GFORSS
Global Food Regulatory Science Society

Global Gateway

Funded by the European Union

JUMUIYA YA AFRIKA MASHARIKI

International Trade Centre

MARKUP II
EU-EAC Market Access Upgrade Programme Phase II

REGIONAL TRAINING ON SCIENTIFIC BASIS OF CODEX WITH FOCUS ON DATA GENERATION AND SUBMISSION FOR STANDARDS SETTING

23-25 July 2025 • Zanzibar, Tanzania

Role of Data in Supporting Evidence-Based Food Regulatory Decision-Making

Day 1: 23 July 2025

Introduction

The **risk analysis paradigm** provides a framework to ensure that food safety and health aspects of Codex standards and related texts are based on risk analysis principles and that there is a **scientific basis** for Codex standards.

This presentation provides an overview of risk analysis as it is understood within Codex, explaining what it is and defining common terms.

Extracted from FAO Training Material

GFORSS
Global Food Regulatory Science Society

Risk Analysis in Codex

From the very beginning, the Codex Alimentarius has been a **science-based activity**.

Risk analysis evolved within the CAC during the 1990s and is now considered an **integral part of the decision-making process of Codex**.

In 1995 the **World Trade Organization Agreement on Sanitary and Phytosanitary Measures** was adopted .

Extracted from FAO Training Material

GFRSS
Global Food Regulatory Science Society

Risk Analysis in Codex (2)

Important policy documents adopted by the Commission related to risk analysis & science:

- ❑ Statements of Principle concerning the role of science in the Codex decision making process and the extent to which other factors are taken into account 1995 (Appendix of the Codex procedural manual).
- ❑ Statements of Principle related to the role of food safety risk assessment, 1997 (Appendix of the Codex procedural manual)
- ❑ Definitions of Risk Analysis Terms related to food safety (Definitions section of Codex procedural manual).
- ❑ The Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, 2003.

Extracted from FAO Training Material

What is Risk Analysis?

Risk analysis is used to:

- ❑Develop an estimate of the risks to human health and safety;
- ❑Identify and implement appropriate measures to control the risks; and
- ❑Communicate with stakeholders about the risks and measures applied.

Extracted from FAO Training Material

It provides food safety regulators with the information and evidence they need for **effective decision-making**, contributing to **better food safety outcomes** and **improvements in public health**.

GFRSS
Global Food Regulatory Science Society

Risk Assessment

- RA is the qualitative or quantitative characterization or estimation of potential adverse health effects associated with exposure of individuals or populations to hazards

physical, chemical, or microbial agents

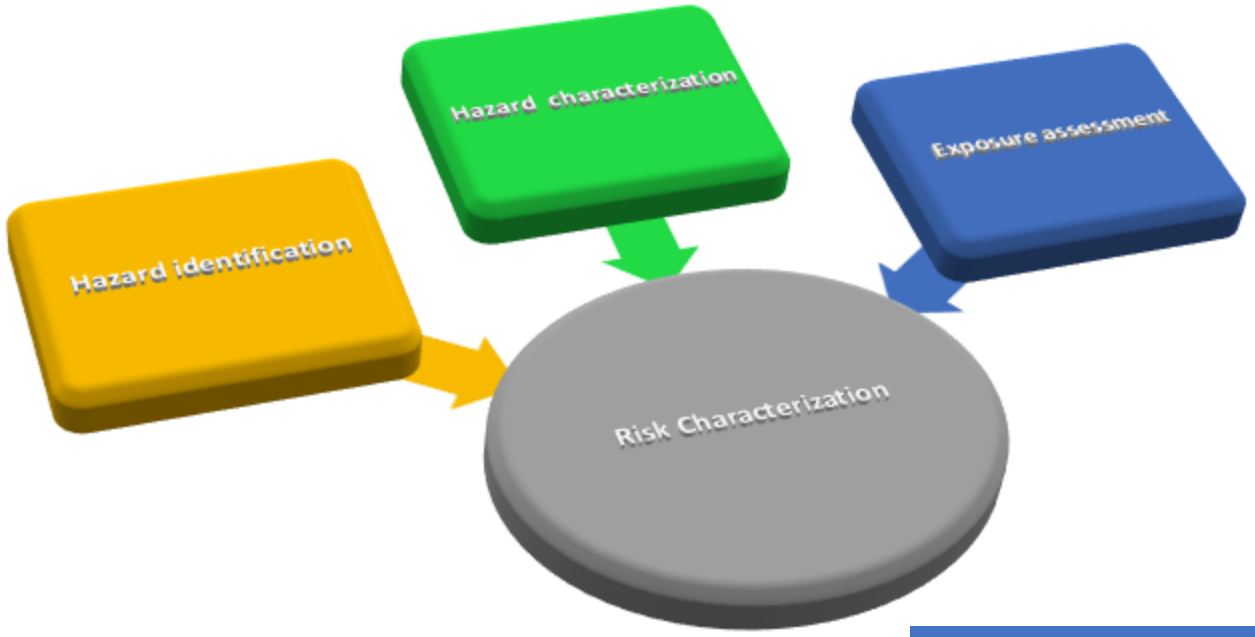
Not used in isolation, but as a part of Risk Analysis

Extracted from FAO Training Material

GFRSS
Global Food Regulatory Science Society

Purpose of Risk Assessment

- A scientifically based process consisting of the following steps:
  - (i) hazard identification,
  - (ii) hazard characterization,
  - (iii) exposure assessment, and
  - (iv) risk characterization



Extracted from FAO Training Material

A systematic examination of an issue to help make better risk management decisions

Risk vs HAZARD

- Risk - A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

- Hazard - A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Extracted from FAO Training Material

GFRSS
Global Food Regulatory Science Society

Key Concept: Hazard vs Risk?

Hazard

Risk

The difference is the EXPOSURE

Extracted from FAO Training Material

Key Concept: Hazard vs Risk? (2)

Hazard

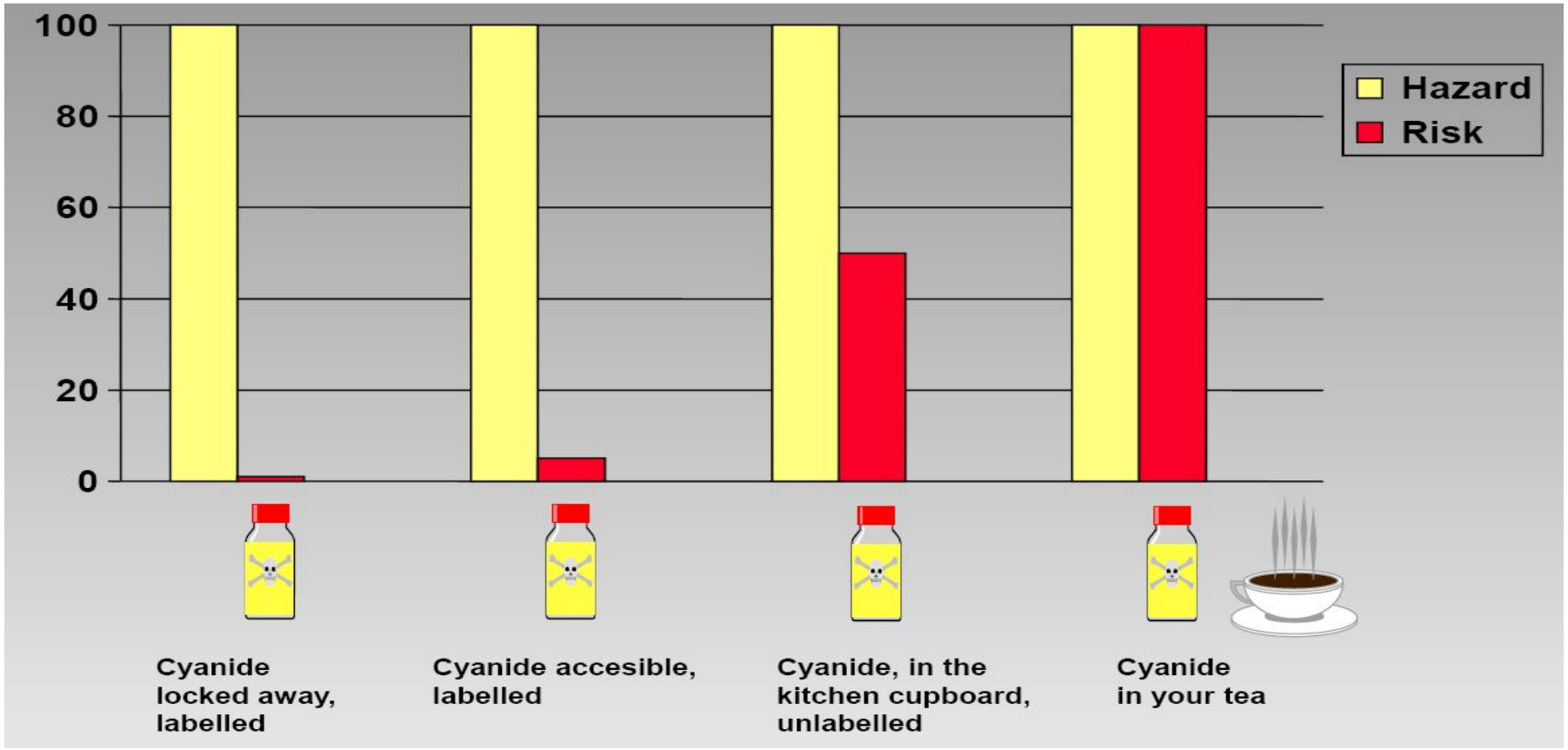
Risk

The difference is the EXPOSURE

Extracted from FAO Training Material

Risk = Hazard x Probability of Exposure

Hazard constant and probability of exposure is increasing



Excerpt Prof. Lemmens Slides – BOKU - Austria

Extracted from FAO Training Material

ISO 31000 Definition

- **Risk** is the "effect of uncertainty on objectives" and an effect is a positive or negative deviation from what is expected.

- A change in the traditional understanding of risk, forcing organizations to tailor risk management to their needs and objectives – a key benefit of the standard.

Extracted from FAO Training Material

GFRSS
Global Food Regulatory Science Society

Risk Assessment Components – Codex Definitions

- Hazard identification – The identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods

- Hazard characterization – The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical, and physical agents which may be present in food

  - A dose-response assessment should be performed if the data are available

- Exposure assessment – The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant

- Risk characterization – The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment

CODEX
CODEX ALIMENTARIUS
1963-2023

Extracted from FAO Training Material

GFRSS
Global Food Regulatory Science Society

Safety or Risk Assessment

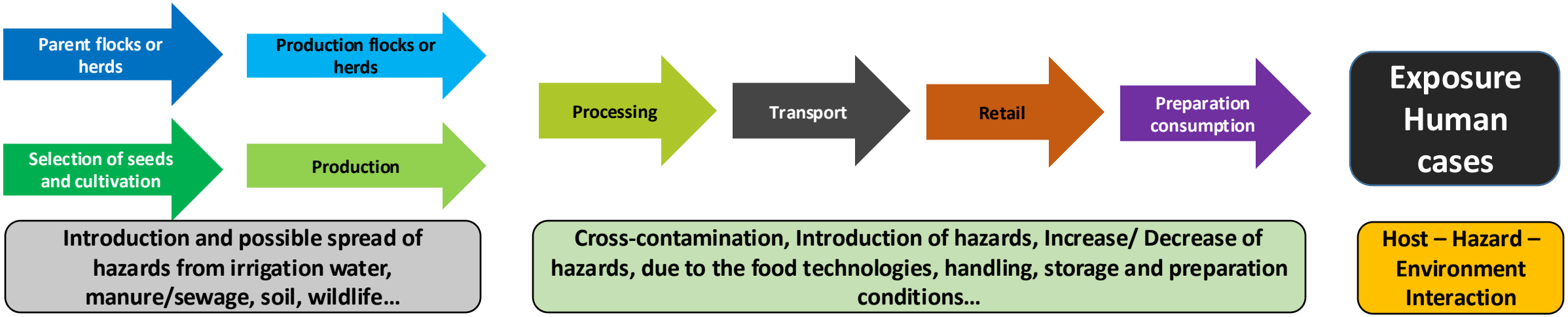
- **Safety assessment**: provides a verdict of what is a 'safe' level based on the conventions of the analysis
- **Risk assessment**: quantifies the level of risk associated with specific exposures and degree of uncertainty inherent in the risk estimate. Used to compare options.
  - Quantitative assessment: the risk is expressed as a mathematical statement of the chance of illness or death after exposure to a specific hazard, and it represents the cumulative probabilities of certain events happening and the uncertainty associated with those events.
  - Qualitative risk assessments: use verbal descriptors of risk and severity (e.g., higher, lower), and often involve the aggregation of expert opinions.

Adapted from "Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food" FDA Threshold Working Group, March 2006

Extracted from FAO Training Material

GFRSS
Global Food Regulatory Science Society

Risk Assessment – Data and the Integrated Approach



Integrate different types of data

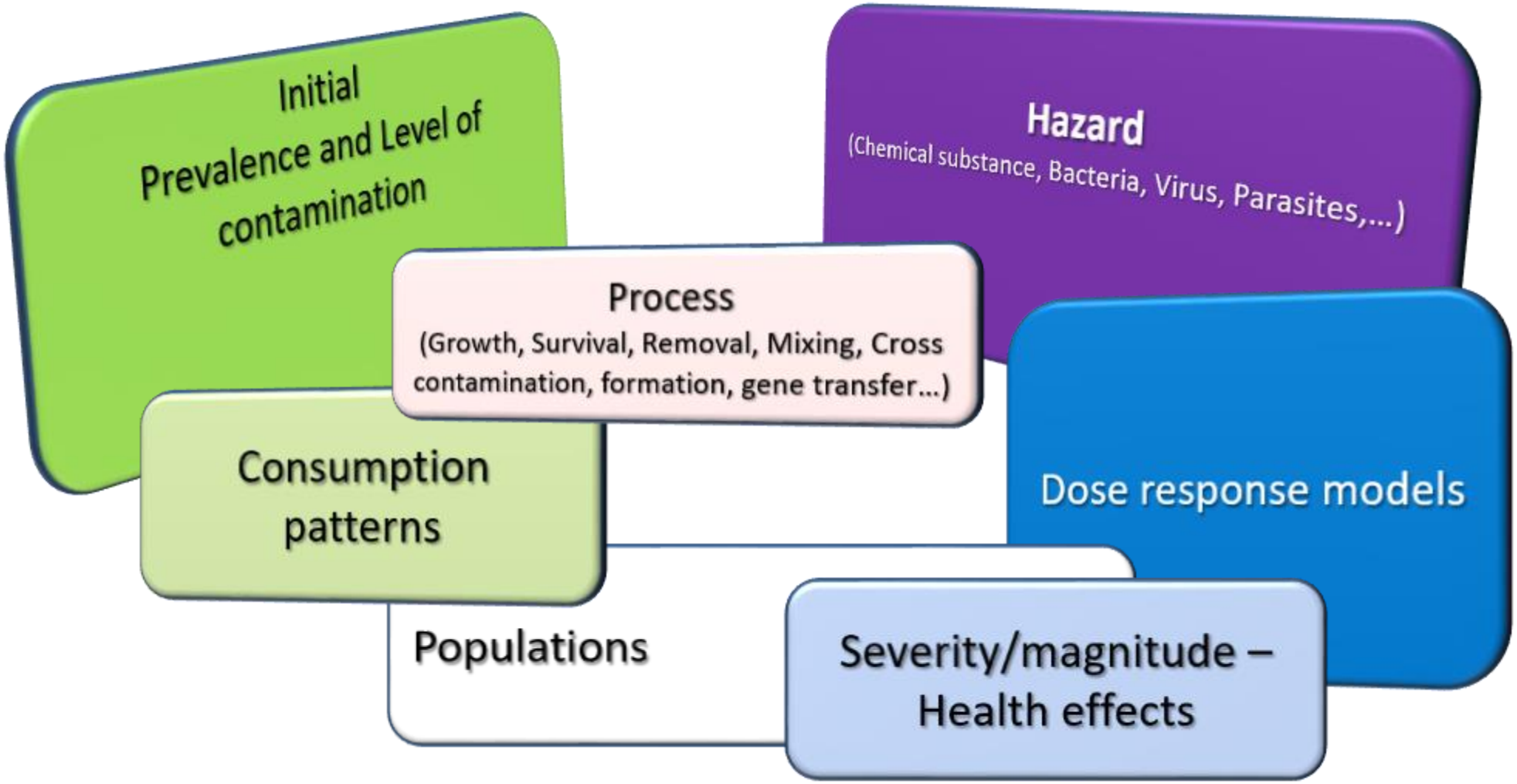
- Foodborne illness surveillance
- Food contamination monitoring
- Environment monitoring
- Animal health surveillance
- Processing data
- Pathogen growth/survival data
- WGS data
- Pathogen virulence
- Toxicological data
- Diet and food handling data

Extracted from FAO Training Material

GFRSS
Global Food Regulatory Science Society

Risk Determinants: Data Needed

Adapted from FDA i-Risk



Extracted from FAO Training Material

GFRSS
Global Food Regulatory Science Society

Relevant Hazard-FOOD Combinations

Determination of the hazard / food combination that will be the subject of the Risk Assessment

- The identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods
  - Question 1: is the agent capable of causing health effects? ✓
  - Question 2: can the agent be present in food?

Extracted from FAO Training Material

GFRSS
Global Food Regulatory Science Society

WHEN Hazards Arise in the Food Supply?

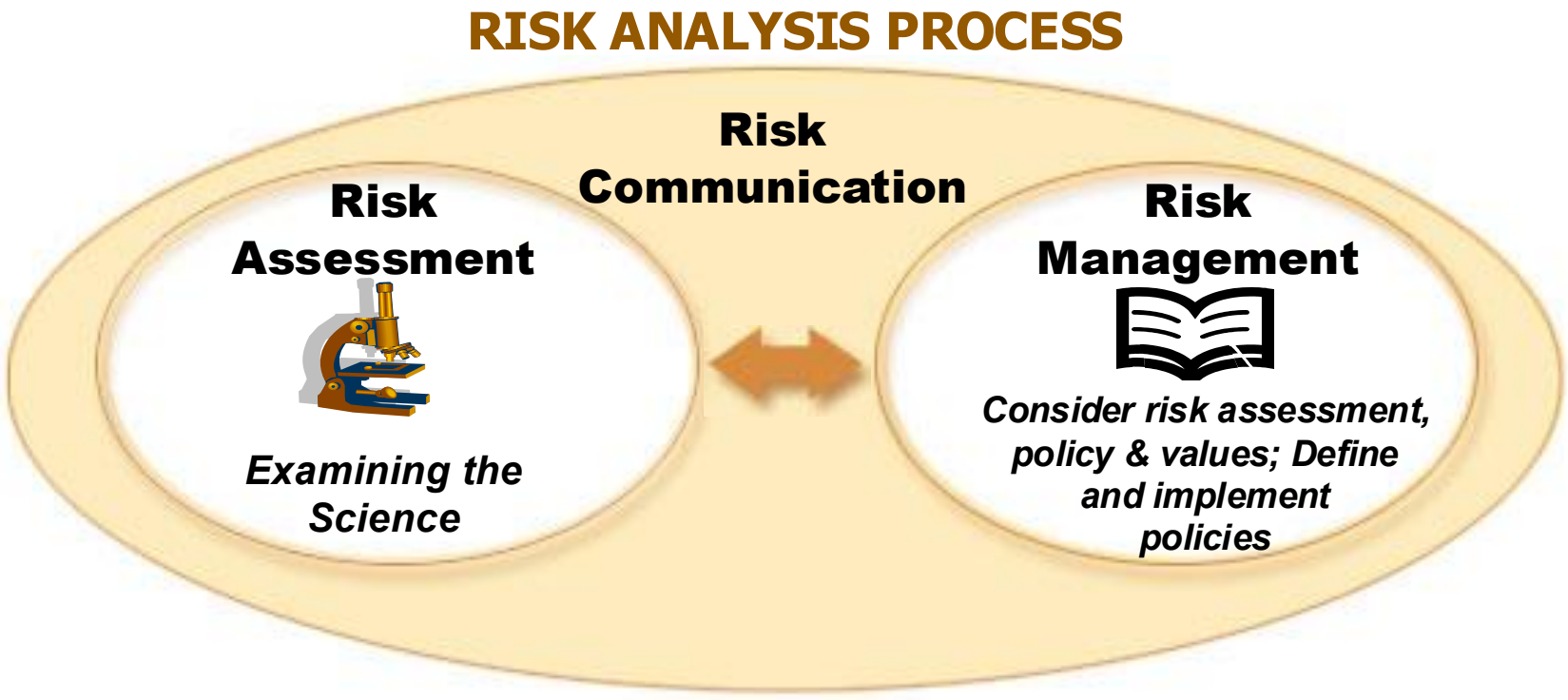
- **Before the raw material enters the food processing**
- **During the storage of raw materials**
- **During the food processing**
- **During the packaging**
- **During the storage of the end-product**
- **During the cooking at home**
- **During its eating**

Extracted from FAO Training Material

GFORSS
Global Food Regulatory Science Society

How Risk Analysis Supports Codex Work

Risk analysis within Codex is a structured, systematic process that examines the potential adverse health effect consequential to a **hazard** or condition of a food, and develops options for mitigating that **risk**.



Extracted from FAO Training Material

Risk Analysis Components

Within Codex, **risk analysis** is defined as a process consisting of three distinct but closely linked **components**:

Risk assessment

Risk management

Risk communication

Extracted from FAO Training Material

GFRSS
Global Food Regulatory Science Society

The Scientific Basis of Codex

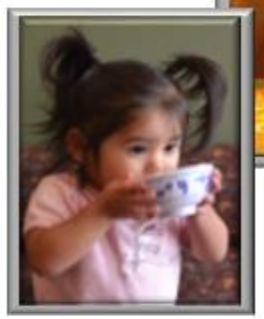
Food and Agriculture Organization of the United Nations

World Health Organization

CODEX ALIMENTARIUS COMMISSION

International Food Safety Standards

Consumer Protection and Fair Food Trade Practices



Extracted from FAO Training Material

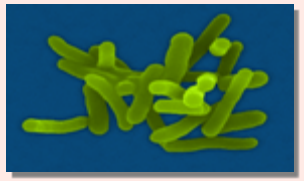
GFRSS Global Food Regulatory Science Society

Risk Managers and Risk Assessors in Codex

International Risk Assessment

• JECFA
(food additives, veterinary drug residues, contaminants in food)

• JMPR
(pesticide residues in food)



• JEMRA (microbiological hazards in food)

• ad hoc expert consultations

Scientific advice

Requests for advice, risk assessment

International Risk Manager

CODEX ALIMENTARIUS COMMISION

CODEX ALIMENTARIUS
1963-2023

Extracted from FAO Training Material

GFRSS
Global Food Regulatory Science Society

Risk Managers and Risk Assessors Beyond Codex

Examples of Risk Analysis in Codex

	Vet Drug Residues in Food	Food derived from GMOs
Conduct of Risk Assessment	JECFA (FAO and WHO)	Governments
Standards setting (risk management)	Codex (CCRVDF and CAC)	Codex (and governments)
Enforcement	Governments	Governments

Extracted from FAO Training Material

GFRSS
Global Food Regulatory Science Society

Risk Analysis – Reference Guidance

Codex Procedural Manual – governing the interaction between Codex and expert bodies (includes Statements of Principle, Definitions of Risk Analysis and the Working Principles for Risk Analysis in the Framework of Codex)

Internal rules within the expert bodies (FAO/WHO Framework for the provision of scientific advice on food safety and nutrition)

Guidance addressed to governments (Working Principles for Risk Analysis for Food Safety for Application by Government, and the FAO/WHO publication "Food safety risk analysis – A guide for national food safety authorities")

Extracted from FAO Training Material

GFRSS
Global Food Regulatory Science Society

Compliance with SPS Agreement

Article 5: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. Members shall ensure that their **sanitary** or phytosanitary **measures** are based on an assessment, as appropriate to the circumstances, of the **risks to human**, animal or plant life or health, taking into account risk assessment techniques developed by the **relevant international organizations**.

2. In the assessment of risks, Members shall take into account **available scientific evidence**; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

Extracted from FAO Training Material

Compliance with SPS Agreement (2)

Article 5: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

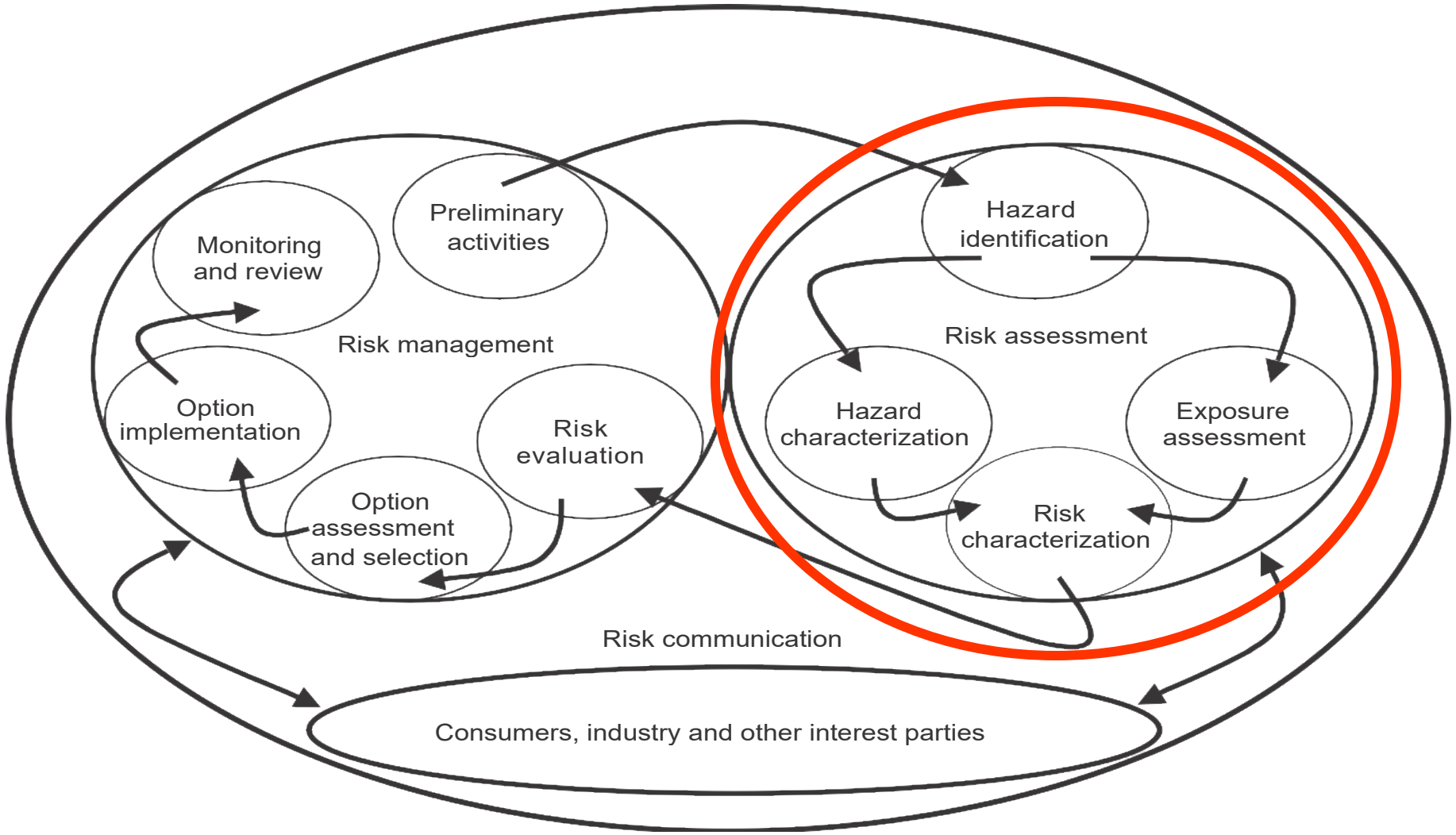
4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, **take into account the objective of minimizing negative trade effects**.

5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member **shall avoid <u>arbitrary</u> or unjustifiable distinctions in the levels it considers to be appropriate in different situations**, (…)

Extracted from FAO Training Material

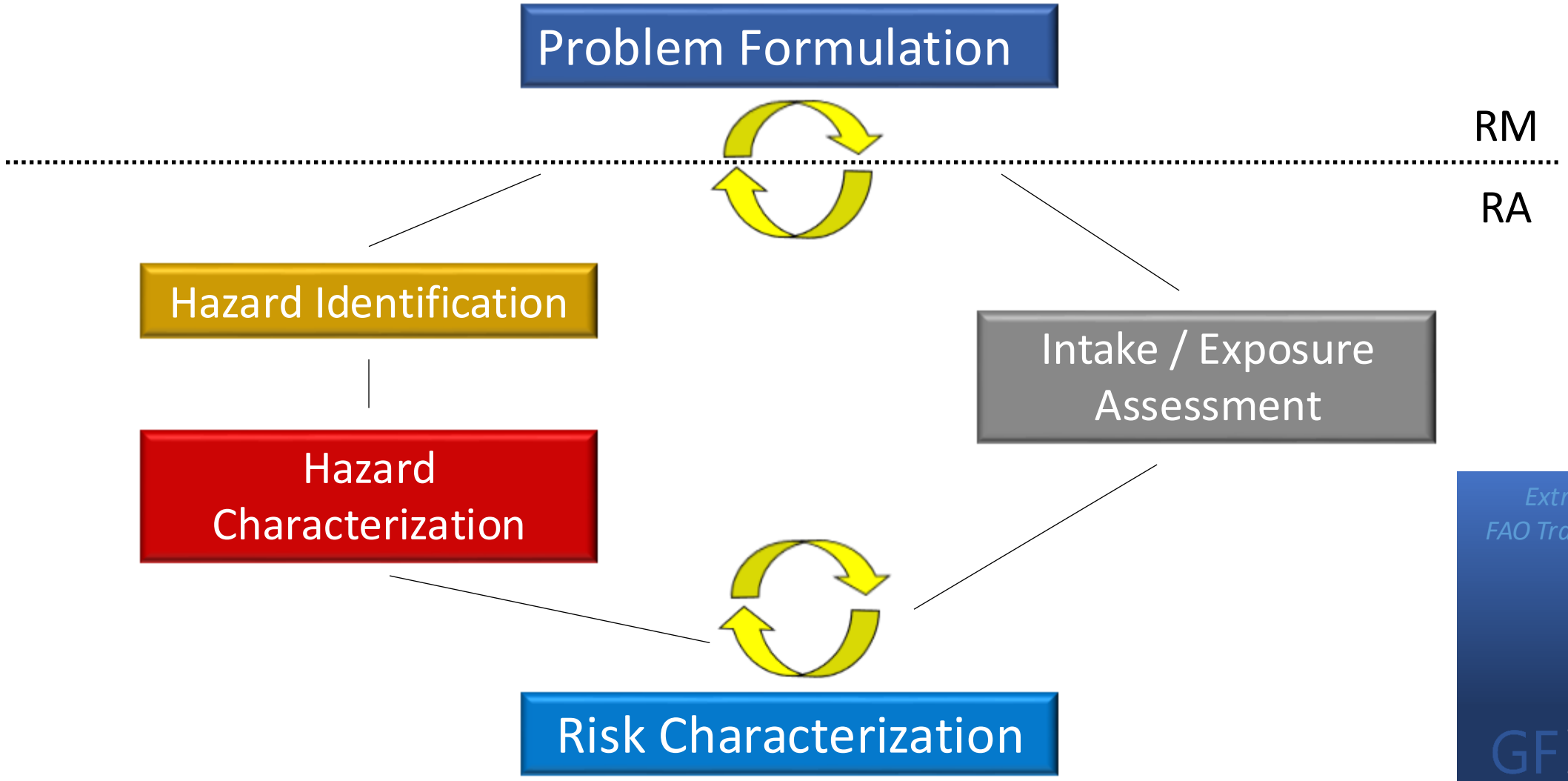
GFRSS Global Food Regulatory Science Society

Moving to Scientific Assessment



Extracted from FAO Training Material

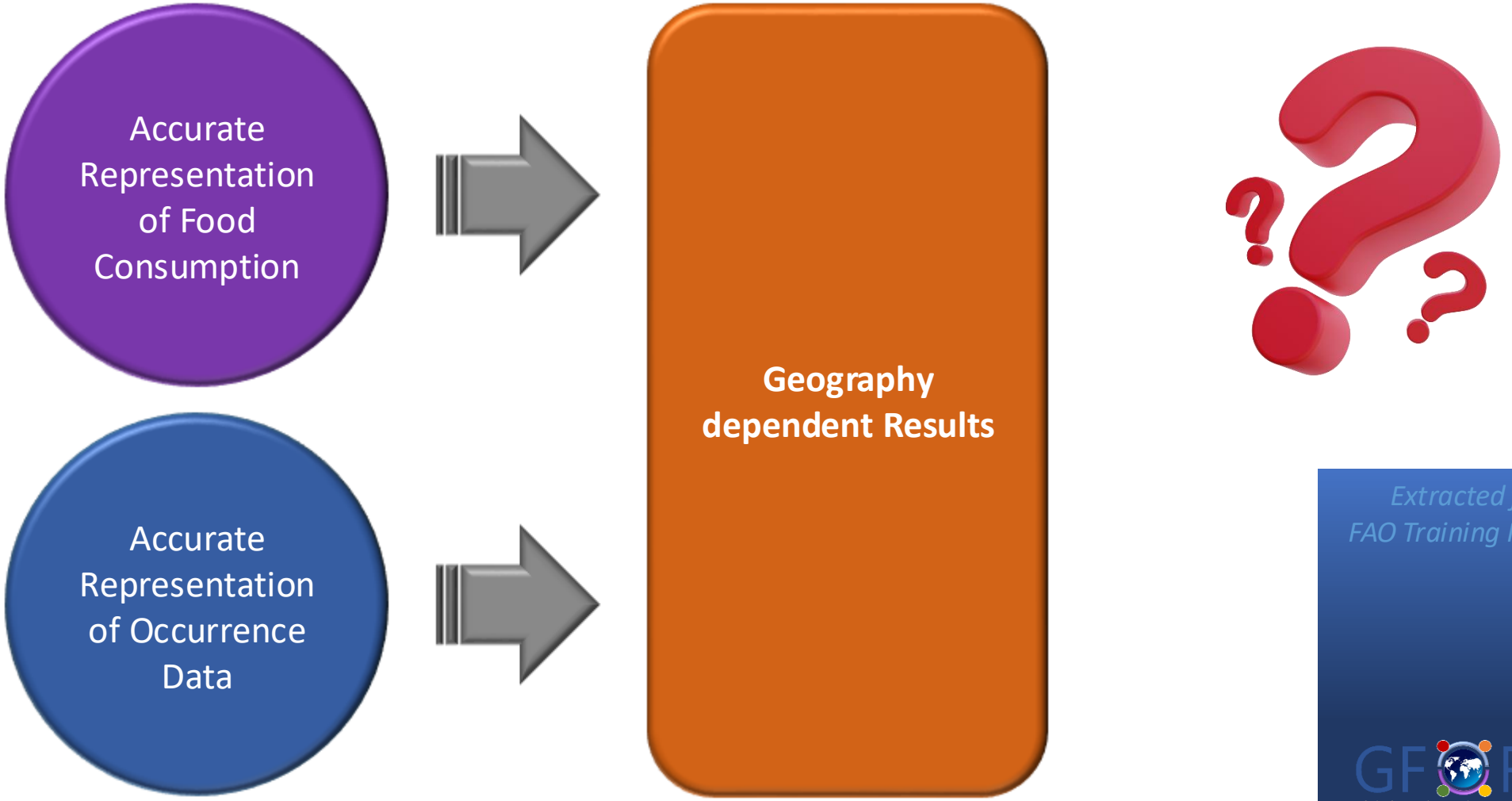
Risk Assessment Procedure: A Scientific Process



Extracted from FAO Training Material


Is a Risk Assessment
Conducted Internationally
Valid for Every Country

What Would Make a Risk Assessment Representative ?



Extracted from FAO Training Material

Assessment of Hazards and Exposure in Food: Data Characteristics

Data for hazard assessment:

- ❑Experimental (toxicological) studies performed according to (inter)national guidelines (e.g. OECD text guidelines)
  - Independent of country or region!
- ❑Human data: epidemiological data; occupational data; volunteer studies
  - May reflect susceptibility (e.g. genetic predisposition, life-style factors)

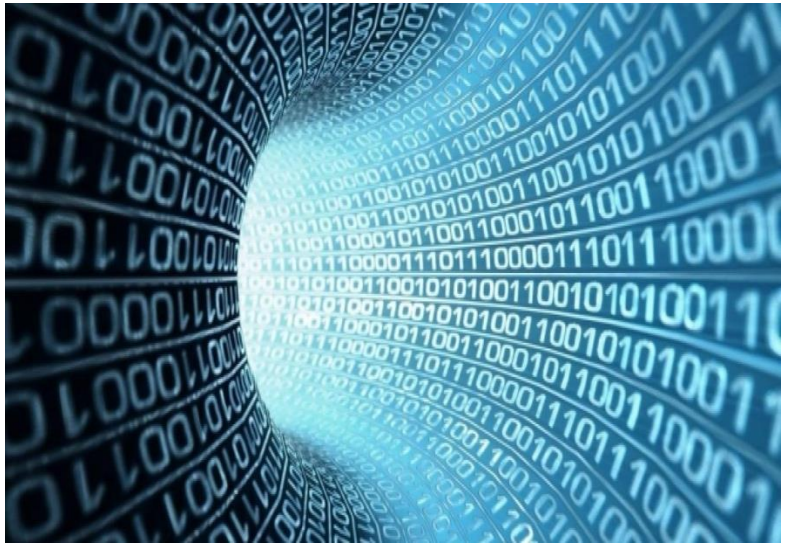
Data for dietary intakes/dietary exposure assessment:

- ❑National occurrence and consumption data
- ❑International and national dietary intakes/exposure estimates

Extracted from FAO Training Material

Assessment of Chemicals in Food

Data sources:



- ❑ Regulatory data submission by manufacturer/ industry
  - For compounds intentionally added to foods
- ❑ Data from governments
  - Monitoring data; epidemiological data; research data
- ❑ Open scientific literature
  - Experimental research, human data

Extracted from FAO Training Material


thank you
danke
謝謝
ngiyabonga
teşekkür ederim
gracias
merci
obrigado
bedankt
dziękuję
go raibh maith agat
kop khun krap
sukriya
terima kasih
arigatô
dakujem
grazie
tapadh leat
mochchakkeram
спасибо
рахмат
Баярлалаа
faafetai lava
kiitos
dankie
dhanyavad
nanni
nandri
bayarlaa
gràçie
enkosi
hvala
mauruuru
köszönöm
vinaka
спасибі
blagodaram
mersi
kia ora
barka
welalin
tack
spas
dank je
misaotra
matondo
paldies
grazzi
mahalo
хвала
asante
manana
obrigada
murakoze
tenki
chokrane
djiere dieuf
tau
дякую
mamnun
akun
dankon
ačiū
chnorakaloutioun
gratias ago
gràcies
sulpáy
taiku
sobodi
děkuji
sagolun
mèsi
didi madloba
najis tuke
kam sah hamnida
rahmat
তোমাকে ধন্যবাদ
ありがとう
tanemirt
rahmet
diolch
dhanyavadagalu
shukriya
mercé
мерси
takk
trugarez
xièxie
감사합니다
ευχαριστώ
شكرًا لك