

Risk Assessment use in the public and private context

Leon Gorris

Director Regulatory Affairs – Global Food Safety

Outline

- Microbiological Risk Assessment (MRA)
- Examples of Government use of Microbiological Risk Assessment
- Use of MRA technology for Exposure Assessment in an Industry context

Microbiological Risk Assessment (MRA)

“Risk Management” drives Risk Analysis



Risk manager owns issue:

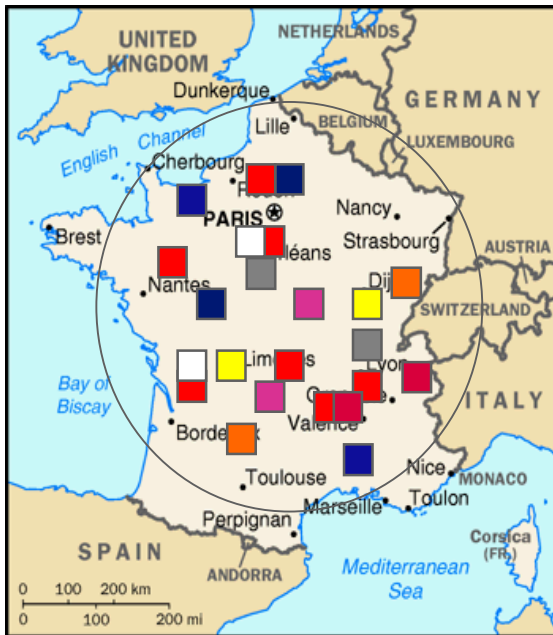
- Decides on need to deal with the issue
- Risk Assessment as appropriate
- Decisions on mitigation options

Iterative interaction with:

- Risk assessors
- Risk communicators
- Stakeholders / interested parties

Microbiological Risk Assessment: purpose?

To provide a basis for **decision-making** by the risk manager



- By systematically assessing the level of **risk** associated to pathogenic microorganisms in foods.
- By making an inventory of “**typical**” risk contributing factors.
- By elaborating possible **risk mitigation** options/strategies (“what if”).

Microbiological Risk Assessment

Risk Assessment

- Hazard Identification
- Hazard Characterisation
- Exposure Assessment
- Risk Characterisation

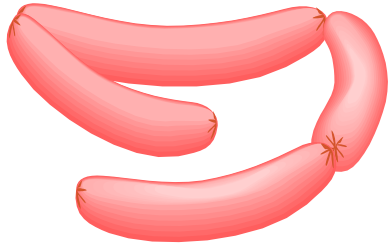
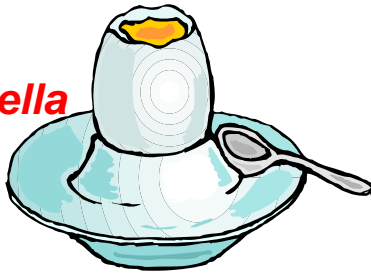
Microbiological Risk Assessment is a **science-based procedure** driven by governments to assess the safety of foods consumed in their population

MRA is most valuable when:

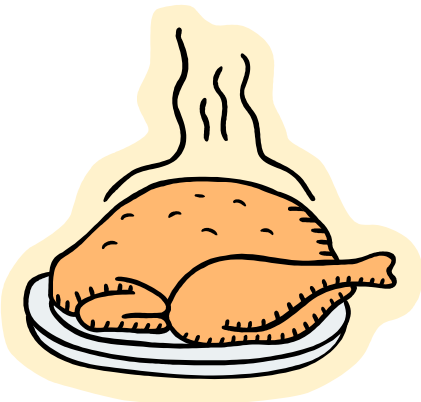
- Highly complex situation
- Variability in operational chains
- Variability within population
- Uncertainty, incomplete knowledge

Microbiological Risk Assessment

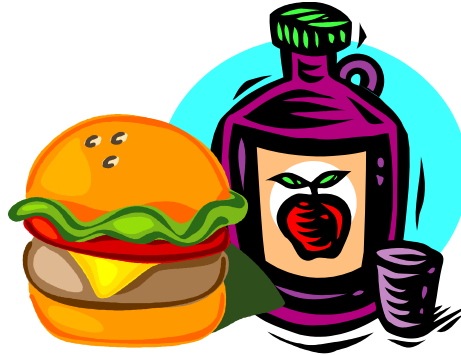
Salmonella



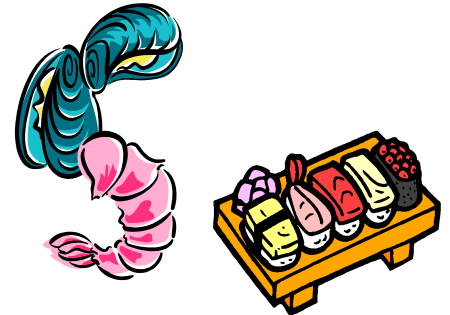
Listeria monocytogenes



Campylobacter



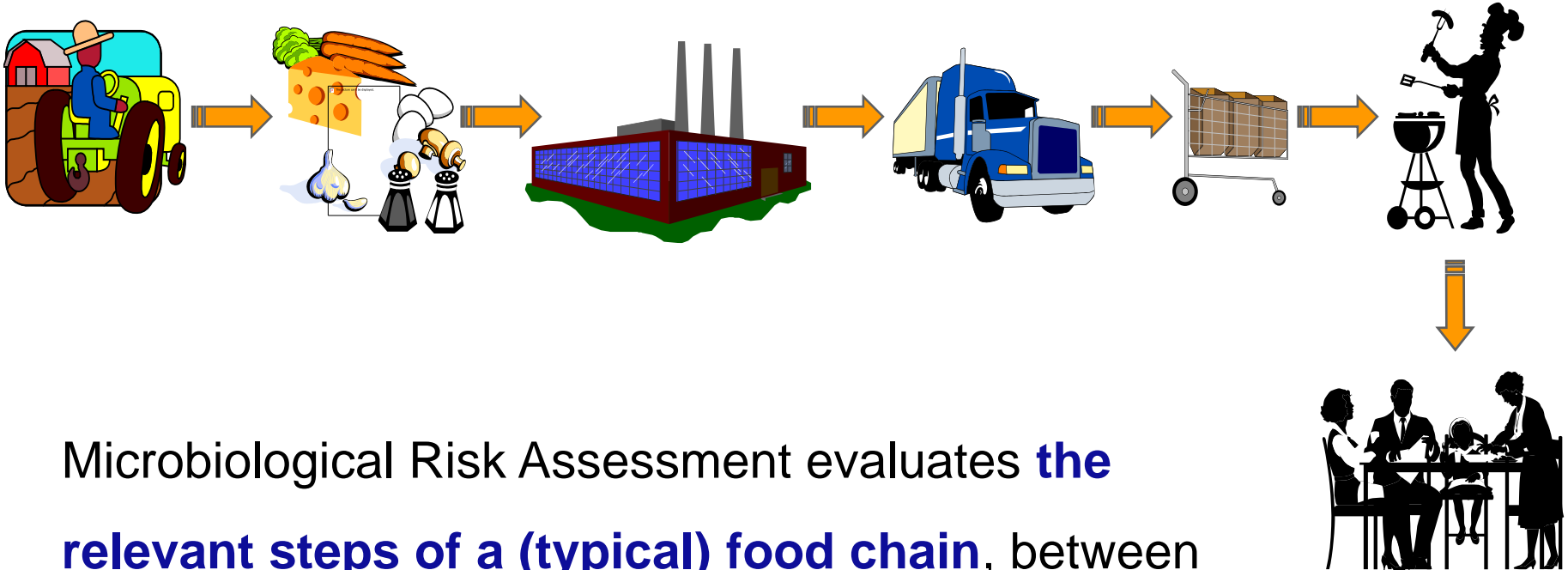
Escherichia coli O157



Vibrio parahaemolyticus

Microbiological Risk Assessment is performed for **pathogen/food combinations** that are associated with foodborne illness

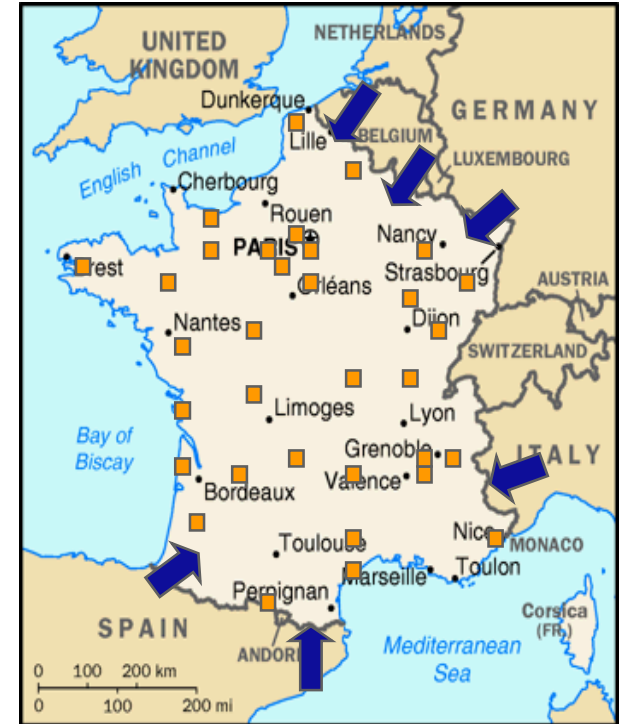
Microbiological Risk Assessment



Microbiological Risk Assessment evaluates **the relevant steps of a (typical) food chain**, between primary production to consumption or part thereof

Microbiological Risk Assessment

- Microbiological Risk Assessment takes into consideration **all foods consumed in a specific country**, whether produced in that country or imported
- It is about the population **exposed** to the hazard



MRA outcome: *Risk estimates*

- **Population level**

- Estimated *number of cases* of illness per year per population (e.g. 100.000 persons) caused by a micro-organism present in a particular food or food group (*risk for population*)

- **Consumer level**

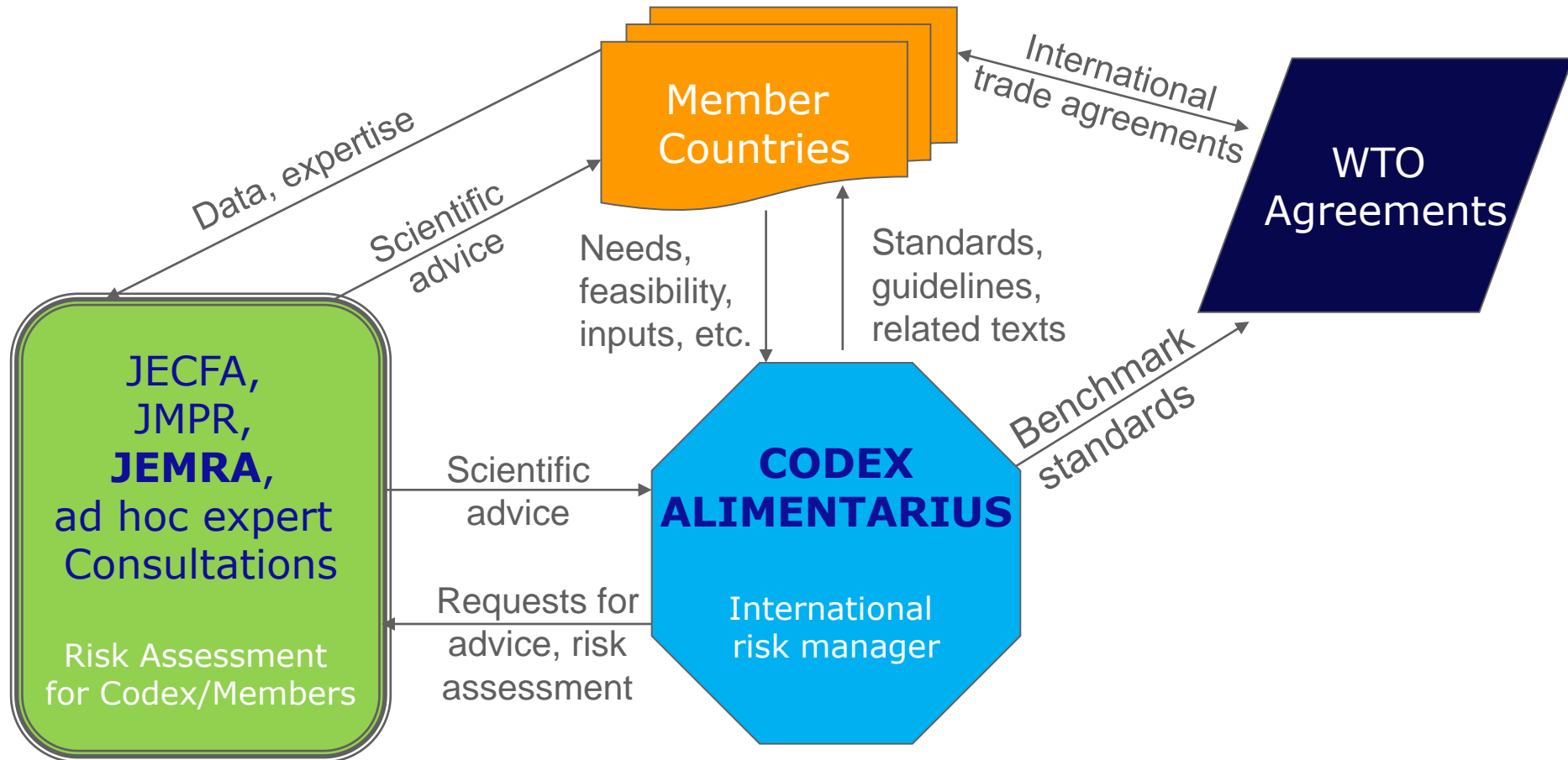
- Chance of illness due to consumption of a specific food-product to which a particular hazard can be associated (*risk for individual consumer, “per serving”*)

MRA outcome: *other outcomes*

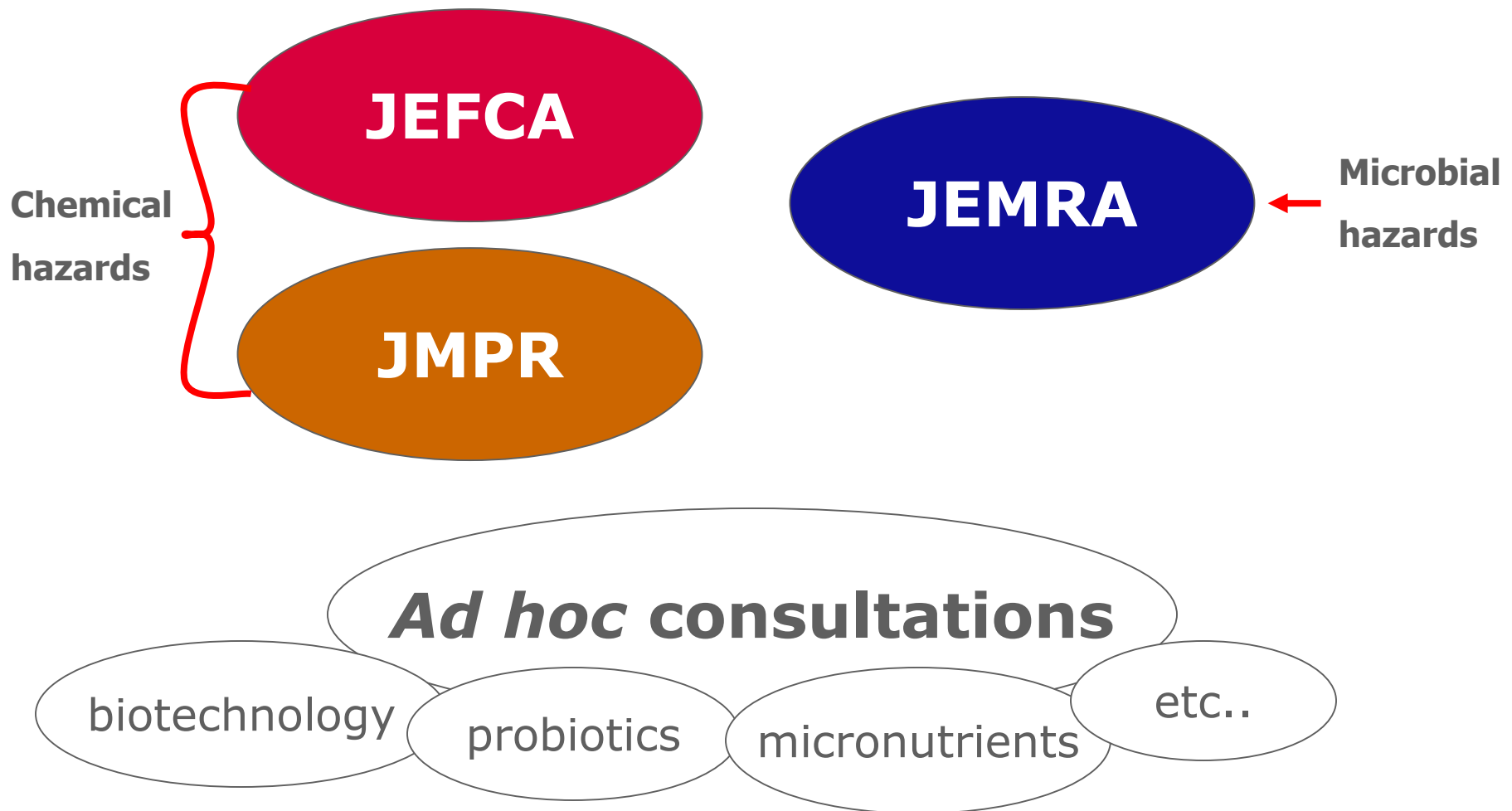
- A **ranking** of foods according to the risk they pose to consumers
 - A specific type of food, different hazards
 - Grouping of foods according to risk categories for one hazard
- **What-if scenarios** for impact of mitigation measures
- **Insight** in the impact of processing, handling, distribution and preparation scenarios on risk
- **Insight** in consumer use and abuse (misuse)

Examples of Government use of Microbiological Risk Assessment

Global Food Standard Setting level



Providers of scientific advice to Codex



Codex Alimentarius Use of MRA

International “risk managers” and “risk assessors”:

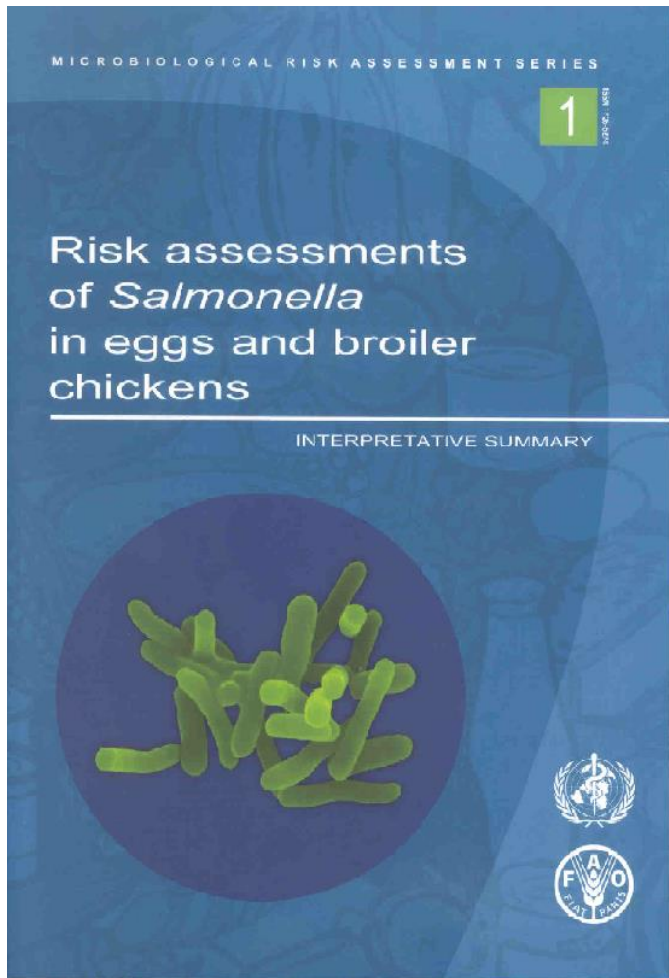
- *Risk Managers:*

- Codex Committee on Food Hygiene (CCFH), i.e. Codex Member States (input: FAO & WHO, Observer organizations)

- *Risk Assessors:*

- JEMRA (Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment), selected experts in microbiology (ecology, public health, epidemiology, statistics, etc.)


JEMRA Output:




CCFH use:

CX/FH 04/10-Add.3 *page 1*

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

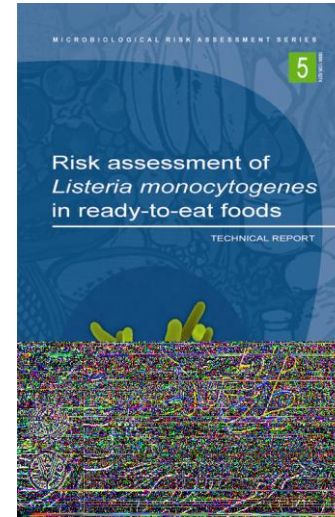
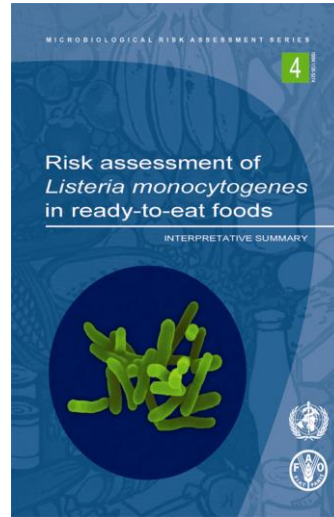
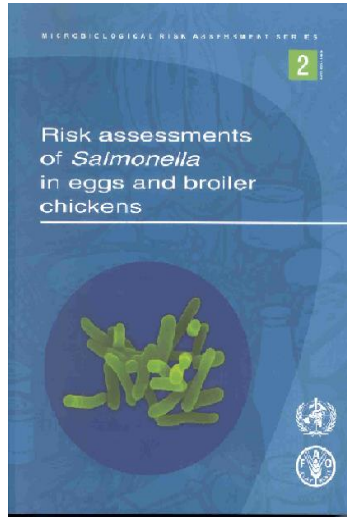
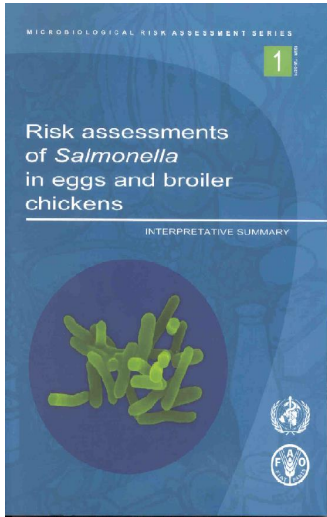
**DISCUSSION PAPER ON RISK MANAGEMENT STRATEGIES FOR *SALMONELLA* SPP. IN
POULTRY**

*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.

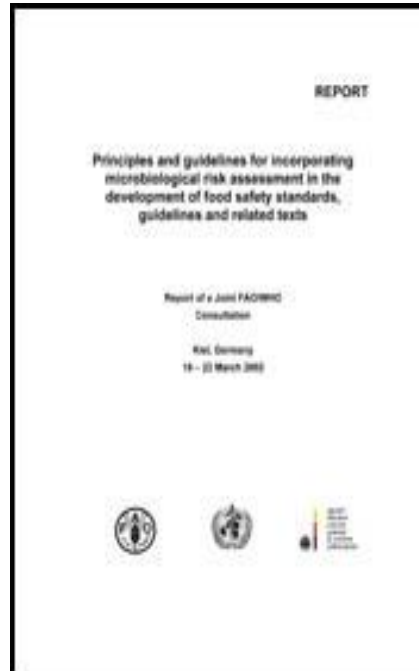
JEMRA Reports & Guidelines



MRA reports



“how to”
guidelines



Guidelines on
principles/process

JEMRA MRAs

Codex Codes

- *Salmonella* spp. in broiler chickens and eggs → Risk management strategies for *Salmonella* spp. in poultry
- ***Listeria monocytogenes* in ready-to-eat food** → **General principles of food hygiene for management of *L. monocytogenes***
- *Campylobacter* spp. in broiler chickens → Risk management strategies for *Campylobacter* spp. in poultry
- *Vibrio* spp. in seafood for the → Risk management strategies for *Vibrio* spp. in seafood
- ***Cronobacter* spp. in powdered infant formula** → **Recommended international code of practice for foods for infants and children**

Some Examples of MRA use

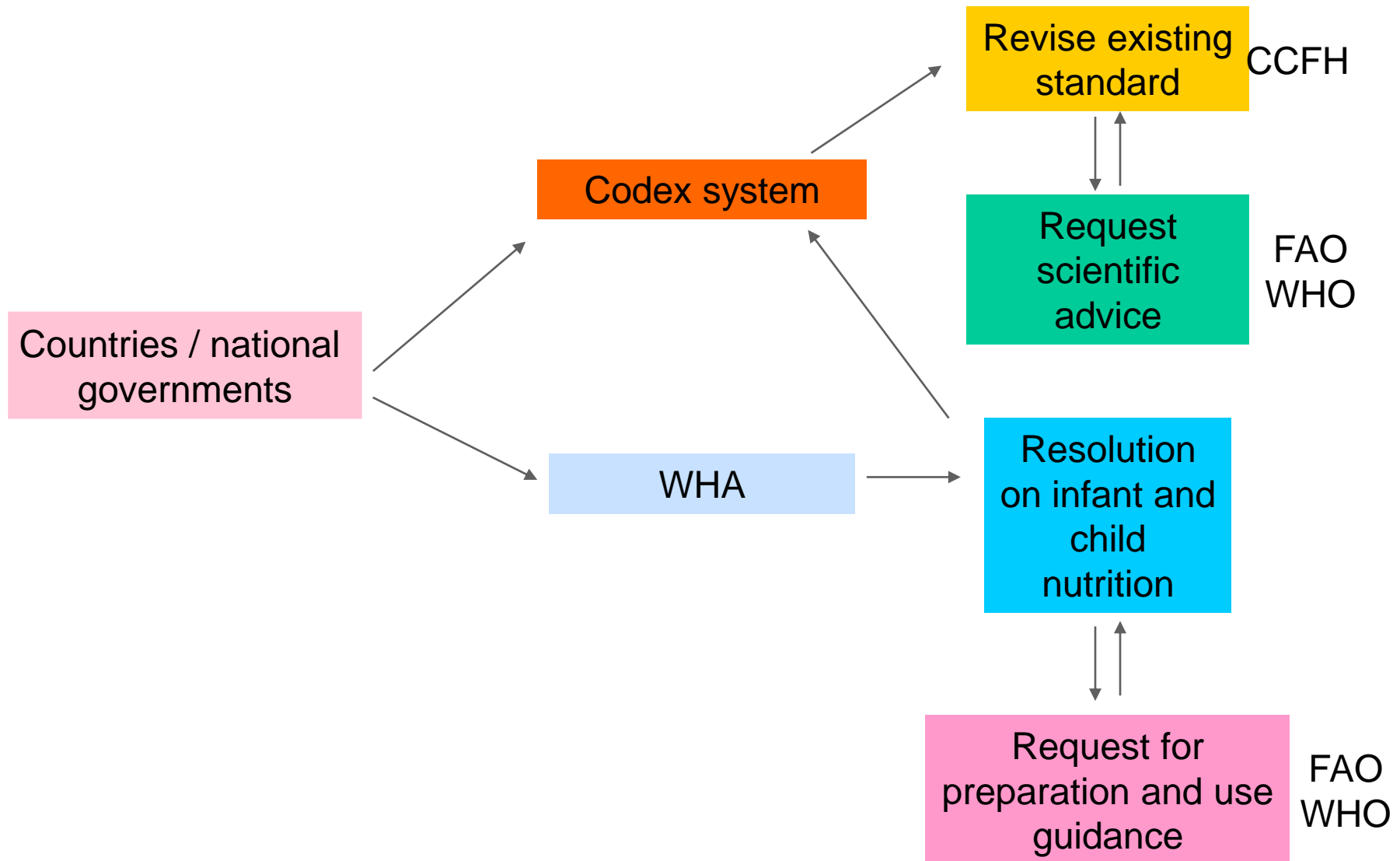
- Pathogens in powdered infant formula
- *Listeria* in Ready-to-eat foods
- *Salmonella* in undercooked chicken

***Cronobacter* spp. (*Enterobacter sakazakii*) in powdered infant formula**

- Associated with sporadic cases or small outbreaks in pre-matures/very young infants
- Primarily associated with consumption of powdered infant formula
- Causes bacteraemia or meningitis in vulnerable infants
- High mortality rate (~10 to 50%) and very delicate “at risk” consumer group



Mitigation need signaled in 2003



JEMRA & CCFH work done in 2004 - 2008

Revision of
Codex standard

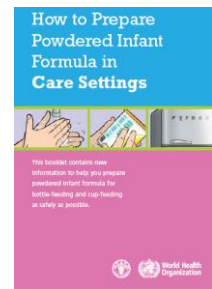
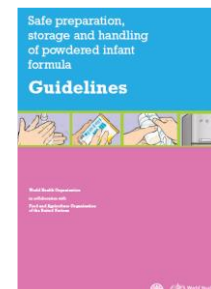


Risk Assessment



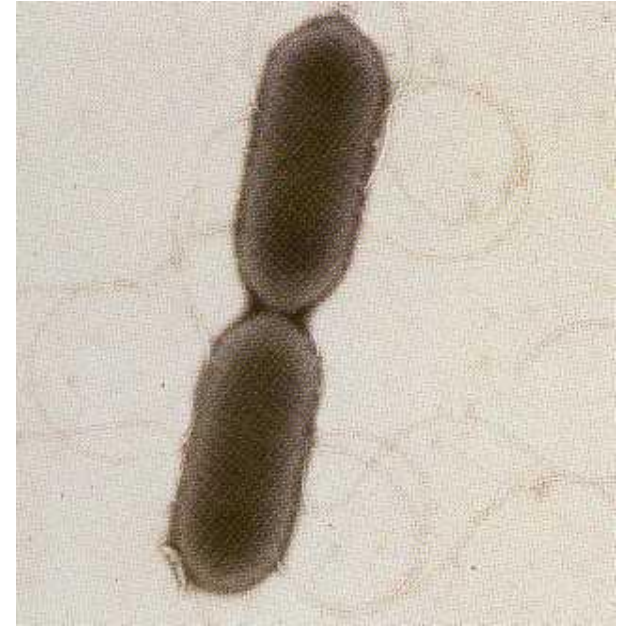
Web based risk
assessment tool

Development of
preparation and use
guidance



Listeria monocytogenes in RTE foods

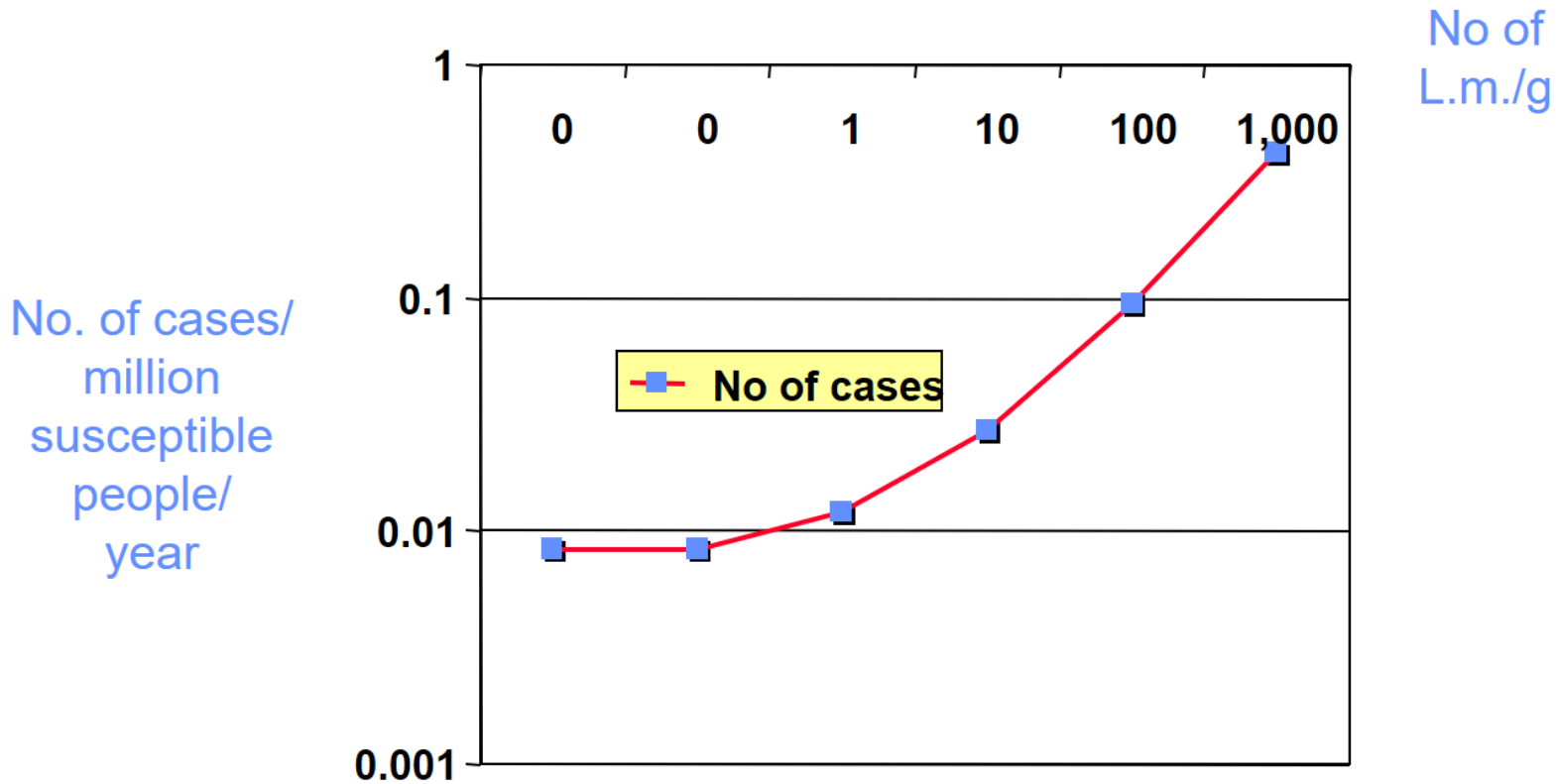
- Food-borne - can grow at chill temperatures; ubiquitous
- May cause listeriosis when present in high numbers in food consumed
- Relatively rare, but serious disease
- High-risk groups include pregnant women, newborn babies, immunocompromised
- Incidence is 0.3-10 cases per million persons in Europe, USA, Australia
- Ready-to-eat foods: no "kill-step" after manufacture until consumption



Typical foods

- Soft cheeses
- Meat products
- Smoked fish
- Deli salads

Estimated number of listeriosis cases as a consequence of contamination level*

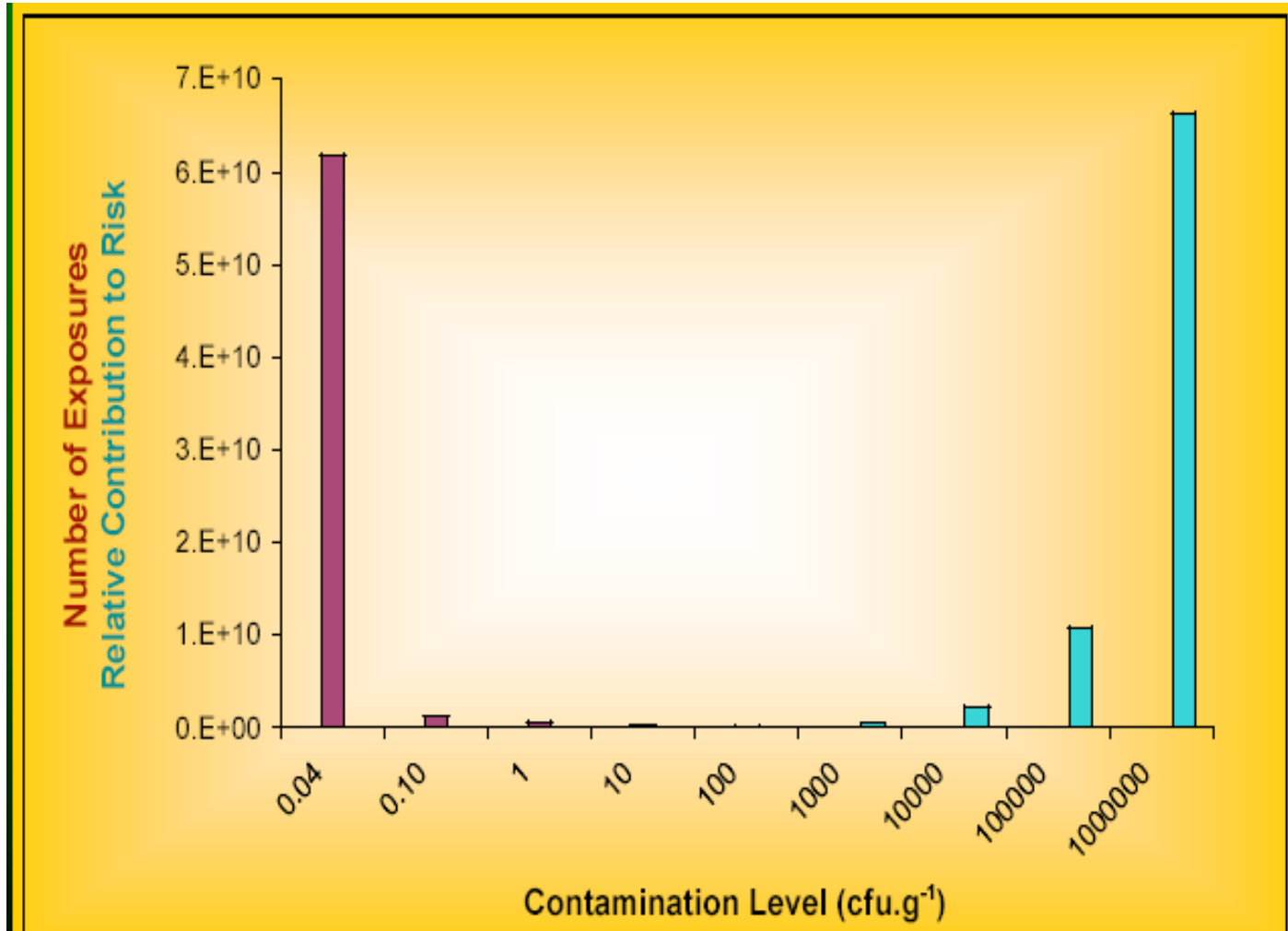


* at point of consumption



FAO/WHO MRA on *L.m.* in RTE foods

Relationship between exposure and risk



(adapted from T. Ross)

FAO/WHO MRA on *L.m.* in RTE foods

Susceptibility of sub-populations

Condition	Relative susceptibility
Transplant	2584
AIDS	865
Cancer – pulmonary	229
Diabetes	25
> 65 years old	7.5
< 65 yrs, healthy	1

FAO/WHO MRA on *L.m.* in RTE foods

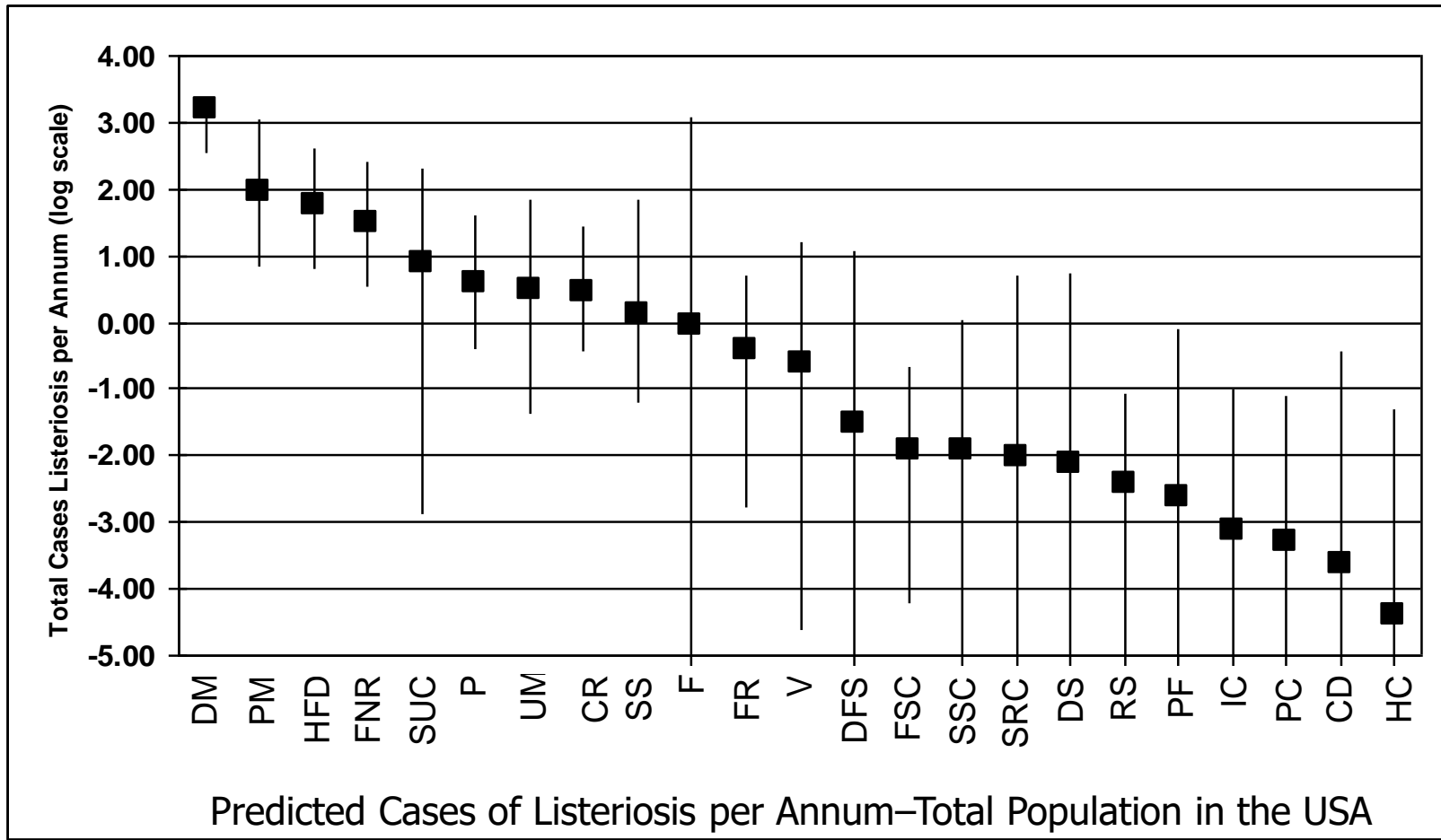
Differences in risk estimates

Food	Mean cases of listeriosis per 10 million people per year	Mean cases of listeriosis per million servings
Milk (pasteurised)	9.1	0.005
Smoked fish	1.6	0.053
Ice-cream	0.012	0.000014
Fermented meat	0.00055	0.0000021

 Highest in risk ranking

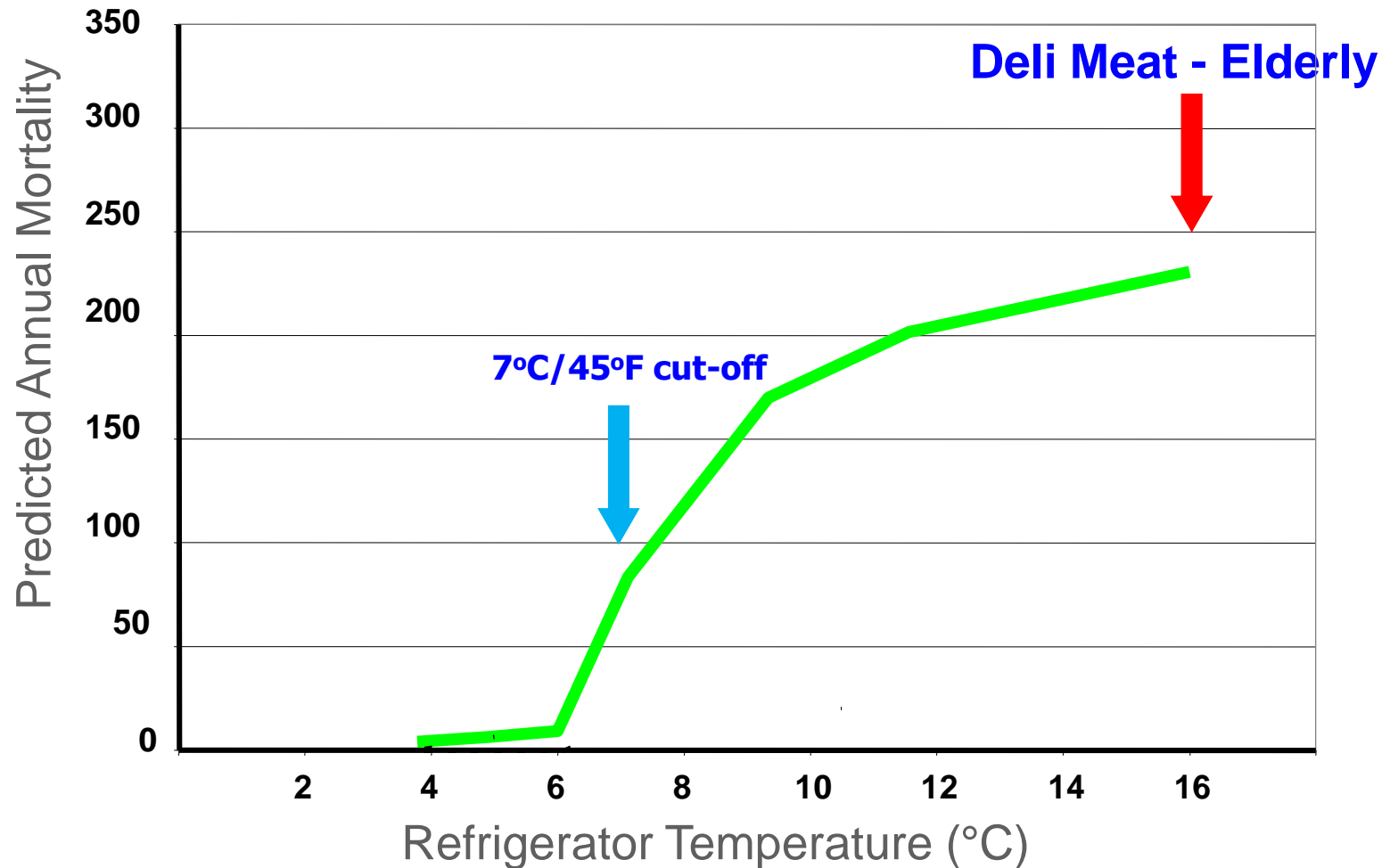
FDA/FSIS *L. monocytogenes* in RTE Foods (2003)

Relative-risk posed by different RTE products



FDA/FSIS *L. monocytogenes* in RTE Foods (2003)

Estimating effectiveness of Interventions (what if scenarios)

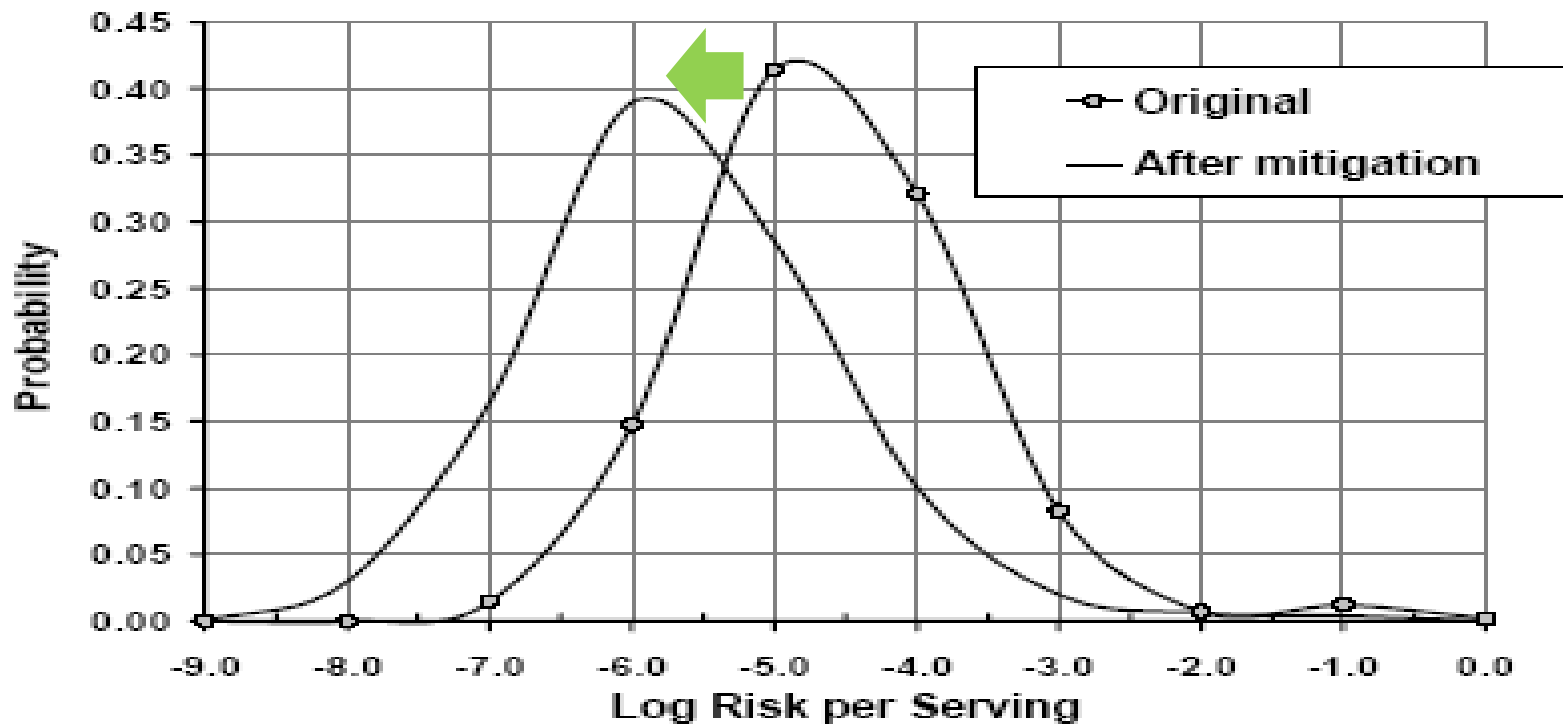




Impact of undercooking



Probability of salmonellosis before and after changing cooking practices



FAO/WHO

Government context use of MRA summary

Risk Analysis in the government context :

- Systematic / structured, transparent and open process
- Objective / based on sound science

Use of Risk Assessment in government context:

- Basis for setting public health goals, risk-based metrics
- Allows for “Informed decision-making” on risk and mitigation options

Use of MRA technology for Exposure Assessment in an Industry context

Does industry need to use Risk Assessment?

- Industry does not need to conduct risk assessments as governments do
- But, Industry needs to ensure that proper food safety management systems (FSMS based on Good Practices and HACCP-principles) are adequately implemented and executed day-by-day
- However, MRA studies may contain valuable information that can help strengthen industry's food safety management systems
 - How different control measures affect risks
 - What handling increases risks
 - Insight in critical processes
 - Insight in unintended use

Can Industry use of MRA techniques (Exposure assessment)

- Yes, examples in presentation of Judith
- Simulation tool, building on predictive modelling, in areas such as:
 - Simulating consumer safety of complex or radical product innovations
 - Evaluating whether performance standards or risk-based metrics (FSO/PO/....) are met
 - Simulating 'safe' changes to reducing heat-processing for quality improvements

Industry context use of MRA summary

Learning from Risk Assessment use by governments

- Learning about factors that increase or reduce risks

Risk Assessment / Exposure assessment

- Systematic/structured, transparent and open process
- Objective / based on sound science

Use of Risk Assessment in government context:

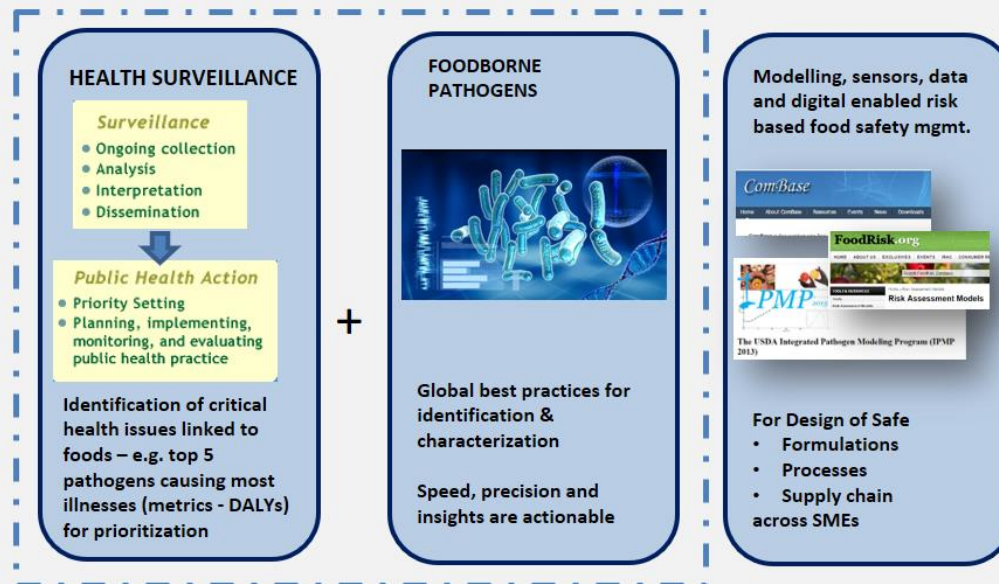
- Simulating changes in product and process design
- Establishing “safety of product design”
- Deciding on management specific measures / HACCP, FSMS

Risk Analysis Pre-requisites

- Data on pathogens & foods (surveillance; incident investigation; epidemiology) - government
- Quantitative methods/approaches for data handling/processing (e.g. Predictive modelling, Risk Assessment; etc)



Microbiological Safety of foods (2017-18): Key area of scientific capacity building



Questions?