

Microbiology Risk Assessment: tools and applications

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Microbiology Safety Scientist

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

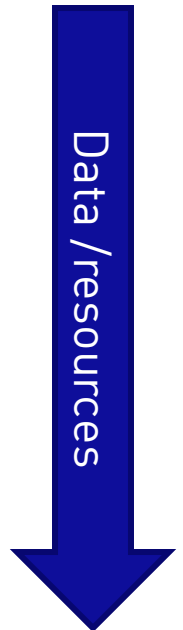
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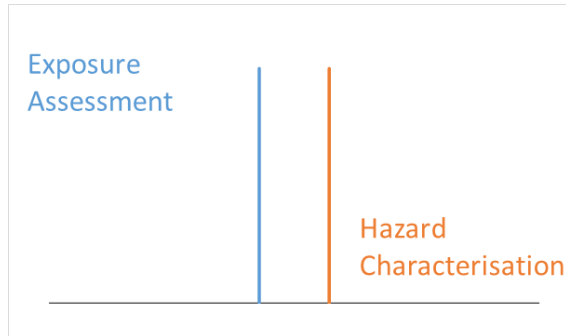
MRA types

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

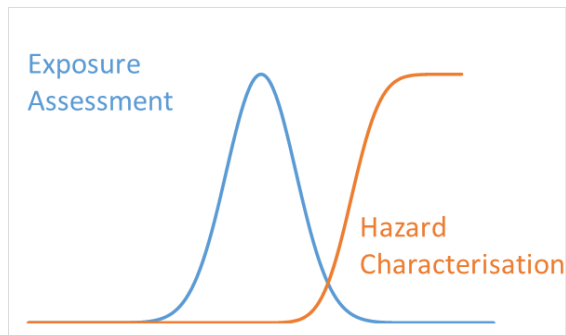


Quantitative MRA



Deterministic

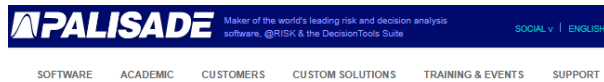
Uses single-point estimate value (e.g. worst case-scenario or an average/mean value)



Probabilistic

Uses probability distributions to characterise randomness, variability and uncertainty

Software tools for probabilistic modelling



Home About Risk analysis software Services Risk Wiki K

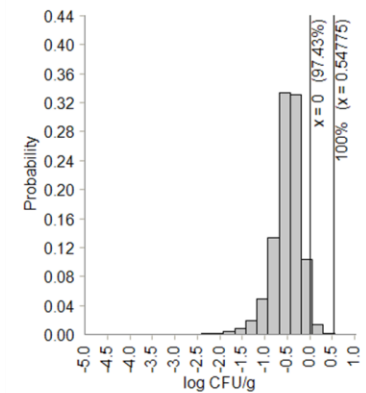
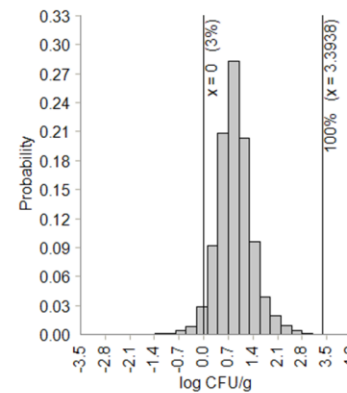
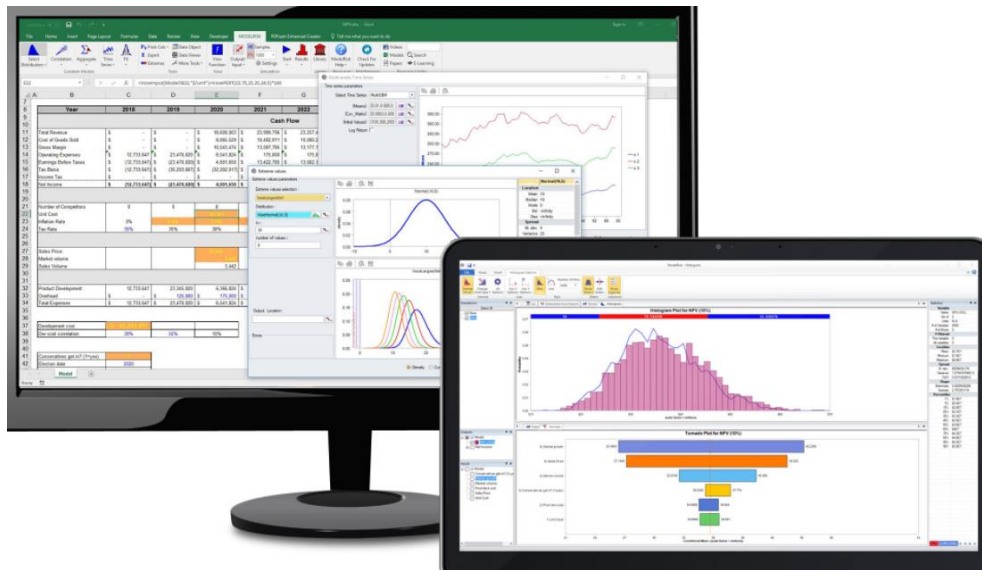
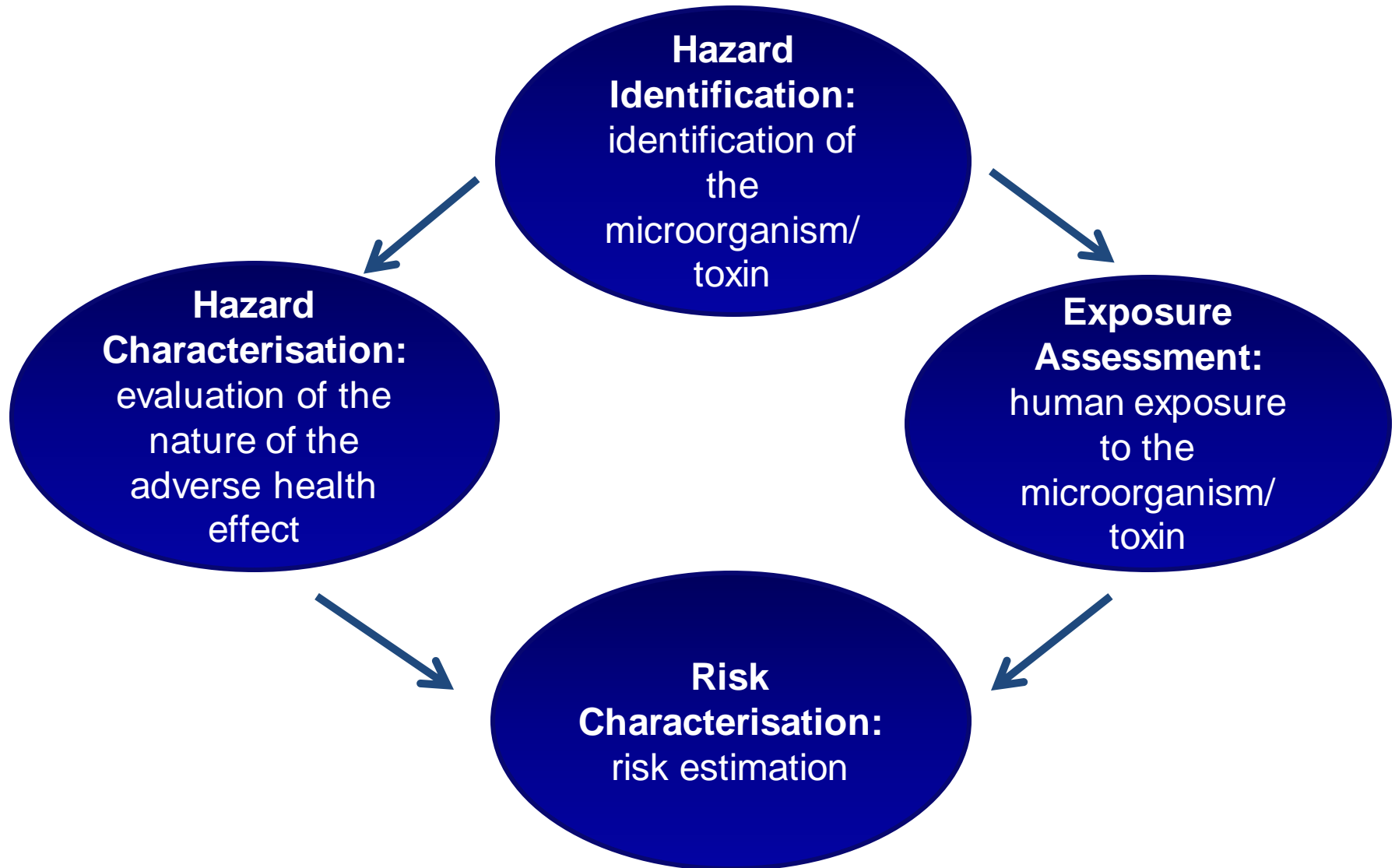


Figure 4. Predicted levels of total *V. parahaemolyticus* in oysters after consumer storage in the long supply chain, in summer (left) and winter (right).

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MRA Structure



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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

Case study material

Bad Bug Book

Bad Bug Book (Second Edition)

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Foodborne Pathogenic Microorganisms and Natural Toxins Handbook

[Download the Bad Bug Book 2nd Edition in PDF \(2.6MB\)](#)

The Bad Bug Book 2nd Edition, released in 2012, provides current information about the major known agents that cause foodborne illness.

Each chapter in this book is about a pathogen—a bacterium, virus, or parasite—or a natural toxin that can contaminate food and cause illness. The book contains scientific and technical information about the major pathogens that cause these kinds of illnesses.

A separate “consumer box” in each chapter provides non-technical information, in

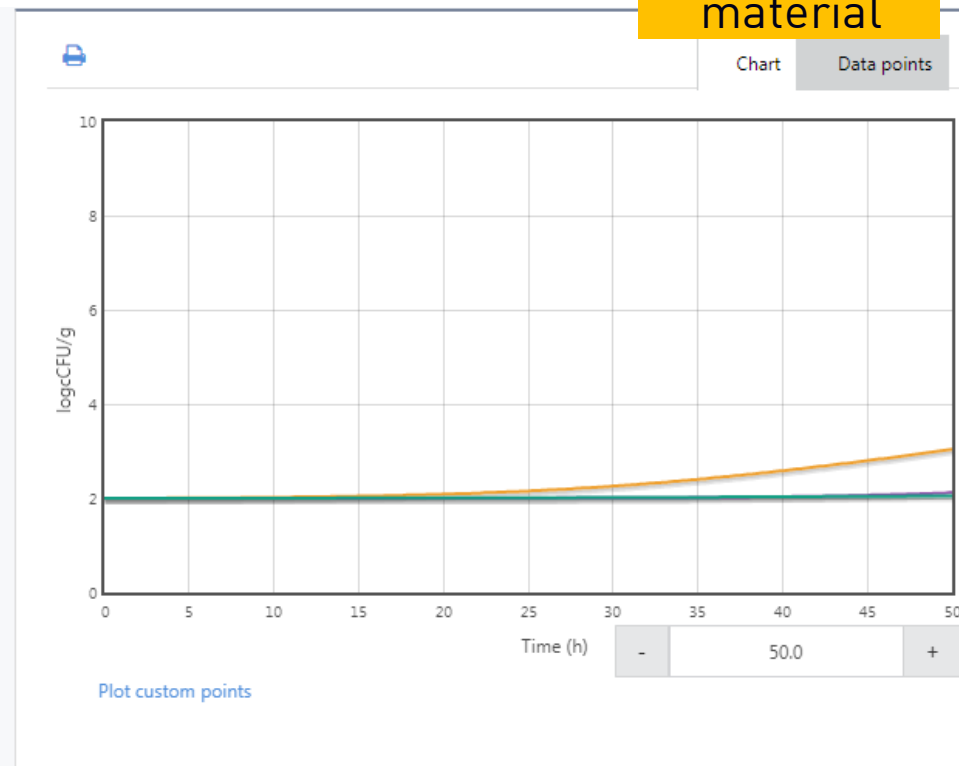
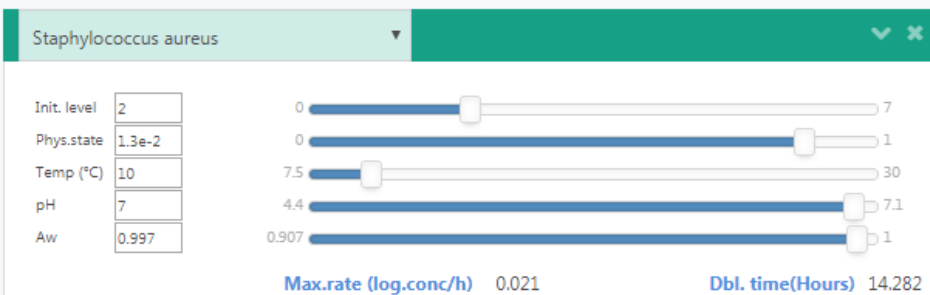
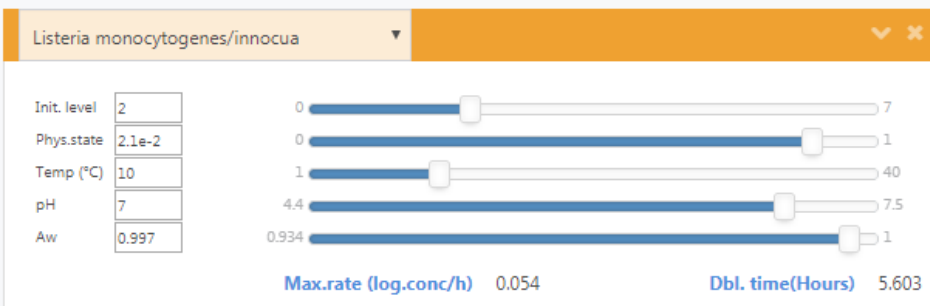
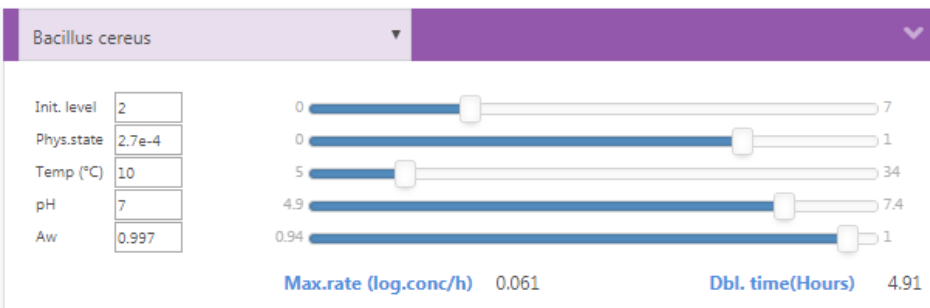


Foodborne Pathogenic Microorganisms and Natural Toxins Handbook
FDA

Hazard ID: use of predictive microbiology tools (example ComBase)

Identification of relevant hazards (e.g. identify the fastest growing microorganism at a specific temperature)

Case study material



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

Case study material

Risk Ranger

Susceptibility and severity		Probability of food containing an infectious dose	
Hazard severity MINOR hazard: patient rarely seeks medical attention		Probability of Contamination of Raw Product per Serving RARE (1 in a 1000)	
How susceptible is the population of interest? VERY e.g. neonates, very young, diabetes, cancer, alcoholic, etc.		Effect of Processing The process USUALLY ELIMINATES hazards (99% of cases)	
Probability of exposure to food		Is there potential for recontamination after processing? NO	
Frequency of Consumption Monthly		How effective is the post-processing control system? NOT RELEVANT - level of risk agent does not change	
Proportion of Consuming Population Very few (5%)		Post-processing contamination increase level None	
Size of Consuming Population 491000		Effect of preparation before eating Meal Preparation USUALLY ELIMINATES hazards (99% of cases)	



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

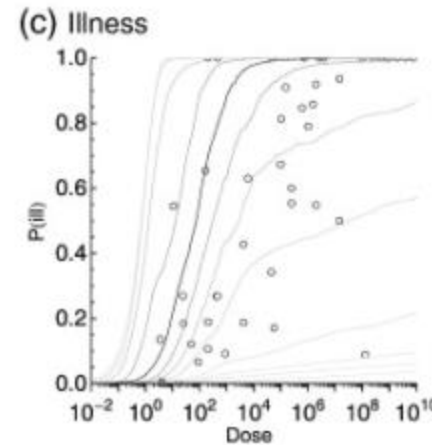


The screenshot displays the WHO website interface. At the top, there is a navigation bar with the WHO logo and the text 'World Health Organization'. To the right of the logo, there are language options: عربي, 中文, English, Français, Русский, and Español. Below the language options are social media icons for RSS, YouTube, Twitter, Facebook, Google+, and Instagram. The main navigation bar includes links for Home, Health topics, Data, Media centre, Publications, Countries, Programmes (highlighted in orange), Governance, and About WHO. A search bar is located on the right side of the navigation bar. Below the navigation bar, the 'Food safety' section is visible, with a sub-section for 'Hazard characterization for pathogens in food and water'. The main content area shows the title 'Microbiological risk assessment series 3, guidelines' and the authors 'FAO/WHO'. There are also social media sharing icons for print, email, Facebook, Twitter, and Google+.

http://www.who.int/foodsafety/publications/mra_3/en/

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.



Peter F.M. *et al* 2010 **Dose-response modeling of *Salmonella* using outbreak data**, IJFP, V 144, I 2, P 243-249

Factors affecting Dose-response:

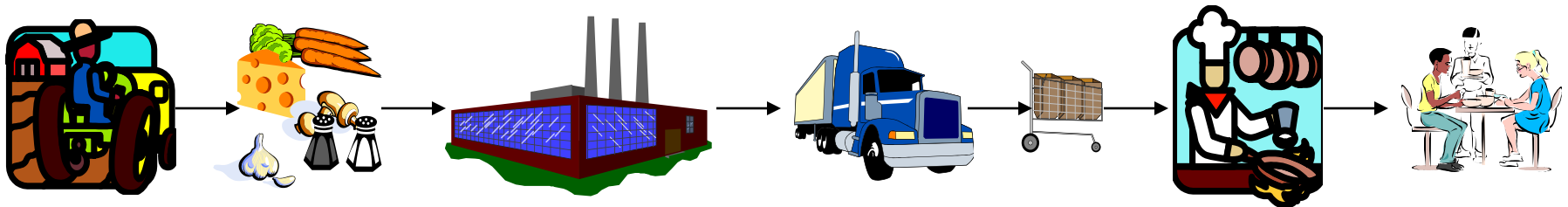
- Microorganism: virulence, persistence
- Host: physiological organs barriers (e.g. stomach pH), age, pregnancy, immunological status
- Food: if they decrease stomach pH or alter microorganism virulence

Exposure assessment: resources

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

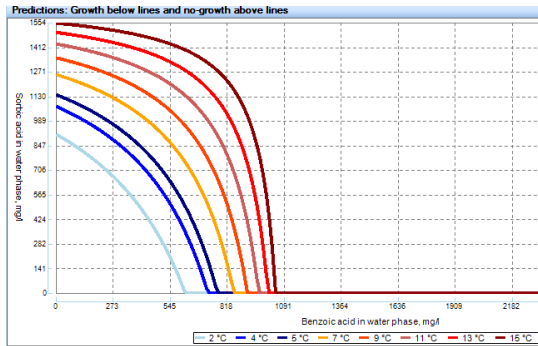
Examples of exposure considerations:

- Frequency of food contamination: season, region
- Patterns of consumption: handling, diet
- Microorganism level in the food over time: processing, packing, distribution and storage



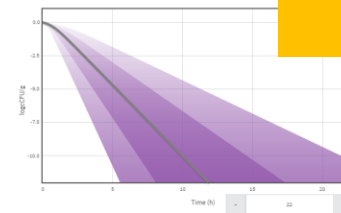
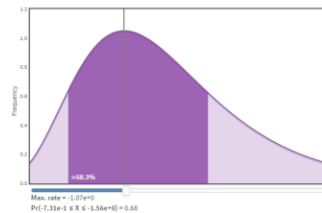
Exposure assessment: use of predictive microbiology tools for survival on food

Food Spoilage and Safety Predictor (FSSP)



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

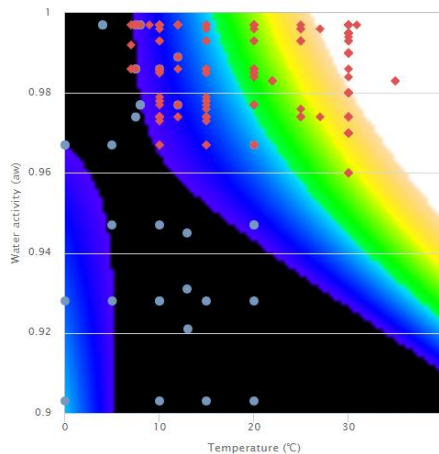
ComBase



Case study material

B. cereus inactivation model
<http://www.combase.cc>

Microbial Responses Viewer (MRV)



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

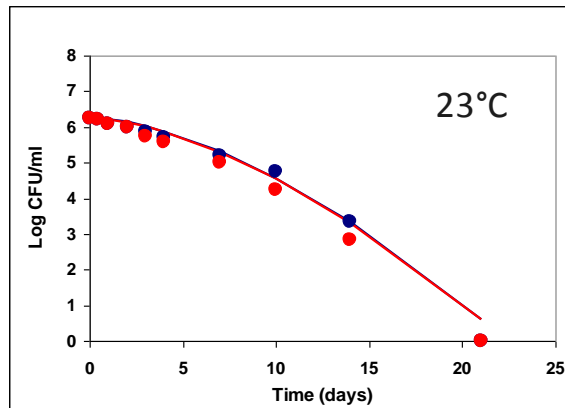
Example: assessing a formulation

Need: mild-taste, less acidic dressings

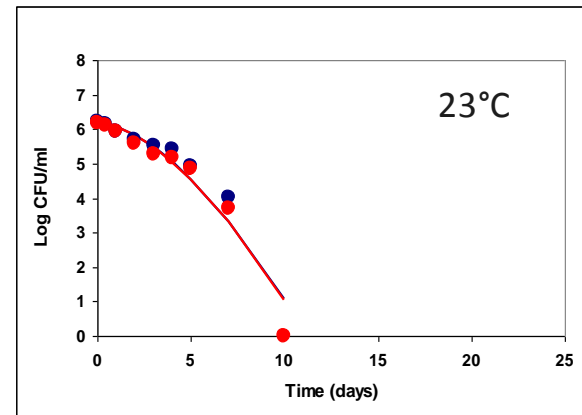
Product: no thermal processing, preservation system by design

Performance Criteria: 5-log reduction

Modelling approach: in-house Weibull model (T, pH, NaCl, acetic acid, preservative A)



Preservative A 0%



Preservative A 0.05%



Exposure assessment: use of predictive microbiology for environmental conditions

Determination of dynamic changes in *L. monocytogenes* levels (e.g. temperature)

Growth Model

Prediction Uncertainty

[Static | **Dynamic**]

[Aw | NaCl]

Time(h)	Temp (°C)
0.00	7.00
12.00	15.00
24.00	7.00
36.00	15.00
48.00	7.00

Listeria monocytogenes/innocua

Temperatures range [1,40]

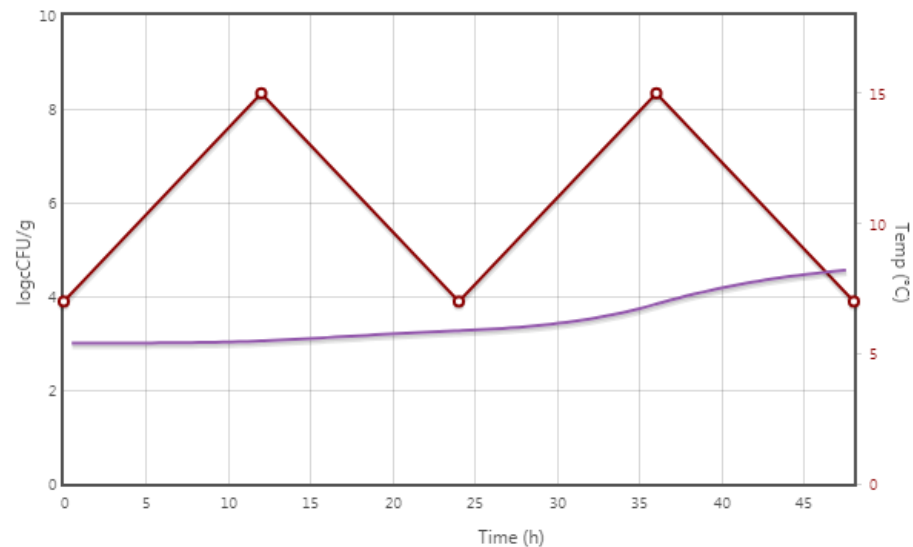
Init. level	3	0	7
Phys.state	2.1e-2	0	1
pH	7	4.4	7.5
Aw	0.997	0.934	1

[Add prediction]

Case study material



Chart Data points



Plot custom points

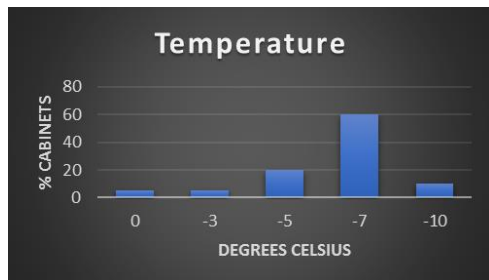
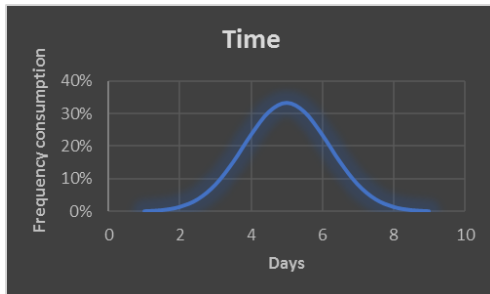
Example: assessing storage temperature

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)



Define temperature limits for our cabinets

*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:

[Int J Food Microbiol](#). 2005 May 25;101(2):123-44. Epub 2005 Jan 7.

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

[Amézquita A¹](#), [Weller CL](#), [Wang L](#), [Thippareddi H](#), [Burson DE](#).



ELSEVIER

International Journal of Food Microbiology

Volume 107, Issue 3, 1 April 2006, Pages 295-303



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, 1}](#), [J.A. Colvin^{a, 2}](#), [P.T. Robbins^b](#), [P.J. Fryer^b](#)

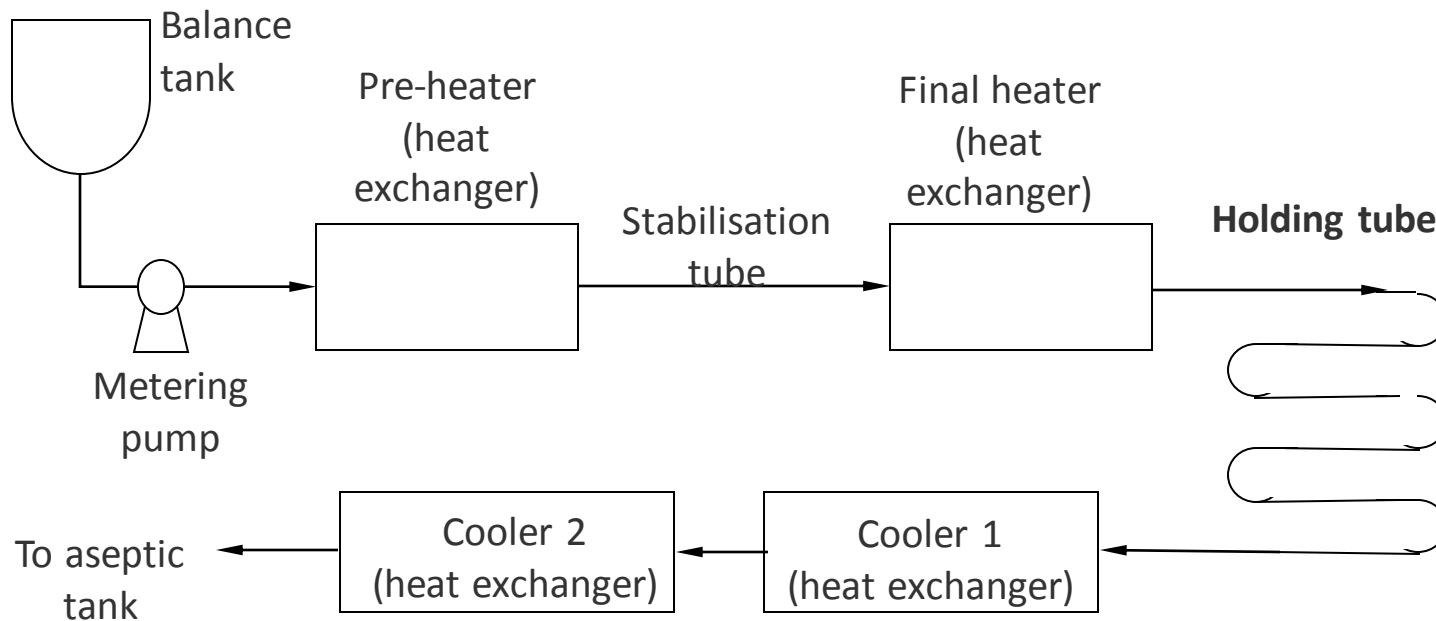
Example: assessing manufacture (1/2)

Need: optimise thermal inactivation process (milder heating)

Product: UHT soups

Performance objective: $0 \log_{10}$ cfu/ kg

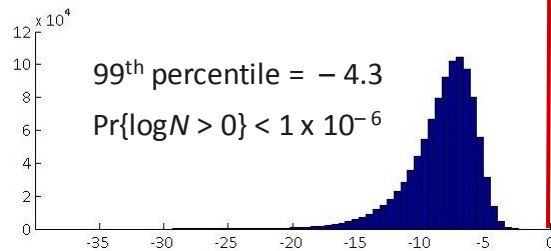
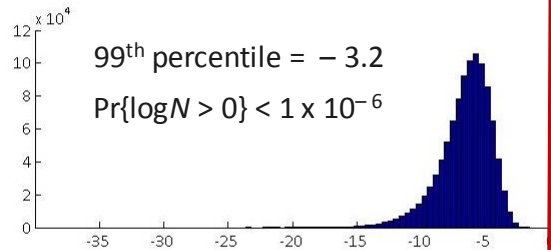
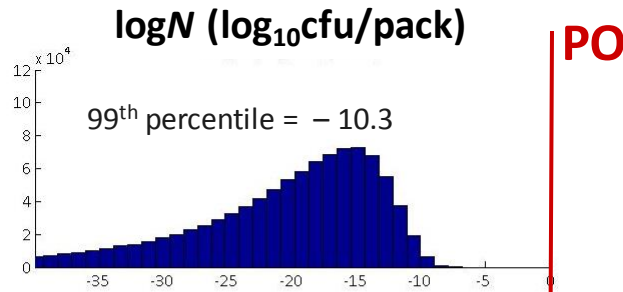
Modelling approach: Stochastic, microbial and physical modelling



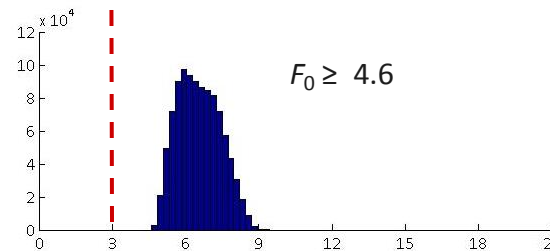
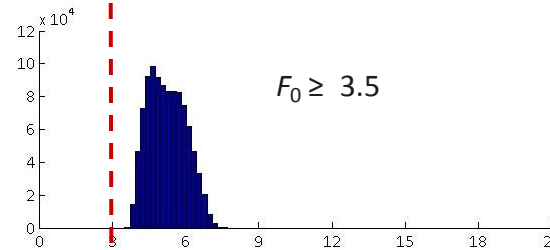
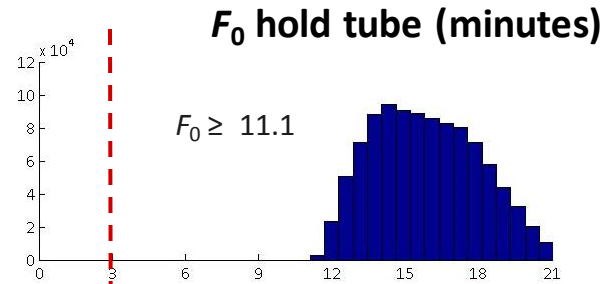
Example: assessing manufacture (2/2)

Criteria 1: spoilage spores

Criteria 2: 12D botulinum cook



0 log₁₀
cfu/ pack



3
minutes

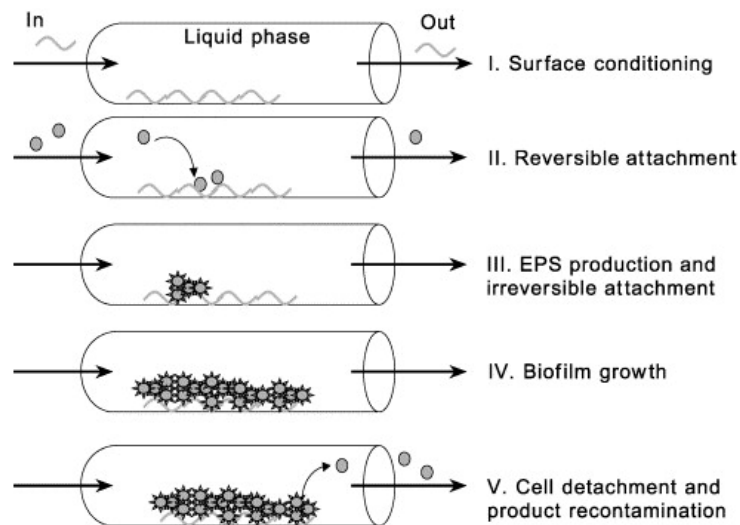
Standard process

Option 1:
Reduction of T_{ext}
heater

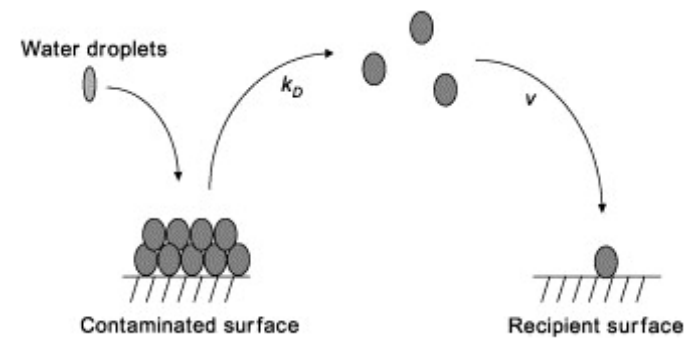
Option 2:
Reduction of heater
length

Exposure assessment: use of models for recontamination

Recontamination through equipment: biofilm process in a pipeline



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



Review

Quantifying recontamination through factory environments—a review

Esther D den Aantrekker ^a, Remko M Boom ^b, Marcel H Zwietering ^c, Mick van Schothorst ^a

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)

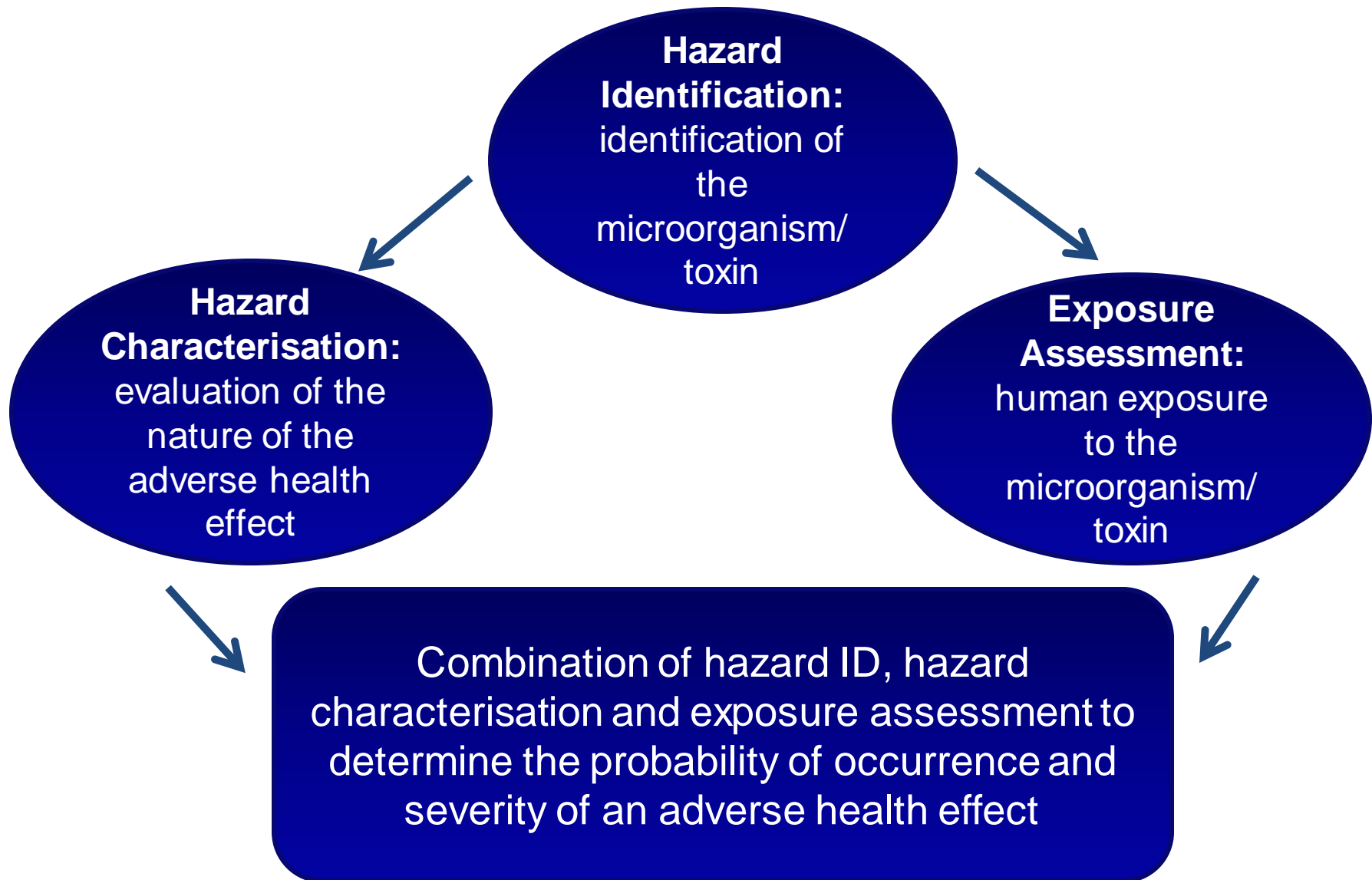
<http://foodrisk.org/resources/display/27>

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).

**Modeling the Effects of Food
Handling Practices on the
Incidence of Foodborne Illness**

**Final Report
Contract No. 223-01-2466, Task Order 1**

Risk characterisation



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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 allow users to conduct fully quantitative, fully probabilistic risk assessments, simulate the food chain, up through consumption, and assess the impact of interventions.

FDA-iRISK[®] 4.0
food-safety modeling tool



- *compares and ranks risks from multiple combinations of foods and hazards (microbial and chemical)*
- *predicts effectiveness of interventions at any step of 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?

Food safety and quality

> Scientific advice > Microbiological risks and JEMRA > Risk assessments

Risk assessments

Pathogen-commodity combinations

The links below are to individual pathogen-commodity risk assessment pages, where you will find related documentation, reports and detailed information:

- Microbiological safety of foods for malnourished populations
- Microbiological hazards associated with fresh produce
- Viruses in foods
- Enterohaemorrhagic *Escherichia coli* (EHEC) in meat and meat products
- Salmonella* in eggs and broiler chickens
- Listeria monocytogenes* in ready-to-eat foods
- Vibrio* spp. in seafoods
- Campylobacter* spp. in broiler chickens
- Enterobacter sakazakii* and other micro-organisms in powdered infant formula
- Foodborne parasites



<http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/risk-assessments/en/>

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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Risk & Safety Assessment

Home > Food > Science & Research (Food) > Risk & Safety Assessment

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Resources for You

- For Food Safety and Health Professionals - Risk Analysis at FDA: A science-based approach to policy decisions (PDF - 593KB)
- FDA-iRisk® version 4.0: A Food-Safety Modeling Tool (PDF - 528KB)
- A Closer Look at FDA-iRisk® version 4.0 (PDF - 333KB)
- For consumers: What Is Risk Assessment, and What Does It Have to Do with My Food?

As the nation's food supply becomes more global and complex, decisions about policies aimed at preventing contamination and illness have become even more important to the public's health. The Food and Drug Administration (FDA) uses risk analysis, a concept and framework fostered by the World Health Organization, to ensure that regulatory decisions about foods are science-based and transparent.

Read more about how FDA's Center for Food Safety and Applied Nutrition (CFSAN) applies risk analysis, from conventional methods to new, far-reaching tools that use advanced technology to prioritize risks and calculate optimal interventions at [Risk Analysis at FDA: Food Safety](#).

Upcoming Assessments

- [Quantitative Assessment of Arsenic in Apple Juice](#)
- Risk Profile: Transmission of Norovirus
- Risk Assessment: Norovirus in Bivalve Molluscan Shellfish

View all Completed and Ongoing Risk Assessment Projects at CFSAN

New list of research needs: [Gaps in the Knowledge Base](#) now available.

Announcements

- FDA releases the [Joint FDA / Health Canada Quantitative Assessment of the Risk of Listeriosis](#)

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Research Paper

A Quantitative Assessment of the Risk of Human Salmonellosis Arising from the Consumption of Almonds in the United States: The Impact of Preventive Treatment Levels

SOFIA M. SANTILLANA FARAKOS,^{1*} RÉGIS POUILLOT,^{1†} RHOMA JOHNSON,¹ JUDITH SPUNGEN,¹ INSOOK SON,¹ NATHAN ANDERSON,² AND JANE M. VAN DOREN¹

¹U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, Maryland 20740; and ²U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Bedford Park, Illinois 60501, USA

MS 16-403; Received 26 September 2016/Accepted 15 December 2016/Published Online 17 April 2017

ABSTRACT

The presence of *Salmonella* on almonds continues to result in product-related outbreaks and recalls in the United States. In this study, the impact of microbial reduction treatment levels (1 to 5 log CFU) on the risk of human salmonellosis from the consumption of almond kernels in the United States was evaluated. An exposure model, including major steps in almond processing, was used to estimate prevalence and levels of contamination of *Salmonella* on almonds at the point of consumption. A *Salmonella* dose-response model and consumption data for almonds in the United States were used to assess risk of illness per

<https://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm>

Tools for specific MRA

JEMRA Risk Assessment for *Cronobacter sakazakii* in Powdered Infant Formula

http://www.fstools.org/esak/RunModel_UsingTheModel.aspx

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

<http://tools.fstools.org/poultryRMTool/>



Risk Assessment for *Cronobacter sakazakii* in Powdered Infant Formula



- Home
- Model Summary
 - Estimating Risk
 - Sampling Plans
 - Risk Reduction
 - Prep and Handling
- The Model
 - Using the Model
 - Prep. and Hand. Guidance
- Useful Links
- Contact Us

Guidance on Using the Model

Use of the model consists of 5 steps, these steps are:

- Step 1:** Define the concentration of *C. sakazakii* in the powder and specify any sampling plans
- Step 2:** Define the Reconstitution Temperature
- Step 3:** Specify Handling and Preparation Scenarios
- Step 4:** Set the Baseline
- Step 5:** Run the Model & Obtain Results

Step 1: Define the Concentration of *C. sakazakii* in the Powder and Specify any Sampling Plans

In Step 1 the contamination level of *C. sakazakii* in the powdered infant formula must be specified. The mean concentration of *C. sakazakii* (in log CFU per gram) and the standard deviation in the concentration, both within a single lot of powder, and between different lots of powder (in log CFU per gram) is required.

In addition, any sampling plan that is to be explored is entered here. The sampling plan is specified in terms of the number of samples tested from a single lot, and the mass of each sample (in grams). Up to 4 sampling plans can be compared (in addition to "no plan").

Changes in risk can be explored for the sampling plans and preparation and handling scenarios in isolation or combination. If only sampling plans are to be explored, then go straight to Step 5 (and go straight to "Run the Model and Obtain Results"), and do not enter anything on the pages after "Define Concentration and Sampling Plans". On the results page ignore the results relating to preparation and handling as there is always a default preparation and handling scenario built into the system.

If no sampling plans are to be considered then it is not necessary to enter any plans in the user interface; simply go to Step 2. The model will use the default setting of "No Plan". This option is always present for sampling plans.

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

(Version 1.0) English

[Home](#) | [Process Flow List](#) | [Tutorial](#) | [User Guide](#) | [Documents](#) | [Send Comments](#) | [Login](#)

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-to-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?

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