

PRODUCT: Cookies, Bars and Bites	
PLANT NAME: Harvest Valley Bakery, Inc™	ADDRESS: 348 Civic Road. La Salle, Illinois 61301
ISSUE DATE: February 20, 2021	SUPERSEDES: May 27, 2019



## Food Safety Plan for Cookies, Bars and Bites

Reviewed by: Skip DeMaso PCQI/QA Manager  
 Approved by: Nancy Jenks, President

Date: 2/20/2021  
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## Company Overview

Company is a bakery that makes a variety of RTE baked goods for the wholesale market.

The following products are produced in the facility using some of the same equipment:

- Cookies
- Bars
- Bites
- Biscotti

Product is made 5 days a week in 1 production shift, followed by cleaning and sanitation.

Both dry cleaning and wet cleaning activities are performed.

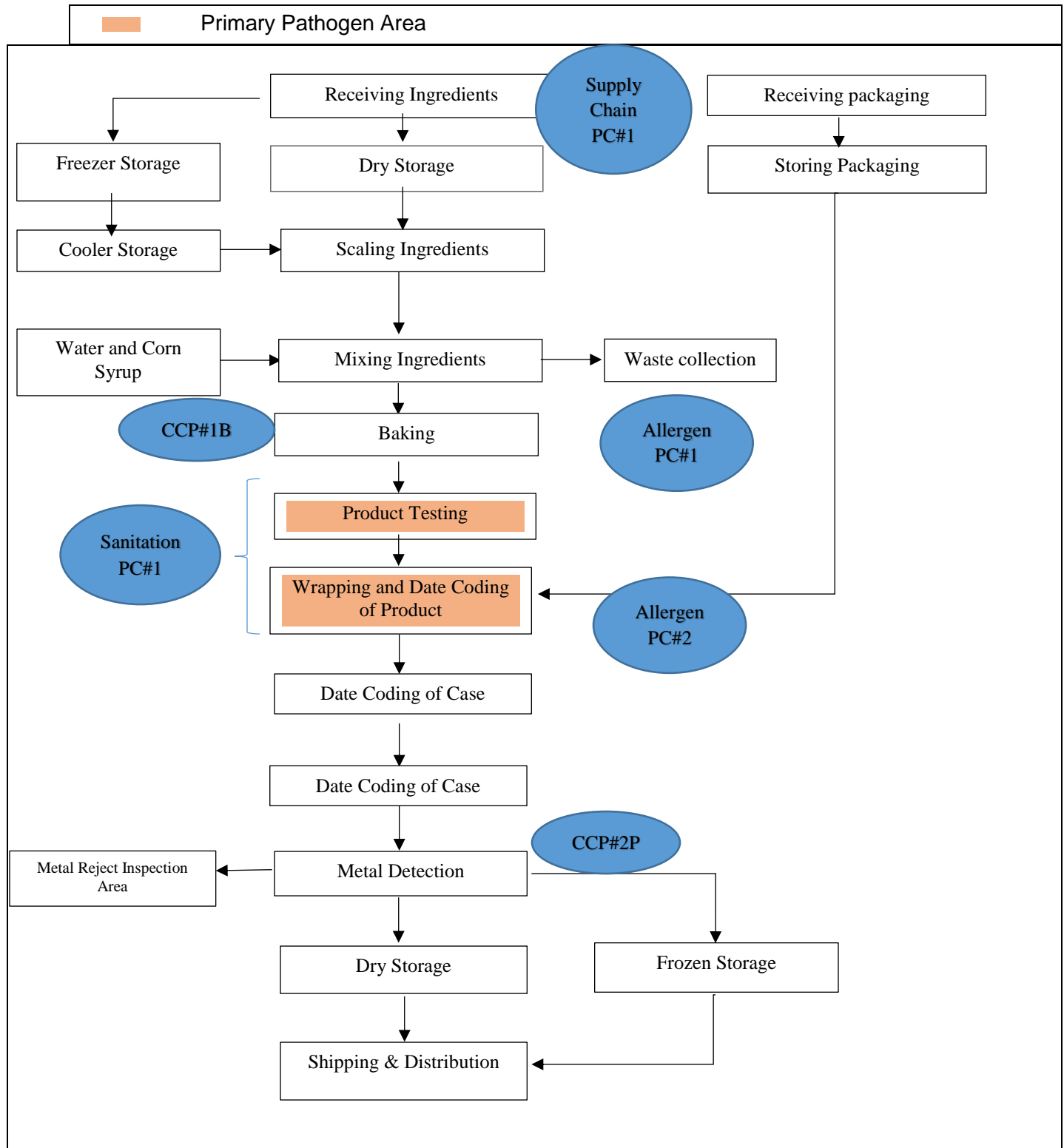
Water is treated and tested per EPA requirements by the City of La Salle. In addition, a water sampling program is in place and water is tested annually from designated sampling points based on risk assessments. An integrated pest control program is also in place.

## Product Description

<b>Product Name</b>	Cookies, Bars and Bites
<b>Product Description</b>	Products are <b>Ready to Eat</b> . The low water activity makes the product shelf stable. Processing involves dry mixing and forming with a baking (process lethality) step.
<b>Important Food Safety Characteristics</b>	Water Activity <= 0.69
<b>Ingredients</b>	Flour, Butter, Salt, Margarine, Oil, Shortening, Granulated sugar, Brown sugar, Sucralose and other sugar substitutes, Liquid Whole Eggs, Fructose, Citric acid, Cinnamon spice, Maltitol, Honey, Polydextrose, Glucose/Sugar Syrup, Molasses, Powdered milk, Flavors and extracts, Cherries, Chocolate, Cocoa powder, Baking powder and Baking Soda, Rolled and Quick Oats, Sunflower seeds, Whey powder, Shortening, Soy Protein Isolate, Rice Crisps, Raisins and Raisin Paste, Apple Sauce, Dough Conditioners and Fiber ingredients, Inulin.
<b>Packaging Used</b>	Food Grade Film
<b>Intended Consumers</b>	General Consumption
<b>Shelf Life</b>	Supplied by Customer
<b>Labeling Instructions</b>	Pre-printed retail boxes/ retail labels, case labels, allergen statement on retail and bulk packaging.
<b>Storage and Distribution</b>	Ambient and Frozen Temperature
<b>Approved:</b> Signature: Print Name: Skip DeMaso	<b>Date:</b> February 20, 2021

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## Flow Diagram



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## Process Narrative

### 1. Receiving Ingredients

Please refer to SOP 11.6 Shipping, Receiving and Storage Procedure

### 2. Receiving Packaging

Please refer to SOP 11.6 Shipping, Receiving and Storage Procedure

### 3. Dry Storage & Freezer/Cooler Storage

The butter is stored in a walk-in cooler that maintains a temperature of between 33- and 39-degrees F. Frozen whole liquid eggs and cherries are stored in a freezer that maintains a temperature between 0 & 20 degrees F. Frozen ingredients are moved to the cooler for thawing prior to use. All other ingredients are stored at ambient temperature. All containers are sealed to avoid cross- contact and cross-contamination during storage. Ingredients that contain allergens are labelled and stored in specific locations with like allergenic ingredients.

### 4. Store Packaging

Material should either be covered during storage or stored in sealed containers to protect from contamination. Packaging is used First-In-First-Out.

### 5. Scaling Ingredients

Ingredients are measured and staged in a dedicated room. The hygiene level of the room is consistent with the requirements of exposed product manufacturing areas. Allergenic materials are weighed on dedicated equipment into dedicated containers using color coded tools dedicated to the allergen. Employees change smocks and gloves before and after handling an allergenic material.

### 6. Water and Corn Syrup Addition

Municipal water is used.

### 7. Mixing Ingredients

### 8. Baking

The facility uses an indirect oven with 4 heating zones.

Cookies and Bars bake for 10 to 12 minutes at 340°F 235°F 380°F 345°F

Brownie Bites bake for 30 minutes 320°F 220°F 320°F 285°F

CoCo Chip Bites bakes for 25 minutes 63°F 64°F 360°F 305°F.

Biscotti Bakes for 25 minutes 320°F 240°F 325°F 275°F

### 9. Product Testing

### 10. Wrapping and Date Coding of Product

### 11. Date Coding and Labeling of Case

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## **12. Metal Detection**

Once the baked products have been shrink-wrapped, they move onto a conveyor belt where it will pass through a metal detector

## **13. Storage (freezing & Ambient)**

After palletization, the product will be placed into a freezer that maintains a temperature of between 0- and 20-degrees F. Shelf Stable product will be moved to a dry storage kept at ambient temperature.

## **14. Shipping**

Please refer to Shipping, Receiving and Storage SOP 11.6 Shipping, Receiving and Storage Procedure. Delivery trucks will be monitored for temperature.

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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 include potentially harmful extraneous matter that may cause choking, injury, or other adverse health effects.

R = Radiological Hazards: Radiological Hazards could be associated with water. We check our water report from the City of LaSalle to make sure the water is free of isotopes. Other than that, we consider the risk to be linked to Japanese imports (Fukushima). Since we don't Import food from Japan, there is no risk.

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			Yes	No			Yes	No
Butter	B	Bacillus cereus Pathogenic E. coli Salmonella spp. L. monocytogenes S. aureus Bacterial growth and/or toxin formation due to lack of time/temperature control	Yes		Unhygienic production & packaging operations, failure to maintain the cold chain.	Supply chain control, supplier approval and monitoring program, Cold chain monitoring onsite, <b>CCP-1B (baking)</b>	See Baking	
	C	undeclared allergens	Yes		Butter (Milk) is a recognized food allergen	Allergen control program- subsequent allergen labelling	See Wrapping and date coding of product	
	P	hazardous extraneous material	Yes		Lack or improper implementation of supplier foreign material program.	Supplier approval and monitoring program, <b>CCP-2P Metal Detection</b>	See Metal Detection	
Margarine	B	Pathogenic E. coli Salmonella spp. L. monocytogenes	Yes		Unhygienic production & packaging operations, Failure to maintain the cold chain.	Supply chain control, supplier approval and monitoring program, Cold chain monitoring onsite, <b>CCP-1B (baking)</b>	See Baking	
	C	Unapproved colors & additives		No	Exceeding permissible levels, using unauthorized chemicals - Not likely to occur.	Supplier approval and monitoring program.		



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			Yes	No			Yes	No
	C	Undeclared Allergens	Yes		Milk is a recognized food allergen	Allergen control program- subsequent allergen labelling	See Wrapping and date coding of product	
	P	hazardous extraneous material	Yes		Lack or improper implementation of supplier foreign material program.	Supplier Approval Program, <b>CCP-2P Metal Detection</b>	See Metal Detection	
Granulated Sugar, Brown Sugar, Velvet Cane Sugar, Powdered Sugar, Baker's Special Sugar	C	non-food chemicals, unapproved color and additives		No	Lack or improper implementation of supplier chemical control program – Not likely to occur. Robust Supplier approval and monitoring program			
	P	hazardous extraneous material	Yes		Lack or improper implementation of supplier foreign material program.	Supplier approval and monitoring program, <b>CCP-2P Metal Detection</b>	See Metal Detection	
Shortening, Canola oil, Soybean Oil	C	non-food chemicals (e.g., preservatives, antioxidants)		No	Lack or improper implementation of supplier chemical control program – Not likely to occur.	Supplier approval and monitoring program		

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			Yes	No			Yes	No
	C	environmental contaminants (e.g., pesticides, herbicides)		No	Domestic suppliers – not likely to occur. .	Supplier approval and monitoring program		
	C	undeclared allergens	Yes		Soy is a recognized food allergen	Allergen control program- subsequent allergen labelling	See Wrapping and date coding of product	
	P	hazardous extraneous material	Yes		Lack or improper implementation of supplier foreign material program.	Supplier approval and monitoring program, <b>CCP-2P Metal Detection</b>	See Metal Detection	
Cocoa Powder, Chocolate Chips, Milk Chocolate, Semi- sweet Chocolate, Ivory Chips	B	Salmonella spp	Yes		Unhygienic production & packaging operations	Supplier approval and monitoring program, <b>CCP-1B (baking)</b>	See Baking	
	C	Undeclared allergens (Soy, Milk)	Yes		Milk and Soy are recognized food allergens	Allergen control program- subsequent allergen labelling	See Wrapping and date coding of product	
	P	Hazardous extraneous material	Yes		Lack or improper implementation of supplier foreign material program.	Supplier approval and monitoring program, <b>CCP-2P Metal Detection</b>	See Metal Detection	
Honey	B	Clostridium botulinum	Yes		Unhygienic production & packaging operations	Supplier approval and monitoring program, <b>CCP-1B (baking)</b>	See Baking	

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			Yes	No			Yes	No
	C	Drug residue Pesticides Chemical hazards due to mis- formulation (e.g. sulfites, yellow #5)	Yes		Honey associated with high risk of Food Fraud.	<b>Supplier Chain Control required for ensure purity and Safety.</b>	See Receiving Honey	
	P	Hazardous extraneous material	Yes		Lack or improper implementation of supplier foreign material program.	Supplier approval and monitoring program, <b>CCP-2P Metal Detection</b>	See Metal Detection	
Liquid Whole Eggs (frozen)	B	Listeria monocytogenes, Salmonella spp.	Yes		Unhygienic production & packaging operations, inadequate lethality step during pasteurization, improper storage temperature	Supplier approval and monitoring program, <b>CCP-1B baking</b>	See Baking	
	C	Undeclared allergen	Yes		Egg is a recognized food allergen	Allergen control program- subsequent allergen labelling	See Wrapping and date coding of Product	
	C	Environmental contaminants (e.g., pesticides, drug residue)	Yes		Product of animal origin – presence of environmental contaminants and drug	<b>Supply Chain Control required to confirm purity</b>		

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			Yes	No			Yes	No
					residue/antibiotics a possibility			
	P	Hazardous extraneous material	Yes		Lack or improper implementation of supplier foreign material program.	Supplier approval and monitoring program, <b>CCP-2P Metal Detection</b>	See Metal Detection	
All Purpose Flour, Cake/Pastry flour, Oat Flour	B	Salmonella spp., E.coli	Yes		Contamination of grain in the field or due to unhygienic handling	Supplier approval and monitoring program, <b>CCP-1B (baking)</b>	See Baking	
	C	Environmental contaminants (e.g., pesticides), Vomitoxin/DON	Yes		Robust Supplier approval and monitoring program. Nonetheless, the presence of mycotoxins must be verified for each delivery. Environmental chemical contamination is not likely.	<b>Supply Chain Control is required</b>	See Receiving Flour	
	C	Undeclared allergen	Yes		Wheat is a recognized food allergen	Allergen control program- subsequent allergen labelling	See Wrapping and date coding of product	

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			Yes	No			Yes	No
	P	Hazardous extraneous material	Yes		Lack or improper implementation of supplier foreign material program.	Supplier approval and monitoring program, <b>CCP-2P Metal Detection</b>	See Metal Detection	
Baking Powder, Baking Soda	C	Non-food chemicals		No	Lack or improper implementation of supplier chemical control program – Not likely to occur.	Supplier approval program		
	P	Hazardous extraneous material	Yes		Lack or improper implementation of supplier foreign material program.	Supplier approval and monitoring program, <b>CCP-2P Metal Detection</b>	See Metal Detection	
Lemon juice	C	Non-food chemicals (e.g., non-food grade), Pesticides.		No	Lack or improper implementation of supplier chemical control program – Not likely to occur.	Supplier approval program		
	P	Hazardous extraneous material		No	Metal or HEM contamination is not likely			
Salt	C	Non-food chemicals (e.g., non-food grade)		No	Lack or improper implementation of supplier chemical control program – Not likely to occur.	Supplier approval program		

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			Yes	No			Yes	No
	C	Excess of food additive		No	Exceeding permissible levels – not likely to occur.	Supplier approval program		
	P	Hazardous extraneous material	Yes		Lack or improper implementation of supplier foreign material program.	Supplier approval and monitoring program, <b>CCP-2P Metal Detection</b>	See Metal Detection	
Cinnamon Spice	B	Bacillus cereus Clostridium botulinum C. perfringens Pathogenic E. coli Salmonella spp.	Yes		Contamination of grain in the field or due to unhygienic handling	Supplier approval and monitoring program, <b>CCP-1B (baking)</b>	See Baking	
	C	Non-food chemicals (e.g., non-food grade/Sudan dyes)		No	Inclusion of toxic dyes has been associated with imported spices from Asia. This product is domestically sourced.	Supplier Approval Program		
	P	Hazardous extraneous material	Yes		Lack or improper implementation of supplier foreign material program.	Supplier approval and monitoring program, <b>CCP-2P Metal Detection</b>	See Metal Detection	
Invert Sugar, Molasses, corn syrup, Polydextrose, Fructose, invert sugar syrup, sugar,	C	Unapproved color and additives		No	Lack or improper implementation of supplier chemical control program – Not likely to occur.	Supplier Approval Program		

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			Yes	No			Yes	No
pomegranate concentrate. Substitutes (Maltitol, Lycasin, Sucralose, Erythritol)	P	Hazardous extraneous material	Yes		Lack or improper implementation of supplier foreign material program. Metal contamination is possible.	Supplier approval and monitoring program, <b>CCP-2P Metal Detection</b>	See Metal Detection	
Milk Powder, Sweet Whey Powder	B	Bacillus cereus Pathogenic E. coli Salmonella spp. L. monocytogenes S. aureus	Yes		Unhygienic production & packaging operations, inadequate lethality step	Supplier approval and monitoring program, <b>CCP-1B baking</b>	See Baking	
	C	Drug residue	Yes		Product of animal origin - Presence of antibiotic in milk a possibility	<b>Supply Chain Program</b>	See Receiving Milk Powder	
	C	Undeclared Allergens	Yes		Milk is a recognized food allergen	Allergen control program- subsequent allergen labelling	See Wrapping and Date coding of product	
	P	hazardous extraneous material	Yes		Lack or improper implementation of supplier foreign material program. Metal contamination is possible.	Supplier approval and monitoring program, <b>CCP-2P Metal Detection</b>	See Metal Detection	

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			Yes	No			Yes	No
Flavors (Vanilla), Extracts and Coloring agents	P	hazardous extraneous material		No	Not likely to occur with liquids.	Supplier approval program		
Raisin paste, Raisins, Apple Sauce, Cherries, Frozen Cherries, Blueberries, Infused Cranberries.	B	Salmonella spp. L. monocytogenes	Yes		Unhygienic production & packaging operations, improper storage temperature	Supplier approval and monitoring program, <b>CCP-1B baking</b>	See Baking	
	C	Pesticides, Undeclared sulfites (≥10ppm)	Yes		Domestically sourced, pesticides not an issue. Sulfites must be declared on the label	Labeling Program (Sulfites)	See Wrapping and date coding of product	
	P	Hazardous extraneous material	Yes		Lack or improper implementation of supplier foreign material program.	Supplier approval and monitoring program, <b>CCP-2P Metal Detection</b>	See Metal Detection	
Soy Protein, Soy Isolate (Profam 873 Isolate).	B	Pathogens including Escherichia coli, Salmonella spp, Listeria monocytogenes	Yes		Unhygienic production & packaging operations, inadequate lethality step.	Supplier approval and monitoring program, <b>CCP-1B baking</b>	See Baking	
	C	Aflatoxins, pesticides, Melamine (FDA import alert)	Yes		Pesticide contamination is not likely (domestic product). Melamine contamination is not likely (domestic	<b>Supply chain Control (Aflatoxin)</b>	See Receiving Soy Protein	



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			Yes	No			Yes	No
					product). Presence of Aflatoxins must be confirmed for each delivery.			
	C	Undeclared Allergens	Yes		Soy is a recognized food allergen	Allergen control program- subsequent allergen labelling	See Wrapping and Date coding of Product	
	P	Hazardous extraneous material	Yes		Lack or improper implementation of supplier foreign material program.	Supplier approval and monitoring program, <b>CCP-2P Metal Detection</b>	See Metal Detection	
Texturers, dough conditioners, and acidulants (Fibersol 2, Inulin, Acesulfame K, Citric Acid, Solka Flok), Monocalcium phosphate, Vitamin Mix.	B	Salmonella spp. (Fiber materials)	Yes		Unhygienic production & packaging operations	Supplier approval and monitoring program, <b>CCP-1B baking</b>	See Baking	
	C	Non-food chemicals		No	Lack or improper implementation of supplier chemical control program – Not likely to occur.	Supplier approval program		
	P	Hazardous extraneous material	Yes		Lack or improper implementation of supplier foreign material program.	Supplier approval and monitoring program, <b>CCP-2P Metal Detection</b>	See Metal Detection	

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			Yes	No			Yes	No
Sunflower seeds, roasted pumpkin seeds, quick and rolled oats, Rice crisps.	B	Salmonella spp. Bacillus cereus (Rice products) Bacterial growth and/or toxin formation due to lack of time/temperature control (Bacillus Cereus Toxin affecting rice Crips)	Yes		Unhygienic production & packaging operations. Inadequate lethality process.	Supplier approval and monitoring program, <b>CCP-1B baking</b>	See Baking	
	C	Unapproved colors & additives		No	Lack or improper implementation of supplier chemical control program – Not likely to occur.	Supplier approval program		
	C	Undeclared allergens (wheat) in oats	Yes		Wheat is a recognized food allergen	Allergen control program- subsequent allergen labelling	See Wrapping and date coding of product	
	P	Hazardous extraneous material	Yes		Lack or improper implementation of supplier foreign material program.	Supplier approval and monitoring program, <b>CCP-2P Metal Detection</b>	See Metal Detection	
Chia Blend, Flax/Buckwheat Blend/Quinoa Blend	B	Salmonella spp., E. coli	Yes, past recalls of Chia seeds due to		Contamination of seeds in the field or due to unhygienic handling	Supplier approval and monitoring program, <b>CCP-1B baking</b>	See Baking	

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			Yes	No			Yes	No
			Salmon ella contami nation					
	C	Pesticides (domestically sourced materials)		No	Foreign materials is controlled by the supplier. Domestically sourced so low risk.	Vendor Management program, Approved supplier 3rd party audit, LOG		
	P	hazardous extraneous material including metal	Yes		Foreign material is controlled by the supplier.	Supplier approval and monitoring program, <b>CCP-2P Metal Detection</b>		See Metal Detection
Receiving shelf stable ingredients	B	Pathogens contamination due to unhygienic carrier handling and conditions		No	Employees from the transportation company are properly trained in maintaining sanitary conditions in the truck	Receiving Program, Freight Services Requirements Policy		
	B	Receiving of non-compliant material/product not meeting specifications		No	Shipping & receiving employees aware of approved vendors and products. Receiving SOP, Personnel training program			
	B	Pathogen contamination due to improper employee handling at receiving		No	Receiving employees are properly trained on receiving and handling food products	Receiving Program, Personnel training program		

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			Yes	No			Yes	No
	C	Contamination by allergens in receiving area or due to improper segregation during transportation		No	Receiving employees follow proper allergen segregation procedures. Receiving employees are properly trained on receiving and handling allergen products.	Receiving Program, Freight Services Requirements Policy, Allergen Program, Personnel training program		
	C	Contamination by non-food chemicals (e.g., mixed loads)		No	Truck drivers are following proper segregation procedures.	Receiving Program, Freight Services Requirements Policy		
	B	Pathogen contamination due to improper employee handling at receiving		No	Receiving employees are properly trained on receiving and handling food products	Receiving Program, Personnel training program		
Receiving Packaging Materials	C	Contamination by non-food chemicals (e.g., mixed loads)		No	Truck drivers are following proper segregation procedures.	Receiving Program, Freight Services Requirements Policy		
Receiving Refrigerated or Frozen Materials (Whole egg, Margarine, Butter)	B	Receiving of non-compliant material/product not meeting specifications		No	Shipping & receiving employees aware of approved vendors and products. Receiving SOP, Personnel training program			

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			Yes	No			Yes	No
	B	Pathogen growth due to time / temperature abuse during transportation	Yes		Trucks not maintaining adequate temperatures, Transportation & Storage Program, Freight Services Requirements Policy.	Cold Chain Monitoring, <b>Process Preventive Control Baking CCP-1B</b>		X
	B	Contamination due to unhygienic carrier handling and conditions		No	Employees from the transportation company are trained and maintain sanitary conditions in the truck. Trucks are inspected upon arrival.	Transportation & Storage Program, Freight Services Requirements Policy, Receiving SOP, Personnel training program		
	C	Contamination by allergens in receiving area or due to improper segregation during transportation		No	Suppliers are required to follow allergen control guidelines.	Transportation & Storage Program, Freight Services Requirements Policy, Receiving SOP, Personnel training program, Allergen program		
Receiving Honey and Products of Animal Origin (Butter, Whole egg, Milk powder)	C	Drug residue Pesticides Chemical hazards due to mis- formulation (e.g. sulfites, yellow #5)	Yes		Honey associated with high risk of Food Fraud.	<b>Supply Chain Control at Receiving</b>	X	

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			Yes	No			Yes	No
Receiving Flour and Soy Protein	C	Mycotoxins (DON/Vomitoxins and Aflatoxins)	Yes		Due to poor agricultural and storage practices. Maximum allowable amount set by FDA is 1PPM max	<b>Supply Chain Control at Receiving</b>	X	
Refrigerated and Freezing Storage	B	Pathogen growth due to time / temperature abuse	Yes		Storage areas not maintaining adequate temperatures, ingredients not being stored under recommended storage temperatures.	Cold Chain Monitoring, <b>Process Preventive Control CCP-1B Baking</b>		X
	B	Pathogen contamination due to condensation falling onto / into uncovered product		No	No open containers in refrigerated storage, spills contained and cleaned.	Transportation & Storage Program, Employee training program		
	C	Cross contamination with allergens during storage		No	Robust allergen storage procedures in effect (no part bags, spills contained and cleaned)	Allergen control program		
Dry Storage	B	Pathogen contamination due to product accumulations (e.g., inappropriate stock rotation)		No	Employees are trained on proper inventory control.	Storage program		

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			Yes	No			Yes	No
B	Pathogen contamination due to inadequate cleaning / sanitizing of area or equipment			No	Cross-contamination is prevented by maintaining appropriate hygiene levels in the facility.	Master Sanitation Program		
B	Pathogen contamination due to damaged cartons / containers (e.g., from fork lift, improper stacking procedures)			No	Contamination during storage is prevented by providing training to warehouse employees	Storage program and Personnel Ingredients Handling Training		
B	Pathogen contamination due to improper employee Hygiene and practices			No	Contamination during storage is prevented by providing training to warehouse employees	Personnel GMP training program		
C	Cross contamination with allergens during storage			No	Allergen storage procedures in effect (no part bags, spills contained and cleaned)	Allergen control program		
C	Contamination by non-food chemicals (e.g., cleaners, sanitizers, lubricants, hydraulic fluids)			No	Employees trained on ingredient and chemical segregation policies	Chemical control program		
P	Contamination from hazardous extraneous material due to changed packaging or due to fork lift			No	Good storing practices are followed	Foreign material control program, personnel GMP program & storage program		

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			Yes	No			Yes	No
		accidents (e.g., wood splinters from damaged pallets) Foreign material falling into uncovered product or by employee handling						
Packaging Storage	B	Pathogen contamination due to product accumulations (e.g., inappropriate stock rotation)		No	Proper inventory control is practiced.	Ingredient Storage program		
	B	Pathogen contamination due to inadequate cleaning / sanitizing of area or equipment		No	Cross- contamination is prevented by maintaining appropriate hygiene levels in the facility.	Master Sanitation Program		
	B	Pathogen contamination due to damaged cartons / containers (e.g., from forklift, improper stacking procedures)		No	Contamination during storage is prevented by providing training to warehouse employees	Storage program and Personnel Ingredients Handling Training		
	B	Pathogen contamination due to improper employee hygiene and practices		No	Employees follow good storage practices	Personnel GMP training program		
	B	Pathogen contamination due to pests (e.g., insects, rodents, birds)		No	Employees follow good storage practices (product must be stored off the floor	Ingredient Storage program and Pest Control program		



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		Yes	No			Yes	No
				and away from the wall), a pest prevention program is maintained.			
	C	Cross-contamination due to inappropriate allergens product storage	No	Employees are trained on proper ingredient segregation policies	Allergen control program		
	C	Contamination by non-food chemicals (e.g., cleaners, sanitizers, lubricants, hydraulic fluids)	No	Employees are trained on proper ingredient segregation policies	Chemical control program		
	P	Contamination from hazardous extraneous material due to changed packaging or due to forklift accidents (e.g., wood splinters from damaged pallets) Foreign material falling into uncovered product or by employee handling.	No	Good Storage Practices are enforced	Foreign material control program, personnel GMP program & storage program		
Scaling Ingredients	B	Pathogen growth due to time / temperature abuse (Whole egg, butter, margarine)	Yes	Inadequate handling and storage of temperature sensitive ingredients could lead to contamination.	Cold chain monitoring, Personnel program, <b>Process Preventive Control Baking CCP#1B</b>		X

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			Yes	No			Yes	No
B	Pathogen contamination due to improper employee handling / operating procedures /equipment			No	Employees follow GMPs and SOPs	Personnel program		
C	Adding chemicals out of specifications results in hazards			No	All additives are GRAS.	Equipment Calibration Program, Employee Training		
C	Cross-contamination with unique allergens	Yes			Before processing Nutritional Choices, Products containing Milk, Soy and Wheat to control for egg residue. Before processing Father's table products containing Egg, Wheat and Milk to control for soy residue Before processing Old Colony, products containing Wheat, Eggs to control for Soy and Milk residue	<b>Allergen Preventive Control</b> (to prevent risk of allergen cross contact)	X	
P	Contamination from hazardous extraneous material (Broken transfer			No	Employees follow the GMP policy, utensils	GMP program, Foreign material control		

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			Yes	No			Yes	No
		scoops and other tools, Employee's personal effects, damaged equipment)			are maintained and inspected.	program, Equipment Maintenance Program		
Water and Corn Syrup Addition	B	Water quality not meeting EPA standard		No	Meters are maintained as per the preventive maintenance program. Municipality provides potability results. The facility also samples and tests process water.	Equipment Maintenance Program, Water Testing Program.		X
	B	Pathogen contamination due to inadequate cleaning / sanitizing of equipment		No	Not likely to present a serious risk. Robust Sanitation Program.	Equipment Maintenance Program		
	C	Radiological hazards, heavy metals		No	Municipality tests water for chemical and radiological contaminants	Water Testing Program		
	P	Contamination from hazardous extraneous material		No	Not likely to occur			
Mixing Ingredients	B	Pathogen contamination due to contaminated utensils / equipment (e.g., improper cleaning)		No	Cross contamination is prevented with environment & equipment managed	Master Sanitation program		

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			Yes	No			Yes	No
					at appropriate hygiene level.			
	B	Pathogen contamination due to improper employee handling		No	Employees follow GMPs and SOPs	Personnel program		
	C	Contamination by non-food chemicals (e.g., cleaners, sanitizers and lubricants)		No	The facility uses approved chemicals, SSOPs are followed to prevent contamination of equipment with chemical residue.	Chemical control program, sanitation program		
	C	Cross-contamination with unique allergens	Yes		Before processing Nutritional Choices, Products containing Milk, Soy and Wheat to control for egg residue. Before processing Father's table products containing Egg, Wheat and Milk to control for soy residue Before processing Old Colony products containing Wheat,	<b>Allergen Preventive Control</b> (to prevent risk of allergen cross contact)	X	

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			Yes	No			Yes	No
					Eggs to control for Soy and Milk residue			
	P	Contamination from hazardous extraneous material, metal to metal contact.	Yes		Employees are trained on GMP. Metal-to-metal contact prevented using metal detection.	<b>Process Preventive Control CCP-2P metal detection</b> Preventative maintenance program		X
Waste Collection	B, P	No identified hazards						
	C	Allergen Cross-Contact (uniforms, gloves)		No	cGMP in effect to control waste and possible allergen cross contact during product changeovers.			
Baking (indirect oven with 4 heating zones)	B	Pathogen survival due to improper temperature distribution / time / temperature applications	Yes		Oven temperature to be monitored (CCP validation)	<b>Process Preventive Control (CCP#1B Baking)</b> – Hourly Temperature Monitoring +/- 10 min	X	
	C	Cross-contamination with unique allergens	Yes		Before processing Nutritional Choices, Products containing Milk, Soy and Wheat to control for egg residue. Before processing Father's table products containing Egg, Wheat and Milk	<b>Allergen Preventive Control</b> (to prevent risk of allergen cross contact)	X	

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			Yes	No			Yes	No
					to control for soy residue Before processing Old Colony products containing Wheat, Eggs to control for Soy and Milk residue			
Product Testing	B	Pathogen contamination due to improper employee handling or unclean equipment and instruments – Primary Pathogen Area	Yes		Employees not following GMPs and SOPs, Food contact and non-food contact surfaces contaminated with environmental pathogens.	<b>Sanitation Preventive Control</b> , Environmental swabbing program	X	
	C	Cross-contamination with unique allergens	Yes		Before testing Nutritional Choices Products containing Milk, Soy and Wheat to control for egg residue. Before processing Father's table products containing Egg, Wheat and Milk to control for soy residue Before processing Old Colony products	<b>Allergen Preventive Control</b> (to prevent risk of allergen cross contact)	X	

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			Yes	No			Yes	No
					containing Wheat, Eggs to control for Soy and Milk residue			
	P	Contamination from hazardous extraneous material (Broken tools, Employee's personal effects, damaged equipment)		No	Employees follow the GMP policy, utensils are maintained and inspected.	GMP program, Foreign material control program, Equipment Maintenance Program		
Wrapping and Date Coding of Product	B	Cross-contamination with environmental pathogens.	Yes		Food-contact surfaces are cleaned and sanitized.	<b>Sanitation Preventive Control</b> , Environmental swabbing program	X	
	C	Cross-contamination with unique allergens	Yes		Before testing Nutritional Choices Products containing Milk, Soy and Wheat to control for egg residue. Before processing Father's table products containing Egg, Wheat and Milk to control for soy residue Before processing Old Colony products containing Wheat, Eggs to control for Soy and Milk residue	<b>Allergen Preventive Control</b> (to prevent risk of allergen cross contact)	X	

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			Yes	No			Yes	No
	C	Allergens (Wheat, Milk, Soy and Egg) are not declared on labels	Yes		Improper label review or use wrong labels.	<b>Allergen Preventive Control</b> (online Label Verification)	X	
	C	Sulfites (preservatives) not declared on labels	Yes		Improper label review or use wrong labels.	Controlled as part of <b>Allergen Preventive Control</b> (online Label Verification)	X	
	P	Contamination from hazardous extraneous material (Employee's personal effects, damaged equipment)		No	Employees follow the GMP policy, equipment is maintained and inspected.	GMP program, Foreign material control program, Equipment Maintenance Program		
Date Coding of Case	B	Pathogen contamination of package due to improper employee handling		No	Employees follow GMPs and SOPs	Personnel program		
Labeling of Case	C	Allergen labeling on case	Yes		Case coding required for Wholesale products	<b>Allergen Preventive Control</b> (online Label Verification)	X	
Metal Detection	P	Metal being missed going through the detector due to malfunction or non-operation of equipment, Failure to remove hazardous extraneous matter	Yes		Metal inclusion may be present from previous operations, equipment may not perform as desired if not maintained & calibrated frequently, proper rejection mechanism should be in place	<b>Process Preventive Control CCP-2P Metal detection</b>	X	



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			Yes	No			Yes	No
Metal Reject Inspection Area	B, C, P	No Hazards identified.						
Dry Storage (Finished product)	B	Pathogen contamination due to product accumulations (e.g., inappropriate stock rotation)		No	Employees are trained on proper inventory control.	Storage program		
	B	Pathogen contamination due to inadequate cleaning / sanitizing of area or equipment		No	Cross-contamination is prevented by maintaining appropriate hygiene levels in the facility.	Master Sanitation Program		
	B	Pathogen contamination due to damaged cartons / containers (e.g., from forklift, improper stacking procedures)		No	Contamination during storage is prevented by providing training to warehouse employees	Storage program and Personnel Ingredients Handling Training		
	B	Pathogen contamination due to improper employee Hygiene and practices		No	Contamination during storage is prevented by providing training to warehouse employees	Personnel GMP training program		
	C	Cross contamination due to inappropriate allergens product storage		No	Employees are trained on storage and allergen segregation controls	Allergen control program		

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			Yes	No			Yes	No
	C	Contamination by non-food chemicals (e.g., cleaners, sanitizers, lubricants, hydraulic fluids)		No	Employees trained on storage and allergen segregation controls	Chemical control program		
	P	Contamination from hazardous extraneous material due to changed packaging or due to forklift accidents (e.g., wood splinters from damaged pallets) Foreign material falling into uncovered product or by employee handling		No	Good storing practices are followed	Foreign material control program, personnel GMP program & storage program		
Frozen Storage	B	Pathogen growth due to time / temperature abuse during storage		No	Baked product. Frozen storage is intended to lengthen the shelf life of the product – quality parameter	Transportation & storage program, Personnel program		
Shipping	B	Pathogen growth due to poor shipping condition (inadequate sanitation, maintenance, condition of shipping container/ trailer / truck)		No	Employees from the transportation company are trained to maintain sanitary conditions in the truck.	Transportation & Storage Program, Freight Services Requirements Policy, Pre-loading inspection SOP		
	B	Pathogen growth due to time / temperature abuse		No	Trucks & Shipping area maintain adequate	Transportation & Storage Program, Freight		

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			Yes	No			Yes	No
		during transportation or in the shipping area prior to transportation			temperatures. Frozen storage is intended to lengthen the shelf life of the product – quality parameter	Services Requirements Policy		
	C	Chemical contamination from contact with incompatible products or materials during transport		No	Trucks carrying mixed loads do follow proper segregation procedures (applicable if trucks are not sealed prior to shipment)	Transportation & Storage Program, Freight Services Requirements Policy		
	P	Contamination from hazardous extraneous material due to improper handling		No	Warehouse employees are trained on shipping policies, proper product handling to avoid product damage..	Transportation & Storage Program, Freight Services Requirements Policy		

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## Process Preventive Controls

Process Control (s)	Hazards(s)	Critical limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Baking- CCP-1B	Pathogen survival due to improper temperature distribution / time / temperature applications (Salmonella spp, E. coli, Staphylococcus aureus)	Internal temp of 165 °F	Internal temperature	The operator checks the internal temperature of the product with a clean thermometer probe and notes the internal temperature of the product	At the end of each lot that is baked	QA/CCP operator	<ol style="list-style-type: none"> <li>Continue baking till temperature is attained</li> <li>If not, Place product on hold &amp; inform supervisor</li> <li>Investigate &amp; assess</li> <li>Document</li> </ol>	QA reviews data hourly	<ul style="list-style-type: none"> <li>CCP monitoring &amp; verification records</li> <li>Corrective action records</li> <li>Calibration records</li> <li>Validation Records</li> </ul>
Metal Detection: CCP-2P	Metal inclusion	Must be able to detect: 2.5mm Fe, 3.0mm NFe, 3.5mmSS	Proper function of metal detector by detection and rejection of metal	Metal detector and metal test wands: 2.5 mm Fe, 3.0 mm NFe, 3.5 mm 316SS	Start-up, hourly, end of production	CCP Operator	<u>No detection/rejection:</u> <ol style="list-style-type: none"> <li>Stop production.</li> <li>Hold all products from last good check.</li> <li>Adjust metal detector settings. Ensure proper metal detector function.</li> <li>Recheck all products from last good check.</li> <li>Document.</li> </ol> <u>Rejected product:</u> <ol style="list-style-type: none"> <li>Hold product.</li> </ol>	QA verifies twice daily	CCP monitoring & verification records  Corrective action records  Calibration/ Validation records

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							<p>2. Pass through metal detector 3 more times to confirm if product contains metal. (All 3 passes must be successful in order to be placed back on the line).</p> <p>3. Investigate. Determine source. Stop production if necessary.</p> <p>4. Destroy product with confirmed metal contamination.</p> <p>5. Document.</p>		
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## Allergen Preventive Controls

### Ingredient Allergen Identification

Raw Material Name	Supplier	Allergens in Ingredient Formulation								Allergens in Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree nut	Peanut	Fish	Shellfish	
Soy Protein				✓						
Butter			✓							
Oats					✓					
Milk Chocolate, Semi-sweet Chocolate, Ivory chips			✓	✓						
Milk Powder			✓							
Whole eggs		✓								
Flour					✓					

### Production Line Allergen Assessment

PRODUCT: Cookies, Bars and Bites	
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Product Name	Production Line	Intentional Allergens							
		Egg	Milk	Soy	Wheat	Tree nut	Peanut	Fish	Shellfish
National Food Group, D&F Marketing and Preferred Meals Products	Shared line				✓				
Preferred Meals, CsFi, Old Colony and Suter	Shared line	✓			✓				
Nutritional Choices	Shared line		✓	✓	✓				
the Father's Table, Graces Best	Shared line	✓	✓		✓				
Cooper Street Cookies	Shared line	✓			✓				

### Scheduling Implications:

**ALLERGEN CHANGEOVER MATRIX: Production scheduling will take all steps possible to minimize allergen impact by reducing allergen changeover.**

1. The following customer's products are produced first as they have only the wheat allergen.
  - a. National Food Group: Allergens: Wheat
  - b. D&F Marketing: Allergens: Wheat
  - c. Preferred Meals: Allergens: Wheat
2. The following customer's products are produced second as they have two allergens; Egg and Wheat.
  - a. Preferred Meals: Allergens: Egg and Wheat
  - b. CsFi: Allergen: Egg & Wheat
  - c. Suter Foods: Allergens: Egg and Wheat
  - d. Old Colony: Allergens: Egg and Wheat
  - e. Cooper Street Cookies: Egg and Wheat

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3. The following customer's products are produced third as they have three allergens: Dairy, Soy and Wheat or Eggs, Wheat and Butter.
  - a. Nutritional Choices: Allergens: Dairy, Soy and Wheat
  - b. The Father's Table: Allergens: Egg, Wheat and Butter

### Allergen Cleaning Implications: (Required)

A full allergen clean is required at the end of the day and after processing a unique allergen.

Before processing Nutritional Choices Products containing Milk, Soy and Wheat to control for egg residue.

Before processing Father's table products containing Egg, Wheat and Milk to control for soy residue

### Allergen Label Verification Listing

Product	Allergen Statement	Label Number
National Food Group, D&F Marketing and Preferred Meals Products	Contains: Wheat Precautionary labeling (if applicable)	See Label specification register
Preferred Meals, Old Colony, CsFi and Suter Foods	Contains: Egg and Wheat Precautionary labeling (if applicable)	See Label specification register
Nutritional Choices	Contains: Milk, Soy and Wheat Precautionary labeling (if applicable)	See Label specification register
The Father's Table	Contains: Egg, Wheat and Milk Precautionary labeling (if applicable)	See Label specification register
Cooper Street Cookies	Contains: Egg and Wheat Precautionary labeling (if applicable)	See Label Specification register

### Allergen Preventive Control Chart



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Allergen Control	Hazards(s)	Criteria	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Wrapping and Date coding of Product	Undeclared allergens	Label number matches product	Confirm that packaging used matches the product	Visual inspection of the label to match the product	Beginning & end of run when labels are changed	Line operator	If label is incorrect, segregate product, inspect back to last good check and relabel. Identify root cause and conduct training as needed to prevent recurrence	QA reviews and initials records and identifies any trends in data	<ul style="list-style-type: none"> <li>Allergen label verification on line log</li> <li>Corrective actions</li> </ul>
Allergen change over operations, including cleaning performed after the use of other allergenic material on equipment	Cross-contamination with allergens not present in the recipe	No residual allergenic material from previous production	Application of effective cleaning; visual inspection prior to start-up, ATP swabbing and sanitize food contact surface	Refer to Allergen change over procedures SOP	After products containing allergenic materials not in the recipe are handled on the line	Sanitation crew	Re-clean line, ATP swabbing and sanitize the food contact surface	Hygiene audit, allergen swabs, sanitize equipment	<ul style="list-style-type: none"> <li>Sanitation log</li> <li>Corrective actions</li> <li>Validation records</li> </ul>

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## Sanitation Preventive Controls

### Zoning and Related GMP Controls

The ingredient measurement room and processing areas are maintained at a higher hygiene level than receiving, storage, and shipping areas, as specified in Sanitation Procedures SOP.

As specified in Employee Hygiene SOP, employees must put on smocks that do not have pockets, change into factory shoes, put on protective equipment (hair net, beard net), and wash their hands before entering ingredient measurement and production areas.

Equipment and utensils that are cleaned out-of-place are cleaned and sanitized in a wash room adjacent to the processing areas. Clean equipment is dried and stored on racks in an area adjacent to the processing area. The cleaning and sanitation crew have a dedicated room to store cleaning equipment.

### Cleaning and Sanitation

The warehouse and loading areas are dry cleaned. Production areas are maintained dry during production. Food Contact surfaces are wet cleaned. Equipment parts are washed in a designated cleaning room. Equipment surfaces and parts are completely dried prior to production.

Refer to Standard Sanitation Operating Procedures for details.

### Microbiological Verification of Sanitation Practices

A Listeria/Salmonella environmental monitoring program is in place to verify that controls are sufficient to prevent the presence and harborage of Salmonella/Listeria in the environment and equipment.

Additional environmental monitoring is conducted in the event of special circumstances; or audit findings suggesting sanitation controls may be inadequate. See: Environmental Monitoring for Special Circumstances (See SOP# QM 111 Environmental monitoring)

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## Supply-chain-applied Preventive Controls Program

The following ingredients or raw materials requiring a supply-chain-applied control because we do not have an effective control in our facility. Each of these approved suppliers is evaluated according to SOP# QM 015 Ingredient and Material Purchasing Procedure. Verification activities are also conducted as noted below.

<b>Raw Material or Ingredient</b>	<b>Wheat Flour (Bulk and Bagged) and Soy Protein</b>
<b>Approved Supplier and location</b>	Domestic Suppliers
<b>Approval Date</b>	Refer to Register of Approved Suppliers
<b>Hazard requiring a Supply-chain-applied Control</b>	<b>WHEAT - DON/Vomitoxin (<math>\leq 1</math>ppm) SOY PROTEIN Aflatoxin (<math>\leq 20</math>ppb)</b>
<b>Preventive Controls Applied by the Supplier</b>	Refer to Supplier Food Safety File
<b>Type(s) of Supplier Verification</b>	3rd party audit of approved supplier and letter of guaranty are kept on file upon approval - certificates of analysis (COA) on each receiving lot
<b>Verification Procedure(s)</b>	<ul style="list-style-type: none"> <li>A copy of a 3rd party audit report is requested from the supplier annually. The audit date, auditor qualifications, audit procedures and audit results are reviewed by our Quality Assurance Manager. Follow up with the supplier takes place, as necessary, to verify that any corrective actions mentioned in the report have been completed, with records maintained for this activity.</li> <li>For each shipment received, the Shipping/Receiving Clerk verifies that the material is from the approved supplier location using the Bill of Lading, documents the check in the incoming goods/ receiving log and files the Bill of Lading.</li> </ul> <p><b>Certificates of Analysis</b> The PCQI or designate:</p> <ul style="list-style-type: none"> <li>checks the COA for compliance with specification (see below),</li> <li>Documents the check and files the COA with supplier records.</li> <li>If the COA is not provided in the required timeframe, the lot is put on hold and a COA is requested.</li> <li>The lot is rejected if no COA is provided for the lot.</li> </ul>
<b>Records</b>	<ul style="list-style-type: none"> <li>Approved Vendor List</li> <li>Certificates of analysis (COA) on each receiving lot</li> <li>A copy of the audit report and verification of corrective actions taken by the supplier maintained on file by the PCQI/Food Safety Coordinator</li> <li>Incoming goods/ receiving log</li> <li>Bill of Lading verifying each shipment came from an approved supplier</li> <li>Corrective action records</li> </ul>

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<b>Raw Material or Ingredient</b>	<b>Honey, Product of Animal Origin (Whole egg, Milk Powder, Butter)</b>
<b>Approved Supplier and location</b>	Domestic Suppliers
<b>Approval Date</b>	Refer to Register of Approved Suppliers
<b>Hazard requiring a Supply-chain-applied Control</b>	<b>Drug residue, Pesticides, non-food grade materials (Not Detected)</b>
<b>Preventive Controls Applied by the Supplier</b>	Refer to Supplier Food Safety File
<b>Type(s) of Supplier Verification</b>	3rd party audit of approved supplier and letter of guaranty are kept on file upon approval - certificates of analysis (COA) on each receiving lot
<b>Verification Procedure(s)</b>	<ul style="list-style-type: none"> <li>A copy of a 3rd party audit report is requested from the supplier annually. The audit date, auditor qualifications, audit procedures and audit results are reviewed by our Quality Assurance Manager. Follow up with the supplier takes place, as necessary, to verify that any corrective actions mentioned in the report have been completed, with records maintained for this activity.</li> <li>For each shipment received, the Shipping/Receiving Clerk verifies that the material is from the approved supplier location using the Bill of Lading, documents the check in the incoming goods/ receiving log and files the Bill of Lading.</li> </ul> <p><b>Certificates of Analysis</b> The PCQI or designate:</p> <ul style="list-style-type: none"> <li>checks the COA for compliance with specification (see below),</li> <li>Documents the check and files the COA with supplier records.</li> <li>If the COA is not provided in the required timeframe, the lot is put on hold and a COA is requested.</li> <li>The lot is rejected if no COA is provided for the lot.</li> </ul>
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## References:

FSPCA Preventive Controls for Human Food, First edition 2016, Instructor Guide.

USDA Safe internal temperatures - [https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/safe-minimum-internal-temperature-chart/ct\\_index](https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/safe-minimum-internal-temperature-chart/ct_index)

Food Fraud Vulnerability Assessment (internal document)

FDA reference for hard/sharp objects

<https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-ice/documents/webcontent/ucm074554.pdf>

References regarding RTE foods and mycotoxins.

[http://www.foodauthority.nsw.gov.au/Documents/scienceandtechnical/microbiological\\_quality\\_guide\\_for\\_RTE\\_food.pdf](http://www.foodauthority.nsw.gov.au/Documents/scienceandtechnical/microbiological_quality_guide_for_RTE_food.pdf)

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ChemicalContaminantsMetalsNaturalToxinsPesticides/ucm120184.htm>

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US FDA Hazard database (2018)

<https://www.foodcontrolmethods.com/guidance/lookup>