Appendix 3: Model Food Safety Plan Teaching Example

Food Safety Plan
for
Frozen Omelets

Reviewed by: *I.N. Charge*, Plant Manager

Date: February 13, 2016

The information in this example is for training purposes only and does not represent any specific operation. Development of a Food Safety Plan is site specific, thus it is highly unlikely that this plan can be adapted to another operation without significant modification.

This teaching model includes required and optional information to illustrate how a Food Safety Plan might be documented. The format may vary significantly for each specific company.

- The **Background Information** section is not required, but is highly useful for organizing the plan and explaining its organization to others. It is essential for a teaching example to clarify underlying assumptions in decisions that are made.
- The **Hazard Analysis** section is required for all Food Safety Plans subject to the *Preventive Controls for Human Food* regulation.
- The Preventive Controls sections (Process, Allergen, Sanitation and Supply-chain) are required ONLY for hazards requiring a preventive control identified by the hazard analysis.
- A Recall Plan is required ONLY when a hazard requiring a preventive control is identified by the hazard analysis.
- Implementation Records are required only for hazards requiring a preventive control.
    - A validation study is required only for process preventive controls.

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Background Information

Company Overview and Food Safety Team

E.G. Food Company's ~150 employees produce egg-based products, including plain omelets, cheese omelets and cheese omelet biscuits. Product is made 5 days a week in one 8 hour production shift, followed by 4 hours for sanitation. Cleaning and sanitizing of all processing equipment is conducted per a master sanitation schedule, which also includes cleaning and sanitizing between different products if needed for allergen control. Municipal water, which is treated and tested per EPA requirements by the city, is used throughout the facility. The company practices hygienic zoning to prevent cooked product exposure to environmental pathogens and employees working in the high hygiene areas wear color coded smocks and dedicated footwear. These employees are instructed on proper hand washing procedures, glove use, and importance of zoning.

Food Safety Team

Name	**Position**	**Training** (Records are in personnel file)
I.N. Charge	Plant Manager	In plant training
F.S. Leader*	QA manager and food safety team leader	FSPCA class
E.F. Ency	Production supervisor	In plant training
I.M. Clean	Sanitation supervisor	In plant training
P.H. Books*	Consultant, PH Books Consulting Service	M.S. & Ph.D. in Food Science and FSPCA lead instructor

*Preventive controls qualified individual

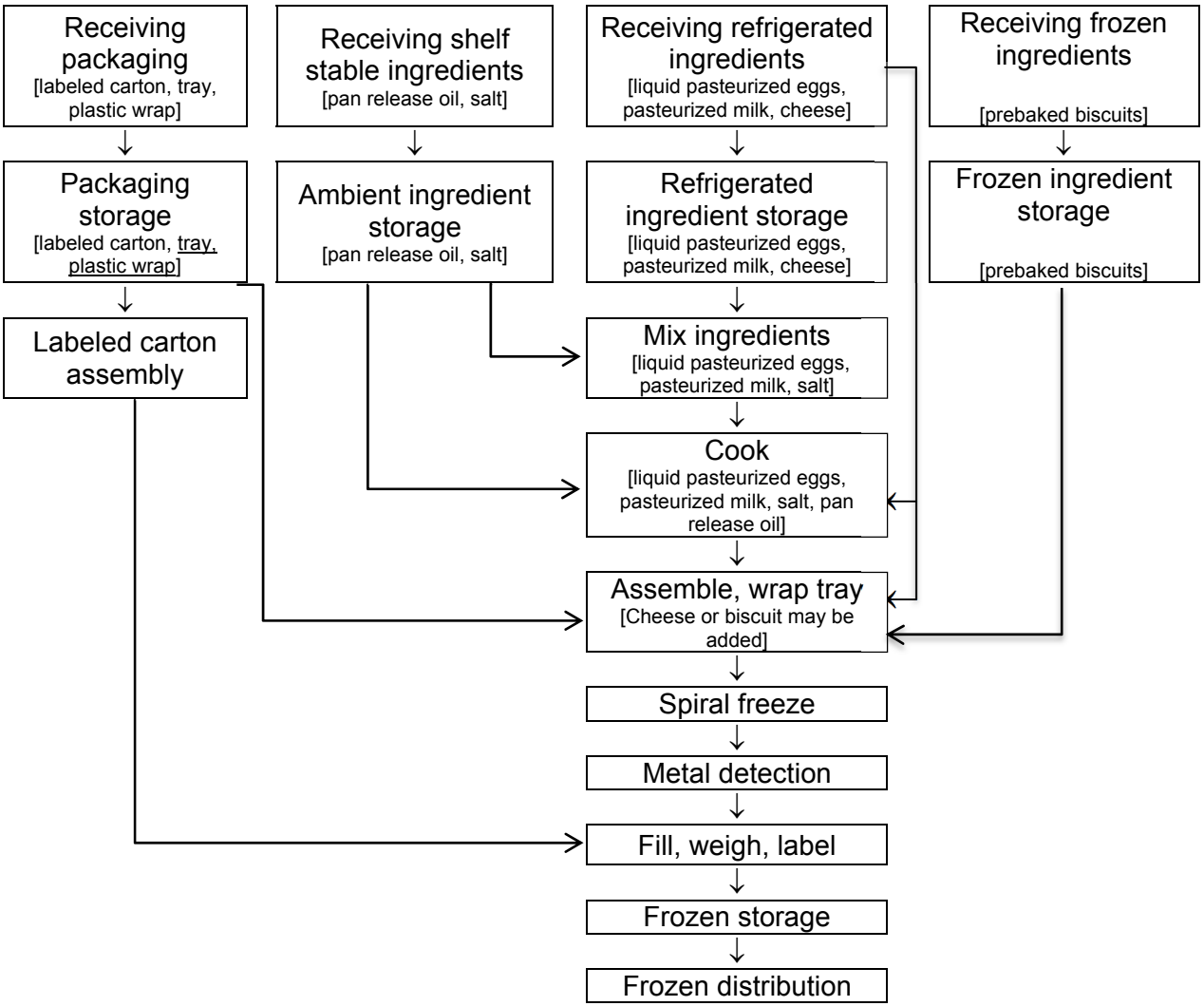
Product Description, Distribution, Consumers and Intended Use

Product Name(s)	**Omelet – Plain, Cheese and Cheese Biscuit**
Product Description, including Important Food Safety Characteristics	Frozen, cooked egg omelet, with or without cheese filling and a wheat biscuit bun pH 7.1 - 7.9, water activity >0.98, no preservatives
Ingredients	Plain: Eggs, milk, pan release oil, salt Cheese: Eggs, milk, cheese, pan release oil, salt Cheese Biscuit: Eggs, milk, cheese, biscuit, pan release oil, salt
Packaging Used	Paperboard trays wrapped with plastic wrap and inserted in a corrugated case.
Intended Use	The product is considered ready-to-eat, but is typically heated to hot holding temperatures (135°F (57°C)) or above for palatability. Heating is typically conducted using microwaves or convection oven. End user may thaw at refrigeration temperatures overnight to reduce cooking time. End users may also add toppings or fillings. Sold for foodservice applications. *Potential abuse:* Some establishments may hold thawed product for longer than the recommended 24 hours.
Intended Consumers	General public
Shelf Life	1 year frozen
Labeling Instructions	Keep frozen or thaw under refrigeration (<41°F (5°C)) for <24 hours before cooking.
Storage and Distribution	Frozen

Approved:*	**Date**:
Signature: F.S. Leader Print name: F.S. Leader	April 11, 2015

*Signature may just be on plan, or may be on each page.

Flow Diagram



NOTE: Text in [square brackets] optional and for teaching purposes

Verified by: F.S. Leader April 11, 2015

Process Description

This Process Narrative was developed for teaching purposes to create a common vision of this hypothetical process among course participants. There is no requirement for an establishment to create such a document; however, a Process Narrative may be useful to guide hazard analysis and to orient auditors. Other company documents outside of the Food Safety Plan may substitute for a Process Narrative, such as ingredient specifications, product specifications, production instructions, standard operating procedures, etc. This Process Narrative does not represent any existing process.

Receiving Ingredients and Packaging:

Ingredients and raw materials are purchased from reputable suppliers that comply with internationally recognized food safety and quality systems. For each ingredient, the same brand is used consistently to minimize variation. Ingredients are stored according to manufacturers' recommendations when specified.

- **Receiving packaging**: Corrugated shippers, paperboard trays and plastic wrap are received in bulk. Specifications require food grade material for trays and plastic wrap that is compatible with frozen storage of food products. Labeled cartons are reviewed for conformance with product allergen requirements and ingredients.
- **Receiving shelf stable ingredients**:
  - *Salt*: Received in 10-pound bags from our distributor. Specifications require food grade salt.
  - *Pan release oil*: The pan release oil contains soybean oil, soy lecithin and natural flavor. It is received from our distributor in 10-gallon jugs.
- **Receiving refrigerated ingredients**:
  - *Eggs*: Refrigerated, pasteurized liquid eggs, processed to meet USDA requirements, are received in 20-pound, bag-in-box containers from our sole source supplier, in refrigerated trucks.
  - *Milk*: Pasteurized Grade A milk is received from a local dairy in 20-pound bag-in-crate containers in refrigerated trucks. The supplier's letter of guarantee states that production practices are in compliance with Pasteurized Milk Ordinance requirements for pasteurized milk products, including animal drug residue testing.
  - *Cheese:* Pre-sliced, pasteurized process cheese is received in 3-pound cases from our sole source supplier. The cheese contains cultured pasteurized milk and skim milk, buttermilk, milkfat, salt, sodium phosphate, tricalcium phosphate, lactic acid, milk protein concentrate, artificial color, and enzymes.
- **Receiving frozen ingredients:**
  - *Biscuits*: Pre-sliced, wheat biscuits are received frozen in 16-pound cases (5 trays of 20 biscuits per case) from our distributor. The biscuits contain enriched bleached flour (wheat flour, niacin, iron, thiamine mononitrate, riboflavin, folic acid), water, shortening (palm oil, mono and diglycerides, polysorbate 60, citric acid), buttermilk solids, sugar, baking powder (sodium acid pyrophosphate, sodium bicarbonate, cornstarch, calcium sulfate, monocalcium phosphate), and salt.

Storing Ingredients and Packaging:

- **Packaging storage**: Labeled cartons and trays are stored in the dry storage room in the packaging area. Plastic wrap is stored in sealed containers to protect from contamination. Packaging is used First-In-First-Out.

- **Ambient ingredient storage**: Salt and pan release oil are stored in the dry storage room in the ingredient area, arranged by ingredient code number. All containers are sealed to avoid allergen cross-contact and cross-contamination during storage. Ingredients containing food allergens are identified and stored in specific locations with like allergenic ingredients, unless allergen cross-contact is not reasonably likely to occur.
- **Refrigerated ingredient storage**: Pasteurized liquid eggs and pasteurized fluid milk are stored in separate designated areas in a cooler that is kept at ≤40°F (≤4.4°C) and used within code date. No open containers are returned to the cooler to minimize the potential for allergen cross-contact with either milk or egg allergens.
- **Frozen ingredient storage**: Frozen biscuits are stored in a designated area separate from finished goods storage. The freezer is maintained at <0°F (-18°C). A partially used case may be resealed and returned to the freezer after use on the line.

Mix ingredients: Eggs, milk and salt are combined in the mixing room using a commercial mixer with a wire whip. The batch size is used within 30 minutes. The temperature of the omelet batter is ≤40°F (≤4.4°C) after mixing. Mixing bowls are taken to the cook line for dispensing. Bowls are moved to a separate room for cleaning at the morning break, at lunch break and after the shift.

Cook: Pan-release oil is used to grease the omelet pans as needed to prevent sticking. Approximately one cup of omelet batter is deposited manually into omelet pans on high heat setting. The pan is swirled and edges of the omelet are lifted with a spatula to allow uncooked (liquid) batter to flow under the cooked portion. Surface temperatures (the coolest point) are periodically measured with an infrared thermometer and are typically >162°F (72°C) when the omelet is fully congealed, the surface is not shiny and thus cooking is complete. A congealed omelet is required to enable assembly. All omelet batter prepared is cooked or discarded – there is no rework.

Assemble, wrap: Cooked omelets are transferred to a table with the cooking spatula. The same table is used to assemble all products.

- *Plain omelets* are folded or rolled by hand to desired shape. Plain omelets are the first product made each day.
- *Cheese omelet* production begins after plain omelet numbers have been prepared. Cheese is brought to the line just in time for production in sufficient quantity to be used in <2 hours. Plain omelets are prepared, and a slice of cheese is placed in the center of the omelet prior to folding or rolling. All cheese is used for product or very small amounts are discarded at the end of the day.
- *Cheese biscuit omelets* are the last item made each day and only prepared when orders require. The required number of biscuits is brought to the line and trays containing 20 biscuits each placed on assembly tables. A folded plain omelet is placed on the bottom biscuit half, a slice of cheese is placed on the omelet, which is then topped with the biscuit top. All biscuit trays removed from a case are used for production or discarded at the end of the day. A partial case (i.e., 1-4 full trays) may be resealed, dated, returned to the freezer and used for the next production.

Twelve (12) omelets or six (6) cheese biscuit omelets are placed on a tray and plastic wrap is applied to cover the tray. Packaging does not reduce the oxygen level.

Spiral freeze: Wrapped trays are placed on a belt that carries the omelets though a spiral freezer. Freezing takes place rapidly, with temperatures dropping from >135°F (57°C) to <41°F (5°C) in <1 hour from the time the omelet is placed on the assembly table. Product exiting freezer is frozen solid, with temperatures continuing to drop to <10°F (-12°C) in frozen storage.

Metal detection: Frozen product in trays is passed through a metal detector. All rejected product is examined for the presence of metal.

Labeled carton assembly: Labeled cartons are assembled as needed at the 'Fill, Weigh, Label' step.

Fill, weigh, label: Four trays of frozen omelets are placed in labeled cartons. Labeled cartons are weighed and sealed, and the lot code is applied. This step takes place in <30 minutes for each case.

Frozen storage: Finished product is stored at <10°F (-12°C) until distributed.

Frozen shipping: Product is shipped in freezer trucks to customers at <10°F (-12°C).

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 (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 potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Receiving packaging	B	None						
	C	Undeclared allergens – egg, milk, soy (wheat in biscuit only)	X		Labeled cartons must declare allergens present in the product and print errors have occurred	Allergen Control – label review for allergen information	X	
	P	None						
Receiving shelf stable ingredients – salt	B	None						
	C	None						
	P	None						
Receiving shelf stable ingredients – pan release oil	B	None						
	C	Allergen – soy	X		Soy lecithin may contain soy allergen that must be labeled to inform consumers. Allergen cross-contact is not an issue – all products contain soy.	Allergen Control – allergen labeling at other steps		X
	P	None						
Receiving refrigerated ingredients – liquid pasteurized eggs	B	Vegetative pathogens such as *Salmonella*	X		While pasteurization minimizes the likelihood of *Salmonella* USDA recommends the product be used in cooked foods. Experience has shown *Salmonella* occasionally occurs in this ingredient.	Process Control - subsequent cook step		X
	C	Allergen – egg	X		Egg is an allergen that must be labeled to inform consumers. Allergen cross-contact is not an issue – all products contain egg.	Allergen Control – allergen labeling at other steps		X
Continued	P	None						

NOTE: Label review could be done only at the labeling step, but many organizations perform this upon receipt because individuals with different skills are needed.

(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? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Receiving refrigerated ingredients – pasteurized Grade A milk	B	Vegetative pathogens such as *Salmonella*	X		Raw milk has a history of association with *Salmonella.* Pasteurization by the supplier or our cook step can control the hazard.	Process Control - subsequent cook step		X
	C	Allergen – milk	X		Milk is an allergen that must be labeled to inform consumers. Allergen cross-contact is not an issue – all products contain milk.	Allergen Control – allergen labeling at other steps		X
	P	None						
Receiving refrigerated ingredients – pasteurized process cheese	B	Vegetative and sporeforming pathogens such as *Salmonella,* pathogenic *E. coli, L. monocytogenes* and *C. botulinum*	X		Pathogens listed were identified as significant by ICMSF (2005) in process cheese. These hazards must be controlled when the cheese is made.	Supply-chain Control – approved supplier and 3rd party supplier audit by a qualified auditor	X	
	C	Allergen – milk	X		Milk is an allergen that must be labeled to inform consumers. Allergen cross-contact is not an issue – all products contain milk.	Allergen Control – allergen labeling at other steps		X
	P	None						
Receiving frozen ingredients – biscuits	B	None						
	C	Allergen - wheat	X		Wheat is an allergen that must be labeled to inform consumers. Allergen cross-contact with other products must be controlled because some products produced on the line do not contain wheat.	Allergen Control – allergen labeling at other steps Sanitation Control – at a subsequent step to prevent allergen cross-contact		X
	P	None						
Storage – Pack-aging & dry ingredients [pan release oil, salt]	B	None						
	C	None						
	P	None						

Continued

(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? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Refrigerated ingredient storage [eggs, milk]	B	Vegetative pathogens such as *Salmonella*		X	Pathogen growth to levels that render the cook step ineffective is not likely to occur			
	C	None						
	P	None						
Frozen ingredient storage [biscuits]	B	None						
	C	None						
	P	None						
Labeled carton assembly	B	None						
	C	None						
	P	None						
Mix ingredients [eggs, milk, salt]	B	None						
	C	None						
	P	Metal	X		Mixer has metal-on-metal contact	Process Control – subsequent metal detection		X
Cook [eggs, milk, salt, pan release oil]	B	Survival of vegetative pathogens such as *Salmonella*	X		Thorough cooking is required to kill vegetative pathogens	Process Control – cooking to achieve a lethal temperature	X	
	C	None						
	P	None						
Assemble, wrap	B	Introduction of environmental pathogens such as *L. monocytogenes*	X		Recontamination may occur if sanitation controls are not in place	Sanitation Controls – prevent recontamination	X	
		Growth of vegetative pathogens such as *Salmonella* and *L. monocytogenes*		X	Time is too short for growth to be reasonably likely.			
	C	Allergen cross-contact from other products handled at this step; e.g., Cheese Omelet Biscuit	X		Biscuits could introduce wheat allergen to other products without control	Sanitation and Allergen Controls – prevent allergen cross-contact	X	
	P	None						

Continued

(1) Ingredient/ Processing Step		(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Spiral freeze	B	Growth of vegetative pathogens such as *Salmonella* and *L. monocytogenes*		X	Time is too short for growth to be reasonably likely			
	C	None						
	P	None						
Metal detection	B	None						
	C	None						
	P	Metal	X		Metal-on-metal contact on the line may introduce metal fragments	Process Control – metal detection	X	
Fill, weigh, label	B	None						
	C	Undeclared allergens – egg, milk, soy (wheat in biscuit only)	X		All products contain egg, milk and soy allergens. The cheese biscuit also contains wheat	Allergen Control – correct labeled carton for product	X	
	P	None						
Frozen storage	B	None						
	C	None						
	P	None						
Frozen distribution	B	None						
	C	None						
	P	None						

Process Preventive Control

Process Control	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Cook	Vegetative pathogens such as *Salmonella*	Omelet temperature is ≥158°F (70°C) instantane-ous before transfer to assembly table	Omelet surface temper-ature is ≥158°F (70°C)	Infrared surface thermo-meter	Each cook station, 4 times per shift, about every 2-3 hours	QA technician or designee	Hold product back to the last good check and evaluate – rework, discard, or release. Determine root cause – retrain or correct as appropriate	Review of Cook Log, Corrective Action and Verification records within 7 working days Daily accuracy check for thermometer Annual calibration of thermometer	Cook Log – cook temp by QA technician Corrective Action records Verification records, including validation study

P.H. Books Consulting Services
123 Research Way, Infoville USA

E.G. Food Company Omelet Cook Validation Study

Determination of lethal cook temperatures for *Salmonella* in egg products

Section 3-401.11 (A) (2) of the *Food Code* (a credible source for science-based recommendations) identifies the following time and temperature combinations as adequate for cooking raw egg-containing products:

- 145°F(63°C) for 3 minutes
- 150°F(66°C) for 1 minute
- 155°F(68°C) for 15 seconds
- 158°F(70°C) for <1 second (instantaneous)

Conclusion: A critical limit of ≥158°F (70°C) for <1 second (instantaneous) will effectively manage the risk of *Salmonella* in omelets based on the *Food Code*. Use of pasteurized eggs adds an extra margin of safety.

Determination that a congealed omelet is a valid visual cue for achieving a lethal temperature

It is well established that coagulation of eggs protein is a function of temperature. Lowe[1] reported that whole egg coagulates at 158°F (70°C), but commented that addition of milk can elevate the coagulation temperature. Stadelman and Cotterill[2] also discuss the influence of non-egg components on elevation of coagulation temperature. Therefore a study was conducted to determine temperatures achieved when omelets coagulated under routine operating conditions and to determine the frequency of temperature measurements.

A calibrated infrared thermometer was used to measure the temperature of the surface of omelets when they were cooked to desired doneness by 10 operators – 5 omelets for each of 10 operators on 3 separate days, for a total of 150 measurements. The omelet batter for each of the 3 separate days used different lots of eggs and milk. Omelets were prepared using standard procedures – one cup of omelet batter was deposited into oiled omelet pans on the high heat setting. Each pan was swirled and edges of the omelet were lifted with a spatula to allow uncooked (liquid) batter to flow under the cooked portion until coagulation was complete, no liquid batter is present, and the surface is no longer shiny.

Conclusion: The minimum temperature observed was 162°F (72°C), which is more than adequate to assure temperatures are above the critical limit of ≥158°F (70°C). The maximum temperature observed was 170°F (77°C). Temperatures will be monitored four (4) times per shift to provide ongoing documentation.

Signed: *P.H. Books* Date: 9 September 2014

Principle Consultant

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[1] Lowe, B. 1937. Experimental Cookery from the Chemical and Physical Standpoint. John Wiley & Sons. Egg section available at http://chestofbooks.com/food/science/Experimental-Cookery/index.html#.UgoI39vnYiR Accessed 12 December 2013

[2] Stadelman, W.J. and O.J. Cotterill (eds). 1995 Egg Science and Technology, 4th Edition, Haworth Press, Inc., Binghamton NY.

Product Testing for Verification

Purpose: To verify the adequacy of process control (cooking) for the hazard of *Salmonella* and the adequacy of sanitation controls to prevent recontamination.

Sample identification: Whole omelets at the assembly table prior to packaging and freezing are sampled. Results from the omelets sampled represent one day of production because cleaning and sanitizing occurs daily.

Sampling procedure: Once per month, five (5) omelets are randomly selected throughout the day. Each omelet is from a different assembly station. Individual omelets are aseptically collected, placed in sterile, plastic sample bags, which are labeled with the date, time, product type, lot number and operator number. Samples are placed on a tray, which is run through the spiral freezer to mimic processing conditions. The frozen omelets are sent to our contract lab, identified below, in an insulated cooler with an ice pack using overnight express mail.

Product from the sampled lot is held until results are received and confirmed to be in compliance with acceptance criteria identified under "Results" below.

Laboratory: *Wee Beasties Laboratory* (987 Critter Drive, Yourtown, USA)

Test conducted: The contract lab samples a portion from each omelet and retains the remaining sample under refrigeration for further testing if results are not acceptable. Each portion is tested individually for *Enterobacteriaceae.* Of the 5 samples taken, 2 can have results between 10 and 100/g. No individual sample can have a count greater than 100/g.

Microorganism	Analytical Method	Sampling plan		Limits/g	
		n	c	m	M
Enterobacteriaceae	AOAC 2003.1	5	2	10	100

n = number of sample units
c = number of sample units that can have results between m and M
m = concentration separating good from marginally acceptable results
M = concentration separating marginally acceptable from unacceptable results

Interpretation of results:
Acceptable results – Release product if either of the following are observed

1. All results are ≤10/g
2. 1 or 2 results between 10 and 100/g; all others ≤10/g

Unacceptable results – Apply corrective action if either of the following are observed

1. More than 2 samples have results between 10 and 100
2. One or more results >100/g

Corrective action for unacceptable results:

1. Determine the disposition of the lot (day's production) by testing 25g from each of the five (5) retained omelets for *Salmonella* and *Listeria monocytogenes.* Product is on hold and release status until negative results are confirmed.
    a. If no pathogen is detected – Release the product and implement other corrective actions below
    b. If either pathogen is detected – Divert the product to rendering and implement other corrective actions

2. Determine root cause
    a. Increase observation of cooking procedures and temperature verification at the Cook step to hourly.
        i. Observe assembly tables for signs of uncooked egg (e.g., liquid egg smears on the tables), which indicates undercooking and will remain and build throughout the day. Focus especially on tables that had the higher counts in the lab results.
        ii. Retrain cooking staff if issues are noted.
    b. Conduct stringent sanitation efforts in the Assemble/Wrap, Cook and hallway between these areas. Increase observation of cleaning procedures at the end of the day and before start up to identify issues. Also observe procedures in the Utensil and Small Equipment wash room and Mixing area.
        i. Make improvements if warranted in any of these areas.
    c. Review environmental monitoring results for *Listeria* spp. to identify potential issues, regardless of whether or not *Listeria* is found in the product.
        i. Direct cleaning and sanitation in areas of potential concern.
    d. If *Salmonella* is detected in sampled product, in addition to observation of cook procedures and temperature verification (see 2a), initiate environmental monitoring for *Salmonella,* focusing on the Assemble/Wrap area and transition hallway between Assemble/Wrap and Cook areas to identify potential environmental sources. Continue weekly until results are negative for 5 consecutive weeks, then reduce to monthly.
    e. Increase routine sampling for *Enterobacteriaceae* to at least weekly until 5 consecutive results are acceptable. Then return to the routine schedule.
3. Provide staff training
    a. Review the situation with staff to alert them to the issue. Seek input on potential areas of improvement that can help resolve the issue.
4. In the event of a persistent issue, engage experts (e.g., testing lab or consultant P.H. Books) for additional assistance.

Process Control	Hazard (s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Metal detection	Metal inclusion	Metal detector present and operating	All of the product passes through an operating metal detector	Visual examination that the detector is on and reject device is working	Beginning, middle and end of shift	Production employee	If the product is processed without metal detection, hold it for metal detection. Correct operating procedures to ensure that the product is not processed without metal detection	Pass X mm ferrous and Y mm non-ferrous and stainless standard wands through detector at start-up, middle and end of shift to assure equipment is functioning. Review of Metal Detector Log and Corrective Action and Verification within 7 working days	Metal Detector Log Manufacturer's Validation Study that determined detector settings and sensitivity standards Corrective action records
		No metal fragments that would cause injury or choking are in the product passing through the metal detector	Kick-out product for the presence of metal fragments	Examine product rejected by electronic metal detector to determine cause of kick-out	When product is rejected	Production employee	If metal is found in product, segregate product, inspect back to the last good check, rework or discard product depending on metal type and prevalence. Identify source of the metal found and fix damaged equipment if relevant		

Allergen Preventive Control

Ingredient Allergen Identification

Raw Material Name	Supplier	Allergens in Ingredient Formulation								Allergens in Precautionary Labeling
		Egg	**Milk**	**Soy**	**Wheat**	**Tree Nut** (market name)	**Peanut**	**Fish** (market name)	**Shellfish** (market name)	
Whole, liquid pasteurized egg	Your Egg Co.	X								None
Grade A pasteurized milk	A Local Dairy		X							None
Pan release oil, ABC Brand	My distributor			X						None
Salt, XYZ Brand	My distributor									None
Buttermilk biscuit	Flaky Co.		X		X					None
Pasteurized process cheese	Cheesy Co.		X							None

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.

Allergen Control	Hazard(s)	Criterion	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Receiving packaging (labeled carton)	Undeclared allergens – egg, milk, soy (wheat in biscuit only)	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	Before release to production	Label coordinator	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
Fill, weigh, label	Undeclared allergens – egg, milk, soy (wheat in biscuit only)	All finished product must have correct labeled carton	Label number matches product	Visual check of carton label to match product number	Beginning and end of run and when label stock is changed	Fill line operator	If label is incorrect, segregate product, inspect back to the last good check, relabel product; identify root cause and conduct training as needed to prevent recurrence	Review of Label Check, Corrective Action and Verification records within 7 working days	Allergen Label Verification listing Allergen Label Check Log; Corrective Action records; Verification records

Allergen Label Declaration

Allergen Verification Listing

Product	Allergen Statement	Label Number
Plain Omelet	Contains: Egg, milk, and soy	P 082015
Cheese Omelet	Contains: Egg, milk, and soy	C 082015
Cheese Omelet Biscuit	Contains: Wheat, egg, milk and soy	B 082015

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)
Plain Omelet	1	X	X	X					
Cheese Omelet	1	X	X	X					
Cheese Omelet Biscuit	1	X	X	X	X Unique allergen				

Scheduling Implications:
Standard practice is to run the Plain and/or Cheese Omelet in the beginning of the shift and the Cheese Omelet Biscuit at the end of the shift to reduce the potential for allergen cross-contact. [*Consider adding when alternate production practices may be permitted, including approval for this, if you wish*.]

Allergen Cleaning Implications: (Required)
A full allergen clean is **required** AFTER production of Cheese Omelet Biscuit because it contains a unique allergen – wheat.

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 cheese or plain omelets after a biscuit run.

Sanitation Preventive Control

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

Assemble/Wrap Table Sanitation

Purpose: Cleaning and sanitizing of the assembly and wrapping table is important to remove potential allergens and reduce microbial cross-contamination or recontamination with environmental pathogens that may impact product safety.

Frequency:

Cleaning: At lunch break, after Cheese Omelet Biscuit production, at the end of daily production.

Sanitizing: Before operations begin, at lunch break, after Cheese Omelet Biscuit production, and at the end of daily production.

Who: Sanitation team member

Procedure:

Note: Blue cleaning tools are to be used ONLY for cleaning after a cheese biscuit run to reduce the potential for unintentional allergen transfer.

Cleaning

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

Sanitizing

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

Monitoring (at frequency indicated above)**:**

Inspect table for residual soil and cleanliness. Record on Daily Sanitation sheet.
Use test strip to measure the quat concentration BEFORE application. Record on Daily Sanitation sheet

Corrections:

If residual soil is observed on the table, reclean and sanitize.
If quat is not at the proper concentration, make a new solution.

Records: Daily Sanitation Sheet

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

Assemble/Wrap Environmental Sanitation

Purpose: Cleaning and sanitizing of the floor and the table support (legs) in the Assemble, Wrap area is important to prevent establishment of environmental pathogens.

Frequency: Daily, after production

Who: Sanitation team member

Procedure:

Cleaning and sanitizing the table support structure

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

Cleaning floors

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

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

Sanitizing

1. Spray floors with a 400-600 ppm quat sanitizer. Spray may also contact non-food contact table legs.
2. Allow floor to air dry overnight.

Monitoring (at each cleaning time)**:**

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

Corrections:

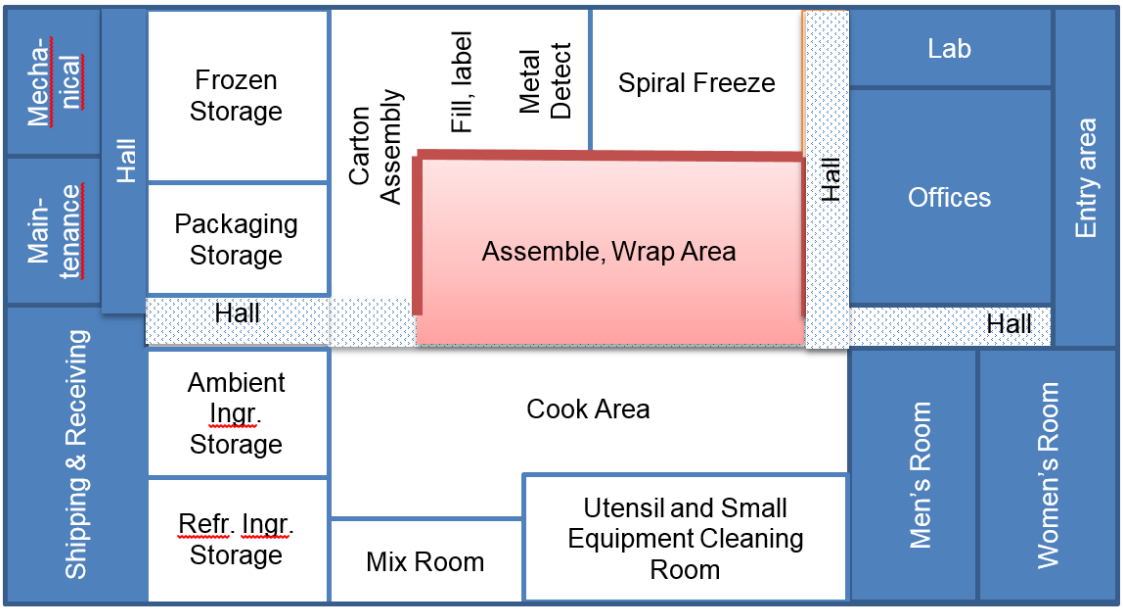
1. If residual soil is observed, reclean and sanitize.
2. If quat is not at the proper concentration, make a new solution.

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

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

Assemble/Wrap Hygienic Zoning

Purpose: Hygienic zoning in the assembly and wrapping table area is important to minimize the potential of re-contamination with environmental pathogens.



Frequency: During production

Who: Employees and other individuals entering the Assemble, Wrap area

Procedure: Employees entering the Assemble Wrap area must (in the order listed):

1. Take a clean, blue smock from the rack outside the production area and put it on. Smocks must cover outer clothing that would be above the assembly table surface.
2. Take the correct size clean rubber boots from the shelves along the wall outside the Assembly Wrap area and put them on over shoes.
3. Take a blue hairnet from the box by the entry and put it on. Ensure that all loose hair is captured. Men with facial hair should also apply beard nets.
4. Wash hands just before entering the Assembly Wrap area following the procedures posted by the sink. Apply a clean pair of gloves.
5. When exiting the room deposit smocks and boots in the receptacles provided. DO NOT return them to the clean smock and shoe cover receptacle.

Maintenance workers and visitors must use foot covers and clean smocks when entering this area. Traffic in this area is minimized during production.

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

Corrections: Employee is instructed to gown properly.

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

Verification: Environmental monitoring and records review within 7 working days

Environmental Monitoring for Sanitation Preventive Control Verification

Purpose: Environmental monitoring is conducted to verify the effectiveness of sanitation and hygienic zoning procedures in the Assemble, Wrap area to control environmental pathogens such as *L. monocytogenes.*

Sample identification: Based on observation when sampling, "worst case" areas are sampled; e.g., standing water or product residue, around table legs, crevasses major traffic areas. Record the specific location sampled.

Sampling procedure: Every other week, sponge swabs are collected during production, at least 3 hours after production starts. Sampling time is not uniform to avoid bias of results. Samples are shipped to the laboratory using the sampling kit provided by the laboratory. Samples are refrigerated and shipped in an insulated cooler with a gel pack with next day delivery. Samples are NOT frozen.

The following number of samples collected each time.

- 4 in Assemble, Wrap area
- 2 in Hall between Assemble, Wrap and Cooking
- 1 at employee gowning area
- 3 other samples based on observed conditions

Laboratory: *Wee Beasties Laboratory* (987 Critter Drive, Yourtown, USA) conducts the analysis using FDA BAM procedures. Analysis is started within 48 hours of sampling.

Test conducted: For routine samples, the contract lab composites sponges from the same area following XYZ[1] recommended procedures to run as one test for *Listeria* species. *Investigation samples must be run individually.* The test result sheet identifies the specific method number used.

Interpretation of results:

Acton for a negative result – Continue routine operations

Corrective action for a positive result:

1. If a composite is positive, the positive areas are re-sampled within a day of notification and prior to implementing intensive sanitation procedures. Additional samples (number depends on size of area) are taken in other potential problem areas in an attempt to identify a site of contamination. All samples are run individually, without compositing.
2. Intensive sanitation procedures are implemented after sampling is complete.
3. Production can continue after sanitation is complete and product can be shipped.
4. If all re-samples are negative, resume the normal sampling frequency.
5. If one or more re-samples are positive, perform corrective action investigation to resolve the issue. Implement a hold and finished product testing procedure per the Product Testing for Verification corrective action protocol.

[1] XYZ would be a scientifically valid method, such as AOAC, ISO, FDA etc.

Supply-chain Preventive Controls 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**
Pasteurized process cheese	Cheesy Co., Cowtown, USA	Vegetative and sporeforming pathogens such as *Salmonella,* pathogenic *E. coli, L. monocytogenes* and *C. botulinum*	10/08/2010	Copy of 3rd party audit by a qualified auditor obtained from supplier	Audit report kept in Supplier Verification file

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: Receiving clerk

Procedure:

1. Verify that each load of Pasteurized Process Cheese was produced by Cheesy Co. located in Cowtown, USA by checking the bill of lading and manufacturer name on the cases received.
2. Document on receiving sheet

Corrections: If product is not from the approved supplier:

1. Receiving clerk places product on hold, notifies QA
2. QA reviews status and
    - Rejects load, or
    - Attaches to the receiving record documentation of verification activity applied for use of cheese from temporary supplier, allowing release for use
    - Marks the receiving record and sample “Food for research or evaluation use” and attaches a sticker stating “Food for research or evaluation use” and retains the shipping document (Bill of Lading) stating that the food is for research or evaluation purposes and cannot be sold or distributed to the public.

Records: Receiving Sheet, Food for Research or Evaluation Use sticker, Bill of Lading

Verification: Receiving records review within 7 working days

Determination of Verification Procedures

Ingredient: Pasteurized Process Cheese

Hazards requiring a supply-chain-applied control: Hazard analysis determined that vegetative pathogens, such as *Salmonella,* pathogenic *E. coli,* and *L. monocytogenes* and the sporeforming pathogen *C. botulinum* are hazards requiring supply-chain-applied controls in the production of pasteurized process cheese. We do not have a kill step for cheese.

Preventive controls applied by the supplier: The pasteurization process must kill the vegetative pathogens when the cheese is made. Cheese formulation must prevent growth of *C. botulinum*.

Conclusion: A 3rd party supplier audit by a qualified auditor is used to verify control of the identified hazards by the approved supplier Cheesy Company, located in Cowtown, USA.

Verification procedures: A copy of a 3rd party audit of their Cowtown location is requested from Cheesy Company on an annual basis and kept on file. The audit date, auditor qualifications, audit procedures and audit results are reviewed. If any requirements are deficient (including auditor qualifications) and follow up discussion with the Cheesy Company's Quality Manager in Cowtown takes place, as necessary, to determine what, if any, verification activities are needed for any deficiencies requiring corrective actions mentioned in the report.

Records: Copy of the audit report and, where necessary, verification of corrective actions taken by the supplier are maintained on file by the Food Safety Team Leader.

Recall Plan

The Recall Plan is maintained by F.S. Leader, with a copy in the Plant Manager's Office.

Implementation Records

Implementation records and forms used for Preventive Controls include the following:

- Monitoring records for preventive controls
    - Cook Log
    - Metal Detection Log
    - Allergen Label Check Log
    - Allergen Run Order Log
    - Daily Sanitation Log
- Corrective actions records
- Verification records
- Supply-chain program records
- Training records for the qualified individuals (in personnel files)
- Food Safety Plan Reanalysis Report

Applicable records and examples of forms follow.

Monitoring Records Forms

Cook Log

Hazard: Vegetative pathogens such as *Salmonella*
Parameters, values or critical limits: Omelet surface temperature is ≥158°F (70°C) instantaneous before transfer to assembly table.
Who, How, Frequency: QA Technician, or designee, checks an omelet surface temperature each cook station 4 times/shift (every 2-3 hr) using an infrared thermometer.
Corrective Action: Hold product back to the last good check and evaluate - rework, discard, or release. Determine root cause – retrain or correct as appropriate.

Date:

Time	Cook Station	Cook name	Temperature (°F)	QA Tech (initials)
Verification Reviewer Signature:			**Date of Review:**	

Metal Detection Log

Hazard: Metal inclusion

Parameters, values or critical limits:

1) All of the product passes through an operating metal detector and
2) No metal fragments that would cause injury or choking are in the product passing through the metal detector

Procedure: Pass X[2] mm ferrous and Y mm non-ferrous and stainless standard wands through detector at start-up, middle, end of shift and when any product change occurs to assure equipment is functioning.

Corrective action:

1) If the product is processed without metal detection, hold it for metal detection. Correct operating procedures to ensure that the product is not processed without metal detection
2) If metal is found in product, segregate product, inspect back to the last good check, rework or discard product depending on metal type and prevalence. Identify source of the metal found and fix damaged equipment if relevant

Date: _____

Time	**Product**	**Lot Number**	**Detector present and on (Yes/No)**	**Detector rejects ferrous, non-ferrous, and stainless standards (Yes/No)**	**Line Operator (Initials)**
Verification Reviewer Signature:			**Date of Review:**		

[2] X and Y values are determined during equipment calibration

Allergen Label Check Log

Hazard: Undeclared allergens

Parameters: All finished product labels must declare the allergens present in the formula as follows:
Plain Omelet: Egg, milk, soy
Cheese Omelet: Egg, milk, soy
Cheese Biscuit Omelet: Wheat, egg, milk, soy

Corrective Action: If label is incorrect, segregate product, inspect back to the last good check, relabel product; identify root cause and conduct training as needed to prevent recurrence

Date	**Time**	**Product**	**Lot Number**	**Proper Label Applied (Yes/No)**	**Line Operator (Initials)**
Verification Reviewer Signature:				**Date of Review:**	

Allergen Run Order Record

Hazard: Allergen cross-contact from other products handled at this step; e.g., Cheese Omelet Biscuit.

Parameter: Routinely, run the Plain and/or Cheese Omelet in the beginning of the shift and the Cheese Omelet Biscuit at the end of the shift to reduce the potential for allergen cross-contact. If necessary, Cheese Omelet Biscuit can be run before the Plain or Cheese Omelet **IF a full allergen clean** is performed AFTER production of Cheese Omelet Biscuit because it contains a unique allergen – wheat.

Corrective Action: If full allergen clean was not performed after running Omelet Biscuit, segregate product, hold all product produced after the Omelet Biscuit up to the next full allergen clean; evaluate product and determine appropriate disposition; identify root cause and conduct training as needed to prevent recurrence

Product Name	**Date**	**Start Time**	**End Time**	**Allergen Clean After Run (Yes/No)**	**Initials for allergen clean**
Verification Signature				**Date:**	

Daily Sanitation Control Record – Omelet Line

Date: _____

Sanitation Area and Goal	Pre-Op Time:	Start Time:	Lunch Break Time:	Post-Op Time:	Comments and Corrections	Operator Initials
Condition & Cleanliness of Food Contact Surfaces						
• Equipment cleaned and sanitized (S/U)*						
• Sanitizer type and strength: Quaternary ammonium compound, 200 ppm Omelet line (ppm)+						
Dish room dip tank (ppm)+						
Prevention of Allergen Cross-Contact • Cleaning after Cheese Omelet Biscuit (S/U/NA)&						
Condition & Cleanliness of Non-food Contact Surfaces • Floors and wall splash zones cleaned and sanitized (S/U) • Sanitizer Strength: Sanitizer Type: Quaternary ammonium compound Strength: 400-600 ppm Floors and wall splash zones (ppm)+						

* S = Satisfactory, U = Unsatisfactory
+ Enter ppm measured per test strip
& NA = not applicable because Cheese Omelet Biscuit run after other products

Verification signature:	Date:

Corrective Action Records

Corrective action records are maintained by the Food Safety Team Leader. An example of the Corrective Action Form follows.

Corrective Action Form	
Date of Record:	Code or Lot Number:
Date and Time of Deviation:	
Description of Deviation:	
Actions Taken to Restore Order to the Process:	
Person (name and signature) of Person Taking Action:	
Amount of Product Involved in Deviation:	
Evaluation of Product Involved with Deviation:	
Final Disposition of Product:	
Reviewed by (Name and Signature):	Date of Review:

Verification Records

Verification records are maintained by the Food Safety Team Leader. Examples of verification forms are included as indicated below:

Verification Record	**Location**
Omelet cook step validation study	Study included in process control section of this plan
Verification of monitoring and corrective action	Documented on the relevant forms, examples of which are in the previous sections
Calibration of monitoring and verification instruments • Daily Thermometer Accuracy Check • Annual Thermometer Calibration Log	Example forms follow
Product Testing	Procedure included with Cook process control record. Results forms provided by testing lab
Environmental Monitoring	Procedure included with Sanitation Preventive Controls. Results forms provided by testing lab
Annual Food Safety Plan Reanalysis Report Form	Example form follows
Supply-chain Program	Procedures includes with Supply-chain Preventive Controls in the Food Safety Plan. Receiving Log maintained in receiving files. Bill of Lading maintained for research product received. Audit results are maintained in by the Food Safety Team Leader
Training	Maintained in personnel files

Daily Thermometer Accuracy Check

Verification: Check each thermometer daily for accuracy. Temperature must be ±2°F (1°C) from standard.

Date of Calibration	Instrument Number	Boiling Water Temp (212±2°F)*	Ice Bath Temp (32±2°F)	Temperature within Specification (Yes/No)	Line Operator (Initials)
Verification Reviewer Signature:				Date of Review:	

* Temperature adjustments may be needed for different altitudes

Annual Thermometer Calibration Log

Verification: Send each thermometer to Accurate Instrument Checker Lab for calibration twice a year. Temperature must be ±2°F (1°C) from standard. Keep records of results on file.

Date of Calibration	Instrument Number	Method of Calibration	Calibration Results	Temperature within Specification (Yes/No)	Line Operator (Initials)
Verification Reviewer Signature:				Date of Review:	

Receiving Log

Verification: Pasteurized process cheese must be received from Cheesy Co., Cowtown, USA

This teaching example is not realistic for many companies because there is only one ingredient requiring a supply-chain-applied control. Most companies have receiving procedures and many require approved suppliers for both quality and safety considerations. Your standard receiving records may be suitable as the record verifying that raw materials and other ingredients requiring a supply-chain-applied control come from an approved supplier if it is set up to do so. A check list, a bar code scan, a computer spread sheet and other methods could be used to verify receipt from approved supplier locations. Use a format that works for your organization, keeping in mind that the record must be created when the activity occurs and that the activity must be verified by or under the supervision of a preventive controls qualified individual.

Supplier Audit Verification

Purpose: Review of 3rd party audit for suppliers of supply-chain-applied control		
Supplier Name, location		
Date of Review		
Date audit conducted		
Audit procedures in the report (yes/no and comments)		
Audit performed by (e.g., certification body name)		
General audit conclusion		
Required corrective action(s) noted		
Supplier response to corrective action		
Trends noted from previous reports		
Conclusions of the review		
Reviewed by:		Date:

Food Safety Plan Reanalysis Report

Checklist	**Date reviewed and initials of reviewer**	**Update needed Yes/No**	**Date Updated Completed:**	**Person Completing the Update** (initial or sign)
List of Food Safety Team				
List of products and processes in place at facility				
Product flow diagrams				
Hazard Analysis				
Sanitation Preventive Controls				
Food Allergen Preventive Controls				
Process Preventive Controls				
Supply-chain Preventive Control Program				
Recall Plan				

(Add rows as needed if different plans are used for different products)