Peeling the Onion of Pathogen Standards for Foodborne Pathogens

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Perspective

- Brief Review of Standard Scheme
- Onion Layers
- Redefining Performance
- Tools to Rebuild the Onion
The primary goal of an FSO is to translate a risk level to a measure that can be applied by food processors.

ICMSF:

$$H_0 - \Sigma R^+ \Sigma I \leq FSO$$

- \( R = \) reductions, \( I = \) Increases
Overall Process

Acceptable Level of Protection

Food Safety Objective

Performance Standard
Log Dose vs. Probability of Infection

- Susceptible Population
- Normal Population

60% threshold

Log Dose:
- 2.5 log
- 3.5 log
Food Safety Objective

- Attempt to define a tolerable and achievable risk level upon which processing criteria can be set.
- Risk level needs to be translated to conditions that are measurable conditions in processing plants.
Food Safety Objective

Processor Criteria / Outputs

Prevalence

Concentration

Dose Response

Risk

Daily Risk

Annual Risk

RISK ASSESSMENT

FOOD SAFETY OBJECTIVE
Goal: to back-calculate tolerable and achievable risk levels to processor outputs
Selected Onion Layers

- Critiques of FSO Scheme
- Explicit Valuation of Outcomes
  - Population vs. Individual
- Accounting for Downstream Handling
- Indirect Risk Mitigation
  - Compliance
  - Inspection
  - Verification Sampling
  - Consumer Education and Labelling
- Defining Total Performance
  - Public Health
  - Food Companies
Critiques of FSO Schemes

- Simplicity is not always helpful
  - Are we reversing progress?
- Both prevalence and concentration matter
- Where do variability and uncertainty fit in?
  - Mean on the Log Scale
  - Back-calculation is very challenging
  - ICMSF eq. is not compatible with QMRA
- Re-contamination is not a log-additive phenomenon
The Goal in 2-Dimensions

Average Log Concentration

Prevalence leaving Process

- 99.00%
- 90.00%
- 70.00%
- 50.00%
- 30.00%
- 15.00%
- 10.00%
- 5.00%
- 3.00%
- 1.00%
- 0.01%

0.0
0.5
1.0
1.5
2.0
2.5
3.0
3.5
4.0
4.5
5.0
5.5
6.0
Explicit Valuation of Outcomes

- Variable Burden of Disease across Hazards
- Net Risk from a Class of Hazards
- Suite of Measures:
  - Per Serving
  - Per Kg
  - Per Million Persons
  - Hybrid Measures
Downstream Handling

- There are a sequence of events between process and risk
- These events need to be considered
- Can be accounted for as realistically as possible or conservatively.
- The following is a crude simplification
Prevalence (contaminated)

- 40% Not Contaminated
  - 20% Growth
    - 90% Under Cook
      - 10% Susceptible 10%
      - 90% Normal 90%
    - 90% Well Cook
      - 10% Susceptible 10%
      - 90% Normal 90%
- 80% No Growth
  - 10% Under Cook
    - 90% Susceptible 10%
    - 90% Normal 90%
  - 90% Well Cook
    - 10% Susceptible 10%
    - 90% Normal 90%
Prevalence (contaminated) 40%

Growth 20%

Under Cook 10%

Susceptible 10%

Normal 90%

Susceptible 10%

Normal 90%

Under Cook 90%

Normal 90%

Susceptible 10%

Normal 90%

Well Cook 90%

Susceptible 10%

Normal 90%

Well Cook 90%

Normal 90%

No Growth 80%

Under Cook 10%

Normal 90%

Susceptible 10%

Normal 90%

Well Cook 90%

Normal 90%

Not Contaminated
Prevalence (contaminated 46%)

- Not Contaminated
  - Growth 20%
    - Under Cook 90%
      - Susceptible 10%
        - Normal 90%
        - Susceptible 10%
          - Normal 90%
            - Normal 90%
              - Normal 90%
                - Normal 90%
        - Susceptible 10%
      - Normal 90%
        - Normal 90%
        - Normal 90%
          - Normal 90%
  - No Growth 80%
    - Under Cook 10%
      - Susceptible 10%
        - Normal 90%
      - Normal 90%
        - Normal 90%
          - Normal 90%
        - Susceptible 10%
      - Normal 90%
        - Normal 90%
        - Normal 90%
          - Normal 90%
  - Well Cook 10%
    - Susceptible 10%
      - Normal 90%
      - Normal 90%
      - Normal 90%
      - Normal 90%

A: 0.08%
B: 0.72%
C: 0.72%
D: 6.48%
E: 0.32%
F: 2.88%
G: 2.88%
H: 25.9%
● **Pathway A**
  - Greatest risk when it occurs
  - Lowest likelihood of occurrence

● **Pathway H**
  - Lowest risk when it occurs
  - Greatest likelihood of occurrence

● **Pathway F**
  - Intermediate rank in both categories
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Defining Reasonable Downstream Scenarios

- Is it possible to define ‘reasonable’ limits on downstream handling
- Extreme Temperature Abuse
- Children Consuming Raw Beef
Hands-off Risk Mitigation

- Compliance and Enforcement
- Inspection
- Verification Sampling
- Recall
- Consumer Education
- Facilitation

Performance Standards for the Regulator?
Redefining Performance

- Ethical Dimensions
  - Individual and Population
  - Shared Burden
- Management Impact
  - Innovation-Friendly
- Burden of Uncertainty
  - Assured versus Designed Safety
  - Resources to Promote Assurance
- Inspection, Verification, Auditing and Sampling
- Multiple Pathogen, Cross-Hazard?
Process Variables

- Prevalence and Concentration
- Lot Size and Pooling
- Pre- and Post-Sampling
  - Indicators
- Formulation
- Package Instructions

- No real need to exclude any viable risk mitigation
Tools to Rebuild the Onion

- Don’t hide the complexity
  - Technically feasible
  - Communication is the only barrier
  - Exploit and facilitate flexibility

- If it sounds too simple …
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