WORKSHOP ON DATA COLLECTION AND ANALYSIS FOR CODEX PROCEEDINGS

Dietary Exposure Assessment: General principles

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OUTLINE/OBJECTIVE

The objective is to provide a comprehensive overview of the topic and its significance in risk assessment and regulation:

1. Especially why it is important, focusing on its role in protecting public health and supporting risk assessment.
2. To explore how dietary exposure assessment can be applied to improve regulatory systems, including its practical benefits for food safety management.
3. The application process and logical steps involved in conducting a dietary exposure assessment.
4. Finally, to share some conclusions and opportunities for strengthening regulatory frameworks and advancing food safety using this tool.

DEFINITION (1/2)

Developed and published in 2009,
Updated in 2020

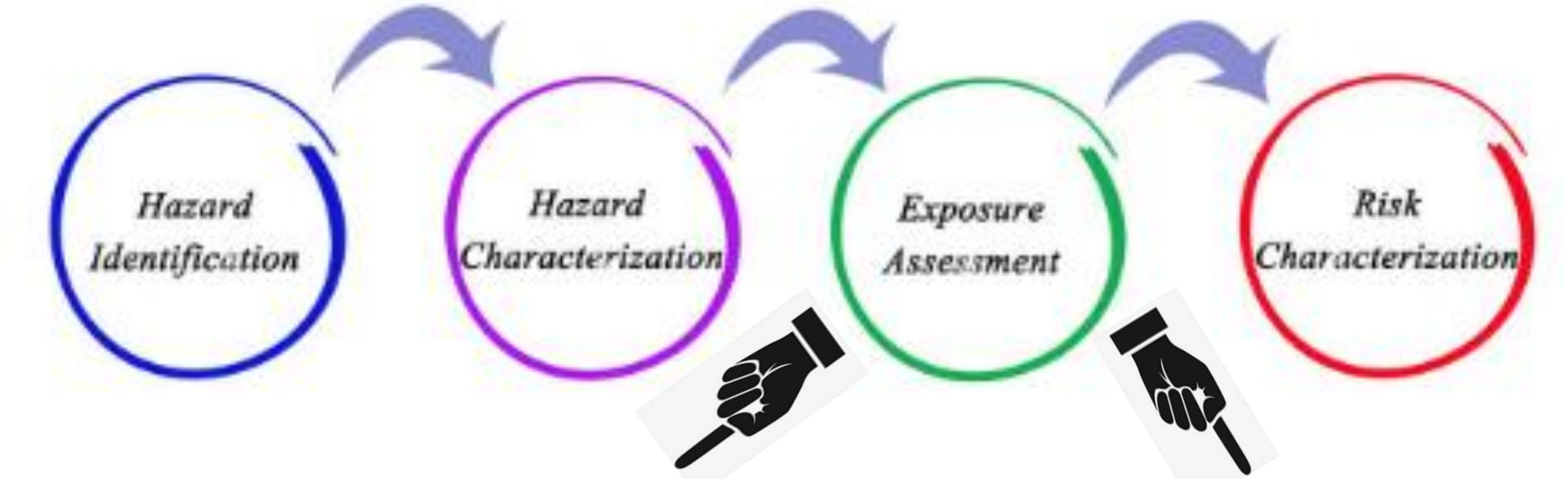
EHC 240: Monograph on the methods and principles for the risk assessment of chemicals in food

"Definition: is the process of qualitative and/or quantitative evaluation of the likely intake of biological, chemical, or physical agents through food, and from other relevant sources if relevant."

$$\text{Dietary exposure} = \Sigma\,(\text{Concentration of chemical in food} \times \text{Food consumption})$$

DEFINITION (2/2)

Dietary exposure assessment is a key step in the four-part risk assessment process, used by Codex, FAO/WHO expert committees like JECFA and JMPR, and other food safety authorities



Estimates **the intake** of hazard (e.g., contaminants, additives, nutrients) **through food consumption for a specific population**.

It combines Key Elements :

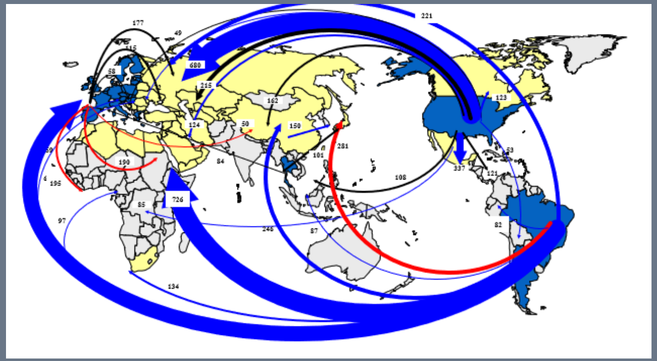
Food Consumption Data + **Hazard Concentration Data**

Potential Exposure Levels.

Why is it important to implement dietary exposure assessment?

Challenges

Nowadays, we are seeing an **increasing burden of food-related risks**. This is mainly due to the **multiplicity of hazards** in our food systems.
For example, we have chemical risks like heavy metals or pesticide residues, microbial risks such as bacteria and viruses, and even allergenic risks from new ingredients.
At the same time, **food production is evolving,** with new products, processing techniques, and global trade. These key risk factors bring new challenges and more **complex exposure scenarios**.



Because of this, **dietary exposure assessment** becomes a key tool. It helps us understand how much of these substances people are actually exposed to, and whether it could pose a risk to health.
This is essential for making sure our **regulatory systems keep up** with today's food safety challenges."

Dietary Exposure Assessment reflect the real-life exposure levels for consumers

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Context and principal objectives

The main reasons why dietary exposure assessment is both important and critical?

We need to make data-driven decisions supported by objective evaluation that balances “risks and benefits”

By DEA

- **better acknowledge the local context**
- **make appropriate choices**
- **reformulate management decisions more effectively, not blindly?**
- **build consumer trust and brand credibility**
- **help us contribute and comply with Codex safety standards (e.g., MRLs, MLs) which is vital for international compliance and trade.**

At the core, it's about building a solid foundation for decision-making, to strengthen food safety, ensure fair market access, and act responsibly in global food trade.

So ultimately, exposure assessment helps us drive smarter decisions in food safety policy and practice."

How it could be applied to improve the regulatory system ?

Main Advantages of Integrating DEA into Food Regulation

In practical situation

"DEA helps make food safety systems smarter, more targeted, and more globally aligned."

Supports Science-Based Decision Making	• Ensures policy relies on realistic, population-specific exposure estimates.
Helps with Proactive Risk Prevention	• Enables early detection and mitigation of foodborne chemical risks.
Is key for Public Health Protection	• Identifies critical exposures for sensitive groups (e.g., infants, pregnant women).
Ensures Codex Alignment	• Facilitates harmonized approaches and mutual recognition across borders.
Brings Economic Efficiency	• Enables early detection and mitigation of foodborne chemical risks.
Improves Regulatory Precision	• Avoids both under- and over-regulation by quantifying actual risk

Key Regulatory functions where DEA plays a critical role

Regulatory Function	How DEA enhances it	Illustrative Examples
In Pre-Market Evaluation	Quantifies expected exposure before authorizing new substances to ensure compliance with health-based guidance values.	*Risk assessment for novel sweeteners, new pesticide active substances, or genetically modified foods.*
It supports Post-Market Surveillance	By monitoring real exposure to detect deviations or new risks under actual consumption scenarios.	*Ongoing analysis of lead in herbs or acrylamide in baked goods in light of changing consumption habits.*
Guides Risk-Based Priority Setting	Helps regulators focus on substances with the highest population-level or subgroup exposure.	*Prioritizing arsenic in rice or aflatoxins in maize for stricter control in vulnerable regions.*
Informs Standard-Setting (MLs, ADIs, TDIs)	justifying Maximum Limits and acceptable daily intakes.	*Re-evaluation of lead MLs in spices or dried bark using worst-case intake scenarios.*
Supports assessment of aggregate & Cumulative Exposure	Integrates dietary and non-dietary exposures for chemicals with shared similar toxicity.	*Organophosphate pesticide exposure via food, water, and indoor residues in children.*
In Public Health Intervention Design	Informs targeted regulatory actions such as bans, risk management plans, or fortification policies.	*Supporting iodine fortification, trans fat bans, or fish consumption advisories due to methylmercury.*
Ensures International Alignment (Codex)	Promoting consistency with global food standards to facilitate trade and protect consumers.	*Alignment with Codex MLs for contaminants and joint FAO/WHO JECFA exposure benchmarks.*
Strengthens Risk Communication & Transparency	Supports clear, evidence-based messaging to consumers and stakeholders.	*Dietary guidance for pregnant women on fish intake due to heavy metals.*
Aids in the Anticipation of Emerging Issues	Evaluates safety of innovative products or contaminants before widespread market penetration.	*DEA of plant-based meat analogs, nanomaterials, or microplastic residues in seafood.*

APPLICATION OF DIETARY EXPOSURE ASSESSMENT

DEA CAN BE APPLIED IN DIFFERENT WAYS, INCLUDING:

Category	Description	Codex-Relevant Examples (With Context)
Timing of Assessment	1. **Pre-market**: Conducted before authorizing a new substance. 2. **Post-market**: Ongoing monitoring after approval. 3. **Contaminant/natural:** Exposure to non-added chemicals.	• Evaluation of novel sweetener, such as aspartame, prior to approval. • Surveillance of organochlorine pesticides in fruits after market release. • Investigation of aflatoxin in nuts in regions with frequent contamination.
Type of Exposure	1. **Acute:** Short-term intake (often a single meal/day). 2. **Chronic (lifetime)**: Ongoing daily intake over a lifetime. 3. **Chronic (shorter-term):** Long exposure over specific life stage or season.	• **Acute:** Estimating short-term exposure to histamine (scombrotoxin) in spoiled fish. • **Chronic (lifetime):** Assessing exposure to cadmium via daily rice consumption. • **Sub-chronic:** Lead exposure in children consuming contaminated spices for several years.
Assessment Scope	1. **Single chemical**: One contaminant or additive. 2. **Aggregate exposure**: Multiple exposure routes for one chemical 3. **Cumulative exposure**: Multiple agents with similar toxicity.	• **Single:** Lead levels in dried bark herbal products consumed daily. • **Aggregate:** Chlorpyrifos exposure via imported fruit + drinking water + environmental inhalation. • **Cumulative:** Grouping organophosphate pesticides with shared neurotoxic effects in dietary modeling.
Methodological Approaches	1. **Deterministic:** Uses fixed key values (e.g. 95th percentile intake × MRL). 2. **Refined deterministic**: Distribution for one variable combined with point estimate for the other. 3. **Probabilistic**: Full distribution modeling.	• **Deterministic:** Worst-case estimate of lead intake—95th percentile dried bark consumption × MRL. • **Refined deterministic:** Using a national food survey (e.g., NHANES) for dietary intake plus a single concentration figure. • **Probabilistic:** Running a Monte Carlo simulation using EFSA's MCRA software to model variability in residue levels and consumption.
Tiered Strategy	**Step-by-step method:** • Tier 1: Conservatively estimate exposure. • Tier 2: Introduce realistic data. • Tier 3: Full probabilistic modeling. **Choice of tier depends on data availability and resources.**	• **Tier 1:** Setting an initial ML for a contaminant using conservative assumptions. • **Tier 2:** Refined input using data from a national monitoring program. • **Tier 3:** Full probabilistic modeling of contaminant, incorporating variability in both residue and consumption.

Key factors (Codex Guidelines)

The approach depend on predefined objectives and key factors

Factor	Description	Example
Purpose of the Assessment	Are we evaluating a new product for approval? Or are we responding to a contamination event? That tell us whether to estimate chronic or acute exposure.	▪ exposure assessment conducted for regulatory approval of a food additive (e.g. sucralose) may require a chronic exposure estimate, ▪ exposure assessment triggered by a contamination incident (e.g. mercury in fish) may focus on acute exposure.
Type of Substance	Nature of the chemical being evaluated. Different substances call for different approaches.	For example, pesticide residues require modeling based on treated crops
Duration and Concern of Exposure	Whether the effect is from long-term or short-term exposure.	Some substances cause harm after long-term exposure (e.g. cadmium accumulation), while others act acutely (e.g. histamine in spoiled fish).
How is exposed? Population Subgroups	Need to assess vulnerable or high-exposure groups separately	Vulnerable groups such as infants, pregnant women, or high consumers (e.g. toddlers consuming large amounts of fruit juice) may be at greater risk and require separate consideration in the assessment.
Available Resources	Availability of data, tools, and expertise for the assessment	Availability of high-quality data (e.g. national dietary surveys, chemical monitoring), analytical capacity, and modeling tools (e.g. Monte Carlo software) will determine whether a deterministic or more refined probabilistic approach can be applied.

By taking into account all these consideration, we ensure our exposure assessment is fit for purpose, evidence based and tailored to protect public health

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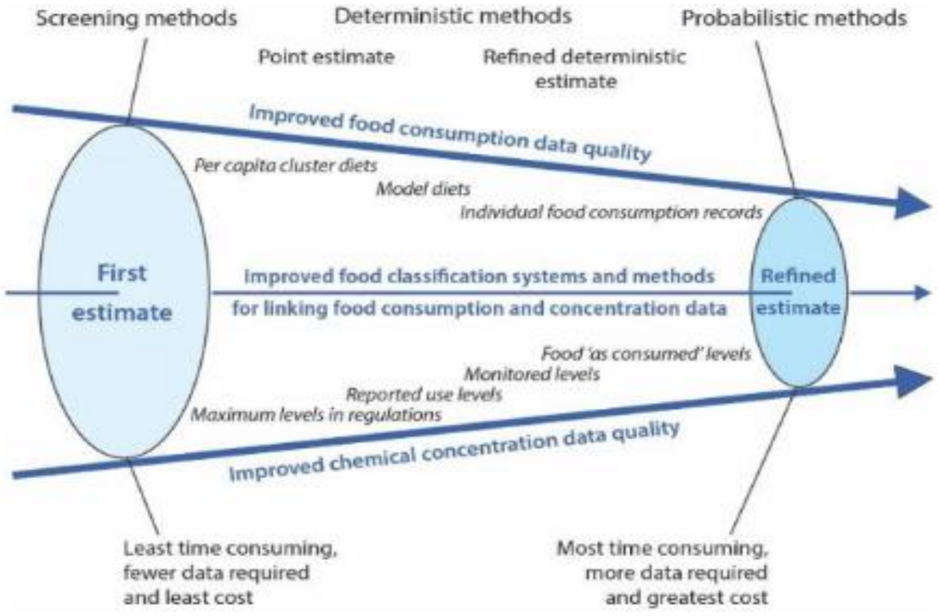
Key Elements (Codex Guidelines)

Dietary exposure assessments may be designed to address specific questions from risk managers

Déterministic Approch

- Calculate risk using point estimates
- Mean values, 95th percentile, worst-case scenario
- Single-point risk estimates
- Conservative approach
- Variability and uncertainty are ignored

Fig. 6.1. Dietary exposure assessment framework



Probabilistic Approach

- Risk calculation using value distributions
- Generation of a risk distribution
- Probability estimation for specific events
- Reflects the impact of variability and uncertainty on risk estimation

Approach	Description	Typical Use
Deterministic	Simple, conservative; uses fixed point estimates (e.g., 95th percentile intake × MRL)	Initial screening, regulatory thresholds
Refined Deterministic	Combines empirical distribution (food consumption or residue) with fixed values	Intermediate assessments, vulnerable subgroups
Probabilistic	Uses full variability and uncertainty modeling (e.g., Monte Carlo simulations)	Detailed risk characterization, cumulative/multi-route exposure
Tiered Approach	Sequential application: start with deterministic, move to refined or probabilistic if needed	Efficient use of resources; according to data availability

Application and logical steps?

DIETARY EXPOSURE ASSESSMENT IS A PART OF RISK ASSESSMENT

DEA IS THE CORE STEP IN THE OVERALL RISK ASSESSMENT PROCESS

To collect Data

Exposure assessment

Estimating how much of the hazard people actually consume

Hazard

EXPOSITION

Résidus

"Hazard Concentration Data"

Consumption

"Amount and frequency of foods consumed"

(e.g., national surveys, individual intake records)"

Hazard identification and characterization

RISK

Risk characterization

Key Elements (Codex Guidelines)

Effective dietary exposure assessment requires:

- ✓ Clear define assessment objectives .
- ✓ High-quality, representative data.
- ✓ Appropriate Use fit-for-purpose methods.
- ✓ Consideration of variability, uncertainty, and vulnerable populations.

Risk managers decide on the level of consumer protection needed

1. **Food Consumption Data** – Amount and frequency of foods consumed (e.g., national surveys, individual intake records).

2. **Hazard Concentration Data** – Levels of the substance in food (e.g., pesticide residues, heavy metals, mycotoxins).

3. **Exposure Calculation**

   - **Deterministic Approach:** Uses average or high-percentile consumption and contamination levels.
   - **Probabilistic Approach:** Models variability and uncertainty in exposure distributions.

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Exposure Calculation: Deterministic approach

EXPOSURE (MG/KG BW/DAY) = (CONCENTRATION IN FOOD × DAILY INTAKE OF FOOD) / BODY WEIGHT

Common Scenarios:

- **Worst-Case**: 95th percentile consumption × MRL/mean concentration.
- **Average Case**: Mean consumption × mean concentration

- **Concentration in food** (mg/kg): the amount of the substance in the food item.
- **Daily intake** (kg/day): the average amount of that food consumed per person.
- **Body weight** (kg): usually assumed average (e.g., 60 or 70 kg for adults).

Example

- Lead concentration in a vegetable = 0.05 mg/kg
- Daily consumption of that vegetable = 0.2 kg/day
- Body weight = 70 kg

Exposure = (0.05 mg/kg × 0.2 kg) / 70 kg = 0.000143 mg/kg bw/day

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Aggregated Exposure Calculation: exposure through the entire diet (total intake)

ESTIMATION OF CONSUMER EXPOSURE

Used for risk characterization
%ADI-TDI / %ARfD For chronic and acute exposure.

whole diet

Dietary amounts of food consumption		Quantity		Concentration
+	=	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

Chronic exposure

- Average Consumption
- Average contamination observed for each product

Acute Exposure

- Consumption on a given day
- A very highly contaminated food (97.5th percentile of observed contamination). Average contamination of other foods

Per person, we multiply the consumption of each food by its residual level (measured levels), we add up the intakes, then we divide by the body weight.

$$\text{Total Exposure} = \frac{\sum_{i=1}^{n}(C_i \times I_i)}{BW}$$

Where:

- *C= concentration of the substance in food item*
- *I = daily intake of food item (kg/day)*
- *n = number of different food items considered*
- *BW = body weight of the individual (kg)*

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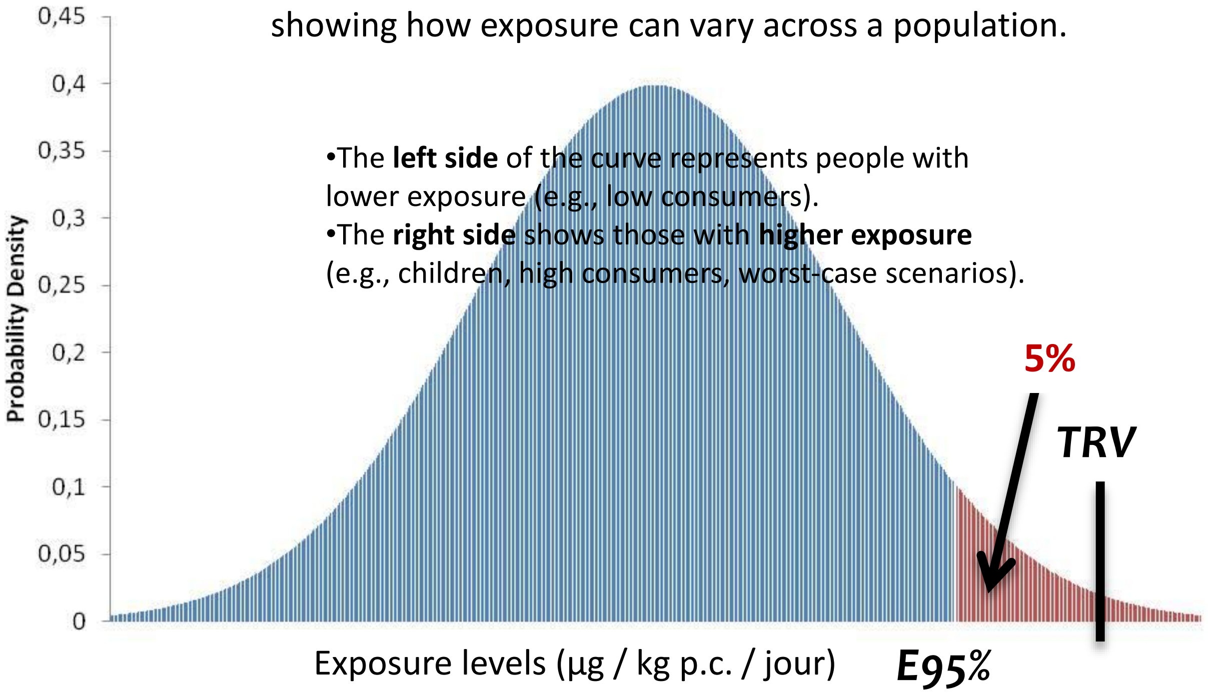
Exposure Calculation: Probabilistic approach

Calculation carried out at the individual level then distribution of exposures by population

This generates a **distribution of possible exposure values**, showing how exposure can vary across a population.



- The **left side** of the curve represents people with lower exposure (e.g., low consumers).
- The **right side** shows those with **higher exposure** (e.g., children, high consumers, worst-case scenarios).

Allows calculation of percentiles (e.g., median, 95th percentile), giving a better understanding of exposure for different individuals or groups.

$$\textbf{Ratio} = \left(\frac{\text{95th Percentile of Exposure}}{\text{TRV}} \right) \times 100$$

Instead of calculating a single exposure value, we run **many simulations Monte Carlo simulation** (e.g., 10,000) where each iteration uses a different set of inputs sampled from realistic distributions (e.g., for food intake, contaminant levels, body weight).

- **95th Percentile of Exposure** = the high-end estimate of exposure (representing more sensitive or high-consuming individuals)
- **TRV (Toxicological Reference Value)** = the benchmark dose (e.g., ADI, TDI) used to assess risk

RISK IS EXPRESSED IN TERMS OF EXCESS COMPARED TO A REFERENCE VALUE

Interpretation:
- A **ratio < 100** suggests that exposure is below the reference value.
- A **ratio ≥ 100** suggests that exposure may exceed safe levels and could be a concern.

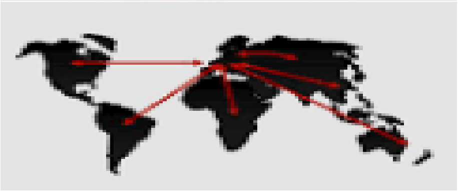
Conclusion

Dietary Exposure Assessment methodology ??

- **Use of conservative, fit-for-purpose methods** to ensure health protection
- **Clear objective definition** to guide method and data selection
- **Consideration of general and vulnerable populations** (e.g., children, pregnant women)
- **Separate assessments for specific subgroups**, when needed
- **Country-specific data reporting**, national estimates
- **Transparent documentation** of models, data sources, assumptions, and uncertainties

Food safety ??

Key Opportunities for Arab Countries : Enhancing DEA Application



- **Generate National Data** on food consumption and contaminant levels to support local risk assessments (*Conduct Dietary Surveys tailored to regional habits and vulnerable groups (e.g., children, pregnant women)).*
- **Strengthen Codex Contributions** by submitting national data to conduct exposure estimates for international ML development.
- **Support National Standard-Setting** using DEA to adapt Codex MLs to local contexts.
- **Quantify Risk Reduction** through intake modeling to inform regulatory decisions.
- **Foster Regional Collaboration** on data sharing, joint surveys, and harmonized methods.
- **Develop Technical Capacity** through training in exposure modeling and risk assessment tools.
- **Improve Public Health Protection** by identifying high-exposure foods and populations at risk.

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