Overview on the development of a risk ranking framework and toolbox for the EFSA Panel on Biological Hazards

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Outline

EFSA mission

BIOHAZ opinion on risk ranking framework

Elements of the Risk Ranking framework

EFSA current activity on risk ranking

2002: Re-casting of EU food safety system and policy

- Food scares (e.g. BSE, dioxins)
- Loss of consumer confidence
- Loss of confidence in EU food trade
- Damaged trust in public authorities
- Creation of national food agencies

As European veterinary experts met yesterday to discuss easing the ban on British beef, the Consumers' Association issued a report claiming the Government had failed to put consumers first in the BSE crisis. Have people been misled? Today, CHRIS ELLIOTT reports on how a Mid-Anglian scientist is attempting to put the crisis in perspective — by launching a crusade to banish misinformation about it.

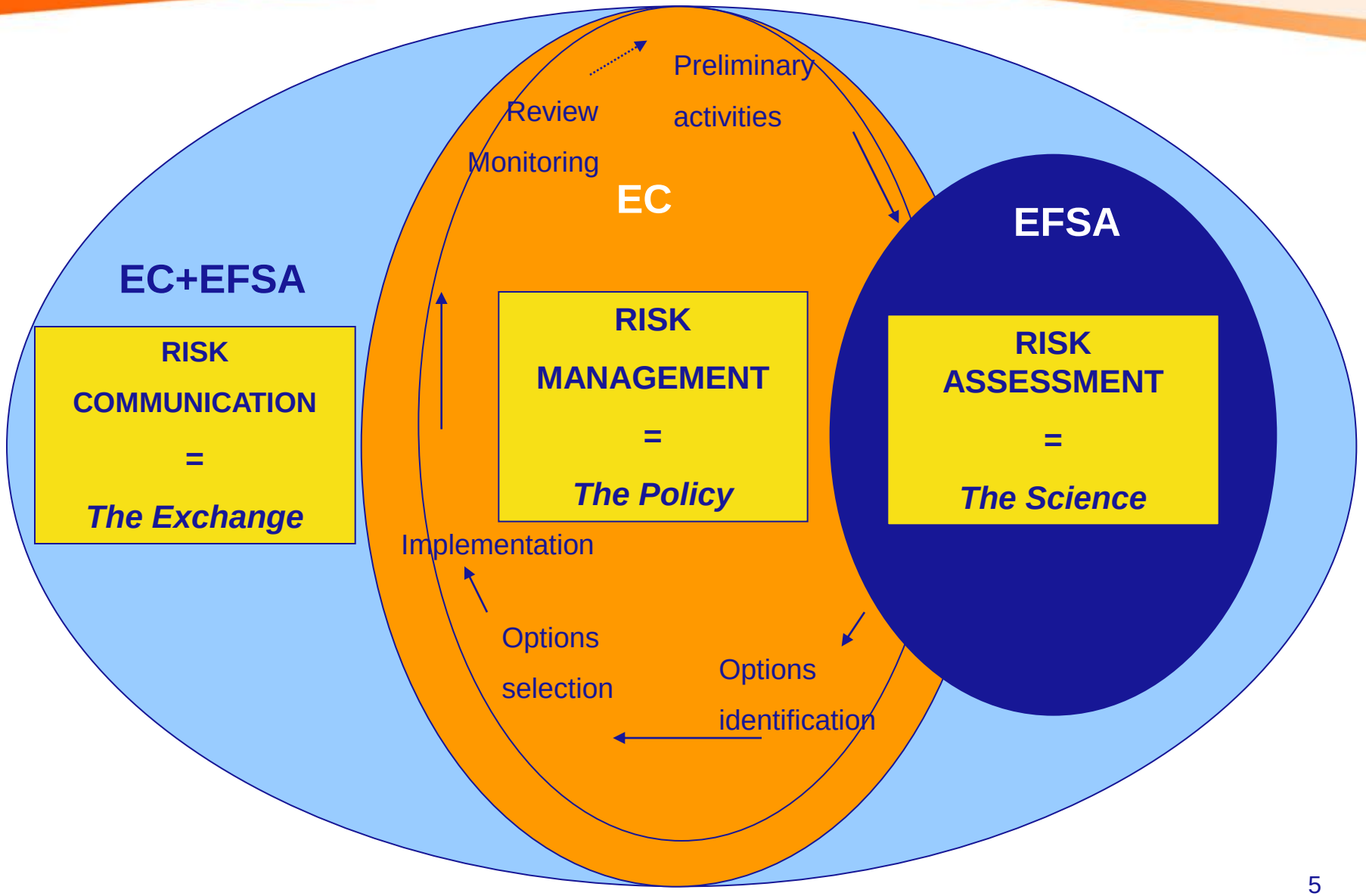
Public just want truth about BSE says expert

EFSA as independent source of scientific advice and communication

EFSA's mission

- Keystone of European Union (EU) risk assessment (RA) regarding food and feed safety
- independent scientific advice and clear communication on existing and emerging risks
- Supports the European Commission, European Parliament and EU Member States in taking effective and timely risk management decisions
- Remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health
- In close collaboration with national authorities and in open consultation with its stakeholders

CODEX Risk Analysis paradigm (CAC, 2001)



HOW: From the “question” to the “answer”

European Commission

European Parliament

Member States

EFSA (“self tasking”)

Question?

European Food Safety Authority

Risk Assessment

Opinion

Risk Management

Consumers

Media

Industry

Professionals

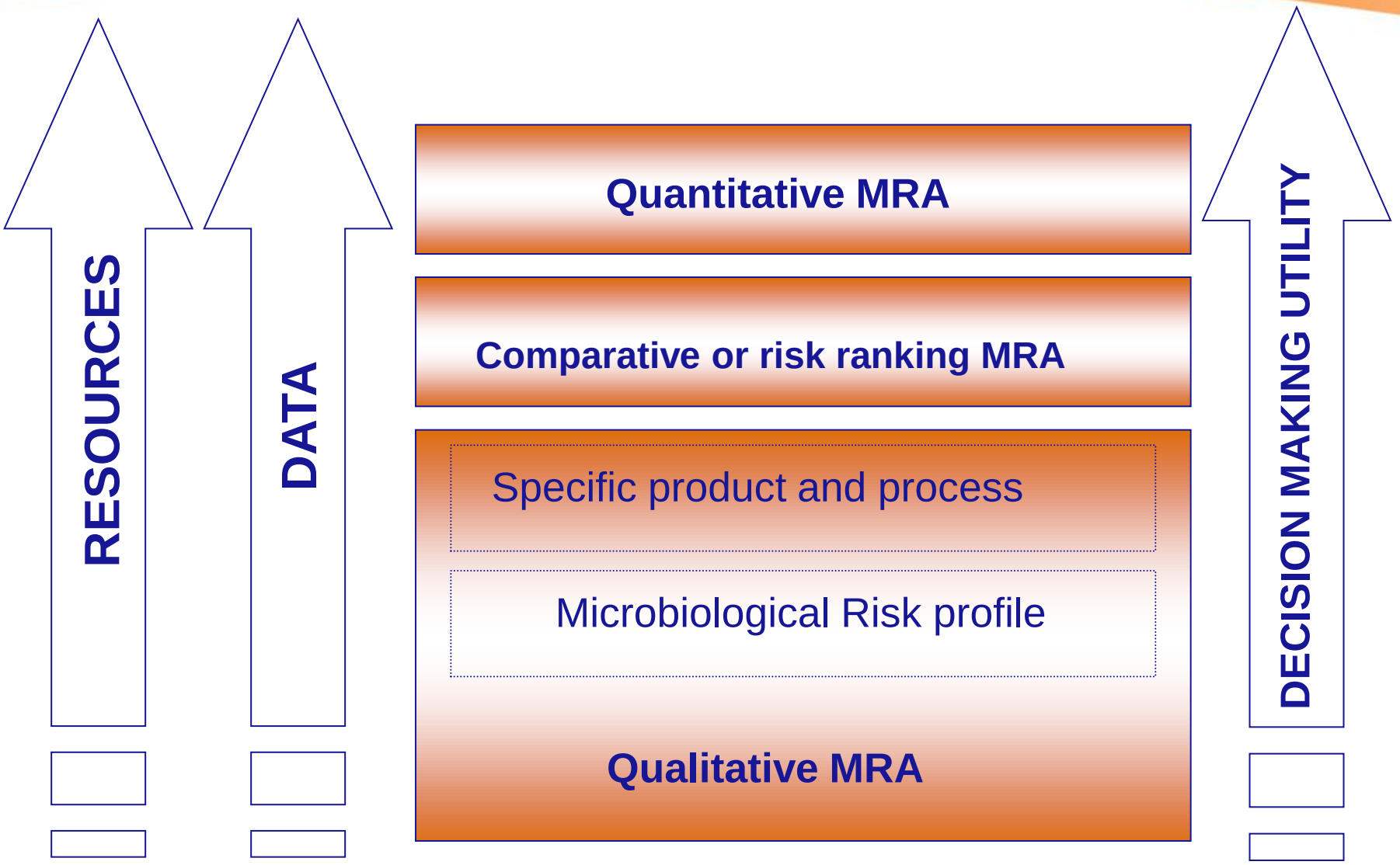
Risk Communication

The BIOHAZ Panel

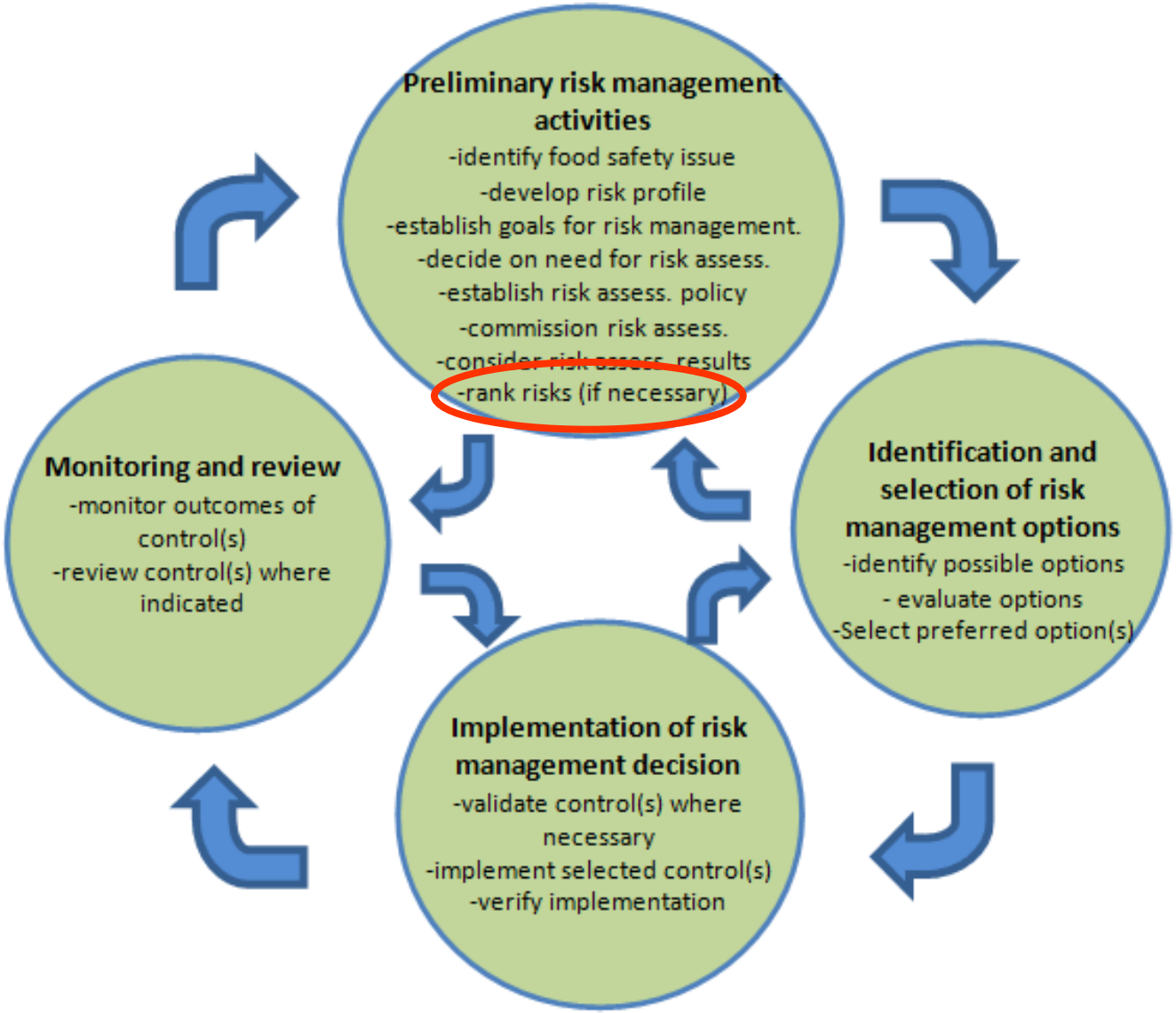
The Panel on Biological Hazards (BIOHAZ) deals with questions on biological hazards relating to Food Safety and Food-borne Diseases, including:

- Food-borne Zoonoses;
- Food Hygiene;
- Microbiology;
- Transmissible Spongiform Encephalopathies;
- Associated Waste Management.

BIOHAZ: Types of MRA



WHO Generic framework for Risk Management



(WHO, 2006)

Risk Ranking: why?

- Risk ranking as **starting point for risk-based priority setting** and resource allocation
- In a science- and risk-based system, resources for food safety deployed so to **maximize the public health benefit achieved through risk reduction**.
- Risk Ranking helps policymakers to **focus attention on the most significant public health problems** and develop strategies for addressing them

BIOHAZ Risk Ranking Framework

European Food Safety Authority

EFSA Journal 2012;10(6):2724

SCIENTIFIC OPINION

Scientific Opinion on the development of a risk ranking framework on biological hazards[1]

EFSA Panel on Biological Hazards (BIOHAZ)[2 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The risk ranking exercises related to biological hazards undertaken in fourteen risk assessments of the EFSA/BIOHAZ Panel were reviewed. The aim was to suggest risk ranking tools to be used in future risk assessments and to analyse strengths and weaknesses of different approaches to risk ranking. It was concluded

Terms of reference

EFSA requests the BIOHAZ Panel:

- To reflect on the **lessons and experiences from risk ranking exercises undertaken by the BIOHAZ** Panel, in particular describing successful approaches and challenges
- To **suggest risk ranking tools** related to biological hazards to be used in risk assessments
- To **analyse strengths and weaknesses** of different approaches to risk ranking on biological hazards

Conclusions (1)

Objective 1. To reflect on the lessons and experiences from risk ranking exercises undertaken by the BIOHAZ Panel, in particular describing successful approaches and challenges

Outcome:

- Fourteen opinions of the BIOHAZ Panel with risk ranking were reviewed as examples. It was concluded that:
  - Different methodology
  - models are fit the purpose
  - the availability of data is determinant
  - time frame

- In order to ensure harmonisation a **conceptual risk ranking framework** comprising nine separate stages has been developed in this opinion *(see next).*

Conclusions (2)

Objective 2. To suggest risk ranking tools related to biological hazards to be used in risk assessments

Outcome:

1. Nine risk ranking tools were identified and reviewed.
2. None of the available tools could be recommended as universal use risk ranking tool for biological hazards
3. For future risk ranking exercises on biological hazards, the possibility to use some of the available tools

There is no universal successful methodology for risk ranking

Risk Ranking has to be specifically tailored to each specific purpose, data availability and time frame

Conclusions (3)

Objective 3. To analyse strengths and weaknesses of different approaches to risk ranking on biological hazards

Outcome:

- The identification of successful risk ranking tools requires a comprehensive review of each model .
- Overall, the strengths and weaknesses of a risk ranking method depend on
  - Inclusion of all variable
  - data reliability,
  - uncertainty and variability
  - probabilities inference
  - the degree of fitness of the results to the purpose of RR

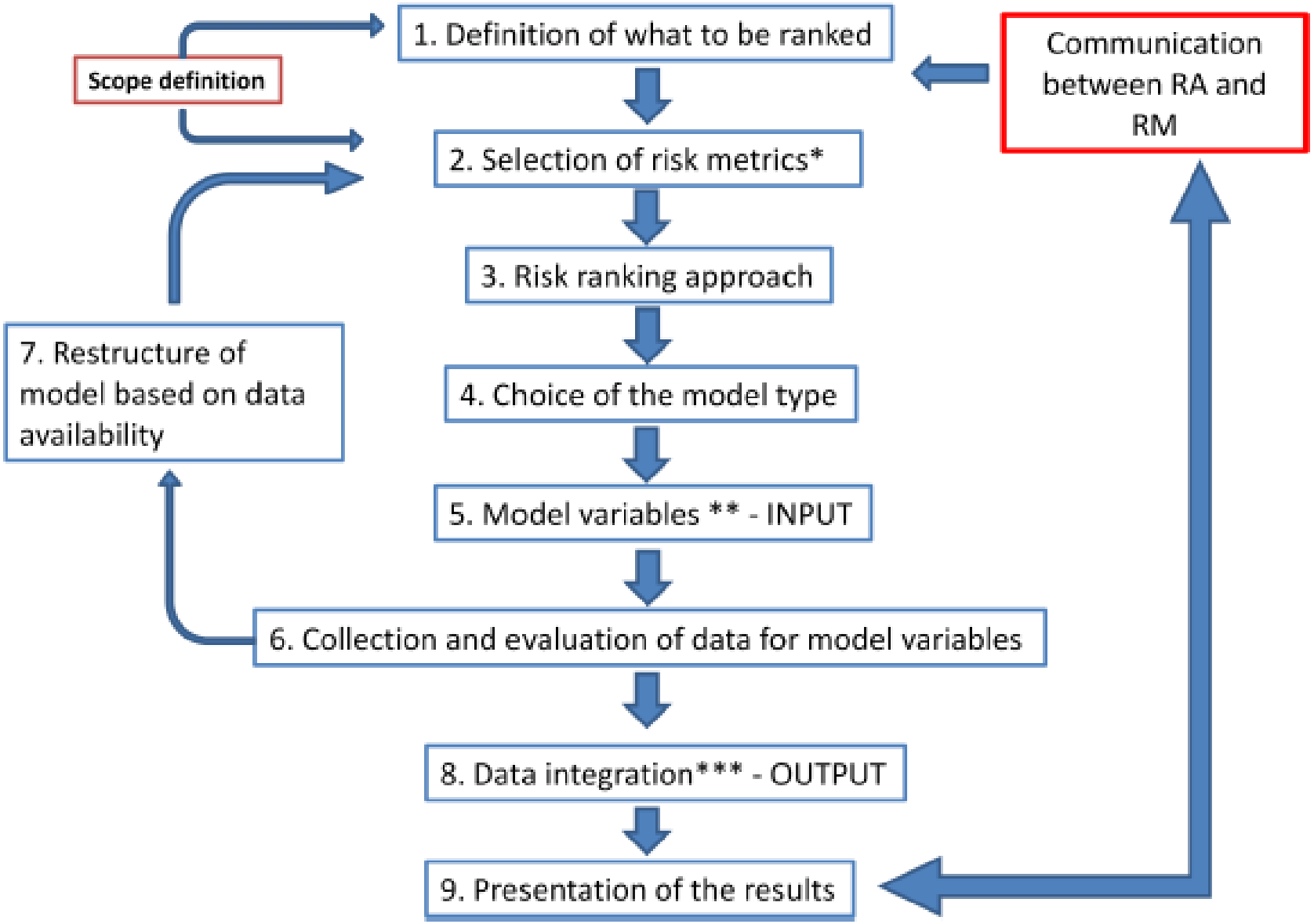
BIOHAZ Risk Ranking Framework

- allow the development of different methodologies

- provide the basis for a consistent presentation of model structure with clearly defined model components

- the reasons for the selection of each component and description of how the final conclusions were reached

BIOHAZ Risk Ranking Framework



1. Definition of what to be ranked

Three general levels on hazard-food combinations:

- **Level 1**: Single hazard in multiple food products (ranking of foods)
- **Level 2**: Multiple hazards in a single food product (ranking of hazards)
- **Level 3**: Multiple hazards in multiple food products (combined ranking of hazards and foods)

2. Risk Metrics

Expression of the risk in a risk ranking process

Risk as “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

2. Risk Metrics

Simplest metric for single hazard in multiple foods:

Number of adverse outcomes (e.g. illnesses, hospitalizations, and deaths)

- Adverse outcome (illness) likelihood **"per serving"**

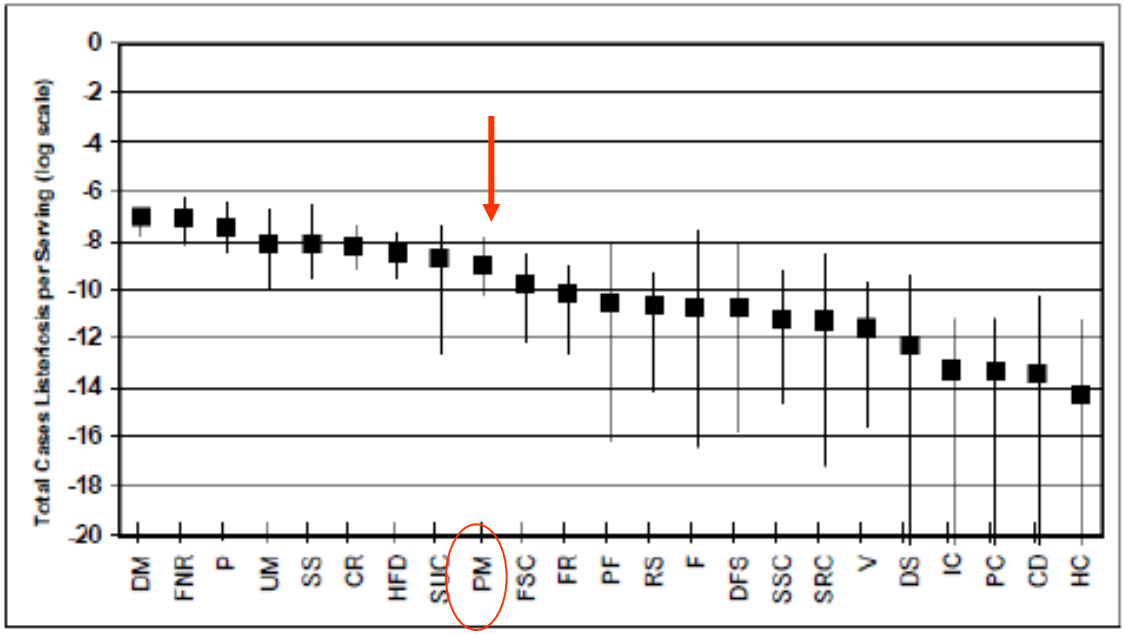
- Adverse outcomes (illness) **"per annum"**

standardized for population size (e.g. per 100,000 per year)

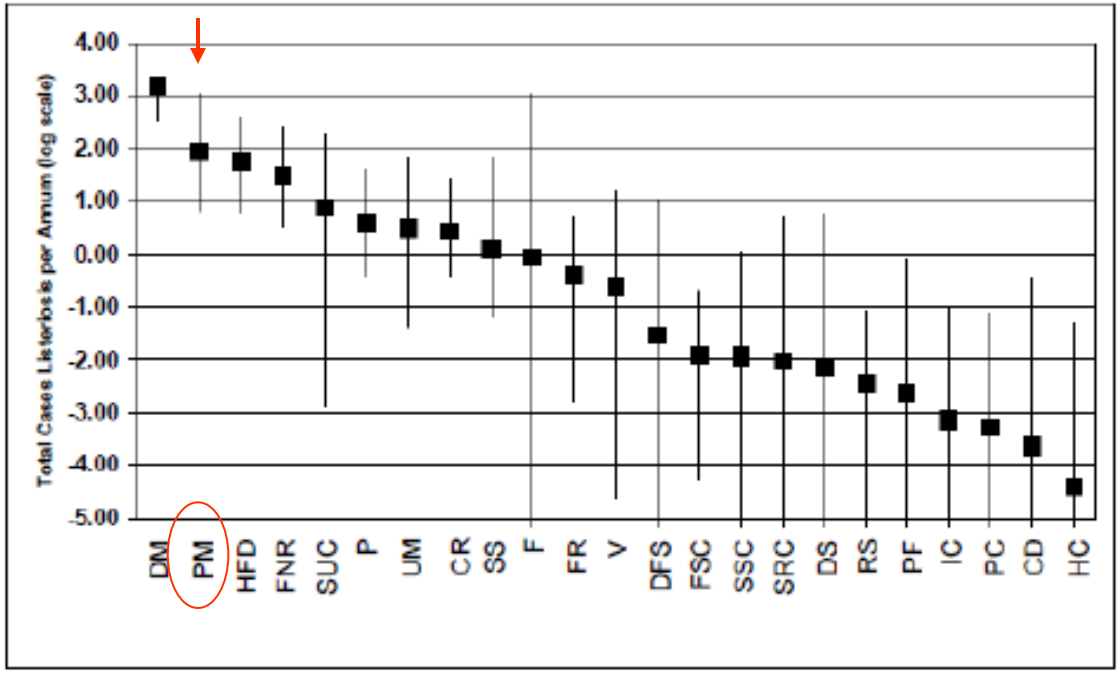
2. Risk metrics

Risk “per serving”

Listeria in pasteruised fluid milk (PM)
FDA/FSIS (2003)



Risk “per annum”



2. Risk Metrics

In case of ranking **multiple hazards**

Challenge: to find metrics to characterize the severity of the health outcomes and compare their overall ***health and/or economic impact*.**

mild gastrointestinal infection

≠

an infection that requires frequent hospitalization or causes permanent disability or death

2. Risk Metrics

Summary measures of public health

- **Disability adjusted life years** (DALYs)
- **Quality-adjusted life years** (QALYs)
- **Health-adjusted life years** (HALYs)

useful for overall estimates of burden of disease
comparisons of the relative impact of specific illnesses and conditions on communities, and in economic analyses.

2. Risk Metrics

Monetary risk metrics

public health impact of foodborne disease is characterized using health economics

Approaches:

(1) the human capital approach;

(2) cost of illness (COI) methods

(3) revealed or stated preferences which also include intangibles (not measurable) factors such as suffering and pain.

BIOHAZ Risk Ranking Framework

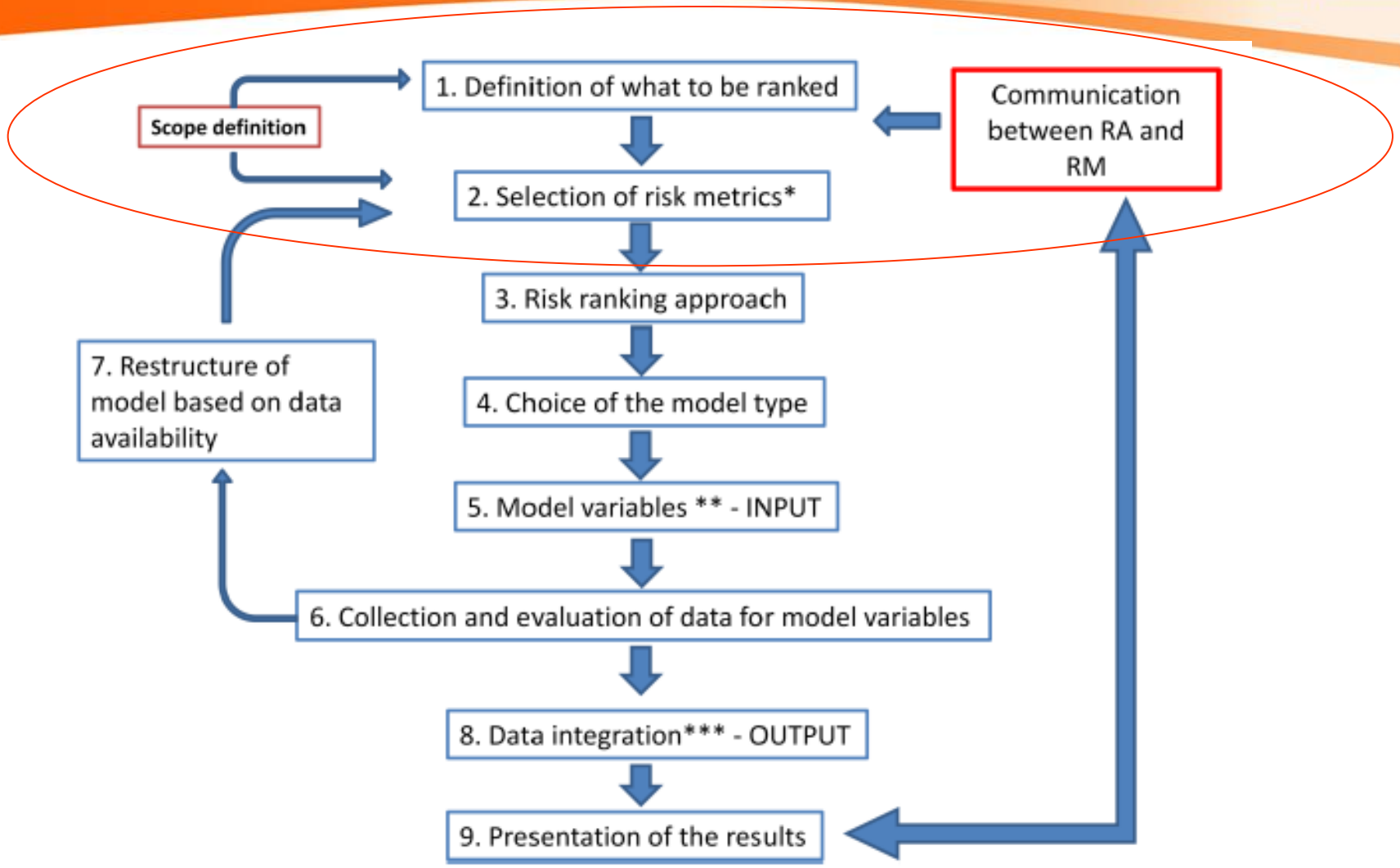
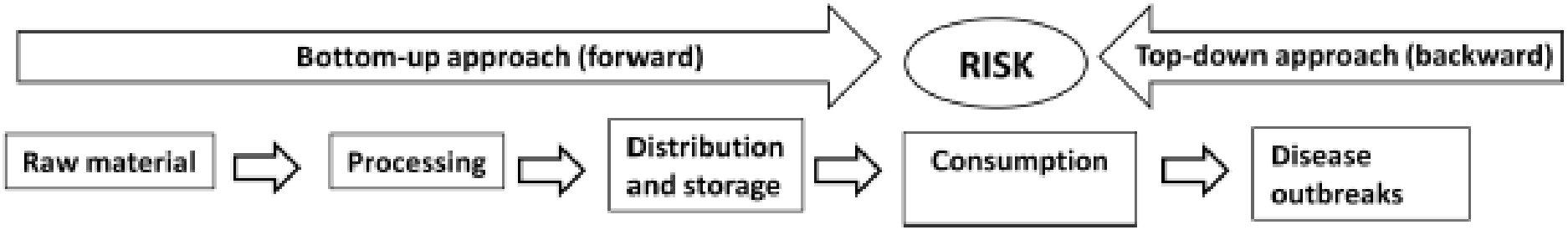


Figure 10: The proposed conceptual risk ranking framework for BIOHAZ Panel

3. Risk Ranking Approach



4. Model type

- **Qualitative:** descriptive or categorical nature
- **Semi-Quantitative:** intermediary level between the textual evaluation of qualitative risk assessment and the numerical evaluation of quantitative risk assessment
- **Quantitative:** numerical expression of risk

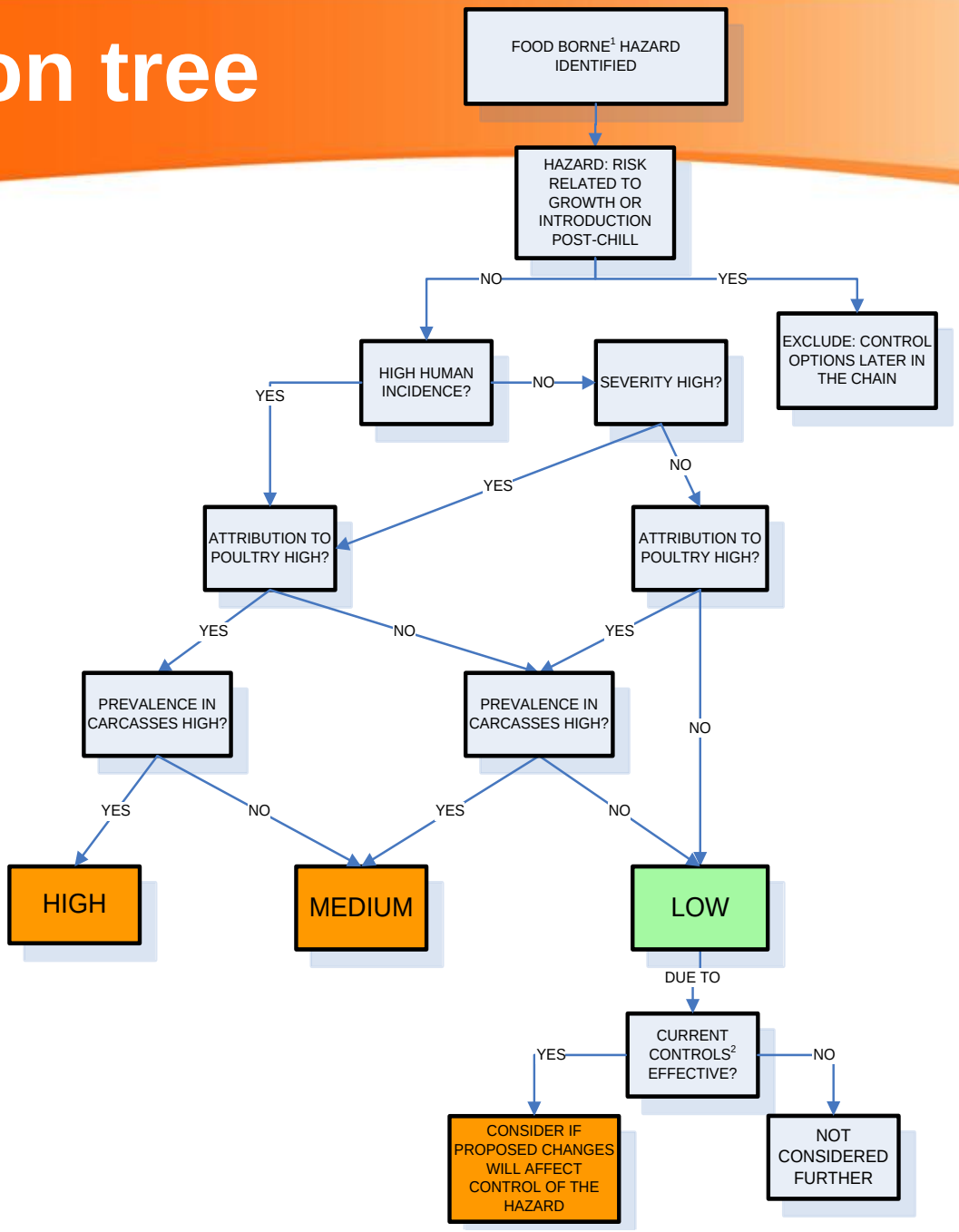
8. Data integration

In **qualitative risk ranking**, information is combined using a set of logical rules to arrive at a final result

a.reasoned opinion

b.decision tree

Decision tree

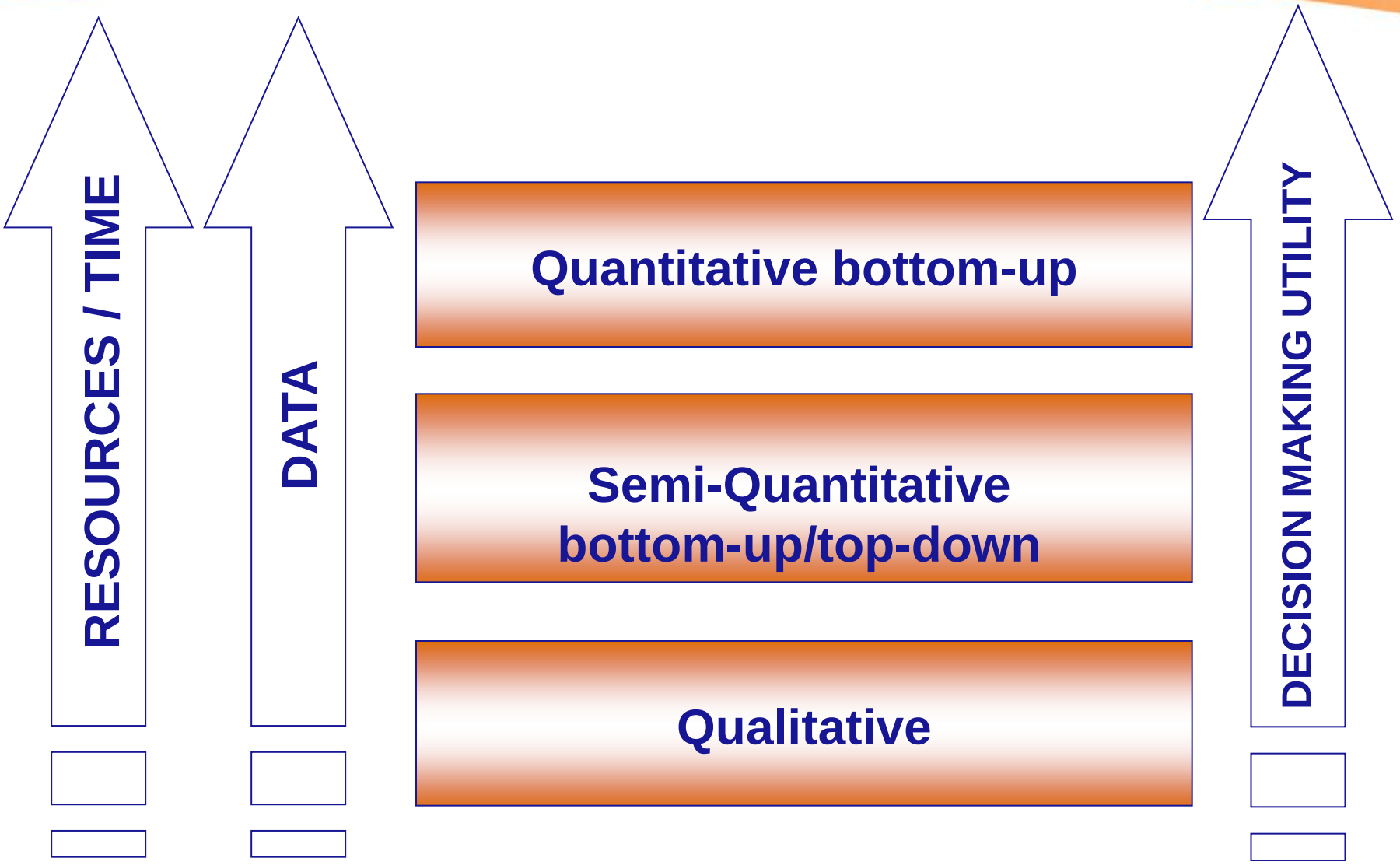


8. Data integration

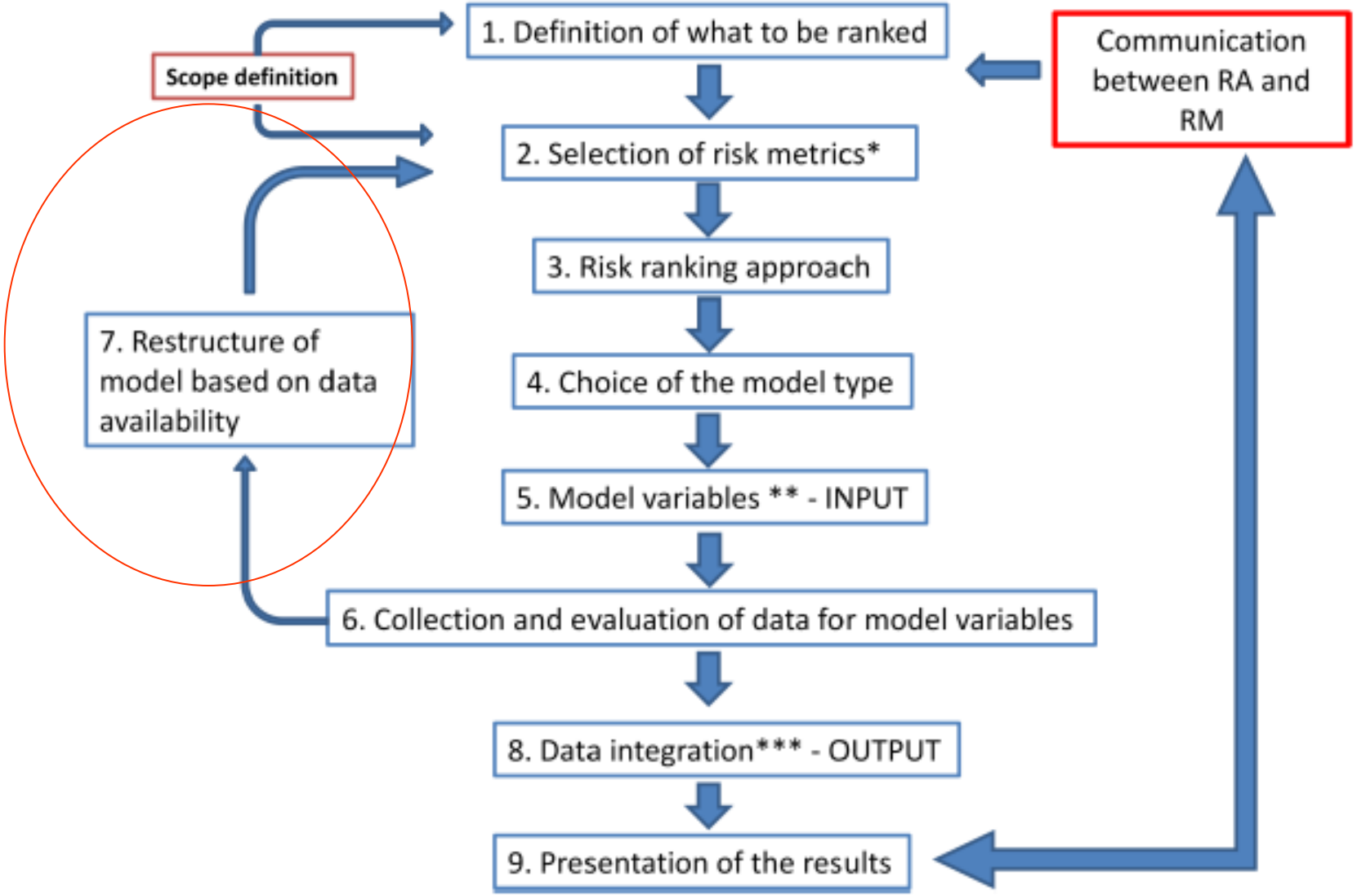
In **quantitative risk ranking,** model equations guide the integration of input parameters to produce risk estimates

In **semi-quantitative risk ranking**, **scores** for each criteria are combined with the appropriate **weights** produce a final risk estimate using simple additive or multiplicative models.

Types of Risk Ranking



BIOHAZ Risk Ranking Framework



5. Model variables

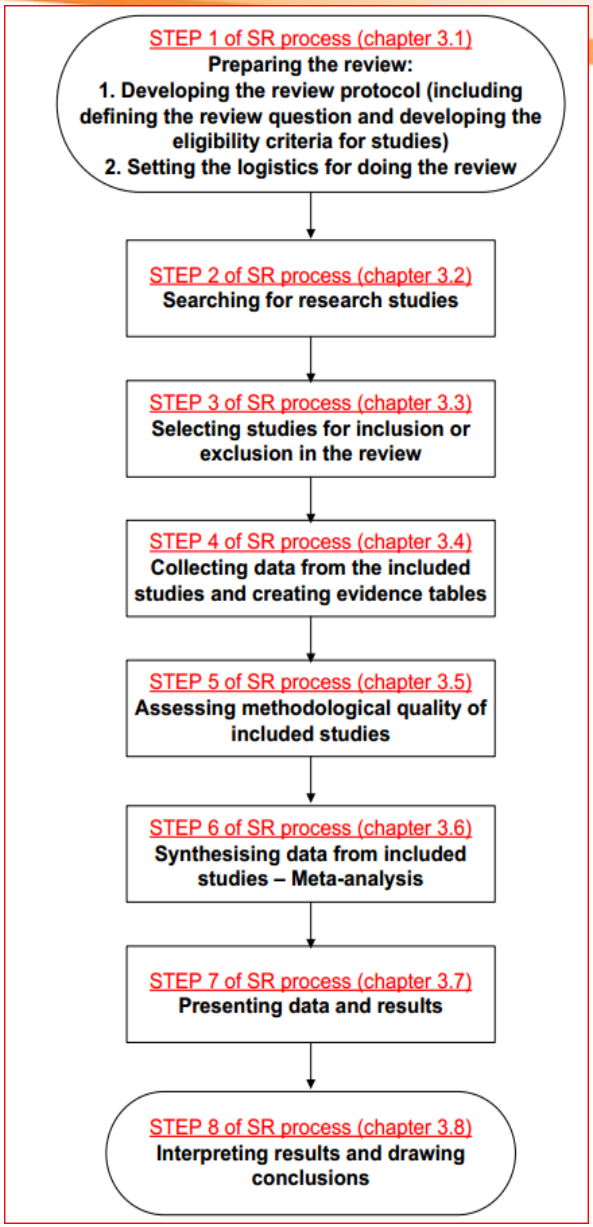
Categories

1. Epidemiological variables
2. Disease severity variables
3. Dose-response variables (pathogens, host, matrix)
4. Exposure variables
   - Probability and level of contamination
   - Processing variables
   - Post-processing variables (storage, retail, kitchen)
   - Consumption variables

6. Collection and evaluation of data for the model variables

Core steps for performing a systematic review based on EFSA guidance

http://www.efsa.europa.eu/it/efsajournal/doc/1637.pdf



Recommendations (1)

- RR with **structured** approach
- RR to be **documented** as fully as possible.
- all processes documented in a **consistent and transparent** so the risk ranking process is reproducible.
- The conceptual risk ranking framework to be used in future risk ranking exercises.
- The proposed framework provides the ability of adopting the **appropriate risk ranking methodology** by selecting different options at each stage.
- Whenever possible **quantitative risk ranking** approaches are preferable.

Recommendations (2)

- Time frame
- Components clearly defined
- Interaction between the risk managers and the risk assessors
- Conceptual framework to lead to design tools for future risk ranking exercises.
- Development of a risk ranking toolbox based on the proposed framework

Current BIOHAZ Risk Ranking activity

efsa
European Food Safety Authority

Development of a risk ranking toolbox for EFSA BIOHAZ Panel

Terms of reference

- To **evaluate the performance** and the data requirements of the available risk ranking tools.
- To investigate methodologies for **introducing uncertainty and variability** in the risk ranking models.
- To design and develop a **risk ranking toolbox** for the EFSA BIOHAZ Panel

- Completion by end of 2014

On going activities on risk ranking issues at EFSA (2)

- Outsourcing activity by Scientific Committee and Emerging Risks Unit (SCER)

Critical review of methodology and application of risk ranking for prioritisation of food and feed related issues, on the basis of the size of the anticipated health impact

Completion by end of 2014

On going activities on risk ranking issues at EFSA (1)

- WG by Scientific Committee and Emerging Risks Unit (SCER) on uncertainty assessment

General ToR:

- guidance on how to characterise, document and explain uncertainties in risk assessment.
- The guidance should cover uncertainties related to the various steps of the risk assessment,

Thank you for your attention!

Acknowledgements:

- EFSA BIOHAZ Panel
- EFSA WG on risk ranking toolbox: Kostas Koutsoumanis, Arie Havelaar, Moez Sanaa, Roland Lindquist, Pablo Fernandez
- EFSA opinion on RR framework : http://www.efsa.europa.eu/en/efsajournal/pub/3137.htm
- Contacts:biohaz@efsa.europa.eu