Agricultural Outlook Forum
Emerging Food Safety Issues in U.S. & Foreign Markets

Emerging Strategies for Managing Food Safety

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Risk Analysis Process

• Risk Assessment
• Risk Management
• Risk Communication
Risk Assessment

- Hazard Identification & Impact
- Hazard Characterization
- Exposure Assessment
  [qualitative and quantitative]
- Risk Characterization
Risk Management

- Safe handling procedures and practices, food processing quality and safety assurance controls, food quality and safety standards
A risk management framework is needed to:

- incorporate scientific information into regulatory and company policies
- assess the efficacy of measures used to control microbial hazards
Steps for managing microbial hazards

1. Information indicates a need for improved control
2. Conduct a risk evaluation
3. Assess risk management options (ALOP)
4. Establish a food safety objective (FSO)
5. Confirm that the FSO is achievable through GHP and HACCP

6. Establish performance/process/product criteria

7. Establish acceptance procedures:
   – audits to approve food suppliers
   – product criteria (e.g., pH, $a_w$, microbiological)
Analytical systematic scientific determinations are preferred.

Emphasis will be placed on the Food Safety Objective (FSO) approach coupled with HACCP that offers a transparent determination in risk management.
Recently proposed by the International Commission on Microbiological Specifications for Foods and on its way to acceptance by Codex Alimentarius

FSO is a statement of the maximum frequency and/or concentration of a microbial hazard in a food at the time of consumption that provides the appropriate level of protection.
Food Safety Objectives integrate scientific data from risk assessment to designate quantifiable frequencies and concentrations that address specific public health demands.

Processor knows level of hazard considered appropriate in final product and designs process considering initial number of pathogens and any subsequent growth after processing during storage, distribution and preparation.
Food Safety Objectives integrate scientific data from risk assessment to designate quantifiable frequencies and concentrations that address specific public health demands.

FSO defines expected level of control that must be achieved to meet the appropriate level of consumer protection, considering storage, distribution, sale, and preparation.
Steps for managing microbial hazards

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### Step 1

Information indicates a need for improved control

<table>
<thead>
<tr>
<th>Disease</th>
<th>Cases/100,000/year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Listeriosis</td>
<td>0.3 - 0.6</td>
</tr>
<tr>
<td>Yersiniosis</td>
<td>0.4 - 1.0</td>
</tr>
<tr>
<td><em>E. coli</em> O157:H7</td>
<td>1.6 - 2.9</td>
</tr>
<tr>
<td>Shigellosis</td>
<td>5.0 - 11.6</td>
</tr>
<tr>
<td>Salmonellosis, nontyphoid</td>
<td>12.0 - 15.1</td>
</tr>
<tr>
<td>Campylobacteriosis</td>
<td>13.8 - 25.2</td>
</tr>
</tbody>
</table>
Step 2
Conduct risk evaluation

Examples:

**Quantitative RA**
- FDA/USDA and WHO/FAO - *Lm* in RTE foods

**Qualitative RA**
- Health Canada - *Salmonella* in cracked eggs
- IFT - *C. botulinum* and *Lm* in cold smoked salmon
- FSIS expert panel - *E. coli* O157:H7 in fermented meats
Step 3
Consider risk management options

- Consider the level of risk that would be tolerable for the hazard (ALOP)
- Identify possible options for controlling the hazard
- Select the preferred option(s)
ALOP examples

ALOP = 0.0 cases of botulism/100,000/year from commercially prepared foods, including foodservice

ALOP = 0.25 cases of listeriosis/100,000/year
Food operators cannot effectively respond to an ALOP

Regulatory authorities cannot use an ALOP to evaluate a food operation
Step 4
Establish a Food Safety Objective (FSO)

A statement of the maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection.
FSO

- An outcome of risk evaluation and risk management and intended to:
  - limit risk among an exposed population
  - inform industry of the expected level of control for food operations.
• Serve as a basis for measuring the effectiveness of:
  – control systems adopted by industry
  – inspection systems adopted by regulatory authorities

• Limited to food safety
FSO example: *Listeria monocytogenes* in Ready-To-Eat Foods

FSO = *L. monocytogenes* shall not exceed 100/g or 3.5 log₁₀ cfu/serving in RTE foods.
In some cases, the desired level of consumer protection is better achieved through a performance criterion.
Performance Criterion (PC)

The expected level of control at one or more steps *in the food chain.*
Performance Criteria

\[ H_0 - SR + SI \leq FSO \]

FSO = food safety objective

\( H_0 \) = initial level of the hazard

SI = total increase (growth or recontamination)

SR = total reduction

(pathogen inactivation or removal)
FSOs and PC can be used:

• as the basis to validate and/or assess the acceptability of a food operation

• to force change in an industry to improve food safety
Response to FSOs and PC

Industry:
establishes control measures
based upon GHP and HACCP

Regulatory authorities:
adjust inspection procedures to
verify the FSOs and/or PC
are being met
Step 5

Confirm that the FSO is achievable through GMPs and HACCP
Basic Control Measures

Controlling initial levels
- Avoiding high risk foods (e.g., undercooked ground beef)
- Selecting ingredients from approved sources

Controlling increase in a hazard
- Preventing contamination (e.g., GMPs)
- Preventing growth of pathogens (e.g., pH, $a_w$)

Reducing a hazard
- Destroying pathogens (e.g., pasteurization)
HACCP

The scientific basis for CCPs and critical limits is in:

• establishing and validating PC, and then
• applying appropriate process and/or product criteria
FSOs and PC can lead to:

• process criteria,
• product criteria and
• default criteria
Step 6

Establish process/product requirements

**Process criteria:**

Heating at 71.7°C for 15 seconds to pasteurize milk

**Product criteria:**

\[ \text{pH} = \leq 4.6 \] for high acid canned foods

**Default criteria:**

Values stated in regulations or guidelines
Step 7
Establish acceptance procedures

Finished product specifications:
• chemical
• physical
• organoleptic
• microbiological
Validation

Collecting evidence to prove that the control measures are effective and the FSO(s) and/or PC will be met.
Basis for process validation

- reports from expert panels
- regulations with a scientific basis
- scientific literature
- laboratory research (e.g., challenge studies)
- commercial experience with process and products
Examples of data collected during production:

– measurements of time-temperature, pH, $a_w$
– microbiological data:
  • initial, in-process, final product
– determining process variability and how to minimize
FSOs and PC are values that must be met; otherwise, they can not be used as a basis for process validation.

FSOs and PC are a line in the sand, not target values.
$H_0 - SR + SI \leq FSO$

$H_0$, SR and SI are concentration or frequency distributions, not point values, for the microbial hazard. The distributions are influenced by many factors such as:

- source of the food or ingredients
- pathogen characteristics
- impact of the food on survival/growth
- conditions of processing
- process variability, etc
Confidence in the safety of a food depends on the ability of the food industry to control variability in \( H_0 \), SR and SI throughout the food chain.

Variability must be considered during process validation to ensure safety but also to avoid over-processing.
Flowchart of Framework in “Emerging Microbiological Food Safety Issues” published by the Institute of Food Technologists www.ift.org
Figure 1: Framework for Food Safety Management

Risk Assessment
- Hazard(s) identified
- Exposure assessed
- Hazard(s) characterized
- Risk characterized

Risk Management
- Consider options, including a Food Safety Objective

Hazard Control and Monitoring
- Agricultural interventions implemented
- GMPs/GHPs implemented
- Baseline level of microbial hazard measured
- Processing safety objective calculated (FSO minus growth during storage and distribution)
- Performance criteria established (baseline minus processing safety objective)
- Method(s) of control selected
- Process-specific hazard analysis conducted
- Critical control points identified

- Process/product criteria established
- Critical limits established
- Monitoring procedures developed and implemented
- Corrective actions implemented (as needed)
- HACCP system verified
- Recordkeeping implemented

- Microbiological criteria established (if necessary)

Food Distribution and Storage
- Pathogen growth prevented or minimized

Food Consumption
- Food Safety Objective met
Framework for Food Safety Management

FSO Approach

- Consider options, including a Food Safety Objective

Risk Management

- Hazard Control and Monitoring

Risk Assessment

- Hazard(s) identified
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- Hazard(s) characterized
- Risk characterized

Public health concern identified
Process/product criteria established

Critical limits established

Monitoring procedures developed and implemented

Corrective actions implemented *(as needed)*

HACCP system verified

Recordkeeping implemented

Microbiological criteria established *(if necessary)*
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- **Processing safety objective met**
  - **Food Distribution and Storage**
    - Pathogen growth prevented or minimized
  
  - **Food Consumption**
    - Food Safety Objective met
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- Public health concern identified
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- HACCP system verified
- Recordkeeping implemented
- Microbiological criteria established (if necessary)
- Processing safety objective met

**Food Distribution and Storage**
- Pathogen growth prevented or minimized

**Food Consumption**
- Food Safety Objective met
Risk Communication

• provides public with results of expert scientific review of food hazard identification and assessment of risk to general population or target group

• provides private and public sectors with information necessary to prevent, reduce, minimize food risks through systems of quality and safety
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