FOOD SAFETY FRIDAYS
BITE-SIZED EDUCATION

Preventive Controls and HACCP

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International Food Safety & Quality Network

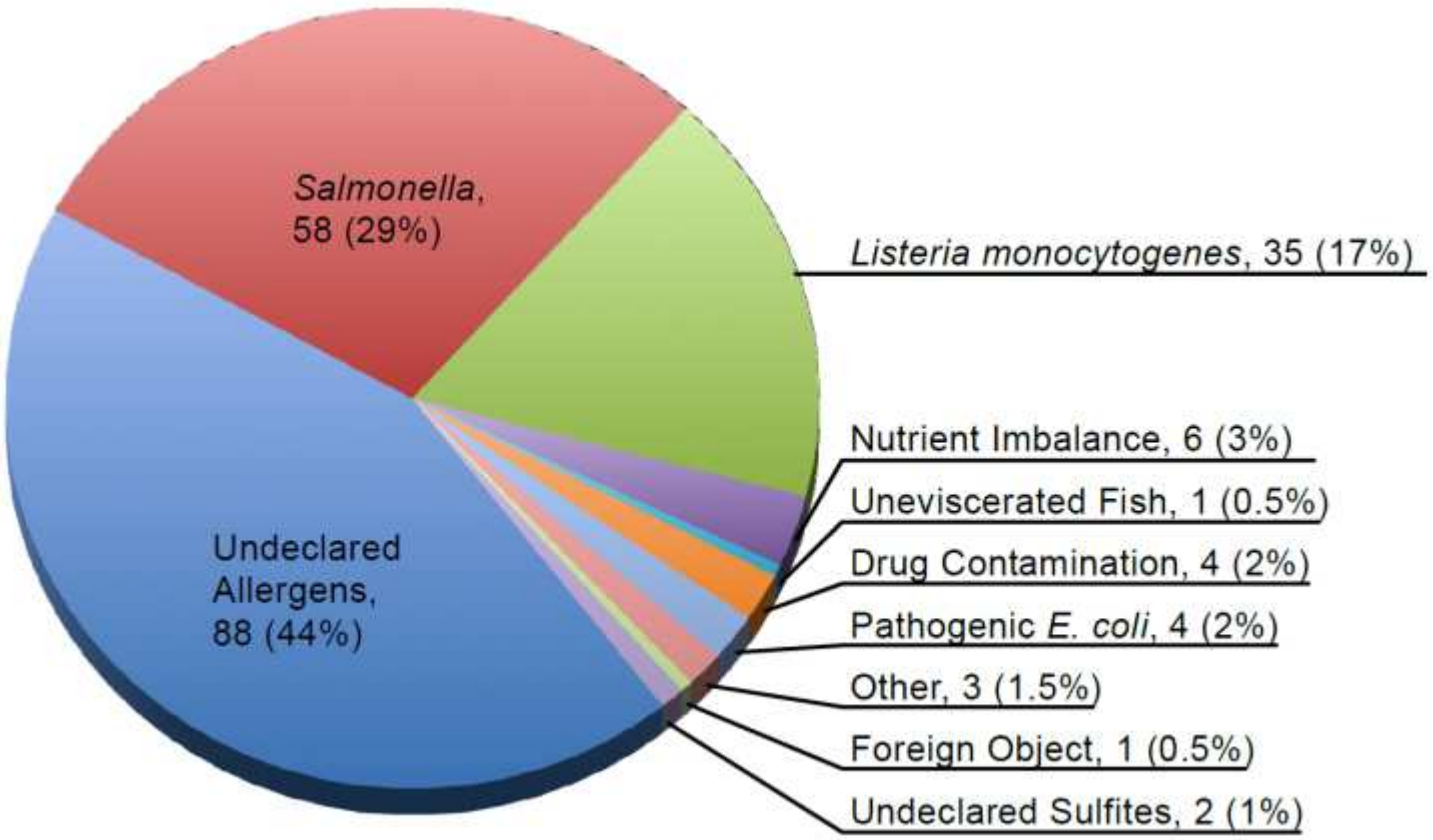
Learning Objective

Consider and understand scope, intent and implications of the final Preventive Controls rule, published on September 17, 2015.

Content

- Recalls by numbers
- Intent and scope of FSMA/HARPC
- Exemptions
- Summary review of HARPC
- Next steps

Recalls by the numbers[1]



1. 4th Annual Reportable Foods Registry (2013)

Intent, Scope and Implications of FSMA/HARPC

- From correction to prevention
  - Reducing the number of failures
- Back to the basics
  - 402 (a) (4)
- Food Safety from “Farm to Fork”
  - Supply-chain applied control
- Global
  - Imports
- Responsibility and accountability
  - Private sector

Exemptions

Exempt from HARPC:

- Seafood
- Juice
- Dietary Supplements
- Thermal Processed Low Acid Canned Food
  - Exempt from micro analysis only

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Part 117 - Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls (HARPC)

- Subpart A - General Provisions
- Subpart B - Current Good Manufacturing Practice
- Subpart C - Hazard Analysis and Risk-Based Preventive Controls (HARPC)
- Subpart D - Modified Requirements
- Subpart E - Withdrawal of Qualified Facility Exemption
- Subpart F - Requirements Applying to Records that must be Established and Maintained
- Subpart G - Supply-Chain Program

Subpart A – General Provisions

New key definitions:

- Qualified individuals
- Hazard, known or reasonable foreseeable hazard, hazard evaluation, and hazard needing a preventive control
- Preventive control
- RTE food
- Supply-chain control

Subpart A – General Provisions

Qualified individual means

- A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties.
  - Line employees
  - Supervisors

Subpart A – General Provisions

Preventive controls qualified individual means

- 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.
- Responsible for developing, implementing and managing the Food Safety Plan.

Subpart A – General Provisions

Qualified auditor means

- A person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required.
  - Own employee
  - Government employee
  - An audit agent of a certification body

Subpart A – General Provisions

Hazard means

- Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

What are the 12 categories of hazards under HARPC?

1. Biological
2. Chemical
3. Physical
4. Radiological
5. Natural Toxins
6. Pesticides
7. Drug Residues
8. Decomposition
9. Parasites
10. Allergens (human food only)
11. Unapproved Additives
12. EMA

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Subpart A – General Provisions

Known or reasonably foreseeable hazard means

- 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.

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Subpart A – General Provisions

Hazard evaluation

- Includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

Subpart A – General Provisions

Hazard requiring a preventive control means

- A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establishes one or more preventive controls to
- significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

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Subpart A – General Provisions

Preventive controls means

- 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 understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Subpart A – General Provisions

Ready-to-eat food (RTE food) means

- Any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize biological hazards.
- The hazard evaluation must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen.

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Role of Environmental Monitoring and Product Testing

- Are verification activities to verify consistency and effectiveness of preventive controls
- Environmental monitoring
  - Done as appropriate for RTE foods
  - Zone based
- Product testing (ingredients, in-process, FP)
  - Done "as appropriate" for type of food
    - Kill step, allergen cleaning, cross contact, supplier verification, etc.
- Require written procedures, corrective actions and recordkeeping if used

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Subpart A – General Provisions

Supply-chain-applied control means

- A preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

Subpart B – Current Good Manufacturing Practice

Key change:

- 24 food allergen controls revisions to the cGMP
  - Personnel, clothing, traffic and practices
  - Building structure/separation of processes
  - Cleaning product zones (equip, bulk and utensils)
    - Cleaning non-product zones (equip/structure)
    - Methods of cleaning (CIP, COP, air or other)
    - Equipment design (cleanability)

Subpart B – Current Good Manufacturing Practice

Key change:

- 24 food allergen controls revisions to the cGMP
  - Adequate Process Controls
    - Procedures to prevent cross-contact at suppliers, during transport, and from receiving to shipping of FP.
    - Separation and handling of raw materials/ingredients, premixes, product in process, rework, and packaging materials to prevent cross-contact

Subpart C – HARPC

- Identify known or reasonable foreseeable hazards associated with
  - Raw materials and ingredients
  - Process
  - Environment
- Document such identification based on verifiable evidence.

Subpart C – HARPC

Hazard evaluation *must consider*:

- Formulation of the food
- Condition, function, design of facility & equipment
- Raw materials & other ingredients
- Transportation practices
- Manufacturing/processing procedures
- Packaging & labeling activities
- Storage & distribution
- Intended or foreseeable use
- Sanitation, including employee hygiene
- Any other relevant factors, seasonal or weather related effects e.g. toxins, bacteria growth, etc.

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Subpart C – HARPC

Undertake a Hazard evaluation

- Assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls

Subpart C – HARPC

Identify Preventive Controls

- Who will control the hazard
- What will be the Preventive Controls
  - Process controls
  - Food allergen controls
  - Sanitation controls
  - Supply-chain controls
  - Recall plan
  - Other controls (procedures, practices and processes)

Subpart C – HARPC

Preventive Control Management Components

- Monitoring
  - Evidence that the planned activity happened (real-time)
- Corrective actions and corrections procedures must describe the steps to be taken to insure that
    - The PC problem is identified and corrected
    - Reduce the likelihood that the problem will recur
    - All affected food is evaluated for safety, and
    - Affected food is prevented from entering commerce if you cannot ensure that the food is not adulterated or misbranded (labeling)

Subpart C – HARPC

Preventive Control Management Components

- Verification
  - Verification of PC implementation and effectiveness
  - Environmental & product testing for RTE foods
- Validation
  - Evidence that the PC controls the hazard
- Reanalysis
  - Every 3 years
  - When a PC or management element fails, market failure, new information about hazards.

Subpart D – Modified Requirements

Applies to qualified facilities

- Based on the US$ value of annual sales and the type of customer, and
- Warehouses
    - Solely engaged in the storage of unexposed packaged products
    - Modified requirements for refrigerated food
- Must submit an attestation
- Must retain records

Subpart E – Withdrawal of Qualified Facilit Exemption

Withdrawal of qualified facility exemption

- In the event of an investigation of a foodborne illness outbreak linked to the facility
- The results of an inspection make it necessary to protect the public health

Subpart F – Records

Requirements Applying to Records

- Original, true copies, or electronic
- Contain actual values and observations
- Be accurate, indelible and legible
- Be created concurrently with the performance of the activity
- Be detailed as necessary
- Information adequate to identify the facility

Subpart F – Records

Requirements Applying to Records

- Requirements for official review
  - All records required must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.
- Public disclosure
  - Records obtained by FDA are subject to the disclosure requirements under 21 CFR part 20 Freedom of Information Act.

Subpart G – Supply-Chain Program

The supply-chain program must include

- Using approved suppliers
- Appropriate verification activities and frequencies
  - Onsite audits
  - Sampling and testing
  - Review of supplier's food safety records
  - Other
- Conducting and documenting verification activities
- Written procedures for receiving raw materials

What Next?

- Until November 2016 to come into compliance.
- Set up a transition team
- Obtain, study and understand the final rule.
- Obtain, study and apply applicable guidance documents.
- Undertake the hazard evaluation.
  - Who will control the hazards needing a PC
  - What will be the PCs
- Develop the written Food Safety Plan.
- Integrate HACCP and HARPC? – options.
- Make sure you engender Qualified Individuals.