Discussion Topics

- Food safety management terminology
  - ALOP – Appropriate Level of Protection
  - FSO – Food Safety Objective
  - PO – Performance Objective
  - MC – Microbiological Criterion
- Food safety management framework
- Food Safety Objectives

Food Safety Framework

Policy
Legal Standards
HACCP
GHP/GMP/GAP
Food Safety Framework

- National Level
  - High level risk management
  - Specific standards, criteria, guidelines

- Company Level
  - Specific hazard management
  - General facility and supply chain management

Steps to Establish an FSO or PO

1. Identify a need for improved hazard control
2. Conduct risk assessment (qualitative or quantitative)
3. Articulate public health goal or Appropriate Level of Risk (ALOP)
4. Calculate level of exposure that would achieve goal (FSO)
5. Evaluate the FSO or PO for feasibility
6. Implement control systems that achieve the FSO or PO

2. Conduct a Risk Assessment

- A scientific process that estimates risk
- Does not set “acceptable” or “tolerable” levels of risk
- Determining the “acceptable” level of risk is a scientific and societal question

Risk Assessment Examples

- USA examples
  - L. monocytogenes
    - RTE foods
    - Retail delis
    - Soft ripened cheese
  - Vibrio: raw oysters
  - Produce risk ranking
  - Escherichia coli O157:H7
  - Norovirus: shellfish
- http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm247806.htm

- FAO/WHO examples
  - L. monocytogenes: RTE foods
  - Salmonella Enteritidis: Eggs and egg products
  - Salmonella: Broilers
  - Vibrio: Shellfish
  - Campylobacter: Broilers
3. Articulate a Public Health Goal (ALOP)

- Appropriate Level of Protection (ALOP) concept introduced by World Trade Organization SPS agreement
  - “Level of protection deemed appropriate by the member [country] establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within a territory”

![Cost of Appropriate Level of Protection](image)

Public Health Goals: Healthy People 2020

**FS1 Reduce infections** by key pathogens commonly transmitted through food

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Baseline (cases/100,000)</th>
<th>Target (cases/100,000)</th>
<th>Target-setting Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>E. coli O157:H7</td>
<td>1.2</td>
<td>0.6</td>
<td>50%↓</td>
</tr>
<tr>
<td>HUS in children &lt;5 yrs</td>
<td>1.8</td>
<td>0.9</td>
<td>50%↓</td>
</tr>
<tr>
<td>Campylobacter</td>
<td>12.7</td>
<td>8.5</td>
<td>33%↓</td>
</tr>
<tr>
<td>L. monocytogenes</td>
<td>0.3</td>
<td>0.2</td>
<td>25%↓</td>
</tr>
<tr>
<td>Salmonella</td>
<td>15.2</td>
<td>11.4</td>
<td>25%↓</td>
</tr>
<tr>
<td>Vibrio</td>
<td>0.3</td>
<td>0.2</td>
<td>25%↓</td>
</tr>
<tr>
<td>Yersinia</td>
<td>0.4</td>
<td>0.3</td>
<td>25%↓</td>
</tr>
</tbody>
</table>

Public Health Goals: Healthy People 2020

**FS-2 Reduce food commodity outbreak-associated infections due to E. coli O157, Campylobacter, Listeria, or Salmonella**

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Baseline (cases/year)</th>
<th>Target (cases/year)</th>
<th>Target-setting Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beef</td>
<td>200</td>
<td>180</td>
<td>10%↓</td>
</tr>
<tr>
<td>Dairy</td>
<td>786</td>
<td>707</td>
<td>10%↓</td>
</tr>
<tr>
<td>Fruits and nuts</td>
<td>311</td>
<td>280</td>
<td>10%↓</td>
</tr>
<tr>
<td>Leafy vegetables</td>
<td>205</td>
<td>185</td>
<td>10%↓</td>
</tr>
<tr>
<td>Poultry</td>
<td>258</td>
<td>232</td>
<td>10%↓</td>
</tr>
</tbody>
</table>
4. Calculate level that will achieve goal (FSO)

- Food operators cannot effectively respond to an ALOP in terms of “number of cases per year” or “probability of disease”
- Regulatory authorities cannot use an ALOP to evaluate a food operation for compliance
- Food Safety Objectives can be a bridge between an ALOP and performance/process criteria

Food Safety Objectives (FSO)

- The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).
  - Codex Alimentarius
- Establishing an FSO is the responsibility of governments
  - The principles can be used by industry to establish controls

Regulatory Process Implications

Food Safety Objectives…
- Incorporate scientific information into regulatory process
- Consider science and societal issues
- Define the limit that must be met, not how it is achieved
- Provide actionable levels for regulatory agency verification

Appropriate Level of Protection & FSO

- Incidence of Disease
- Hazard
- Prevalence
- Concentration of Hazard
- FSO
5. Evaluate the FSO for feasibility

- To avoid undue societal costs, feasibility must be addressed
- Example: *Vibrio parahaemolyticus* in Raw Oysters
  - FDA Risk Assessment

<table>
<thead>
<tr>
<th>Potential FSO/g</th>
<th>Cases/ year</th>
<th>% of Harvest Excluded</th>
</tr>
</thead>
<tbody>
<tr>
<td>100,000</td>
<td>4950</td>
<td>1</td>
</tr>
<tr>
<td>10,000</td>
<td>4250</td>
<td>5</td>
</tr>
<tr>
<td>1000</td>
<td>2250</td>
<td>25</td>
</tr>
<tr>
<td>100</td>
<td>500</td>
<td>70</td>
</tr>
</tbody>
</table>

6. Implement control to meet the FSO

- Few formal FSOs have been articulated
- Performance Objectives (PO) and standards do exist
- Performance Objective:
  - The maximum frequency and/or concentration of a hazard in a food at a point in the supply chain that provides or contributes to the appropriate level of protection (ALOP).
**Food Safety Objectives**

\[ H_0 - \sum R + \sum I \leq \text{FSO or PO} \]

Starting level

Food Safety Objective (FSO)

Hazard level at moment of consumption

Reduction

Increase

Recontamination or growth

Performance Objective (PO)

Hazard level in the supply chain

**Microbiological Criterion (MC)**

- A risk management metric which indicates the acceptability of a food, or the performance of either a process or a food safety control system following the outcome of sampling and testing for microorganisms, their toxins/metabolites or markers associated with pathogenicity or other traits at a specified point of the food chain.

**Given an FSO or PO…**

- Industry can design processes to meet the FSO or PO
- Regulators can verify compliance with the FSO or PO
- The effectiveness of performance or process standards can be evaluated
- The equivalence of approaches can be evaluated, which is important for international trade

**FSO/POs in the Food Chain**

- Primary production
- Manufacturing
- Transport
- Retail
- Preparation
- Consumption

**Performance Objective**

- PO
- Control Measure
- Performance criterion

**Food Safety Objective**

- PO
- Control Measure
- Performance criterion

Control Measure

Performance criterion

Public health burden

Exposure

Slide based on JL Cordier 2007
Summary

• Food Safety Objectives (FSO) and Performance Objectives (PO) are useful tools for linking public health goals to informative objectives for industry to meet.

• Governments and intergovernmental agencies (e.g., Codex) define FSOs and POs:
  – Industry can establish POs for portions of the supply chain under their control.

• Governments can evaluate the impact of their standards on improving public health.

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Summary continued

• Industry evaluates acceptability of a process based on FSOs and POs.

• Industry manages risk using HACCP and GHP to control:
  – Initial levels ($H_0$)
  – Increase in a hazard ($\Sigma I$)
    • Growth and recontamination
  – Reducing a hazard ($\Sigma R$)