Fit For Purpose Risk Assessment

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World Health Organization

China reports big rise in food-poisoning deaths

Koreans Name Food Safety as Biggest Headache

Growers defensive as doctor raises starfruit danger

Chinese milk powder contaminated with melamine sickens 1,253 babies

Improvements in food safety urged

Salmonella Outbreak Exposes Food-Safety Flaws

Vietnam to intensify food safety

HIGH MERCURY LEVELS ARE FOUND IN TUNA SUSHI

Source of Tainted Tomatoes May Stay a Mystery

U.S. company recalls about 286,000 pounds of meat

Mums-to-be warned of fish danger

Salmonella-Tainted Tomatoes Linked to Markets, Restaurants

Consumer Group Seeks Ban on Some Food Dyes

EU: Could Ban Mozzarella Unless Gets Contamination Info

Health group urges overhaul of US food safety system

FOOD POISONING CAN BE A LONG-TERM PROBLEM

Japan scare over China dumplings

Food Safety and Olympic challenge for Beijing

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Global challenges for Risk Assessment

- Many different hazards, in all foods, from everywhere
- Mixtures (chemicals)
- Interacting hazards
- Food trade
- Advances in analytical methods
- Estimates for food-borne disease burden

Interacting Hazards – what do we know?

Examples of chemicals affecting the immune system:

- Mycotoxins:
  - Trichothecenes (DON)
  - Fumonisins
  - Aflatoxins (HEP and AFB)
- Dioxins

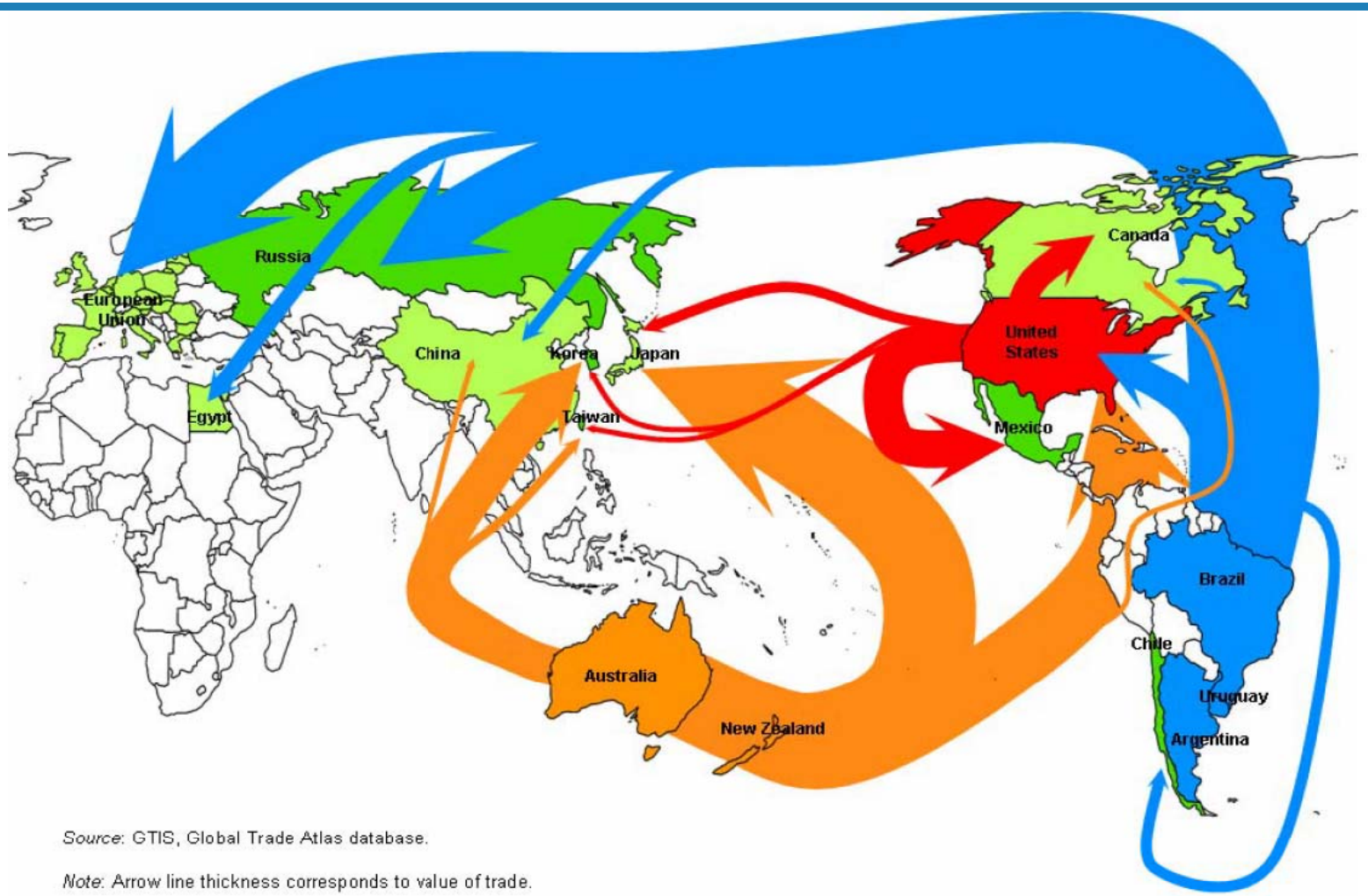
Food key exposure route for many important hazard

Impact on infectious diseases?

Food trade: a global interdependance

987 billion dollars of exports of food in 2009 *[WTO]*

- All types of food are now concerned by global and complex flows
- Thus, hazards also travel easily and quickly from one source to global dissemination



Source: GTIS, Global Trade Atlas database.

Note: Arrow line thickness corresponds to value of trade.

World beef trade flows, 2007

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Advances in analytical methods

- Increased sensitivity
- Multi-residues methods
- New tools
- New methods
- Rapid in/on-line control

RECENT ADVANCES IN ANALYTICAL METHODS FOR MYCOTOXINS
Maragos, Chris
Journal of the Japanese Association of Mycotoxicology
May 20, 2004

Determination of pesticides in tea by isotope dilution gas chromatography-mass spectrometry coupled with solid-phase micro-extraction
Jie Feng
***Anal. Methods*, 2012, Accepted Manuscript**
DOI: 10.1039/C2AY25749A, Paper

Identification and quantification of methylated PAHs in sediment by two-dimensional gas chromatography/mass spectrometry
Ewa Skoczynska, Pim Leonards and Jacob de Boer
***Anal. Methods*, 2012, Accepted Manuscript**
DOI: 10.1039/C2AY25746G, Paper

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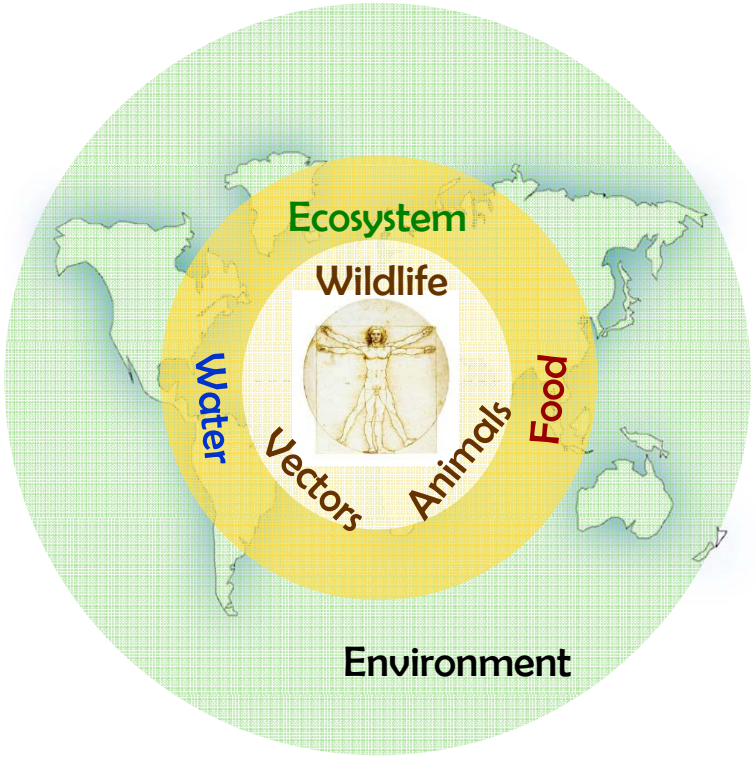
Burden of Disease Estimates

- Zoonotic diseases (Emerging and endemic):
  - disease or infection that is naturally trans-missible from vertebrate animals to humans
  - Animals essential in maintaining zoonotic infections in nature
  - 1940 – 2004: 335 events of newly emerging infectious diseases – 60% zoonotic



nature Vol 451|21 February 2008|doi:10.1038/nature06536

LETTERS

Global trends in emerging infectious diseases

Kate E. Jones[1], Nikkita G. Patel[2], Marc A. Levy[3], Adam Storeygard[3]†, Deborah Balk[3]†, John L. Gittleman[4] & Peter Daszak[2]

- Non Communicable Diseases: cancer, CVD, diabetes, obesity

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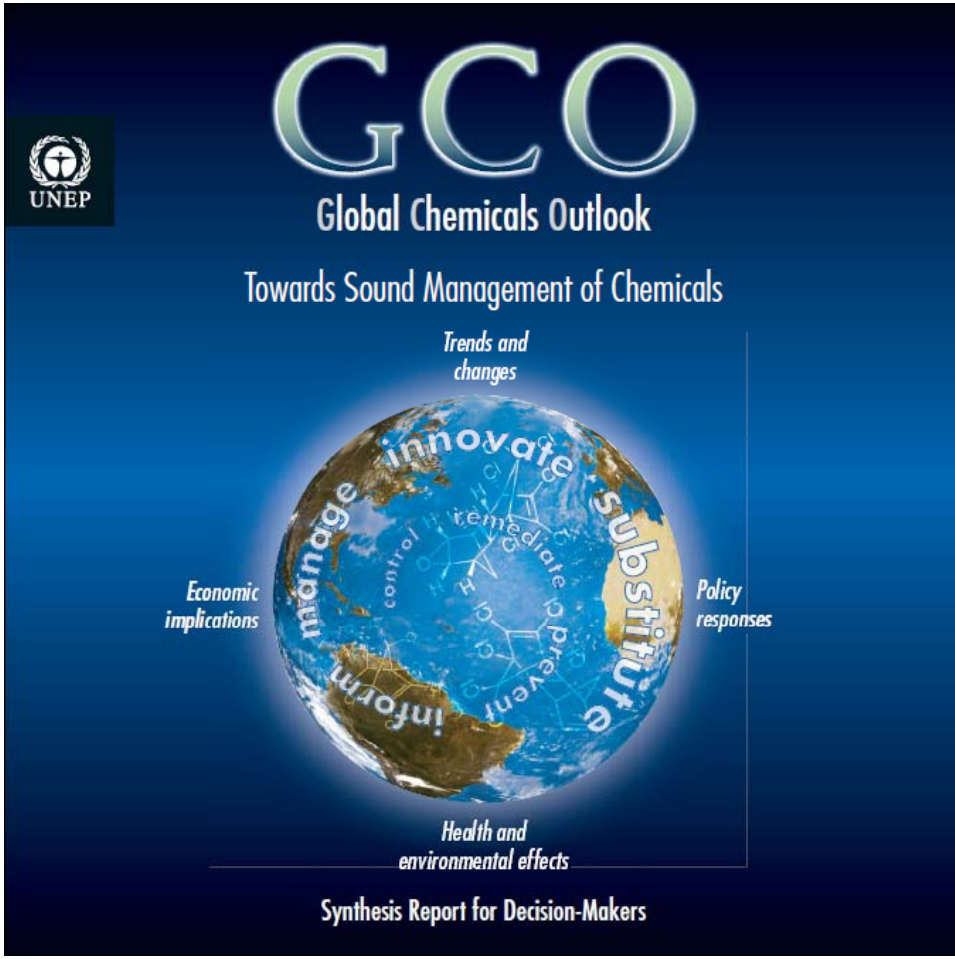
Hazards

- 'Micro'biological hazards: limited number of pathogens, parasites, now viruses
- The world of chemicals:

  The exact number of chemicals on the global market is not known but under the pre-registration requirement of the European Union's chemicals regulation, REACH, 143,835 chemical substances have been pre-registered. This is a reasonable guide to the approximate number of chemicals in commerce globally.

  - Natural toxins
  - Process contaminants
- New technologies and risk benefit



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Microbiological risk assessment

Listeria monocytogenes

Salmonella

***Escherichia coli* O157**

Vibrio parahaemolyticus

Campylobacter

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

(single pathogen, one product type, whole chain)

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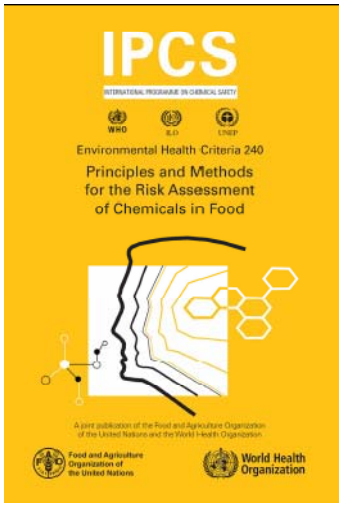
Chemical risk assessment

- Hazard assessment: inherent property of the chemical, independent of source, occurrence etc., some impact of processing
- Exposure assessment: source specific



EHC 240: Principles and methods for the risk assessment of chemicals in food

WHO 2009

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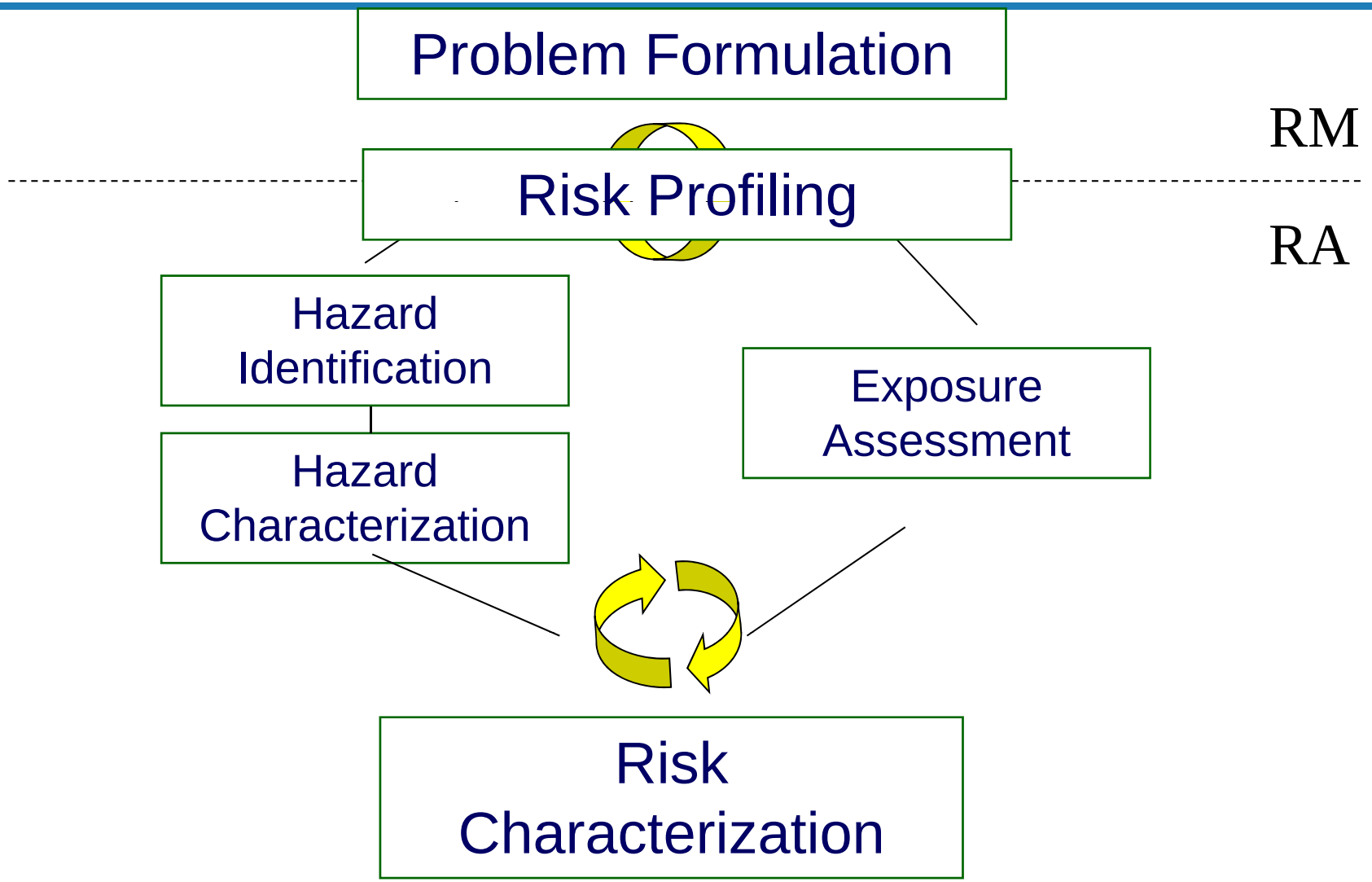
Risk Assessment: A Scientific Process



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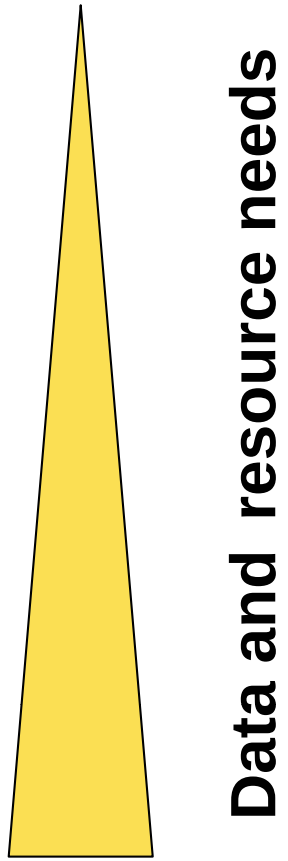
Types of Risk Assessment

- Rapid risk assessment – emergencies
- Qualitative RA – due to lack of data or lack of health concern
- Quantitative RA – derivation of HBGV, or full expression of probability of adverse health outcome at defined level of exposure



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Basic principles of risk assessment

- Identify problem (ranking of hazards)
- Identify available information
- Define the scope of risk assessment
- Bring together relevant expertise - microbiologists, toxicologists, epidemiologists, modellers, veterinarians, chemists, etc.
- Ensure there is interaction between risk assessor and risk manager - common understanding of problem
- Recognise limitations in data, resources - be transparent
- Take the whole database into account - Integrate results
- Reporting – data sources, assumptions, conclusions, uncertainties and data gaps

Fit-for-purpose….targeted to needs

- Scientific rationale:
  - Hazard profile
  - Exposure estimates
  - Disease burden

- 'Emotional' rationale:
  - perception

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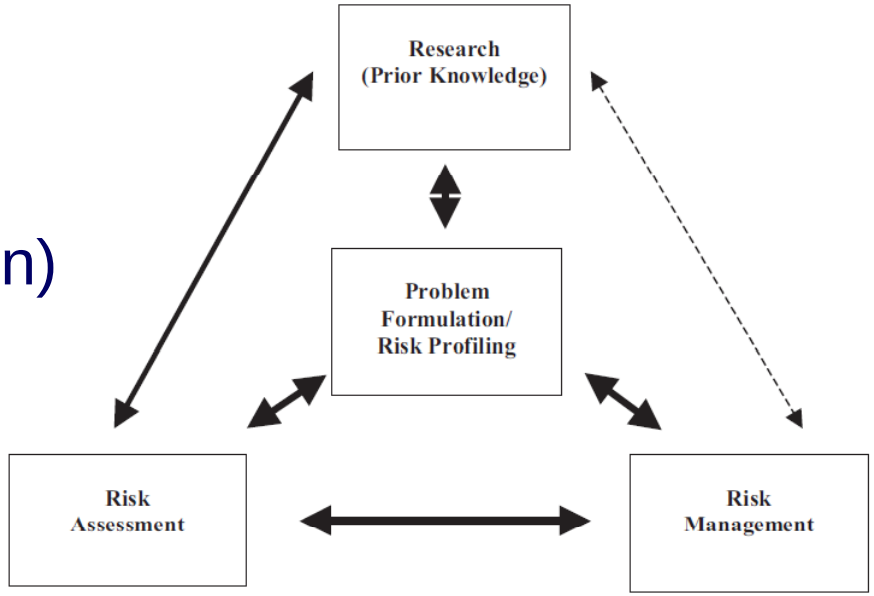
Problem formulation and preliminary risk profiling

- *Goal*: determination of need and extent of RA

- *Elements*:
  - Level of concern (toxic potential, exposure potential, sensitive population)
  - Occurrence, production, use pattern
  - Mitigation measures
  - Risk management options
  - Prioritization



- *Output*: risk assessment plan

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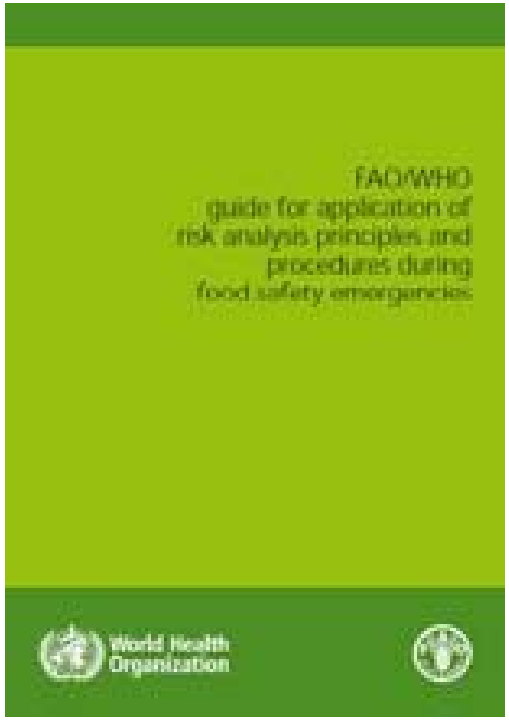
Rapid risk assessment

- Limited information
- Limited time



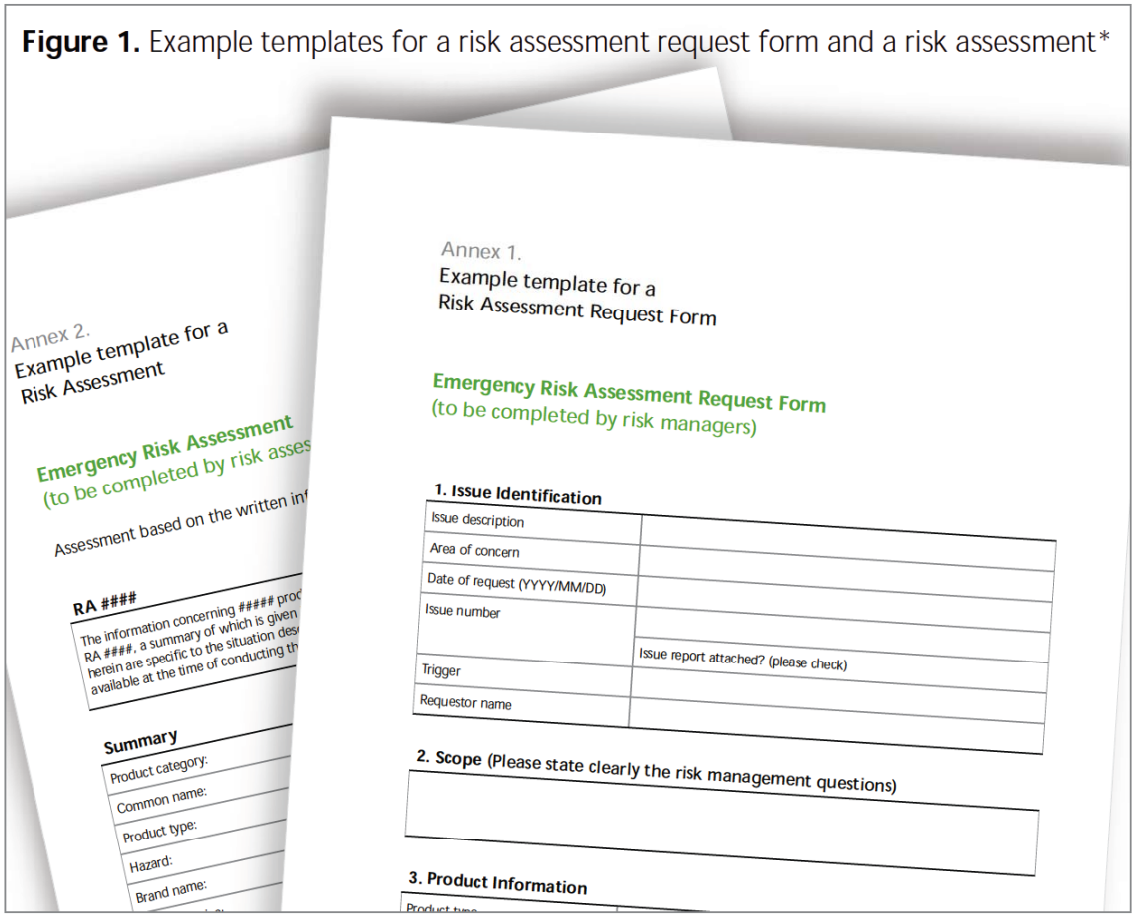


Figure 1. Example templates for a risk assessment request form and a risk assessment*

Annex 2.
Example template for a
Risk Assessment

Emergency Risk Assessment
(to be completed by risk asses

Assessment based on the written in

RA ####

The information concerning ##### proc
RA ####, a summary of which is given
herein are specific to the situation des
available at the time of conducting th

Summary

Product category:
Common name:
Product type:
Hazard:
Brand name:

Annex 1.
Example template for a
Risk Assessment Request Form

Emergency Risk Assessment Request Form
(to be completed by risk managers)

1. Issue Identification

Issue description	
Area of concern	
Date of request (YYYY/MM/DD)	
Issue number	
	Issue report attached? (please check)
Trigger	
Requestor name	

2. Scope (Please state clearly the risk management questions)

3. Product Information

http://whqlibdoc.who.int/publications/2011/9789241502474_eng.pdf

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Proposal

for fit for purpose risk assessment approach

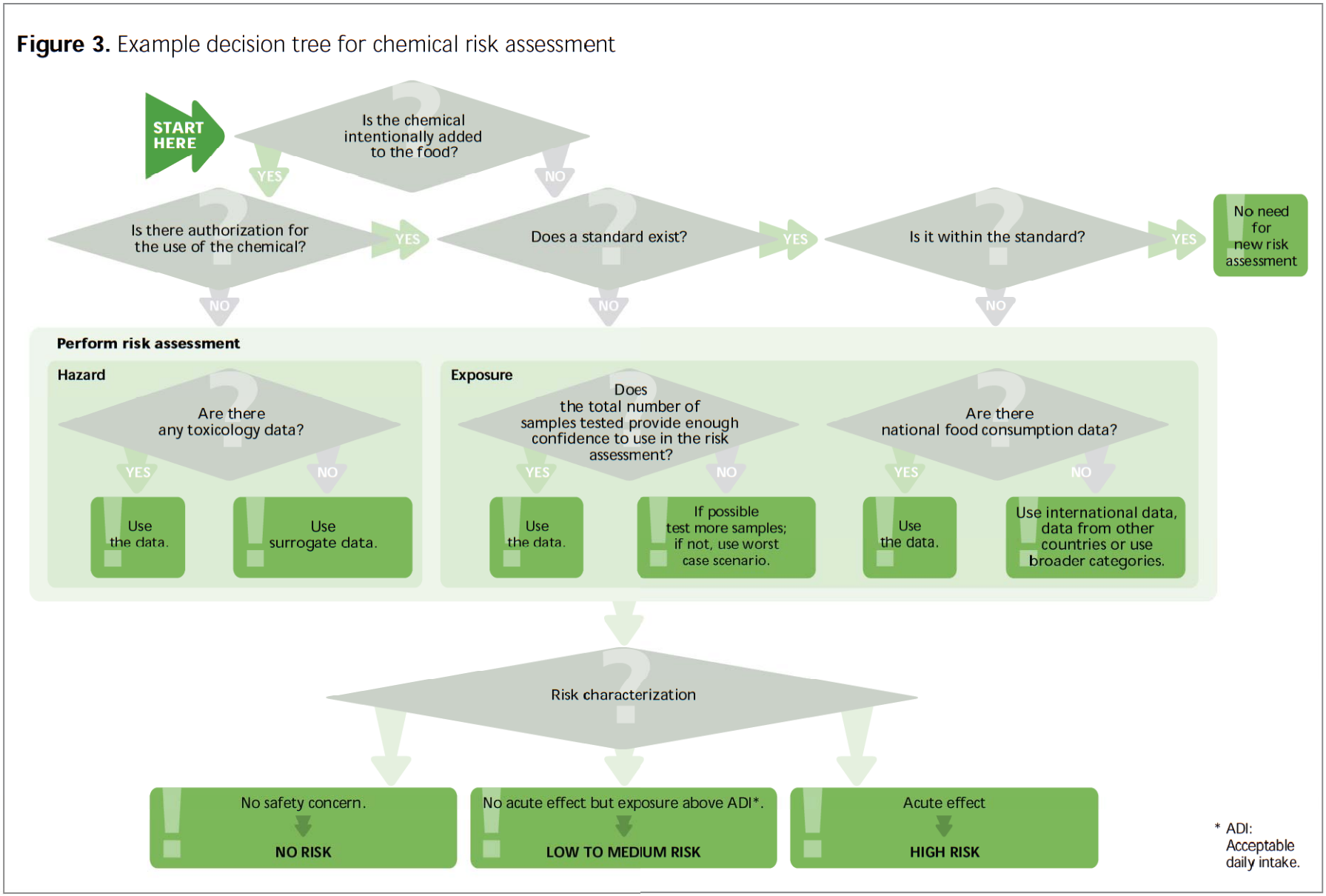
- Development of a step-wise approach for a transparent prioritization and fit for purpose risk assessment approach

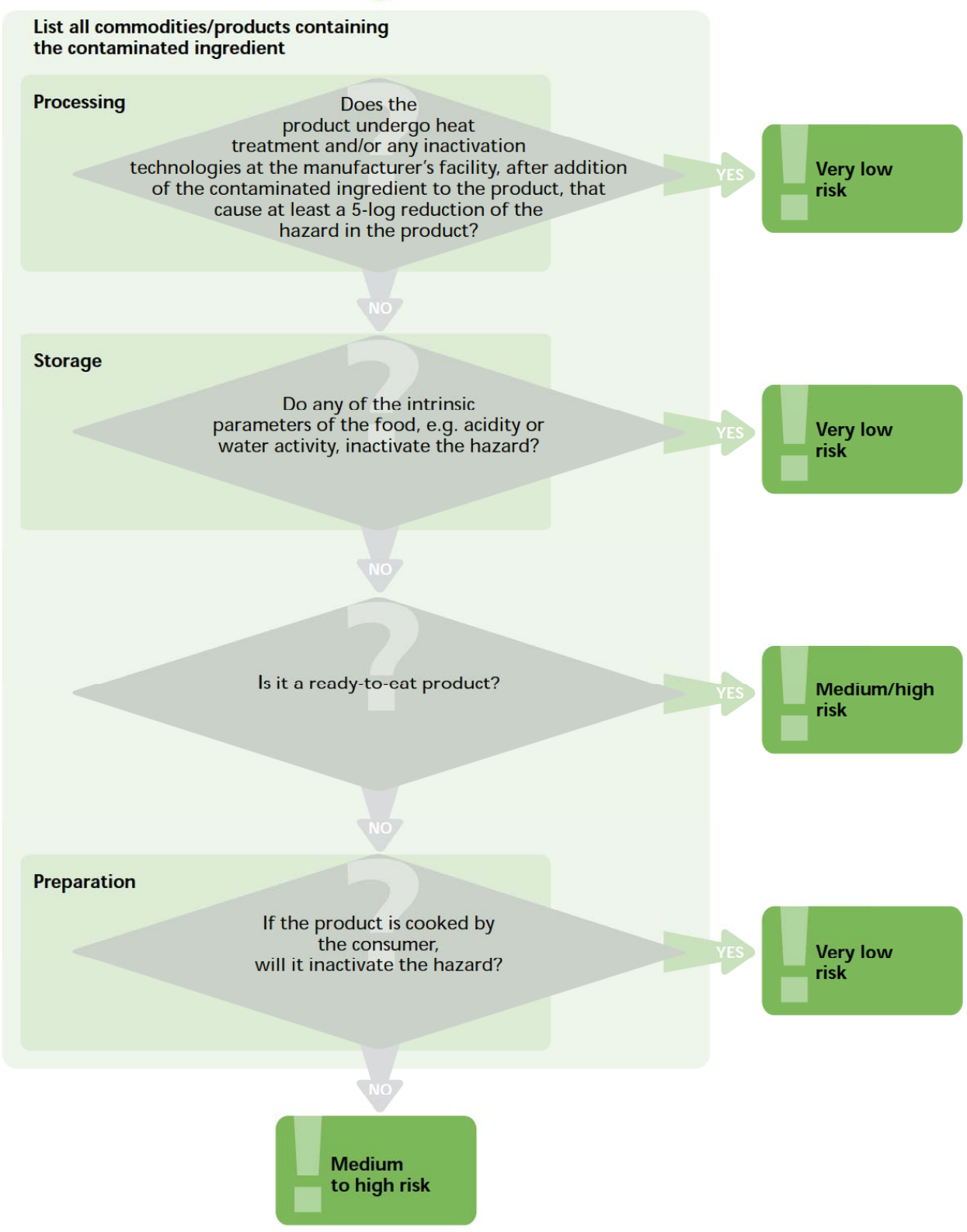
- What is needed?
  - Systematic collection of guidance tools
  - Accessibility of existing relevant assessments
  - Transparent description of processes and procedures
  - Detailed description of problem formulation and preliminary risk profiling steps, incl. roles and responsibilities

- And……
  - International agreement
  - Political will

Decision tree for chemical risk assessment

Figure 3. Example decision tree for chemical risk assessment





Decision tree for microbiological risk assessment


Thank you