Microbiology Risk Assessment: tools and applications

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Outline

- Microbiology Risk Assessment (MRA) general principles
- MRA types
- MRA structure
- Resources and tools for each MRA element
- Other general tools and resources for MRA
- Take home messages
MRA General Principles

• Science-based
• Functional separation between Risk Assessment and Risk Management
• Structured approach
• Clear state of purpose: why we do it and what we want from it
• Transparent
• Identification of constraints: cost, time, resources
• Determination of uncertainty
• Quality and precise data
• Reviewed and updated to include relevant information as it becomes available
• Includes microbial dynamics in food
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MRA types

As long as it facilitates the selection of risk management options, it can be:

• **Qualitative MRA:** less time consuming, easier to understand by large audience

• **Comparative or risk ranking MRA**

• **Quantitative MRA:** depends on the availability of data, requires mathematical training
Quantitative MRA

Deterministic
Uses single-point estimate value (e.g. worst case-scenario or an average/mean value)

Probabilistic
Uses probability distributions to characterise randomness, variability and uncertainty
Software tools for probabilistic modelling

Figure 4. Predicted levels of total *V. parahaemolyticus* in oysters after consumer storage in the long supply chain, in summer (left) and winter (right).
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MRA Structure

Hazard Identification: identification of the microorganism/toxin

Exposure Assessment: human exposure to the microorganism/toxin

Risk Characterisation: risk estimation

Hazard Characterisation: evaluation of the nature of the adverse health effect
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Hazard ID: resources

Identification of biological and chemical agents capable of causing adverse health effects and which may be present in a particular food

Foodborne pathogen information sources: published literature, epidemiological studies, foodborne disease reports, surveillance and outbreak investigations

[Image: Bad Bug Book (Second Edition)
Foodborne Pathogenic Microorganisms and Natural Toxins Handbook
Download the Bad Bug Book 2nd Edition in PDF (2.6MB)]

https://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/
Hazard ID: use of predictive microbiology tools (example ComBase)

Identification of relevant hazards (e.g. identify the fastest growing microorganism at a specific temperature)
Hazard ID: use of risk ranking tools (example Risk Ranger)

Identification of relevant hazards (e.g. identify the microorganism that can cause a higher risk)

- Susceptibility and severity
- Probability of exposure to food
- Probability of food containing an infectious dose

Can provide with relative risk estimates for different products, pathogens and processing combinations
Hazard characterisation: resources

Evaluation of the nature of the adverse health effects, a dose–response assessment should be performed if the data are obtainable.

Dose-response information: literature, public health databases, published MRA

Hazard characterisation: models for dose-response

Mathematical modelling of the dose-response: probability of a specified response from exposure to a specific pathogen (or its toxins) in a specified population as a function of the ingested dose.

Factors affecting Dose-response:

• Microorganism: virulence, persistence
• Host: physiological organs barriers (e.g. stomach pH), age, pregnancy, immunological status
• Food: if they decrease stomach pH or alter microorganism virulence

Exposure assessment: resources

Estimate of the likelihood of the hazard occurrence in foods at the time of consumption and their level

Examples of exposure considerations:
• Frequency of food contamination: season, region
• Patterns of consumption: handling, diet
• Microorganism level in the food over time: processing, packing, distribution and storage
Exposure assessment: use of predictive microbiology tools for survival on food

Food Spoilage and Safety Predictor (FSSP)

L. monocytogenes growth no growth boundary depending on temperature
http://fssp.food.dtu.dk/

ComBase

Microbial Responses Viewer (MRV)

Salmonella spp growth no growth boundary depending on temperature and aw
http://mrviewer.info/

B. cereus inactivation model
http://www.combase.cc
Example: assessing a formulation

Need: mild-taste, less acidic dressings
Product: no thermal processing, preservation system by design

Performance Criteria: 5-log reduction
Modelling approach: in-house Weibull model (T, pH, NaCl, acetic acid, preservative A)
Exposure assessment: use of predictive microbiology for environmental conditions

Determination of dynamic changes in *L. monocytogenes* levels (e.g. temperature)
Example: assessing storage temperature

Need: uncertain retail conditions
Product: super-chilled dairy-based drinks

Performance Criteria: Probability product exceeding max allowed levels
Modelling approach: Stochastic (temperatures and time in cabinet)

*Fictitious time and temperature profiles for presentation purposes, different to those used in the real assessment
Exposure assessment: use of food processing models

Integration of the manufacturing process:

**Development of an integrated model for heat transfer and dynamic growth of Clostridium perfringens during the cooling of cooked boneless ham.**


**Predicting the thermal inactivation of bacteria in a solid matrix: Simulation studies on the relative effects of microbial thermal resistance parameters and process conditions**

B.M. Mackey a, A.F. Kelly a, J.A. Colvin a, P.T. Robbins b, P.J. Fryer b
Example: assessing manufacture (1/2)

Need: optimise thermal inactivation process (milder heating)
Product: UHT soups

Performance objective: $0 \log_{10} \text{cfu/kg}$
Modelling approach: Stochastic, microbial and physical modelling
Example: assessing manufacture (2/2)

Criteria 1: spoilage spores

Criteria 2: 12D botulinum cook

**Standard process**

Option 1: Reduction of $T_{ext}$ heater

Option 2: Reduction of heater length
Exposure assessment: use of models for recontamination

Recontamination through equipment: biofilm process in a pipeline

1. Surface conditioning
2. Reversible attachment
3. EPS production and irreversible attachment
4. Biofilm growth
5. Cell detachment and product recontamination

Recontamination via the air: removal of bacteria from a surface

International Journal of Food Microbiology
Volume 80, Issue 2, 25 January 2003, Pages 117-130

Quantifying recontamination through factory environments—a review

Esther D den Aantrekker, Ramko M Boom, Marcel H Zwistering, Mick van Schothorst
Exposure assessment: use of models for food handling practices

Estimation of the effects of various retail and household practices on the incidence of foodborne illness

Example: FDA Food Handling Practices Model (FHPM)
   http://foodrisk.org/resources/display/27

FHPM includes four stages: source contamination stage, contamination stage (retail and household channels), pathogen control stage (retail and household channels), and foodborne illness stage (retail and household channels).
Risk characterisation

Hazard Identification: identification of the microorganism/toxin

Hazard Characterisation: evaluation of the nature of the adverse health effect

Exposure Assessment: human exposure to the microorganism/toxin

Combination of hazard ID, hazard characterisation and exposure assessment to determine the probability of occurrence and severity of an adverse health effect
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Other food safety tools

**FDA-iRISK 4.0** is a Web-based risk-assessment tool developed by the U.S. Food and Drug Administration (FDA). It allows users to conduct fully quantitative, fully probabilistic risk assessments, simulate the food chain, up through consumption, and assess the impact of interventions.

- compares and ranks risks from multiple combinations of foods and hazards (microbial and chemical)
- predicts effectiveness of interventions at any step of the food-supply chain, from farm to consumer
- calculates public-health outcomes of food-production practices and interventions
- is useful to risk managers and others, for decision-making; e.g., prioritization, resource allocation

link to webinar: https://www.youtube.com/watch?v=4fOEnZRmR8w
Where to find published examples of MRA?


https://www.fda.gov/food/scienceResearch/RiskSafetyAssessment/default.htm
Tools for specific MRA

JEMRA Risk Assessment for Cronobacter sakazakii in Powdered Infant Formula

JEMRA Risk Management Tool for the Control of Campylobacter and Salmonella in Chicken Meat
http://tools.fstools.org/poultryRMTool/

Risk Management Tool for the Control of Campylobacter and Salmonella in Chicken Meat

Welcome

This web site provides access to a risk management simulation tool based on the Codex Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat.

The tool can describe the complete production-consumption flow path described in the guidelines. These models are referred to as process flows. Users may investigate one or both pathogens and determine which steps to include in the process flow.

The tool is designed to compute the residual risk between a baseline process flow and a process flow applying selected interventions as outlined in the guidelines. The residual risk measure may be used to evaluate the overall effectiveness of the applied interventions.

FAO and WHO would also like to express their appreciation to all those who have contributed to the development of this tool.

Please review the guidelines, user guide, tutorial, supporting documents and disclaimer before using this tool.

Please login or register.
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Take home messages:

• MRA needs to be fit-for-purpose and enough to inform risk management, full risk assessment may not be necessary.

• Results may be qualitative, semi-quantitative or quantitative, and they may include outputs from specific modelling tools.

• There are many modelling tools that can be used for MRA, they require critical use: suitability to the question being asked and awareness of their limitations.

• MRA is a scientific based approach, needs to be transparent and clearly state all assumptions/uncertainties.

• MRA is used by risk managers as a decision tool and it is a guide for policy makers, set public health priorities and define mitigation options.
Questions?