MRA basic awareness course

Topic 3 - Lecture 1

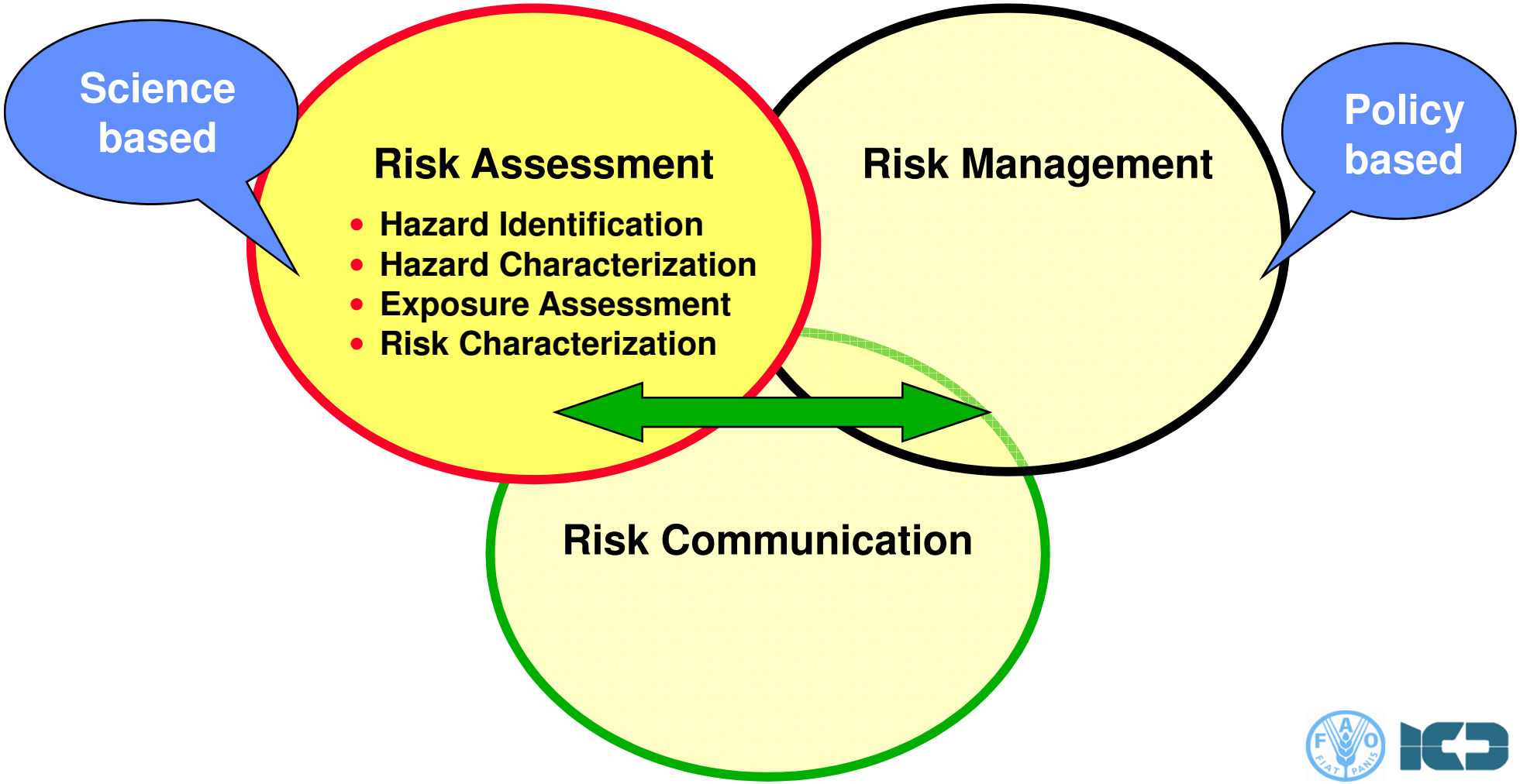
Microbiological Risk Assessment: Principles and concept

http://www.sp-lab.net/fao/MRA/

Purpose of lecture

- Understand Microbiological Risk Assessment (MRA) principles
- Explain the purpose of MRA
- Illustrate various outcomes of MRA

Codex Risk Analysis Framework



What is MRA?

Microbiological Risk Assessment is a
science based process
driven by governments to assess
the severity of illness
and its probability of occurrence
as a consequence of
the exposure to a certain
food/pathogen combination

Purposes of MRA in MRM

Provide support to governments

- **To assess risks to public health posed by a hazard in a food**
- **to evaluate the need for mitigation measures and options for mitigation**
- **to design food safety improvement programmes**

Fitting MRA in the MRM structure

- Preliminary MRM activities (Topic 2)

- Evaluation of MRM options (Topic 5)
- Implementation of MRM decisions (Topic 6)
- Monitoring and review

MRA attributes

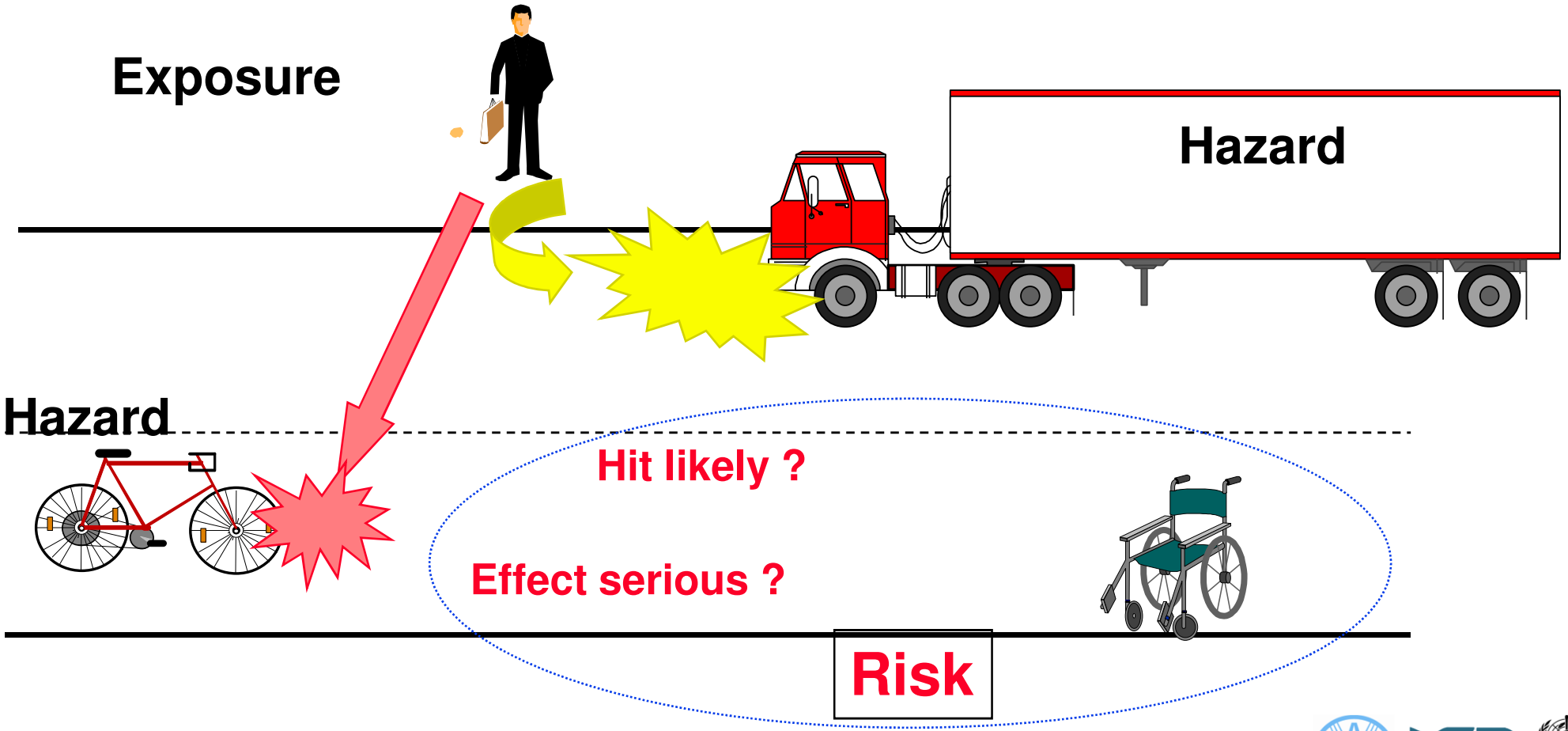
In order to answer a management question, the data should be:

- structured
  to clearly tell what we know
- descriptive
  to characterize how well we know it
- transparent
  to reveal any bias

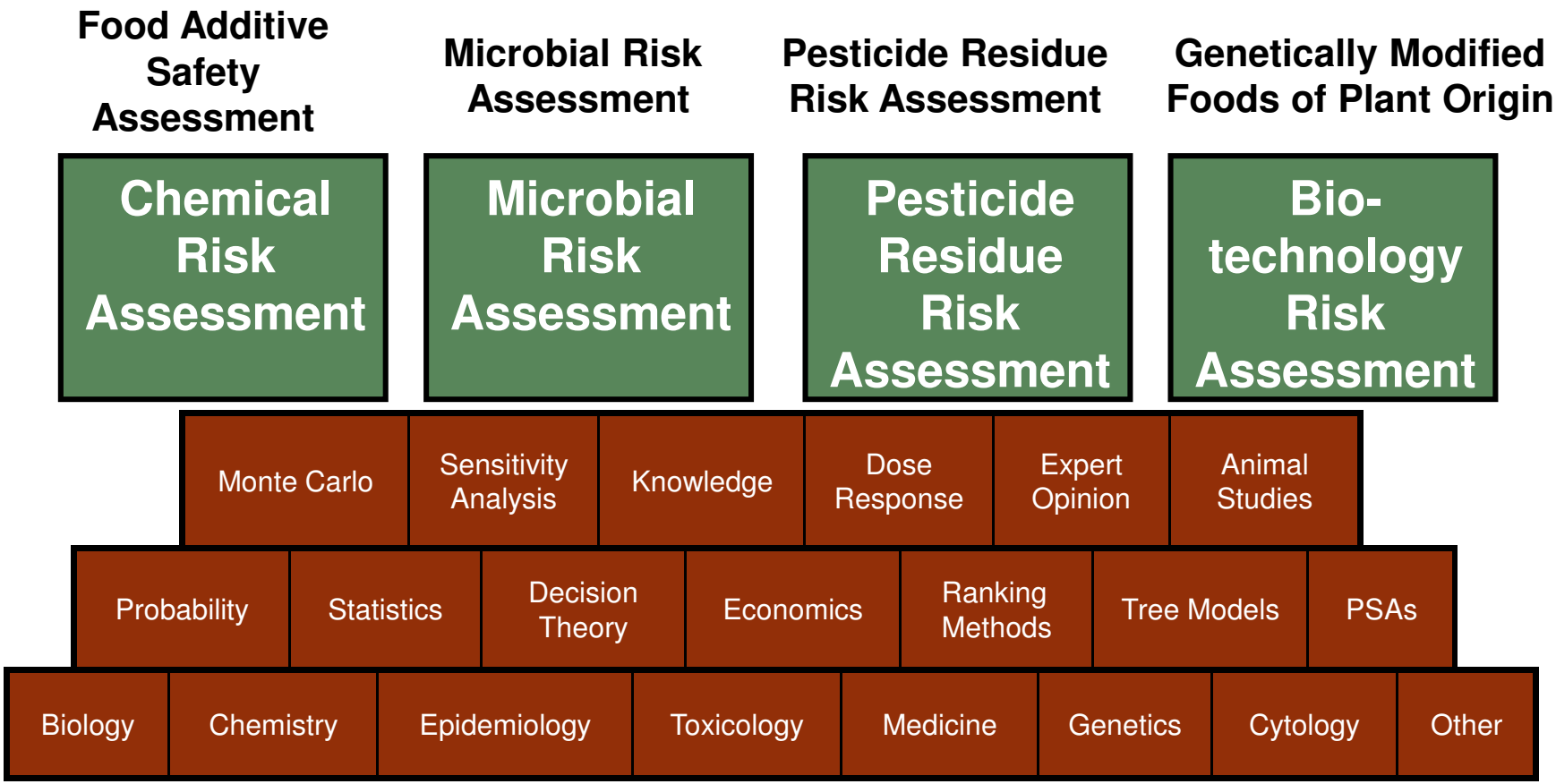
MRA terms

- Hazard — Agent causing an adverse effect
- Exposure — Estimation of likely intake
- Severity — The extent of the adverse health effect
- Risk — A *Combination* of the probability of an adverse effect and its severity

Risk and hazard



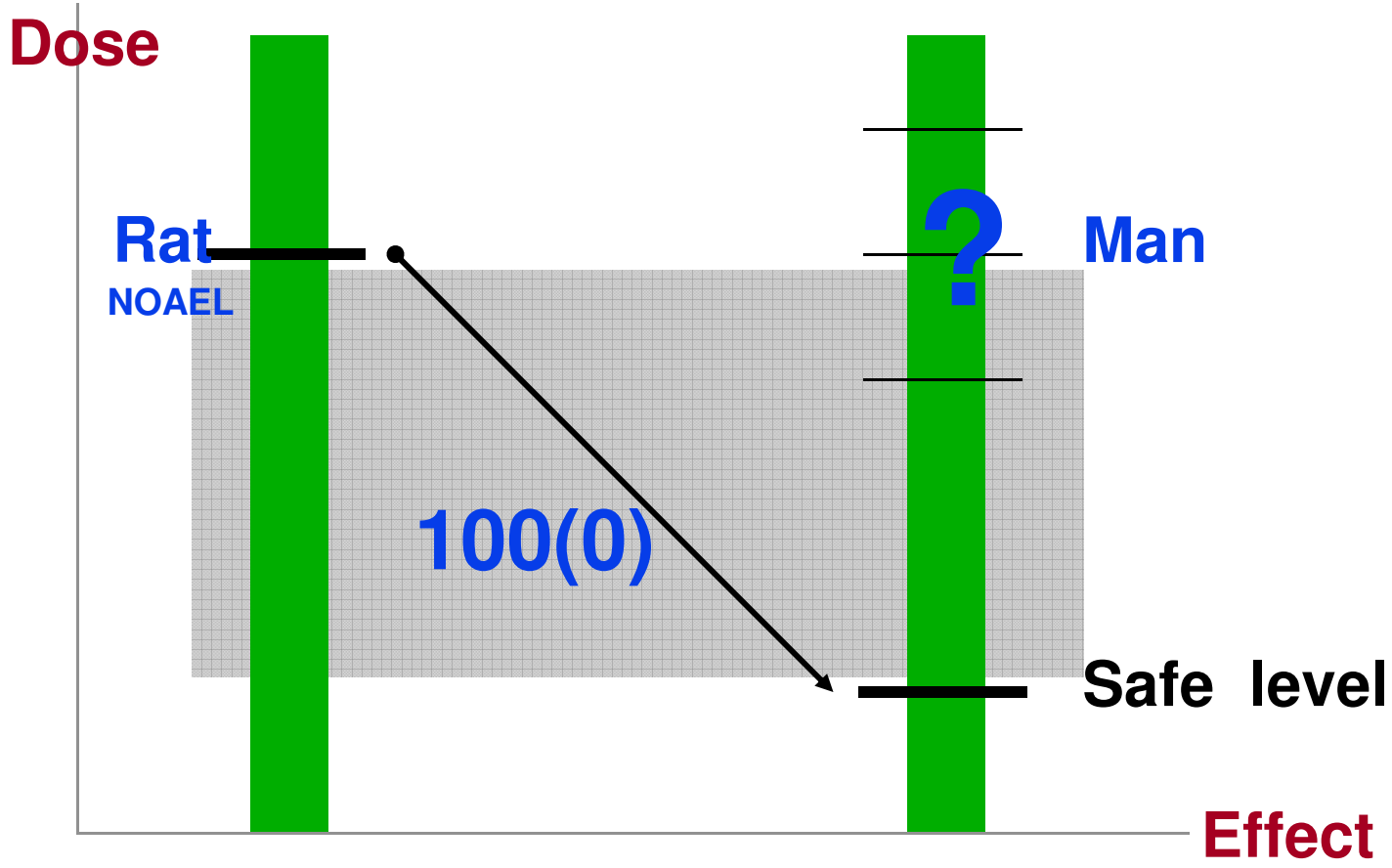
Major Risk Assessment Models



Chemical hazards

- **Most effects are not acute**
- **Many hazards can be effectively controlled at the farm level**
- **Manufacturing has little effect on many chemical hazards**
- **Acceptable levels have been defined for many chemical hazards**

Safety factor in chemical RA



A safety factor is applied to deal with uncertainty

Microbiological hazards

- Most effects are acute
- Many hazards cannot be effectively controlled at the farm level
- Manufacturing, commercialisation, preparation and use have a large effect on many microbiological hazards
- Acceptable levels have not been defined for most microbial hazards
- In risk characterisation, no safety factors are applied

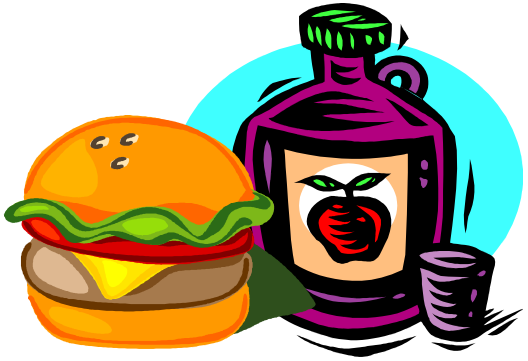
Acceptable level?

A MRA does *not* provide information whether the risk associated with the level (prevalence and/or concentration) of a microbe in a food is *acceptable* or not

This is a decision that Risk Managers need to make, with input from stakeholders (regulators, consumers, industry)

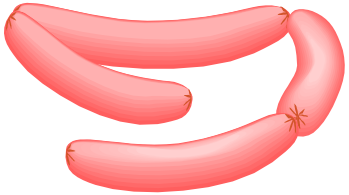
Microbiological risk assessment

Salmonella

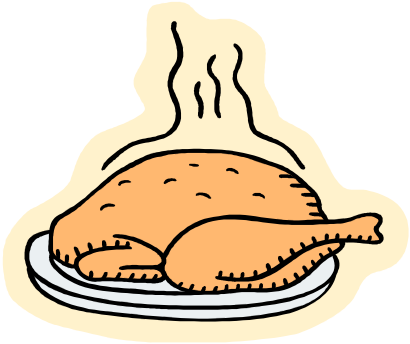


Escherichia coli O157

Vibrio parahaemolyticus



Listeria monocytogenes



Campylobacter

Microbiological risk assessment is performed for pathogen/food combinations that are associated with food-borne illness

(single pathogen, one product type, whole chain)

Inputs to MRA

- Science (multidisciplinary)
  - Data
  - Knowledge
  - Experts
- Tools
  - Statistics
  - Ranking
  - Simulation (e.g. Monte Carlo)
  - Knowledge elicitation
- Infrastructure
  - Epidemiology
  - Food consumption
  - Outbreak investigation
  - Consumer behaviour
- Framework
  - Risk analysis

Types of MRAs

- Product Pathogen Pathway risk assessment
  - One pathogen/one food - absolute risk estimate
- Risk ranking
  - One pathogen/multiple foods - relative risk estimate
- Geographical risk estimate
  - Risk of introduction into a region (e.g. BSE / TSE)
- Risk/Risk trade-off
  - Nitrites versus C. botulinum in sausages

Outcomes of MRAs

1. The chance for a person of falling ill by consuming a food serving
2. The estimated number of illnesses (e.g. per 100.000/year in a country) due to consumption of a specific food/pathogen combination
3. The relative risk posed by a pathogen in different food products or uses
4. Risk estimates for different processing, distribution and consumer use conditions and risk reduction scenarios

Example of outcome (1)

The estimated chance that a person in the USA would get Salmonellosis by eating a serving of shell eggs is 3.3×10^{-6}

(Attendant uncertainties not mentioned)

USA MRA

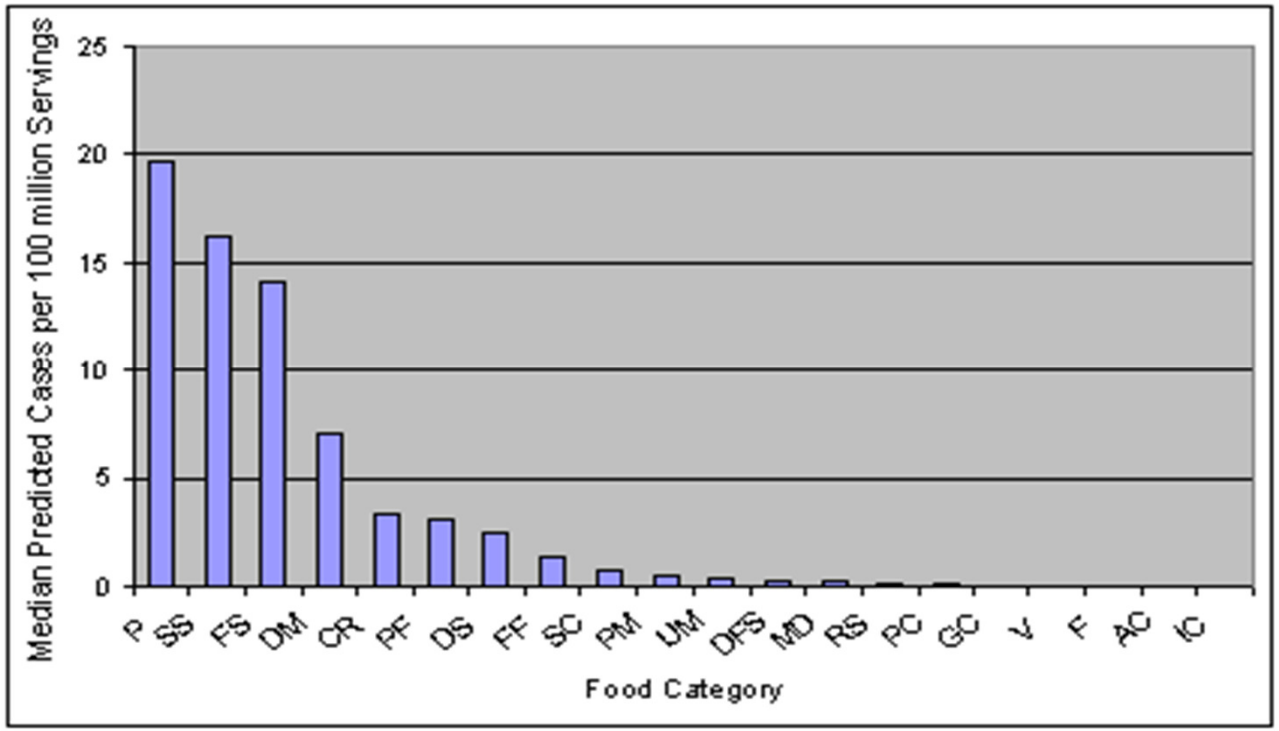
Example of outcome (2)

It is estimated that circa 30 cases of listeriosis per year in the USA (280 Mio inhabitants) are caused by eating cold frankfurters

USA MRA

Example of outcome (3)

Predicted relative risks associated with food categories for the USA population based on the median predicted cases of listeriosis per 100 million Servings.

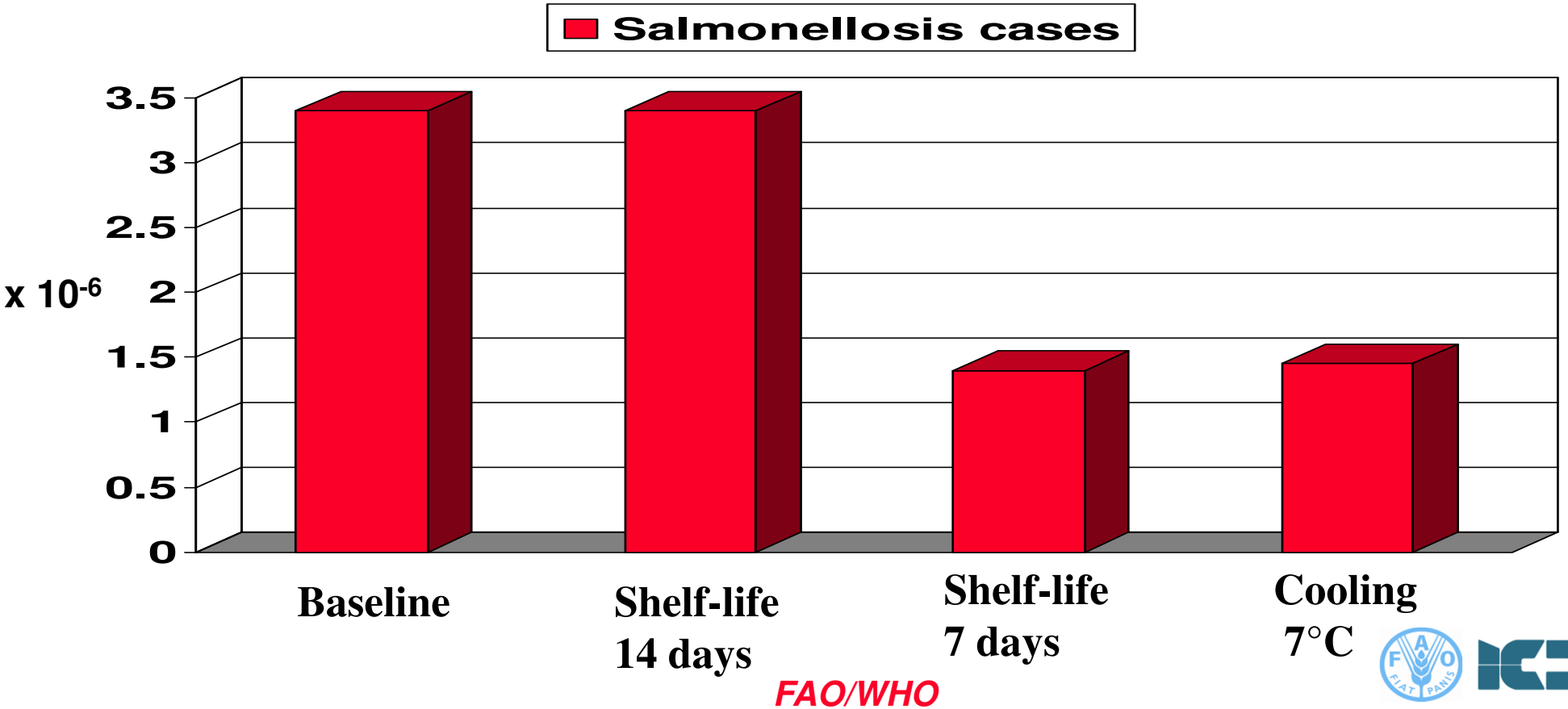


P = Pâtê and Meat Spreads
SS = Smoked Seafood;
FS = Fresh Soft Cheese
DM = Deli Meat
PF = Preserved Fish
DS = Deli Salads
SC = Soft Mold-Ripened Cheese
PM = Pasteurized Fluid Milk
UM = Unpasteurized Fluid Milk;
MD = Miscellaneous Dairy Products
RS = Raw Seafood;
PC = Heat-Treated Natural Cheese
V = Vegetable
F = Fruits
AC = Aged Chees
IC = Ice Cream

(CFSAN, FDA, USDHHS, FSIS, USDA, 2001)

Example of outcome (4a)

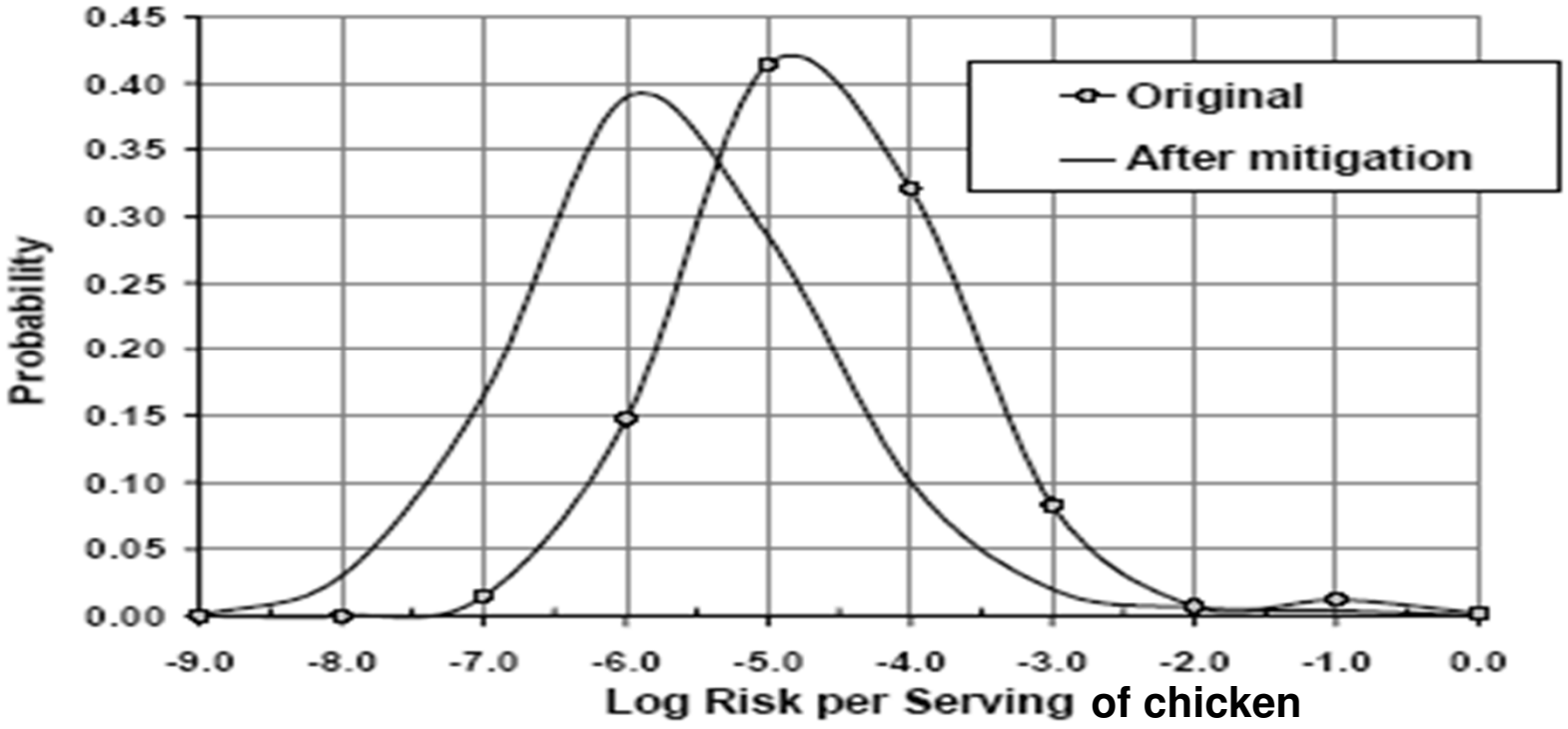
Probability of illness per serving of shell eggs



FAO/WHO

Example of outcome (4b)

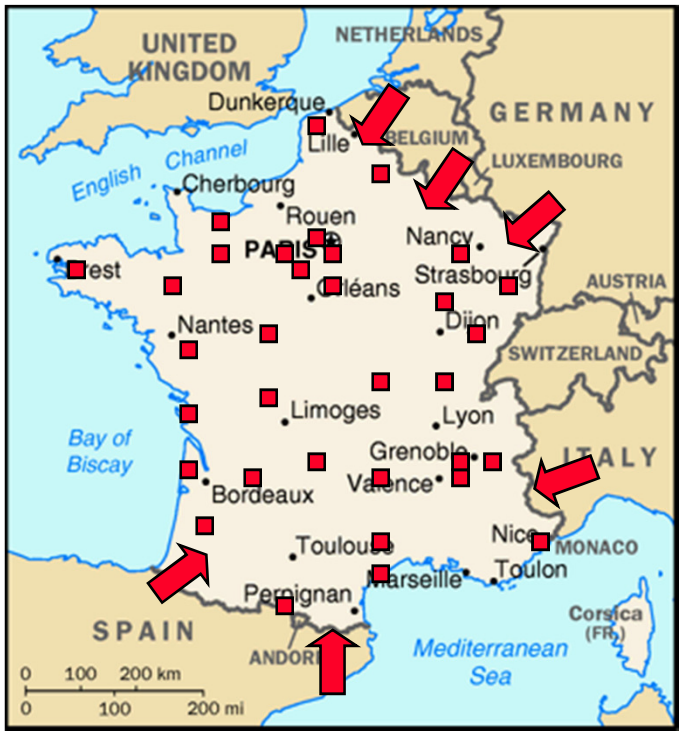
Probability of salmonellosis before and after changing cooking practices



FAO/WHO

MRA in MRM

A governmental MRA considers all foods consumed in a specific country, whether produced locally or imported



Examples of MRAs

FAO/WHO

Salmonella Enteritidis in eggs
Salmonella spp. in broilers
L. monocytogenes in ready-to-eat foods
Vibrio spp. in seafood
Campylobacter spp. in broilers

Canada

Campylobacter jejuni in fresh poultry
Salmonella spp. in cracked eggs
L. monocytogenes in raw milk cheese
E. coli O157:H7 in ground beef
Toxoplasma gondii in pork

USA

Salmonella in shell eggs
Vibrio parahaemolyticus in raw oysters
Listeria in ready-to-eat retail foods
E. coli O175:H7 in ground beef

Netherlands

Bacillus cereus in pasteurised milk
Campylobacter spp. in broiler chicken
E. coli in steak tartare
B. cereus in vegetable puree

MRAs must report

- **Key assumptions**
- **Inconclusive or controversial scientific information**
- **Estimates of risks with attendant uncertainties**
- **An indication of the degree of variability and scientific uncertainty**
- **Possible undertakings to complete the data so that the MRA may be improved, if necessary**

FAO/WHO Expert Committees

Risk Assessment is done and advise on acceptable levels for chemical hazards is given by

The Joint FAO-WHO Expert Committee on Food Additives (JECFA)

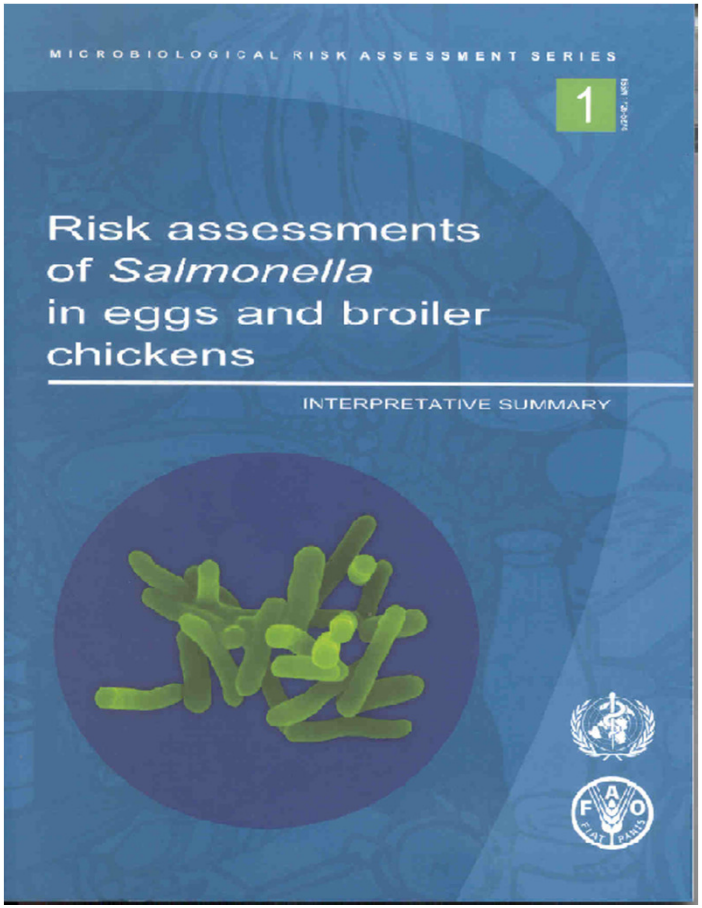
The Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

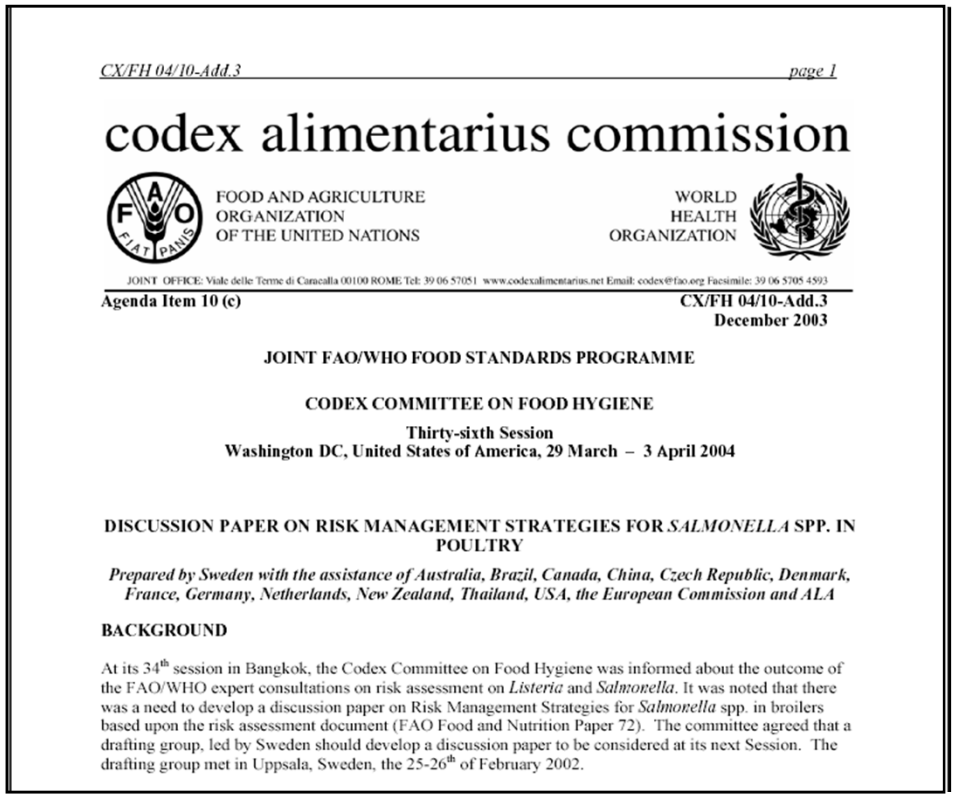
Risk Assessment is done but no advise on acceptable levels for microbial hazards is given by

The Joint FAO-WHO Expert Meeting on Microbiological Risk Assessment (JEMRA)

JEMRA output

CCFH use





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codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 10 (c) **CX/FH 04/10-Add.3**
December 2003

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-sixth Session
Washington DC, United States of America, 29 March – 3 April 2004

DISCUSSION PAPER ON RISK MANAGEMENT STRATEGIES FOR *SALMONELLA* SPP. IN POULTRY

Prepared by Sweden with the assistance of Australia, Brazil, Canada, China, Czech Republic, Denmark, France, Germany, Netherlands, New Zealand, Thailand, USA, the European Commission and ALA

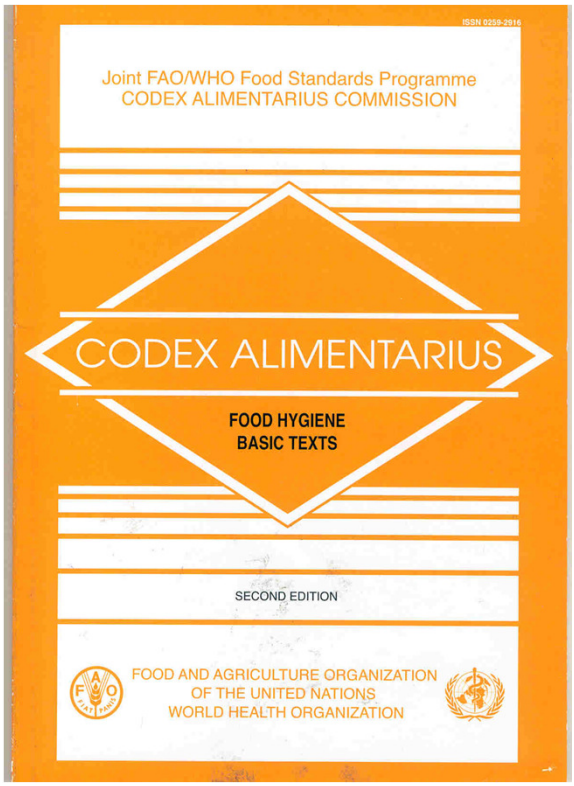
BACKGROUND

At its 34th session in Bangkok, the Codex Committee on Food Hygiene was informed about the outcome of the FAO/WHO expert consultations on risk assessment on *Listeria* and *Salmonella*. It was noted that there was a need to develop a discussion paper on Risk Management Strategies for *Salmonella* spp. in broilers based upon the risk assessment document (FAO Food and Nutrition Paper 72). The committee agreed that a drafting group, led by Sweden should develop a discussion paper to be considered at its next Session. The drafting group met in Uppsala, Sweden, the 25-26th of February 2002.

Codex principles of microbiological risk assessment

- The Codex Commission has published *The principles and guidelines for the conduct of MRA* [CAC/GL-30 (1999)]

- The principles are described in the following slides



Key Points

- MRA is a well defined process
- MRA is done to answer questions formulated by Microbiological Risk Managers
- These questions can be very different in nature, thus also the outcomes of MRA may be presented in many forms

MRA basic awareness course

Topic 3 - Lecture 2

Microbiological Risk Assessment methodology

Purpose of lecture

- Understand the four steps/stages of Microbiological Risk Assessment (MRA)
- Explain some problems and issues that need to be considered
- Explain probabilistic approach

MRA

- A *scientifically* based process consisting of the following components
  - Hazard identification
  - Hazard characterization
  - Exposure assessment
  - Risk characterization

- *Codex Alimentarius*

Hazard Identification (1)

Purpose

Determination of the agent / food combination that will be the subject of the MRA and description of the microorganism and/or its toxin

Normally Risk Managers will include part of this in their briefing of the Risk Assessors

Hazard Identification (2)

Reactive

a case or an *outbreak* of foodborne disease has occurred, the causative microorganism has been identified and the risk of its occurrence in one or more foods has to be estimated

Hazard Identification (3)

Proactive

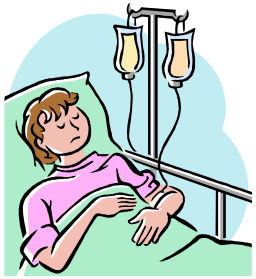
a microorganism is suspected to be a hazard, a link to foodborne disease is not definitely established, the likelihood that this microorganism in a food is causing an adverse health effect has to be estimated

Society has not experienced the hazard before and the possible extent of the problem is not known

Hazard characterization (1)

Purpose

The qualitative and/or quantitative evaluation of the nature, severity and duration of the adverse effects associated with one or different levels (frequencies / numbers) of microbiological agents that may be present in the food of concern



Hazard characterization (2)

Factors influencing risk

- the *food* (e.g. fatty, liquid)
- the *pathogen* (e.g. number, pathogenicity)
- the *host* (e.g. age, health status)

Hazard characterization (3)

At least two categories of consumers have to be distinguished

- "normal" population
- "susceptible" individuals

Susceptible consumers

Young

Old

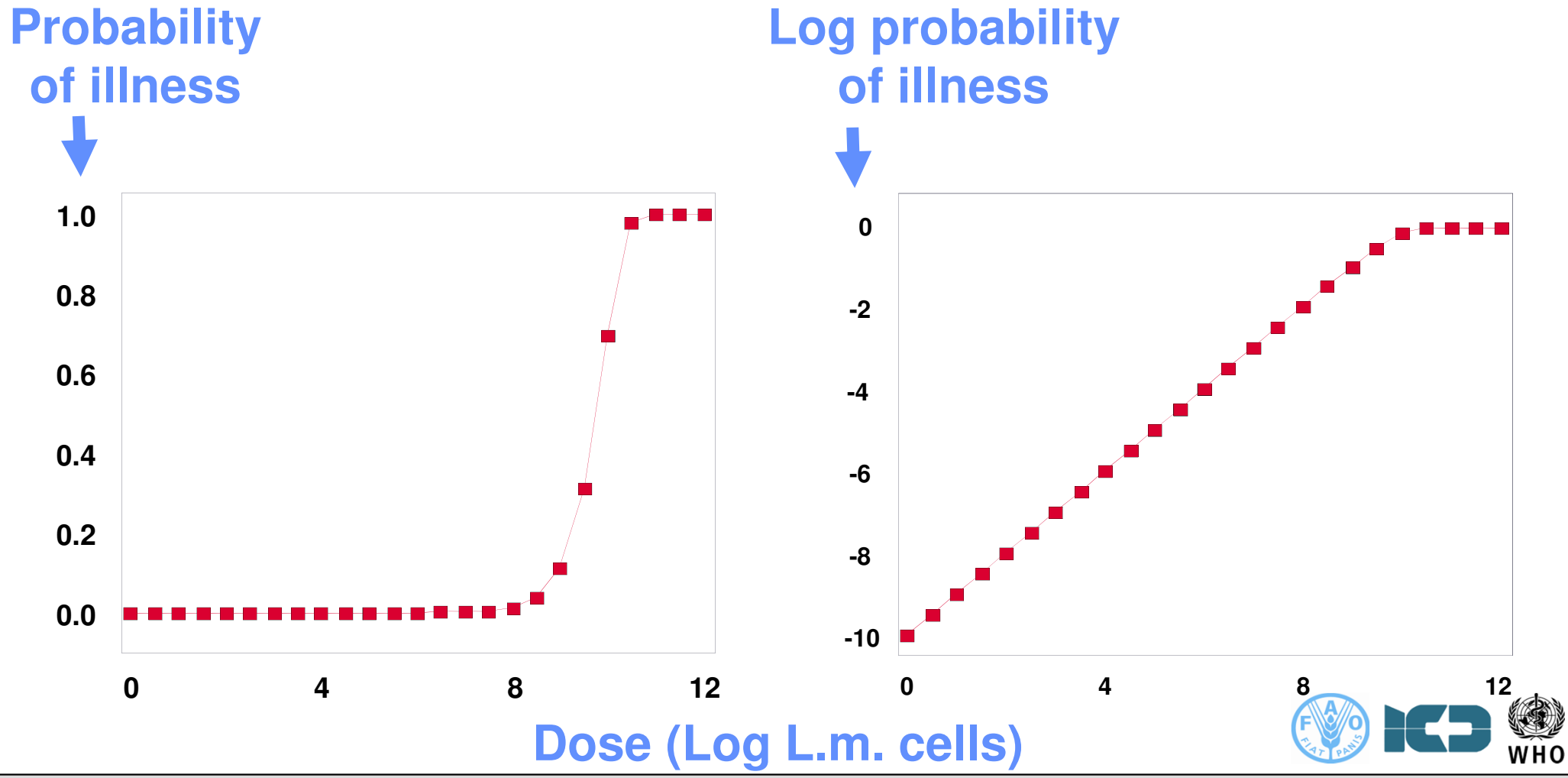
Diseased

Immuno-compromised

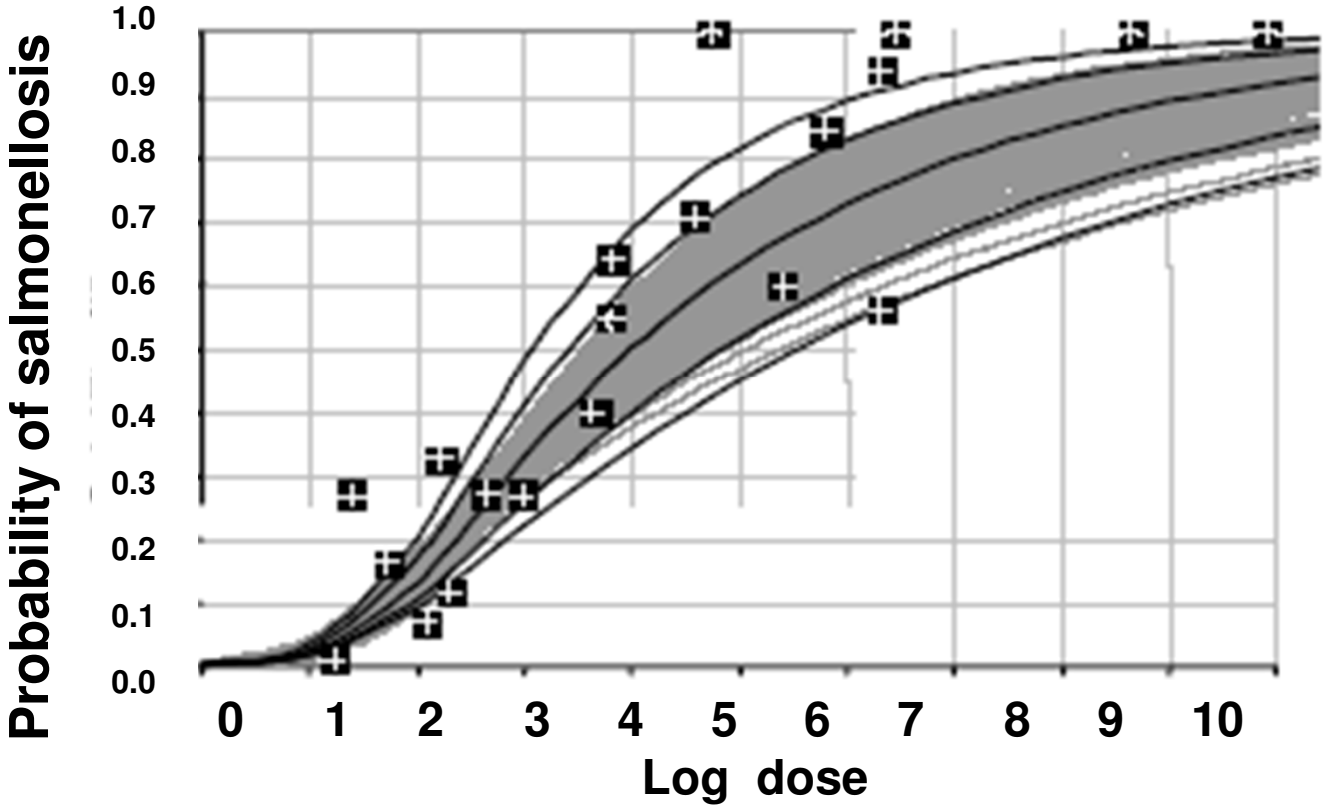
Malnourished

Tourists

L.m. dose – response curves for susceptible persons



Dose response curves with attendant uncertainties for salmonellosis



Issues in hazard characterization

- Availability and use of epidemiological data
- Use of animal models and data
- Use of human feeding trials data
- Pathogen virulence data
- Pathogen-food matrix knowledge
- Data concerning susceptibility of consumers
- and more ...

Exposure Assessment

Purpose

The estimation of the likely intake of a hazard and/or certain levels of a hazard in a certain food by the population or part of the population

Pathogen / Product / Pathway analysis (1)

Determination and quantification of prevalence in raw materials survival during processing recontamination growth survival during preparation contamination and growth prior to consumption

The data are used in mathematical models

Product / Pathogen / Pathway analysis (2)

- $H_o - \Sigma R + \Sigma I_{RC+G} = H_p$

Starting level

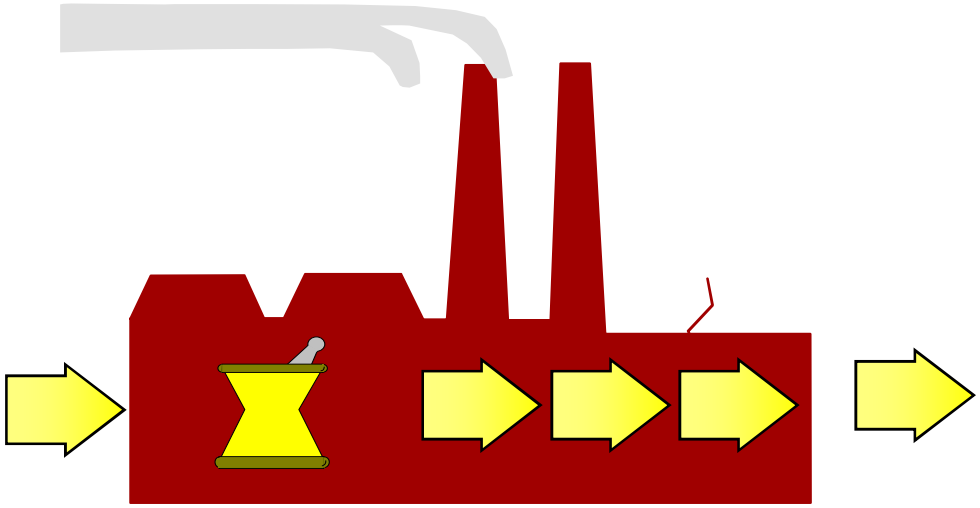
Reduction

I =Increase due to:
RC=Recontamination
G =Growth

Hazard level in product *

*** FSO and PO are more precise expressions**

Exposure Assessment example



- Frequency of contamination
- Level of contamination

- Factory:
  - ✓ mixing
  - ✓ pasteurisation
  - ✓ cool/freeze
  - ✓ packing
- Distribution
  - ✓ time/temperature

- Use of product
  - ✓ child / healthy adult
  - ✓ portion size
  - ✓ consumption frequency

Hypothetical production process

Issues in Exposure Assessment (1)

- Consumer use and dietary intakes often not well known
- Data are scarce (non-existent) for certain food categories/outlets (e.g. retail, catering, street vending, small kitchens) or for new food categories/markets
- Some data have been collected as a result of an outbreak, this is not a normal situation

Issues in Exposure Assessment (2)

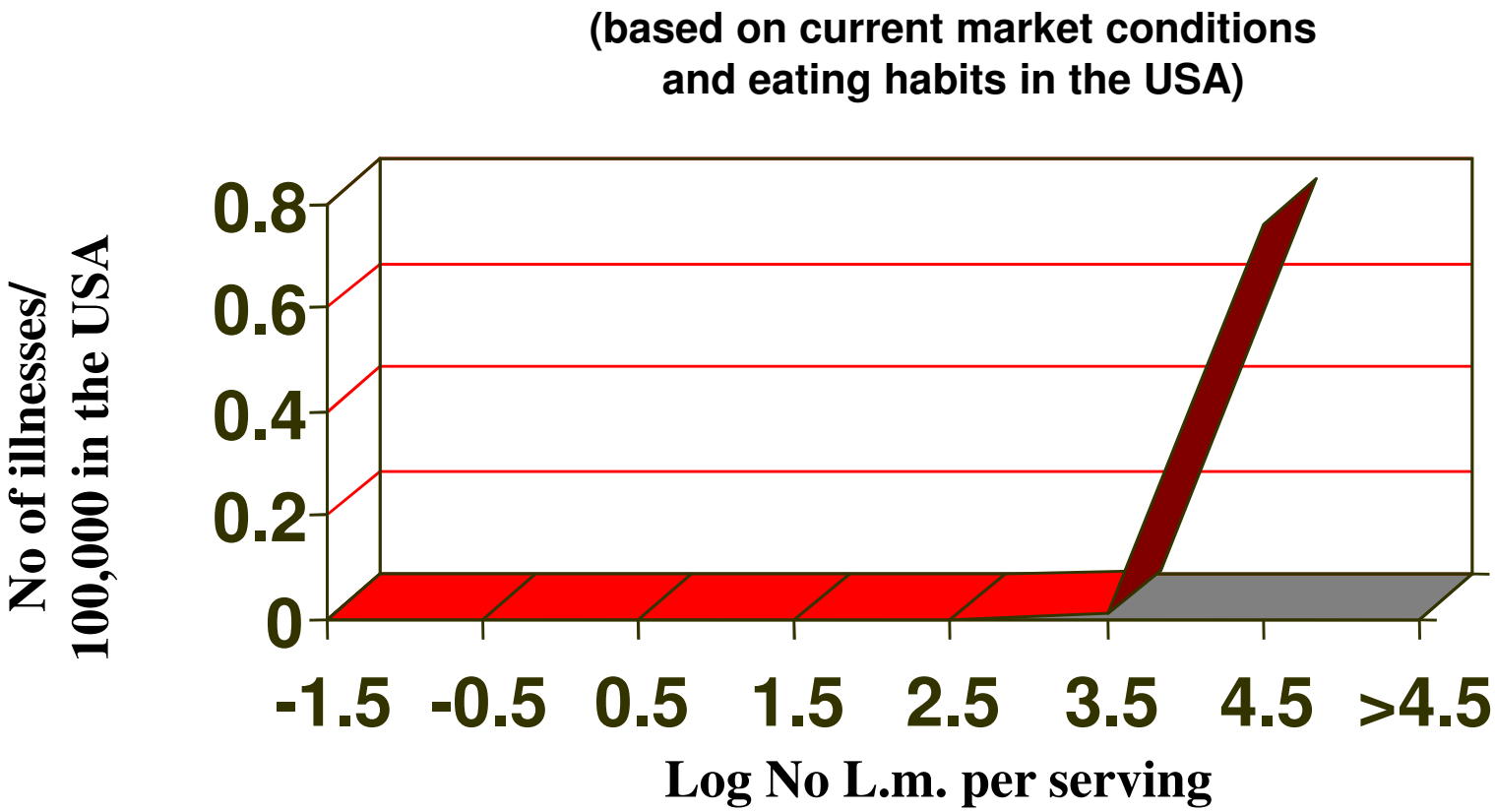
- Available data and models on inactivation and/or growth of pathogens do not apply across the whole food chain up to the point of consumption
- Recontamination after production or preparation often not considered
- Uncertainty and variability in data and models are often not transparent

Risk characterization

Purpose

The quantitative and/or qualitative estimation of the *probability* of occurrence and *severity* of defined adverse health effects in a given population due to the consumption of a certain pathogen/food combination

Risk Characterization curve



Based on FAO/WHO report

Issues in Microbiological Risk characterization

- Use of *worst case* scenarios
- (biological) *variability* and attendant *uncertainties* are often not considered or expressed
- Validation of the models

Calculation of Risk Estimate

HC

- Define microorganism and its virulence
- Define target consumer group and effect
- Use specific dose-response data
- Determine fate of microorganism during production, distribution, preparation & use

EA

- Determine consumption practices
- Calculate risk estimate with attendant uncertainties (assumptions specified!)

Precision of estimate

Three factors of influence

1. variability
2. uncertainty
3. lack of data

Variability

Variability **is a property of nature, the diversity of things. Cannot be reduced through further study or additional measurements.**

Lammerding, 1999

Uncertainty

???

Uncertainty **is our ignorance - lack of knowledge. In many cases, it can be reduced through further study or expert information.**

Lammerding, 1999

Types of calculations

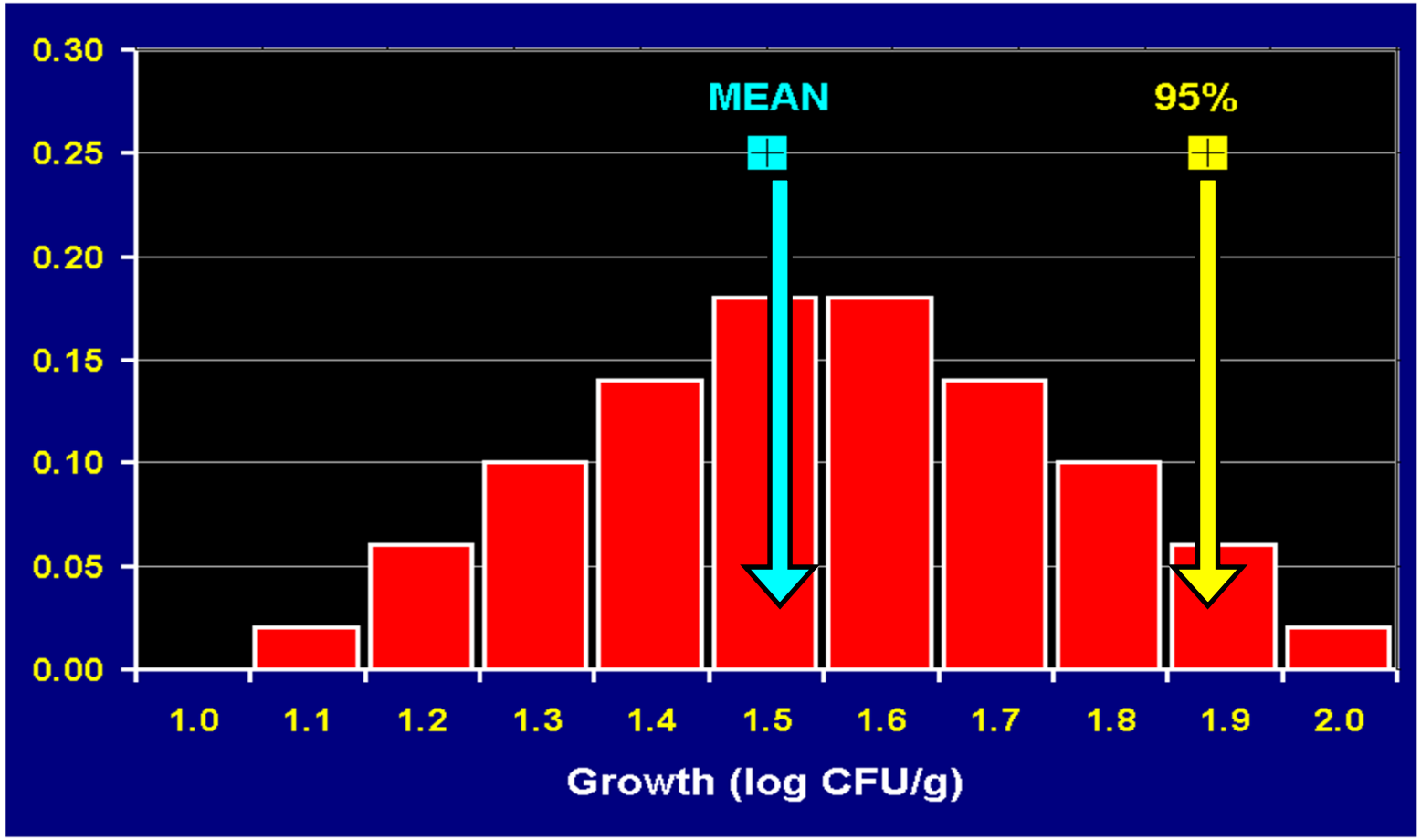
Deterministic

- point estimates of (absolute) risk level

Probabilistic

- distributions of (absolute) risk level

Point estimates and distribution of growth



Point Estimates

MEAN VALUES

Organism, Concentration
= 2.0 log CFU/g
Organism, Growth
= 3.5 log CFU/g
Organism, Inactivation
= 4.5 log CFU/g
***cont. level* = 1.0 log CFU/g**
Amount Consumed
= 53 g
Exposure=2.7 log or 530 CFU/serving

WORST CASE (95%)

Organism, Concentration
= 3.0 log CFU/g
Organism, Growth
= 4.5 log CFU/g
Organism, Inactivation
= 3.5 log CFU/g
***cont. level* = 4.0 log CFU/g**
Amount Consumed
= 85 g
Exposure=5.9 log or 850000 CFU/serving

[Concentration + Growth - Inactivation] x Amount Eaten

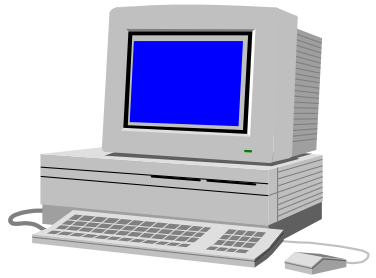
Probabilistic Risk Assessments

- Calculate risk as a function of the distributions of input values
- Generate a distribution of risk
- Characterise the likelihood of events
- Reflect the variability and uncertainty in the risk estimate
- Recognise the variation that exists in the real world

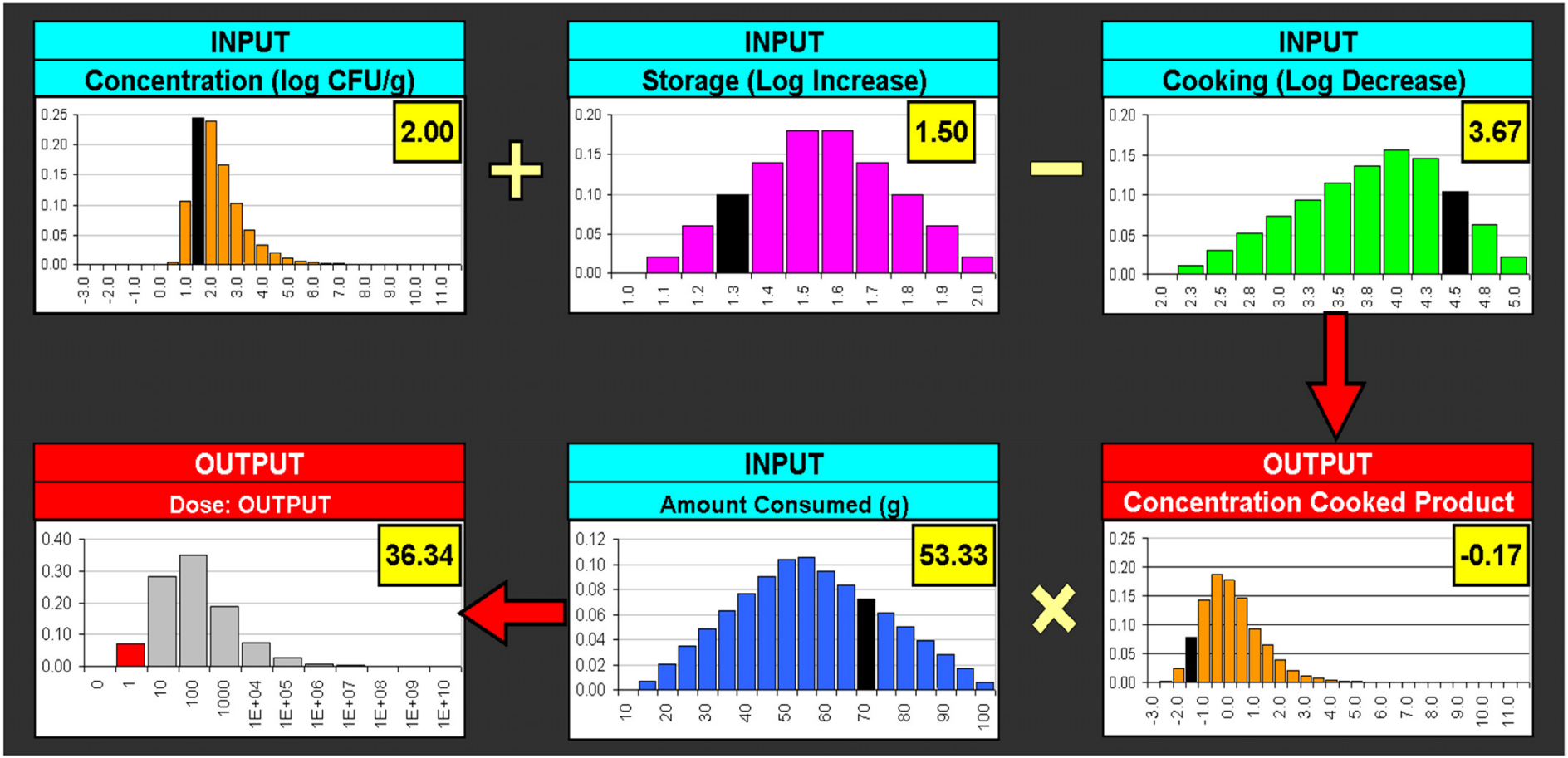
Probabilistic Risk Assessments

Monte-Carlo simulation

- sampling from probability distributions which describe variation and uncertainty
- distributions based on actual data or assumptions
- repeated large number of times (iterations)

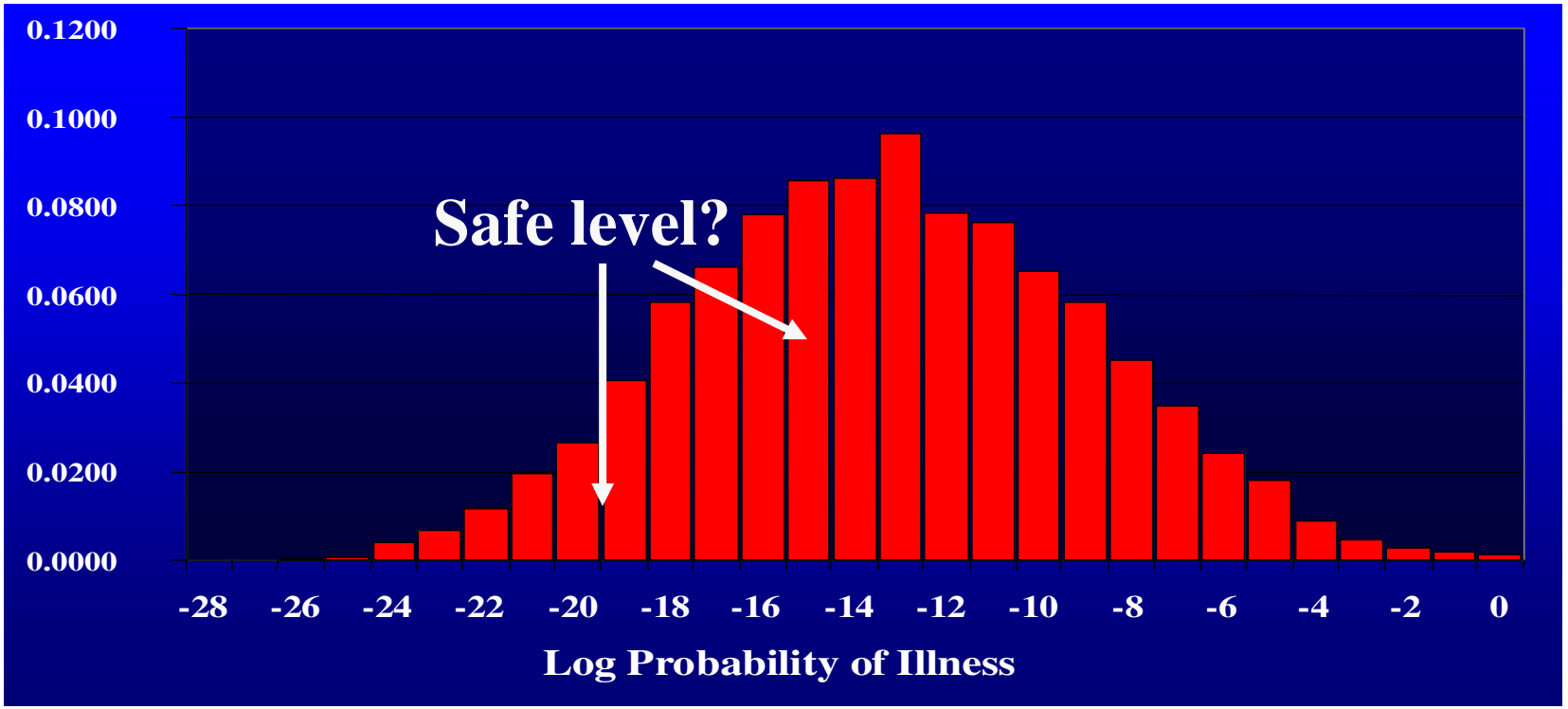


Probabilistic estimates



Probabilistic Risk estimate

Range of possible outcomes
Likelihood of various outcomes



Requirements for Risk Assessment

Risk Assessments generally require

- experienced risk assessors
- significant effort
- large volumes of a variety of data
- mathematical modelling approaches
- resilience to dig through complexity

What Makes a Good Risk Assessment?

- Good questions from the risk manager!
- Appropriate team composition
- Magnitude of effort in line with task
- Open attitude, no up-front bias
- Sound science
- Informed and transparent assumptions
- Reliable data
- Limited, articulated uncertainty
- Good documentation

Key Points

- Although the structure of MRA is easy to understand, experts are needed to use the methodology
- Models for growth and inactivation as well as for dose/response relationships are needed in quantitative MRA
- Good data are needed to perform a reliable PPP analysis
- When no such data are available assumptions have to be made, these should be presented as part of the outcome