



Hazards and Hazard Analysis

Outline

- Describe the end goal – start thinking about what documents you will need for your plan, and what you need to develop those documents.
- Determine the steps to develop those preliminary materials
- Review hazards
- Identify resources helpful in this process
- In groups, develop your preliminary documents

Contents of a Food Safety Plan

Required

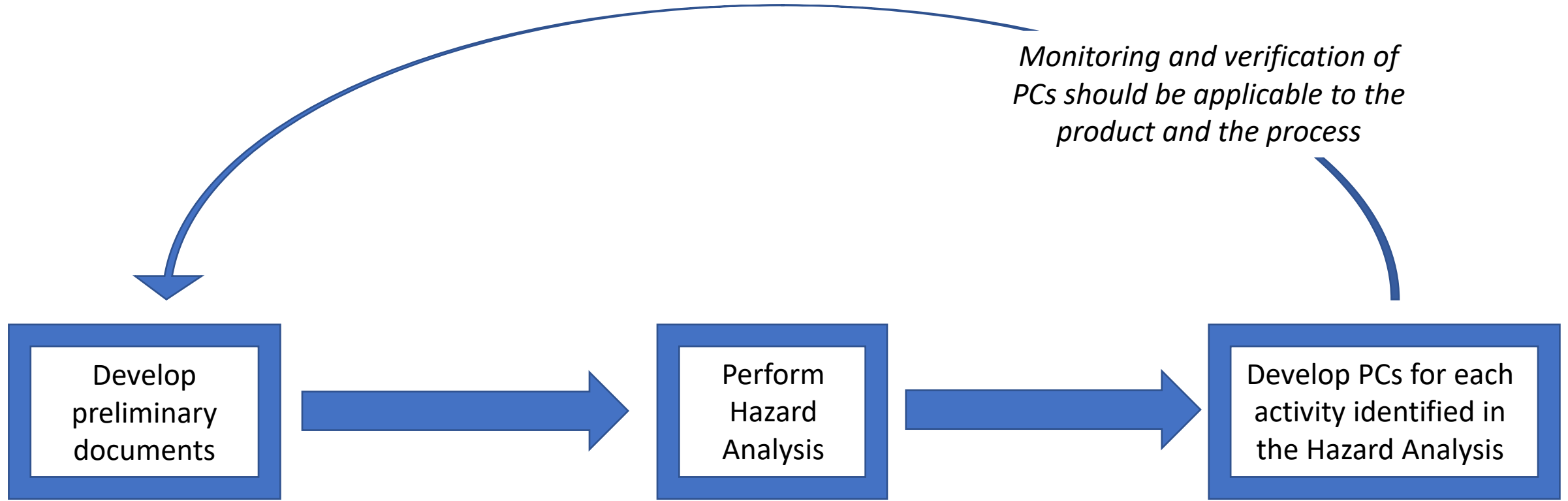
- Hazard analysis
- Preventive controls*
 - Process, food allergen, sanitation, supply-chain and other
 - Recall plan*
- Procedures for monitoring, corrective action and verification*

Useful

- Facility overview and Food Safety Team
- Product description
- Flow diagram
- Process description

* Required when a hazard requiring a preventive control is identified





Monitoring and verification of PCs should be applicable to the product and the process

Develop preliminary documents

Perform Hazard Analysis

Develop PCs for each activity identified in the Hazard Analysis

Consider how hazards are potentially influenced by distribution, process, intended consumers and use

Consider hazards relevant to the product and the process, and what type of PC program is relevant for their control

Hazard

A biological (microbial), chemical or physical agent reasonably likely to cause food borne illness or injury in the absence of it's control

Hazards or Agents:

Biological – bacteria, fungi, viruses, parasites

Chemical – Allergens, toxins, antibiotics, cleaners

Physical – glass, metal, wood chips (injury)

Biological Hazards of Concern in Selected Ingredients

Ingredient Source	Potential Biological Hazards
Raw milk and raw milk products	<i>Campylobacter, Salmonella, Brucella, Mycobacterium spp., Strep group A</i>
Soft cheese	<i>L. monocytogenes</i>
Eggs	<i>Salmonella</i>
Meat and poultry	<i>Salmonella, EHEC*, C. perfringens, Campylobacter (poultry), L. monocytogenes, Y. enterocolitica (pork)</i>
Grains and cereal products	<i>Salmonella, EHEC, B. cereus (rice)</i>
Fruits - fresh	<i>Salmonella, EHEC, L. monocytogenes, viruses, parasites</i>
Tree nuts/peanuts	<i>Salmonella, EHEC</i>
Vegetables - fresh	<i>Salmonella, EHEC, L. monocytogenes, viruses, C. botulinum, parasites</i>
Refrigerated RTE	<i>L. monocytogenes</i>
Spices	<i>Salmonella, EHEC, C. perfringens</i>
Non-potable water/ice	<i>Salmonella, EHEC, viruses, parasites</i>

*EHEC = Enterohemorrhagic *E. coli*

Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food

JANUARY 2018

[Download the Draft Guidance Document](#)

[Read the Federal Register Notice](#)

Draft

Not for implementation. Contains non-binding recommendations.

- [Appendix 1: Potential Hazards for Foods and Processes \(PDF: 1 MB\)](#)
- [Appendix 2: Food Safety Plan Forms \(PDF: 261KB\)](#)
- [Appendix 3: Bacterial Pathogen Growth and Inactivation \(PDF: 165KB\)](#)
- Appendix 4 – Sanitation and Hygienic Zoning (coming soon)

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food>

“Hazard” Does Not Necessarily Refer To:

- Violations of regulatory standards not directly related to food safety, e.g.:
 - Economic fraud*
 - Standards of identity
- Undesirable conditions that generally are not hazards requiring a preventive control, e.g.:
 - Spoilage*
 - Insect fragments
 - Hair
 - Filth
- The above may be subject to other regulatory requirements

* Unless associated with a specific safety issue

Biological Hazards

Potential controls for biological hazards include:

- Prevent contamination
 - Ingredients, people, and then environment are potential sources of contamination
- Kill them
 - Spores are harder to kill than vegetative bacteria, viruses and parasites
- Control growth (bacteria only)
 - When you can't prevent contamination or kill bacteria, you must control growth
 - Time, temperature, pH, water activity, atmosphere, competition, preservatives and combinations can help

Infections and Intoxications

Foodborne infection

- Pathogen invades the body after consumption of contaminated food
- Growth in the food may not be necessary to cause illness
- Examples
 - Pathogenic *E. coli*
 - *Salmonella*
 - *Listeria monocytogenes*
 - All viruses and parasites

Foodborne intoxication

- Pathogen growth in the food produces a toxin that causes illness when consumed
- No growth in food = No toxin = No illness
- Examples
 - *Staphylococcus aureus*
 - *Clostridium botulinum*
 - *Bacillus cereus*

Product-Pathogen Identification and PC

**Pasteurized
Milk**

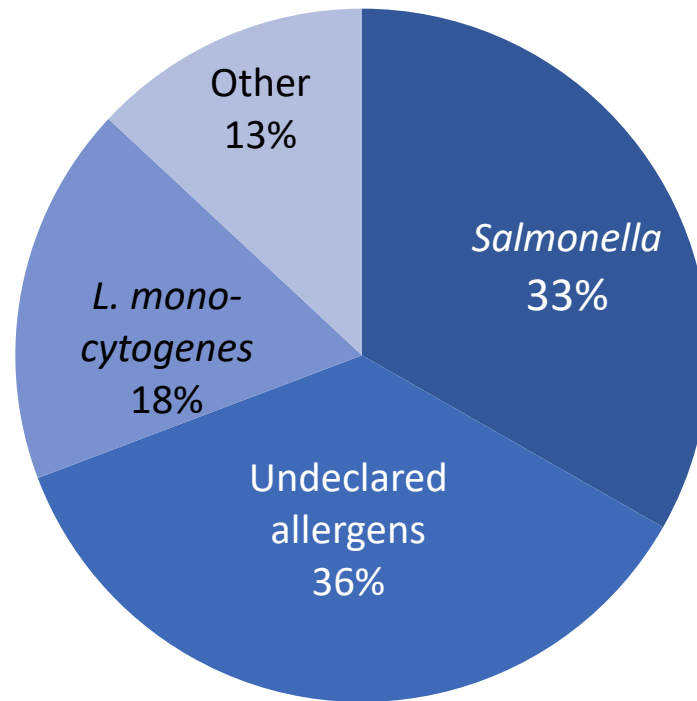


Fresh Herbs



Reportable Food Registry Identifies Concerns

**Reportable Food Registry Reports
2009-2013**



- Electronic portal for industry to report foods when use is reasonably likely to cause illness, injury or death
- Biological hazards in foods are reported most frequently
- Undeclared allergens represent about 1/3 of reports

Biological Agents Cause More Outbreaks

Reported Foodborne Illness Outbreaks 2009–2013

Hazard Type	Outbreaks	Illnesses	Hospitalizations	Deaths
Biological	2,545	52,750	3,552	99
Chemical	163	663	67	5
Physical		Not collected		
Unknown	1,204	13,770	286	3

Adapted from: CDC Surveillance for Foodborne Disease Outbreaks, United States Annual Reports, 2009-10, 2011, 2012, 2013

Product-Pathogen Identification and PC

Cookie Dough Ice Cream



Fruit Popsicle



Chemical Hazards Examples

- Naturally occurring
 - Food allergens, mycotoxins, decomposition by-products
- Used in formulation
 - Food additives, color additives, preservatives
- Unintentionally or incidentally present
 - Cleaning and sanitizing chemicals, pesticides, industrial chemicals, heavy metals, drug residues, radiological hazards

Major Food Allergens (The Big 8)

- Milk
- Egg
- Peanut
- Tree nuts
- Fish
- Crustacean Shellfish
- Wheat
- Soy

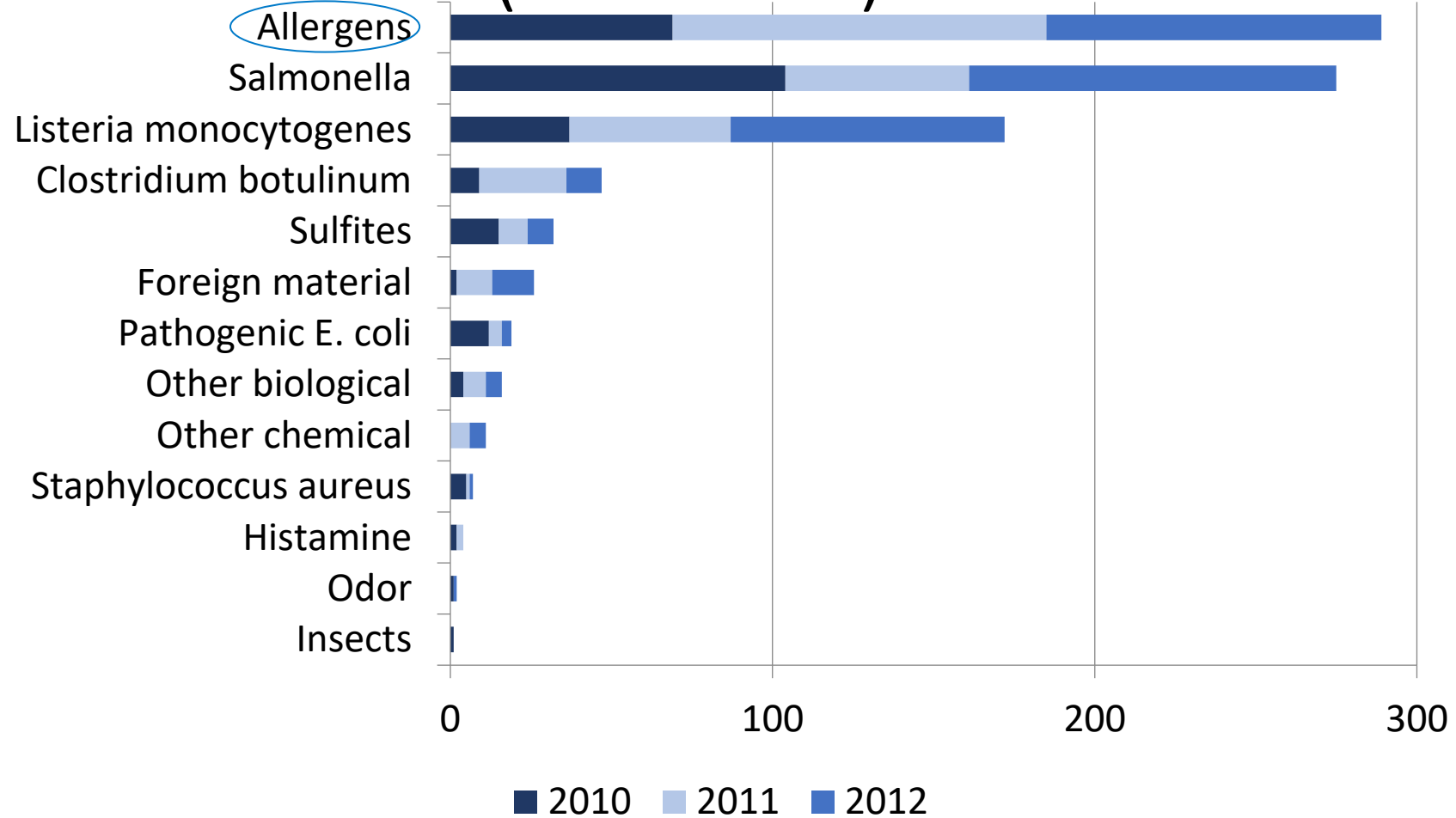


90% of food allergic reactions are caused by these allergens



Photo Sources: Microsoft Clip Art and KMJ Swanson (soybeans)

FDA Food Recalls (2010-12)



Adapted from: FDA 2010 Recalls, Market Withdrawals and Safety Alerts

Avoidance is the Primary Treatment

- Complete avoidance of the allergen is the primary treatment for food allergies
- This requires:
 - Individual responsibility to avoid and prepare for accidental exposure
 - Those supplying or preparing food to provide accurate information and safe food

Known Causes of Allergen Recalls

Most Common	Number
Wrong label or package	137
Terminology not correct	85
No carry-through of info from ingredient	70
Cross-contact	52
Wrong ingredient	31
Rework	9

Other	Number
Knowledge	28
Ingredient mislabeled	26
Not updated after formula change	22
Computer error	21
In process	19
Other	14
No declaration	12

Adapted from Gendel and Zhu 2013

Mycotoxins

Chemical Hazards Produced by Certain Molds

- Aflatoxins
 - Peanuts, dried corn (maize), tree nuts, certain spices
- Ochratoxin A
 - Coffee, raisins, wine, cereal grains, certain spices
- Fumonisin
 - Dried corn
- Deoxynivalenol (DON)
 - Wheat and barley
- Zearalenone
 - Wheat and barley
- Patulin
 - Fruits

- Factors that increase concern
 - Certain weather patterns, e.g., drought stress
 - Insect damage
 - Slow drying
 - Poor storage

Physical Hazards

Foreign material such as metal, glass, wood splinters, or plastic fragments that might cause injury (e.g. laceration) or present a choking hazard.

Sources:

- Glass: bottles, jars, light fixtures, gauge covers
- Metal: metal on metal, equipment parts
- Plastic: field, packaging material, pallets, employees, equipment covers (Plexiglas®)
- Wood: field, pallets, boxes, building structure
- Stones: fields

Sources of Information - Personnel

- Your employees
- Consultants and auditors
- Process authorities and subject matter experts
- University specialists
- Government agencies
- Trade associations
- Suppliers, buyers and laboratory analysts

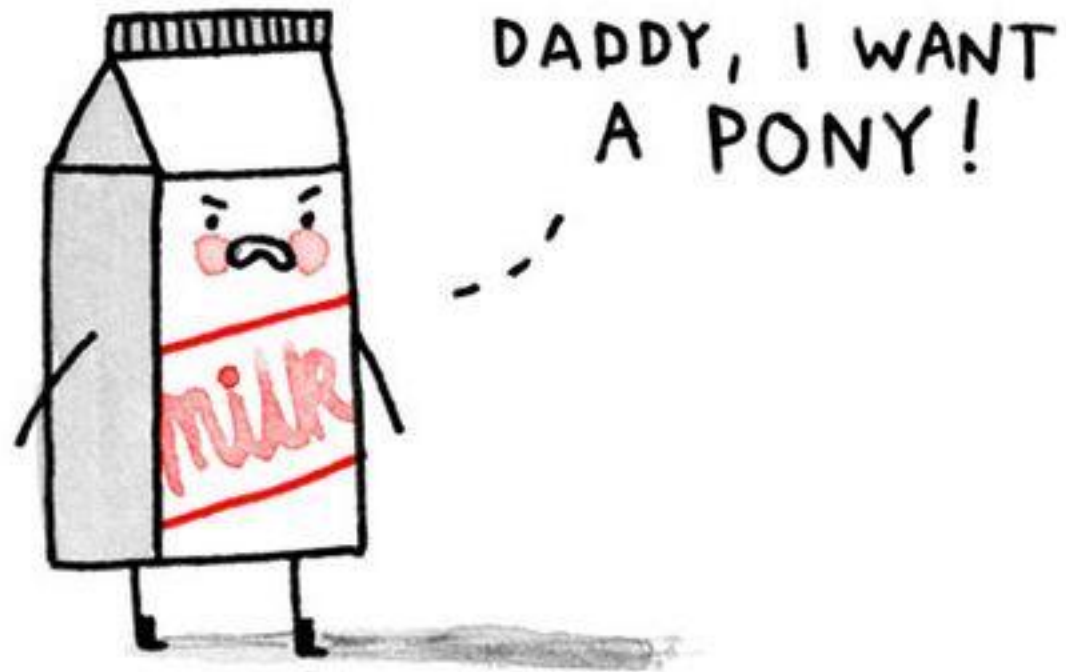
Sources of Information – Publications

- *Hazard Analysis and Preventive Controls for Human Food* training curriculum
- FDA publications
- Peer reviewed literature
- Trade association publications
- References used to develop this curriculum

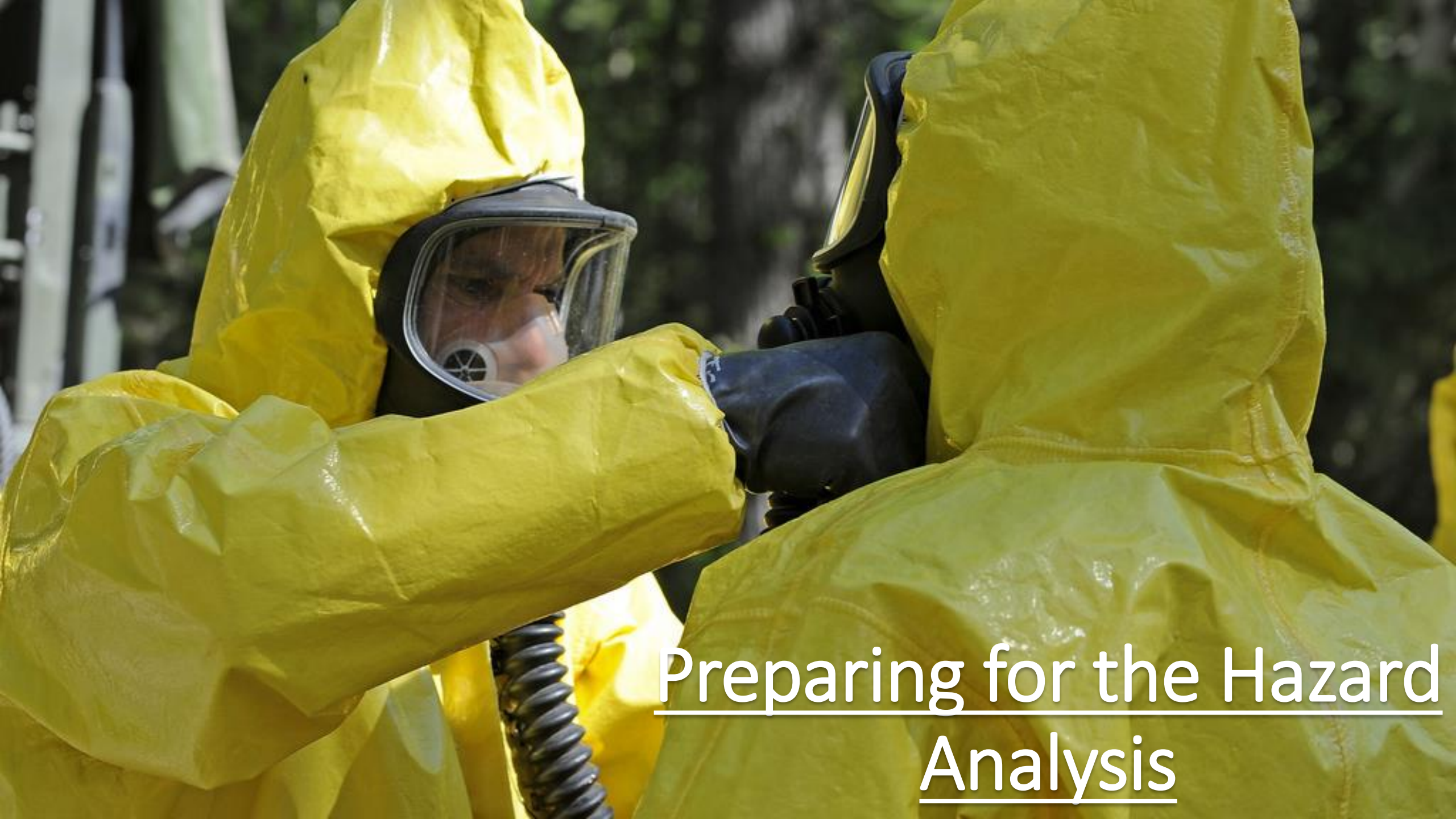
Sources of Information – Reliable Internet Sites

- FSPCA website
- FDA website
- Other U.S. agency resources
 - Centers for Disease Control and Prevention
 - FoodSafety.gov
 - U.S. Department of Agriculture
- International agency resources, e.g.,
 - Canadian Food Inspection Agency
 - Codex Alimentarius Commission
 - European Food Safety Authority
- Trade association websites

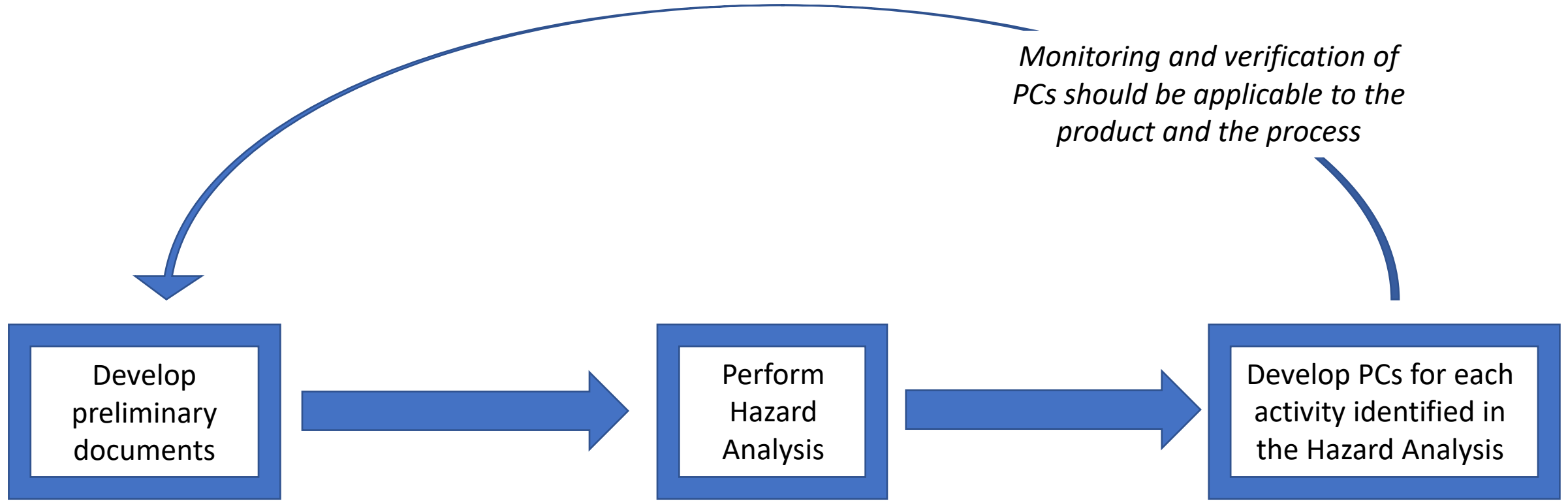
Quick: What hazards are associated with dairy products?



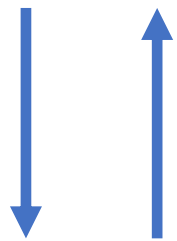
SPOILED MILK



Preparing for the Hazard
Analysis



Monitoring and verification of PCs should be applicable to the product and the process



Consider how hazards are potentially influenced by distribution, process, intended consumers and use

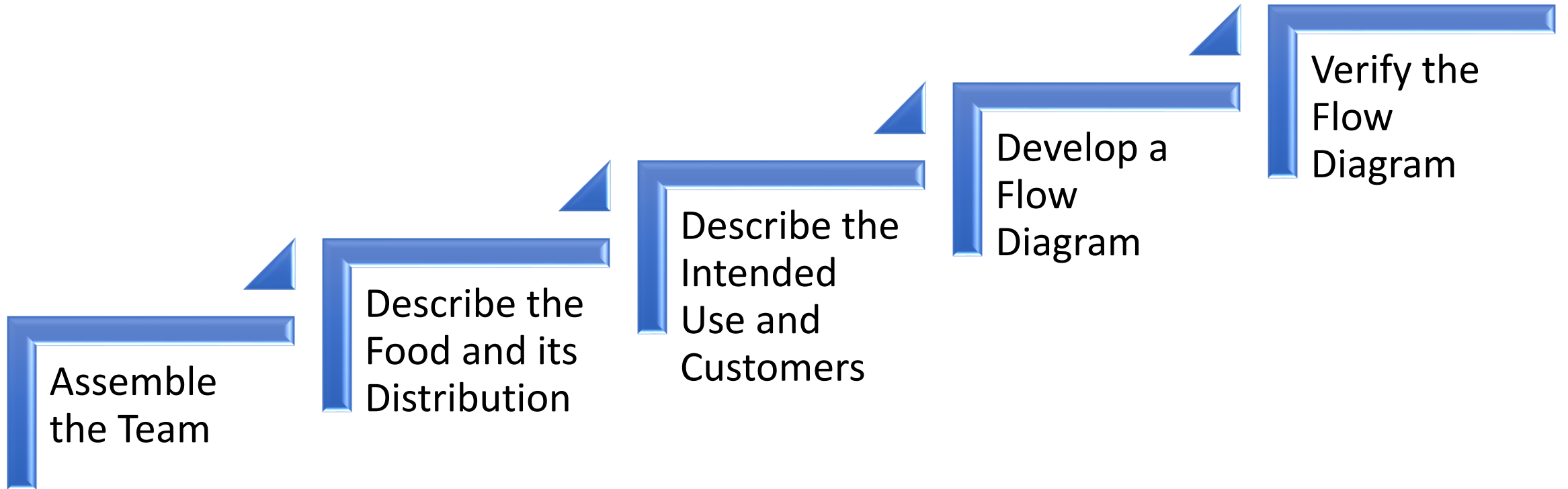


Consider hazards relevant to the product and the process, and what type of PC program is relevant for their control

Vocabulary

- Preliminary steps
 - Optional or informal actions performed prior to the hazard analysis in order to facilitate the process of Food Safety Plan development.
- Prerequisite programs
 - Procedures, including Good Manufacturing Practices (GMPs), that provide the basic environmental and operating conditions necessary to support the Food Safety Plan.
- Preventive controls
 - A dedicated control system for those activities identified in the hazard analysis as requiring a control.
- Food safety plan
 - Written set of procedures for monitoring, verifying, and correcting PCs. Also may including supporting documentation.

Preliminary Steps



Facility Overview

<i>Company Name</i>	<i>Address</i>
<i>Telephone Number</i>	<i>Website/Email</i>
<i>Company Owner</i>	<i>PPS</i>

<i>Description of Business</i>	<i>Size of Facility (Sq. Footage)</i>
<i>Number of Employees</i>	<i>Number of Shifts</i>
<i>Scope of Products Produced</i>	

<i>Building Description</i>	<i>Age of Facility</i>
<i>Roof Materials</i>	<i>Wall Materials</i>
<i>Flooring Materials</i>	<i>Neighbors (i.e. farm, residential, industrial, waste site)</i>

<i>Major Processing Equipment</i>
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Describe the Product and Its Distribution

- The Product Description should include:
 - The product names(s)
 - Important food safety characteristics of the product, if any (e.g., pH, a_w , preservatives)
 - Ingredients
 - Packaging type
 - Shelf life
 - Storage and distribution

Describe the Intended Use and Consumers

- This may be combined with product description information and should include:
 - Intended use and reasonably foreseeable unintended use
 - Intended consumers (e.g., general public, infants, elderly)
 - Labeling instructions relevant to food safety

At-risk Populations

- These groups are more susceptible to foodborne illness:
 - Infants and young children
 - Elderly persons
 - Pregnant women
 - Immune-suppressed persons
- Additional controls may be necessary if your product is designed specifically for these populations, e.g.,
 - Infant formula
 - Special diets for medical settings
 - Foods prepared for nursing homes
 - Foods targeted toward young children

Product Description

Product _____ Issue Date _____
 Supersedes _____

Product Name(s)	
Important food safety characteristics <i>(a_w, pH, processing, RTE, requires additional cooking)</i>	
Ingredient list	
Packaging used	
Labeling requirements/ instructions for use	
Shelf life	
Storage, distribution, & handling	
Distribution area/outlets	
Intended consumers	
Intended use	

Company Name _____ Telephone Number _____

Address _____ Email/Website _____

Version/Date _____ Supersedes _____

Approved by (*print name*) _____ Title _____

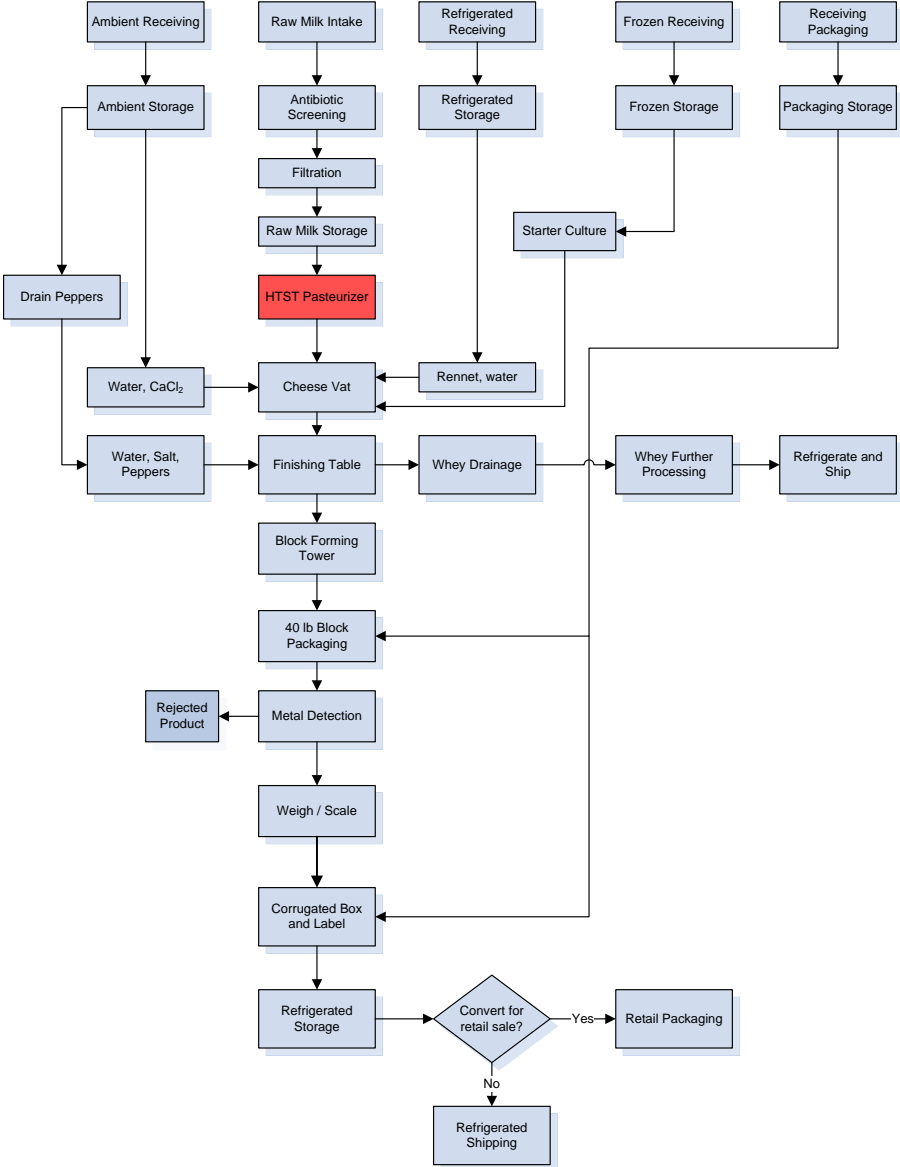
Approval Signature _____ Date Signed _____

Product Name(s)	Pepper Jack Cheese
Product Description, including Important Food Safety Characteristics	Pepper Jack cheese is a pasteurized semi-soft natural cheese with added peppers. Product supports limited growth of a number of pathogens during processing and early aging; however natural pH (5.0 – 5.4), competitive inhibition from the cheese starter culture, enzymatic activity and salt during the short aging process has the potential to reduce or eliminate pathogens over time. Diced peppers in brine drained prior to addition after pasteurization.
Ingredients	Pasteurized milk, peppers, salt, cultures, enzymes, calcium chloride.
Packaging Used	40 # block final package is high density polypropylene bag shrink-wrapped and heat sealed. 1 # retail chunk package is high density polypropylene bag vacuum packed and heat sealed with the label applied prior to case packing in corrugated box.
Intended Use	Initially stored as 40 # blocks in film-lined corrugated boxes for short aging period. Distributed using refrigerated trucks (35 °F – 45 °F) to conversion facilities for further consumer packaging and sale to retail stores and foodservice distributors. 1 # retail chunk is sold at cheese plant retail store as well as local retail stores.
Intended Consumers	Ready to eat product for industry and consumers.
Shelf Life	180 days at 35 °F – 45 °F.
Labeling Instructions	40 # block case: Plant number, Vat number, Manufacture Date and Block weight. Retail label: Keep refrigerated; Best used by date Retail label allergen statement: Contains: milk
Storage and Distribution	Refrigerated storage and retail and foodservice distribution.

Develop a Flow Diagram and Describe the Process

- Flow diagram is an important tool to describe the process
- Include all the process steps within the facility's control
- Include reworked product, by-product and diverted product, if applicable
- Develop a written description for each step in the flow diagram

Verify the Flow Diagram



Build: Preliminary Documents



Hazard Analysis



Process to Identify Hazards and Controls

1. List process steps and ingredients
2. Identify **known or reasonably foreseeable** (i.e., potential) **food safety hazards**
3. Determine if the hazard **requires a preventive control**
 - Severity and probability in the absence of control
4. Justify the decision
5. Identify preventive controls for significant hazards

Hazard Analysis	PRODUCT:		PAGE X of Y
PLANT NAME			ISSUE DATE mm/dd/yy
ADDRESS			SUPERSEDES mm/dd/yy

(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
	B						
	C						
	P						

Hazard Analysis Form Example -
other formats may be used

Examples of Other Hazard Analysis Formats

(1) Ingredient/ Processing Step	(2) <u>Reasonably foreseeable</u> food safety hazards introduced, controlled or enhanced at this step (B=biological; C=chemical, including radiological; P=physical)	(3) Hazard severity	(4) Is hazard a significant hazard?	(5) Justify your decision for column 4	(6) What <u>preventive</u> control(s) are applied to significantly minimize or prevent the food safety hazard?	(7) Is this step a CCP?
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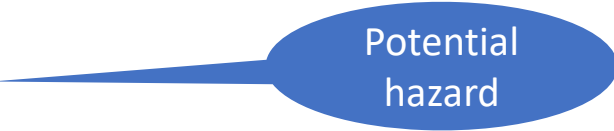
(1) Ingredient/ Processing Step	Hazard description			Hazard evaluation				Preventive control(s)		
	(2) Identify <u>reasonably foreseeable</u> food safety hazards introduced, controlled or enhanced at this step	(3) Origin or source of the hazard	(4) Nature of the hazard [hazardous level in end product]	(5) Likelihood of occurrence	(6) Severity of health effect	(7) Is hazard significant requiring a preventive control?	(8) Justify decision for column (7)	(9) What control measure(s) are applied to significantly minimize or prevent the food safety hazard?	(10) Nature of control measure	
									CCP	Other

Hazard Definitions (21 CFR 117.3)

Hazard

- Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Known or reasonably foreseeable hazard

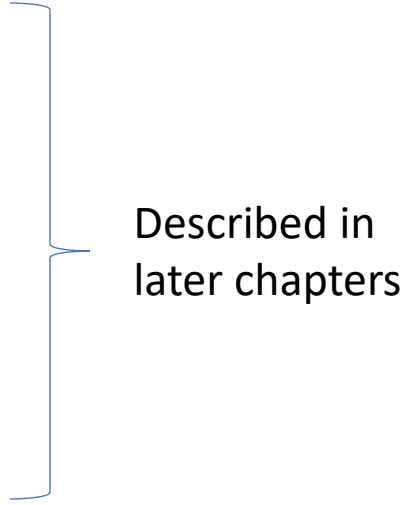


Potential
hazard

- A biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

Preventive Controls May Include:

- Process preventive controls
- Food allergen preventive controls
- Sanitation preventive controls
- Supply-chain program



Described in
later chapters

Hazard Evaluation Considerations

- Formulation of the food
- Condition, function and design of facility and equipment
- Raw materials and ingredients
- Transportation practices
- Processing procedures, including rework
- Packaging and labeling activities
- Storage and distribution
- Intended or reasonably foreseeable use
- Sanitation including employee hygiene
- Others relevant factors

Evaluating Severity of Food Safety Hazards

- Requires consideration of various factors that may include:
 - the magnitude and duration of the illness or injury,
 - the possible impact of secondary problems (chronic sequelae) and
 - the susceptibility of intended customers to foodborne illness (e.g., children versus adults).

Evaluating Likelihood of Occurrence

- Requires consideration of factors including:
 - Data from past foodborne illness outbreaks
 - Recall data from similar products
 - Information in the scientific literature
 - Historical information in the establishment
 - Regulatory guidance
 - Trade association information
 - University extension documents

Potential Preventive Control Examples

Biological hazards

- Process controls that kill pathogens
 - E.g., cooking
- Process controls that prevent growth; e.g.,
 - Time/temperature controls
 - Checking formulation
- Supply-chain programs for sensitive ingredients used without a kill step
- Sanitation controls that prevent recontamination

Chemical hazards

- Supply-chain programs
- Allergen labeling
- Sanitation controls to prevent allergen cross-contact

Physical hazards

- Process controls such as
 - Filtering, metal detection, X-ray devices

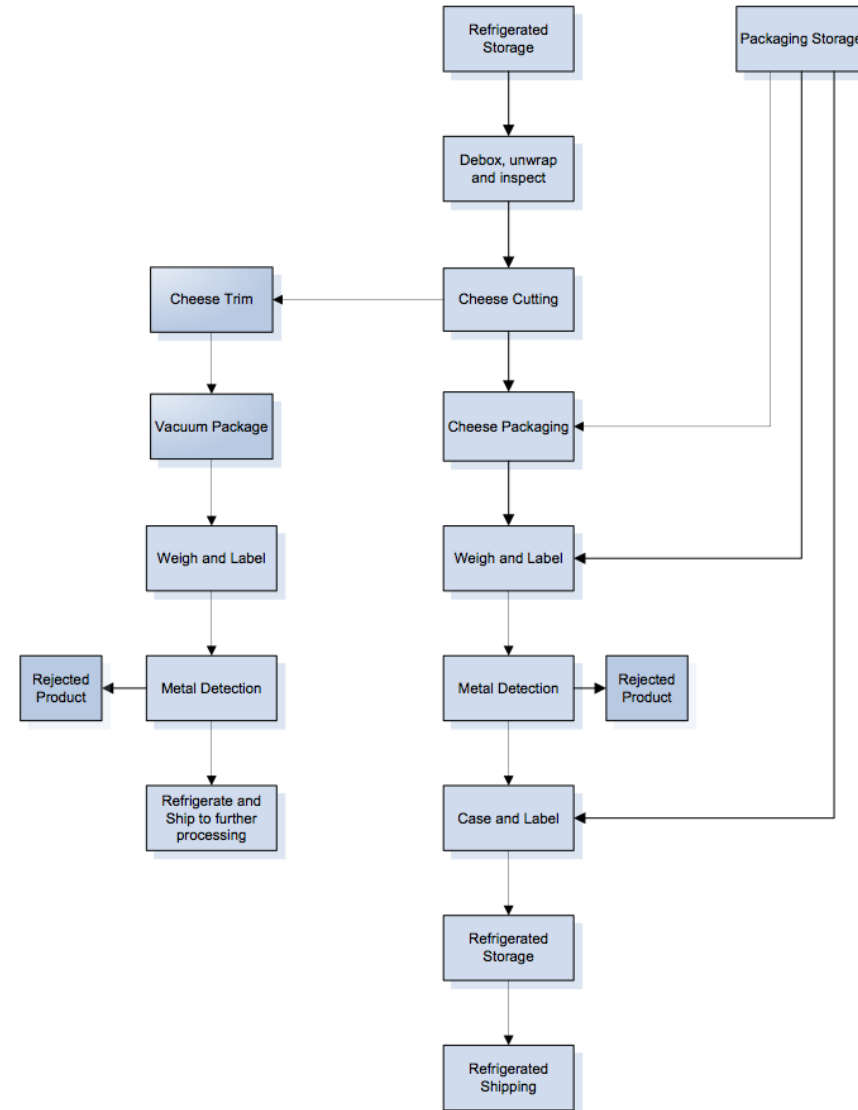


PRODUCT(S): Pepper Jack Cheese – Ready-to-Eat
PLANT NAME: Wisconsin Cheese Company
ADDRESS: 123 Main Street, Monterey, USA

PAGE 5 of 22
ISSUE DATE: 11/11/2016
SUPERSEDES: 10/28/2016

Model Review: Pepper Jack Cheese

Flow Diagram – Retail Packaging



Hazard Analysis	PRODUCT:		PAGE X of Y
PLANT NAME			ISSUE DATE mm/dd/yy
ADDRESS			SUPERSEDES mm/dd/yy

(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
	B						
	C						
	P						

Hazard Analysis Form Example -
other formats may be used

Build: Hazard Analysis

