HACCP vs. HARPC

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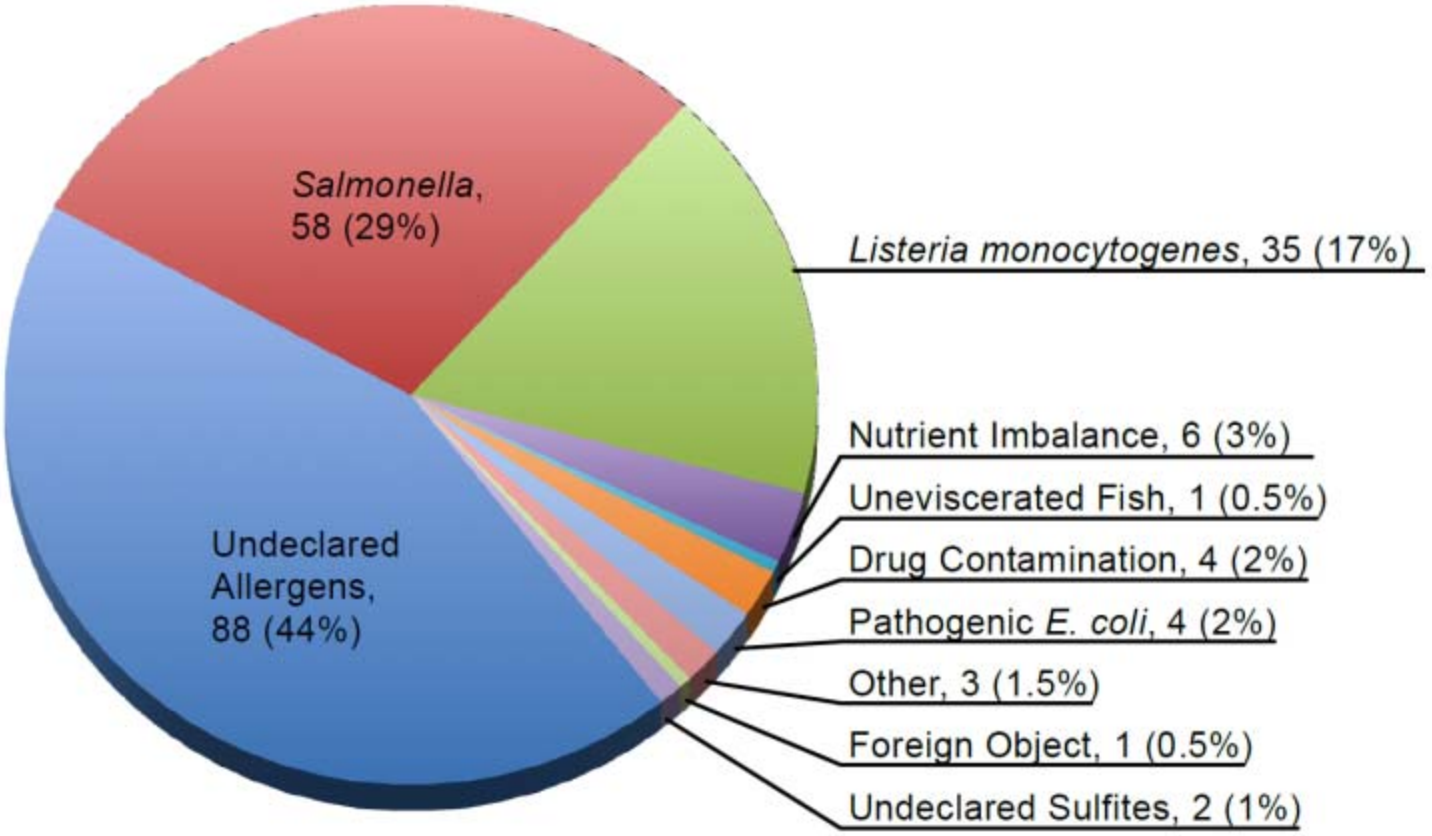
Intent, Scope and Implications of HARPC

- **From correction to prevention**
  - Reducing the number of failures
- **Back to the basics**
  - 402 (a) (4) from 402 (a) (3)
- **Food Safety from "Farm to Fork"**
  - Supply chain applied control
- **Global**
  - Food imports
- **Responsibility and accountability**
  - Private sector

Recalls by the Numbers

- Recalled products typically numbered in the hundreds in the past decade
- By 2009, thousands of products were being recalled annually
- Possible reasons?
  - Increased imports
  - Growing complexity of the supply chain
  - Better detection and recognition of food safety problems
  - Better reporting by manufacturers, i.e., RFR

Recalls by the Numbers, continued



Source: 4th Annual Reportable Foods Registry (2013)

Preventive Controls Qualified Individual

- FDA-recognized training
  - FSPCA (Food Safety Preventive Controls Alliance)
  - Train lead instructor(s) to subsequently train employees
  - Or otherwise qualified (training/experience)

Preventive Controls Qualified Individual

To do or oversee:

- Preparation of a Food Safety Plan
- Validation of Preventive Controls
- Review of records for implementation and effectiveness of
- Preventive Controls
- Appropriateness of corrective actions
- Reanalysis of Food Safety Plan
- FDA will assess qualified individuals (real plant conditions vs. records)
- What will you present to the FDA?

Your Food Safety Plan

Must include:

- Hazard analysis methodology & results
- Identification of preventive controls
- Supply chain program as required
- Recall plan
- Monitoring, corrective action, and verification procedures
- Validation

Your Food Safety Plan

- "Written" means
  - Food Safety Plan
  - Procedures & records
- Must be prepared or overseen by one or more Preventive Controls Qualified Individuals (PCQI)
- The owner, operator, or agent in charge of the facility must sign and date the food safety plan:
  - Upon initial completion and
  - Upon any modification

HARPC Development Requirements

- Must be written regardless of outcome
- Must be based on experience, illness data (recalls), scientific papers, including guidance documents and other information
- Must include raw materials/ingredients, process and environment
- Must consider specific factors cited in the rule
- Must identify "known or foreseeable hazards"
  - Includes B, C, P, radiological and EMA
- Must complete a risk analysis to identify who will control the hazard and the appropriate control

The 12 Categories of Hazards Under HARPC

What are they?

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. Intentional

The 12 Categories of Hazards Under HARPC

Biological

Parasites

Chemical

Natural Toxins
Pesticides
Drug Residue
Allergens
Decomposition
Unapproved Additives

Physical

Hazards not covered under HACCP

- Radiological
- Intentional: EMA

Risk-Based Preventive Controls

Potential PCs:

Prerequisite Programs

- Sanitation
- Personnel practices
- Chemical control
- Allergen control
- Maintenance
- Water quality
- Environmental monitoring
- Supplier control
- Other

Specific operational and non-operational activities:

- Temperature
- Change over cleaning
- Calibration
- Rework
- Hand washing
- Rinse water pH
- Pre-op/operational inspection
- Other

Process Steps:

- Cooking
- Cooling
- Strainers/Sifting
- Metal detection
- Bottle Washing
- Ozone or UV treatment
- Optical scanner
- Irradiation
- Sanitizing
- Other

Environmental Risk Assessment

The hazard evaluation must include an assessment

- of environmental pathogens whenever a ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a pathogen reduction treatment.
- or otherwise includes a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

PC Management Components

- Monitoring
- Corrections and corrective action
- Verification
- Validation
- Supply chain program
- Record review for all the above
- Reanalysis of Food Safety Plan
- Recall plan

PC Management Components

Corrective action procedures must describe the steps to be taken to insure that:

- The PC violation is identified, recorded 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)

PC Management Components

Verification Procedures

- Monitoring is being implemented as written
- Appropriate decisions about corrective actions are being made
- Hazards are effectively minimized or prevented
- Calibration
- Product testing for pathogen or other hazard
- Environmental monitoring
- Review of records

PC Management Components

Validation

- For PCs as appropriate by PCQI
- Prior to implementation of Food Safety Plan, or
- Implemented 90 days after production begins
- Don't need to validate:
  - Food allergen controls
  - Sanitation controls
  - Recall plan
  - Supply chain program
  - Other PC if written justification in provided

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Integrating HARPC and HACCP

HARPC

- Similar concepts to HACCP!
- Somewhat different from HACCP!
- Include in HACCP, subset or separate?
- What to do?

HARPC ≠ HACCP

HARPC = or ≠ HACCP?

HACCP	HARPC	Solutions
International Codex	21 CFR Part 117	
HACCP Team and Coordinator	Preventive Control Qualified Individual(s)	
Flow diagram required and verified on the floor	Not required	
Product description, intended use, and technical parameters	Product and technical parameters	
3 hazards, B, C, and P	12 hazards + intentional + EMA	
Hazard Analysis by team	Hazard Analysis by PCQI with FDA Guidance	

HARPC = or ≠ HACCP?

HACCP	HARPC	Solutions
Identifies Critical Control Points (CCPs)	Identifies Risk-Based Preventive Controls (PCs)	
Requires critical limits for CCPs	Requires parameters for RBPCs, as appropriate	
CCPs must be validated	Validation of RBPCs, as appropriate	
Requires verification / validation	As appropriate, verification / validation	
CCP corrective action: reprocess, animal food or destroy	RBPC corrective action allows for product evaluation	

HARPC = or ≠ HACCP?

HACCP	HARPC	Solutions
Specific documented monitoring and corrective action	Documented monitoring with flexibility	
Reassess when changes occur and yearly validation	Reassess when changes occur and every three years	
Does not require check on supplier regulatory compliance	If supplier controls used, must include verification activities, including regulatory compliance history	
Finished product testing not required for validated kill steps	As appropriate, product testing e.g. (RTE)	

Your Options

- FDA does not require a HACCP Program
  - Except seafood, juice
- It is an OPTION to eliminate your HACCP Program, however:
- Reasons to retain a HACCP Program:
  - Recognized/required by domestic and foreign customers
  - AIB requirement
  - GFSI requirement (BRC, SQF, IFS, FSSC 22000)
  - Retain emphasis on food safety culture