

Product: Clemson Ice Cream (variety of flavors)
Plant Name: Clemson's '55 Exchange Creamery
Address: Newman Hall, Clemson, SC 29634

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Issue Date: 12/9/2016
Supersedes: N/A

Food Safety Plan for Clemson Ice Cream

Prepared by: Kathryn Worley

Reviewed by: _____

Date: _____

Print Name: _____

Title: _____

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Company Overview

'55 Exchange is a very-small (~20 employees, less than \$1 million in sales), student run facility that makes a variety of ice creams that are intended to be ready-to-eat. Some ice cream flavors include:

Vanilla	Butter Pecan	Peach	Black Cherry
Chocolate	Strawberry	Lemon Custard	Coffee
Cookies and Cream	Orange Passion	Golden Tiger	Caramel Cookie Dough
Mint Chocolate Chip	Dark Chocolate Chip	Greek Vanilla Frozen Yogurt	Additional flavors available as created by students

Product is made 1-2 days a week in a single 5-8 hour production shift. Ice cream production starts with washing, assembling, and sanitizing the machine and surrounding area, followed by production (freezing only) of the ice cream, and ends with disassembly and washing of the production space and machine. The ice cream is sold only in '55 Exchange as scoops or prepackaged tubs directly to the consumer. It is not sold elsewhere in any form.

Food Safety Team

Name	Position	Training
Dr. John U. McGregor	Faculty Advisor	
Sara Stancil Cothran*	Faculty Advisor	FSPCA class
Kinsey MacDonald	Director of Manufacturing Operations	

*Preventive controls qualified individual

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Product Description

Product Name(s)	Clemson Ice Cream (Variety of Flavors)
Product Description, including important food safety characteristics	Clemson Ice Cream is a frozen, ready-to-eat dessert that is packaged in 3-gallon food-grade cardboard boxes and covered with a cardboard lid. Prepackaged 58 oz tubs are also hand-filled. The frozen ice cream is placed in a deep freezer, then moved to a storage freezer, and distributed to the '55 Exchange on campus.
Ingredients	Mix (Milk, cream, sugar, nonfat dry milk, whey, ranger stabilizer blend), and other ingredients found in tables 1-3
Packaging Used	3-gallon ready-to-assemble boxes with a cardboard lid or 58 oz. tub with a plastic lid.
Intended Use	Ready-to-Eat
Intended Consumers	Customers of '55 Exchange- Retail
Shelf Life	1-2 years, frozen
Labeling Instructions	Keep Frozen, Label Allergens on Pre-packaged tubs (Vanilla- Contains milk)(Chocolate- Contains Milk. May Contain eggs, wheat, soy. Made in a facility that also uses peanuts and tree nuts).
Storage and Distribution	Frozen storage and retail serving directly to consumer
Approved: Print Name:	Signature: Date:

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Ingredients

Table 1: Shelf-Stable Ingredients used in Clemson Ice Cream

Shelf-Stable Ingredients	Supplier	Packaging
Apple strudel Base	Dippin' Flavors	25 lb. bag in box
Bordeaux Cherries	Dippin' Flavors	3 gallon pail, 25 lbs
Butter Pecan Syrup	Dippin' Flavors	25 lb. bag in box
Butterfinger	US Foods	3 lb. bag in box
Cheesecake Base	Dippin' Flavors	25 lb. bag in box
Chocolate Liquid Chip	Dippin' Flavors	25 lb. bag in box
Chocolate Variegate	Dippin' Flavors	20 lb. plastic pail
Dutch Chocolate	Dippin' Flavors	25 lb. bag in box
Emerald Green Color	Dippin' Flavors	1 qt. HDPE plastic
Espresso Base	Dippin' Flavors	25 lb. bag in box
Four Berry 100% Crushed Smoothie	Dr. Smoothie	6- 46 oz plastic bottles
Frosted Animal Cookies	US Foods	
Heath Bar	US Foods	3 lb. bag in box
Nutella	Grocery Store	13 oz plastic jar
Orange Extract	Dippin' Flavors	1 gal. plastic jug
Oreos	US Foods	2.5 lb. bag in box
Pecans	Golden Kernel	
Pineapple Orange Bits	Dippin' Flavors	25 lb. bag in box
Pistachio Flavor	Dippin' Flavors	1 qt. HDPE plastic
Pretzels	US Foods	7 lb. bag in box
Pumpkin Pie Base	Dippin' Flavors	25 lb. bag in box
Reese's Peanut Butter Cups	US Foods	5 lb. bag in box
Salty Caramel Variegate	Dippin' Flavors	1 gal. plastic pail
Strawberry Puree	Dippin' Flavors	25 lb. bag in box
Strawberry Solid Pack	Dippin' Flavors	3 gallon pail, 25 lbs
Twix	US Foods	5 lb. bag in box
Vanilla Extract	Lochhead	1 gal. plastic jug

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Vanilla Wafers	US Foods	13.3 oz. bag in box
White Chocolate Sauce	Dippin' Flavors	62 oz. plastic jar

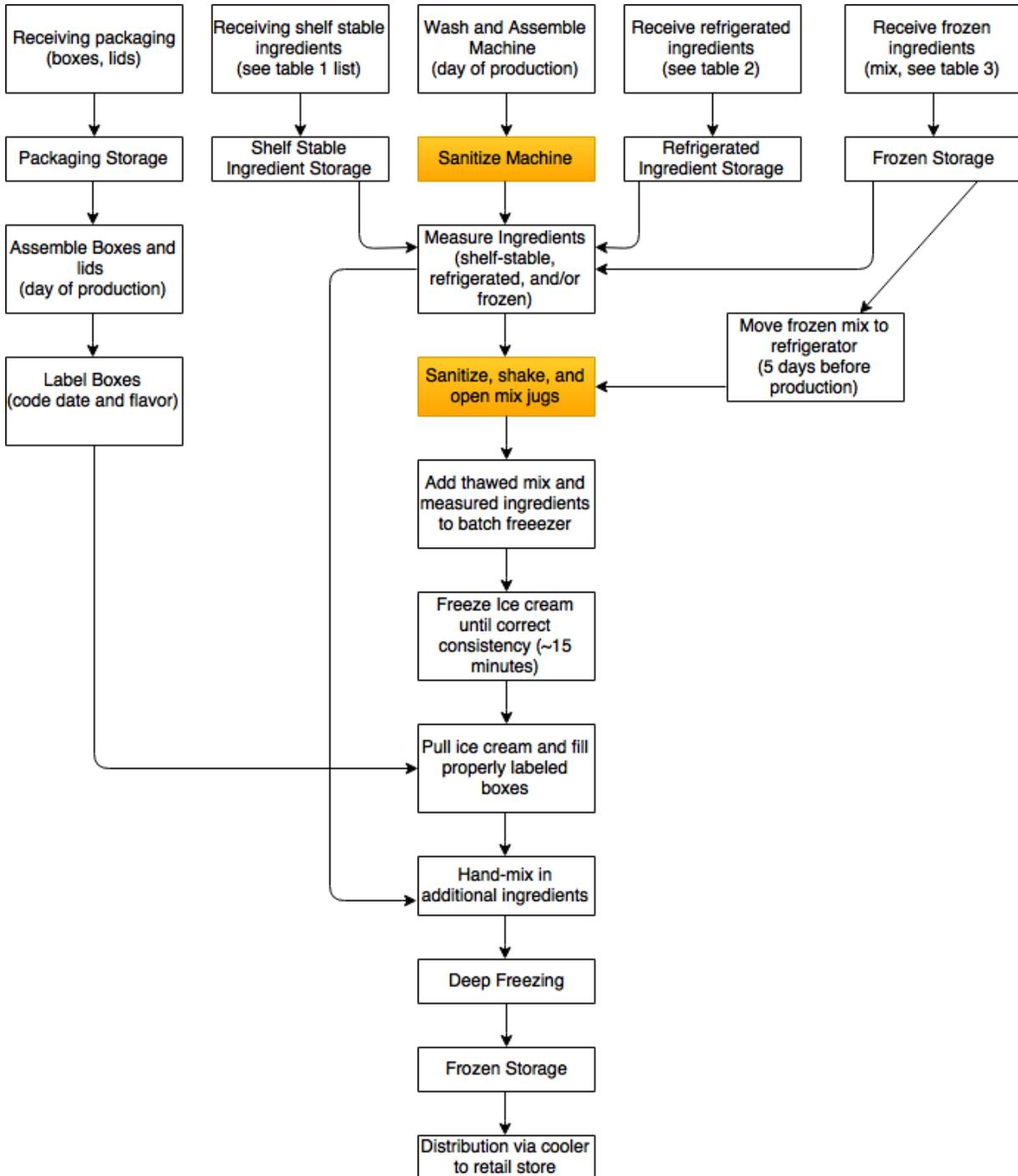
Table 2: Frozen Ingredients used in Clemson Ice Cream

Frozen Ingredients	Supplier	Packaging
Cheesecake Bites	Dippin' Flavors	20 lb. bag in box
Cookie Dough	US Foods	10 lb. bag in box
Flav-R-Flakes	Dippin' Flavors	35 lb. bag in box
Fudge Pieces	Dippin' Flavors	25 lb. bag in box
Welch's Grape Juice Concentrate	Grocery Store	11.5 oz. can
Liquid Ice Cream Mix	Hunter Farms	1 gal. plastic jugs
PB Truffles/Cups	Dippin' Flavors	30 lb. bag in box

Table 3: Refrigerated Ingredients used in Clemson Ice Cream

Refrigerated Ingredients	Supplier	Packaging
Banana Cream Pie Base	Dippin' Flavors	5 gal. bag in pail, 50 lb.
Buttermint Background	Dippin' Flavors	1 gal. plastic jug
Cappuccino Chip Blend	Dippin' Flavors	25 lb. bag in pail
Caramel Variegate, Heavy	Dippin' Flavors	50 lb. plastic pail
Chopped M&M	US Foods	8 lb. bag in box
Graham Crunch	Dippin' Flavors	40 lb. bag in box
Greek Vanilla Yogurt	Grocery Store	32 oz. plastic jar
Lemon Custard Base	Dippin' Flavors	25 lb. bag in box
Orange Sunset	Dippin' Flavors	1 gal. plastic jug
Peach Fresh Flavor	Dippin' Flavors	1 gal. plastic jug
Peaches (diced, stabilized)	Dippin' Flavors	45 lb. bag in box
Snickers	US Foods	5 lb. bag in box

Flow Diagram



Verified by:
Signature:
Date:

Process Narrative

Receiving Ingredients and Packaging

Ingredients and raw materials are purchased from a broker that offers products only from verified suppliers. Ingredients are stored appropriately according to manufacturer's requirements.

- **Receiving Packaging:** Unlabelled 3-gallon boxes and unlabelled lids are received in bulk. Unlabelled 58-oz. tubs and plastic lids are also received in bulk. Specifications require food grade material compatible for frozen foods. Visual inspection of boxes for damage upon arrival.
- **Receiving Shelf-Stable Ingredients:**
 - **Dippin' Flavors:** Ingredients shown in table 1 from Dippin' Flavors are delivered via an unrefrigerated FedEx truck.
 - **US Foods:** Ingredients shown in table 1 from US Foods are delivered via a refrigerated US Foods truck.
 - **Lochhead:** Ingredients delivered via an unrefrigerated truck.
- **Receiving Frozen Ingredients:**
 - **Ice Cream Mix:** Received frozen in boxes of four 1-gallon jugs of liquid ice cream mix from Hunter Farms, NC. Specifications require the pre-pasteurization of the mix for microbial reduction for vegetative pathogens. Truck must be below freezing temperatures.
 - **US Foods:** Ingredients shown in table 2 from US Foods are delivered via a refrigerated US Foods truck. The front section of the truck has a freezer.
 - **Dippin' Flavors:** Ingredients shown in table 2 from Dippin' Flavors are delivered via FedEx on dry ice.
- **Receiving Refrigerated Ingredients:**
 - **Dippin' Flavors:** Ingredients shown in table 3 from Dippin' Flavors are delivered via an unrefrigerated FedEx truck. Unopened ingredients are ok to be shipped unrefrigerated according to Sensient Flavors QA (email attached).
 - **US Foods:** Ingredients shown in table 3 from US Foods are delivered via a refrigerated US Foods truck.

Storing Ingredients and Packaging

- **Packaging Storage:** Unlabelled 3-gallon boxes, cardboard lids, 58-oz tubs and plastic lids are stored in the dry storage room in the production area. Packaging is used First-In-First-Out and partially used cases are taped to close during storage.
- **Shelf-Stable Ingredients:** Ingredients seen in table 1 under ingredients, are stored at room temperature (~70F). Ingredients are used First-In-First-Out and partially used cases are taped to close during storage. Dutch chocolate blend, chocolate liquid chip, apple strudel base, bordeaux cherries, butter pecan syrup, butterfinger, cheesecake base, chocolate variegate, emerald green color, espresso base, heath bar, orange extract, pineapple orange bits, pistachio flavor, pumpkin pie base, Reese's peanut butter cups, salty caramel variegate, strawberry solid pack, strawberry puree, twix, and white chocolate sauce are refrigerated after opening. Pecans are stored in the freezer for extended shelf-life.
- **Frozen Ingredients:** Ingredients seen in table 2 under ingredients, are store in the freezer (-11F). Ingredients are used First-In-First-Out and partially used cases are taped to close during storage. Pecans and other allergens are stored on the bottom shelf in the freezer to reduce the risk of cross contamination.

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- **Refrigerated Ingredients:** Ingredients seen in table 3 under ingredients, are store in the refrigerator (~35F). Ingredients are used First-In-First-Out and partially used cases are taped to close during storage. Graham crunch is stored in the freezer for extended shelf life. Nuts (peanuts and tree nuts) are stored on the bottom shelf in the cooler to reduce the risk of cross contamination.

Thawing Mix: Mix is moved from the freezer (-11F) to the refrigerator (35F) 5 days prior to production for thawing.

Washing and Assembling Machine: The unassembled machine is washed using hot, soapy water (EcoLab General Cleaner 2171 at a rate of 1 oz. per 3 gallons of water) the day of production. The water for both the sink and the hose are run for 1 minute prior to filling containers or spraying the machine. The machine pieces are then rinsed and assembled on a sanitized surface. The inside of the machine is also cleaned using a scrub brush and hot soapy water, followed by a rinse. Small pieces of the machine (such as the o-rings) are sanitized in 100 ppm solution for 2 minutes. The machine is then assembled and closed.

Sanitize machine and other equipment: A bucket of 100 ppm (23mL EcoLab XY-12 sanitizer in 5 gallons water) is created. The 100 ppm sanitizer is poured into the ice cream machine and the machine is turned on to high speed, pulsing for 2 minutes. The sanitizer is then empty as much as possible from the machine into another bucket. Due to the slope of the machine, water is the poured into the machine and pulsed to dilute the sanitizer residue remaining in the barrel of the machine. The remaining sanitizer water is used to sanitize all other equipment (i.e. measuring cups, spatulas, etc.).

Assemble Boxes and Label: Boxes are assembled and lid placed on top. The boxes are then labeled with the code date (code of mix and date of production) on the front side of the box. The flavor is then written on both the front side of the box and on the top of the lid.

Measure Ingredients:

Ingredients are transported from their storage location using a push cooler in small batches.

- **Shelf-Stable:** Ingredients are opened and measured one run before use. Ingredients used for mixing in at the end are separated from the ingredients that are included into the machine.
- **Frozen:** Ingredients are opened and measured one run before use. Ingredients used for mixing in at the end are separated from the ingredients that are included into the machine. The ingredients are then returned to the cooler until the next run.
- **Refrigerated:** Ingredients are opened and measured one run before use. Ingredients used for mixing in at the end are separated from the ingredients that are included into the machine. The ingredients are then returned to the cooler until the next run.

After use, ingredients are returned to their proper storage location.

Sanitize, Shake, and Open Mix Jugs: A bucket of 200 ppm (46 mL EcoLab XY-12 Sanitizer in 5 gallon water) is created. Mix jugs are shaken by hand and submerged in the sanitizer solution for a minimum of 30 seconds. The mix jugs are then opened, paying special attention to keeping the top and tamper evident sealing band attached and out of the machine.

Add Thawed Mix and Other Measuring Ingredients to Ice Cream Freezer: Pour mix into the machine. After mix is added, crush gallon jugs and return the tamper evident band and lid to the top of the jug to make sure all pieces are accounted for. Add the measured ingredients for the beginning of the batch.

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Freeze Ice Cream: Turn the motor and compressor switch on. Add additional ingredients as necessary when stated on the recipe (chocolate liquid chip ~5 minutes, chocolate flav-R-flakes ~6 minutes, etc.). Allow ice cream to freeze on low speed (165 rpm) for about 6 minutes, and then increase speed (200 rpm) for the remaining 2-3 minutes, or until correct consistency. Turn the compressor switch off once correct consistency is achieved.

Pull Ice Cream and Fill Labeled Boxes: The ice cream is pulled from the machine into the properly labeled boxes.

Hand Mix-In Additional Ingredients: Additional ingredients are mixed-in by hand using a spatula.

Deep Freezing: Filled ice cream boxes are promptly (within 5 minutes) placed in the -40F freezer for hardening.

Freezer Storage: Ice cream is moved from the hardening freezers to the -11F freezer, where the frozen ingredients are stored. Ice cream with peanuts or tree nuts are stored on the lower shelves.

Distribution: Students distribute the ice cream by moving the ice cream from the storage freezer to the retail center using the push cooler.

Good Manufacturing Practices and Standard Operating Procedures

See Production Training Manual

*Note: The machine is not washed or sanitized before the next run of ice cream

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 potential food safety hazards introduced, controlled, or enhanced at this step		(3) Do any potential food safety hazards require a preventative control		(4) Justify your decision for column 3	(5) What preventive control measure(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 Packaging	B	None						
	C	None						
	P	None						
Receiving Shelf-Stable Ingredients [Oreos, vanilla wafers, pretzels, frosted animal crackers]	B	None						
	C	Allergen- Wheat	X		Wheat is an allergen that must be labeled to inform consumers. Allergen cross-contact is an issue as flavors are made one after another.	Allergen Control- Proper labeling and informing consumers that all flavors (except vanilla) may contain wheat		X
	P	None						
Receiving Shelf-Stable Ingredients [Dutch Chocolate]	B	None						
	C	None						
	P	None						
Receiving Shelf-Stable Ingredients [Chocolate Liquid Chip]	B	None						
	C	Allergen- Soy	X		Soy is an allergen that must be labeled to inform consumers. Allergen cross-contact is an issue as flavors are made one after another.	Allergen Control- Proper labeling and informing consumers that all flavors (except vanilla) may contain soy		X

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	P	None						
Receiving Shelf-Stable Ingredients- [Nutella]	B	None						
	C	Allergen- Tree Nut (Hazelnut)	X		Tree Nuts are an allergen that must be labeled to inform consumers. Allergen cross-contact is an issue as flavors are made one after another.	Allergen Control- Flavors containing Tree Nuts and/or peanuts are made after other flavors to reduce the likelihood that there will be cross-contamination. Proper labeling and informing consumers that all flavors (except vanilla) may contain Tree Nuts.		X
	P	None						
Receiving Shelf-Stable Ingredients [Vanilla Extract]	B	None						
	C	None						
	P	None						
Receiving Shelf-Stable Ingredients [Apple Strudel Base, Bordeaux Cherries, Espresso Base Dark Roast, Pineapple Orange Bits, Strawberry Solid Pack, Strawberry Puree]	B	None			High acid foods			
	C	None						
	P	None						
Receiving Shelf-Stable Ingredients- [Reese's Peanut Butter Cup, and Butterfinger]	B	Vegetative pathogens such as Salmonella and E. coli	X		Pathogens listed are known to be found in peanuts/peanut butter. These hazards must be controlled by the supplier	Supply-Chain Control- 3rd party audit	X	
	C	Allergen- Peanuts Allergen- Milk Allergen- Soy	X		Peanuts, soy, and milk are allergens that must be labeled to inform consumers. Allergen cross-contact of peanuts and soy is an issue as flavors are made one after another. Allergen cross-contact of milk is not an issue as all flavors contain milk	Allergen Control- Flavors containing Tree Nuts and/or peanuts are made after other flavors to reduce the likelihood that there will be cross-contamination. Proper labeling and informing consumers that all flavors (except vanilla) may contain soy and peanuts.		X
	P	None						
Receiving Shelf-	B	None						

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Stable Ingredients [Emerald Green Color]	C	None						
	P	None						
Receive Shelf- Stable Ingredient Four Berry 100% Crushed Smoothie	B	None						
	C	None						
	P	None						
Receiving Shelf- Stable Ingredients [Twix]	B	None						
	C	Allergen- Wheat Allergen- Milk Allergen- Soy	X		Wheat, soy, and milk are allergens that must be labeled to inform consumers. Allergen cross-contact of wheat and soy is an issue as flavors are made one after another. Allergen cross-contact of milk is not an issue as all flavors contain milk	Allergen Control- Proper labeling and informing consumers that all flavors (except vanilla) may contain wheat and soy		X
	P	None						
Receiving Shelf- Stable Ingredients [Orange Extract, Pistachio Flavor]	B	None						
	C	None						
	P	None						
Receiving Shelf- Stable Ingredients [Salty Caramel Variegate]	B	None						
	C	Allergen- Milk	X		Milk is an allergen that must be labeled to inform consumers. Allergen cross-contact of milk is not an issue as all products contain milk.	Allergen Control- Proper labeling and informing consumers that all flavors contain milk.		X
	P	None						
Receiving Shelf- Stable Ingredients [Cheesecake Base]	B	None			High acid food (pH ~2.5-3.1)			
	C	Allergen- Milk	X		Milk is an allergen that must be labeled to inform consumers. Allergen cross-contact of milk is not an issue as all products contain milk.	Allergen Control- Proper labeling and informing consumers that all flavors contain milk.		X
	P	None						
Receiving Shelf-	B	None			High acid food (pH 3.0-3.6)			

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Stable Ingredients [Butter Pecan Syrup]	C	None						
	P	None						
Receiving Shelf-Stable Ingredients [Heath Bar]	B	None						
	C	Allergen- Tree Nuts (almonds) Allergen-Milk Allergen- Soy	X		Tree Nuts, soy, and milk are allergens that must be labeled to inform consumers. Allergen cross-contact of Tree Nuts and soy is an issue as flavors are made one after another. Allergen cross-contact of milk is not an issue as all flavors contain milk	Allergen Control- Flavors containing Tree Nuts and/or peanuts are made after other flavors to reduce the likelihood that there will be cross-contamination. Proper labeling and informing consumers that all flavors (except vanilla) may contain soy and Tree Nuts.		X
Receiving Shelf Stable Ingredients [White Chocolate Sauce]	B	None						
	C	Allergen- Soy Allergen- Milk	X		Soy and milk are allergens that must be labeled to inform consumers. Allergen cross-contact of soy is an issue as flavors are made one after another. Allergen cross-contact of milk is not an issue as all flavors contain milk	Allergen Control- Proper labeling and informing consumers that all flavors (except vanilla) may contain soy.		X
Receiving Shelf-Stable Ingredients [Chocolate Variegate]	B	None						
	C	None						
Receiving Shelf-Stable Ingredients [Pumpkin Pie Base]	B	None			High acid food (pH 3.0-3.6)			
	C	None						
Receiving Frozen Ingredients [Pecans]	B	None						
	C	Allergen- Tree Nuts	X		Tree nuts are an allergen that must be labeled to inform consumers. Allergen cross-contact is an issue as flavors are made one after another.	Allergen Control- Flavors containing Tree Nuts and/or peanuts are made after other flavors to reduce the likelihood that there will be cross-contamination		X

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	P	Shells	X		Pecans must be shelled by supplier and fragments could remain	Supply Chain Control- Verified Supplier and 3rd Party Audit	X	
Receiving Frozen Ingredients [Cheesecake Bites]	B	Vegetative pathogens such as Listeria monocytogenes	X		Listeria can survive in frozen temperatures. This pathogen must be controlled by the supplier	Supply Chain Control- Verified Supplier and 3rd Party Audit	X	
	C	Allergen- Wheat Allergen- Milk	X		Wheat and milk are allergens that must be labeled to inform consumers. Allergen cross-contact of wheat is an issue as flavors are made one after another. Allergen cross-contact of milk is not an issue as all products contain milk.	Allergen Control- Proper labeling and informing consumers that all flavors (except vanilla) may contain wheat and all flavors contain milk		X
	P	None						
Receiving Frozen Ingredients [Chocolate Chip Cookie Dough]	B	Vegetative Pathogens such as Listeria monocytogenes	X		Cookie dough has recently been recalled due to the presence of Listeria. This pathogen must be controlled by the supplier.	Supply Chain Control- Approved Supplier and 3rd party audit	X	
	C	Allergen- Wheat Allergen- Soy Allergen- May contain Tree Nuts, peanuts, egg, milk	X		Wheat and soy are allergens that must be labeled to inform consumers. Allergen cross-contact is an issue as flavors are made one after another.	Allergen Control- Proper labeling and informing consumers that all flavors (except vanilla) may contain wheat and soy		X
	P	None						
Receiving Frozen Ingredients [Chocolate Flav-R-Flakes]	B	None						
	C	Allergen- Soy	X		Soy is an allergen that must be labeled to inform consumers. Allergen cross-contact is an issue as flavors are made one after another.	Allergen Control- Proper labeling and informing consumers that all flavors (except vanilla) may contain soy		X
	P	None						
Receiving Frozen Ingredients [Old Fashion Fudge Pieces]	B	None						
	C	Allergen- Peanuts			Peanuts are an allergen that must be labeled to inform consumers. Allergen cross-contact is an issue as flavors are made one after another.	Allergen Control- Flavors containing Tree Nuts and/or peanuts are made after other flavors to reduce the likelihood that there will be cross-contamination. Proper labeling and informing consumers that all flavors (except vanilla) may contain		

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						peanuts.		
	P	None						
Receiving Frozen Ingredient [Grape Juice Concentrate]	B	None						
	C	None						
	P	None						
Receiving Frozen Ingredients [Peanut Butter Truffles/Cups]	B	Vegetative pathogens such as Salmonella and E. coli	X		Pathogens listed are known to be found in peanuts/peanut butter. These hazards must be controlled by the supplier.	Supply-Chain Control- approved supplier, 3rd party audit	X	
	C	Allergen- Peanuts Allergen- Soy Allergen- Milk	X		Peanuts, soy, and milk are allergens that must be labeled to inform consumers. Allergen cross-contact of peanuts and soy is an issue as flavors are made one after another. Allergen cross-contact of milk is not an issue as all flavors contain milk	Allergen Control- Flavors containing Tree Nuts and/or peanuts are made after other flavors to reduce the likelihood that there will be cross-contamination. Proper labeling and informing consumers that all flavors (except vanilla) may contain soy and peanuts.		X
	P	None						
Receiving Frozen Ingredients [Liquid Ice Cream Mix]	B	Vegetative pathogens such as Salmonella	X		Raw milk has a history of association with Salmonella. Pasteurization by the supplier can control the hazard	Supply-Chain Control- approved supplier, 3rd party audit	X	
	C	Allergen- Milk	X		Milk is an allergen that must be labeled to inform consumers. Allergen cross-contact of milk is not an issue as all products contain milk.	Allergen Control- Proper labeling and informing consumers that all flavors contain milk.		X
	P	None						
Receiving Refrigerated Ingredients [Banana Cream Pie Base]	B	None			pH=4.2 and Brix = 60			
	C	None						
	P	None						
Receiving Refrigerated Ingredients [Snickers]	B	Vegetative pathogens such as Salmonella and E. coli	X		Pathogens listed are known to be found in peanuts/peanut butter and in eggs. These hazards must	Supply-Chain Control- approved supplier, 3rd party audit	X	

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					be controlled by the supplier			
	C	Allergen- Peanuts Allergen- Milk Allergen- Soy Allergen- Egg	X		Peanuts, soy, and milk are allergens that must be labeled to inform consumers. Allergen cross-contact of peanuts and soy is an issue as flavors are made one after another. Allergen cross-contact of milk is not an issue as all flavors contain milk	Allergen Control- Flavors containing Tree Nuts and/or peanuts are made after other flavors to reduce the likelihood that there will be cross-contamination. Proper labeling and informing consumers that all flavors (except vanilla) may contain soy, egg, and peanuts.		X
	P	None						
Receiving Refrigerated Ingredients [Heavy Caramel Variagate Sauce]	B	None			High sugar content			
	C	Allergen- Milk	X		Milk is an allergen that must be labeled to inform consumers. Allergen cross-contact of milk is not an issue as all products contain milk.	Allergen Control- Proper labeling and informing consumers that all flavors contain milk.		X
	P	None						
Receiving Refrigerated Ingredients - [Lemon Custard Base]	B	Vegetative pathogens such as Salmonella	X		Salmonella is known to be found in eggs. These hazards must be controlled by the supplier	Supply-Chain Control- approved supplier, 3rd party audit	X	
	C	Allergen- Egg Allergen- Milk	X		Egg and milk are allergens that must be labeled to inform consumers. Allergen cross-contact is an issue as flavors are made one after another. Allergen cross-contact of milk is not an issue as all flavors contain milk	Allergen Control- Proper labeling and informing consumers that all flavors (except vanilla) may contain egg and all flavors contain milk.		X
	P	None						
Receiving Refrigerated Ingredients [M&M's]	B	None						
	C	Allergen- Soy Allergen- Milk	X		Soy and milk are allergens that must be labeled to inform consumers. Allergen cross-contact of soy is an issue as flavors are made one after another. Allergen cross-contact of milk is not an issue as all flavors contain milk	Allergen Control- Proper labeling and informing consumers that all flavors (except vanilla) may contain soy and all flavors contain milk.		X
	P	None						

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Receiving Refrigerated Ingredients [Sunset Orange Color]	B	None						
	C	None						
	P	None						
Receiving Refrigerated Ingredients [Peaches, Diced and Stabilized]	B	None			High Acid Food (pH=3.7)			
	C	None						
	P	None						
Receiving Refrigerated Ingredients [Buttermint Background, Peach Fresh Flavor Extract]	B	None						
	C	None						
	P	None						
Receiving Refrigerated Ingredients [Greek Vanilla Yogurt]	B	None						
	C	Allergen- Milk	X		Milk is an allergen that must be labeled to inform consumers. Allergen cross-contact of milk is not an issue as all products contain milk.	Allergen Control- Proper labeling and informing consumers that all flavors contain milk.		X
	P	None						
Receiving Refrigerated Ingredients [Graham Crunch]	B	None						
	C	Allergen- Wheat	X		Wheat is an allergen that must be labeled to inform consumers. Allergen cross-contact is an issue as flavors are made one after another.	Allergen Control- Proper labeling and informing consumers that all flavors (except vanilla) may contain wheat		X
	P	None						
Receiving Refrigerated Ingredients [Cappuccino Chip Blend]	B	None						
	C	Allergen- Soy Allergen- Milk	X		Soy and milk are allergens that must be labeled to inform consumers. Allergen cross-contact of soy is an issue as flavors are made one after another. Allergen cross-contact of milk is not an issue as all flavors contain milk	Allergen Control- Proper labeling and informing consumers that all flavors (except vanilla) may contain soy.		X

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	P	None						
Storing Packaging Ingredients	B	None						
	C	None						
	P	None						
Storing Shelf-Stable Ingredients	B	None						
	C	Allergen cross-contact during storage			Peanuts and tree nuts are stored on the bottom shelf in order to reduce the likelihood of cross-contact to other ingredients. Vanilla is stored in a separate location (window sill). Cross-contact of vanilla (allergen free except milk) is unlikely.	Allergen Control- Visual inspection that ingredients are stored in the proper location		X
	P	None						
Storing Frozen Ingredients	B	Vegetative pathogens	X		If temperature is not kept within range, possible pathogen growth	Process Control- Temperature Monitoring		X
	C	Allergen cross-contact during storage			Peanuts and tree nuts are stored on the bottom shelf in order to reduce the likelihood of cross-contact to other ingredients. Vanilla is stored in a separate location (window sill). Cross-contact of vanilla (allergen free except milk) is unlikely.	Allergen Control- Visual inspection that ingredients are stored in the proper location		X
	P	None						
Storing Refrigerated Ingredients	B	Vegetative pathogens	X		If temperature is not kept within range, possible pathogen growth	Process Control- Temperature Monitoring		X
	C	Allergen cross-contact during storage			Peanuts and tree nuts are stored on the bottom shelf in order to reduce the likelihood of cross-contact to other ingredients. Vanilla is stored in a separate location (window sill). Cross-contact of vanilla (allergen free except milk) is unlikely.	Allergen Control- Visual inspection that ingredients are stored in the proper location		X
	P	None						
Thaw Mix	B	Vegetative pathogens			If temperature is not kept within range, possible	Process Control- Temperature Monitors		

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					pathogen growth			
	C	None						
	P	None						
Wash, Assemble, and Sanitize Machine	B	Environmental pathogens such as L. monocytogenes and S. aureus	X		Recontamination may occur if environmental control or GMPs are not followed	Sanitation Control- training on GMPs	X	
	C	Residual Chemicals		X	Rinsing residual soap from machine and allowing ample time for sanitizer to exit the machine should be sufficient	Sanitation Control- training on GMPs	X	
	P	None						
Assemble and Label Boxes	B	None						
	C	None						
	P	None						
Measure Ingredients	B	Environmental pathogens such as L. monocytogenes and S. aureus	X		Recontamination may occur if environmental control or GMPs are not followed	Sanitation Control- training on GMPs	X	
	C	None						
	P	None						
Sanitize Jugs, remove lids	B	None					X	
	C	None						
	P	Plastic lids and tamper evident plastic tabs	X		Small pieces are easy to fall into ice cream machine	Process Control- Keep lid and tamper evident tabs attached, visual inspection	X	
Add thawed mix and ingredients to batch freezer	B	Environmental pathogens such as L. monocytogenes and S. aureus	X		Recontamination may occur if environmental control or GMPs are not followed	Sanitation Control- training on GMPs	X	
	C	None						
	P	Spatulas or other equipment	X		Students may lose grip of spatulas when scraping all the ingredients	Process Control- Visual Inspection		X
Freeze ice cream until correct consistency	B	None						
	C	None						

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	P	None						
Pull ice cream into labelled boxes	B	None						
	C	Undeclared Allergens	X		Improper labeling of the flavor can lead to undeclared allergens	Allergen Control- Visual Inspection	X	
	P	None						
Hand Mix-In Additional Ingredients	B	Environmental pathogens such as L. monocytogenes and S. aureus	X		Recontamination may occur if environmental control or GMPs are not followed	Sanitation Control- training on GMPs	X	
	C	None						
	P	None						
Deep Freezing	B	Growth of environmental pathogens		X	Product is frozen in under 1 hour and pathogens won't grow in frozen product			
	C	None						
	P	None						
Frozen Storage	B	None						
	C	None						
	P	None						
Distribution	B	None						
	C	None						
	P	None						

Preventive Controls

Process Preventive Controls

Process Controls	Hazard(s)	Criteria	Monitoring				Corrective Actions	Verification	Records
			What	How	Frequency	Who			
Remove lids from mix jugs	Plastic from lids or tamper evident tabs	All lids and tabs must be accounted for	Number of tabs and lids	Recapping all mix jugs with tab and lid after emptied into machine	Every production run	Production Staff	If all lids and tabs are not accounted for 1) turn off machine from the main power source. 2) empty machine, ensuring plastic is removed 3) identify root cause 4) conduct training to prevent recurrence	Faculty advisor, PCQI, or production manager reviews and initials records monthly.	Corrective Action Records, Verification Records, Production Monitor Records
Add thawed mix and ingredients to batch freezer	Spatulas or other physical hazards	All spatulas and equipment must be accounted for and in good condition	Pieces of equipment	Making sure all equipment is in good condition (spatulas not missing a piece)	Every production run	Production Staff	If all equipment is not accounted for or in good condition 1) turn off machine from the main power source. 2) empty machine, ensuring plastic is removed 3) identify root cause 4) conduct training to prevent recurrence	Faculty advisor, PCQI, or production manager reviews and initials records monthly.	Corrective Action Records, Verification Records, Production Monitor Records
Storing Refrigerated Ingredients	Growth of pathogens	Temperature must be between 33-41F	Temperature of walk-in cooler	Continuous temperature monitoring	Continuous	Temperature monitoring system	If temperature is not within range 1) check actual thermometer reading 2) identify root cause 3) calibrate thermometers as necessary	Weekly review of temperature monitor log by faculty advisor, PCQI, or production manager. Yearly thermometer calibration	Thermometer calibration records, verification records, corrective action records, temperature log (online)
Storing Frozen Ingredients	Growth of pathogens	Temperature must be below 20F	Temperature of walk-in freezer	Continuous temperature monitoring	Continuous	Temperature monitoring system	If temperature is not within range 1) check actual thermometer reading 2) identify root cause 3) calibrate thermometers as necessary	Weekly review of temperature monitor log by faculty advisor, PCQI, or production manager. Yearly thermometer calibration	Thermometer calibration records, verification records, corrective action records, temperature log (online)

Allergen Preventive Controls

Allergen Controls	Hazard(s)	Criteria	Monitoring				Corrective Actions	Verification	Records
			What	How	Frequency	Who			
Storing Shelf-Stable, Refrigerated, and Frozen Ingredients	Cross-contact of ingredients without allergens	Nut (tree nut and peanuts) are stored on bottom shelf	Proper storage location of nut allergen ingredients	Visual inspection that ingredients are stored on bottom shelf	Each Production	Production Manager or designee	<p>If allergen product is stored in the wrong place: 1) move ingredient to proper location 2) retrain employee on proper storage</p> <p>If cross-contact occurs: 1) isolate the ingredient. 2) label any products that include the ingredient that the allergen is present.</p>	Faculty advisor, PCQI, or production manager reviews and initials records monthly.	Corrective Action Records, Verification Records, Production Monitor Records
Pull ice cream into labeled boxes	Undeclared allergens	Correct flavor printed on box	Label matches product	Visual inspection of all finished product boxes to ensure proper flavor labeling	Each Production Run	Production Staff	<p>If label is incorrect 1) segregate product, inspect back to last good check, relabel the boxes with proper flavor. 2) identify root cause. 3) conduct retraining as necessary</p>	Faculty advisor, PCQI, or production manager reviews and initials records monthly.	Corrective Action Records, Verification Records, Production Monitor Records

Allergen Declaration

- Vanilla- Contains milk.
- All other flavors (not containing nuts)- Contains milk. May contain soy, egg, or wheat. Processed in a facility with peanuts and tree nuts.
- All other flavors (containing nuts)- Contains milk. May contain soy, egg, wheat, peanuts, and/or tree nuts.

A sign is posted in the store to inform customers of the allergens. The label on the 58 oz. tubs declares the allergens as listed above.

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Allergen Scheduling and Cleaning Implications

Flavor	Intentional Allergens							
	Egg	Milk	Soy	Wheat	Tree Nuts	Peanuts	Fish	Shellfish
Vanilla		X						
Chocolate		X						
Dark Chocolate Chip		X	X					
Cookies & Cream		X		X				
Mint Chocolate Chip		X	X					
Lemon Custard	X	X						
Orange Passion		X						
Butter Pecan		X			X			
Strawberry		X						
Black Cherry		X						
Coffee		X						
Golden Tiger		X						
Greek Vanilla Fro-Yo		X						
Cheesecake		X		X				
Banana Pudding		X		X				
Caramel Cookie Dough		X	X	X				
English Toffee Heath		X	X		X			
Hot Apple Pie		X		X				
Chocolate Fudge Brownie		X				X		

*More flavors available. Allergens are listed in the hazard analysis for each individual ingredient. Because of the large variety of flavors and allergens, we focus on eliminating the cross-contact of peanuts and tree nuts, and all other flavors may contain wheat, soy, and/or eggs. Milk is present in all flavors so is not a concern.

Scheduling Implications:

Standard practice is to run vanilla first to reduce the potential for cross-contact of all allergens (other than milk). Flavors not containing peanuts and/or tree nuts are run following the vanilla to reduce the potential for allergen cross-contact of nuts. Finally, flavors containing peanuts and/or tree nuts are run last.

Allergen Cleaning Implications:

A full allergen cleaning and sanitation is **required** AFTER the production of flavors containing peanuts and/or tree nuts because they contain the unique allergen of peanuts and/or tree nuts.

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Sanitation Preventive Controls

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

Ice Cream Freezing Machine (barrel and other parts)

- **Purpose:** Cleaning and sanitizing of the ice cream freezing machine is important to remove potential allergens and reduce microbial cross-contamination or recontamination with environmental pathogens that may impact product safety.
- **Frequency:** Machine and pieces are cleaned and sanitized before beginning production. All equipment is recleaned after production the same day.
- **Who:** Production staff member(s)
- **Procedure:**

Cleaning

1. Remove gross soil by spraying with water
2. Wipe surface of barrel with a white bristle cleaning brush, dipped in EcoLab 2171 General Cleaner (1 oz. per 3 gallon water).
3. Wash pieces of unassembled machine with a white bristle cleaning brush, dipped in EcoLab 2171 General Cleaner (1 oz. per 3 gallon water).
4. Rinse barrel and pieces of unassembled machine with clean hot water. Detergent remaining on the surface can inactivate the sanitizer.

Sanitizing

1. Sanitize pieces of unassembled machine by dipping in 100 ppm EcoLab XY-12 Sanitizer (hypochlorite) for 2 minutes.
 2. Sanitize barrel of machine by pouring 100 ppm EcoLab XY-12 Sanitizer (hypochlorite) into the assembled machine and pulsing the dasher for 2 minutes.
- **Monitoring:** Inspect the pieces of machine and the barrel for residual soil and cleanliness. Record on Daily Sanitation sheet.
 - **Corrections:** If residual soil is observed on the machine or pieces, reclean and sanitize.
 - **Records:** Daily sanitation Sheet
 - **Verification:** Supervisor reviews and signs Daily Sanitation Sheet within 10 working days.

Ingredient Preparation Table Sanitation

- **Purpose:** Cleaning and sanitizing of the ingredient preparation table is important to remove potential allergens and reduce microbial cross-contamination or recontamination with environmental pathogens that may impact product safety.
- **Frequency:** Table is cleaned and sanitized the before beginning and at the end of daily production.
- **Who:** Production staff member
- **Procedure:**
 - Cleaning
 1. Remove gross soil with a cloth.
 2. Wipe surface of table with a yellow bristle cleaning brush, dipped in EcoLab 2171 General Cleaner (1 oz. per 3 gallon water).
 3. Rinse table with clean hot water. Detergent remaining on the surface can inactivate the sanitizer.
 - Sanitizing
 1. Sanitize table by spraying with 200 ppm EcoLab XY-12 Sanitizer (hypochlorite) and let sit.
 2. Allow to air dry.
- **Monitoring:** Inspect the table for residual soil and cleanliness. Record on Daily Sanitation sheet.
- **Corrections:** If residual soil is observed on the table, reclean and sanitize.
- **Records:** Daily sanitation Sheet
- **Verification:** Supervisor reviews and signs Daily Sanitation Sheet within 10 working days.

Environmental Sanitation

- **Purpose:** Cleaning the floors is important to reduce microbial cross-contamination or recontamination with environmental pathogens that may impact product safety.
- **Frequency:** Daily, after production
- **Who:** Production staff member
- **Procedure:**

Note: Separate tools are used for floors because of the potential for higher levels of contamination. All floor cleaning supplies are red.

 - Cleaning
 1. Remove gross soil with squeegee
 2. Scrub floor using a red bristle brush, or mop with a disposable mop head and EcoLab General Cleaner 2717 and hot water. Change mop head as necessary.
 3. Rinse floor with clean, hot water.
 4. Squeegee floors until dry.
- **Monitoring:** Inspect the floor and surrounding area for residual soil and cleanliness. Record on Daily Sanitation sheet.
- **Corrections:** If residual soil is observed on the floor or walls, reclean and sanitize.
- **Records:** Daily sanitation Sheet
- **Verification:** Supervisor reviews and signs Daily Sanitation Sheet within 10 working days.

Supply-Chain Preventive Control Program

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

Ingredient (requiring supply-chain- applied control)	Approved Supplier	Hazard(s) requiring supply-chain-applied control	Date of Approval	Verification Method	Verification Records
Reese's Peanut Butter Cup, Snickers and Butterfingers	US Foods	Pathogens such as Salmonella and E. coli are known to be found in peanuts/peanut butter.			
Peanut Butter Truffles/Cups	Dippin' Flavors	Pathogens such as Salmonella and E. coli are known to be found in peanuts/peanut butter.	11/17/2016	3rd Party Audit	Audit Certification in Records
Liquid Ice Cream Mix	Hunter Farms	Vegetative pathogens such as Salmonella	12/8/2016	3 rd Party Audit	Audit Certification in Records
Lemon Custard Base	Dippin' Flavors	Pathogens such as Salmonella	11/17/2016	3 rd Party Audit	Audit Certification in Records

Receiving Procedure for Ingredients Requiring a Supply-chain-applied Control

- **Purpose:** Ensure that all ingredients requiring a supply-chain-applied preventive control are received from approved suppliers with appropriate preventive controls in place.
- **Frequency:** Each delivery
- **Who:** Stocker
- **Procedure:**
 1. Verify that each load of ingredients was produced by the approved supplier by checking the bill and manufacturer's name on the cases received.
 2. Write the ingredients received, how many, and the ingredient codes.
 3. Document on receiving sheet.
- **Corrections:** Any product requiring supply chain control that is not from a verified supplier must be sent back or verified by testing that ingredients are ok.
- **Records:** Receiving sheet
- **Verification:** Within 5 working days after receiving the order by Manager, PCQI, or Faculty Advisor.

Other Supply Chain-Verification

- A copy of each ingredient specification must be kept on file.
- DHEC Plant Reports must be kept on file.
 - Reports include the following:
 - Date Sample was collected by DHEC
 - Date Sample was plated
 - Temperature of sample at both collection and receipt
 - Ice cream flavor
 - Ice cream code
 - Standard Plate Count/mL (must be less than 250 estimated)
 - Coliform Count (must be less than 1 estimated)
 - Phosphatase (must be less than 1 ug/mL if tested)

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Recall Plan

Recall Team

Dr. Johnny McGregor

Faculty Advisor and Senior Operations Manager

johnny@clemson.edu

Mobile: (864) 650-0817

Office: (864) 656-3397

Fax: (864) 656-0331

Sara Stancil Cothran

Faculty Advisor and Senior Sales Manager, PCQI

sstanci@clemson.edu

Mobile: (864) 508-0875

Kinsey MacDonald

Student Director of Operations

kinseym@g.clemson.edu

Mobile: (803) 807-6835

Theresa Pometto

Student Director of Sales

tcpometto@g.clemson.edu

Mobile: (515) 298-0878

Bruce Rushton

South Carolina Department of Health and Environmental Control (DHEC)

rushtobw@dhec.sc.gov

Bonita Chester

FDA Recall Coordinator- Resident in Charge

300 Executive Center Dr., Suite 200 B, Greenville, SC 29615

Office: (864) 234-9966

Fax: (864) 234-0806

Updated information of the local FDA recall coordinator:

(<http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123522.pdf>)

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Other Important Contacts

Retail Center- '55 Exchange

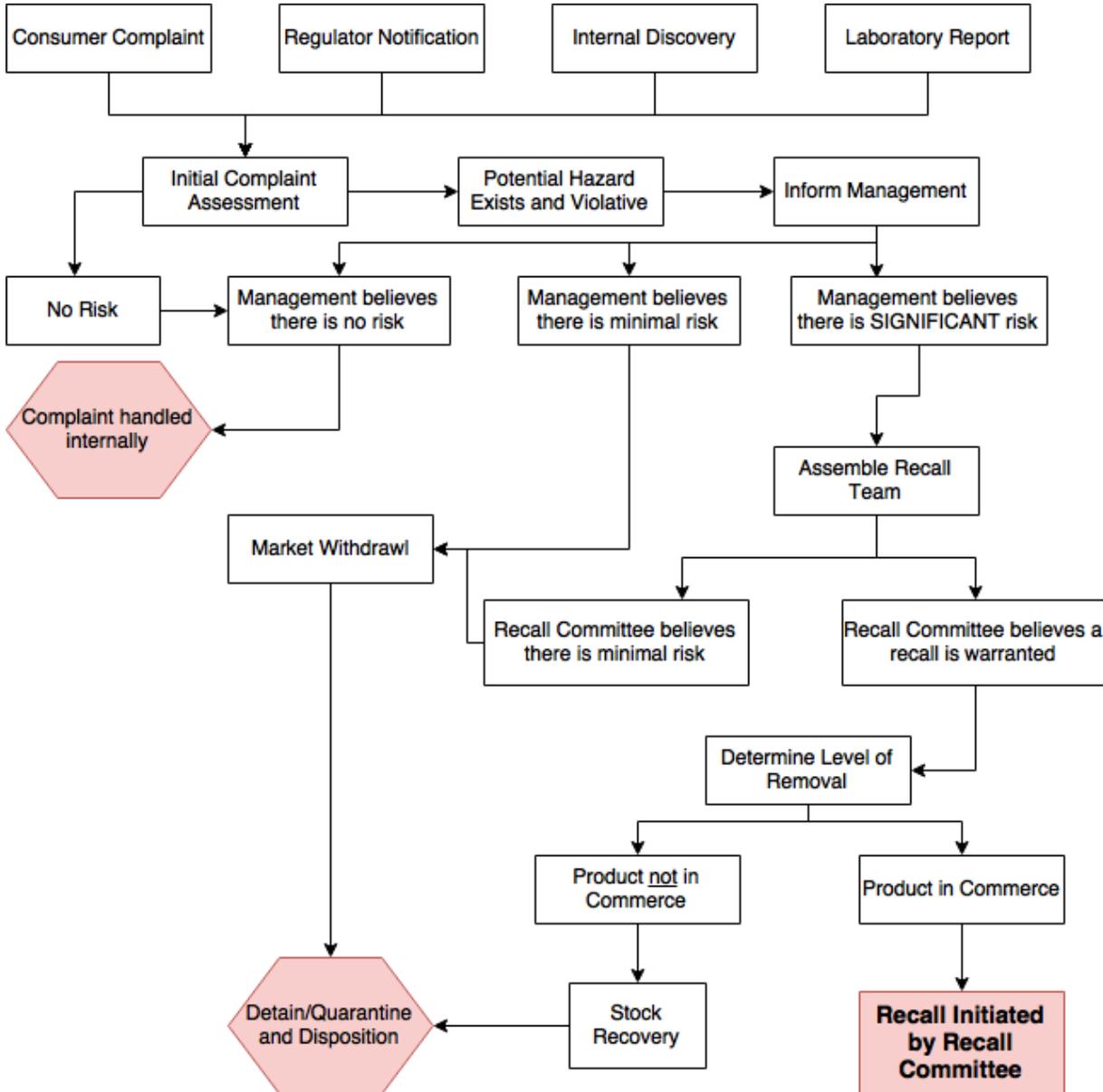
Hendrix Student Center- 720 McMillan Rd, Clemson, SC 29634
(864) 656-2155

Suppliers

See tables 1-3 in the background section for information on ingredient and supplier relationships.

- *Dippin' Flavors*
Mary McCole- mary@lilar.com
1820 South 3rd Street, St. Louis, MO 63104
1-800-886-DIPN (3476)
- *Hunter Farms*
Dwight Moore, Director- dmoore@harristeeter.com
1900 North Main Street, High Point, NC 27262
336-889-1363
- *US Foods*
Billy Hilger- william.hilger@usfoods.com
800 Food Service Drive, Fort Mill, SC 29715
1-800-624-5244
- *Lochhead Vanilla*
Darian Rottmann- darian@lochheadvanilla.com
527 Axminster Drive, Fenton, Missouri 63026
Office: 618-524-4398 Cell: 618-645-2770
- *Golden Kernel Pecan Company*
David Summers or Bill Summers
5244 Cameron Road, Cameron, SC 29030
(803) 823-2311

Deciding if a Recall Action is Necessary Flowchart



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Recall Steps:

Once it has been determined that a recall is necessary, follow these steps:

Step 1: Assign Responsibilities

Assemble the recall team to determine who will be responsible for each task.

Step 2: Gather Evidence

Gather lab test results (if applicable) and customer complaints.

Step 3: Analyze Evidence

Determine the root cause of the recall.

Step 4: Remove recalled ice cream from '55 Exchange Retail Center.

Bring recalled ice cream back to a designated recall spot (top loading freezer) in the production space **IF** it will not put other products at risk. If it will put other products at risk, carefully note how many 3-gallon boxes and 58-oz. tubs of each flavor were removed from the store, with their product codes and flavors. Take pictures as evidence as to what recalled products were removed.

Step 5: Inform FDA

Communicate with the FDA about the recall. Form templates are following.

Step 6: Contact Suppliers (if applicable)

If the root cause was due to a contaminated ingredient, inform the supplier of the recall via email or fax. Supplier information is listed under "Other Important Contacts" above. A draft letter to be sent to the suppliers follows.

Step 7: Inform Customers

Public contact listed in the recall team will inform customers if there is a possibility that their ice cream tub is contaminated. Let the customer know the code date (located on the bottom of the tub) and flavor. Customers will be informed via the '55 Exchange Website (www.clemson.edu/icecream). Also inform all customers via the website that if they were affected by the product (had the effects of the recall after consuming the product) to call Dr. Johnny McGregor.

Step 8: Monitor the recall

Determine how many of the 58-oz tubs were sold and how many 3-gallon boxes of ice cream were produced, sold, and still remaining in inventory. Maintain a log of all decisions made throughout the recall. This can be done by looking at the production run sheet to see how much ice cream was made. The difference between the amount made and amount still in inventory is how much was sold.

Step 9: Dispose of the product

After determining that all of the recalled product has been removed from the store, dispose of by following the procedure under "Product Destruction" in FDA Communication.

Step 10: Apply for termination of the recall

Speak to the FDA Recall Coordinator (information above) to get proper documentation.

Step 11: Debrief

Set up a meeting with the recall team to discuss the recall and how things went. Discuss how to improve on the recall plan.

Step 12: Prepare for Legal Issues

Contact an attorney for any legal issues that may arise.

Step 13: Reanalysis of Food Safety Plan is Required

Corrective action to ensure that the same recall does not happen again involves analyzing the food safety plan. The plan may need modification, and/or employees may need to be retrained to enhance the implementation effectiveness.

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Product Destruction/Reconditioning

- Method of Destruction
 - Bag ice cream into black plastic trash bags. Throw ice cream into landfill.
- Contact the local FDA District recall Coordinator (found under "other important contacts") prior to product destruction. FDA will review the proposed method of destruction and may choose to witness the destruction.
- Keep documentation, such as photos, of product destruction (and whether the destruction was witness by FDA investigator).

FDA Communication

Fill in the following pages. Send the following information to the local FDA District Recall Coordinator (found above in Recall Team).

Recalling Firm

'55 Exchange Creamery (Manufacturing)
Newman Hall, Clemson, SC 29634
Manufacturer, Own-Label Distributor

'55 Exchange is a student run enterprise. It services the university campus through serving homemade ice cream to customers of '55 Exchange Retail Operation. The ice cream is frozen on campus and brought to the retail center using a large push cooler and sold only to customers of '55 Exchange Retail Center. The ice cream is never shipped by '55 Exchange or sold/distributed off campus. Customers may buy tubs of ice cream in the retail center on campus to take home.

55 Exchange Contacts

Position	Name, Title	Contact Information
Recall Coordinator and Public Contact	Dr. John U. McGregor Faculty Advisor	Mobile: (864) 650-0817 Office: (864) 656-3397 Fax: (864) 656-0331 Email: johnny@clemson.edu

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Recalled Product Information

Product Name(s) / Flavor(s)	Clemson Ice Cream - Flavors
Product Description, including important food safety characteristics	Clemson Ice Cream is a frozen, ready-to-eat dessert that is packaged in 3-gallon cardboard boxes and covered with a cardboard lid. Prepackaged 58 oz tubs are also hand-filled. The frozen ice cream is placed in a deep freezer, then moved to a storage freezer, and distributed to the retail store on campus.
Ingredients	Liquid Ice Cream Mix (Milk, cream, sugar, nonfat dry milk, whey, ranger stabilizer blend), and other ingredients found in tables 1-3
Packaging Used	3-gallon ready-to-assemble boxes with a cardboard lid or 58 oz. tub with a plastic lid.
Intended Use	Ready-to-Eat
Intended Consumers	Customers of '55 Exchange- Retail
Expected Shelf Life	1-2 years, frozen
Labeling Instructions	Keep Frozen
Storage and Distribution	Frozen storage and retail serving directly to consumer
Product Number(s) Involved <i>Ice Cream Mix Code followed by the Date (MM/DD/YY)</i> Ex. 07516071916	
Approved: Print Name:	Signature: Date:

*Bolted Text=Add necessary information for the recall.

Include:

- Individual package label: (**2** pictures of the labeled 3-gallon box and/or 58 oz. tubs). The pictures should include a picture of the packaging with the code (and where to find it) and the flavor.

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Reason for the Recall

Explain in detail how product is defective or in violation	
Explain how the defect affects the performance and/or safety of the product. Include an assessment of the health risk associated with the deficiency, if any.	
If recall is due to a foreign object (physical hazard), describe the object's' size, composition, hardness, and sharpness.	
If the recall is due to a contaminant (cleaning fluid, etc.) explain the level of contaminant in the product. Provide the MSDS for the contaminat.	
If the recall is due to failure of the product to meet product specifications, provide the specifications and report all test results. Include copies of sample analysis, if applicable.	
If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), descriptions(s), and formulation(s).	
Explain how the problem occurred and the date it occurred. (e.g. mishandling,	
Explain if the problem/defect affects ALL units subject to recall, or just a portion of the units in the production run. (e.g. all flavors after_____).	
Explain why this problem affects only those products subject to recall. (e.g. flavor was made after other flavors)	
Provide detailed information on complaints associated with the product/problem: <ul style="list-style-type: none"> ● Date of complaint ● Description of complaint (including injury or illness) ● Product Number Involved 	
Health Hazard associated with the product	
If South Carolina DHEC is involved in this recall, identify contact.	

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Volume of Recalled Product

Total quantity produced	
Date(s) produced	
Quantity Distributed to '55 Exchange	
Date(s) distributed (approx.)	
Quantity on Hold	
Indicate how the product is being quarantined	
Estimate amount remaining in the marketplace (if all 3-gallon boxes have been removed from the store, estimate 0 3-gallon boxes. If tubs are effected, determine the amount of tubs sold after the recalled tubs had been brought to the store).	
Provide the disposition of the marketed product (e.g. destroy).	

Distribution Pattern: '55 Exchange only distributes to the 1 retail location in Hendrix Student Center on Clemson University Campus. Clemson's Ice Cream is not sold under Government Contract or to a school lunch program.

Consignee List

Retail Center- '55 Exchange

Address: Hendrix Student Center- 720 McMillan Rd, Clemson, SC 29634

Contact Name: Sara Stancil Cothran or Student Director of Sales

Retail Center Phone: (864) 656-2155

Recalled Product was Delivered? _____

Recalled Product was Sold? _____

Effectiveness Check

Consignee	Recall Contact (name and contact info)	Date Contacted	Method of contact (phone, email, fax, letter, website)	Date of response	Number of products returned
'55 Exchange Retail Center	N/A (within house)		Face-to-Face		
'55 Exchange Customers	N/A		Website	Keep a list (name, date, response) of all customers	

Recall effectiveness = 100 x (# product recovered/ total product distributed)

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Draft Recall Notice

'55 Exchange Voluntarily Recalls Clemson [Flavors] Ice Cream Representing [X] Quantity [No Other Product Affected]

Contact
[Name]
[Phone/Email]

FOR IMMEDIATE RELEASE- [date] - '55 Exchange is voluntarily recalling [quantity] of [boxes/tubs] of [Flavor, specific description] ice cream with product code [code]. [Insert reason for recall].

This action relates only to '55 Exchange products with any of these flavors and codes printed on the package:

- [Insert code date]
- [Flavors]

Only these specific codes are impacted. Retail is asked to remove all product with codes listed below out of sales immediately. Customers should dispose of the product by [how] and call the number listed above. Anyone with questions may call the number listed or visit our website for further instructions.

'55 Exchange is conducting this voluntary recall because [product name(s)] [reason for recall]. [Modify as necessary. We have not received any reports of illness associated with this product, but we are voluntarily recalling this product out of caution.]

'55 Exchange promotes itself on it's high quality, and safe ice cream. [Insert more]

For more information or assistance, please contact us at [phone] (Monday to Friday, 9:00 a.m. to 5:00 p.m. EST) or via email at [email].

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Implementation Records and Forms

Implementation records and forms used for Preventive controls include the follow:

- Monitoring records for preventive controls
 - Personal Practices
 - Ingredient Codes
 - Employee Training
 - Daily Sanitation Control Records
- Incident Report/ Corrective action records
- Supply-chain program records
 - Ingredient Specifications from Supplier (updated as new specs arise or new ingredients are added)
 - DHEC Test Results
 - 3rd Party Audit Certifications
- Training records for the qualified individuals
- Food Safety Plan Reanalysis Report

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Daily Production GMP Monitoring Records

Instructions:

Monitoring procedure: During every production, the production manager monitors to ensure each requirement is met. Put a check in the box if OK. Put an X in the box if something is WRONG.

Corrective actions: If requirements are not met, the monitor takes corrective action (ex. verbal warning, retrain, etc.) and records on this sheet.

#	Requirement	Date			
1	Employees come to work clean and follow good personal hygienic practices during work				
2	Employees follow hand washing procedure and wash hands frequently				
3	Employees wear designated clothing in good repair and follow clothing, headwear, and footwear procedures				
4	Employees report to management any injury occurred during work and cover it to prevent cross contamination				
5	Employees with a transmittable disease do not handle food or work in production area				
6	Visitor access to facility is controlled				
7	Visitors follow personnel practices policy				
8	All lids and tamper evident tabs off mix jugs are accounted for				
9	Boxes are properly labeled with the correct flavor				
10	Ingredients are stored in proper location (nut allergens)				
	Initials				

Corrective Actions

Date	Deviation	Corrective Action	Corrected By:

Reviewed by: _____ Date: _____

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Ingredient Codes

Daily Production Ingredient Codes			
Directions: Fill in any lot #, manufacture/expiration date that you can find on the ingredient package. Please note: unknown symbols should not be used on this sheet. If unsure, write a note.			
Mix Code:			
Ice Cream Flavor	Ingredient	Code	Manufacture/ Expiration Date

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Incident Report/ Corrective Action Form

This includes personal injury/safety, food quality and/or safety.

*Personal injury must also complete University Form.

Completed by: _____

NOTE: When an incident occurs, management must be notified immediately. Follow up by filling in this form and giving it to management.

Information on the incident

Date: _____

Time of incident: _____

Nature of incident: _____

Location of incident: _____

Employee name: _____

Description of the incident: _____

(Complete this section only if the incident affected food safety.)

Supervisor's name: _____

Shift: _____

Product affected: _____

Code Date: _____

Action taken: _____

Additional comments: _____

Supervisor's signature: _____

Reviewers Signature: _____ **Date:** _____

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Daily Sanitation Control Records

Sanitation Area and Goal	Pre-Op Time:	Start Time:	Post-Op Time:	Comments and Corrections	Operator Initials
Condition of Equipment (Is all equipment working properly and intact?) (S/U)					
Equipment is cleaned and sanitized (no visible residue, not slimy to touch, etc.) (S/U)					
Prevention of allergen cross contact (clean after nuts) (S/U/NA)					
Tables cleaned and sanitized (S/U)					
Floors and wall splash zones cleaned and sanitized (S/U)					
S= Satisfactory					
U= Unsatisfactory (write correction to make satisfactory)					
NA= Not applicable because nut allergens are run after other products					
Verification Signature:				Date:	

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Semester Creamery Sanitation Tasks

Directions: Place a check in the "Completed" Column once task is complete. Person who completed the task initials in the next column.

Task #	Task	Completed	Initials
1	Clean rain boots (use red brush)		
2	Clean drying rack (scrub and reorganize)		
3	Clean defrosted -40F freezers (inside and out)		
4	Wipe down sinks, splashguard, under sinks and all surrounding area		
5	Wipe down dry storage shelves and reorganize in creamery		
6	Wipe down dry storage shelves and reorganize in Newman 114		
7	Clean and sanitize tub and lid containers (white storage containers)		
8	Clean and sanitize all buckets		
9	Scrub trash can		
10	Mop dry storage area of creamery		
11	Pressure wash/scrub floors/grout (hose and red brush)		
12	Scrub floor trimming (red brush)		
13	Clean all walls (yellow brush)		
14	Clean hose and nozzle		
15	Wipe down all doors and door handles		
16	Clean windows		

Verified by:		Date:	
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Food Safety Plan Reanalysis Checklist

The food safety plan must be reviewed at least every 3 years. If the FDA determines it is necessary to respond to new hazards, a significant change that creates the potential for new hazards, new information surfaces about potential hazards associated with the product, after a food safety problem, or when a preventive control is ineffective, the food safety plan must be analyzed prior to the 3 year requirement.

Food Safety Plan Reanalysis Checklist				
Reason for Reanalysis:				
Task	Date Reviewed and Initials	Is Update Needed? (yes/no)	Date Task Completed	Signature of Person Completing the Task
List of Food Safety Team with individual responsibilities				
Product Flow Diagram				
Hazard Analysis				
Process Preventive Controls				
Food Allergen Preventive Controls				
Sanitation Preventive Controls				
Supply-Chain Program				
Recall Plan				
Updated Food Safety Plan Implemented				
Updated Food Safety Plan signed by faculty advisor				
Reviewer Signature:			Date Reviewed:	