EU-FORA Fellowship Programme

Risk Assessment for Food Safety – an introduction

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UNIVERSITÀ DEGLI STUDI DI PERUGIA

UNIVERSITY OF CRETE

Outline

EU-FORA Fellowship Programme

- Burden of foodborne disease
- EU Regulations and the establishment of EFSA
- Hazard and Risk – what is the difference?
- The three elements of Risk Analysis
- Steps in Food Safety Risk Assessment

Material in this presentation is derived from the 2018 EU-FORA Induction Training Programm and other sources

Foodborne disease (food poisoning)

WHO:

“a disease of infectious or toxic nature, caused by, or thought to be caused by, the consumption of food and water”

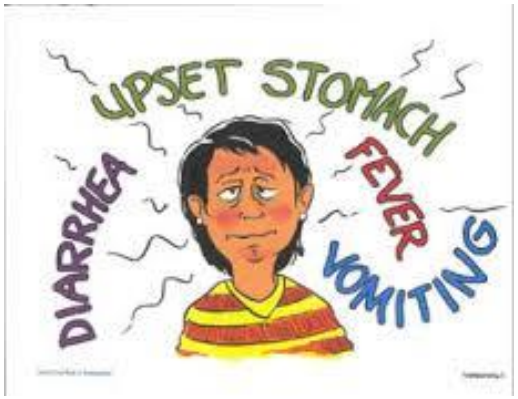
a large (> 40) and diverse range of agents

Sources:

- Domestic and wild animals
- Human origin (Enteroviruses, Salmonella typhi and Vibrio cholera)
- Environment (Clostridium botulinum, Bacillus spp., and mycotoxigenic molds)

Symptoms:

- acute gastroenteritis
- nonintestinal symptoms




WHO ESTIMATES OF THE GLOBAL BURDEN OF FOODBORNE DISEASES
The burden of foodborne diseases is substantial
Every year foodborne diseases cause:
almost
in 10
people to fall ill
33 million
healthy life years lost
Foodborne diseases can be deadly, especially in children <5
420 000
deaths
Children account for
1/3
of deaths from foodborne diseases
FOODBORNE DISEASES ARE PREVENTABLE.
EVERYONE HAS A ROLE TO PLAY.
For more information: www.who.int/foodsafety
#SafeFood
Source: WHO Estimates of the Global Burden of Foodborne Diseases, 2015.
World Health Organization

Foodborne diseases in the WHO European Region

WHO ESTIMATES OF THE GLOBAL BURDEN OF FOODBORNE DISEASES

Every year

23 million people fall **ill**

5 000 people **die**

Diarrhoeal diseases are responsible for most foodborne illnesses

Norovirus infection = almost 15 million cases

***Campylobacter* = nearly 5 million cases**

FOODBORNE DISEASES ARE PREVENTABLE.
EVERYONE HAS A ROLE TO PLAY.

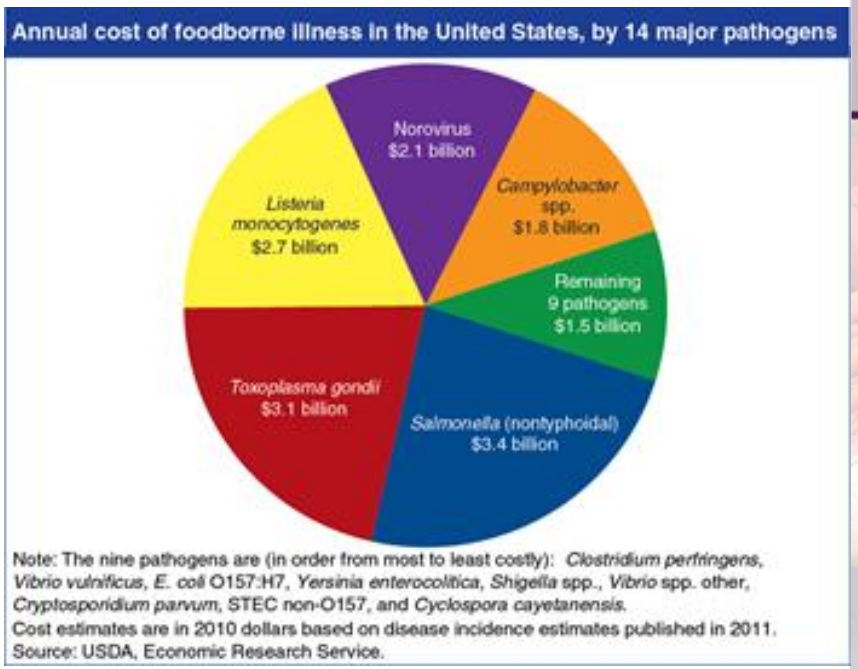
For more information: **www.who.int/foodsafety**

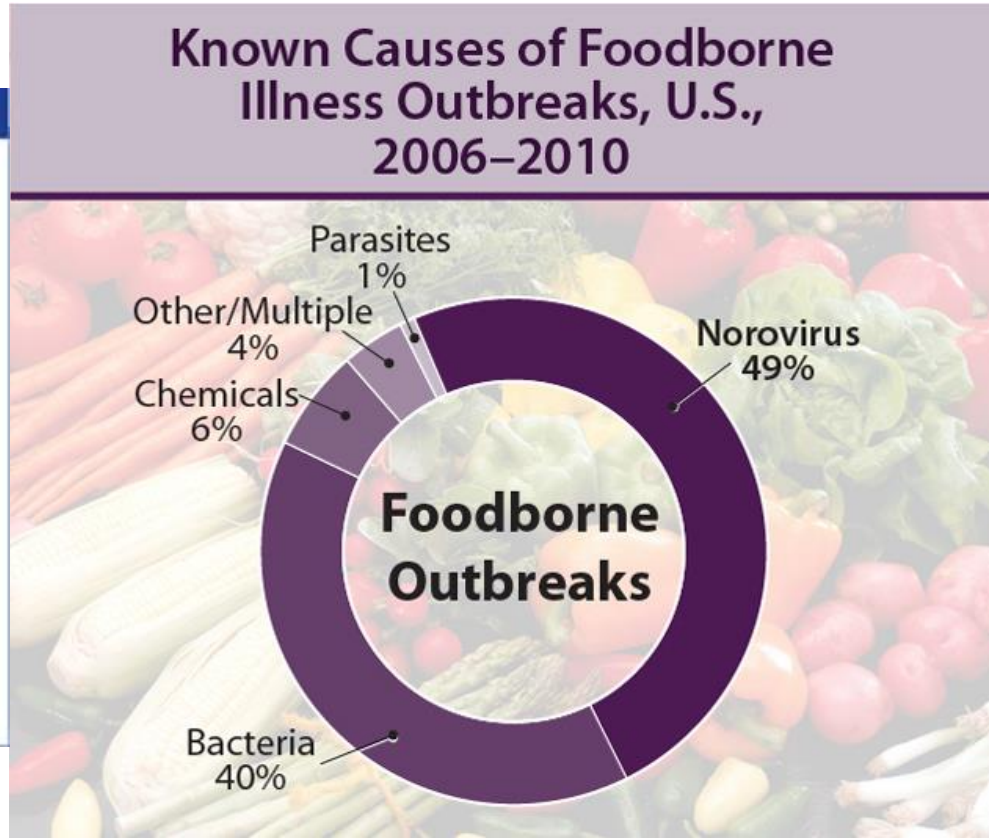
#SafeFood

Source: WHO Estimates of the Global Burden of Foodborne Diseases. 2015.

World Health Organization

USA Data – Causes and Annual Cost





https://www.cdc.gov/features/dsnorovirus/figure3.html

Each year, microbial pathogens cause an estimated 76 million cases of foodborne illness, including 5200 deaths in the USA.

Mead *et al*., Centers for Disease Control and Prevention (CDC).

EU Data – Ranking of illness and burden

Rank	Illnesses	Rank	DALYs
1.	Norovirus	1.	Non-typhoid *Salmonella* spp
2.	*Campylobacter* spp	2.	*Campylobacter* spp
3.	Non-typhoid *Salmonella* spp	3.	*Toxoplasma gondii*
4.	*Toxoplasma gondii*	4.	Norovirus
5.	*Giardia* spp	5.	*Listeria monocytogenes*
6.	*Cryptosporidium* spp	6.	Dioxin
7.	Shiga toxin-producing *E.coli*	7.	*Brucella* spp
8.	Hepatitis A virus	8.	Hepatitis A virus
9.	*Ascaris* spp	9.	*Echinococcus multilocularis*
10.	Enterpathogenic *E.coli*	10.	*Mycobacterium bovis*

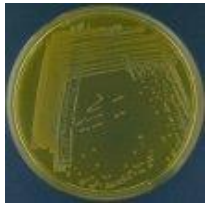
http://www.euro.who.int/__data/assets/pdf_file/0003/295248/Presentation-DrKruse-FERG-event-Cph-031215.pdf

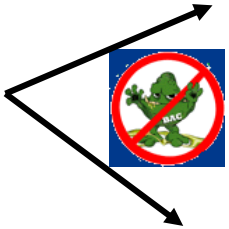
Traditional Food Safety Management

End Product Sampling and Testing

Is the product

safe?





Yes

No

Food Safety

Qualitative (Discrete) variable

Available online at www.sciencedirect.com

ScienceDirect

Current Opinion in Food Science

Moving towards a risk-based food safety management

Konstantinos P Koutsoumanis and Zafiro Aspridou

Classical hazard-based approaches to food safety relying heavily on regulatory inspection and sampling regimes cannot sufficiently ensure consumer protection. It is now generally accepted that a modern food safety management system should link the hazards to public health and be based on prevention rather than end product testing and control. The last decade food safety management at international level has been moved towards a more risk-based approach to food safety control with regulators around the world adopting the risk analysis framework as the basis for their decision-making. This review paper presents an overview of the structure and function of a risk based food safety management and the interaction between risk managers, risk assessors and stakeholders.

Address
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(WTO) suggested for the first time, in the mid-1990s, a risk assessment basis for food safety. SPS Agreement introduced the term 'appropriate level of health protection' (ALOP) as the 'Level of protection deemed appropriate by the member (country) establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory'. With ALOP, WTO changed the question 'is the food safe?' to 'what is the level of product safety?' and transformed food safety from a discrete (safe/unsafe) to a continuous (risk) variable recognizing that 100% safety (or zero risk) does not exist. The European Commission followed with Regulation (EC) 178/2002 which clearly states that food safety should generally be founded on science using the Risk Analysis framework [2]. In 2003, the Codex Alimentarius Commission adopted the Principles for Food Safety and Risk Analysis to be used in the Codex framework. During the last decade, considerable progress has been made in developing a framework and principles for risk analysis with many guidance documents for the application of risk management and risk assessment by governments [3–6].

"Food Safety should be founded on science using the Risk Analysis framework"

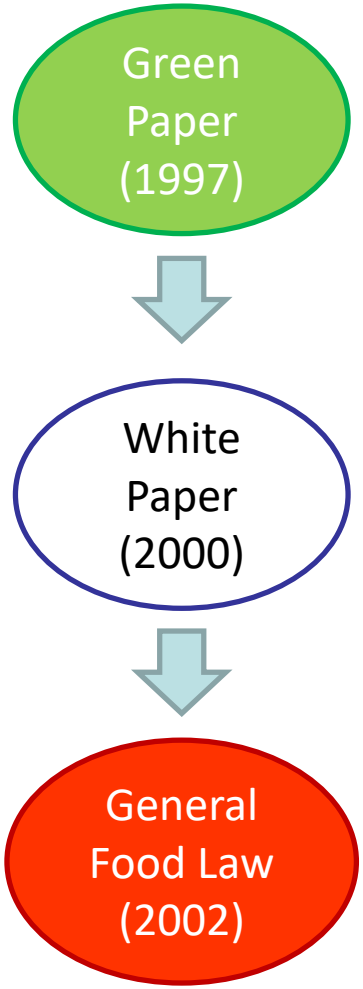
Regulation (EC) 178/2002 and the Establishment of EFSA

General principles

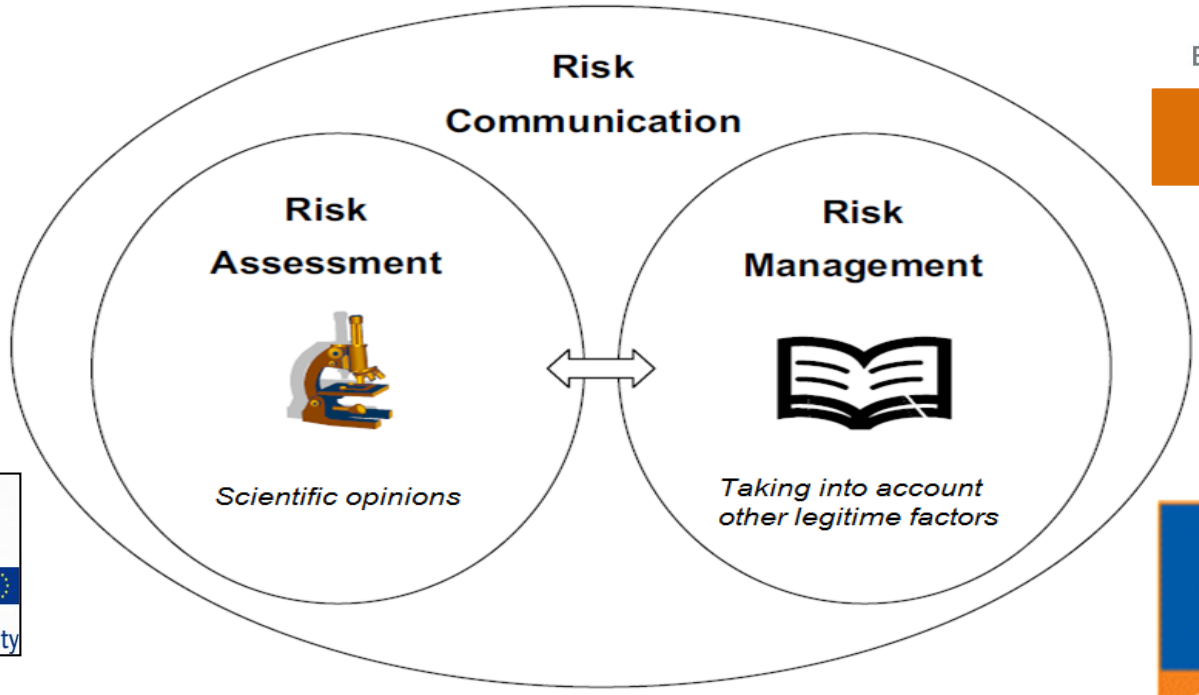
- Objectives
  - High level of protection of human life and health
  - Protection of consumers' interests
  - EU-wide free movement of human food and animal feed
  - Consideration of existing or planned international standards
- **Risk analysis principle**
- Precautionary principle
- Protection of consumers' interests
- Principles of transparency

Integrated approach – through whole food chain

Setting up the European Food Safety Authority



Risk Analysis Principle at EU level



European Parliament

EU Parliament

Member States

EU Commission

efsa
European Food Safety Authority

"In order for there to be confidence in the scientific basis for food law, **risk assessments** should be undertaken in an **independent, objective and transparent** manner, **on the basis of the available scientific information and data.**"

What is the role of EFSA?

How does it work?

EU Commission

EU Parliament

Member States

EFSA self mandate

EFSA receives a question

EFSA's scientists evaluate, assess, advise

Adoption and communication

EFSA AT A GLANCE

> **450** staff

> **1,500** experts

1,000 meetings/year

20% tele-meetings

5,000 outputs /
500 a year

ESTABLISHED

2002

https://www.youtube.com/watch?v=KSluc9igxkA

http://www.efsa.europa.eu/

Hazard vs Risk – what is the difference?

Are Hazard and Risk the same thing?

The following video shall explain the difference betweend a hazard and a risk.

https://www.youtube.com/watch?v=PZmNZi8bon8

Concepts: Hazard vs Risk

- **Hazard:**

Something that has the potential to have negative effect on our health. We call that negative effect unwanted outcome.

- **Hazard:**

A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect (*Codex Alimentarius Commission*)

A condition or physical situation with a potential for an undesirable consequence (*Society for Risk Analysis*)

Types of hazards in food

Biological hazards

Bacteria (and their toxins), Viruses, Parasites, Yeasts, Moulds, Prions

Chemical hazards

Toxins, Environmental contaminants (metals, dioxins and polychlorinated biphenyls), Food additives (e.g. Sodium nitrate), Processing-induced contaminants (e.g. Acrylamide), Pesticides, Veterinary drugs, Disinfectant agents

Physical hazards

Bone fragments, fruit pits, glass, plastic

Allergens

Mostly protein compiunds in milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soya

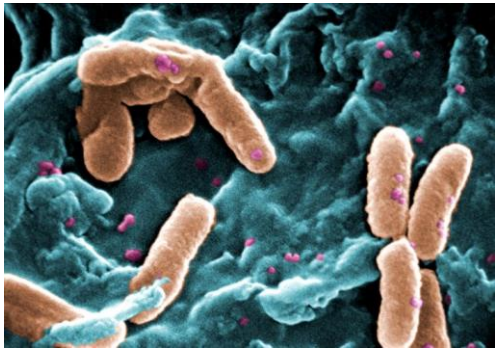


Image Source: https://pixabay.com

Image Source: https://pixabay.com

Concepts: Hazard vs Risk

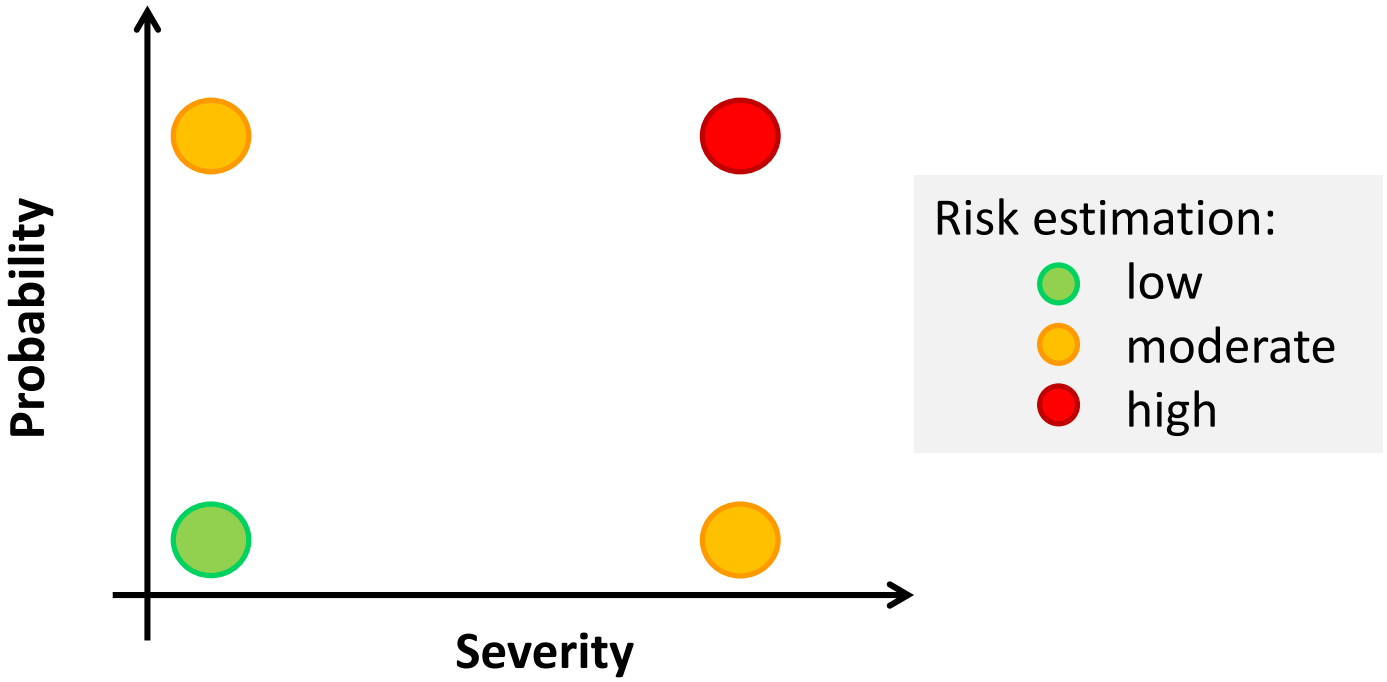
Risk:

- a situation involving exposure to danger
- the possibility that something unpleasant will happen

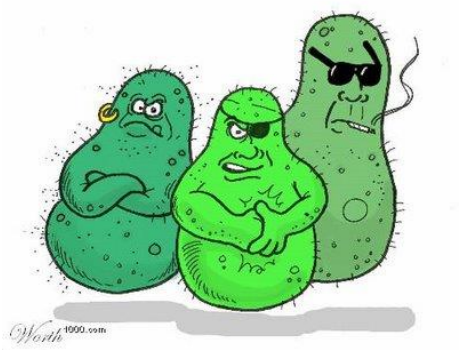
(*Compact Oxford English Dictionary of Current English*)

Risk:

- A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food. (*Codex Alimentarius Commission – CAC*)



Risk Factors



Risk of suffering a foodborne illness

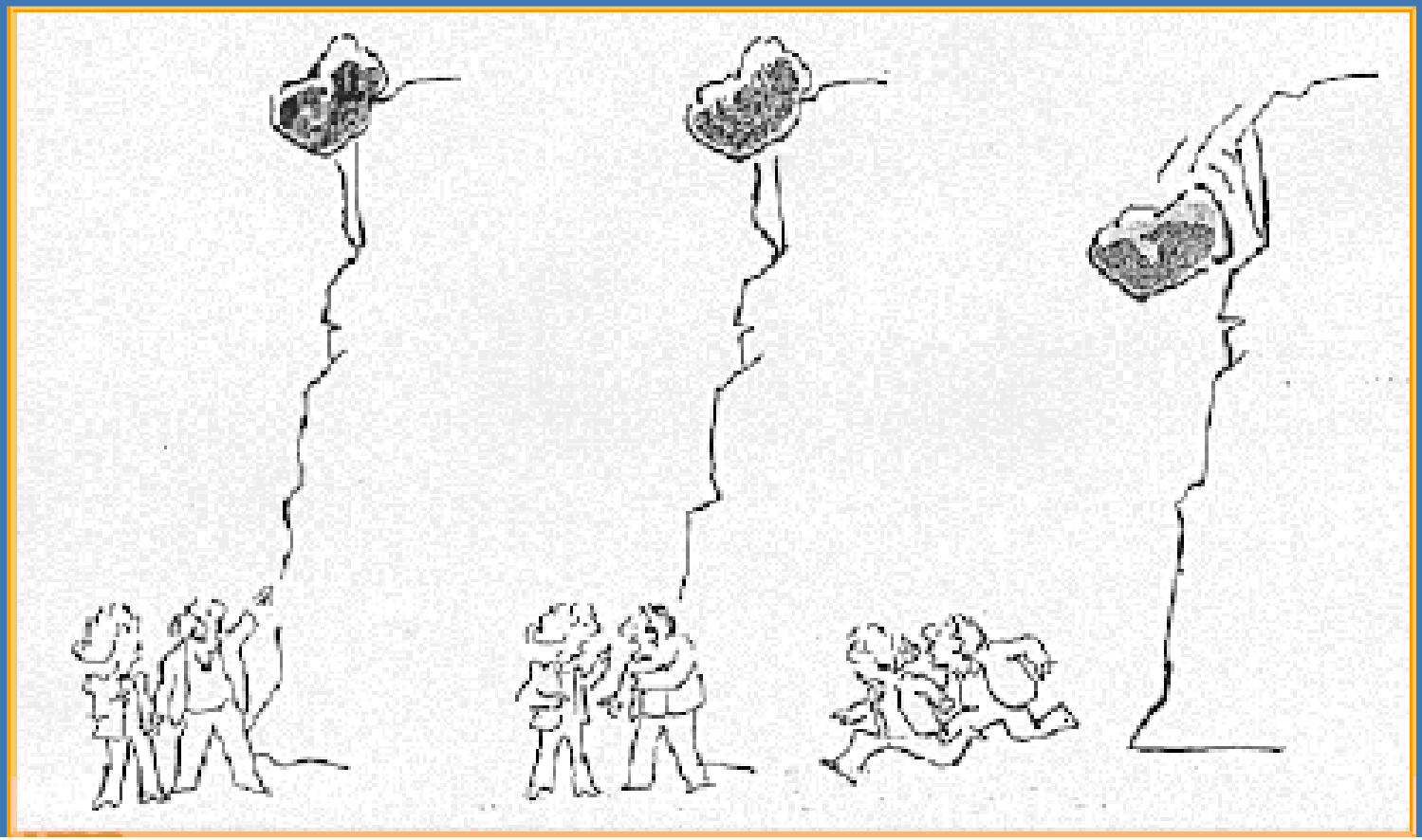
The factors that are influencing or are associated with the risk of causing adverse effects (e.g. Infection) in specific subpopulations vary from person to person and from case to case

Sources: pic1 http://www.mackayhannah.com/conferences/care-of-vulnerable-people-in-scotland; pic2 http://www.thegrocer.co.uk/buying-and-supplying/food-safety/rotten-produce-prosecution-for-bradford-shopkeeper/518888.article; pic 3 http://www.healthyfoodhome.com/washing-fruits-and-vegetables/; pic 4 http://symbolsnet.com/symbols/cooking-symbol.html; pic 5 worth1000.com

The three elements of Risk Analysis

Risk Assessment is a component of Risk Analysis (WHO/FAO, 1995):

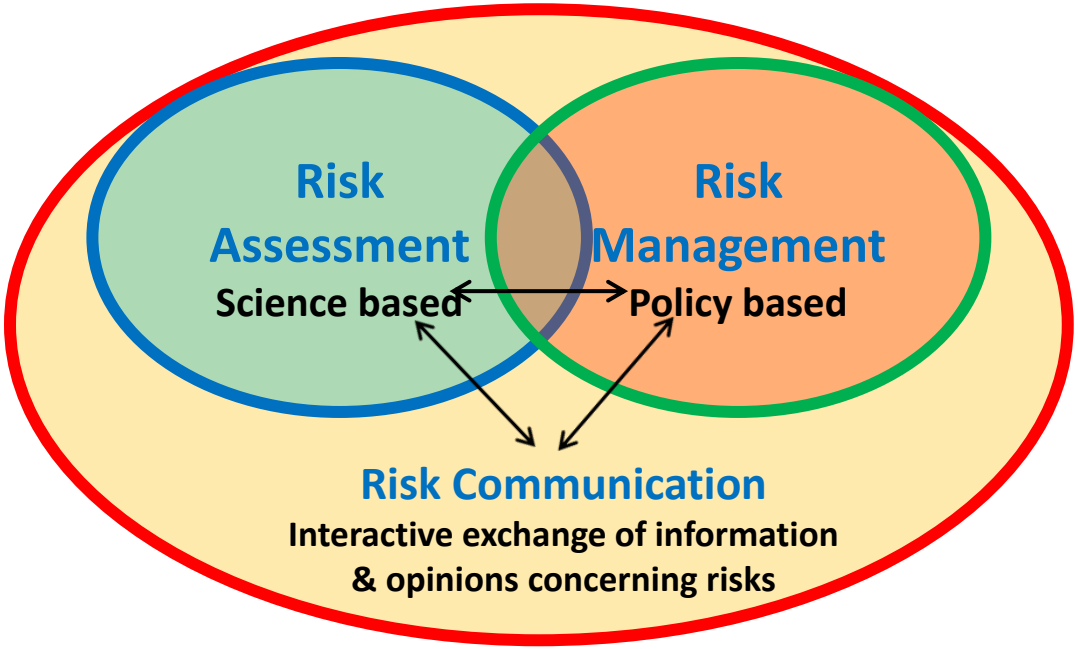
Risk Assessment | **Risk Communication** | **Risk Management**



The three elements of Risk Analysis

Risk Analysis

Risk assessment (RA) aims to estimate the **probability of harm** resulting from **human exposure to hazards** present in foods



Risk management (RM) is about **dealing with risk.**

RM is informed by risk assessment

RM takes into account factors such as

- Economics
- Legislation
- Politics

Risk analysis is not an absolute science. It is influenced by social, political and – sometimes – religious norms.

Framing the Risk Question

- ✓ Hazard (e.g EHEC, mercury in fish, nitrites as food additives)
- ✓ What is the Purpose of risk assessment?
- ✓ Appropriate risk assessment question
- ✓ Risk assessment team composition

Define a Risk assessement question e.g

Risk of infection due to *E. coli* in ground beef for small children

Risk Assessment Pathway

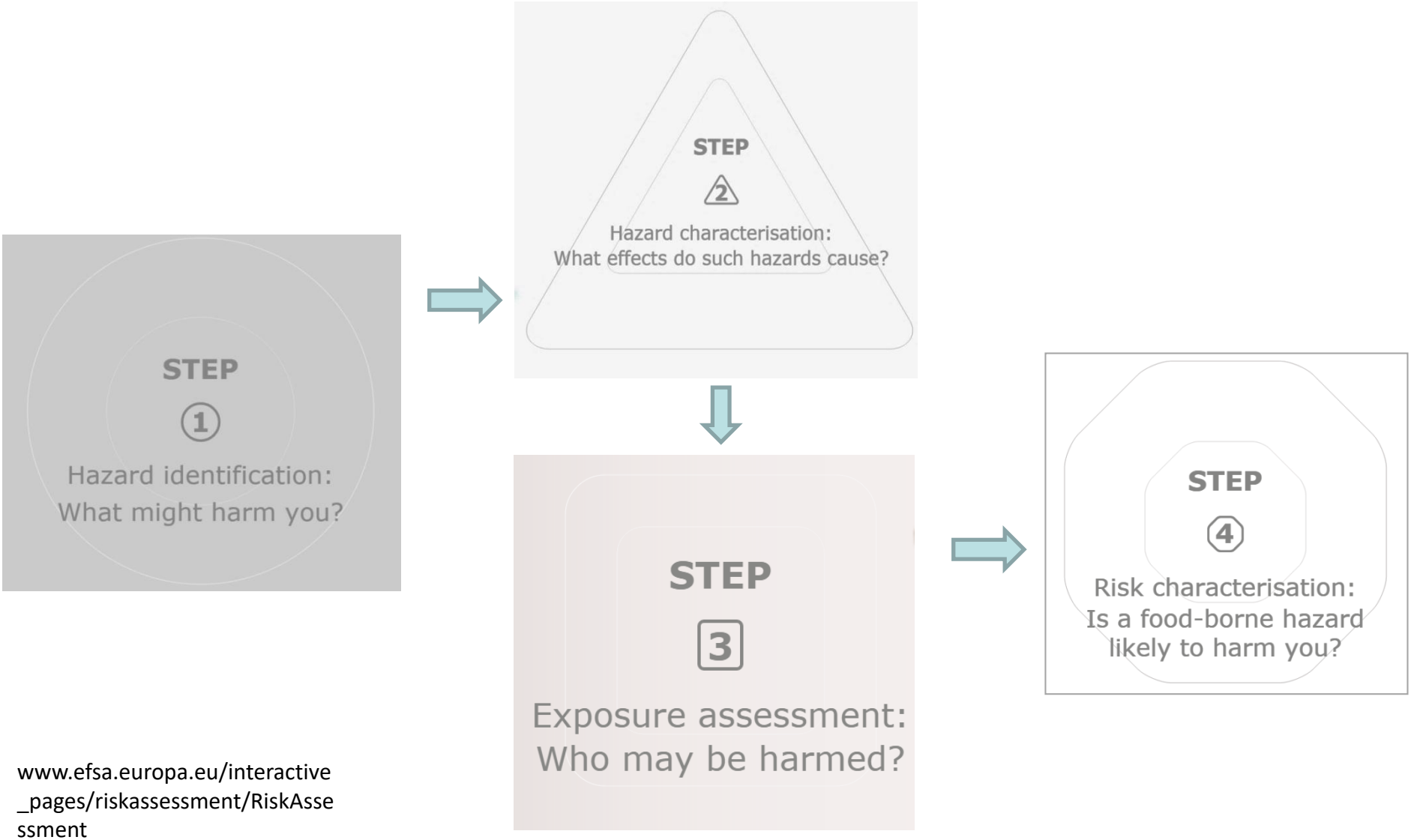
Risk estimate

- What do you need to know/investigate to answer your question?

The EFSA Model

1. HAZARD IDENTIFICATION
2. HAZARD CHARACTERIZATION
3. EXPOSURE ASSESMENT
4. RISK CHARACTERIZATION

The 4 steps in Risk Assesment



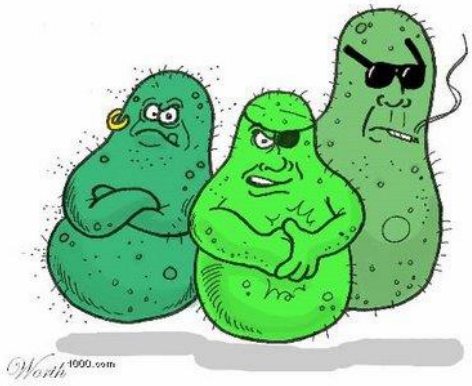
www.efsa.europa.eu/interactive_pages/riskassessment/RiskAssessment

The 4 steps in Risk Assesment

1. Hazard identification

«What might harm you?»

e.g. a biological, chemical or physical hazard



The hazard identification is a **qualitative process that involves the collection and evaluation of all available epidemiological data and all information on behavior of the hazard in the food, the effect of various factors and the pathogenesis**. The source of these data are from scientific papers, databases from inspection, epidemiological studies and laboratory animal studies.

Image Source: https://es.sott.net/article/4422-Las-resistencias-bacterianas-ponen-en-peligro-la-eficacia-de-muchos-antibioticos

The 4 steps in Risk Assesment

2. Hazard characterization

«What effects do such hazards have?»

HC describes the **nature, severity and duration of adverse health effect** from ingestion of the microbial hazard. It aims also to develop a **dose-response relationship** between the amount of bacteria / toxin that people ingest and the likelihood that they will become ill.

- controlled clinical studies
- disease outbreaks
- animal trails

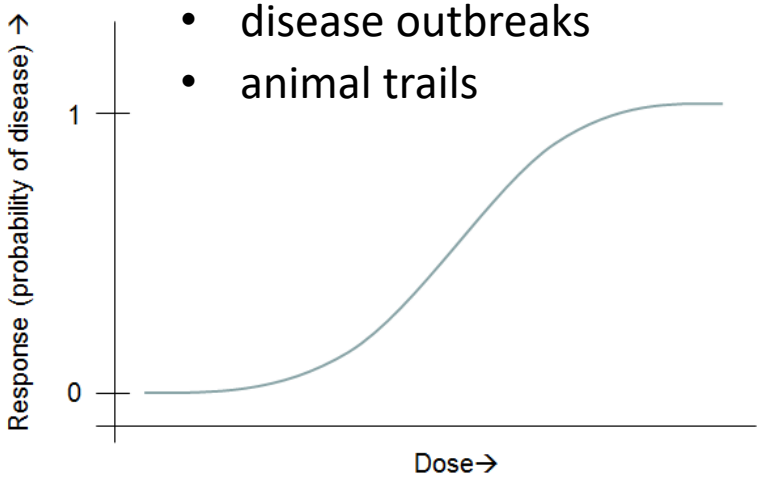
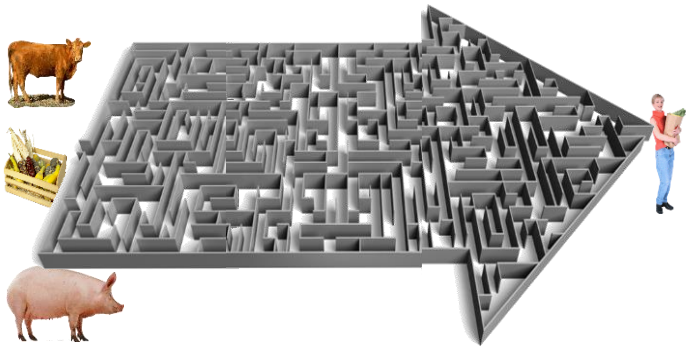


Image source: http://www.mackayhannah.com/conferences/care-of-vulnerable-people-in-scotland

The 4 steps in Risk Assesment

3. Exposure assessment

«Who may be exposed and thus affected? How high is the exposure?»



Exposure assessment determines the likelihood that an individual (or population) will be exposed to a hazard and the quantity/numbers likely to be ingested. (e.g. Colony forming Units (CFU's) per serving)

Which Data are needed ?

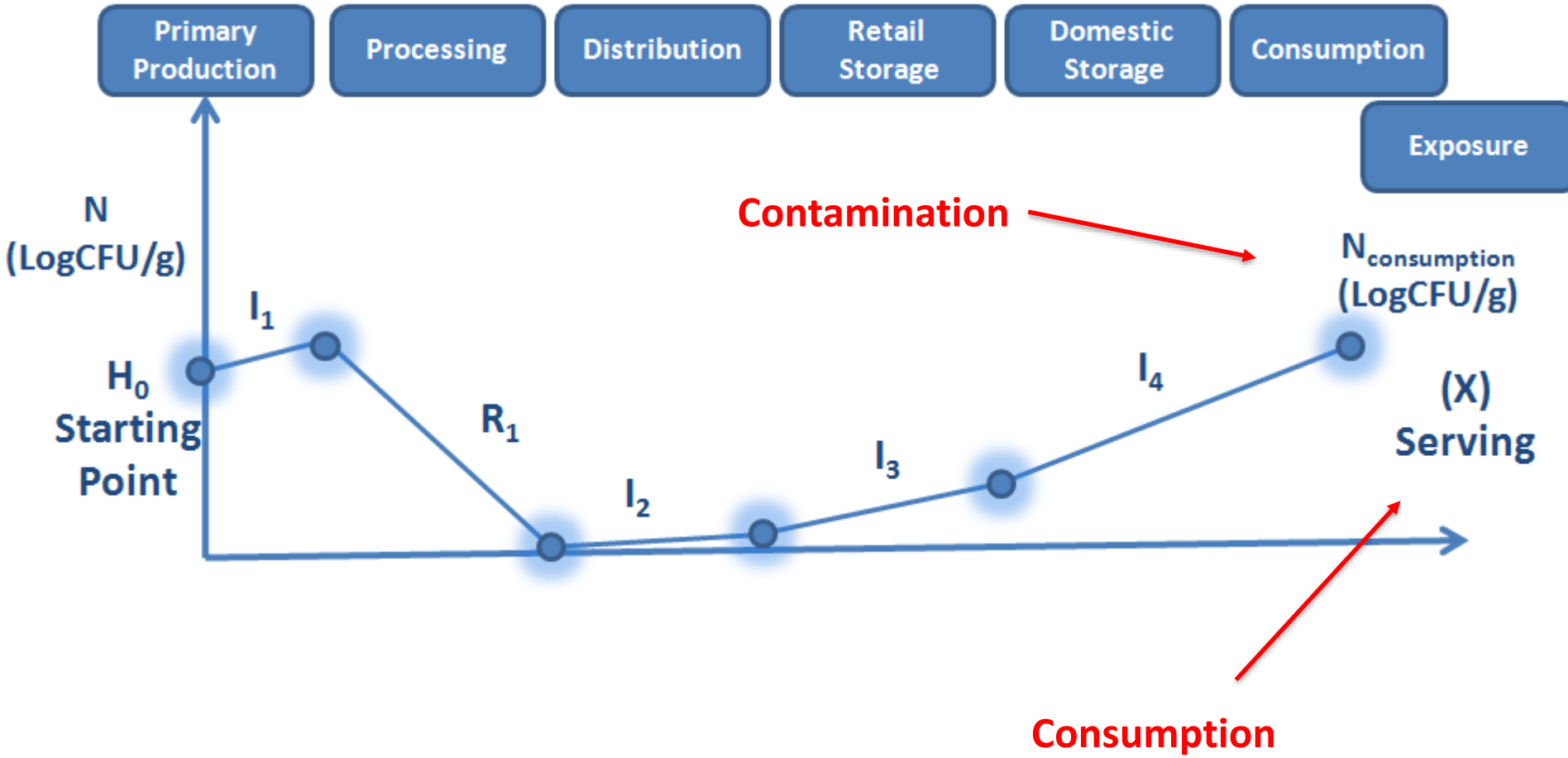
- **The amount and frequency of consumption of each food**
- **The prevalence or concentration of the pathogen/chemical present in the food**

Exp = f(Consumption; Contamination)

Image Source: http://en.engormix.com/feed-machinery/articles/food-safety-supply-present-t39328.htm

The 4 steps in Risk Assesment

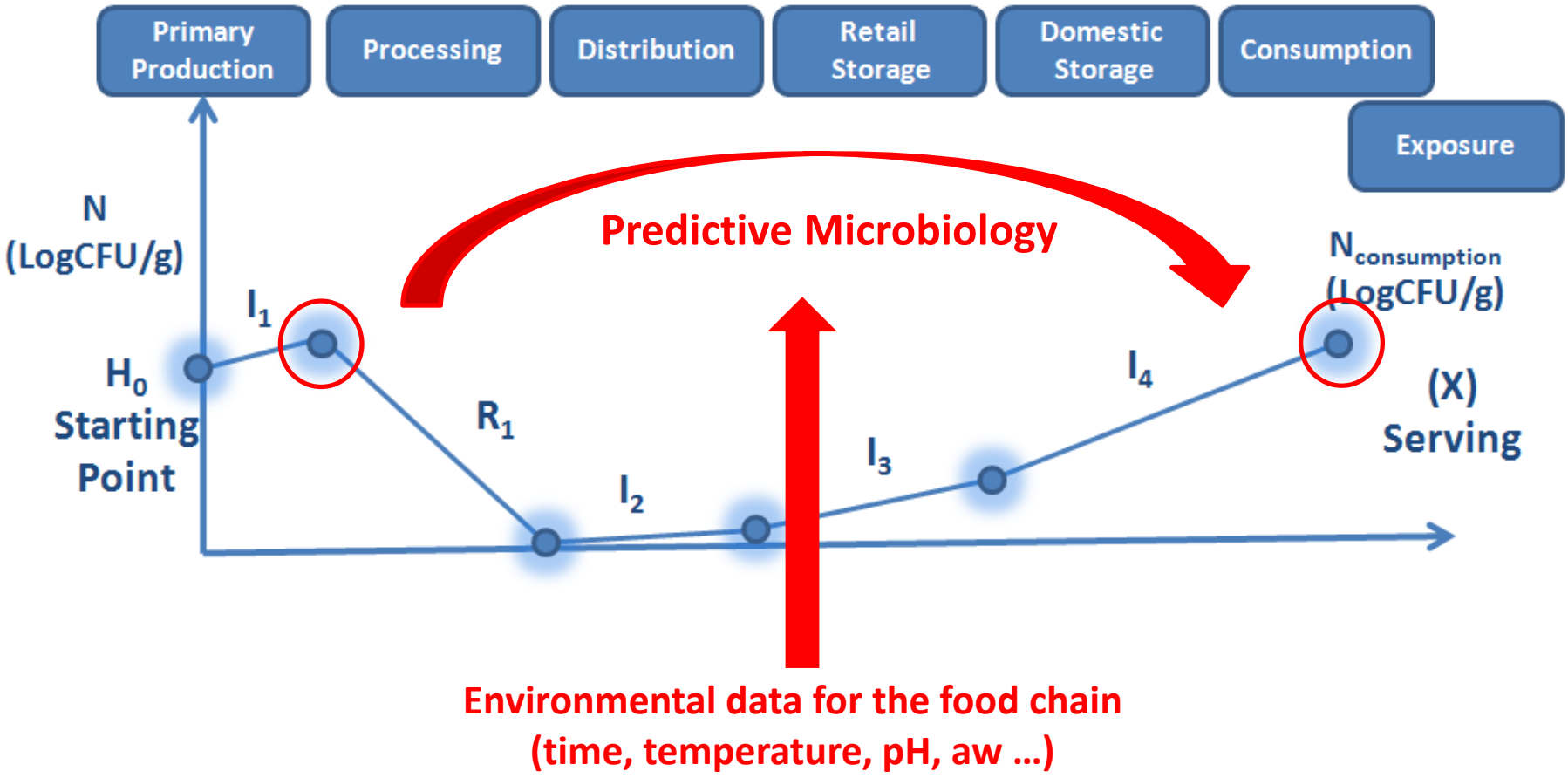
3. Exposure assessment – the pathway in MRA



Can you identify any possible difficulties in the pathway?

The 4 steps in Risk Assesment

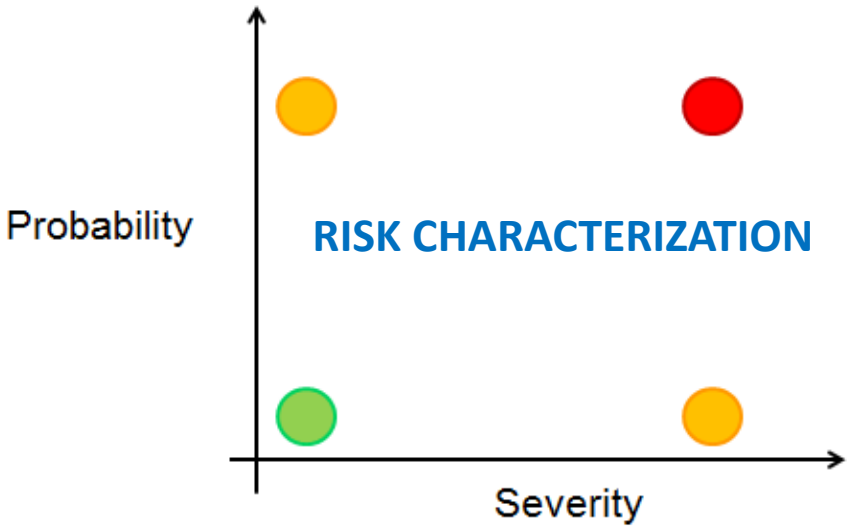
3. Exposure assessment – tools



The 4 steps in Risk Assesment

4. Risk characterization

«Is a foodborne hazard likely to cause harm?»



1. HAZARD IDENTIFICATION
2. HAZARD CHARACTERIZATION
3. EXPOSURE ASSESMENT

Quantitative (10%, 20%, 90%...)
Qualitative risk (unlikely, likely...)

Hmm...
Can the Risk be zero?

100% Safety (zero risk) does not exists and should not be expected

The output of Risk Assessment

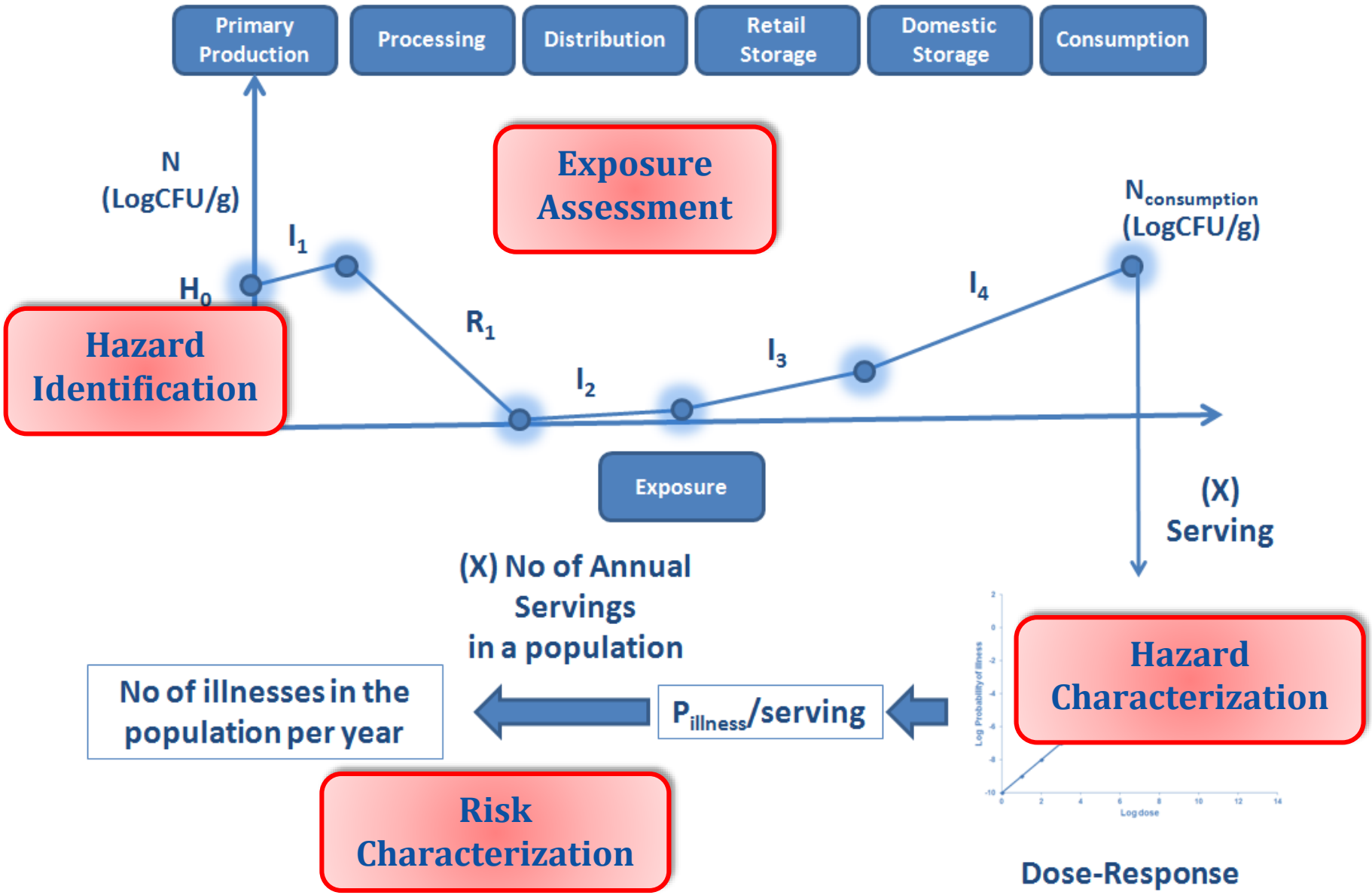
is a probability (Risk)

e.g 10^{-6}

e.g in QMRA:

Number of cases of (a certain) illness per year per (e.g.) 100.000 persons in a given population caused by a certain micro-organism or group of microorganisms in a particular food or food type

Risk Assesment Infograph



Further Remarks: Chemical *vs* Microbial RA

Chemical

- Effects have long latency periods or may be poorly established particularly at low doses
- **No multiplying**
- Bioaccumulation, bioconcentration, remobilization and transformations
- Consideration of body weight, age, and metabolic capacity differences

Microbial

- Effects have short latency periods and may have acute symptoms even at low doses
- **Growth/survival/death in food and in hosts**
- Interaction between food, host and pathogen
- Host immunity and susceptibility influences the onset of an infection

Challenges in Risk Assesment

- Technical, scientific methods are used BUT:
- Most risk assessments use **some kind of model**.
  - Different scenarios of risk management can be explored
  - Models
    - Are simplifications of reality
    - need data to inform them
    - will always have limitations
    - But they are all we have and can be useful if “handled with care”

- Risk assessment is about “predicting” the future. As we do not know the future, there will always be **uncertainty**
  - Uncertainty needs to be reduced as much as possible
  - Residual uncertainty needs to be acknowledged and taken into account in decision making and communication

https://www.youtube.com/watch?v=ToPrATT-ISo&index=3&list=PL77B6F5984D1D92AE

Take Home Message

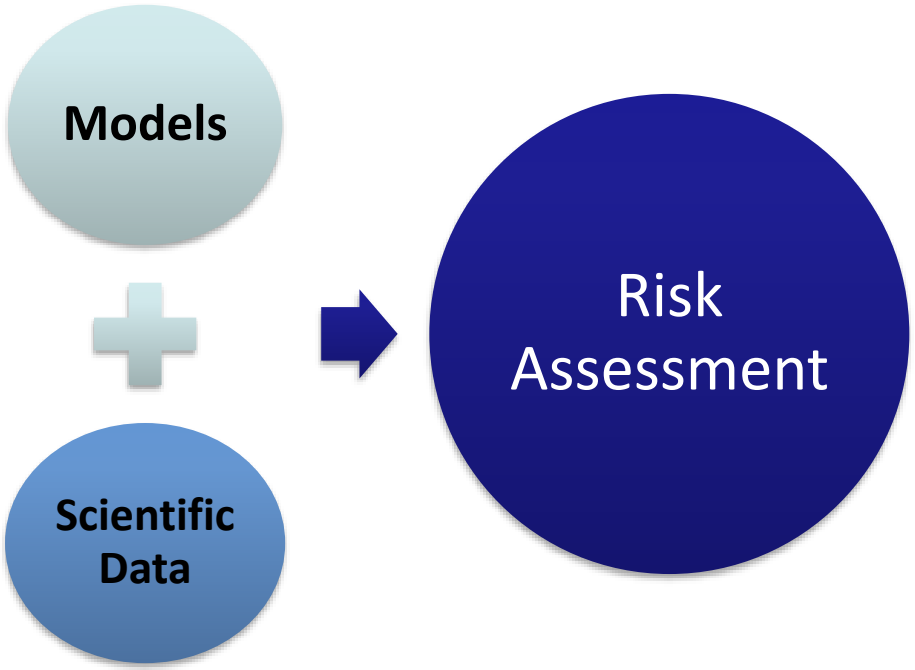
Moving towards a Risk-based food safety management system

Food Safety should be founded on SCIENCE using the Risk Analysis framework

Risk assessment is the technical, scientific part.

As it is about predicting the future, **mathematical models** of reality are needed to describe and sometimes quantify the probability of harm and the consequences.

Uncertainty needs to be acknowledged and taken into account in decision making and communication



Risk Assessment helps to keep Risk Management flexible by assessing different scenarios

Grazie!
Thank you!