The Voice of the U.S. Spice Industry

What is a Food Safety Plan? How do you Build One?

Food Directions LLC

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On the Agenda

- FSMA and HARPC
- Getting Started
- The Components of a Food Safety Plan
  - Hazard Analysis
  - Preventive Controls
  - Corrective Actions
  - Recall Plan
- Enforcement
- Q/A

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Food Safety Modernization Act

- FSMA
  - Shifts the focus FROM responding to contamination TO prevention
  - Calls for industry to take a fresh look at processes and procedures
  - Focuses on high risk foods and circumstances
  - Gives FDA unprecedented authority to review records and take action

HARPC

- The system used to control the different hazards found in different facilities that manufacture food.
  - Each food manufacturing facility owned and operated by a food company must have its own HARPC plan if there are any differences in the foods it manufactures between facilities.
  - The food company must include each validated HARPC plan for each of its facilities in its food safety plan.

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Isn’t HACCP the Same Thing?

HACCP	HARPC
Hazards defined as radiological, biological, chemical and physical.	Hazards include radiologicals, natural toxins, pesticides, drug residues, decomposition, parasites, allergens and unapproved food and color additives. The hazards can be naturally occurring or may be unintentionally introduced. Hazards to be identified and evaluated also include those that can be intentionally introduced, including by acts of terrorism, and these hazards will be regulated under a separate rule called the Intentional Adulteration rule.

: HACCP vs. HARPC

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Getting Started

- ✓ Identify Your Food Safety Team
- ✓ Designate Your Preventive Controls Qualified Individual
- ✓ Perform Gap Analysis/Hazard Analysis
- ✓ Write up Food Safety Plan
- ✓ Determine Record Keeping System
- ✓ Establish System to Maintain and Document Training

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Food Safety Team

- *Example of Food Safety Team*
  - Plant Manager
  - QA manager and food safety team leader
    - Preventive controls qualified individual
  - Production supervisor
  - Sanitation supervisor
- Consultant

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

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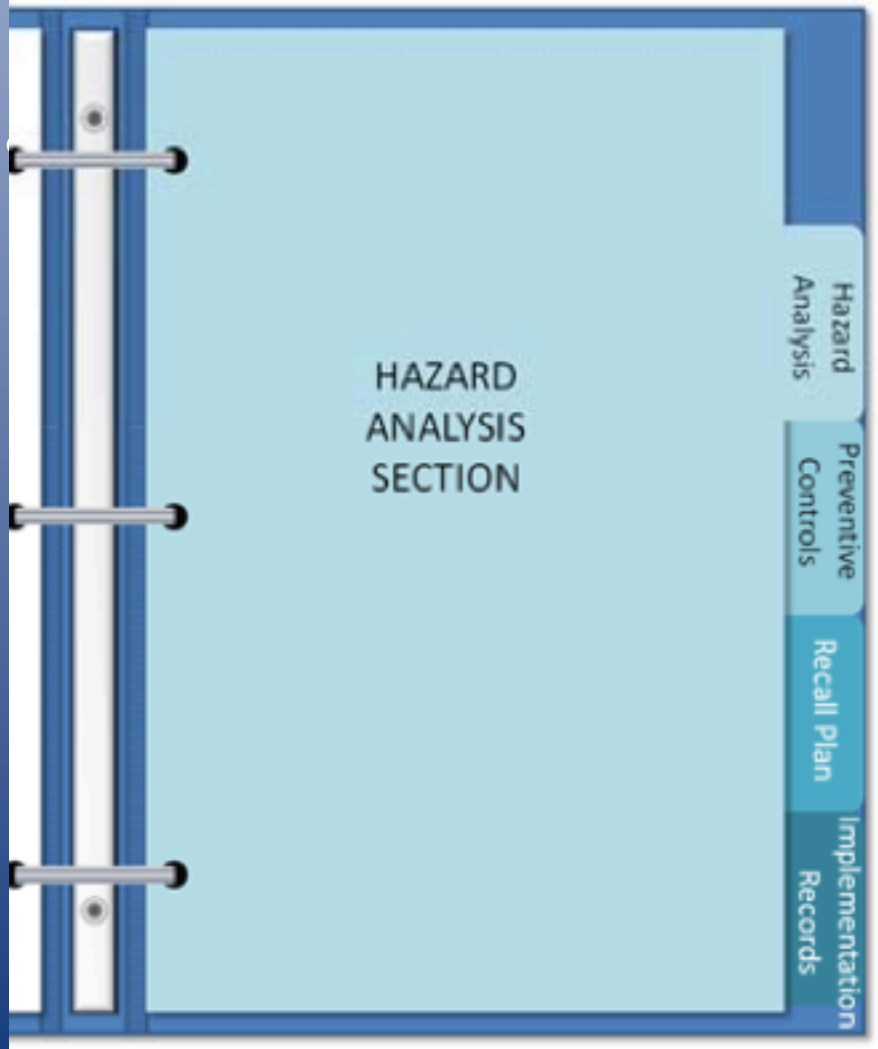
Hazard Analysis – Required



- Drives decision making for the controls that must be included in the Food Safety Plan

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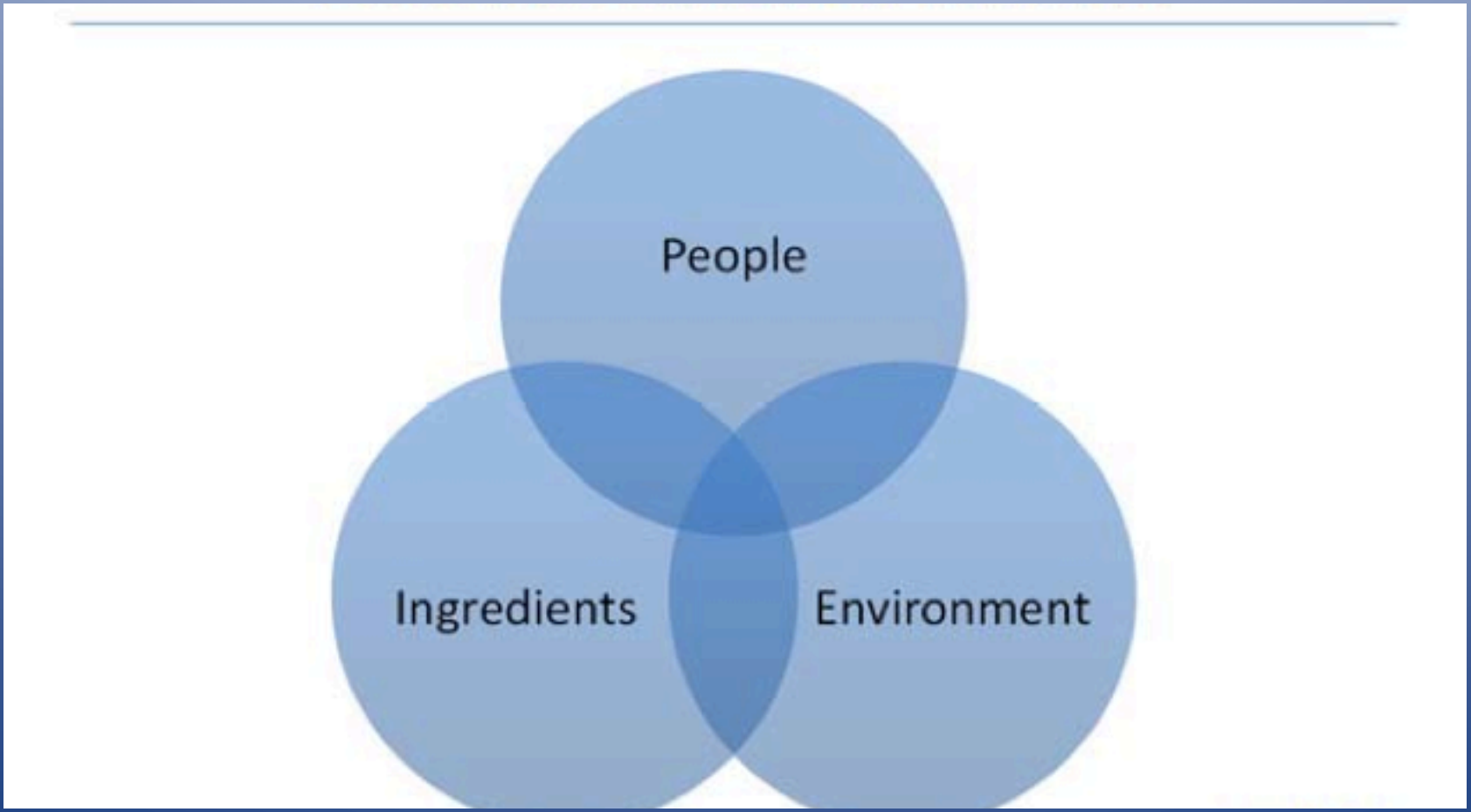
Hazard

- *Hazard:* Any biological, chemical (including radiological) or physical agent that has the potential to cause illness or injury.
- *Known or reasonably foreseeable 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.

Where do Hazards Originate?



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 potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
	B							
	C							
	P							

Hazard Analysis Form Example -
other formats may be used

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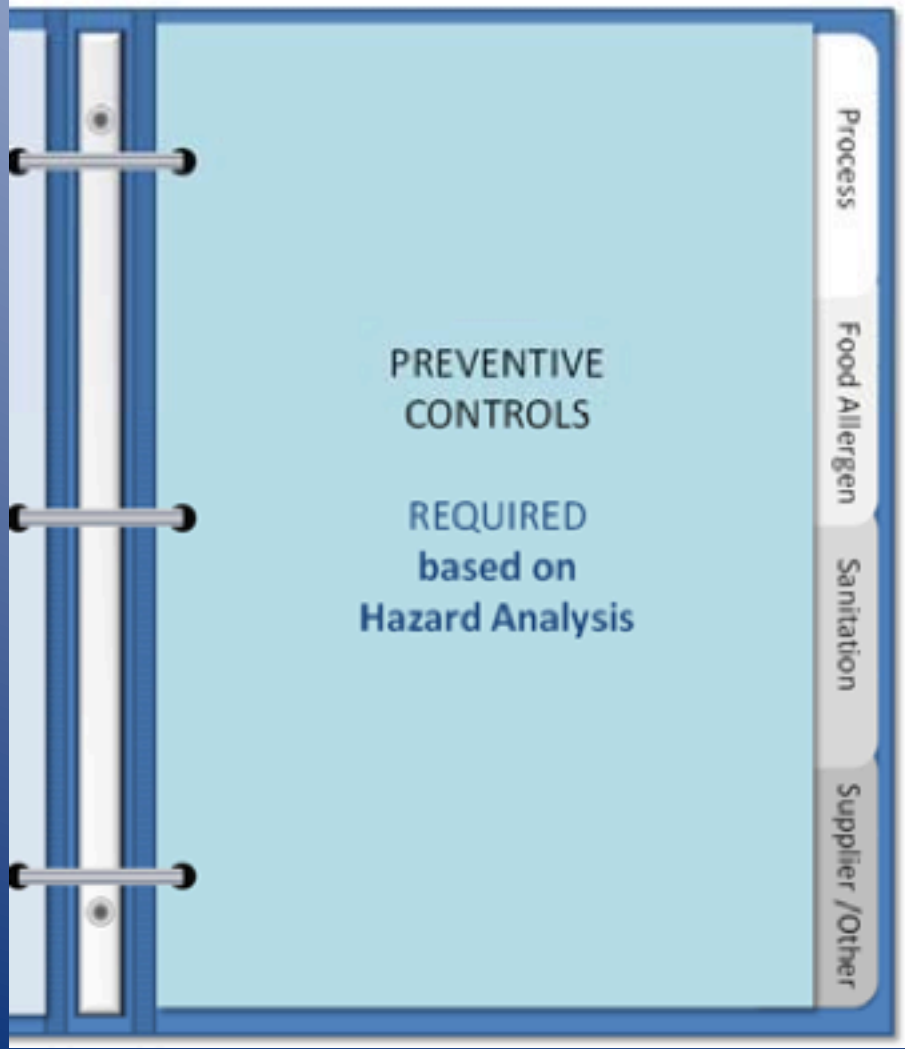
Preventive and Other Controls May Include:



Process preventive controls
- Process specific controls

Food allergen preventive controls
- Accurate labeling
- Cross-contact prevention

Sanitation preventive controls
- Environmental pathogens
- Cross-contamination, cross-contact

Other preventive controls
- If needed

Supply-chain preventive controls

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Potential Preventive Control Examples

Biological hazards

- Process controls that kill
  - 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

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Other Preventive Control Considerations

- Does it actually control the identified hazard?
- Can you monitor the control?
- Does it have an effect on other preventive controls?
- How much process variability exists where the control is applied?
- How severe are the consequences if the control fails?
- Is the control specifically applied to eliminate or reduce the level of a hazard?
- Does the control enhance other controls?

Food Safety Plan (cont.)

- Written corrective action procedures for each hazard (specifying what actions the facility will take to correct problems that arise)

Corrective Action Examples

Process Examples

- Immediate adjustment of process
- Employees stop line when deviation occurs
- Apply alternate process
- Repair equipment
- Retrain employees
- Evaluate operation

Product Examples

- Hold product
- Evaluate product
- Determine product disposition
  - Release, rework or destroy product

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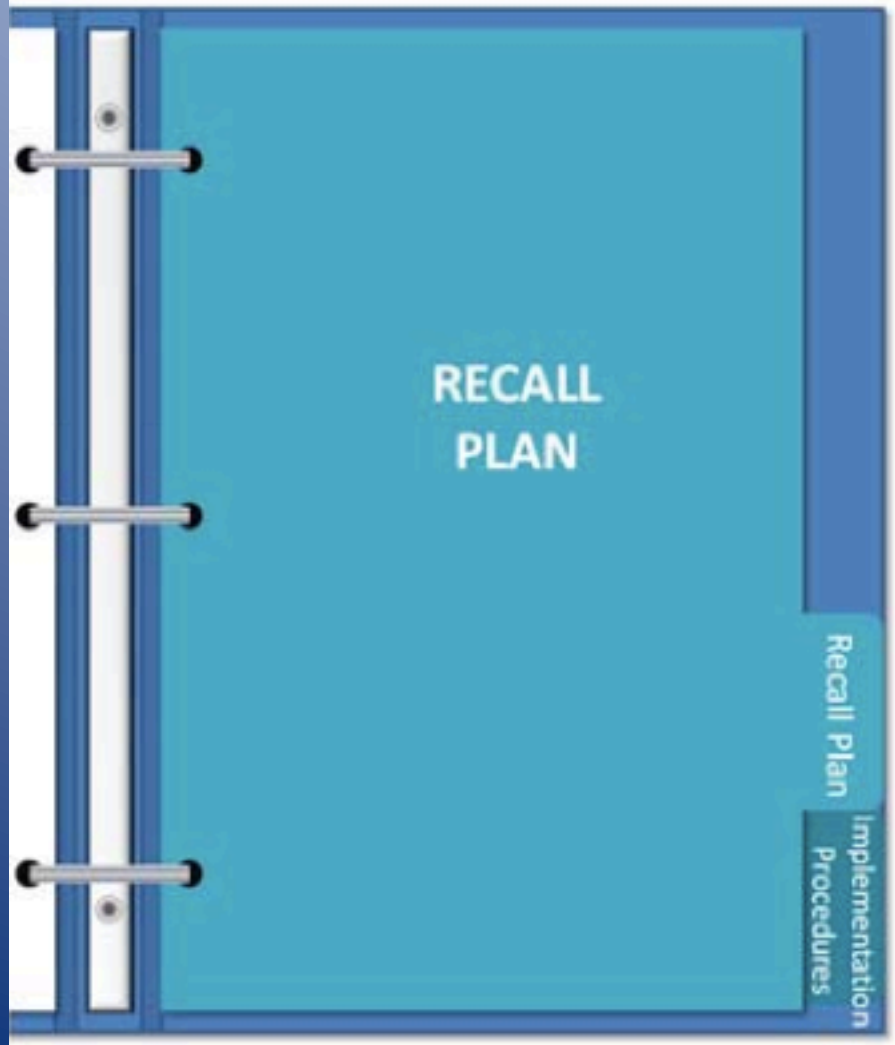
Supply Chain Program

- One of the most notable new mandates of the FSMA preventive controls rule is the requirement for a supply-chain program, the purpose of which is to "provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented."

Recall Plan



- Required when a hazard requiring a preventive control is identified
- What to do when something goes wrong

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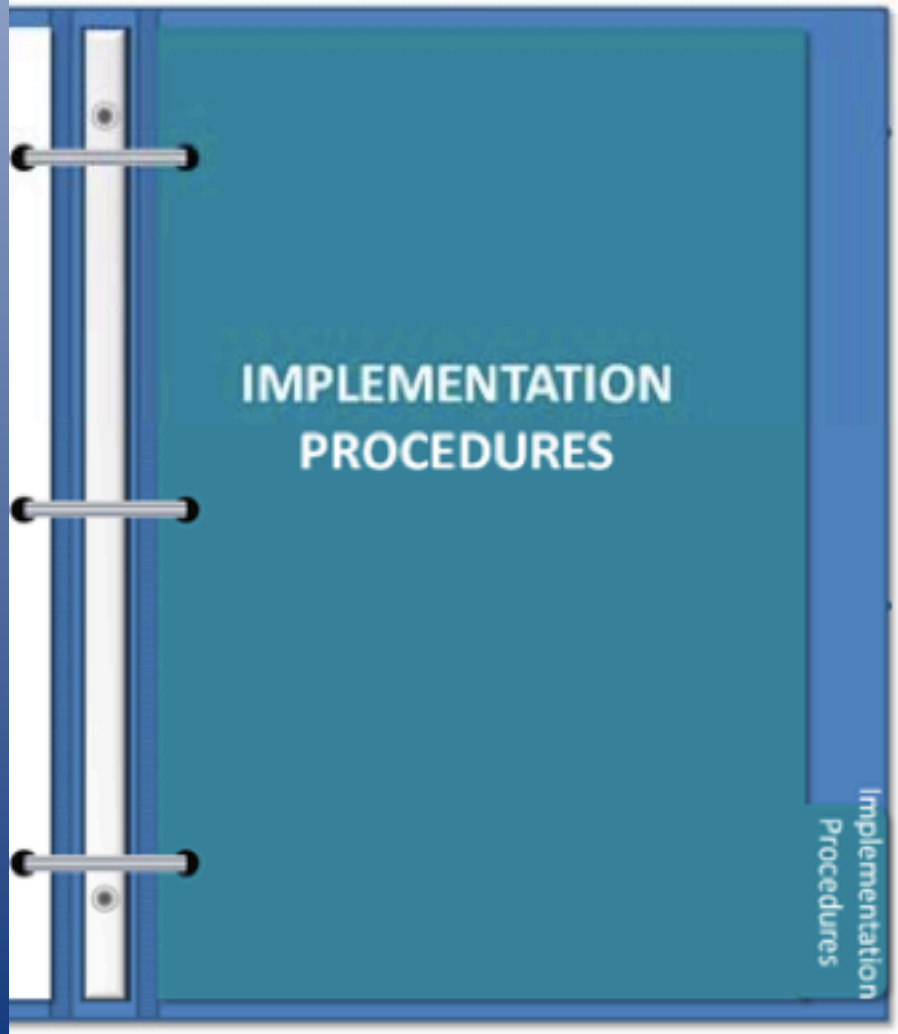
Implementation Procedures



Examples that may be required include:

- Validation studies
- Procedures for monitoring, verification and corrective action

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Supplier Approval and Verification

- Written supplier approval and verification program

- Written verification procedures

What Might Be Monitored?

Depends on process, examples include:

- Temperature
- Time
- Volume / weight
- Line speed
- Flow rate
- Bed depth
- Acid addition
- pH
- Water activity
- Chemical concentration
- Appearance
- Process performance
- Many others

Documentation

- Document EVERYTHING
- In the words of FDA
  - –If it is not documented, it didn't happen!!

Don’t Forget to Re-assess

- Regular self-assessments by management and employees within a food facility can be helpful to demonstrate preventive controls and any corrective actions made to a failed preventive control. They can provide real-time monitoring of each of the preventive controls (to enable corrective actions and prevent recalls)

Training

- Individuals must be qualified by education, training, or experience to manufacture, process, pack or hold food
- Individuals must receive food hygiene and food safety training
- Supervisors responsible for ensuring compliance must have appropriate knowledge, training or experience

When all is said and done…….

THANK YOU!

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