



Writing Your Food Safety Plan

Food Safety Modernization
Act (FSMA) Part II

Food, Nutrition, and Packaging Science Department
College of Agriculture, Forestry and Life Sciences

223 P&A Bldg. Clemson, South Carolina (864) 656-3397

CLEMSON
COOPERATIVE EXTENSION

Overview of Regulation



President Obama
signed FSMA into law
January 4, 2011

Responding



Preventing

4.8 million 128,000 3,000



Americans Yearly

Final Rule was
published on
September 17, 2015

Cost of a Recall



Quick Facts

- Chipotle has over 2,000 Restaurants
- “Food with Integrity” (Fresh instead of Frozen)
- Followed regulations, but no HACCP plan

Costs

- **Food Safety Training Cost: ???**
- **Sales Decline: 23.6%** (\$1.2 billion to \$998.4 million)
- **Promotions: Profits fell 82%** due to promotions (\$140.2 million to \$25.6 million)
- **Legal Costs: ???**

Estimated Cost of Recall: >\$300 Million

- <http://fortune.com/2016/07/21/chipotles-e-coli-hangover-lingers-as-sales-plunge-again/>
- <http://www.denverpost.com/2016/07/21/decline-in-chipotle-sales-slows-but-restaurant-chain-is-slow-to-recover-from-food-safety-crisis/>
- <http://ir.chipotle.com/phoenix.zhtml?c=194775&p=irol-reportsAnnual>

Cost of Recall



Quick Facts

- Jeni's Splendid Ice Cream has 23 Scoop Shops
- High-End Groceries
- Online Mail Orders
- \$25 million Annual Sales
- 265 tons of Ice Cream Disposed

Costs

2015 and 2016 Recalls

- **Cleaning Kitchen:**
\$200,000
- **Disposal of Ice Cream:**
\$2.5 million
- **Cost of Training: ???**
- **Economic Impact: ???**

Estimated Cost of a Recall: **>\$2.7 Million**

- <http://www.foodsafetynews.com/2016/08/130962/#.WAozIJMrKb8>
- <https://jenis.com/recall/>
- <http://www.inc.com/kimberly-weisul/how-one-small-company-became-the-jedi-knights-of-ice-cream.html>



FDA Authority

- More Inspections
- Mandatory Recall
- Expanded Record Access
- Expanded Administrative Detention
- Suspension of Registration
- Enhanced Product Tracing
- Third Party Lab Testing

Some Compliance Dates



Very Small Business

September 17, 2018

(less than \$1 million per year in annual sales and market value of products held without sale)

*Exempt from hazard analysis and risk-based preventive controls with documentation

Small Business

September 17, 2017

(less than 500 employees)

Other Businesses

September 17, 2016

Business subject to PMO

September 17, 2018

Retail Establishments

*Exempt

Qualified Facility



A facility that is a very small business

or both of the following apply

(1) during the 3-years preceding, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end users exceeded the average annual monetary value of food sold to all other purchasers; and

(2) the average annual monetary value of all food sold during the 3-years preceding was less than \$500,000, adjusted for inflation



Where to Begin?

Designate a Food Safety Team

- Preventive Control Qualified Individual (PCQI)
- Recall Team
- Employees
- Qualified Auditor

Training for PCQI through Food Safety Preventive Control Alliance (FSPCA)

Training course dates can be found at www.ifsh.iit.edu/fspca

Training - FSPCA Preventive Controls for Human Food

PCQI Responsibilities: Preparing the Food Safety Plan, Validation of Preventive Controls, Review of Records, and Reanalysis of Food Safety Plan



What's Required in your Food Safety Plan?

- 1** Current Good Manufacturing Practices
- 2** Hazard Analysis
- 3** Preventive Controls
- 4** Monitoring and Corrective Action
- 5** Verification and Validation
- 6** Recall Plan
- 7** Reanalysis of Food Safety Plan

Components of your CGMPs

- Personnel
- Plant and grounds
- Sanitary operations
- Defect Action Levels
- Equipment and utensils
- Processes and controls
- Warehousing and distribution
- Sanitary facilities and controls
- Holding and distribution



Hazard Analysis



1. List process steps and ingredients

2. Identify known or reasonable foreseeable food safety hazards

3. Determine if the hazard requires a preventive control

4. Justify the decision

5. Identify preventive controls for significant hazards

Preventive Controls



Process Controls

Pasteurization
Heat Treatment (Cook Time)

Sanitation Controls

GMPs in Place
Daily Sanitation

Supply-Chain Controls

3rd Party Audit

Allergen Controls

Cross Contact Prevention
Proper Storage

Monitoring and Corrective Action

- **Monitoring:** written procedures, including frequency of performance
- **Corrective Action:** used to identify and correct a problem with implementation of preventive control

KEEP RECORDS

Minimum of 2 years





Verification and Validation

Verification: are the controls in the plan being properly implemented?

Validation: does the plan actually control the hazards?



Environmental Monitoring
for Ready-To-Eat Foods
(i.e. ice cream)



Recall Plan



Required for any food with a hazard requiring a preventive controls



Must describe steps to take and assign responsibility to:

- Notify direct customers
- Notify the public
- Conduct effectiveness checks
- Execute disposition of food

Food Safety Plan Reanalysis

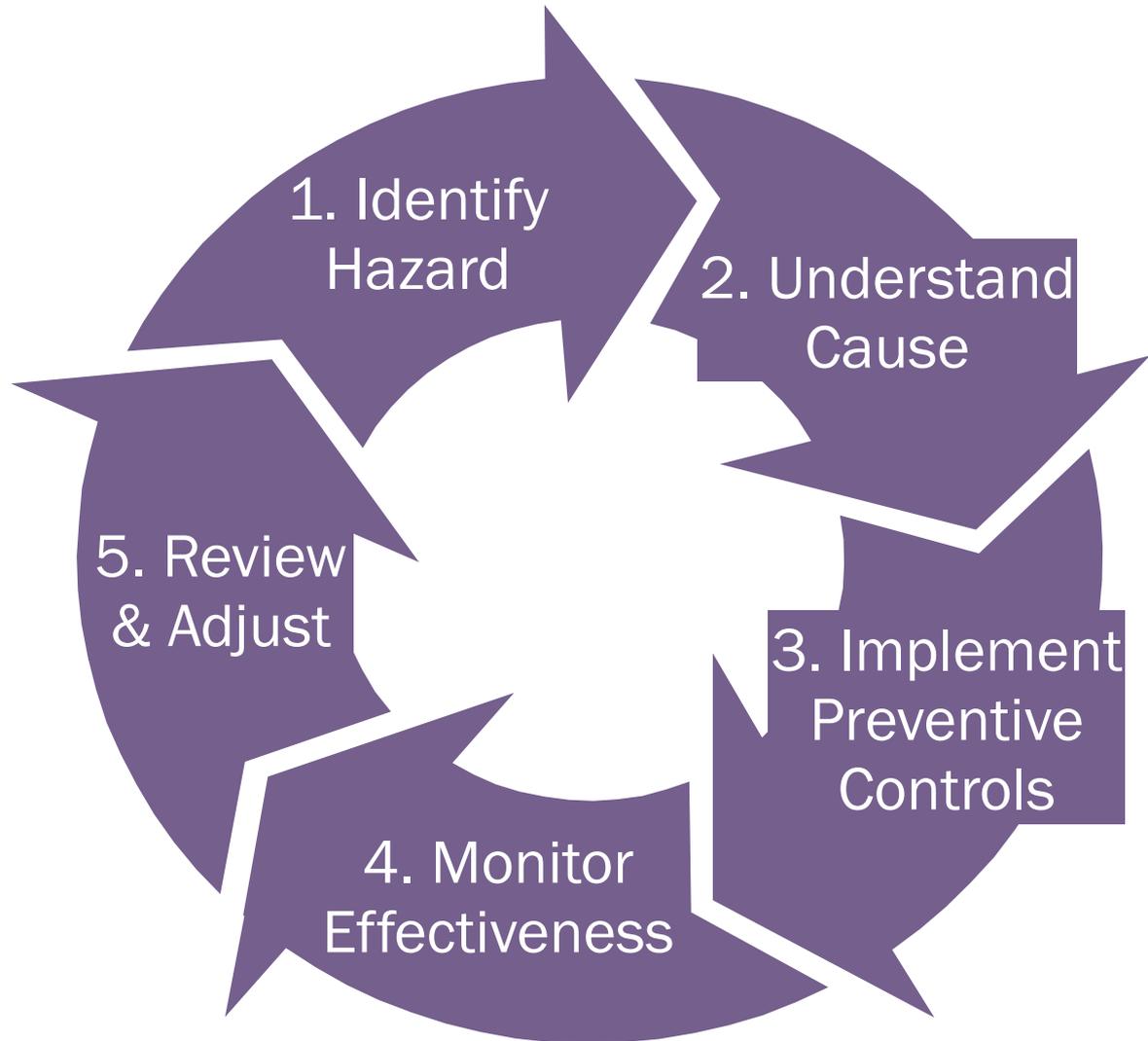
Reanalysis must be Performed:

- At least every 3 years
- Major change to product/process
- New potential hazards
- Preventive control is ineffective
- Unanticipated problem



Reanalysis must be performed or overseen by the PCQI

Summary





Unforeseen Issue

Outdated ingredient specs
not matching supplier
procedures

What Will it Cost?



- Initial
 - Employee (75% of time for 3 months, \$20/hr.): **\$7,200**
 - PCQI Certification: **\$700-900**
 - Mock Recall (1 day (8hrs.), 5 Employees, \$20/hr.): **\$800**
- On Going
 - Labor/Recording Keeping: (25% of time, 1 year est., \$20/hr): **\$10,400**
 - Training: **\$1,209/employee**
 - 3rd Party Audit (Eagle Certification Group): **\$3,800**

Estimated Cost for Food Safety Plan: \$24,209

Resources



- Clemson Extension (Example Food Safety Plan, Training Manual, and PowerPoint)
 - <http://www.clemson.edu/extension/publications/index.html>
- Food Safety Preventive Control Alliance (FSPCA)
 - <https://www.ifsh.iit.edu/fspca>
- FDA
 - <http://www.fda.gov/Food/GuidanceRegulation/FSMA/>
 - <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/ucm496263.htm>



Katie Worley
kpworle@g.clemson.edu

Dr. Johnny McGregor
johnny@clemson.edu

Food, Nutrition, and Packaging Science Department
College of Agriculture, Forestry and Life Sciences

223 P&A Bldg. Clemson, South Carolina (864) 656-3397

CLEMSON
COOPERATIVE EXTENSION



**Quiz: What are
your requirements
for FSMA?**

Group Activity



Question 1

You buy Mr. Green Jeans farm fresh strawberries from the local farmers market to use in your ice cream. Your company has made an average of \$1.5 million over the past 3 years selling to grocery stores and scoop shops and has 50 employees. You are not required to follow PMO. **What is your FSMA classification (small, very small, retail, etc.) and what procedures would you need to follow under FSMA?**

Question 1 Answer

- Classification: Small Business
- Required for FSMA:
 - GMPs and a Food Safety Plan (Hazard Analysis, Preventive Controls, Recall Plan, etc.)
 - Preventive Controls may include:
 - Washing the strawberries to reduce chemical hazards (pesticides) and remove physical hazards such as rocks
 - Heat Treating the strawberries to reduce biological hazards
 - Supply Chain Control

Additional Information Question 1

- If a farm falls under the produce law, which regulates the water purity and other safety hazards, then they will have a certificate that ensures that the produce is safe. If the farm is exempt from the produce law, they may have a GAPs audit.
- As a business, you need to decide if you will use a supplier that does not have GAPs audit or fall under the produce law. If you choose to use the supplier lacking these, what processes will you do to control the hazards?

Question 2

Your company receives mix from a commercial mix manufacturer and you batch freeze to make ice cream. Your average sales are \$750,000 annually by selling ice cream in your scoop shop and at fairs and festivals in a concession trailer. The fairs are over a 300 mile radius in the tri-state area. **What is your FSMA classification (small, very small, retail, etc.) and what procedures must you follow?**

Question 2 Answer

- Classification: Very Small Business (Qualified Facility)
- Required for FSMA:
 - GMPs and Training Records
- Recommended:
 - Make sure your suppliers are compliant with FSMA
 - Maintain records

Question 3

An ice cream mix manufacturing company has 25 employees and has an average gross sales of \$1.5 million. The mix is then distributed wholesale. You are required to comply with the PMO. **What is your FSMA classification (small, very small, etc.) and what are you required to make available to your customers?**

Question 3 Answer

- Classification: Small Business (Subject to PMO)
- Required to Provide to Customers:
 - Allow customers to perform a 3rd party audit or you as the company can have a 3rd party audit done on your facility and provide all customers with the audit report
 - Food Safety Reports

Question 4

Your 25 person company makes ice cream that is sold in your retail operations. You also distribute to restaurants and grocery stores in Austin, Dallas, and Fort Worth. Your gross sales are \$2.5 million annually, of which 30% is in your retail scoop shop, 10% is sold to local restaurants and 60% is sold in grocery stores. **What is your FSMA classification (small, very small, retail, etc.) and what are your requirements?**

Question 4 Answer

- Classification: Small Business
- Required for FSMA:
 - Everything!
 - GMPs, Hazard Analysis, Preventive Controls, Monitoring/Verification/Validation, Recall Plan, Reanalysis

Katie Worley
kpworle@g.clemson.edu
www.linkedin.com/in/katie-worley



Dr. Johnny McGregor
johnny@clemson.edu

Food, Nutrition, and Packaging Science Department
College of Agriculture, Forestry and Life Sciences

223 P&A Bldg. Clemson, South Carolina (864) 656-3397

CLEMSON
COOPERATIVE EXTENSION