Application of Food Safety Risk Management Metrics at Government Level

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Responsibility of Governments as it Relates to Food Safety

Policy
- Freedom of Choice
- Food Security
- Public Health Protection
- Economic Development

Fair Trade in Safe Food


- Product criterion (PdC)
  - Chemical and physical characteristics of a food
- Process criterion (PCC)
  - Specific treatment for safety (e.g., 70°C 2 min)
- Microbiological criterion (MC)
  - Acceptability of a 'lot' of food or verification of a process
- Food Safety Objective (FSO)
  - Maximum frequency and/or concentration of a pathogen in a food at the time of consumption that provides or contributes to the ALOP (e.g., <100cfu/g L. monocytogenes in RTE food)
- Performance Objective (PO)
  - Maximum frequency and/or concentration of a microbiological hazard in a food at that point in the food chain (e.g., Absence of L. m in 25g at end production)
- Performance Criterion (PC)
  - Outcome that should be achieved by a control measure or a series or a combination of control measures (e.g., 6-log reduction)
Example 1: Pasteurisation of Milk-Process Criteria

PcC 72°C 15 sec

PcC 63°C 30 min


Example 2: Low Acid Canning - Product and Process Criteria Liked

PdC pH >4.6

PcC 121.1°C 2.5 min

Risk Based Approach to setting Micro Criteria - New Zealand

Target <10% samples >3.78 log cfu/carcass post chill
MC: n=45 m=3.78 log cfu/carcass c=6 (moving window)

e.g. turkey mince, chicken sausages, Chinese-style duck breasts

What the lab tests for

No. samples to test

Lab testing method

Result

Where samples should be taken
**Risk Based Approach to Setting Micro Criteria: Denmark**

The critical limit of the MC is a critical relative risk \( RR_{\text{crit}} \). If \( RR_{\text{food lot}} > RR_{\text{crit}} \), the food lot does not comply with the MC.

E.g. Assume \( RR_{\text{crit}} = 10 \)

\[
\begin{align*}
N_{\text{crit}} &= 10000^{\frac{10}{12}} = 4 \\
N_{\text{food lot}} &= 0.452 N_{\text{crit}} = 0.452 \\
N_{\text{crit}} &= 8.396 \\
N_{\text{food lot}} &= 1.647 N_{\text{crit}}
\end{align*}
\]

**Codex: Microbiological Risk Management - Annex II 2007**

- **Product criterion (PdC)**
  - Chemical and physical characteristics of a food
- **Process criterion (PcC)**
  - Specific treatment for safety (e.g., 70°C 2 min)
- **Microbiological criterion (MC)**
  - Acceptability of a ‘lot’ of food or verification of a process
- **Food Safety Objective (FSO)**
  - ‘Newer’ Metrics
  - Maximum frequency and/or concentration of a pathogen in a food at the time of consumption that provides or contributes to the ALOP (e.g., <100cfu/g L. monocytogenes at the end of shelf life)
- **Performance Objective (PO)**
  - Maximum frequency and/or concentration of a microbiological hazard in a food at that point in the food chain (e.g., Absence of L. m in 25g at end production)
- **Performance Criterion (PC)**
  - Outcome that should be achieved by a control measure or a series or a combination of control measures (e.g., 6-log reduction)

**Food Safety Objective**

- Set at the point of consumption
- Quantitative target
- Provides a link between HACCP and the Appropriate Level of Protection (ALOP)

**SPS Agreement and the Appropriate Level of Protection**

Sanitary and Phyto-Sanitary Agreement (SPS) Annex A: Definitions No. 5:

“Appropriate level of sanitary or phytosanitary protection – The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.”

*NOTE: Many Members otherwise refer to this concept as the “acceptable level of risk.”*
Problems with the ALOP Concept

* Expression: Qualitative or Quantitative (SPS Agreement)

* Qualitative examples exist but are vague
  * e.g. “A high level of protection of human life and health should be assured in the pursuit of Community policies.”
  * EU General principles of food law 178/2002

* Quantitative examples don’t seem to exist at Government level

Example: Quantified ALOP for Campylobacter in Chicken meat

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Foodborne Illness Acquisition in the United States—Major Categories

Elsie Scallan,1 Robert M. Hookstra, Frederick J. Mead, Linda S. Fennell, Jennifer M. Shattuck, Sarah K. Middowson,
Elizabeth O. Kelley, Linda C. Kissinger, Sharon L. Hoekstra, and Andrew J. Safford

845,024 domestic cases

USA population (per year) 312,000,000

ALOP = 848 domestic cases of campylobacteriosis per million population USA due to consumption of broiler meat

“Handling, preparation and consumption of broiler meat may account for 20% to 30% of human cases of campylobacteriosis”

To set an FSO you need a Quantified ALOP

* “A common factor in all documents [Kiel MRM 2000, 2002] is that the ALOP is preferably expressed as the (allowable) incidence of illness in a certain exposure scenario (per 100,000 population per year, per 10,000 servings, etc.).”

* “the ALOP would be specified as the maximum incidence of illness or infection in a population that is considered tolerable under the current conditions”

Current conditions e.g.:
  - Food safety controls
  - Population variability
  - Food consumption patterns

Relating FSO to ALOP Needs Data

Dose Response data
1. Probability of infection given consumption of H. pylori (P_{in})
2. Probability of illness given infection (P_{ill})

Consumption data
1. Number of saves per million population per year (S)
2. Units of chicken consumed per person per serve (M)

FSO = \log_{10}(ALOP/(S \times P_{in} \times P_{ill} \times M))

Practical considerations on food safety objectives

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Example: FSO for *Campylobacter* in Chicken meat

Calculate ‘FSO’

\[ FSO = \log_{10}\left(\frac{A}{(5 \times P_{it} \times P_{ext} \times M)}\right) \]

\[ FSO = \log_{10}\left(\frac{848}{(1.06E8 \times 0.33 \times 0.0035 \times 100)}\right) \]

FSO = -4.16 log₁₀ cfu/g

(geometric mean 1cfu per ~14.5kg cooked broiler meat)

Where

- M=100 g/person/serve - Irish food consumption data
- S=106 million serves/year/million population - Irish food consumption data
- ALOP = 848 cases/million population (slide 15)
- P(ill)=0.33 - WHO/FAO Campylobacter RA dose response curve
- P(inf)=0.0035 - WHO/FAO Campylobacter RA dose response curve

Real Life Example: FDA- Juice HACCP Performance Criterion (PC)

* Fresh Produce Subcommittee (FPS) of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF--the Committee)
  Recommendation:
  - *Escherichia coli* O157:H7 or *Listeria monocytogenes* as the target organisms
  - 5 log reduction in the target pathogen(s) or a reduction in yearly risk of illness to less than 10⁻³, assuming consumption of 100 ml of juice daily

Real Life Example: Risk management of raw beef in Japan

PcC: Surface Heat Treat Beef

\[ \text{1cm below from the surface, at } 60^\circ\text{C, >2 min} \]

Farm → Slaughter → Meat processing → Restaurants → Consumption → Illness

PO at the end of processing

Microbiological testing (*Enterobacteriaceae*)

FSO

190 cases/year

<1 case/year

Goal

Slide: Provided by Prof. Hajime Toyofuku and modified
Logic behind development of PO

- **PO**
  - Process Criteria
  - 10% of FSO to take growth and cross contamination into account
  - Reduce the number of VTEC by 1000X

- **FSO**
  - Linear in the low dose
  - Reduce the No of cases by (1000X)

- **ALOP**
  - Factor = cases * uncertainty
  - 1000 = 200 * 5

0.0014 cfu/g

0.014 cfu/g

Verify with MC

Original level: 14 cfu/g

Thoughts on Barriers to Adoption of ‘newer’ RM Metrics by Governments

- **Technical issues (Data and Knowhow)**
  - Lack of good data on food-borne disease
  - Lack of attribution studies
  - Lack of good quantitative consumption data
  - Uncertainty in or lack of dose response curves
  - Lack of food chain quantitative risk assessment
  - Lack of quantitative data on steps in the food chain

- **Political issues**
  - Low Industry push and no public pull
  - Smaller industry lacks technical ability to meet FSC - prefers clear direction (PrC, PdC)
  - Consumers just want safe food
  - Political reluctance
  - Difficult to ‘sell’ a non-zero tolerance target for foodborne disease
  - High cost of data generation

Summary and Conclusions

- Governments are comfortable with traditional risk metrics (MC, PdC, PCC) but some are trying to move to a better risk basis for them.
- There has been very limited use of ‘newer’ risk metrics (FSO, PO, PC) by Governments although reasons for this are not clear.
- Literature establishes routes for developing the ‘newer’ metrics but extensive data requirements may limit adoption in the majority of countries.
- The future may only see slow adoption of ‘newer’ metrics unless data and knowhow improves at Government level.
- Adoption of the ‘newer’ risk management metrics would facilitate innovation by food businesses whilst protecting public health.