



FoodIndustry
COUNSEL LLC

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COMPLYING WITH FSMA'S PREVENTIVE CONTROL
RULE AS A SMALL BUSINESS



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COMPLYING WITH FSMA'S PREVENTIVE CONTROL RULE AS A SMALL BUSINESS

Why is FSMA needed?

What is the Preventive Control Rule?

Who is covered and relevant deadlines?

What are the Key Elements?

What might a "compliant" plan look like?

What resources are available to build your own?



FDA FOOD SAFETY
MODERNIZATION ACT

FOOD SAFETY PLAN BUILDER



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COMPLYING WITH FSMA'S PREVENTIVE CONTROL
RULE AS A SMALL BUSINESS



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE



FDA FOOD SAFETY
MODERNIZATION ACT



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COMPLYING WITH FSMA'S PREVENTIVE CONTROL RULE AS A SMALL BUSINESS

526 pages



40 slides



FDA FOOD SAFETY
MODERNIZATION ACT



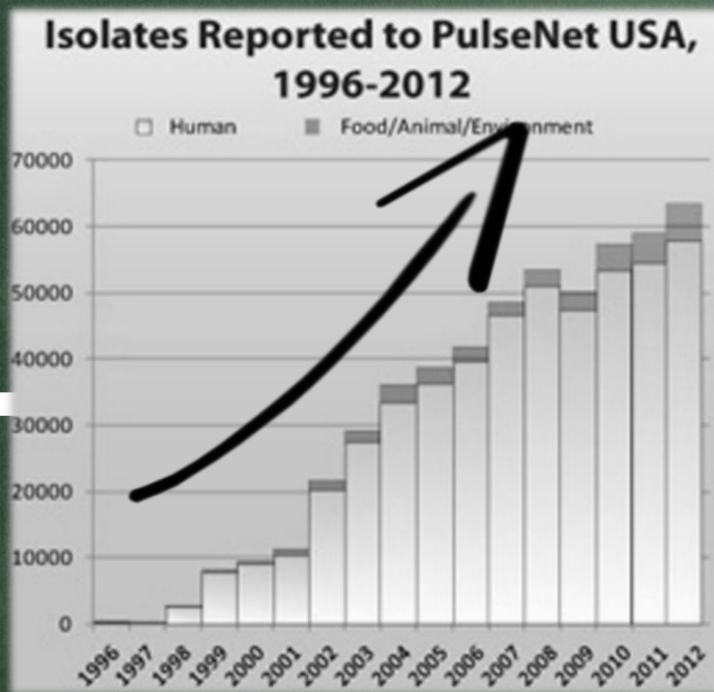
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WHY WAS FSMA NEEDED?

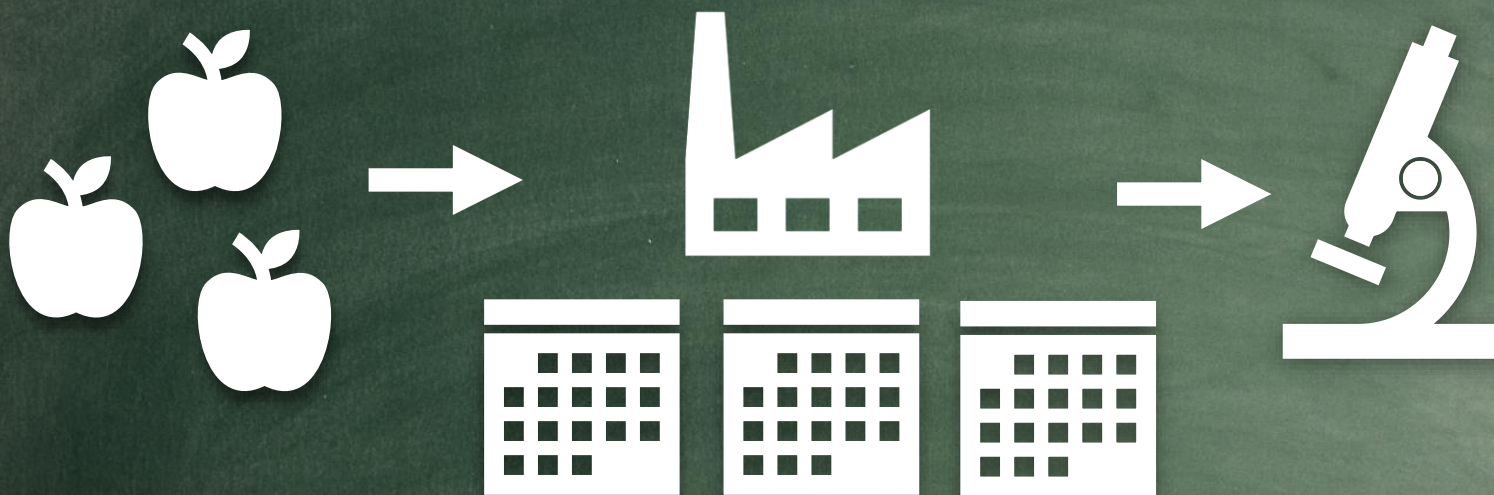


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WHY WAS FSMA NEEDED?



WHY WAS FSMA NEEDED?



WHY WAS FSMA NEEDED?



FDA WAS COMMANDED TO
MAKE OUTBREAKS AND RECALLS STOP



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WHY WAS A NEEDED?

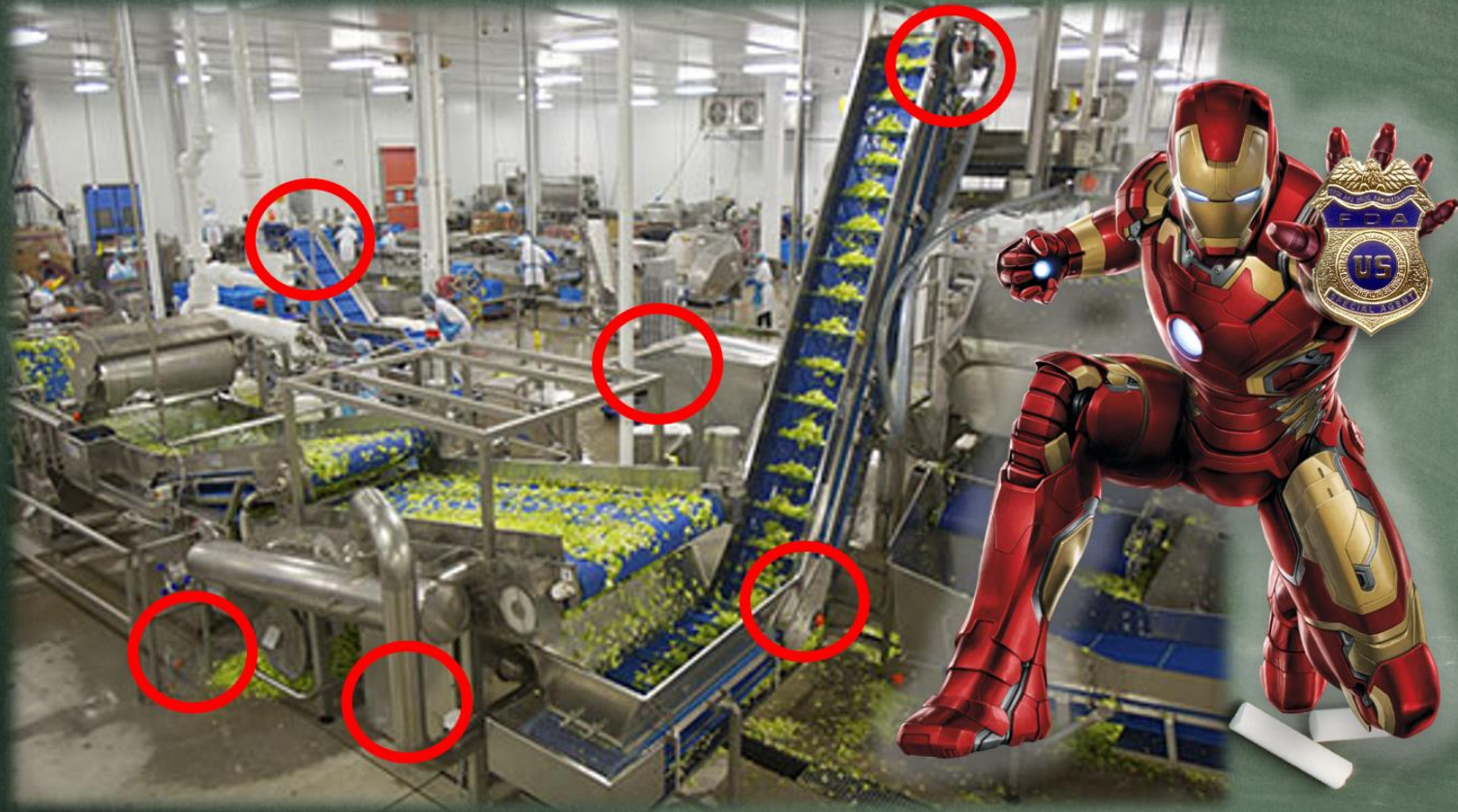


FBI WAS COMPELLED TO
MAKE BREAKS AND CALLS STOP



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WHY WAS FSMA NEEDED?



TITLE 21 OF THE CODE OF FEDERAL REGULATION PART 117

21 C.F.R. 117.1 et seq.



FEDERAL REGISTER

Vol. 80 Thursday,
No. 180 September 17, 2015

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1, 11, 16, 106, 110, *et al.*
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based
Preventive Controls for Human Food; Final Rule

Current Good Manufacturing Practice, Hazard
Analysis, and Risk-based Preventive Controls

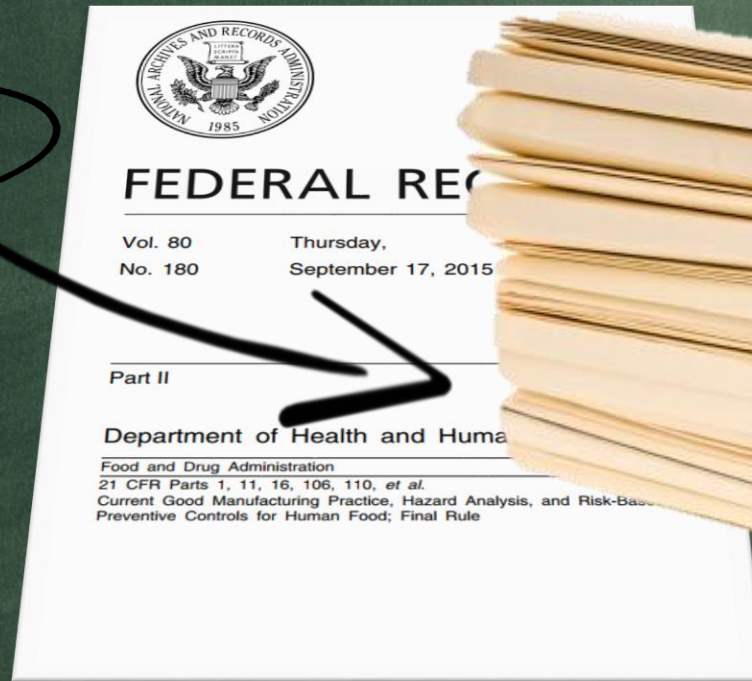


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TITLE 21 OF THE CODE OF FEDERAL REGULATION PART 117

21 C.F.R. 117.1 et seq.

262 pages

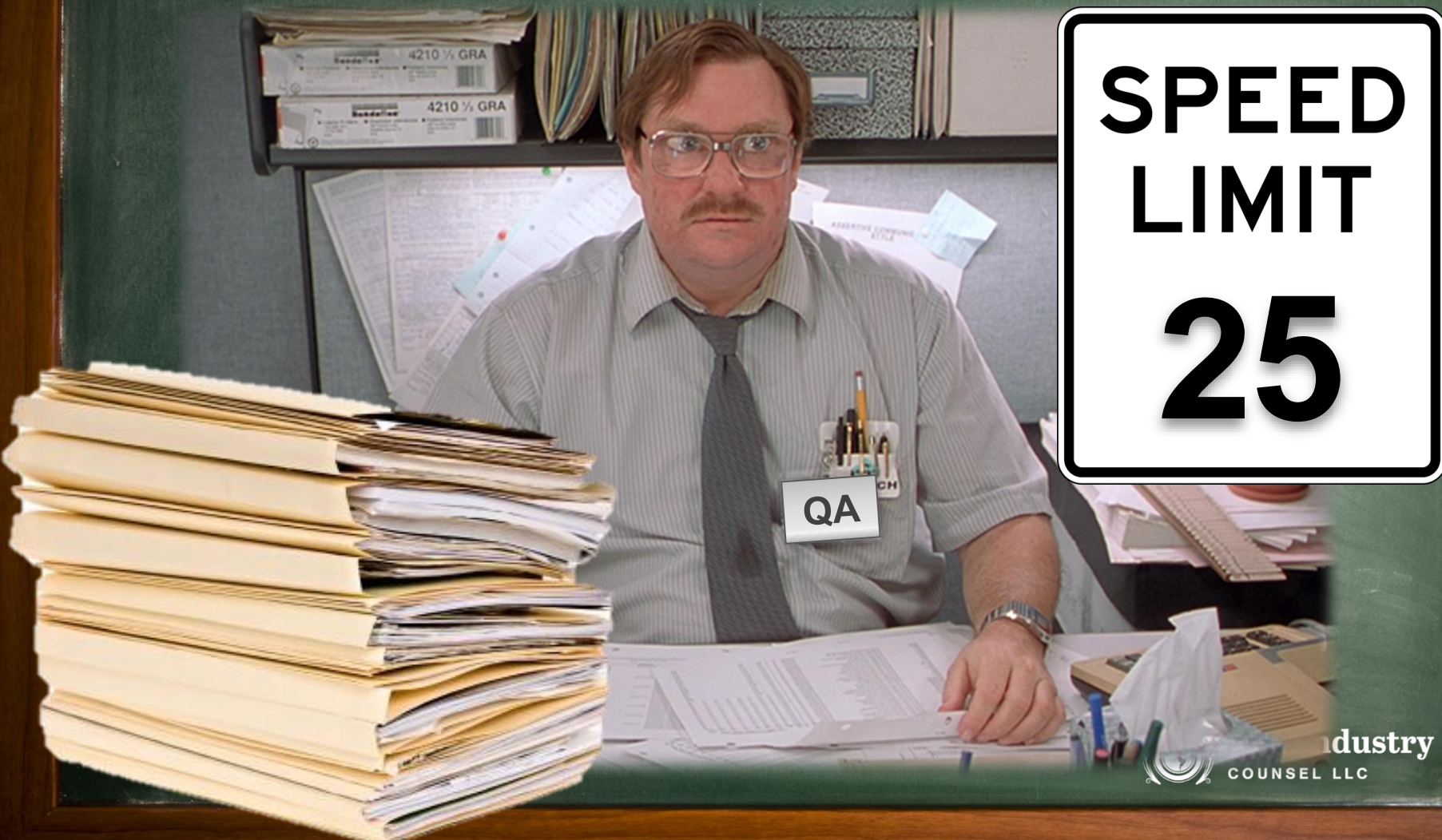


Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls



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TITLE 21 OF THE CODE OF FEDERAL REGULATION PART 117



TITLE 21 OF THE CODE OF FEDERAL REGULATION PART 117

21 C.F.R. 117.1 et

SUBPART A: General Provisions

SUBPART B: Current Good Manufacturing Practice

SUBPART C: Hazard Analysis and Preventive Controls

SUBPART D: Modified Requirements

SUBPART E: Withdrawal of Qualified Facility Exemption

SUBPART F: Requirements Applicable to Records

SUBPART F: Supply Chain Program



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WHO IS COVERED?

Food facilities that are required to register with FDA

Facilities that manufacture, process, pack or hold human food for consumption in the United States*



*Farms and Retail Establishments are exempt

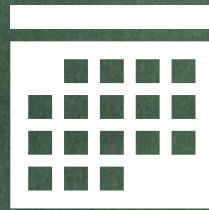


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WHAT ARE THE COMPLIANCE DEADLINES?

General Compliance Deadline: September 18, 2016

Small Businesses Deadline: September 18, 2017*



*Companies with less than 500 employees



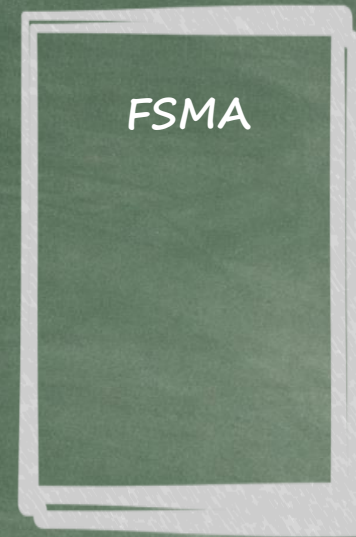
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WHAT ARE THE MAIN ELEMENTS?

PREVENTIVE CONTROLS
QUALIFIED INDIVIDUAL



WRITTEN FOOD
SAFETY PLAN



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WHAT ARE THE MAIN ELEMENTS?

PREVENTIVE CONTROLS
QUALIFIED INDIVIDUAL



A “Qualified Individual” is an individual who has successfully completed training in the development and application of risk-based preventative controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply an effective food safety system
[may be an employee of the facility]

FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE



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WHAT ARE THE MAIN ELEMENTS?

WRITTEN FOOD SAFETY PLAN

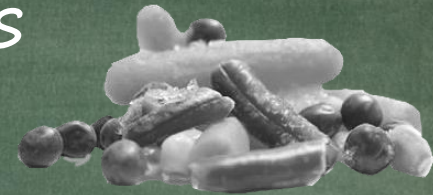


- **Hazard Analysis**
(to identify reasonably foreseeable food safety risks)
- **Preventative Controls**
(to control for and minimize those risks)
- **Verification and Monitoring Procedures**
(to verify and monitor that the controls are working)
- **Corrective Action Procedures**
(to correct any deviations and prevent recurrence)
- **Supply Chain Program**
(to identify hazards and needed controls, and approve suppliers)
- **Recall Plan**
(what to do in the event of a recall)



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FROZEN IQF VEGETABLES



WRITTEN FOOD
SAFETY PLAN



HAZARDS

Fields
Harvest
Receipt
Cutting
Environment
Allergens
Foreign Objects
Packaging

Biological
Chemical
Physical

CONTROLS

GMPs
Facilities
Wash systems
IQF Tunnel
Validations
EMPs
Metal detection
Finished Product Testing

VERIFICATION
& MONITORING

CORRECTIVE
ACTIONS



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EXAMPLE:



PRODUCT(S) Ground Black Pepper	PAGE 1 of 12
PLANT NAME: Example	ISSUE DATE 2/24/2016
ADDRESS: 123 ABC Street, USA	SUPERSEDES 10/20//2015

Selected Sections of a

Food Safety Plan
for
Ground Black Pepper

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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EXAMPLE:



PRODUCT(S) Ground Black Pepper	PAGE 2 of 12	
PLANT NAME: Example	ISSUE DATE	2/24/2016
ADDRESS: 123 ABC Street, USA	SUPERSEDES	10/20/2015

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For Training Purposes Only



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EXAMPLE:



PRODUCT(S) Ground Black Pepper	PAGE 3 of 12	
PLANT NAME: Example	ISSUE DATE	2/24/2016
ADDRESS: 123 ABC Street, USA	SUPERSEDES	10/20//2015

Company Overview

This example company is a small firm that makes a variety of spices that may be single spices or blends. They are assumed to be ready-to-eat because they may be used as is or in cooked products. Products include ground black pepper, black pepper rub (which includes whey protein, sugar and salt); and green, white and black peppercorn mix. The black pepper rub is blended in a separate room to prevent cross-contact issues. The only potential concern for allergen cross-contact is at filling.

Product is made 5 days a week in one 8 hour production shift, followed by 2 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. Water is treated and tested per EPA requirements by the city. An integrated pest control program is also in place. The company follows guidance from the American Spice Trade Association for production of safe and clean spices.

This Food Safety Plan covers production of ground black pepper. Other products have separate Food Safety Plans.

Product Description

Product Name(s)	Ground Black Pepper
Product Description, including Important Food Safety Characteristics	Dried ground black pepper
Ingredients	Black peppercorns
Packaging Used	Food grade steel container with plastic lid
Intended Use	The product is considered ready-to-eat. It is used to flavor prepared foods or used as part of a recipe
Intended Consumers	General public
Shelf Life	~ 2 years ambient
Labeling Instructions	None
Storage and Distribution	Dried, ambient temperature
Approved: Signature: F.S. Leader Print name: F.S. Leader	Date: 10/8/2015



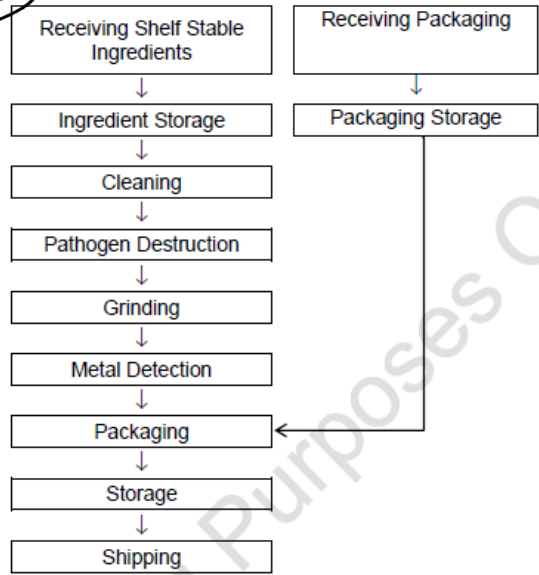
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EXAMPLE:



PRODUCT(S) Ground Black Pepper	PAGE 4 of 12	
PLANT NAME: Example	ISSUE DATE	2/24/2016
ADDRESS: 123 ABC Street, USA	SUPERSEDES	10/20/2015

Flow Diagram



Verified by: _____ Date _____

NOTE: Several more steps are usually included in a real process. This process is for teaching-purposes only.



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EXAMPLE:



PRODUCT(S) Ground Black Pepper	PAGE 5 of 12	
PLANT NAME: Example	ISSUE DATE	2/24/2016
ADDRESS: 123 ABC Street, USA	SUPERSEDES	10/20/2015

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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EXAMPLE:



PRODUCT(S) Ground Black Pepper	PAGE 6 of 12
PLANT NAME: Example	ISSUE DATE 2/24/2016
ADDRESS: 123 ABC Street, USA	SUPERSEDES 10/20//2015

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

ELEMENT 1

Hazard
Analysis



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EXAMPLE:



PRODUCT(S) Ground Black Pepper	PAGE 7 of 12
PLANT NAME: Example	ISSUE DATE 2/24/2016
ADDRESS: 123 ABC Street, USA	SUPERSEDES 10/20//2015

(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		
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	Process Control: 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	Sanitation Control: Zoning and dry sanitation	X			
	C None								
	P Metal	X				Equipment failure can potentially introduce metal	Process Control: Subsequent metal detection		X
Metal detection	B None								
	C None								
	P Metal	X		Potential equipment failure at grinding step	Process Control: Metal detection	X			
Packaging	B Environmental pathogens such as <i>Salmonella</i>	X		Post pasteurization contamination, cross contamination	Sanitation Control: Zoning and dry sanitation	X			
	C Undeclared allergens	X				Other products packed contain allergens	Allergen Control: prevent allergen cross-contact	X	
	P None								
Storage	B None								
	C None								
	P None								
Shipping	B None								
	C None								
	P None								

ELEMENT 1

Hazard Analysis



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EXAMPLE:



PRODUCT(S) Ground Black Pepper	PAGE 8 of 12
PLANT NAME: Example	ISSUE DATE 2/24/2016
ADDRESS: 123 ABC Street, USA	SUPERSEDES 10/20/2015

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.

ELEMENT 2
Preventive
Controls
(Process)

ELEMENT 3
Monitoring /
Verification

ELEMENT 4
Corrective
Actions



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EXAMPLE:



PRODUCT(S) Ground Black Pepper	PAGE 9 of 12
PLANT NAME: Example	ISSUE DATE 2/24/2016
ADDRESS: 123 ABC Street, USA	SUPERSEDES 10/20/2015

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.

ELEMENT 2
Preventive
Controls
(Allergens)



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EXAMPLE:



PRODUCT(S) Ground Black Pepper	PAGE 10 of 12	
PLANT NAME: Example	ISSUE DATE	2/24/2016
ADDRESS: 123 ABC Street, USA	SUPERSEDES	10/20/2015

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.

ELEMENT 2
Preventive
Controls
(Sanitation)



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EXAMPLE:



PRODUCT(S) Ground Black Pepper	PAGE 11 of 12
PLANT NAME: Example	ISSUE DATE 2/24/2016
ADDRESS: 123 ABC Street, USA	SUPERSEDES 10/20/2015

Hygienic Zoning/ Environmental Monitoring

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

Contains Nonbinding Recommendations

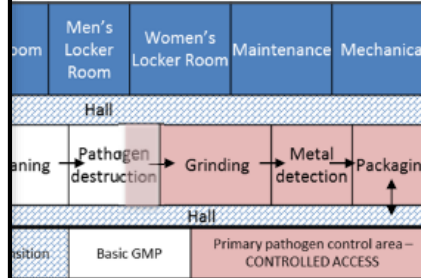
Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 180 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2007-D-0494 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
January 2017**



Individuals entering the Post Pathogen Destruction area (in

g the Post Pathogen Destruction area must (in the order

ck from the rack outside the production area and put them
outer clothing that would be above the processing line.
from the box by the entry and put them on over shoes.
n the box by the entry and put it on. Ensure that all loose
th facial hair should also apply beard nets.
entering the area following the procedures posted by the
of gloves.
deposit smocks, shoe covers and hair nets in the
O NOT reuse disposable items after entering

ors must follow the procedures above but use white foot
s when entering this area. Traffic in this area is minimized

ervisor visually observes the presence of the properly
efore start up and after lunch break, and every 2 hours.
ructed to gown properly.

g Record, Environmental Monitoring Sampling Record

onitoring for verification of sanitation preventive controls
week.

ELEMENT 2

Other
Controls
(Hygienic
Zoning)

(Environmental
Monitoring)



EXAMPLE:

PRODUCT(S): Ground Black Pepper
PLANT NAME: Example
ADDRESS: 123 ABC Street, USA
PAGE 31 of 32
ISSUE DATE: 03/24/2018
SUPERSEDES: 00000000

ELEMENT 2



Is Lm reasonably foreseeable?

- Supplier Approval Program
- Certificates of Conformance
- Require Raw Material Testing
- Require Environmental Monitoring
- Conduct Audits and Verification Activities

Finished Product Testing

FDA Recommends Testing:

- Verification Purposes
- Periodic Testing
- Sample for Lm
- Test and Hold

EXAMPLE:



PRODUCT(S) Ground Black Pepper	PAGE 12 of 12	
PLANT NAME: Example	ISSUE DATE	2/24/2016
ADDRESS: 123 ABC Street, USA	SUPERSEDES	10/20//2015

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.



EXAMPLE:

RECALL PLAN

21 C.F.R 7.40-59

- Health Hazard Assessment
- Depth of the Recall
- Recall communications
- Public Warning
- Effectiveness Checks



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FDA FOOD SAFETY PLAN BUILDER



FOOD SAFETY PLAN BUILDER



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FDA FOOD SAFETY PLAN BUILDER

Food Safety Plan Builder - New*

File Edit View Tools Help

Facility Information Preliminary Steps GMP & Other Prerequisite Programs Hazard Analysis & Preventive Controls Determination Process Preventive Controls Food Allergen Preventive Controls Sanitation Preventive Controls

Facility/Company Name: Facility Identifier Numbers:

Address: Country:

City, State: Postal Code:

Phone Numbers: Phone Mobile
Other Fax

Description	Number
FDA Food Facility Registration Number	<input type="text"/>

Facility Description:

Employee Description:

Product Description:

Food Safety Team:

Primary Contact(s)	Preventive Controls Qualified Individual	Name	Title	Phone
<input type="text"/>				



FOOD SAFETY PLAN BUILDER



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FDA FOOD SAFETY PLAN BUILDER

Facility Information
Preliminary Steps
Good Manufacturing Practices (GMP) & Prerequisite Programs
Hazard Analysis & Preventive Controls Determination
Process Preventive Controls
Food Allergen Preventive Controls
Sanitation Preventive Controls
Supply-Chain Preventive Controls
Recall Plan
Reanalysis of Food Safety Plan
Food Safety Plan Report
Signature
Recordkeeping Procedures
Important Contacts
Supporting Documents



FOOD SAFETY PLAN BUILDER



FDA FOOD SAFETY PLAN BUILDER



<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm539791.htm>



FOOD SAFETY PLAN BUILDER



RECORD KEEPING REQUIREMENTS

Records must be maintained with respect to all elements of the food safety plan

Offsite records must be made available within 24 hours

Must be maintained for a period of 2 years



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