Using risk assessments to set performance objectives and performance criteria that achieve a food safety objective

ICMSF/RAC/ILSI/IAFP/IFT Symposium on Relating Microbiological Testing and Microbiological Criteria to Public Health Goals

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Note: This presentation represents the author’s views and not necessarily FDA policy.

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**Process Risk Assessment**

Exposure assessment → Hazard characterization
Dose-response relationship

Risk characterization

Raw ingredients → Pasteurization → Storage & Trans. Periods → Consumption → Illness

Process Risk Assessment

Performance Objectives
(freq and/or cfu/g)

Microbiological Criteria
(freq--cfu/g--sampling)

Raw ingredients
Pasteurization
Storage & Trans. Periods
Consumption
Illness

Acceptable Level Of Protection
(cases/yr)
(cases/serving)

Performance Criteria
(logs inactivation)
Process Criteria
(°C - min)

Food Safety Objective
(freq and/or cfu/g)

Microbiological Criteria
(freq--cfu/g--sampling)

Hypothetical FSO paradigm for cut lettuce

\[ H_0 + \sum R + \sum I < FSO \]

<table>
<thead>
<tr>
<th>ALOP Log(Illness/serving)</th>
<th>FSO Log(CFU/serving)</th>
<th>FSO Log(CFU/g)</th>
<th>PO / MC RETAIL Log(CFU/g)</th>
<th>PO / MC MANUFACTURING Log(CFU/g)</th>
<th>PO RAW LETTUCE Log(CFU/g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>-4.0</td>
<td>6.0</td>
<td>4.3</td>
<td>2.3 / 1.3</td>
<td>1.3 / 0.3</td>
<td>1.2</td>
</tr>
<tr>
<td>-5.0</td>
<td>5.0</td>
<td>3.3</td>
<td>1.3 / 0.3</td>
<td>0.3 / -0.7</td>
<td>0.2</td>
</tr>
<tr>
<td>-6.0</td>
<td>4.0</td>
<td>2.3</td>
<td>0.3 / -0.7</td>
<td>-0.7 / -1.7</td>
<td>-0.8</td>
</tr>
<tr>
<td>-7.0</td>
<td>3.0</td>
<td>1.3</td>
<td>-0.7 / -1.7</td>
<td>-1.7 / -2.7</td>
<td>-1.8</td>
</tr>
<tr>
<td>-8.0</td>
<td>2.0</td>
<td>0.3</td>
<td>-1.7 / -2.7</td>
<td>-2.7 / -3.7</td>
<td>-2.8</td>
</tr>
<tr>
<td>-9.0</td>
<td>1.0</td>
<td>-0.7</td>
<td>-2.7 / -3.7</td>
<td>-3.7 / -4.7</td>
<td>-3.8</td>
</tr>
</tbody>
</table>
FSO and food process lots

Distributions of samples within a lot

Lot mean + 3 std < FSO  $\approx 0.14\% > FSO$

Just rejectable lot

Ave. = -1.0  
$s = 0.8$

73.2% 26.5% 0.14%
Using binomial distribution to determine number of samples

![Binomial Distribution Chart]

Microbiological Criteria

- Given a sampling, sample prep and analytical protocol:
  - Ave. = -1.0
  - s = 0.8
  - m = -0.5 \log_{10} \text{cfu/g}
  - 95% confidence in rejecting lot
  - c = 0
  - n = 10
Same lot, different sampling protocol

Steps in setting a MC

1. Determine the standard deviation of samples within lots of the food
   Given sampling & analytical protocol
   Adjust test sensitivity so 15-40% of samples are positive

2. Determine number of samples to reach desired confidence of detecting at least 1 positive
   \( c = 0 \)

3. If not satisfactory, adjust sampling and analytical protocol to reduce within lot variation and repeat
Process control chart with FSO and MC

Log CFU/g at PO

Lots

FSO m
Mean count

UCL

Detectable limit

Process mean

Mean count

Process control chart with lowest FSO and MC
Process mean, UCL, PO, FSO and MC relationship

- Sample (serving) < process mean + 3 process standard deviations + 3 within lot standard deviations ≤ FSO/PO
- The UCL = process mean + 3 process standard deviations
- The FSO > UCL + 3 within lot standard deviations

Two dimensional process risk assessments

- Variation—real differences in parameter values
- Uncertainty—lack of knowledge about the true value of the parameter
  - Lack of quality studies
  - Less relevant studies
  - Poor methodology
- Enter parameter values and calculate RA
  - cfu/serving < UCL/MC/PO/FSO?
  - Sensitivity analyses
Data with variation and uncertainty

**Storage time**

Pert (min, most likely, max)

- Pert(0.5, 5, 13)
- Uncertainty most likely Uniform(3, 7)
- Uncertainty max Uniform(10, 16)

Cumulative output of 2D risk assessment at PO
Cycles of increased process control

Designing a process to meet a FSO

1. Collect data and run 2-dimensional RA
2. If samples from lots (servings) fail FSO, use sensitivity analysis to determine parameter(s) contributing most to uncertainty, collect better data, rerun RA
3. If samples (servings) still fail FSO, use sensitivity analysis to determine parameter(s) contributing most to variation, reduce variation, update data, rerun RA
4. If samples (servings) still fail FSO, change process (POs or PCs) to reduce entire distribution to meet FSO
5. Collect new data, rerun RA and validate process meets FSO, verify continued compliance
Process Risk Assessment

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Performance Criteria

Process Criteria

Food Safety Objective