Codex & Food Safety Risk Management Metrics

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Part 1: Parma

Update from the 3rd physical working group on the revision of Codex Microcriteriaria Principles at the EFSA in Parma (last week)
Purpose and Scope of the Codex MC Principles Revision

- Update the existing guidance document on MC for foods (1997)
- The scope of new work (started 2010) involves:
  - updating the establishment and application of MC by govts and industry in line with the latest knowledge and practices
  - introducing the new risk management metrics (FSO, PO and PC) and other quantitative microbiological limits (e.g. process control criteria, testing for HACCP verification)
  - providing guidance on the relationship between MC and MRM metrics and other quantitative microbiological limits, including the application of MC in the context of risk metrics and other quantitative microbiological limits.
What have we achieved in 2 years?

• Three physical working groups (Tokyo, Grange and Parma)
• A new main document (maybe 50% longer)
  – aiming for final adoption at CAC July 2013
• Seven practical examples on establishing and applying MC
  – developed over the last six months
  – lead country and 3-5 mentee countries (Codex Trust Fund)
    • DCs: enhanced involvement and building capacity
  – presented in Parma last week
• Examples will be circulated as Addendum after harmonisation
  – may become Annex 1 (Examples), Annex 2 (Statistical and Mathematical Considerations - FAO/WHO expert meeting)
Defining the concepts: 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* at a specified point of the food chain"

*In the Codex document microorganisms include but are not limited to:

– Bacteria, viruses, moulds, yeasts, and algae;
– Protozoa and helminths;
– Their toxins/metabolites; and
– Their markers associated with pathogenicity (e.g. virulence-related genes or plasmids) or other traits (e.g. anti-microbial resistance genes) where/when linked to the presence of viable cells where appropriate.
Defining the concepts: MRM metrics

• **FSO, Food Safety Objective**
  – 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)

• **PO, Performance Objective:**
  – The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides, or contributes to, an FSO or ALOP as appropriate

• And, not really a MRM metric, but close:

• **ALOP, the Appropriate Level of 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 (Def by WTO 1995)
What is intended to be achieved?

Pathogen Level

Enter slaughter

Time

PO

MC

PO

FSO

Point of consumption

ALOP
Towards a risk-based approach:

• Efforts have been going on for a decade
• The risk-based angle is being used increasingly in Codex Committee on Food Hygiene:
  – there must be a link between the level of hazard in a food, and the risk for the consumer
  – therefore, it should be possible to translate the level of protection to a microbiological criterion
• Ongoing efforts to reduce the complexity of risk assessment can (and will) help facilitate the development of risk-based MC
Relationship between MC, ALOP and other MRM Metrics (1)

- MC may be used by competent authorities and FBOs, to operationalise the ALOP either directly or through other microbiological risk management metrics (e.g., PO, FSO). This requires the use of quantitative risk assessment.
- The risk estimation (itself based on source attribution studies) should include a combination of factors such as:
  - the prevalence and concentration distribution of target microorganisms, as well as any changes in these after the step for which the MC has been set
- The risk assessment should include a characterization of the variability inherent to the food production system and express the uncertainty in the risk estimate
Relationship between MC, ALOP and other MRM Metrics (2)

• An MC can be linked directly to the ALOP, without explicit articulation of an FSO or a PO.
  – One approach involves testing the acceptability of individual lots and evaluating the acceptable relative risk to public health of the lot as compared to the ALOP
    • the Danish example
  – Another approach is to link an MC directly to an ALOP using a risk assessment model to estimate the reduction in public health risk as a result of applying corrective actions to lots or processes that do not conform with the MC
    • the New Zealand example
Relationship between MC, ALOP and other MRM Metrics (3)

• Statistical models can be used to translate a PO or FSO to an MC. To establish such an MC for a food, an assumption needs to be made regarding the distribution of the target microorganism in the food.
  – a log-normal distribution is often assumed and a default value for the standard deviation applied
• Furthermore, the maximum frequency and/or concentration of the hazard needs to be defined in the FSO or PO. If a concentration is used as a limit, also the proportion (e.g. 95%, 99%) of the distribution of possible concentrations that satisfies this limit should be defined.
NEW from Parma: No hierarchy

"MC are established based on knowledge of the microorganisms and their occurrence and behaviour along the food chain. When considering the establishment of MC, a variety of approaches can be used depending on the risk management objectives and the available level of knowledge and data. These approaches can range from developing MC based on empirical knowledge related to GHPs, to using scientific knowledge of control through a system such as HACCP, to conducting a risk assessment. The choice of the approach should be aligned with the risk management objectives and decisions relating to food safety and suitability."
NEW from Parma: Moving Windows

- For ongoing verification of performance of food safety control systems, an MC can be applied across a defined time frame and sampling frequency (window)
  - while it may not identify particular lots as non-conforming, it provides a continuous metric for checking the acceptability of the performance of the food safety control system
- The moving window approach is a practical and cost beneficial way of checking continuous microbiological performance of a food safety control system through generation of various inputs/data that enables a targeted analysis. It allows appropriate intervention in case of shifts in process control.
- Should not be confused with trend analysis which compares data over a longer time period and which is not a part of an MC.
Moving Windows sampling plans

A moving window is:
A specified number of units → Individual or pooled
taken at a specified frequency → Systematic (routine)
over a specified time period → Defined by “n” + frequency

When designing the sampling frequency, consideration should be given to the following:

• The number of processing lines subjected to the verification;
• Sufficient production frequency (e.g. daily production);
• Distribution of organisms in food; and
• Probability of detection
The moving window concept is a distinct combination of sampling approaches (n, c, m, M) and interpretation of results:

- a 3-class plan based on n, c, m and M, or
- a 2-class plan based on n, c and m, where “m” is the average result of n samples

3-class plan with n = 5, c = 2
NEW from Parma: General Principles

- An MC should be appropriate to protect the health of the consumer and/or ensure fair practices in the food trade
- The purpose of establishing and applying an MC should be clearly articulated
- The establishment of microbiological criteria should be based on scientific advice and analysis and follow a structured and transparent approach
- The required stringency of MC used should be appropriate to its intended purpose
General Principles (continued)

- MC should be established based on knowledge of the microorganisms and their occurrence and behavior along the food chain
- An MC should be practical and feasible and established only when necessary
- Periodic reviews of MC should be conducted, as appropriate, in order to ensure that MC continue to be relevant to the stated purpose under current conditions and practices
Part 2: Doubts?

Personal reflections on microbiological criteria
Are MC science-based?

- Certainly not pure science, more like risk-based:
- MC are still a combination of many factors:
  - epidemiological knowledge
  - analytical constraints
  - economic feasibility
  - political pressure, etc.
- Statistical truths on sampling are known but ignored
- Presently the science is improving
Lot rejection is only one purpose

- This most traditional of applications overshadows our grasp of the various other purposes and mechanisms by which MC work their possible magic:
  - process hygiene assessment
  - communicating product specifications B2B
  - verification of food safety systems
  - validating microbiological limits at CCPs
  - communicating society's tolerable level of risk to FBOs (=what should they achieve, at least)
The European experience

- Regulation 2073/2005 in force since Jan 1, 2006
- Clear division between two sets of MC:
  - **Food safety criteria**
    - applied to products placed on the market during their shelf-life
    - CA: recall, maybe reprocess to eliminate hazard
  - **Process hygiene criteria**
    - applied during the processing stage
    - CA: improve hygiene and quality of raw materials
The EU experience (contd.)

- **GOOD:**
  - having official limits is helpful to the FBO
  - sampling frequency flexible depending on results
  - general awareness of verification has improved

- **BAD:**
  - sampling frequencies differ bw. MSs and FBOs
  - sampling results (or numbers) are not reported
  - new MCs added for political reasons (sprouts)
Politically established MC

• When the EU Regulation on MC was done, it was largely based on science and pragmatic thinking.
• Lately, there have been attempts to establish/add new MC based on political pressure ("something must be done!")
  – sprouted seeds and VTEC
• Sometimes again, MC are not established, although they would increase public health ("too embarrassing for some countries, trade will suffer", etc.)
  – Campylobacter in raw poultry
On the emerging MRM metrics

- All MC are risk-based, only the accuracy differs
- MRM metrics might ease the work of risk managers?
  - review of MC and its effects should become easier
- Are of little consequence to the FBO; MC will look the same regardless of their genesis
- At this point, the bridge between theory and application is not sufficiently stable
- The door should be left open, but while we wait for the killer app traditional MC remains the norm
Review of MC

• The risk management framework should be used to continuously improve the MC in relation to their effectiveness
  – a review will result in retention, adjustment or revocation of an MC, as appropriate
  – when MC have been developed to address specific risk outcomes they should be reviewed against those outcomes and, if shown not to be effective, they should be revoked

• Does this happen? Not as often as it should.
The case for MC

1. MC will contribute to improved public health directly
   • by rejection of contaminated food lots
   • by informing FBOs on process hygiene status

2. MC will also improve public health indirectly
   • through fear of non-conformance in FBOs, which leads to them improving food hygiene practices
     • fear is less dependent on statistical strength

3. No MC is counterproductive to public health
   • might be for business though (in the short run), but testing for verification needs to increase anyhow
THANK YOU!
QUESTIONS?