Complying with Preventive Control Rules for Human Food

Dr. Ramakrishnan Nara
Perry Johnson Registrars Food Safety
(PJR, USA)

Objectives

- To make participants aware of the basics of Food Safety Modernization Act
- To help participants understand the requirements of Preventive Control Rules for Human Food

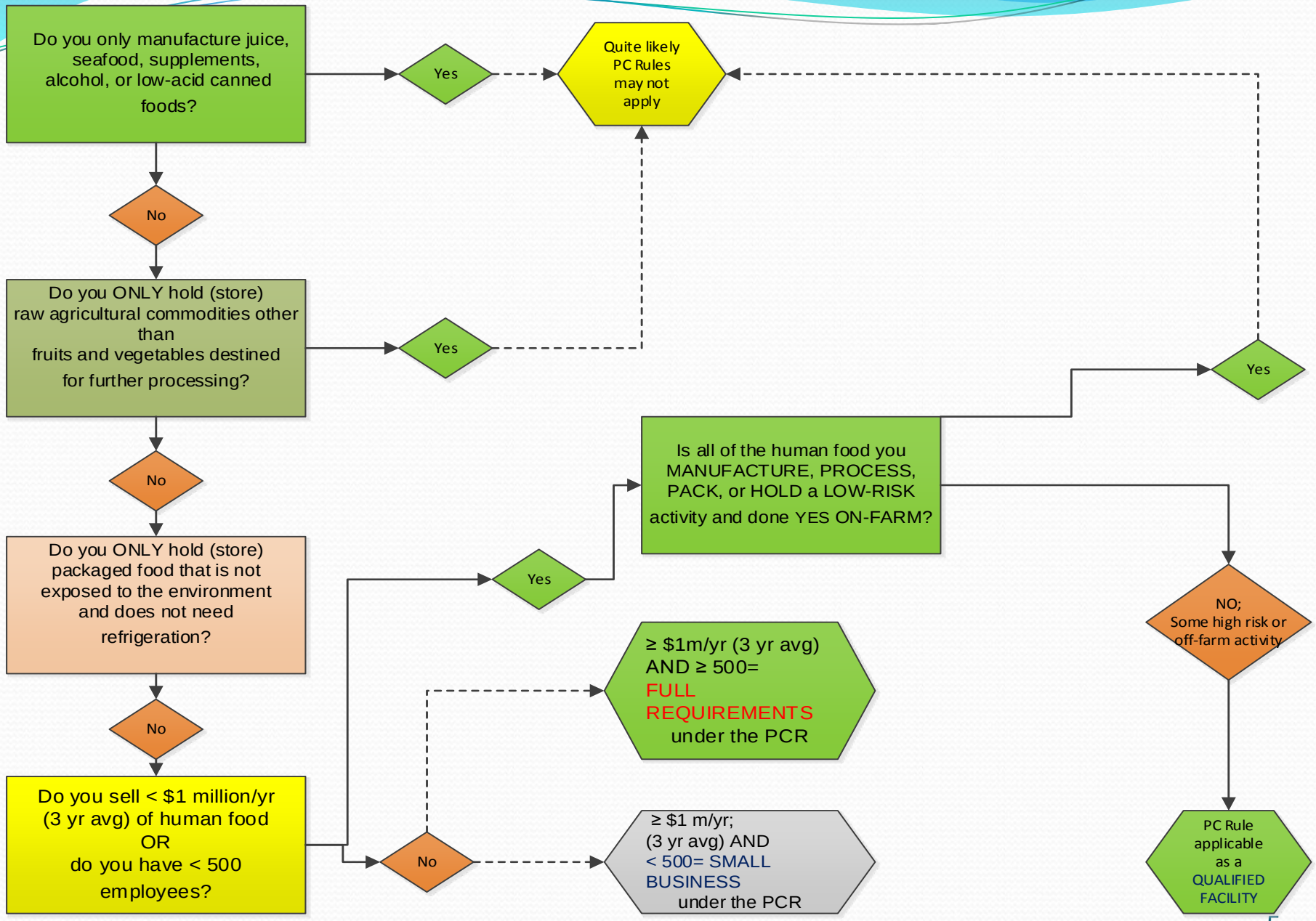
Part A
Introduction to
Food Safety Modernization Act (FSMA)

Is FSMA Applicable to you?

- Produce Rule
- Preventive Control Rule

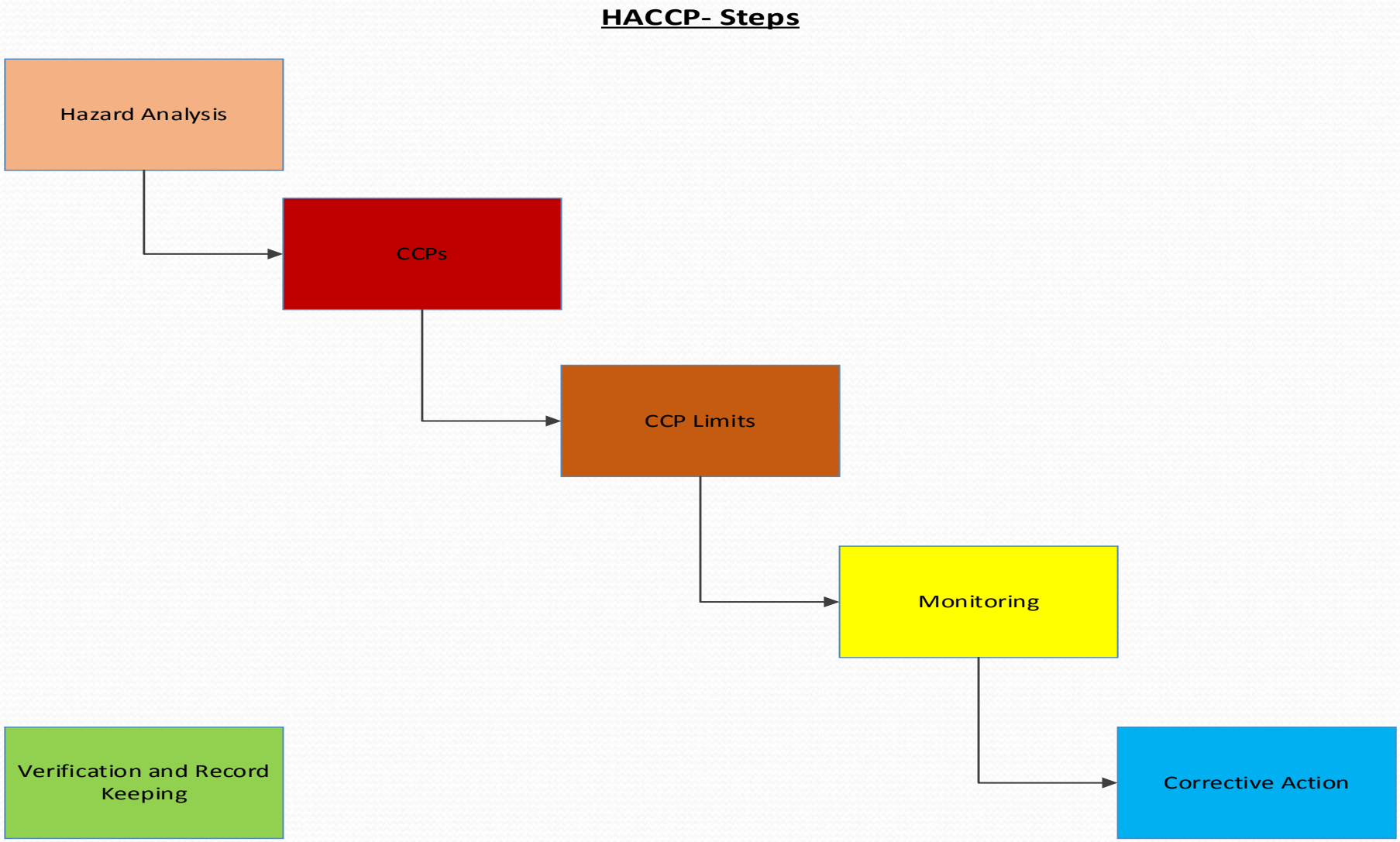
(Ref: Flow chart of National Sustainable Agriculture Coalition, November 2014)

PC Rules Decision Tree

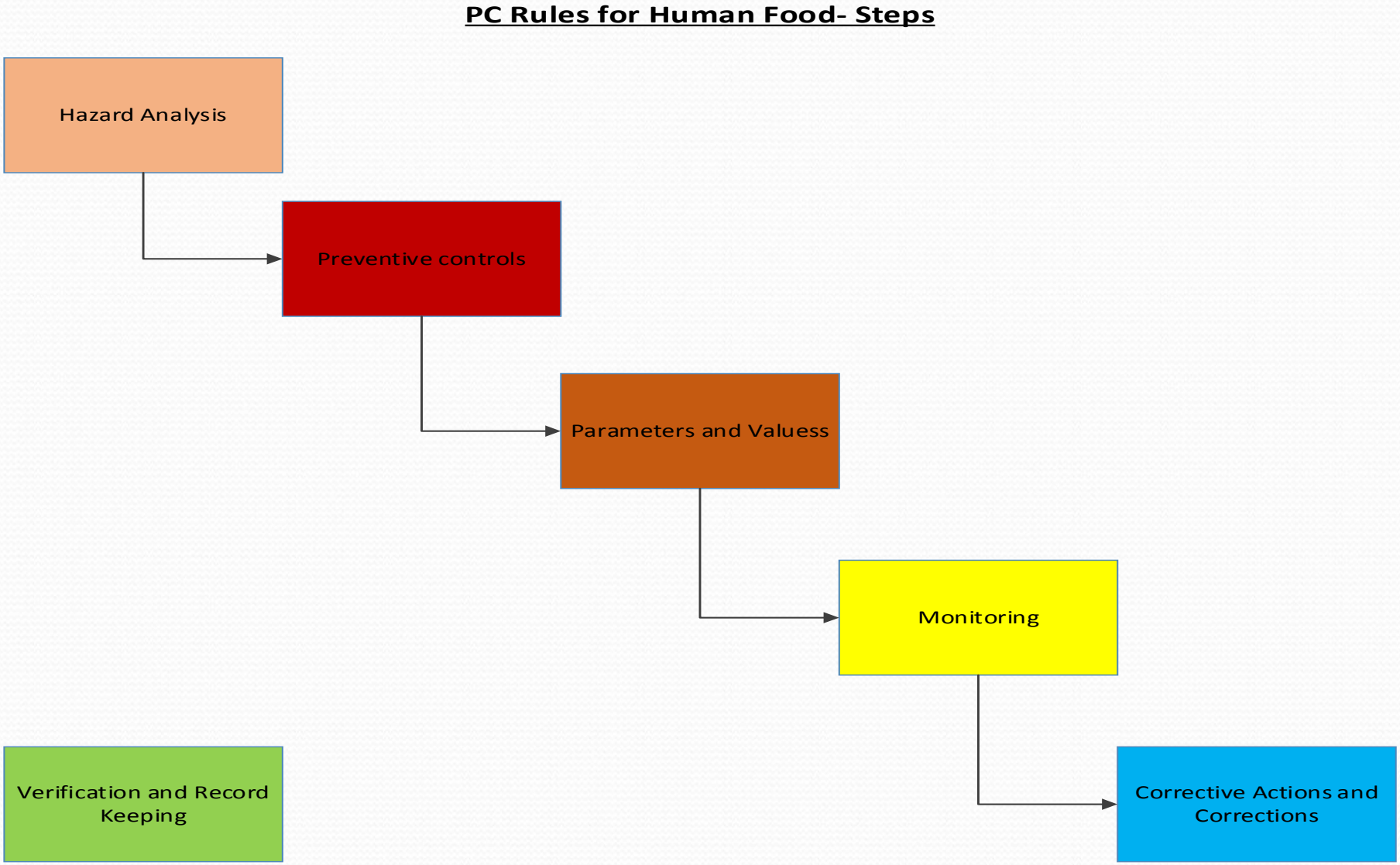


Part B
Introduction to Preventive Control Rules for Human Food

HACCP and PC Rules for Human Food



HACCP and PC Rules for Human Food



PC Rules for Human Food

Includes the following elements:

- Hazard Analysis
- Preventive Controls/Parameters
- Monitoring
- Record keeping
- Corrective Actions
- Verification
- Recall Program
- Calibration

Food Safety Plan

(including procedures for monitoring, corrective action and verification)

GMP and other Pre-requisite programs

Food Safety Plan as per PC Rules for Human Food

- Requirements of a Food Safety Plan (CFR Part 117.126)
- Contents of a Food Safety Plan(CFR Part 117.127)
- Preparation of Food Safety Plan by a Qualified Individual

Requirements of a Qualified Individual

As per 21 CFR 117.3

- A qualified individual who has successfully completed training in the development and application of risk-based preventive 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 a food safety system.

Part C

Components of A Food Safety Plan As Per Preventive Control Rules for Human Food

Hazard Identification in PC Rules for Human Food

- Biological hazards
- Chemical hazards (incl. Radiological)
- Physical hazards
- Economically motivated hazards

Importance of Thorough Hazard Analysis

Crucial to the success of the overall food safety program

- A proper hazard analysis can:

- Identify hazards requiring a preventive control
- Focus resources on essential preventive controls
- Identify operations that require improvement

- An improper hazard analysis can result in:

- An ineffective Food Safety Plan
- An unmanageable Food Safety Plan
- Potential regulatory action

Hazard Analysis Form-Example

(Ref: FSPCA Instructor Manual Feb. 2015)

(1) Ingredient / Processing Step	(2) Reasonably foreseeable 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 preventive control(s) are applied to significantly minimize or prevent the food safety hazard?	(7) Is this step a CCP?

	Hazard description			Hazard evaluation				Preventive control(s)		
(1) Ingredient/ Processing Step	(2) Identify reasonably foreseeable 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 Evaluation in PC Rules for Human Food

- Occurrence of hazard Vs Severity of illness
  - Contamination of food with biological hazards
  - Contamination of food with chemical hazards (including radiological)
  - Contamination of food with physical hazards
- Requirement to evaluate environmental pathogens
- Specific factors in hazard evaluation
  - Product formulation
  - Design of facility and equipment
  - Raw materials
  - Manufacturing/processing procedures
  - Packaging/labeling
  - Storage and distribution, incl. Transportation

Example of a Hazard Evaluation Form

Hazard Analysis	PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit		PAGE X of Y
PLANT NAME	E.G. Food Company	ISSUE DATE	mm/dd/yy
ADDRESS	360 Culinary Circle, Mytown, USA	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? Yes	(3) No	(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	(6) No
Receiving refrigerated ingredients – liquid pasteurized egg	B	Vegetative pathogens such as *Salmonella*	X		While pasteurization minimizes the likelihood of *Salmonella* USDA recommends the product be used in cooked foods. Experience has shown *Salmonella* occasionally occurs in this ingredient.			
	C	Allergen – egg	X		Egg is an allergen that must be labeled to inform consumers. Cross-contact is not an issue – all products contain egg.			

Definition of Preventive Control

As per 21 CFR 117.3 Definitions

"Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understand of safe food manufacturing, processing, packaging, or holding at the time of the analysis."

Preventive Controls As per PC Rules

- Process preventive controls
- Food allergen preventive controls
- Sanitation preventive controls
- Supply-chain program
- Recall plan
- Other preventive controls

Examples of Preventive Controls- Biological

- 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

Examples of Preventive Controls-Chemical

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

Examples of Preventive Controls- Physical

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

Preventive Controls-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?

Example of Process Preventive Control Form- Ref: FSPCA Instructor Manual 2015

(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
Cook [eggs, milk, salt, pan release oil]	B	Survival of vegetative pathogens such as Salmonella	X		Thorough cooking is required to kill vegetative pathogens	Process Control – Cooking to achieve a lethal temperature	X	
Metal detection	P	Metal	X		Metal-on-metal contact on the line may introduce metal fragments	Process Control – metal detection	X	

Example of Allergen Preventive Control Form - Ref: FSPCA Instructor Manual 2015

(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
Receiving packaging	C	Undeclared allergens – egg, milk, soy (wheat in biscuit only)	X		Labeled cantons must declare allergens present in the product and print errors have occurred	Allergen Control – label review for allergen information	X	
Assemble, wrap	C	Allergen cross-contact from other products handled at this step; e.g., Cheese Omelet Biscuit	X		Biscuits could introduce wheat allergen to other products without control	Sanitation and Allergen Control – prevent cross-contact	X	
Fill, weigh, label	C	Undeclared allergens – egg, milk, soy (wheat in biscuit only)	X		All products contain egg, milk and soy allergens. The cheese biscuit also contains wheat.	Allergen Control – correct labeled carton for product	X	

Example of Sanitation Preventive Control Form-Ref: FSPCA Instructor Manual 2015

(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
Assemble, wrap	B	Introduction of environmental pathogens such as *L. monocytogenes*	X		Recontamination may occur if sanitation control is not in place	Sanitation Controls – prevent recontamination	X	
	C	Allergen cross-contact from other products handled at this step; e.g., Cheese Omelet Biscuit	X		Biscuits could introduce wheat allergen to other products without control	Sanitation and Allergen Control – prevent cross-contact	X	

Example of Supply Chain Preventive Control Form-Ref: FSPCA Instructor Manual 2015

(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
Receiving refrigerated ingredients – pasteurized process cheese	B	Vegetative and sporeforming pathogens such as *Salmonella*, pathogenic *E. coli*, *L. monocytogenes* and *C. botulinum*	X		Pathogens listed were identified as significant by ICMSF (2005) in process cheese. These hazards should have been controlled when the cheese was made.	Supplier Control – 3rd party supplier audit by a qualified auditor		X

Parameters and Values in PC Rules

- Parameters
- Values
- Critical limits (CCPs)

Monitoring in PC Rules for Human Food

- Requirement for written procedures for monitoring
- Frequency of monitoring

Record Keeping in PC Rules for Human Food

- Records of monitoring of Preventive Controls
- Records Review
- Records required by Preventive Control Rules

Corrective Action in PC Rules for Human Food

- Requirement
- Procedure
- Corrective action for unanticipated problem
- Documentation

Verification in PC Rules for Human Food

- Verification Requirements
  - Verification of monitoring
  - Verification of corrective actions

- Validation Requirements
  - Validation of preventive controls
  - Validation by a qualified individual prior to implementation and on reanalysis
  - Validation based on scientific and technical information

Preventive controls for which validation is not required

Validation need not address:

- The food allergen controls that would be established as per PC Rules for HF
- The sanitation controls that would be established ; and
- The recall plan that would be established as per PC Rules for HF

Calibration as per PC Rules

- Requirement
- Frequency

Product testing and PC Rules for Human Food

- Raw material testing
- Finished product testing in verification
- Environmental monitoring

Food Sector Categories Vs FSMA

GFSI FSC	Is FSMA applicable?	Is PC Rule applicable?
Farming 1 (animal, poultry)	No	No
Farming 1 (Fish)	Yes	No (Seafood HACCP as per 21 CFR 123)
Farming 1 (Shelled egg)	Yes	Yes
Farming 2 (Fruits &Vegetables)	Yes	No
Farming 2 (Grains)	Yes	No
Processing 1 (slaughtering of meat)	No	No
Processing 1 (Fish & fish products)	Yes	No(Seafood HACCP as per 21 CFR 123)
Processing 1 (Dairy products)	Yes	Yes

Food Sector Categories Vs FSMA-contd.

GFSI FSC	Is FSMA applicable?	Is PC Rule applicable?
Processing 2 (Juices-unpasteurized & pasteurized)	Yes (partly)	No (as per 21CFR 120)
Processing 2 (preserved fruits and vegetables)	Yes	Yes
Processing 3 (Thermally processed low-acid foods)	Yes (in conjunction with 21 CFR Part 113)	Yes(in conjunction with 21 CFR Part 113)
Processing 3 (Alcoholic beverages)	No (as per TTB regulations)	No
Biochemical (food ingredients)	Yes	Yes
Animal feed	Yes	Yes
Importers	Yes	Yes
Retail	No	No
Food packaging manufacturing	No	No
Transport	Yes	Yes (temp. sensitive

Questions?