



## **Training on Probabilistic Risk Assessment**

*16 November 2025 • Dubai, United Arab Emirates*

# **Positioning Risk Assessment in Evidence-Based Food Regulatory Decision-Making**

# Risk Analysis Provides Structure to Food Regulatory Decisions <sup>2</sup>

- ❑ **Risk Analysis** is the **logical framework** that underlies **decision-making** concerning all kinds of risks (not only for food safety and nutrition)
- ❑ Applied to Food Safety and Nutrition Decision-Making Developed through the FAO/WHO Food Standards Program and particularly the Codex Alimentarius Commission (Codex)



# Definition of Food Risk Analysis

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*An **iterative and highly interactive** process that should be followed by food **decision-makers** to address food safety and nutrition issues, using **robust evidence**, including **scientific information** and regular exchange with all parties and stakeholders involved*

**Comprises 3 components :**

**Risk Assessment**

**Risk Management**

**Risk Communication**



# Risk Analysis Paradigm Provides Structure

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## Robust Food Decisions



## The Risk Analysis Paradigm and Risk Assessment in Particular



## ENSURING FOOD SAFETY AND ANIMAL AND PLANT HEALTH MEASURES SET OUT THE BASIC RULES IN THE WTO



### ☐ SPS Agreement

- Applies to **all sanitary and phytosanitary measures** which may, directly or indirectly, affect international trade.

### ☐ TBT Agreement

- Ensures that technical regulations, standards, and conformity assessment procedures are **non-discriminatory and do not create unnecessary obstacles to trade**.
- Applies to **all products, including industrial and agricultural products**
- **Does not apply** to sanitary and phytosanitary measures as defined in 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.



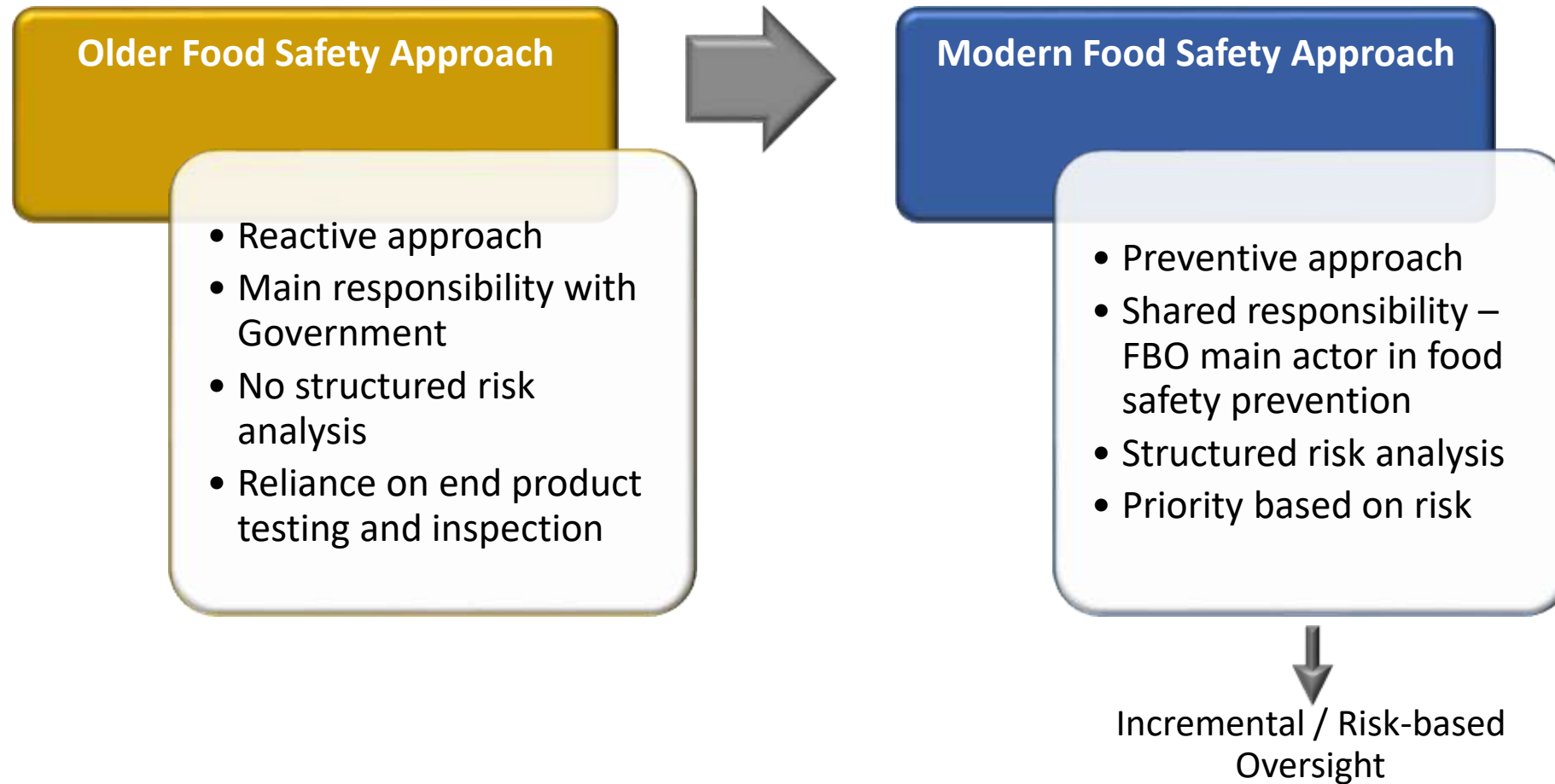
## Article 5: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

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 arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations (...)**



# Moving Towards Risk-based Interventions

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Address Emerging Food Safety Issues:  
Reactive Risk Assessment



Inform Food Regulatory Decisions:  
Rule Making / Standard Setting

# 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 .

## 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.

# 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.

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**.

# 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

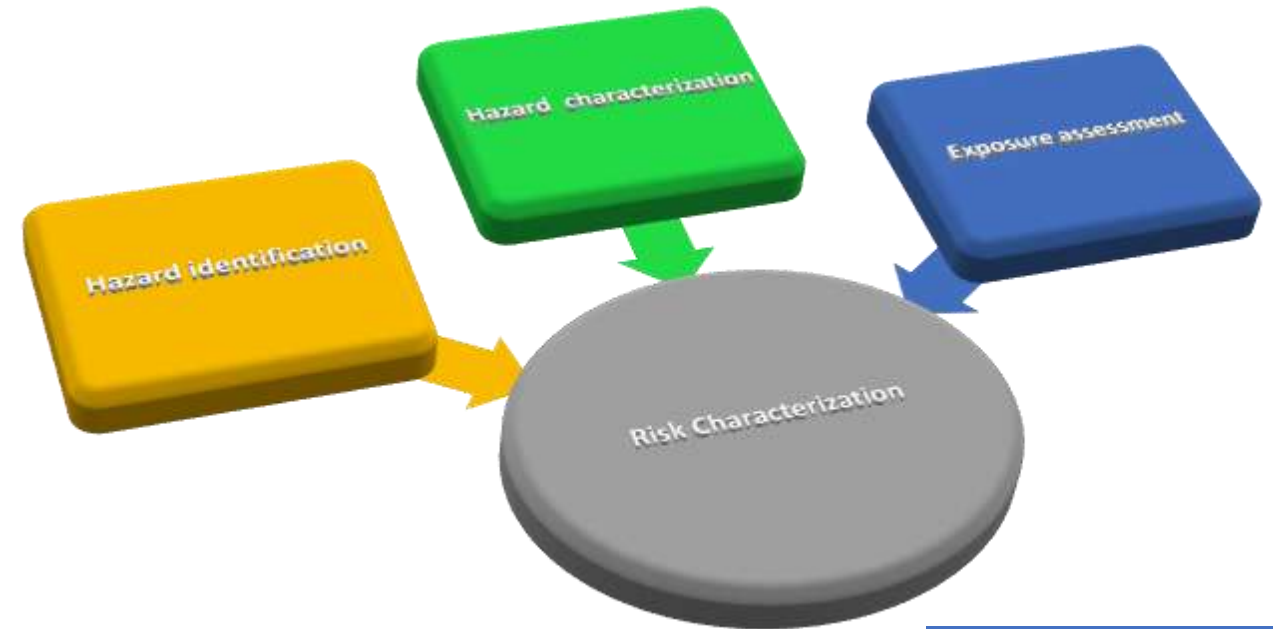
Not used in  
isolation, but  
as a part of  
**Risk Analysis**



# 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



**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**.



# Key Concept: Hazard vs Risk?

## Hazard



## Risk



# The difference is the EXPOSURE

## Key Concept: Hazard vs Risk? (2)

### Hazard



### Risk



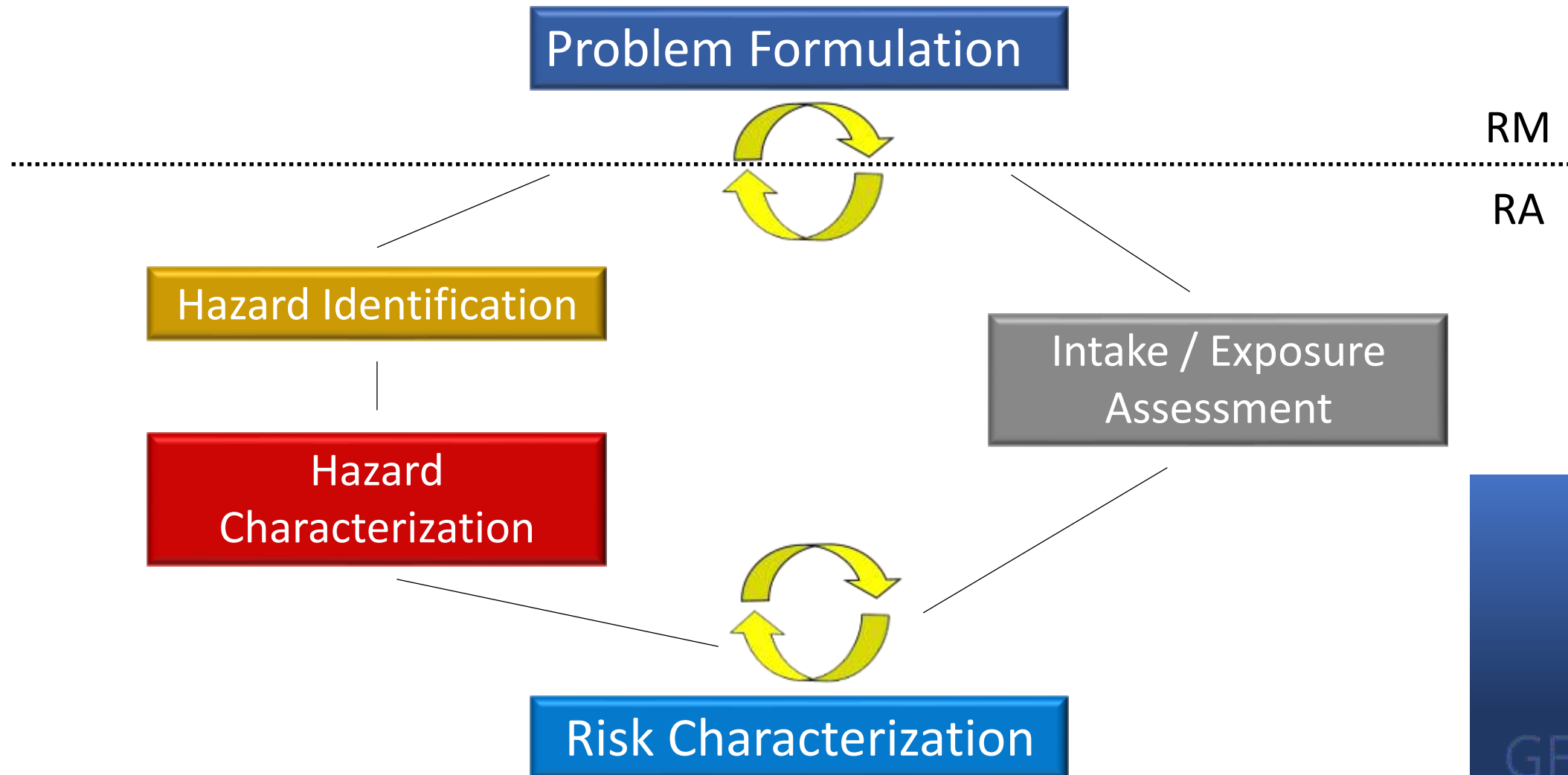
The difference is the **EXPOSURE**

# 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



# Risk Assessment Procedure: A Scientific Process





**Is a Risk Assessment  
Conducted Internationally  
Valid for Every Country**

# Dietary Intakes/Dietary Exposure Assessment

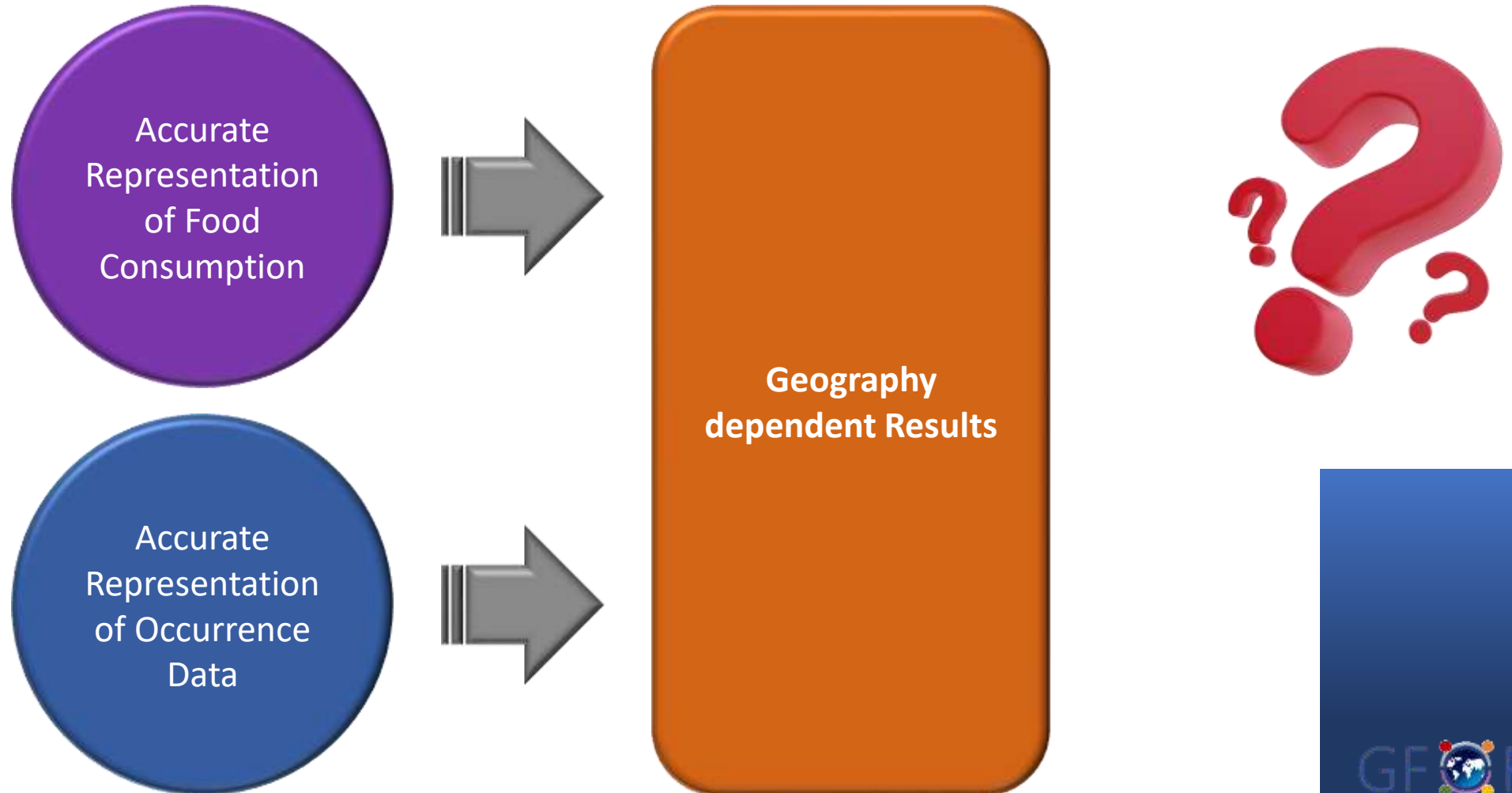
**Occurrence of  
Food Chemicals**



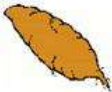
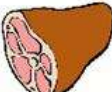
**Food  
consumption**



# What Would Make a Risk Assessment Representative ?



# Deterministic Versus Probabilistic

| Amount brought by each food |                                                                                          | Amount Consumed (g/day) |       | Occurrence data (µg/g) |        | Body weight (kg) |   | Intake / Exposure (µg/kg/day) |  |
|-----------------------------|------------------------------------------------------------------------------------------|-------------------------|-------|------------------------|--------|------------------|---|-------------------------------|--|
| Overall Diet                |         | =                       | 141,9 | X                      | 0,0093 | / 65             | = | 0,020                         |  |
|                             | +<br>   | =                       | 198,4 | X                      | 0,0009 | / 65             | = | 0,003                         |  |
|                             | +<br>   | =                       | 191,5 | X                      | 0,0076 | / 65             | = | 0,022                         |  |
|                             | +<br>  | =                       | 541,4 | X                      | 0,0025 | / 65             | = | 0,021                         |  |
|                             | +<br> | =                       | 315,0 | X                      | 0,0007 | / 65             | = | 0,003                         |  |
|                             |                                                                                          |                         |       |                        |        | Total            | = | 0,070 (µg/kg/day)             |  |

# Different Populations / Different Consumption Patterns



Adult population



Pregnant w



Small children



Infants

**Special groups:**  
vegetarians,  
diabetics, ethnic  
groups and different  
socio-economic  
strata ...

Dose apportée  
par chaque aliment = Quantité  
consommée x Niveau  
résiduel

Ensemble du  
régime  
alimentaire

|                                                                                       |   |       |   |        |
|---------------------------------------------------------------------------------------|---|-------|---|--------|
|    | = | 141,9 | x | 0,0093 |
| +                                                                                     |   |       |   |        |
|   | = | 198,4 | x | 0,0009 |
| +                                                                                     |   |       |   |        |
|  | = | 191,5 | x | 0,0076 |
| +                                                                                     |   |       |   |        |
|  | = | 541,4 | x | 0,0025 |
| +                                                                                     |   |       |   |        |
|  | = | 315,0 | x | 0,0007 |

# Occurrence Levels Vary Consumption Patterns Vary



# Exposure Assessment: Re-creating ... Simulating the reality .... Realities ....

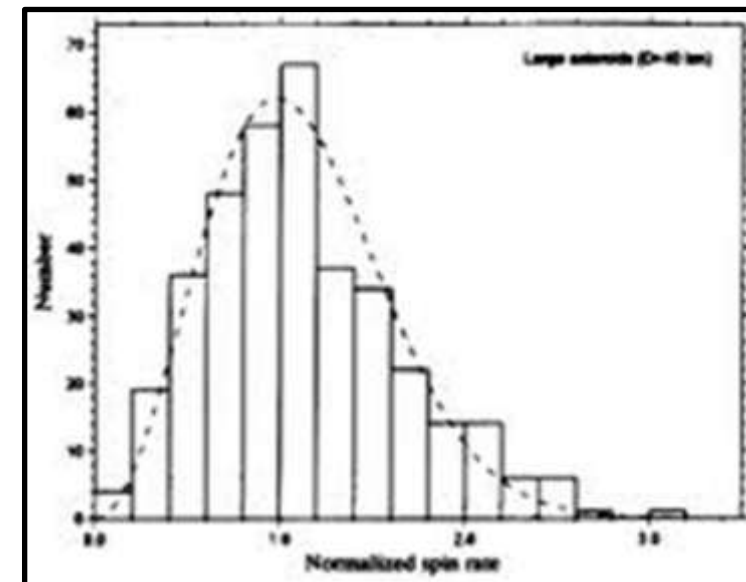
Random Runs

| IDENTI  | viande | vin  | cereal | pain | cafe | fruitleg | sec | riz  | alcool |
|---------|--------|------|--------|------|------|----------|-----|------|--------|
| 1000103 | 150    | 0    | 585    | 120  | 0    | 0        | 320 | 200  | 0      |
| 1000302 | 30     | 0    | 90     | 410  | 22   | 0        | 0   | 0    | 0      |
| 1000802 | 188    | 0    | 705    | 600  | 0    | 175      | 0   | 100  | 0      |
| 1000902 | 360    | 0    | 250    | 670  | 0    | 0        | 200 | 150  | 0      |
| 1000102 | 1020   | 0    | 200    | 700  | 67   | 0        | 100 | 600  | 0      |
| 1000404 | 270    | 0    | 586    | 790  | 70   | 0        | 0   | 910  | 0      |
| 1000601 | 275    | 0    | 100    | 840  | 51   | 0        | 0   | 100  | 0      |
| 1000801 | 200    | 0    | 610    | 880  | 94   | 615      | 0   | 150  | 0      |
| 1000401 | 195    | 0    | 450    | 980  | 70   | 0        | 80  | 1200 | 0      |
| 1000101 | 400    | 770  | 1000   | 1030 | 67   | 0        | 200 | 400  | 0      |
| 1000502 | 175    | 800  | 260    | 1040 | 126  | 500      | 0   | 0    | 0      |
| 1000601 | 275    | 0    | 100    | 840  | 51   | 0        | 0   | 100  | 0      |
| 1000301 | 740    | 0    | 515    | 1095 | 0    | 0        | 0   | 0    | 0      |
| 1000702 | 193    | 0    | 400    | 1114 | 175  | 0        | 320 | 0    | 0      |
| 1000403 | 185    | 0    | 75     | 1140 | 15   | 0        | 0   | 1550 | 0      |
| 1000402 | 195    | 0    | 375    | 1145 | 70   | 0        | 80  | 1200 | 0      |
| 1000601 | 275    | 0    | 100    | 840  | 51   | 0        | 0   | 100  | 0      |
| 1000701 | 280    | 0    | 335    | 1494 | 121  | 0        | 320 | 0    | 0      |
| 1000901 | 430    | 5520 | 0      | 1680 | 82   | 0        | 0   | 150  | 0      |
| 1000201 | 609    | 4360 | 260    | 2386 | 357  | 0        | 990 | 0    | 0      |
| 1000703 | 460    | 0    | 365    | 2838 | 26   | 0        | 320 | 0    | 0      |

X

| viande | vin  | cereal | pain | cafe  | fruitleg | sec  | riz | alcool |
|--------|------|--------|------|-------|----------|------|-----|--------|
| 0.75   | 0.55 | 0.5    | 0.2  | 1     | 0.2      | 0.5  | 0.5 | 0.05   |
| 0.2    | 0.01 | 0.5    | 2.7  | 1     | 0.05     | 0.5  | 0.5 | 0.05   |
| 0.5    | 0.01 | 0.5    | 0.5  | 1     | 0.19     | 0.1  | 0.5 | 0.05   |
| 0.2    | 0.89 | 0.5    | 0.5  | 1     | 0.06     | 0.5  | 1.4 | 0.05   |
| 0.5    | 0.01 | 0.5    | 0.2  | 0.04  | 0.5      | 1.6  | 0.5 | 0.05   |
| 0.2    | 0.01 | 0.5    | 0.5  | 0.04  | 0.05     | 0.04 | 0.5 | 0.05   |
| 0.34   | 0.01 | 0.5    | 0.5  | 1     | 0.02     | 0.1  | 0.5 | 0.05   |
| 0.2    | 0.01 | 0.5    | 0.2  | 0.04  | 0.5      | 0.5  | 0.5 | 0.05   |
| 0.2    | 0.01 | 0.5    | 0.2  | 0.04  | 0.07     | 0.5  | 0.5 | 0.05   |
| 0.1    | 0.01 | 0.5    | 0.9  | 1     | 0.44     | 0.5  | 0.5 | 0.05   |
| 0.2    | 0.04 | 0.05   | 0.3  | 0.2   | 0.13     | 0.04 | 0.5 | 0.05   |
| 0.5    | 0.01 | 0.5    | 0.5  | 0.1   | 0.46     | 0.2  | 0.5 | 0.05   |
| 0.2    | 0.01 | 0.5    | 0.5  | 1.6   | 0.24     | 0.5  | 0.5 | 0.05   |
| 0.2    | 0.01 | 1      | 0.2  | 0.2   | 0.1      | 0.5  | 0.5 | 0.05   |
| 0.2    | 0.01 | 0.5    | 0.5  | 0.08  | 0.06     | 0.5  | 0.5 | 0.05   |
| 0.2    | 2.89 | 1      | 0.2  | 0.05  | 0.05     | 0.5  | 0.5 | 0.05   |
| 0.2    | 1.48 | 0.5    | 0.5  | 0.88  | 0.08     | 0.2  | 0.5 | 0.05   |
| 0.2    | 0.01 | 0.5    | 0.5  | 0.066 | 0.5      | 0.5  | 0.5 | 0.05   |
| 0.2    | 0.21 | 0.5    | 1.2  | 1     | 0.2      | 0.1  | 0.5 | 0.05   |
| 0.5    | 0.01 | 0.8    | 0.5  | 0.05  | 0.05     | 0.5  | 0.5 | 0.05   |
| 0.2    | 0.01 | 0.5    | 0.5  | 3.2   | 0.11     | 0.5  | 0.5 | 0.05   |

Product term by term and dividing by the body weight



[illegible]