

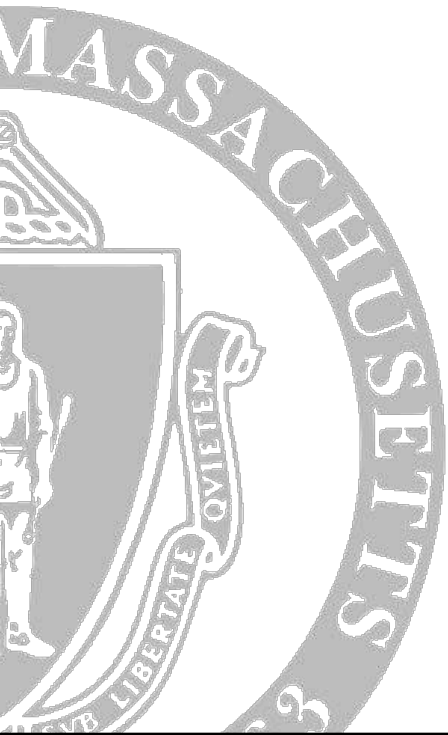
# Special Food Processing Requirements

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## UMass Food Science Extension

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### Research

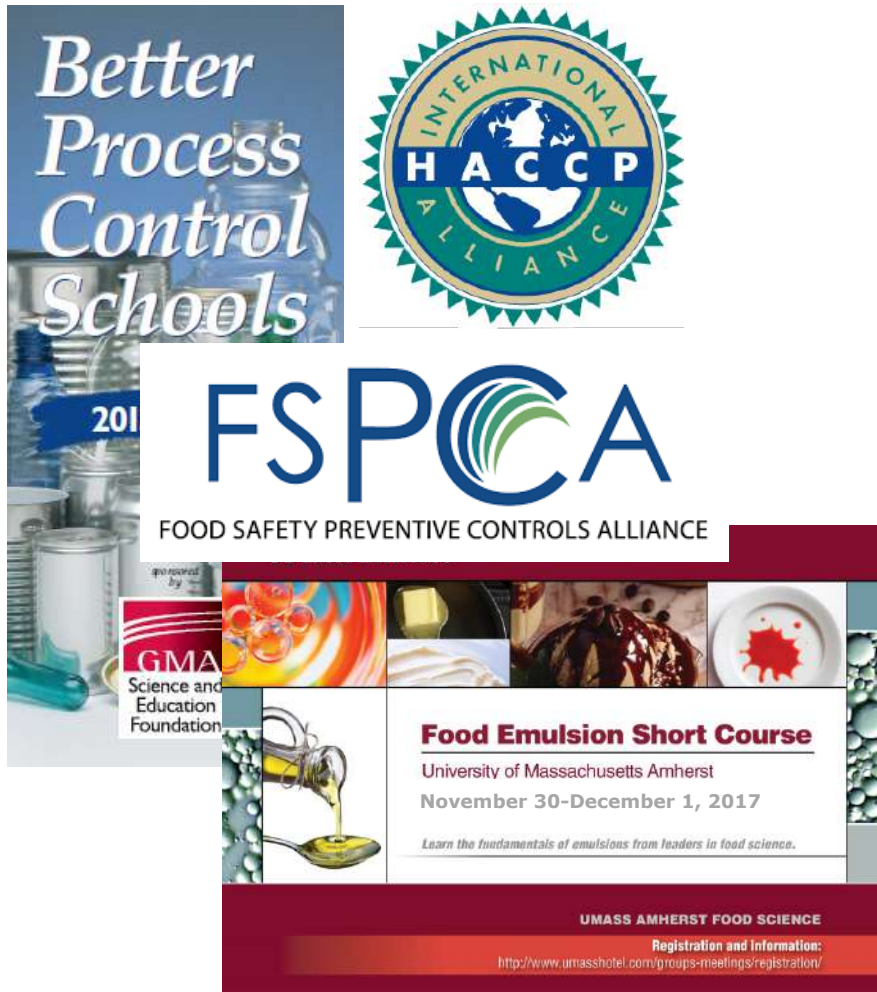
- Produce safety
- Product development

### Extension

- Regulatory compliance trainings
- Technical support
- Short courses



## Extension Activities



## Short Courses

- Preventative Controls for Human Food: June 2018
- Better Process Control School: Nov 2018
- Rapid Method (SERS): Dec 2018
- Lipid Oxidation: coming 2019!

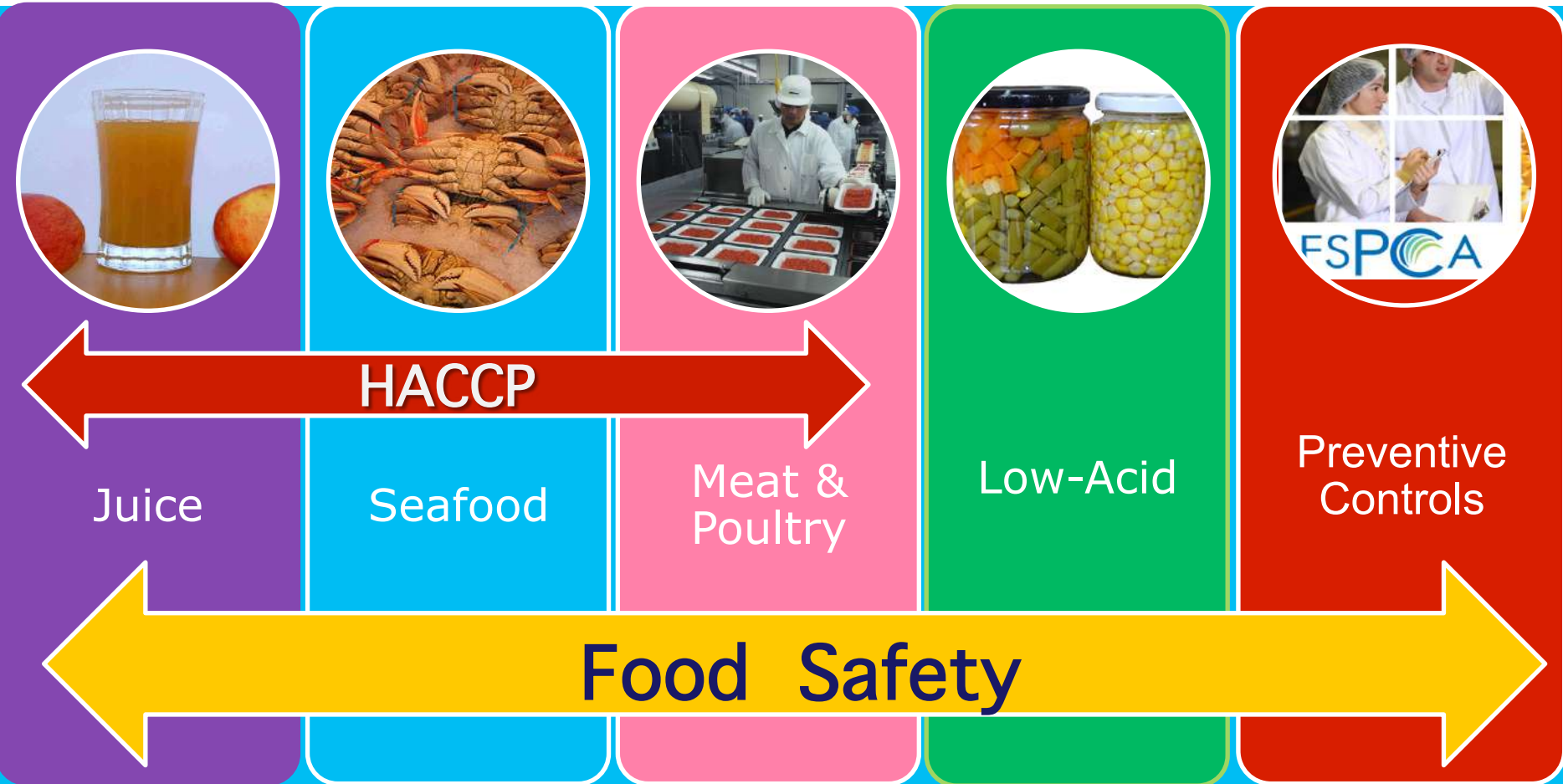
# Food Safety Regulation

## Regulation

- USDA
  - Meat
  - Poultry
  - Egg Products
- FDA
  - Other food products
  - Dietary supplements
  - Bottled water
  - Food additives
  - Infant formulas

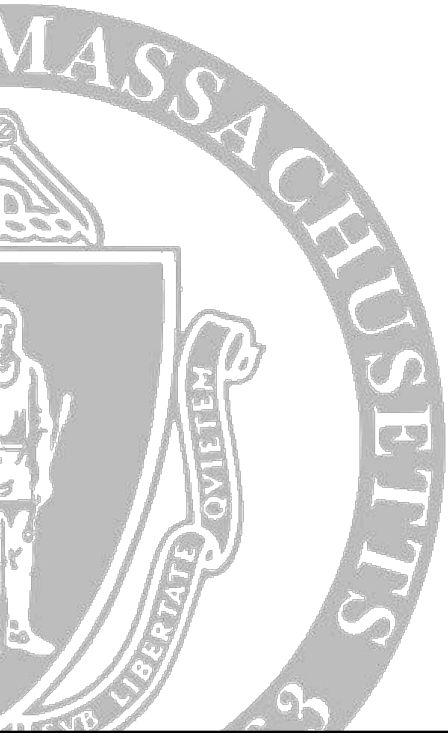


# Food Safety Regulation: Processing (wholesale)



# Shelf Stable Acidified Foods

21 CFR 117 - Current Good  
Manufacturing Practice, Hazard  
Analysis, and risk-based preventive  
controls for Human Food





## Shelf Stable “Canned” Foods



## Commercially Canned Foods

### Canning:

- *"method of food preservation that renders a food and its container commercially sterile by the application of heat, alone or in combination with pH and/or Aw and/or other chemicals"*
- Commercially Sterile = **shelf stable**
- Free of microorganisms of public health significance and others under non-refrigerated conditions

*Codex Alimentarius*



## Common Canning Methods

- **Conventional Canning** – fill product in container, seal it, treat (high heat under pressure)
- **Aseptic** – sterilizing the food and the container *separately* and filling & sealing in a commercially sterile environment
- **Formulation Control (Acidified)** – lowering the finished product pH ( $\leq 4.6$  and  $A_w \leq 0.85$  )



## Canned Products

- Low-acid canned foods (LACF)
  - pH **above** 4.6
- Acidified low-acid foods\*
  - Formulated **below** 4.6
- Acid foods
  - Natural pH  $\leq$  4.6

*\*Sauerkraut, kimchi, and similar fermented foods are **not** considered "acidified foods" under the FDA Acidified Foods rules.*

## Canning Regulations: Thermally Processed Foods

Code of Federal Regulation	Specific to:	Summary of Regulation
CFR 110	GMP	Good Manufacturing Practices
CFR 113	Low-acid Foods	<ul style="list-style-type: none"> <li>• Ex. Canned green beans, lentil soup</li> <li>• pH &gt;4.6 &amp; Aw &gt;0.85</li> </ul>
CFR 114	Acidified Foods*	<ul style="list-style-type: none"> <li>• Ex. Pickled products,</li> <li>• pH &lt; 4.6 &amp; Aw &gt; 0.85</li> </ul>
CFR 117	Current Good Manufacturing Practice, Hazard Analysis, and risk-based preventive controls for Human Food	<ul style="list-style-type: none"> <li>• Hazard analysis</li> <li>• Preventive controls*</li> <li>• Process, food allergen, sanitation, supply-chain and other</li> <li>• Recall plan*</li> <li>• Management of PC: Procedures for monitoring, corrective action and verification*</li> </ul>

- **Excluded:** refrigerated products, jellies/jams/preserves, fermented foods and products with Aw <0.85.

## Getting Started

1. Establish conditions for thermal processing (hermetically sealed containers)
  - 108.25: acidified
  - 108.35: low-acid
2. Process Authority Review
  - Cornell
  - Univ. Maine
  - NC State
3. All processors\* shall register with the FDA
4. All operators of thermal processing products (low acid & acidified) must attend a training approved by FDA Commissioner (BPCS)
  - UMass is hosting BPCS – November 2018



## Scheduled Process

School of Food and Agriculture



December 28, 2017

Ryan Claudino  
100 Holdsworth Way  
Amherst, MA 01003-9282  
INVOICE # 3233

Dear Ryan:

<b>SAMPLE</b>	<b>pH</b>	<b>WATER ACTIVITY @ 25 C</b>
1) Dill Relish	3.64	0.975
2) Dilly Beans	3.59	0.985

**Test Results:**

Based on the pH results, you met our recommendations of an overall product pH level of 4.20 or

### **Dilly Beans:**

- The product temperature must be monitored prior to water bath canning. The temperature must be at least **100 deg F** or higher before water bath processing. You must check the center of the coldest container, which is usually the first container filled after all the containers from the entire batch have been filled.
- The products must be hot filled into sanitized jars and immediately water bath canned. **A water bath canning time of 10-minutes is adequate for 16-ounce containers or less and**
- **also 32-ounce containers.**
- Be sure to have at least 1 inch of water covering your containers and you are timing your water bath processing time once the water reaches a rolling boil (212 deg F) with the containers in the water bath.



## BPCS – UMass, November 2018



- Acidified Only, November 2018
- <http://ag.umass.edu/upcoming-events>

## UMass – Product Development

- Establish FDA approved scheduled processes for acidified shelf-stable foods to increase usage of specialty crops
- 12 science based, minimally processed value-added products (acidified shelf-stable products)
- Goal - increase the production of specialty crops through value-added processing



# UMass – Product Development

Product	Size	Scheduled Process	Standard Operating Procedure	Production Ready
Bread and Butter Pickles	8 oz.	Yes	Yes	Yes
Bread and Butter Pickles	16 oz.	Yes	Yes	Yes
Pickled Beets	8 oz.	Yes	No	No
Pickled Beets	16 oz.	Yes	No	No
Pickled Turnips	8 oz.	Yes	No	No
Pickled Turnups	16 oz.	Yes	No	No
Pickled Radishes	8 oz.	Yes	No	No
Pickled Radishes	16 oz.	Yes	No	No
Diced Tomatoes	16 oz.	Yes	No	No
Diced Tomatoes	32 oz.	Yes	No	No
Diced Tomatoes	64 oz.	Yes	No	No
Zucchini Pickles	16 oz.	Yes	Yes	Yes
Blueberry Jam	8 oz.	Yes	Yes	In Process
Apple Butter	8 oz.	Yes	Yes	Yes
Pickled Dill Beans	8 oz.	Yes	Yes	No
Red Hot Sauce	8 oz.	In Process	Yes	No
Dill Relish	8 oz.	Yes	Yes	No

# Preventive Controls for Human Food

21 CFR 117 - Current Good Manufacturing Practice, Hazard Analysis, and risk-based preventive controls for Human Food

## Food Safety Modernization Act (FSMA)

- Most sweeping reform of food safety in US since 1937 Food, Drug and Cosmetic Act.
- Seven Rules
  1. Produce Safety Rule
  - 2. Preventive Controls for Human Food**
  3. Foreign supplier verification programs
  4. Accreditation of third-party auditors for foreign facilities
  5. Preventive controls for animal food
  6. Mitigation for intentional adulteration
  7. Sanitary transportation of human and animal food



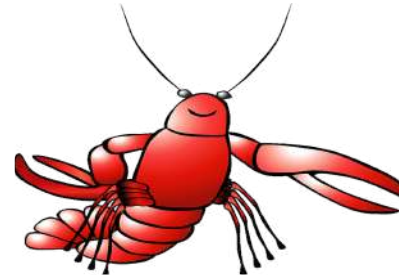
# Other Risk-based Food Safety Programs



US Space  
program



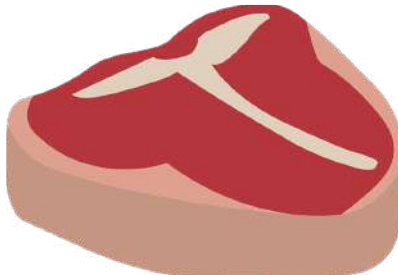
Low-acid canned  
food regs



FDA Seafood  
HACCP regs



FDA Juice  
HACCP regs



USDA HACCP  
regs



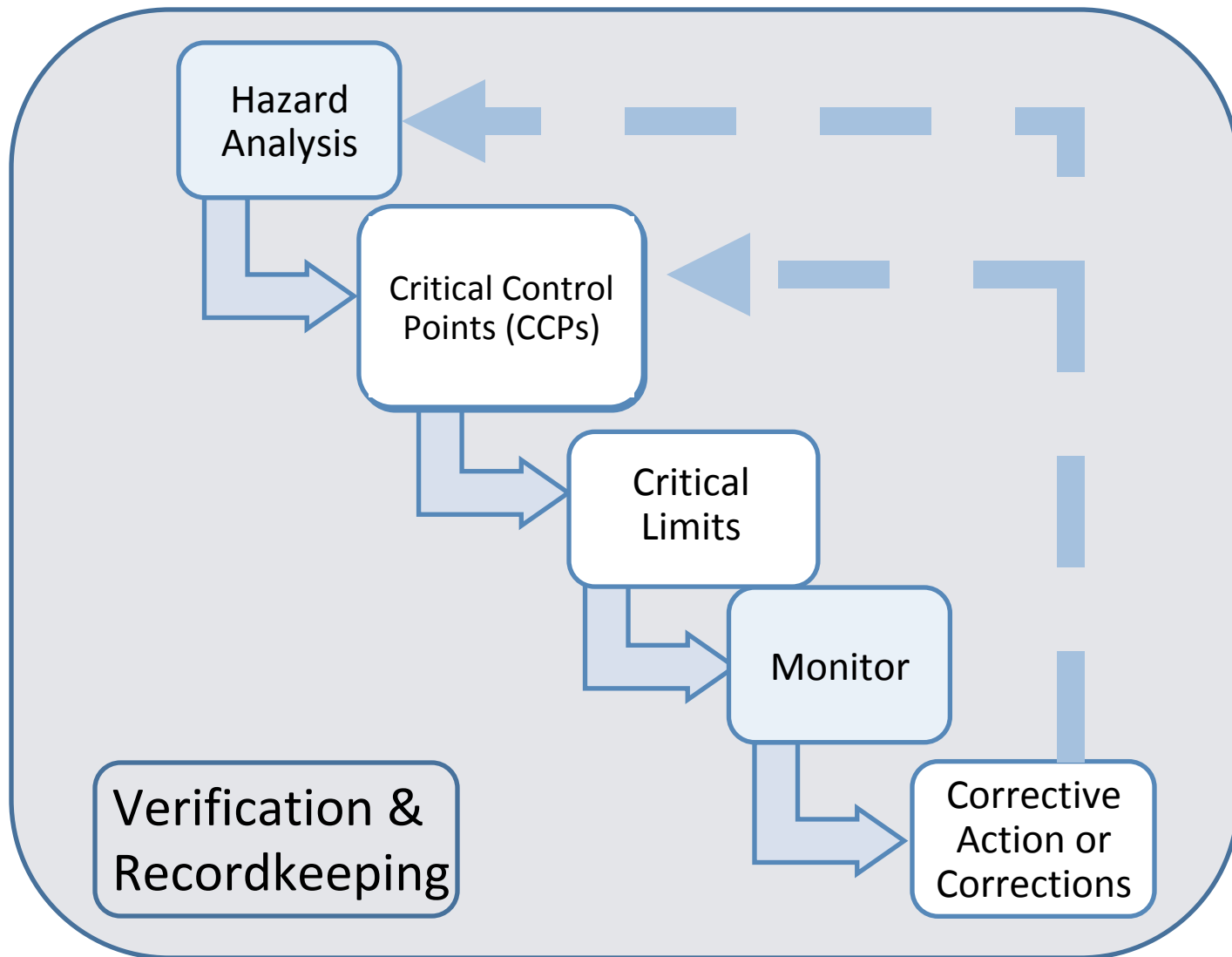
Codex HACCP  
Annex



NCIMS Dairy  
HACCP

Image source: Microsoft clip art

# Preventive Controls Include More Than HACCP



## Requirements

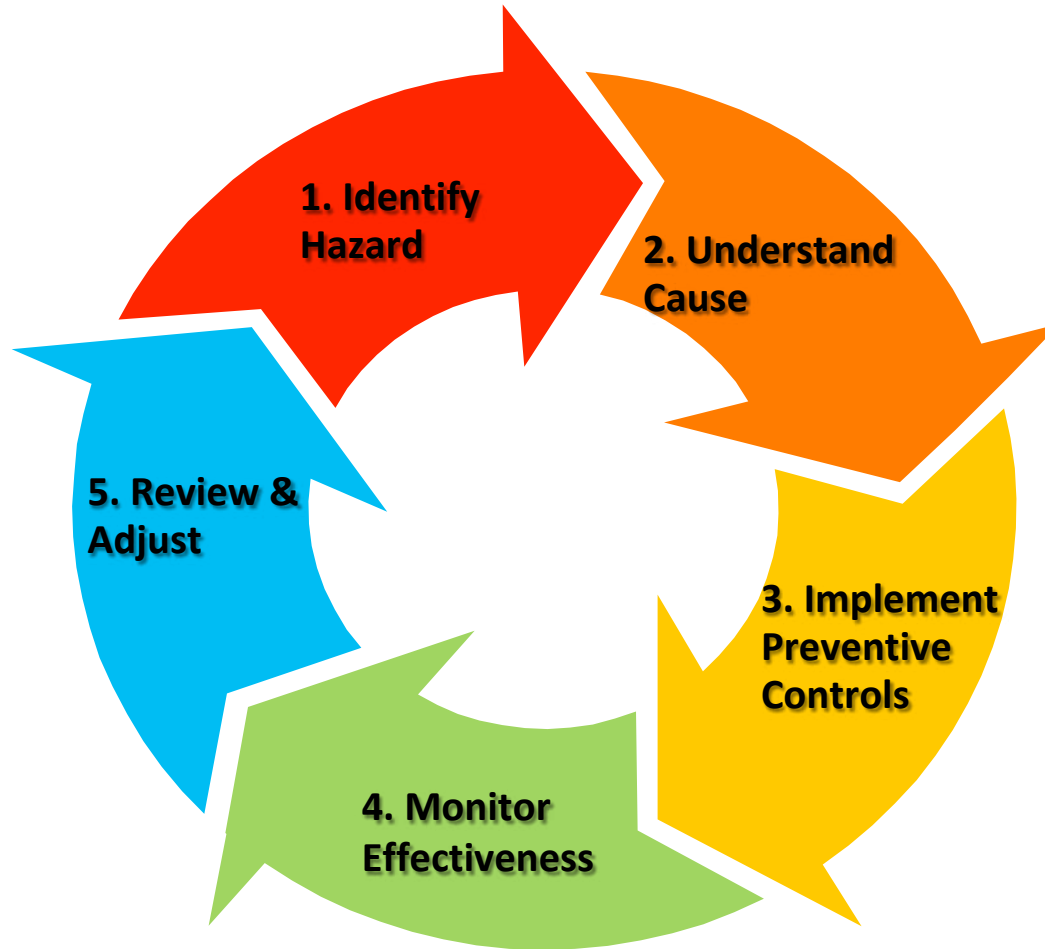
# CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

## Subparts of PC Rule CFR 117

- A. General Provisions
- B. Current Good Manufacturing Practice
- C. Hazard Analysis and Risk-based Preventive Controls
- D. Modified Requirements
- E. Withdrawal of a Qualified Facility Exemption
- F. Requirements Applying to Records that Must be Established and Maintained
- G. Supply-chain Program



# General Approach to Preventive Controls



# Contents of a Food Safety Plan

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## 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



# Definitions

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## ■ Food Safety Plan

- A set of written documents that is based on food safety principles; incorporates hazard analysis, preventive controls, supply-chain programs and a recall plan; and delineates the procedures to be followed for monitoring, corrective actions and verification.
- Adapted from 21 CFR 117.126

## ■ Food safety system

- The outcome of implementing the Food Safety Plan and its supporting elements

- Requirements of FSMA for covered facilities to establish and implement a food safety system that includes a hazard analysis and risk-based preventive controls.
  - A written food safety plan specific to your facility and products
  - Required to have one Preventive Controls Qualified Individual (PCQI)

# Food Safety Plan Overview Summary

- A written Food Safety Plan, specific to the facility, is required to include a hazard analysis
- When hazards requiring a preventive control are identified, the following are required, as appropriate:
  - Preventive controls
    - Process, food allergen, sanitation, supply-chain and others determined through the hazard analysis process
    - A recall plan
  - Implementation procedures
    - E.g., validation studies and monitoring, corrective actions and verification procedures
- The format is flexible

# Challenges - Preventive Controls Rule

- Validation justification
  - Technical competency
  - Scientific availability
- Resources
  - FDA PC Guidance
  - TAN
- Uncertainty of compliance
  - State
  - Processor
- Awareness
- Capacity challenges
- Liability & accountability



[http://foodsafety.merieuxnutrisciences.com/wp-content/uploads/2017/04/shutterstock\\_566689867.jpg](http://foodsafety.merieuxnutrisciences.com/wp-content/uploads/2017/04/shutterstock_566689867.jpg)

# FSMA Support: Produce & Preventive Control

## Preventive Control

- FDA
  - 2017 Compliance Audit
  - NECAFS – April 16<sup>th</sup>
- FSPCA
  - Food Safety Preventive Control Alliance Conference
- Extension
  - PC Trainings
  - Application Research
- Regional Centers





# Food Safety Management Training for Small and Emerging Food Businesses: Integrating a Food Safety Culture from Concept to Commercialization

Project Status:  
Planning Period

Amanda Kinchla, UMass-Amherst, [amanda.kinchla@foodsci.umass.edu](mailto:amanda.kinchla@foodsci.umass.edu); Nicole Richard & Lori Pivarnik, URI  
FSOP, USDA-NIFA Grant

## Problem Statement / Issue Definition:

- The development of shared-use processing facilities - challenged with regulation and food safety compliance.
- Increase feasibility of locally and regionally produced agricultural products, - provide a focused educational delivery of customized training to food entrepreneurs to understand critical food safety considerations from concept to commercialization.

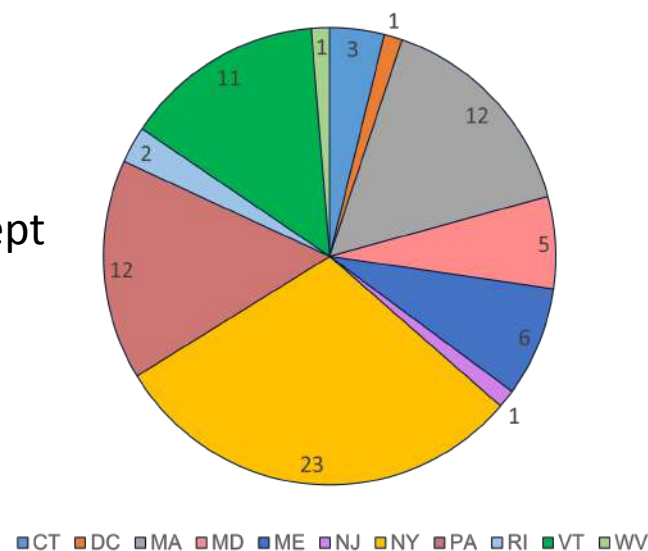
## Approach / Methods:

- Conduct a needs assessment
- Develop a curriculum and online training tools, field a pilot test and evaluate
- Implement a sustainable food safety program

**Results / Outcomes:** The outcome of this project will be a sustainable food safety program, specifically tailored to the needs of small and emerging food businesses. This will include online tools, a food safety educational program, and a “train the trainer” curriculum to provide technical support for the northeast region.

**Current Status:** Established advisory board; Draft needs assessment; Survey review – targeted this summer; Survey administered – September 2019.

Northeast Regional Food Hubs (77) reported  
by National Good Food Network



# Summary

- Value-added foods have different regulatory requirements depending on the food product and risk
- Juice – HACCP
- Seafood – HACCP
- Meat & Poultry HACCP
- Canned Foods
  - Product formulation verified
  - Scheduled Process
  - Filing with government (FDA)
  - Training
- Preventive Controls
  - Hazard analysis
  - Preventive controls\*
    - Process, food allergen, sanitation, supply-chain and other
    - Recall plan\*
  - Procedures for monitoring, corrective action and verification\*

# Thank you Questions?

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