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PLANT NAME: Example	ISSUE DATE	2/24/2016
ADDRESS: 123 Xyz Street, USA	SUPERSEDES	10/22/2015

Selected Sections of a

Food Safety Plan for Peanut Butter

Teaching Example

Reviewed by: _____ Plant Manager Date: _____

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



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Company Overview

This example company is a small firm that makes a variety of peanut butter products, including creamy, chunky and extra chunky peanut butter, and peanut butter with chocolate swirl spread.

- Product is made 5 days a week in one 8 hour production shift, followed by 4 hours for sanitation. A sanitary facility program is in place, with dry cleaning procedures enforced in most production areas of the facility to minimize establishment of environmental pathogens. A separate wet-washing room is used for washing, drying and sanitizing small equipment.
- Regular and frequent roof integrity inspections are conducted because the root cause of a previous *Salmonella* contamination event was traced to water infiltration into the facility through a roof leak.
- Water is treated and tested per EPA requirements by the city. An integrated pest control program is also in place.

This Food Safety Plan covers production of peanut butter products except for the Peanut Butter Chocolate Swirl product, which has a separate Food Safety Plan.

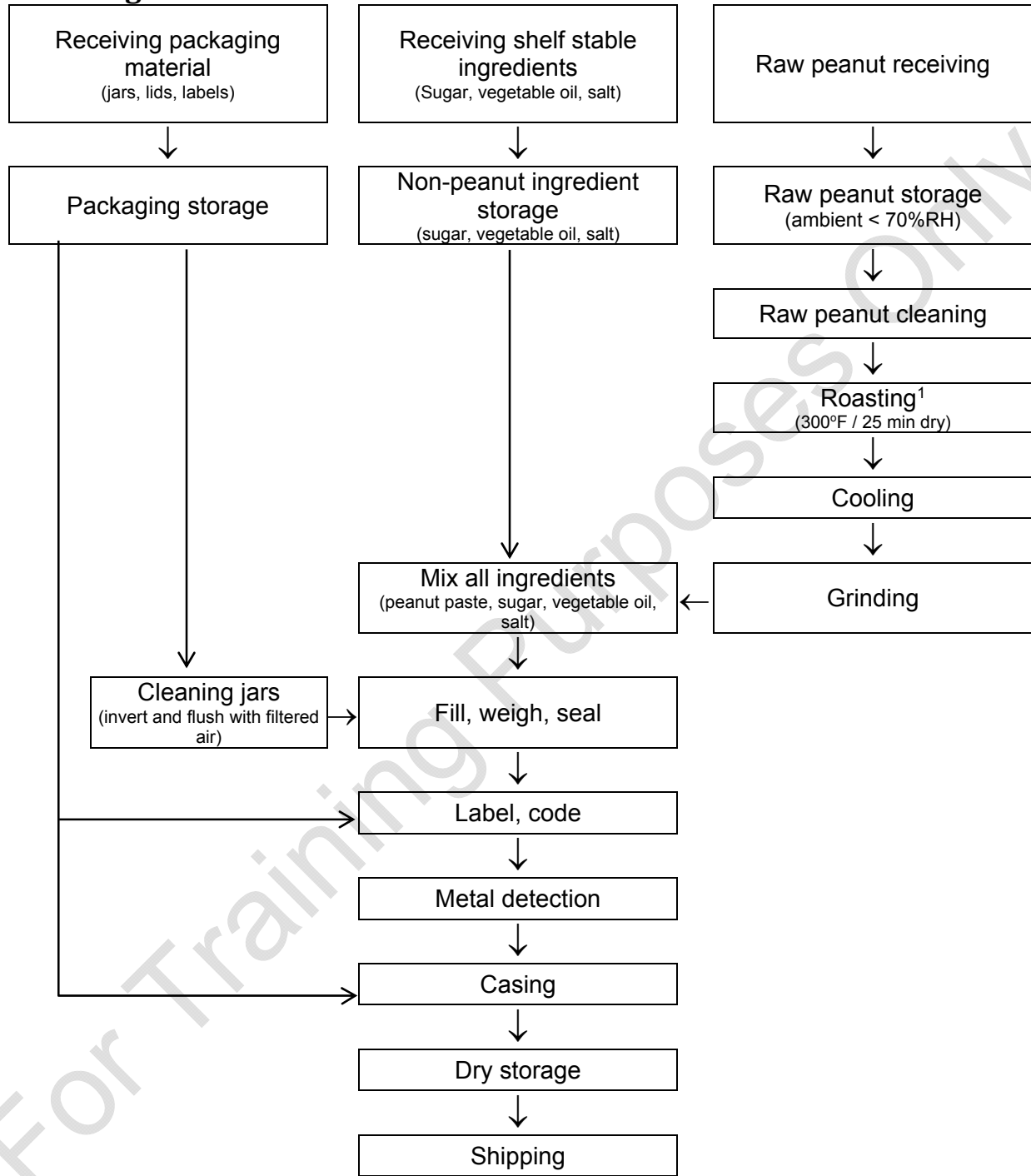
Product Description

Product Name(s)	Peanut Butter – Creamy, Chunky and Extra Chunky	
Product Description, including Important Food Safety Characteristics	Peanut butter with varying sizes of peanut particulates depending on the variety. $a_w < 0.35$ pH about 6.3	
Ingredients	Peanuts, sugar, hydrogenated vegetable oil and salt	
Packaging Used	Plastic container, paper / foil induction lid-stock, plastic closure. The headspace of jars is flushed with nitrogen (N ₂) prior to sealing to delay organoleptic deterioration.	
Intended Use	The product is ready-to-eat	
Intended Consumers	General public	
Shelf Life	Nine months ambient, unopened	
Labeling Instructions	Contains peanuts	
Storage and Distribution	Ambient	
Approved: Signature: <i>F.S. Leader</i> Print name: F.S. Leader	Date: 8 August 2015	



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Flow Diagram



¹ Typically, a blanch step occurs after roasting. The blanch step is omitted from this model for simplicity.



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Process Narrative

Receiving packaging material

Corrugated shippers, shrink film, plastic containers, plastic lids and labels are received individually cased. Specifications require food grade material for packaging material that is compatible with ambient storage of food products. Vendors provide a certificate of conformance that packaging materials and inks meet food safety and regulatory requirements.

Receiving shelf stable ingredients

Sugar and salt are received in 50 lb. bags. Hydrogenated vegetable oil (rapeseed and refined soy) are received in 5 gallon plastic pails. Nitrogen is received in gas cylinders and a certificate of analysis (COA) is provided to ensure it is food grade.

Receiving shelf stable ingredients

Shelled peanuts are received on trucks from several sheller locations. Each sheller is required to submit a COA for aflatoxin and indicating the product meets edible grade standards. The aflatoxin specification is <15 parts per billion (ppb) average maximum for subsamples with no individual reading >25 ppb. Control of extraneous material (shells, stems, skins, stones, plastic metal, etc.) in peanuts is a primary responsibility of suppliers, who have systems to sort and inspect peanuts prior to shipment.

Packaging storage

Corrugate, shrink film, plastic containers, plastic lids and labels are stored in a dry storage area and segregated from raw food material. Packaging is used on a First-In-First-Out basis.

Non-peanut ingredient storage

Sugar, hydrogenated vegetable oil and salt are received and stored at ambient conditions in an area separate from raw peanuts. These materials are used on a First-In-First-Out basis.

Raw peanut storage

Raw peanuts are stored in a segregated area at ambient temperature and <70% relative humidity. Raw peanuts are used on a First-In-First-Out basis.

Raw peanut cleaning

Prior to roasting, shelled raw peanuts are visually inspected and passed over a vibratory conveyor to remove residual foreign material, including sticks, rocks or metal pieces. A HEPA-filtered air stream is used to remove light extraneous material such as shell fragments.

Roasting²

Peanuts are conveyed through a roaster in a continuous process that applies forced heated air uniformly from above and below the peanut bed. The bed is kept at an even depth of two inches through the use of a leveling device. The peanuts are exposed to minimum of 300°F for 25 minutes. Air velocity and circulation are maintained to ensure adequate time and temperature in all areas of the oven including "cold spots." A process validation study performed on this specific process equipment demonstrated that these conditions provide a minimum 5-log reduction of *Salmonella*. The bed depth, time and temperature are all monitored during peanut roasting.

Cooling

Roasted peanuts are cooled under ambient conditions prior to grinding.

² Typically, a blanch step occurs after roasting. The blanch step is omitted from this model for simplicity.



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Grinding

Peanuts are conveyed across a magnet to a grinder where the peanuts are coarse ground to a paste consistency.

Mixing all ingredients

The peanut paste is pump-conveyed to a mixer to which sugar, salt and oil are added. The batch is mixed until ingredients are adequately dispersed.

Cleaning jars

Inverted jars are blown with HEPA-filtered, de-ionized air to remove foreign material prior to filling.

Fill, weigh, seal

Peanut butter is dispensed into cleaned jars to the appropriate fill weight. Nitrogen is injected into the headspace after filling, thin foil induction seal (compatible with metal detection) and the plastic caps are applied. NOTE: The swirl product uses a different filler head that incorporates the chocolate into the product at this step.

Label, code

Immediately after the capping, the lot identifier code is printed on each jar and labels are applied. Labels are checked prior to adding to the labeler to ensure the correct label is used. The label contains an allergen declaration statement that this product contains peanuts.

Metal detection

The product is passed through a metal detector. Rejected product is examined to isolate metal, determine its source, and direct corrective action.

Casing

Jars are placed by hand into corrugate cases, with 12 jars per case. Cases are sealed and coded with lot information.

Dry storage

Finished product is stored ambient warehouses until distributed.

Shipping

Product is shipped in ambient trucks to customers.



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Hazard Analysis

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

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

C = Chemical (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
Receiving packaging- jars and lids	B None						
	C None						
	P None						
Receiving packaging - labels	B None						
	C Undeclared allergen (peanut)	X		Product contains peanut as an ingredient	Allergen control –Label review upon receipt for correct allergen information	X	
	P None						
Receiving non-peanut ingredients – salt, sugar, oil	B None						
	C None						
	P None						
Receiving raw peanuts	B Non- sporeforming pathogens such as <i>Salmonella</i>	X		Raw peanuts have a history of contamination with vegetative pathogens from the environment or harvesting	Process control – Subsequent roasting destroys <i>Salmonella</i>		X
	C Aflatoxin	X		Aflatoxin may be present due to growth of <i>Aspergillus flavus</i> during growth, harvesting or storage.	Supply-chain Control - Verification of supplier Certificate of Analysis	X	
	Unapproved pesticide		X	Unapproved pesticides may be present in imported peanuts but are less likely in domestically sourced peanuts. Domestic peanuts are used			
	P Foreign material e.g., wood, metal, plastic, stones		X	Grinding and milling would reduce the size to a non-hazardous nature. Supplier controls these to prevent adulteration and potential equipment damage.			
Packaging storage	B None						
	C None						
	P None						
Non-peanut ingredient storage	B None						
	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
Raw peanut storage	B None						
	C Aflatoxin		X	The dry conditions and short storage time prevents production of aflatoxin			
	P None						
Raw peanut cleaning	B Environmental pathogens such as <i>Salmonella</i>	X		Raw peanuts nuts may contain <i>Salmonella</i> than can contaminate the environment	<i>Sanitation control</i> – Hygienic zoning needed to contain potential <i>Salmonella</i> in this pre-roast area	X	
	C None						
	P Foreign material; e.g., wood, metal, plastic, , stones		X	Grinding and milling would reduce the size to a non-hazardous nature or material would damage equipment to prevent processing			
Roasting	B Non-sporeforming pathogens such as <i>Salmonella</i>	X		Non-sporeforming pathogens may be present in the raw peanuts	<i>Process control</i> – Roasting step destroys <i>Salmonella</i> by thermal treatment	X	
	C None						
	P Foreign material - metal		X	Data from subsequent metal detection demonstrates that metal fragments originating from the roasting rarely occur due in part to preventive maintenance			
Cooling	B Environmental pathogens such as <i>Salmonella</i>	X		<i>Salmonella</i> harbored in the environment could contaminate exposed product in cooling	<i>Sanitation control</i> – Zoning and dry cleaning procedures	X	
	C None						
	P None						
Grinding	B Environmental pathogens such as <i>Salmonella</i>	X		<i>Salmonella</i> harbored in the environment could contaminate exposed product	<i>Sanitation control</i> – Zoning and dry cleaning procedures	X	
	C None						
	P Foreign material - metal	X		Metal fragments could be generated during the grinding process	<i>Process control</i> – Metal detection at later step		X
Mixing all ingredients	B Environmental pathogens such as <i>Salmonella</i>	X		<i>Salmonella</i> harbored in the environment could contaminate exposed product	<i>Sanitation control</i> – Zoning and dry cleaning procedures	X	
	C None						
	P Foreign material - metal	X		Metal fragments could be generated during the mixing process. Preventive maintenance reduces the occurrence.	<i>Process control</i> – Metal detection at later step		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
Cleaning jars	B Environmental pathogens such as <i>Salmonella</i>		X	Air filter that traps <i>Salmonella</i> is in place and on a preventive maintenance program, which eliminates the potential for contaminated air being used.			
	C None						
	P None			Cleaning of jars has not detected any hazards using current packaging material			
Fill, weigh, seal	B Environmental pathogens such as <i>Salmonella</i>	X		<i>Salmonella</i> harbored in the environment could contaminate exposed product	<i>Sanitation control</i> – Zoning and dry cleaning procedures	X	
	C Undeclared milk allergen from chocolate spread product	X		Chocolate spread, which is also produced in the facility, contains milk, which is a food allergen.	<i>Allergen control</i> –Dedicated filler for milk-containing products to prevent cross- contact	X	
	P None						
Label, code	B None						
	C Undeclared allergen - peanut	X		It is essential that the correct label is on the package to inform allergic consumers	<i>Allergen control</i> – Allergen label verification	X	
	P None						
Metal detection	B None						
	C None						
	P Foreign material - metal	X		Metal could be present in the raw materials, generated from equipment or introduced by employees	<i>Process control</i> – metal detection	X	
Casing	B None						
	C None						
	P None						
Dry storage	B None						
	C None						
	P None						
Shipping	B None						
	C None						
	P None						

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Process Preventive Controls

Process Control(s)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Roasting	Non-sporeforming pathogens such as <i>Salmonella</i>	Minimum roast time: 25 minutes	Length of roast cycle	Measure time-in to time-out with stop watch and metal test unit run through oven	Beginning of shift and after any adjustment	Roaster operator	If roasting is interrupted, product is held and evaluated to determine if it can be re-processed. If a processing parameter was not met, reprocess batch using alternate validated process; identify root cause and determine actions needed to address it; conduct training as needed to prevent recurrence. Also segregate and evaluate product, rework or discard as appropriate.	Operator verifies the roaster bed depth, temperature and roasting time are accurate and operating properly during the processing run once each day during morning shift. QA manager reviews and initials records within a week of preparation and compares performance with past results to determine trends. Maintenance manager ensures that roaster and monitoring equipment are calibrated. Finished product tested for Enterobacteriaceae once every 2 weeks. <i>Salmonella</i> is analyzed if hygiene Enterobacteriaceae counts are found out of specification.	Roasting log, including time, temperature and depth records. Recording device calibration records. Corrective action logs. Validation study establishing roasting parameters
		Bed depth ≤2 inches	Bed depth leveling bar height	Leveling bar height is set at 2 inches high at oven inlet	Check at startup and end of day				
		Oven temperature minimum 300°F Note: to achieve 5 log reduction of <i>Salmonella</i>	Oven air temperature	Recording thermometer at the coldest locations (i.e., inlet and outlet of oven)	Continuous with visual check of recorded data at start-up and once per day at each location				
Metal Detection									

See Food Safety Plan in curriculum for an example for potential wording for metal detection. Parameters can vary depending on the product, packaging, detection system, etc.



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Allergen Preventive Controls

Allergen Declaration on Packaged Product

Allergen Controls	Hazard(s)	Criterion	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Receiving packaging material - Labels	Undeclared allergen (peanuts)	Correct ingredient and allergen information is printed on the label	Presence of peanut in ingredient list and "contains" statement on label	Visual inspection to ensure all allergens in the formula are on the label	Each batch of printed labels before release to production	Label coordinator	Reject label, request replacement with correct information from label printer.	Label coordinator verifies declared allergens match current formula monthly and each formula change. Preventive Controls Qualified Individual or designee reviews records within 7 working days.	Product label review form. Ingredient formula Corrective action records
Label verification – Label, code step	Undeclared allergen (peanuts)	Correct labels are loaded into labelling equipment	Correct label is loaded onto labelling equipment	Visual inspection	Each time labels are loaded onto machine	Operator	Return material to warehouse, request correct labelling.	Verify label review procedure Review records to evaluate trends	Allergen label check log Production deviation log

Allergen Label Verification Listing	
Products	Allergen Statement
Plain, Chunky, and Extra Chunky	Contains: Peanut
Peanut Butter Chocolate Swirl	Contains: Peanut, milk



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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, Chunky and Extra Chunky Peanut Butter	1						X		
Peanut Butter Chocolate Swirl	1 (same line but different filler head)		X Unique allergen				X		

Scheduling Implications: Plain, Chunky and Extra Chunky flavors can be run in any order, depending on demand. Do NOT use the Peanut Butter Chocolate Swirl filler for these products 1) to prevent cross-contact with milk allergen in the chocolate and 2) to avoid the swirl pattern in the filled container. Standard practice is to run the Peanut Butter Chocolate Swirl in the end of the shift **and use the filler* dedicated to the chocolate swirl product.**

Allergen Cleaning Implications: Dry cleaning procedures must be used in all production areas. If peanut-only filler head is mistakenly used for Peanut Butter Chocolate Swirl product, dismantle filler and remove parts for wet washing in the isolated wet wash room.

Allergen Scheduling Implications

Allergen Controls	Hazard(s)	Criterion	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Dedicated filler for milk-containing products to prevent cross-contact	Undeclared milk allergen from chocolate spread product	Peanut-dedicated filler is in place	Only peanut – dedicated filler is used for peanut only products	Visual observation that the correct filler is in place	Beginning of shift and at each formula change	Line operator	Segregate all product back to last good check. Discard or rework into peanut chocolate swirl product. Replace correct filler. Determine why wrong filler was used and retrain.	QA manager reviews and initials records within a week of preparation Review records to evaluate trends	Filler check log Corrective action records



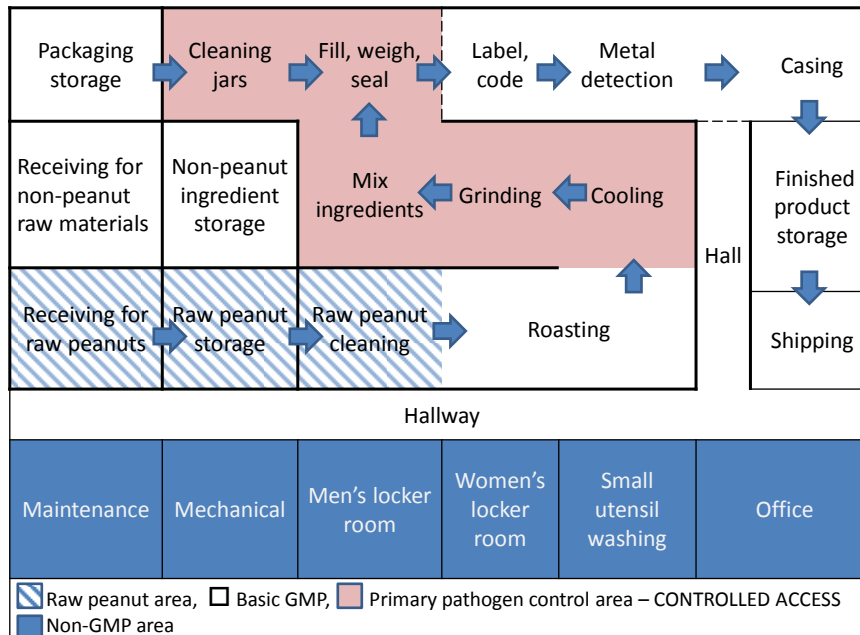
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Sanitation Preventive Controls

NOTE: See Food Safety Plan in curriculum for an example of potential wording for cleaning and sanitation procedures. Parameters can vary depending on the product, equipment, etc. Dry cleaning would be appropriate in this plan.

Hygienic Zoning

Purpose: Hygienic zoning is important to minimize the potential of re-contamination with environmental pathogens. The Flow Diagram highlights areas managed as zones and the basic plant layout below illustrates raw peanut and primary pathogen control areas. Two primary preventive controls are used for hygienic zoning: 1) air flow control and 2) *dedicated personnel in sensitive areas*.



1. Air flow control

A positive air balance (i.e., air flows out of the area) is maintained between primary pathogen control processing areas and other areas of the factory. A negative air balance (i.e., air flows in) is maintained between raw peanut handling and other areas of the factory, and air flow direction is verified.

Frequency: Weekly and when plant changes occur

Procedure: The system was set up during installation by a competent heating, ventilation and air conditioning (HVAC) technician.

Monitoring: Air flow test using procedure XYZ at entrances, exits, and air handling vents.

Corrections: If airflow is not flowing in the correct direction:

- Correct air flow
- Increase environmental monitoring in area where flow is in the wrong direction.
- Review environmental monitoring data. Assess risk, determine if action against product is needed, document rationale for actions.

Verification: 1) Environmental monitoring and 2) records review within 7 working days

Records: Weekly Air Flow Record, Environmental Monitoring Sampling Record, lab results



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2. *Dedicated personnel in sensitive areas*

The post-roasting areas of the factory are physically segregated from areas where raw peanuts are handled. Processing areas where ingredients and products are exposed (primary pathogen control areas above) are managed at a higher hygiene level than raw peanut, warehouse and receiving areas.

Frequency: During production and cleaning

Who: Employees and other individuals entering primary pathogen control or raw peanut areas

Procedure:

Primary pathogen control area

Employees entering **primary pathogen control** areas must (in the order listed):

1. Take a clean, blue smock from the rack outside the production area and put it on.
2. Take the correct size clean rubber boots from the shelves along the wall outside the controlled 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 controlled 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 follow the above but use foot covers and clean smocks when entering this area. Traffic in this area is minimized during production.

Raw peanut zone:

Raw peanuts are received separately from other ingredients and other raw materials. Raw peanuts are stored in a dedicated, segregated area. A negative air balance (i.e., air flows in) is maintained between raw peanut handling and other areas of the factory. Personnel involved in the processing of raw peanuts are dedicated to this activity. These personnel do not enter other processing areas of the factory. Employees working in **raw peanut** areas wear grey smocks and dedicated footwear.

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. If raw peanut boots or smocks are worn outside of the raw peanut area, areas visited by the employee are sanitized following dry sanitizing procedures.

Verification: 1) Environmental monitoring and 2) records review within 7 working days

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



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Environmental Monitoring for Sanitation Preventive Control Verification

Purpose: Environmental monitoring is conducted to verify the effectiveness of sanitation and hygienic zoning procedures in the primary pathogen control zones to control environmental pathogens such as *Salmonella*.

Sample identification: Based on observation when sampling, “worst case” areas are sampled; e.g., signs of moisture, product accumulation areas, crevasses, major traffic areas. Routine sampling sites include non-food contact surfaces and environmental surfaces. Record the specific location sampled.

Sampling procedure: The primary pathogen control area is tested monthly for the presence of *Salmonella*. Ten (10) stick swabs, sponge swabs, or accumulated product 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.

Laboratory: *Wee Beasties Laboratory* (987 Critter Drive, Yourtown, USA) conducts the analysis using validated procedures identified on their report. Analysis is started within 48 hours of sampling. The lab notifies the facility by phone any positive result is observed.

Test conducted: All samples are tested individually for *Salmonella* without compositing. The test result sheet identifies the specific method number used.

Interpretation of results:

Records are reviewed within 7 working days of creation. If *Salmonella* spp. are found in routine testing, corrective actions are applied.

1. If a routine (non-food-contact-surface) sample is positive, the positive area is 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. Food contact surfaces are also included in re-sampling, focusing around positive sites.
2. Intensive dry cleaning sanitation procedures are implemented after sampling is complete.
3. Production may continue after sanitation is complete, but product is placed on hold until environmental re-sample results are reported to be negative.
4. If all re-samples are negative, resume the normal sampling frequency and release product.
5. If one or more non-food-contact surface 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.
6. If one or more *food contact* surface re-samples are positive, product is considered to be contaminated with *Salmonella*. Destroy or divert product to a process that inactivates *Salmonella*. Halt production and initiate investigation to determine and correct root causes. Perform reanalysis of relevant parts of the Food Safety Plan to prevent recurrence.



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Supply-chain Preventive Controls Program

Determination of Verification Procedures

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

Preventive controls applied by the supplier: An approved supplier sorts peanuts to remove damaged kernels and conducts aflatoxin testing (using a valid method listed on their results report) to verify their control procedures.

Verification activities: A certificate of analysis for each lot of shelled peanuts is used to verify supplier control.

Verification procedures: For each lot received, trained receiving personnel:

- review the supplier certificate of analysis for aflatoxin to verify that the following parameters are met:
 - < 15 ppb aflatoxin average maximum for sub-samples with no individual reading > 25 ppb
- inspect incoming lots for mold.

Records: Certificate of Analysis for each lot, incoming goods log, and verification of corrective actions taken by the supplier are maintained on file by the Food Safety Team Leader.

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
Shelled peanuts	Nuts2U Co., Cropville, USA	Aflatoxin	10/08/2010	Supplier's Certificate of Analysis (COA) with each shipment	COA and incoming goods log, corrective records

Receiving procedures: For each shipment received, the receiving clerk:

- verifies that the product is from an approved supplier
- reviews each COA against acceptance criteria above
- verifies that each lot in the shipment is accompanied by a COA
- verifies that no mold is observed per procedure #XYZ
- documents the above in the incoming goods log.