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Process Narrative

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 shelf stable ingredients:

Black Peppercorns are typically received in 50 pound bags with appropriate labeling and coding to ensure adequate traceability.

Receiving packaging:

Food grade steel containers and plastic lids are received in a bulk shipment on pallets. Specifications require food grade material for packages that is compatible with dried storage of food products.

Ingredient storage:

Dried black peppercorns are stored in the dry ambient storage room dedicated for ingredients, arranged by ingredient code number. All containers are sealed to avoid contamination during storage.

Packaging storage:

Containers and lids are stored in dry ambient storage segregated from ingredients. Packages are stored in covered containers to protect from contamination.

Cleaning:

As received, peppercorns may be contaminated with dust, dirt, stones, metal and other foreign material. The peppercorns are cleaned by passing over sieves of varying sizes and magnets to separate foreign material and provide uniform peppercorn size. Unusual findings of foreign material and extraneous vegetative material are investigated. A library of "unusual findings" photographs are maintained for training purposes and may include wire, extraneous vegetative material, rodent droppings or other filth, etc. Many of these represent potential adulteration issues, which are addressed by contacting the supplier and potential delisting as an approved supplier. No allergen containing materials are passed over these devices.

Pathogen destruction:

A validated heat treatment method is used for pathogen destruction. Testing post-process for *Salmonella* is conducted daily to verify efficacy.

Grinding:

Material is ground according to product specifications to achieve correct particle size for food application and appearance. Grinding occurs on a mill line utilizing roller mills and sifter screens. Screen size is selected to obtain desired particle size.

Metal detection:

Finished product passes through an in line metal detector prior to packaging since the product is packaged in a metal can. Rejected material is diverted prior to filling in the metal container. All rejected product is examined for the presence of metal.

Packaging:

Ground black pepper is packaged in a metal tin with a plastic lid and coded with the appropriate lot and day code designation. The finished product is cased and coded.

Storage:

Finished product is stored ambient and dry 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 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
Receiving shelf stable ingredients – peppercorns	B Vegetative bacteria such as <i>Salmonella</i> and pathogenic <i>E. coli</i>	X		<i>Salmonella</i> and pathogenic <i>E. coli</i> recalls and outbreak history	Process Control: Subsequent inactivation step		X
	C Pesticides	X		Imported product	Supply-chain Control: Verification of supplier Certificates of Analysis for pesticide residues	X	
	P Foreign material (e.g., stones, wire etc.)		X	Unavoidable foreign material is associated with the growing and harvesting environment. Subsequent grinding eliminates potential physical hazards, but presents potential adulteration issues. Metal may damage grinding equipment.			
Receiving packaging	B None						
	C None						
	P None						
Ingredient storage	B None						
	C None						
	P None						
Packaging storage	B None						
	C None						
	P None						
Cleaning	B None						
	C None						
	P Foreign material		X	Addresses potential adulteration but not safety - see above for receiving peppercorns			

continued



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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 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
Pathogen destruction	B Vegetative pathogens such as <i>Salmonella</i> and pathogenic <i>E. coli</i>	X		History of outbreaks and recalls show these organisms may be present	<u>Process Control</u> : Heat treatment for pathogen reduction	X	
	C None						
	P None						
Grinding	B Environmental pathogens such as <i>Salmonella</i>	X		Post pasteurization contamination, cross contamination	<u>Sanitation Control</u> : Zoning and dry sanitation	X	
	C None						
	P Metal	X		Equipment failure can potentially introduce metal	<u>Process Control</u> : Subsequent metal detection		X
Metal detection	B None						
	C None						
	P Metal	X		Potential equipment failure at grinding step	<u>Process Control</u> : Metal detection	X	
Packaging	B Environmental pathogens such as <i>Salmonella</i>	X		Post pasteurization contamination, cross contamination	<u>Sanitation Control</u> : Zoning and dry sanitation	X	
	C Undeclared allergens	X		Other products packed contain allergens	<u>Allergen Control</u> : prevent allergen cross-contact	X	
	P None						
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 Activities	Records
			What	How	Frequency	Who			
Pathogen Destruction	Vegetative pathogens such as <i>Salmonella</i> and pathogenic <i>E. coli</i>	X°F for Y ¹ minutes as a heat treatment for peppercorns	Review time and temperature on recording chart to meet parameters listed under critical limits	Chart recorder	After initial temperature is reached, conduct continuous monitoring by visual check of recording instrument chart during each run.	Pathogen destruction equipment operator	If parameters are not met then reprocess. Determine the root cause of processing failure and correct to prevent recurrence.	Calibrate equipment once per month QA manager or designee reviews and initials records daily Quarterly generic <i>E. coli</i> and <i>Salmonella</i> testing	Pathogen Destruction Processor Log Recording device calibration records Corrective actions Validation study by American Spice Trade Association demonstrating that the time/temperature exposure for peppercorns heat is sufficient for a 5-log inactivation. Copy of report is in the plan.
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.						

¹ An actual plan would insert specific temperature and time. No specific numbers are used in this model to prevent misapplication of parameters that may not apply to a specific product.



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Allergen Preventive Controls

Allergen Cross-contact Prevention

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)
Ground black pepper	1								
Green, white and black peppercorn mix	1								
Black pepper rub	1		X Unique allergen						

Scheduling Implications: Black pepper rub is the only product that contains a food allergen (milk from whey protein). This product is run at the end of the day. A capital request has been submitted to obtain a dedicated filler for this product to minimize the risk of allergen cross-contact.

Allergen Cleaning Implications: Dry cleaning procedures must be used in all production areas. The filler head is completely dismantled after the Black Pepper Rub product is run for through cleaning using alcohol wipes to ensure that there is no visible residue. Swabs have been taken to validate the effectiveness of this cleaning method to remove milk protein to non-detectable levels on a routine basis. The cleaning crew is trained on this procedure, including its importance.



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Sanitation Preventive Controls

Allergen Cleaning of Filler

Purpose: Remove the food allergen, milk, from the filler head to prevent potential allergic reaction in sensitive individuals and to prevent mis-labeling of product.

Frequency: After each run of Black Pepper Rub

Who: Sanitation crew

Procedure:

1. Completely dismantle filler chute following dismantling photograph and take parts to the cleaning area.
2. Wet wash parts that can be exposed to water (refer to photo²)
3. Use food contact surface grade alcohol wipes to wipe down parts that cannot be exposed to water until there is no visual residue (refer to photo)
4. Allow filler parts to dry completely!
5. Reassemble dry filler parts prior to production

Monitoring: Visually observe the filler parts prior to reassembly of the filler to ensure they are both clean and dry.

Corrections: If the filler head is not properly clean (e.g., visible residue or wet), the employee is instructed on how to properly clean the parts and the importance of doing so to prevent potential allergic reactions.

Records: Allergen cleaning log

Verification: Visual inspection of the parts prior to assembly by the sanitation supervisor. Allergen cleaning log is reviewed within one week.

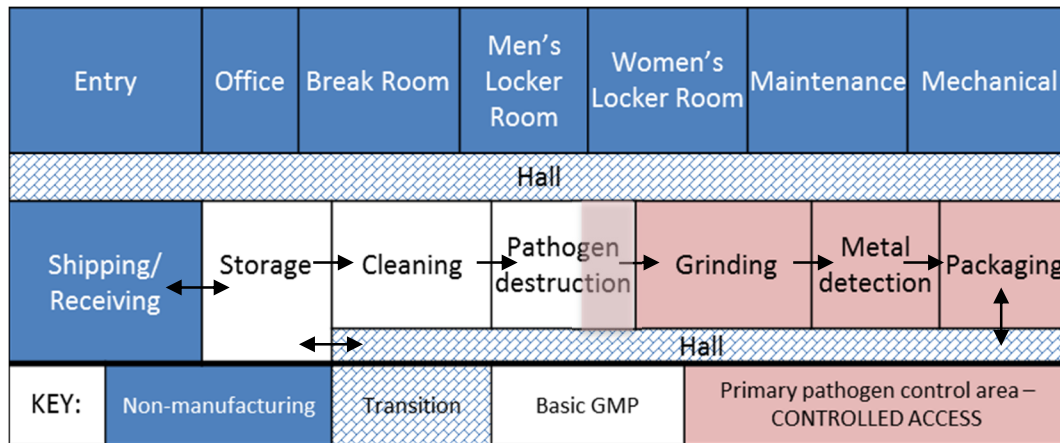
² Photo not provided for training but would be useful for the cleaning team to ensure consistent results



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Hygienic Zoning/ Environmental Monitoring

Purpose: Hygienic zoning in post-pathogen destruction area is important to minimize the potential of re-contamination with environmental pathogens.



Frequency: During production

Who: Employees and other individuals entering the Post Pathogen Destruction area (in pink or light shading above)

Procedure: Employees entering the Post Pathogen Destruction area must (in the order listed):

1. Take a clean, blue smock from the rack outside the production area and put them on. Smocks must cover outer clothing that would be above the processing line.
2. Take blue shoe covers from the box by the entry 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 area following the procedures posted by the sink. Apply a clean pair of gloves.
5. When exiting the room deposit smocks, shoe covers and hair nets in the receptacles provided. DO NOT reuse disposable items after entering uncontrolled areas.

Maintenance workers and visitors must follow the procedures above but use white foot covers and clean white 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 for verification of sanitation preventive controls and records review within one week.



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Supply-chain-applied Controls

Hazards requiring a supply-chain-applied control: Hazard analysis determined that pesticides require a supply-chain-applied control for raw black peppercorns. Our process does not reduce pesticides.

Preventive controls applied by the supplier: The supplier sources pepper from producers that use good agricultural practices and apply only approved pesticides. Periodic pesticide screening is conducted by the supplier to verify compliance.

Verification activities: The supplier sends Certificates of Analysis (COA) for pesticide residues for our review to verify supplier control for these hazards, minimum quarterly.

Verification procedures: The Quality Supervisor:

- verifies that copies of COAs received from the supplier for pesticide residues comply with regulatory requirements following procedure XYZ
- verifies that quarterly submission of COA requirements have been met
- enters the date of the results of the review into the Pesticide Screen Log

Records: COA copies for pesticides, Pesticide Screen Log, Incoming Goods Log, Approved Supplier List, and verification of corrective actions taken by the supplier are maintained on file by the Quality Manager.

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
Black peppercorns	Spice4U Co., Port, USA	Pesticides	10/08/2010	Supplier's Certificate of Analysis (COA) quarterly	COA, Pesticide Screen Log, Incoming Goods Log, corrective records

Receiving procedures: For each shipment received, the receiving clerk verifies that the product is from an approved supplier and documents this in the Incoming Goods Log.