Preventive Controls for Human Food Workgroup: How We Got Here

Presented by:
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Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

(21 CFR Part 117)

Aka Preventive Controls for Human Food
Aka PCHF
The Food Safety Modernization Act (FSMA)

- Produce Safety Rule
- Preventive Controls for Human Food
- Foreign Supplier Verification Programs
- Accreditation of Third-party Auditors for Foreign Facilities
- Preventive Controls for Animal Food
- Mitigation for Intentional Adulteration
- Sanitary Transportation of Human and Animal Food
- Mitigation Strategies to Protect Food Against Intentional Adulteration
Training Alliances

- Comprised of industry, academia and regulatory partners
- Developed standardized training curriculum
FSPCA PCHF Training Curriculum

• Standardized curriculum recognized by FDA
• Aligns with FSMA PCHF rule
• Provides education regarding risk-based preventive controls
• Challenges encountered among less experienced small and medium scale processors
Regional Centers

- FDA and USDA funded the development of a national center as well as 4 regional centers
  - Goals aimed at improving coordinated training, education and outreach efforts related to food safety and compliance with FSMA.
Northeast Center to Advance Food Safety (NECAFS)

Focuses on coordination and facilitation of the Northeast regional network to support a national food safety training, education, extension, outreach, and technical assistance system among small and medium-sized producers and small processors, specifically around the FSMA Produce Safety Rule and the FSMA Preventive Controls for Human Foods Rule.
NECAFS Annual Conference and Meeting

Provides an opportunity for regional partners to connect in person to discuss current training, education and outreach trends and activities related to the FSMA associated Produce Safety Rule and the Preventive Controls for Human Food Rule.
Back where it all began... 2018

PCHF focused meeting at 2\textsuperscript{nd} NECAFS conference

- **Goal**: build a cohesive strategy to address the needs of small to medium-sized food processors impacted by the FSMA PCHF rule.
- **Objective**: facilitated group discussions to determine successes, challenges and opportunities regarding the PCHF standardized curriculum training program.
- **Outcome**: determine priorities or focus areas for immediate group work
2018 Meeting Summary

• Small and medium-scale facilities with less food safety experience struggled
  • understanding how the FSMA PCHF regulation impacts them
  • attending FSPCA training
  • finding reliable resources for help
  • knowing where to go for training and help

• Need for regional coordination of PCHF related activities
Priorities Identified

AWARENESS

RESOURCES

EVALUATION
Before we adjourned….

Identified workgroup (WG) leads for each priority

Identified volunteer WG partners for each priority
Roadmap to Resources Workgroup
Roadmap to Resources Workgroup

Goal:

• Build a catalog of resources under defined categories specific to the needs of small and medium-scale facilities impacted by FSMA PCHF

Objectives:

• Create category content outline
• Identify and pool resources for each category
• Design and electronically publish and distribute
Acknowledgements: Resources Subgroup

**Volunteer Resources Subgroup Participants**

- **Jason Bolton**, Ph.D., Associate Extension Professor and Food Safety Specialist, Academic Director of Innovation Engineering, University of Maine
- **Amanda Chin**, soon to be former Student and Extension Outreach Researcher, University of Massachusetts Food Science Program
- **Cathy Davies**, CEO, Food Industry Employment Program
- **Elizabeth Demmings**, Ph.D., Program Coordinator, Institute for Food Safety at Cornell University
- **Chelsea Matzen**, former FSMA Project Director, National Farmers Union
- **Billy Mitchell**, FSMA Training Coordinator, National Farmers Union
- **Michele Pfannenstiel**, CEO Dirigo Food Safety
- **Rohan Tikekar**, Ph.D., Associate Professor and Extension Specialist, University of Maryland
- **Christopher Von Achen**, M.S., former Student and Extension Research Assistant, University of Massachusetts Food Science Program

**NECAFS Staff Support (Current and Previous)**

- **Annie Fitzgerald**, M.L.I.S., Research Specialist, University of Vermont
- **Andrea Gilbert**, Graduate Assistant, University of Maryland
- **Dave Seddon**, MBA R.D. L.D., CEO/SQF Auditor, Peakcore, LLC | CEO, Maine Farm and Sea Cooperative

**PC Working Group Leads**

- **Amanda Kinchla**, M.S., Extension Associate Professor, University of Massachusetts Amherst
- **Luke Laborde**, Ph.D., Professor of Food Science, Penn State University
- **Nicole Richard**, M.S., Research Associate/Food Safety Specialist, University of Rhode Island
Toward Building the ‘Roadmap to Resources’

• Outlined and defined project
• Developed resource categories and descriptions
• Created rubric to assess resources*
  • Relevance, quality and content
• Searched for resources online
• Vetted resources against the rubric
• Catalogued approved resources

*Initial rubric template provided by Amanda Kinchla, Dept. Food Science, UMass Amherst
Approved Resources: Specific to the PCHF Rule

- Complying with the PCHF Rule, 24.8%
- GMPs, 15.4%
- Allergens, 6.8%
- Sanitation SOPs, 4.3%
- Developing a Food Safety Plan, 23.9%
- Validation Studies and Processes, 14.5%
- Production Specifications, 3.4%
- Environmental Monitoring Program, 6.8%
Toward Building the ‘Roadmap to Resources’

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• Created rubric to assess resources*
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• Searched for resources online
• Vetted resources against the rubric
• Catalogued approved resources
• Incorporated resources into website design/layout
• Started to evaluate and conduct pilot testing

*Initial rubric template provided by Amanda Kinchla, Dept. Food Science, UMass Amherst
The NECAFS Preventive Controls for Human Food (PCHF) site was developed by a consortium of food safety experts, academics, regulators, and practitioners from the Northeast United States to connect food processors with the resources necessary to comply with the Preventive Controls for Human Food Rule.
Connect to Resources

Roadmap to Resources
Learn more about the Preventive Controls for Human Food Rule and where to find answers to your questions.

Templates, Examples & Forms
Here you can find sample and real working documents that food processors can use to follow the Preventive Controls for Human Foods Rule. These resources can serve as a useful reference as users create their own unique, tailored documentation and plans.

Connect to a Professional
Find preventive controls educators, experts, and specialists in your area.

Find out more
Want to be listed in the directory?

Join here: https://go.uvm.edu/pcspecialist
Popular Topics

Complying with the PCHF Rule

Tools for determining requirements under the Preventive Controls for Human Food (PCHF) rule and resources on how to comply with basic requirements.

View resources

Developing a Food Safety Plan

Food Safety Resources for developing an easy-to-follow and compliant food safety plan.

View resources

Sanitation SOPs

Resources and trainings for developing sanitation standard operating procedures (SOPs; also known as SSOPs).

View resources
Welcome to the Roadmap to Resources. This roadmap is intended to provide you with key resources available to help you meet requirements in the FDA's Food Safety Modernization Act Preventive Controls for Human Food (PCHF) rule.

The Roadmap to Resources is divided into twelve categories to provide resources tailored to the specific needs of small and very small processors who must comply with the PCHF rule.

You can find links to each of the twelve core topics listed below along with a general introduction and selected article that summarizes each topic.

Complying with the PCHF Rule

On this page of the PCHF site, you will find tools for determining requirements and guidance for the PCHF Rule and resources on how to comply with the rule. For a quick introduction to the topic, check out this resource: "FSMA FAQs: What are the Basic Requirements of FSMA's Preventive Controls Rules for Human Food?".

Find out more
Complying with the PCHF Rule

Tools for determining requirements under the Preventive Controls for Human Food (PCHF) rule and resources on how to comply with basic requirements.

VIEW BY CATEGORY:  
- Please select -

(or you can view by keyword)

Getting Started

FSMA FAQs: What are the Basic Requirements of FSMA's Preventive Controls Rules for Human Food?
A quick questions and answers sheet that explains the basic components of the preventive controls rule and who needs to comply with them.

Tags: Qualified Facility, Covered Facility

Exemptions

Completing Form FDA 2541a for Acidified Foods
A guide for producers of shelf-stable acidified foods and low acid canned foods on completing FDA documentation.

Tags: Acidified Foods, Process Controls, LACF

Establishment Registration & Process Filing for Acidified Foods

Records

Guidance for Industry: What You Need To Know About Establishment, Maintenance, and Availability of Records

Small Entity Compliance Guide

A guidance publication explaining which records producers are required to maintain, how long they must be held, which records are
FSMA FAQs: What are the Basic Requirements of FSMA's Preventive Controls Rules for Human Food?

Link

Author
Carolina Farm Stewardship Association

Source
Carolina Farm Stewardship Association

Summary
A quick questions and answers sheet that explains the basic components of the preventive controls rule and who needs to comply with them.

State(s)
- North Carolina
- South Carolina

Year
2019

Language
- English

PCHF Category
- Complying with the PCHF Rule » Getting Started

Keywords
- qualified facility
- covered facility
Getting Started

FSMA FAQs: What are the Basic Requirements of FSMA's Preventive Controls Rules for Human Food?
A quick questions and answers sheet that explains the basic components of the preventive controls rule and who needs to comply with them.

TAGS: QUALIFIED FACILITY, COVERED FACILITY

Establishment Registration & Record Keeping
A quick questions and answers sheet that explains which records producers are required to maintain, how long they must be retained, and how to submit records to the FDA.

TAGS: ACIDIFIED FOODS, PROCESS CONTROLS, LACF
Complying with the PCHF Rule

Tools for determining requirements under the Preventive Controls for Human Food (PCHF) rule and resources on how to comply with basic requirements.

VIEW BY CATEGORY: - Please select -
(or you can view by keyword)

Getting Started

FSMA FAQs: What are the Basic Requirements of FSMA’s Preventive Controls Rules for Human Food?
A quick questions and answers sheet that explains the basic components of the preventive controls rule and who needs to comply with them.

Tags: QUALIFIED FACILITY, COVERED FACILITY

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Tags: ACIDIFIED FOODS, PROCESS CONTROLS, LACF

Records

Guidance for Industry: What You Need to Know About Establishment, Maintenance, and Availability of Records
A guidance publication explaining which records producers are required to maintain, how long they must be held, which records are required from “qualified facilities,” and how records are to be maintained.

Small Entity Compliance Guide
A guidance publication explaining which records producers are required to maintain, how long they must be held, which records are required from “qualified facilities,” and how records are to be maintained.
**Qualified Facility**

**FSMA FAQs: What are the Basic Requirements of FSMA’s Preventive Controls Rules for Human Food?**
A quick questions and answers sheet that explains the basic components of the preventive controls rule and who needs to comply with them.

TAGS: QUALIFIED FACILITY, COVERED FACILITY

**FSMA FAQs: Is my business a farm mixed-type facility?**
A question and answer sheet that clarifies the differences between a retail food establishment and a farm mixed-type facility, which FSMA rules apply, and some exceptions to the rule.

TAGS: FARM, MIXED-TYPE FACILITY, COVERED FACILITY

**FSMA FAQs: What are the Special FSMA Rules for Low-Risk Processing?**
A list explaining the conditions that must be met for farms of a certain size that perform certain actions to not need to follow the HRP or SCP (supply chain program) portions of the preventive controls rule.

TAGS: LOW-RISK FOODS, QUALIFIED FACILITY
User Experience Survey Development

• A paid quality improvement program– designated not research
• Survey developed in Qualtrics to take one hour
• Demographic information, first impressions, activities, suggestions and takeaways
• Sought feedback from 20 processors
• Used several tactics to contact processors
  • Contacted processors directly, members of the PC working group contacted their network, Cornell Food Venture Center newsletter
Preliminary Results

• Feedback has been limited.
• Most mentioned positive: Accessible layout
• Most mentioned drawback: Some links are broken
• Recruitment is still open
  • Contact Annie for more information
Next Steps

• Survey food safety communicators for site content
  • https://go.uvm.edu/pchfsite
• Implement feedback from both surveys
• Survey content for information gaps
• Launch and promote site
• Potential future projects
  • Analysis of gaps in available resources
  • Developing new resources to fill in gaps identified
Anticipated Timeline

- Surveys (6 weeks) January 15 – February 26
- Implementation (4 weeks) February 26 – March 26
- Site survey and correcting gaps (6 weeks) March 26 – May 7
- Launch and promotion (4 weeks) May 7– May 28
Awareness Campaign Workgroup
Goal:

- Increase awareness of the FSMA PCHF regulation, especially among small and medium-scale facilities.

Objectives:

- Identify food safety communicators in Northeast region
- Develop portfolio outreach/awareness products
- Disseminate products to food safety communicators
Current Status: Awareness Campaign

- Identify food safety communicators in Northeast region
  - Status: On-going
  - Directory of Services
Current Status: Awareness Campaign

- Develop portfolio outreach/awareness products
  - Promotional materials: completed
  - Awareness outreach materials
  - NECAFS Preventive Controls for Human Food (PCHF) site
- Status: Paused
Current Status: Awareness Campaign

Build website content
- Roadmap to Resources
- Templates, Examples & Forms
- Connect to a Professional

Status: Website Feedback

Relationship Building
- AFDO
- Other regulatory organizations (i.e. MEHA)

Communication Plan
- Target “buy in” from AFDO for dissemination
- Demonstrate curating rigor of the provided resources
- Identify new approaches to find small processors where they frequent
Evaluation: Training to Implementation Gap Analysis Workgroup
Evaluation: Training to Implementation Gap Analysis Workgroup

Goal:

- Identify knowledge gaps contributed to difficulties after taking the FSPCA PCHF training.

Objectives

- Develop PCHF training evaluation tool
- Promote regional usage
- Identify supports needed for compliance with PCHF rule
How to View the Evaluation Tool

• Complete Google form (access link in the chat)
• Receive an email
  • Copy of the evaluation tool
  • Instructions on how to utilize the tool
• This data are intended to provide a regional picture of topic areas where workshop participants have difficulties.
• This data will be integrated with regional and national efforts.
• Summary of your workshop evaluation
• Summary of regional efforts
Questions?

Contact: Evaluation Workgroup Lead
Nicole Richard
University of Rhode Island
nicolerichard@uri.edu
Workgroup Timeline

2018
Identified focus areas or priorities and established workgroup leads.

2019
Hired 2 project coordinators and formalized each plan of action.

2020 - 2021
Implemented each workgroup’s plan of action.

Recap
Looking Forward

Tomorrow’s discussion: 11:00 am – 12:30 pm
https://www.uvm.edu/extension/necafs