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PLANT NAME:	Cookie Mania	ISSUE DATE 09/06/2019
ADDRESS:	1 Cookie Land Boulevard, Sweetsville MA 04313	SUPERSEDES 03/30/2016

Selected Sections of a Food Safety Plan Teaching Example- Small Scale Operation

Food Safety Plan for Chocolate Chip Cookie

Developed by: Matt Cook PCQI Date: 09/07/2019

Approved by: Bill Manage Plant Manager Date: 09/12/2019

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

This Food Safety Plan template is modeled after forms developed for the FSPCA Preventive Controls for Human Food curriculum, and can be modified to reflect the need of individual establishment needs. FSPCA has no input on individual establishment Food Safety Plans.

There is no standardized or mandated format for a Food Safety Plan, but the information should be arranged in a progressive manner that clearly explains the thought process for the hazard analysis and the individual steps in the Food Safety Plan. Forms used for process preventive controls may be adapted for other types of preventive controls, but other formats are entirely acceptable if it works for your organization and contains all of the required information.

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Company Overview

[Provide a brief description of the company. Consider listing members of the food safety team, if you have one. Consider including a company organization chart and/or plant layout, if it helps explain the food safety plan]

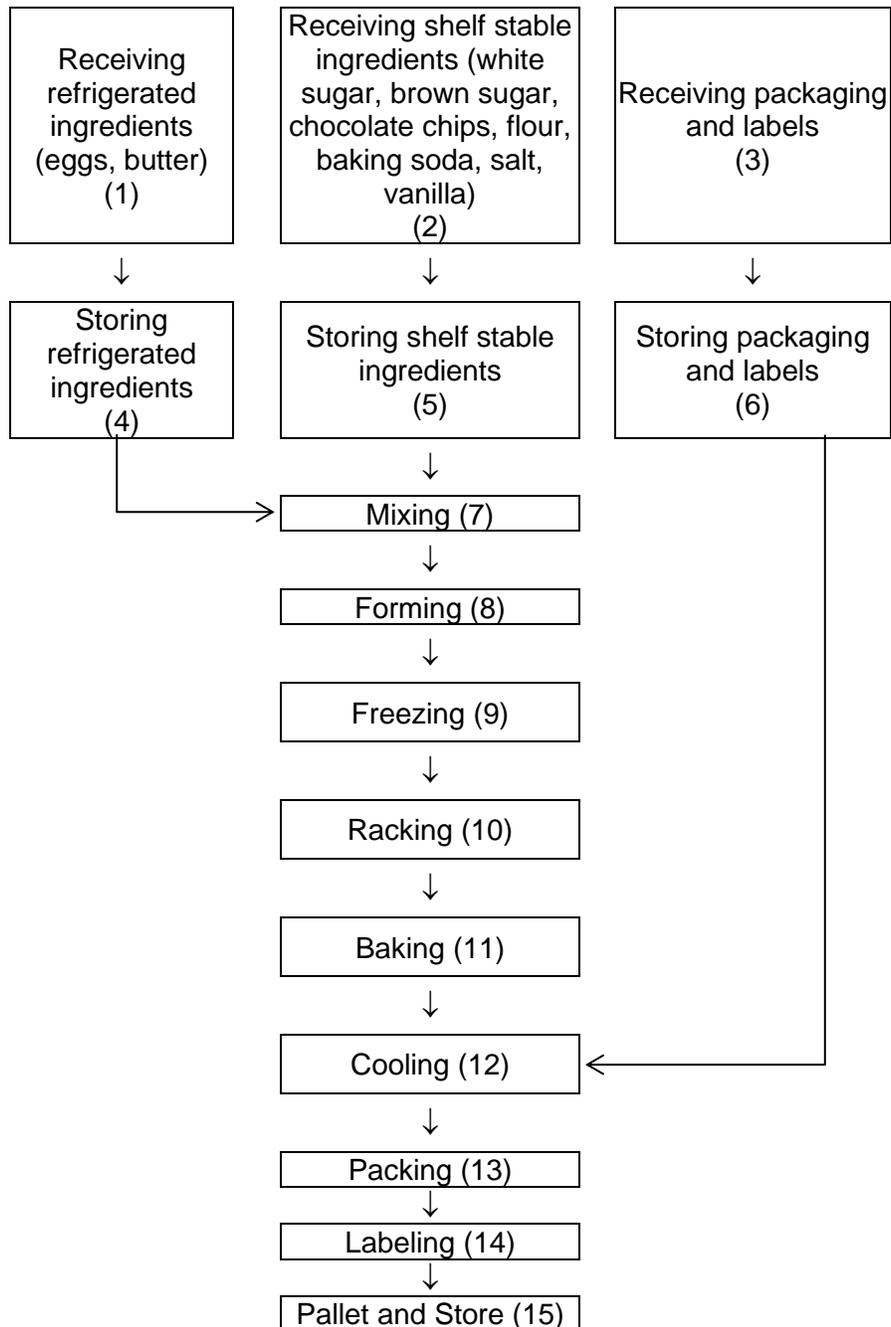
Product Description

Product Name(s)	Chocolate Chip Cookie
Product Description, including Important Food Safety Characteristics	All-natural, preservative free, shelf stable fresh baked chocolate chip cookie. Water activity <0.50.
Ingredients	Flour, chocolate chips, butter, white sugar, brown sugar, egg, salt, baking soda, vanilla
Allergens	Wheat, Milk, Egg
Packaging Used	Plastic trays, wrapped with plastic wrap and inserted into cardboard boxes
Intended Use	Ready to eat product
Intended Consumers	General public
Shelf Life*	6 months
Labeling Instructions*	Ready to eat
Storage and Distribution*	Store in cool, dry place.

*[*Provide information relevant to food safety]*

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Flow Diagram



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Process Narrative

[A text description of each step in the flow diagram can provide more food safety and/or control information than can be shown easily in the flow diagram and important to understanding the process]

Receiving Ingredients and Packaging Materials

Ingredients and packaging materials are purchased from approved suppliers that comply with internationally recognized food safety and quality systems. Suppliers that provide ingredients and raw materials that have a history of the presence of significant hazards for which we do not have an effective control in our facility are evaluated through an on-site audit (trusted third party audit) and are included in a supplier verification program. For each ingredient, the same brand is used consistently to minimize variation

Receiving Refrigerated Ingredients (1):

Butter: received from Ingredients R Us in 50lb cases, in refrigerated trucks

Egg: Liquid eggs received from Ingredients R Us in 20lb bags, in refrigerated trucks

Receiving Shelf Stable Ingredients (2):

Flour: received from Ingredients R Us in 50lb bags

Chocolate chips: received from Ingredients R Us in 25lb bags

White sugar: received from Ingredients R Us in 50lb bags

Brown Sugar: received from Ingredients R Us in 25lb bags

Salt: received from Ingredients R Us in 25 lb bags

Baking soda: received from Ingredients R Us in 25 lb bags

Vanilla: received from Ingredients R Us in 1 gallon jugs

Receiving Packaging (3):

18-cookie plastic trays, plastic wrap, and cardboard boxes are received in bulk. Suppliers provide a Certificate of Conformance that packaging materials and inks meet food safety and regulatory requirements. Cardboard box labeling is visually inspected for conformance with product allergen requirements and ingredients.

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Storing Ingredients and Packaging

Ingredients are stored according to manufacturers' recommendations when specified.

Storing refrigerated ingredients (4): Butter and pasteurized eggs are stored immediately after receipt in a cooler that is kept $\leq 40^{\circ}\text{F}$, and used in a first-in-first out method, based on code date.

Storing shelf stable ingredients (5): White sugar, brown sugar, chocolate chips, flour, baking soda, salt and vanilla are stored in the dry storage room (temperature $<75^{\circ}\text{F}$), in the ingredient area, arranged by ingredient code number. 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.

Storing Packaging (6): Plastic trays, plastic wrap, and cardboard boxes are stored in the dry storage room, adjacent to the ingredient area. Unused packaging is covered during storage between uses. Plastic wrap is stored in sealed containers to protect from contamination. Packaging is used first-in-first-out.

Mixing (7): Ingredients are measured and mixed in the mixing room, using a kettle mixer. Mixing of all ingredients takes place within no longer than 15 minutes. Dough temperature is taken post-mixing. Mixing bowls are taken to the former, where the dough is transferred to the former. At the end of production, bowls and mixing blades sent to the utensil cleaning area. Once cleaned, bowls and mixing blades are visually inspected for signs of damage or missing parts.

Forming (8): Dough is transferred from bowls to the former using a company-approved utensil, where it is formed into 28 gram dough rounds for baking.

Freezing (9): Rounds are passed through a liquid nitrogen flash freezer (set at -120°F), where they stay for 5 minutes until their internal temperature is lowered below $<32^{\circ}\text{F}$.

Racking (10): Dough rounds are placed on metal trays in 4 rows of 5. 10 metal trays are placed on each rack before baking.

Baking (11): Full racks are placed on rotating platforms (3 rotations per minute) in walk in ovens, and cooked for 13 minutes at $\geq 350^{\circ}\text{F}$, before being removed. Oven temperature is taken using a thermometer, and monitored on an exterior temperature display.

Cooling (12): Cookie racks are removed from the oven 10 minutes after baking is completed, and cooled to below 80°F within an hour of removal.

Packing (13): Racks of cooled cookies are brought to packing room, and transferred by manually into plastic trays, surrounded by plastic wrap, and sealed. Trays are then packed into exterior cardboard packaging. General GMP's are followed by employees through packing process.

Labeling (14): Lot information is printed onto each sealed package.

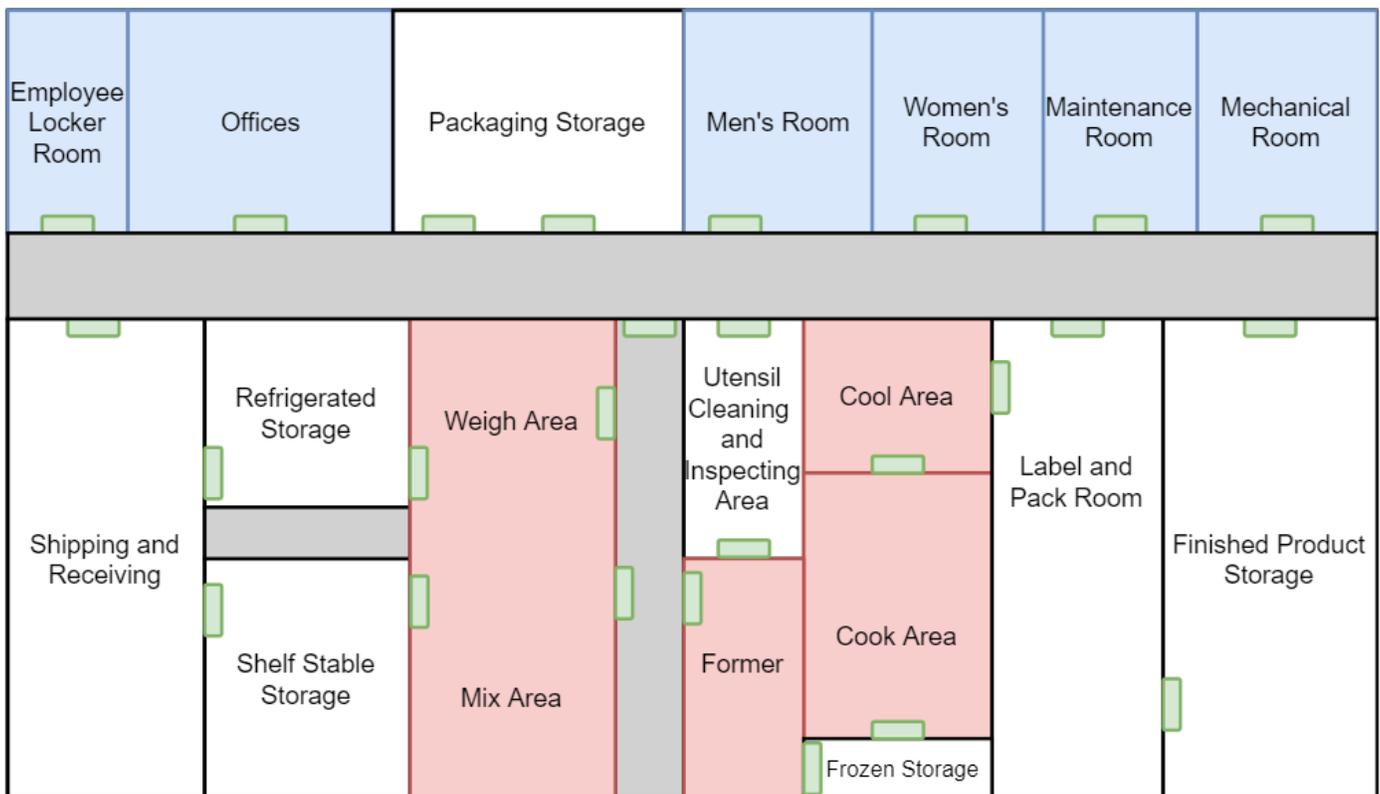
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Pallet and Store (15): Cases are transferred by hand to pallets, which are sealed in plastic. Pallets are transferred by fork lift to the warehouse where they are stored under ambient condition at < 70% RH until shipping.

Facility Layout

Blue: non-manufacturing area
White: basic GMP zones

Grey: hallway/transition area
Red: Primary pathogen control areas



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Hazard Analysis

Hazard identification (column 2) considers known or reasonably foreseeable hazards (i.e., potential hazards) 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

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
1) Receiving refrigerated ingredients (eggs, butter)	B Vegetative pathogens such as <i>Salmonella</i>	X		While pasteurization minimizes the likelihood of <i>Salmonella</i> , USDA recommends the product be used in cooked foods. Experience has shown <i>Salmonella</i> occasionally occurs in this ingredient	Process Control-subsequent cook step		X
	C Allergen- Egg, milk	X		Egg and milk are allergens that must be labeled to inform consumers. Allergen cross-contact is not an issue- all products contain egg and milk.	Allergen Control-allergen labeling at other steps		X
	P None						
2) Receiving shelf stable ingredients (w/b sugar, chocolate chips, flour, baking soda, salt, vanilla)	B Vegetative pathogens such as <i>Salmonella</i> and <i>E. coli</i>	X		Experience has shown <i>Salmonella</i> can occur in chocolate, and <i>E. coli</i> and <i>Salmonella</i> can occur in flour.	Process Control-subsequent cook step		X
	C Allergen- wheat	X		Wheat is an allergen that must be labeled to inform consumers. Allergen cross-contact is not an issue- all products contain wheat	Allergen Control-allergen labeling at other steps		X
	P Metal- flour	X		Experience shows metal can occur in flour due to grinding process	Process Control-Metal Detection-visual (inspection of utensils and equipment for damage/missing parts)		X

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
3) Receiving packaging and labels	B	None						
	C	Undeclared allergens- egg, milk, wheat	X		Labeled boxes must declare allergens present in the product, and there is history of print errors occurring	Allergen Control-label review for allergen information	X	
	P	None						
4) Storing refrigerated ingredients	B	Vegetative pathogens such as <i>Salmonella</i>		X	Pathogen growth to levels that render the cook step ineffective is not likely to occur			
	C	None						
	P	None						
5) Storing shelf stable ingredients	B	None						
	C	None						
	P	None						
6) Storing packaging and labels	B	None						
	C	None						
	P	None						
7) Mixing	B	Vegetative pathogens such as <i>Salmonella</i>	X		Subsequent bake step will kill <i>Salmonella</i> . <i>B. cereus</i> & <i>S. aureus</i> can be a risk in dough, but the time between mixing and the subsequent bake step is not long enough for growth.	Process Control-subsequent cook step		X
	C	None						
	P	Metal	X		Mixer has metal on metal contact	Process Control-Metal detection-visual (inspection of utensils and equipment for damage/missing parts)	X	

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?		
		Yes	No			Yes	No	
8) Forming	B	Vegetative pathogens such as <i>Salmonella</i>	X		Subsequent bake step will kill <i>Salmonella</i> , but dough portion size is essential for proper cooking	Process Control-dough portion size	X	
	C	None						
	P	None						
9) Freezing	B	None						
	C	None						
	P	None						
10) Racking	B	Vegetative pathogens such as <i>Salmonella</i>		X	Pathogen growth to levels that render the cook step ineffective is not likely to occur due to short duration of forming			
	C	None						
	P	None						
11) Baking	B	Survival of vegetative pathogens, such as <i>Salmonella</i>	X		Thorough cooking is required to kill vegetative pathogens	Process Control-time/temperature to achieve a lethal temperature (see validation study)	X	
	C	None						
	P	None						
12) Cooling	B	None			Cooling is to avoid condensation in packaging, to reduce spoilage organisms (quality). Water activity post cooking is below threshold for spore forming pathogens, therefore there is no hazard			
	C	None						
	P	None						
13) Packing	B	None			General GMP's are followed by employees, therefor there is no hazard			
	C	None						
	P	None						

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
14) Labeling	B	None						
	C	Allergens- egg, dairy, wheat	X		Egg, dairy, and wheat are allergens that must be labeled to inform consumers. Labels are checked for accuracy at receiving, and since only one product is made, there is no risk of using the wrong label for the product.	Allergen Control- correct labeling		X
	P	None						
15) Pallet and store	B	None						
	C	None						
	P	None						

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Process Preventive Controls

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Forming	Vegetative pathogens such as <i>Salmonella</i>	Dough portion: ≤28 grams/cookie	Dough portion weight	Dough portion: check weight of 3 individual dough portions using a calibrated scale before baking	Every batch	QA tech or an employee qualified by training	Hold batch and evaluate- rework or discard Determine root cause- fix former if necessary	Review of Portion Logs, Corrective Action and Verification records within 7 working days Daily calibration of scale Yearly calibration of former	Portion Log- recorded for every batch, signed by qualified employee Corrective action records Verification records, including validation study (same as time/temperature validation study)

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Process Preventive Controls

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Baking	Vegetative pathogens such as <i>Salmonella</i>	Temperature: Oven temperature is $\geq 350^{\circ}\text{F}$, Time: Batch bakes for ≥ 13 minutes	Time and temperature	<i>Temperature:</i> Interior oven thermometer logs temperature during batch <i>Time:</i> Record time batch is placed in oven Calculate and record when batch should be removed from the oven Record time removed from the oven and total bake time	<i>Temperature:</i> Continuous recording during each back. Check log after each batch <i>Time:</i> Every batch	QA tech or an employee qualified by training	Hold batch and evaluate-rework or discard Determine root cause- fix oven if necessary, retrain employees on importance of parameters meeting or exceeding critical limits	Review of Time/temperature log Corrective Action and Verification records within 7 working days Ongoing thermometer accuracy checks via second interior thermometer Annual calibration of both thermometers	<i>Temperature Log-</i> automatically recorded, signed by qualified employee Time/temperature Log-recorded for every batch, signed by qualified employee Corrective action records Verification records, including validation study

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Process Preventive Controls

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Metal Detection-Visual	Metal inclusion	No broken or missing metal parts from equipment	The presence of broken or missing metal parts from equipment	Visually check the equipment for broken or missing parts	Before starting operations each day, and at the end of operations each day	Production employee	Hold all product produced since the previous satisfactory equipment check until it can be run through a metal detector. If it cannot be run through a metal detector, destroy all product produced since the previous satisfactory equipment check	Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were properly addressed.	Records of equipment inspections, corrective actions taken, and records review

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Food Allergen Preventive Controls

Food Allergen Ingredient Analysis

Raw Material Name	Supplier	Food Allergens in Ingredient Formulation								Allergens in Supplier's Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	
Liquid Egg	Ingredients R Us	X								Egg
Flour	Ingredients R Us				X					Wheat
Butter	Ingredients R Us		X							Milk
Chocolate Chip	Ingredients R Us		X							Milk

NOTE:

The above format is an alternative for an allergen specific hazard analysis. If you choose to use a form like this, then there is no need to duplicate allergen considerations in your hazard analysis chart. Duplication of information in multiple forms can create extra work and may lead to inconsistencies.

Some organizations may even choose to do an ingredient hazard analysis that considers not only allergens, but also other hazards. This may be a useful option for you.

How to Use the Chart

List all ingredients received in the facility. Identify allergens contained in each ingredient by reviewing ingredient labels or contacting the manufacturer. Any allergens listed in "May contain" or other precautionary labeling on ingredients should be listed in the last column and reviewed to determine if allergen labeling is needed on the finished product.

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Allergen Verification Listing

Product	Allergen Statement	Label Number
Chocolate Chip Cookie	Contains: Egg, milk, and wheat	CC 068925

Allergen Scheduling and Cleaning Implications

Production Line Allergen Assessment

Product Name	Production Line	Intentional Allergens							
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)
Chocolate Chip Cookie	1	X	X		X				

Scheduling Implications:

[State the order in which products should be run to minimize allergen cross-contact. Consider adding when alternate production practices may be permitted, including approval for this, if you wish.]

Allergen Cleaning Implications:

[Identify when cleaning to prevent allergen cross-contact is required]

There are currently no allergen cleaning implications related to allergen cross-contact, as there is only 1 product, and it contains all allergens found within the facility.

How to Use This Form

Complete for each production line. Identify each allergen contained in each product produced on the line. Identify any allergens unique to a specific product, then indicate scheduling information (i.e., run unique allergens last) and allergen cleaning information (i.e., full allergen clean before running products without the allergen).

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Food Allergen Preventive Controls

Allergen Control Step	Hazard(s)	Criterion	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Receiving packaging (labeled box)	Undeclared allergens-egg, milk, wheat	All finished product labels must declare the allergens present in the formula, per listing	Ingredient listing and allergen declaration matches product	Visual check of carton label to match product formula	On arrival of packaging, before release to production	Employee qualified by training	If label is incorrect, reject labels and return to supplier, or destroy. Identify root cause and conduct training as needed to prevent recurrence	Review of Label Verification, Corrective Action and Verification records within 7 working days	Allergen Label Verification listing; Allergen Label Verification log; Corrective Action Records; Verification records

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Bake Step Validation Study*

The extension specialist provided Cookie Processor A's PCQI with a published study by Lathrop et al., (2014) on survival of Salmonella during baking of peanut butter cookies. The published study showed that peanut butter cookie dough made with peanut butter inoculated with high levels of Salmonella (28 g portions of dough, water activity (aw) of 0.82) and baked at 350°F (177°C) for 15 minutes had no detectable Salmonella. Cookies baked for 13 minutes showed at least a 5.2 log reduction in Salmonella. In that published study, the cookie temperature at the end of 15 minutes was 229°F (109°C).

The extension specialist identified the following processing parameters that need critical limits for food safety in Cookie Processor A's heat treatment:

- Convection oven temperature (°F) to achieve specified minimum product temperature;
- Baking time in oven (minutes); and
- Dough delivery process resulting in the specified cookie portion weight (g)

To determine critical limits for those processing parameters when baking cookies in batches in Cookie Processor A's convection oven, and demonstrate that these critical limits can be achieved in Cookie Processor A's convection oven, the extension specialist conducted in-house heat distribution tests on Cookie Processor A's ovens and heat penetration tests on the cookies using a fully loaded oven (each oven rack contained a full tray of cookies, deposited in 28 g portions using a dough depositor). These in-house heat distribution and heat penetration tests showed that all parts of each of Cookie Processor A's oven were at or above 350°F (177°C) when the ovens were set at that temperature and that the coldest cookie temperature was above 230°F (110°C) after 13 minutes. In addition, aw determinations by an outside laboratory on the cookie dough were equal to or greater than 0.82 using Cookie Processor A's recipes.

Based on the in-house tests, and the published study by Lathrop et al. (Lathrop, 2014), the extension specialist determined that the baking process of 350°F or greater for a minimum of 13 minutes (operating limit of 15 minutes) would provide adequate lethality for Salmonella for the recipe tested, so long as cookie dough portions did not exceed 28 g. The extension specialist informed Cookie Processor A that any subsequent change to the cookie recipe should be evaluated to determine whether it would impact these determinations.

Based on the information obtained from the extension specialist, Cookie Processor A's PCQI established three critical limits for the production of the cookies to ensure adequate lethality:

- The critical limit (minimum value) for the baking temperature is 350°F (177°C);
- The critical limit (minimum value) for the baking time is 13 minutes; and
- The critical limit (maximum value) for the cookie dough portion size is 28 g

*Adapted from FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry *Draft Guidance* (Pages 156-161)

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Bake Step Verification Protocol*

The following are calibrated at least annually

- The recording thermometer that monitors oven temperature
- The dough depositor
- The scales used to check the weights of cookie portions.

Within a week of record creation, the PCQI

- Reviews calibration logs (records of calibrating monitoring equipment) to make sure that the devices are properly calibrated using the appropriate methods and at the appropriate frequencies as specified in the calibration procedures;
- Checks the baking record sheets and the temperature recording chart for monitoring records for temperature and time (i.e., time when the cookies enter the oven, calculated time for removal, and time the cookies were removed from the oven) to verify that the oven temperature was at least at the critical limit of 350°F (177°C) and that the cookies were baked for 15 minutes;
- Checks the dough weight logs for the cookie dough portion weighing records to verify that none of the dough portions exceeded 28 g in weight; and
- Initials and dates each of the records reviewed in the place marked "Verified by."
- The PCQI reviews the corrective action records within a week of a deviation, and initials and dates each of the records reviewed in the place marked "Verified by"

* Adapted from FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry *Draft Guidance* (Pages 156-161)

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Metal Detection Validation Study

Procedure adapted from the 4th Edition of the FDA Fish and Fishery Products Hazards and Controls Guidance which outlines the use of controlling the hazard of metal inclusion through “periodically examining the processing equipment for damage that can contribute to metal fragments to the product”.

Found in pages 389-392

Metal Detection Verification Protocol

Within a week of record creation, the PCQI

- Checks the Metal Detection log to verify there were no signs of damage present to mixing bowls or mixer blades
- Signs and dates each record
- Reviews, signs and dates corrective action records within a week of deviation

