contact non-food contact table legs.
2. Allow floor to air dry overnight.

Monitoring (at each cleaning time):

1. Inspect floor and surrounding area of residual soil and cleanliness. Record on Daily Sanitation sheet.
2. Use test strip to measure the QUAT concentration BEFORE application. Record on Daily Sanitation
3. sheet.

Correction:

If residual soil is observed, re-clean, and sanitize.

If QUAT is not at the proper concentration, make a new solution.

Records: Daily Sanitation Sheet, Daily Hygienic Zoning Record, Environmental Monitoring Sampling record and lab results.

Verification: Environmental monitoring (frequency per procedure) and supervisor records review within 7 working days.

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Allergen Cleaning of Filler

Purpose: Remove the food allergen (milk, wheat, and egg) from the head to prevent allergen cross contact and prevent mislabeling of product.

Frequency: After each run of Breadfruit Flour, Breadfruit Cake Mix, and Breadfruit Pancake Mix

Who: Sanitation crew

Procedure:

1. Completely dismantle filler chute following dismantling photograph and take parts to cleaning area.
2. Wet wash parts that can be exposed to water (refer to photo²).
3. Use food contact surface grade alcohol wipes to wipe down parts that cannot be exposed to water until there is no visual residue (refer to photo)
4. Allow parts to dry completely
5. Reassemble dry parts prior to production

Monitoring: Visually observe the filler parts prior to reassembly of the filler to ensure they are both clean and dry.

Corrections: If the filler is not properly clean (e.g. visible residue or wet), the employee is instructed on how to properly clean the parts and the importance of doing so to prevent potential allergic reactions.

Reaction: Allergen cleaning log

Verification: Visual inspection of the parts to assembly by the sanitation supervisor. Allergen cleaning log is reviewed within one week.

² Photo not provided for training but would be useful for the cleaning team to ensure consistent results

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Supply-chain-applied Controls

Hazards requiring a supply-chain-applied control: Hazard analysis determined that aflatoxin require a supply-chain-applied control for raw breadfruit. Our process does not reduce aflatoxin.

Preventive controls applied by the supplier: An approved supplier or producers sort breadfruit to remove damaged fruit. The approved suppliers or producers should follow the Good Agricultural Practices and the breadfruit postharvest guide to harvest and store breadfruit from the growth of Aspergillus.

Verification activities: The supplier sends Certificates of Analysis (COA) for aflatoxin residues (or documents to control the growth of Aspergillus on breadfruit) for our review to verify supplier control for these hazards.

Verification procedures: The Quality Supervisor:

- Verifies that copies of COAs received from the supplier for aflatoxin residues comply with regulatory requirements following procedure XYZ (or documents to control the growth of Aspergillus on breadfruit)
- Verifies that quarterly submission of COA requirements have been met
- Enters the date of the results of the review into the aflatoxin Screen Log

Records: COA copies for aflatoxin Screen Log, Incoming Goods Log, Approved Supplier List, and verification of corrective actions taken by the supplier are maintained on file by the Quality Manager.

Approved Suppliers for Ingredients Requiring a Supply-chain-applied Control

Ingredients (requiring supply-chain-applied control)	Approved Supplier	Hazard(s) requiring supply-chain-applied control	Date of Approval	Verification method	Verification records
Breadfruit	Breadfruit Pacific, USA	Aflatoxin	06/20/2018	Supplier's Certificate of Analysis (COA) with each shipment	COA and incoming goods log, corrective records.

Receiving procedures: For each shipment received, the receiving clerk verifies that the product is from an approved supplier and documents this in Incoming Goods Log.