WORKSHOP ON DATA COLLECTION AND ANALYSIS FOR CODEX PROCEEDINGS

Preliminary calculation of effects of MLs on the reduction of dietary exposure to the contaminant from the target commodity(ies) at hypothetical MLs

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INTRODUCTION

Different important steps are applied within codex framework throw the structured process for the establishment of safety standards. Generally, this process begins with scientific risk assessments conducted by expert bodies, **JECFA** for food additives and contaminants, and **JMPR** for pesticide residues. These bodies provide key inputs such as ***health-based guidance values and dietary exposure estimates***.

Following this, **Codex working groups** may be convened in some cases to analyze available data, assess potential impacts on trade and public health, and propose appropriate MLs. These efforts feed into Codex Committee discussions, ensuring that final standards are both evidence-based and aligned with international food safety goals.

During the presentation, we will focus on one of these preliminary steps: ***the assessment of how hypothetical maximum levels (MLs) can reduce dietary exposure to contaminants in specific commodities***. This type of analysis not only supports our shared goal of improving food safety through science-based regulation and global harmonization, but also provides valuable insight into the potential impact of MLs, helping risk managers/Codex make informed, proportionate decisions.

OUTLINE

In this talk, I will:

1. Outline the **methodology** for conducting preliminary exposure calculation of effects of MLs on the reduction of dietary exposure.
2. Demonstrate how these calculations can inform **Codex deliberations**.
3. Share a simplified case study using **hypothetical MLs** to highlight practical application.

This work supports:

- ✓ Improved data collection strategies,
- ✓ Stronger scientific justifications in Codex discussions,
- ✓ Enhanced regional participation in the standard-setting process.

INTRODUCTION

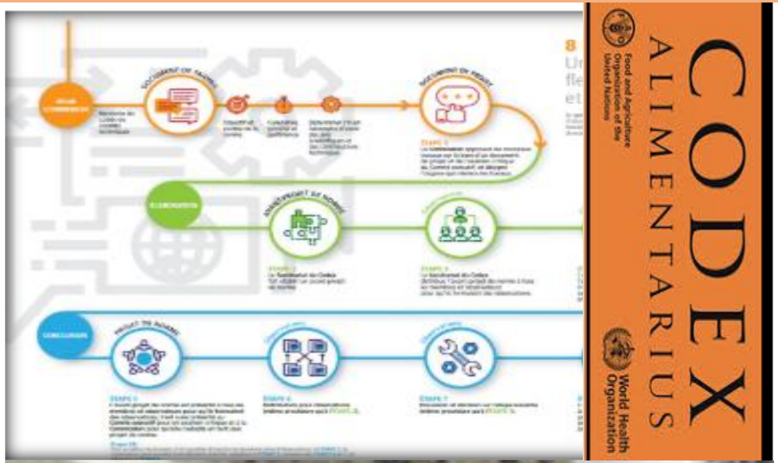
The Codex Alimentarius, through its scientific advisory bodies such as the Joint FAO/WHO Expert Committee (JECFA, JMPR, etc.) and WG, adopts a structured methodology to support risk management decisions.

A key component of this process is the preliminary calculation of the potential impact of hypothetical Maximum Levels (MLs) on dietary exposure to specific contaminants from target commodities.

This methodology is designed to estimate how different ML scenarios may influence overall dietary exposure levels, thereby aiding in the assessment of risk reduction benefits.

The approach typically involves the use of **food consumption data, occurrence data** for the contaminant in relevant commodities, to simulate exposure **under various hypothetical MLs**.

These calculations serve as a screening tool to inform whether proposed MLs could effectively reduce exposure without disproportionately affecting trade, ensuring consumer protection while maintaining food security and market feasibility.



Benefits and goals

Apply the Codex stepwise approach for the establishment of standards

- Assess whether proposed standards (e.g., MLs) are protective of public health,
- **Adapt international guidance** to local food consumption patterns and contaminant occurrence,
- Support the development of **science-based food safety standards** that reflect **local environmental and dietary realities**, while aligning with **Codex principles**.
- Supports the application of the **ALARA principle** (As Low As Reasonably Achievable), as practical risk management tools to minimize consumer exposure while considering feasibility for trade facilitation.

Examples of Application in the Codex Framework

CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda item 5

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON CONTAMINANTS IN FOODS
Eighteenth Session
23-27 June 2025
Bangkok, Thailand
MAXIMUM LEVELS FOR LEAD IN CERTAIN FOOD CATEGORIES

(Prepared by the Electronic Working Group chaired by Brazil)

MAXIMUM LEVELS FOR LEAD IN CERTAIN FOOD CATEGORIES

Table 4. Effect of implementing hypothetical MLs for lead on dried bark (n = 768), based on the UB approach.

ML (mg/kg)	Mean levels (mg/kg)	Sample rejection (%)	Intake reduction* (%)
No ML	0.68	0.0	0.0
3.0	0.60	2.6	12
2.5	0.57	4.0	16
2.0	0.49	8.2	27
1.5	0.40	14.8	41
1.0	0.31	23.7	55

ANALYSIS OF THE OCCURRENCE DATA OF LEAD IN SPICE MIXTURES

Table 3: Projection of rejection rates based on ML scenarios

ML Scenario	Data points	Mean lead concentration (mg/kg)	Lead concentration 95th Percentile (mg/kg)	Rejection rate (%)
No ML	5250	0.60	1.03	0
ML: 2 mg/kg	5148	0.21	0.78	1.9
ML: 1 mg/kg	4982	0.17	0.57	5.1

ANALYSIS OF OCCURRENCE DATA OF AFLATOXINS IN CEREALS

Cereal	ML Scenario (µg/kg)	Data points	Mean AFT concentration (µg/kg)	High AFT concentration 95th Percentile (µg/kg)	Rejection rate (%)
Maize flour	**No ML**	**718**	**9.80**	**15.42**	**0**
	ML: 15	681	0.69	2.84	5.2
	ML: 10 (CXS-193-1995)	675	0.59	2.39	6.0
Maize	**No ML**	**839**	**10.25**	**12.22**	**0**
	ML: 15 (CXS-193-1995)	801	0.54	1.74	4.5
	ML: 10	793	0.42	1.14	5.5
Polished rice	**No ML**	**4425**	**0.67**	**0.80**	**0**
	ML: 5 (CXS-193-1995)	4414	0.64	0.80	0.25
Husked rice	**No ML**	**340**	**1.41**	**1.52**	**0**
	ML: 20 (CXS-193-1995)	334	0.38	0.75	1.8
	ML: 15	332	0.28	0.70	2.4
Wheat	**No ML**	**794**	**0.86**	**1.00**	**0**
	ML: 5	793	0.85	1.00	0.13
Wheat flour	**No ML**	**475**	**1.63**	**1.00**	**0**
	ML: 5	469	0.33	1.00	0.13
Other cereals	**No ML**	**605**	**2.78**	**1.00**	**0**
	ML: 5	591	0.50	1.00	2.3

General concept

Purpose is to evaluate the potential public health benefit of proposed MLs before they are officially adopted and to ensure that MLs are effective in reducing dietary exposure without causing unnecessary barriers to trade or food supply.

Current Dietary Exposure Calculation

- To collect occurrence data and consumption data
- To calculate current deterministic exposure (mean, high-level)

Exposure Under ML

- To define hypothetical MLs
- To calculate deterministic exposure under the new ML

Intake reduction under ML application

- Is the current exposure close to or exceeding the TRV?
- Does the proposed ML significantly reduce health risk?
- Would you recommend adopting the new ML?

Codex stepwise methodology

Step 1: Define the Risk Management Scenario

- Identify the contaminant of concern.
- Specify the food commodity under consideration.
- State the proposed ML for evaluation (e.g., reduction from 0.2 mg/kg to 0.1 mg/kg).
- Describe the regulatory context or rationale (e.g., public health, trade concerns, alignment with JECFA).

Codex stepwise methodology

Step 2: Collect and Prepare Input Data

Occurrence Data:

How much of the contaminant (e.g., pesticide, heavy metal) is present in food items.

collect statistical measures like the mean (average), median (middle value), percentiles (e.g., 95th percentile showing high exposure), and the full distribution (spread) of contaminant levels.

Reliable sources include surveillance programs like GEMS/Food, which monitor contaminants globally, and scientific literature reporting contaminant levels.

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Food Consumption Data

how much of different foods people eat

This data comes from national or international dietary surveys that record the amounts and types of foods consumed by various populations. Using accurate consumption data ensures that exposure assessments reflect real eating habits.

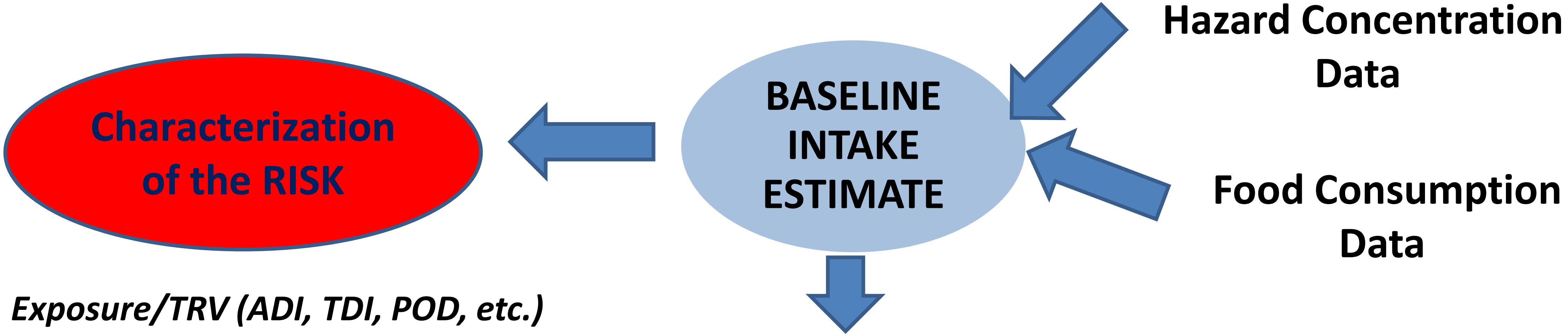
Clean and standardize the data to ensure quality and consistency.

Body Weight and Target population

Since exposure is often expressed relative to body weight (e.g., mg contaminant per kg body weight), knowing the average or group-specific body weights is important. For adults, a default weight of 60 kg is often used, but when assessing vulnerable groups like children, specific body weights are needed for accuracy.

Codex stepwise methodology

Step 3: Estimate Current Exposure



Exposure/TRV (ADI, TDI, POD, etc.)

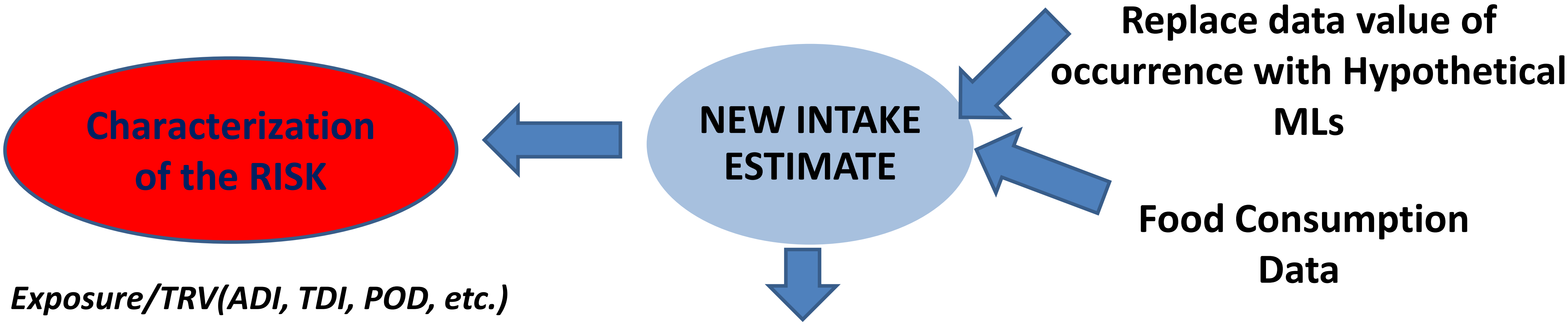
Calculate how much of the hazard people consume using:

$$\text{Intake } (\mu g/kg\ bw/day) = \frac{(\text{Mean concentration} \times \text{Consumption})}{\text{Body weight}}$$

Use deterministic approaches depending on data availability.

Codex stepwise methodology

Step 4: Estimate Exposure Under the hypothetical MLs



$$\text{Intake } (\mu g/kg \text{ bw/day}) = \frac{(\text{Mean concentration} \times \text{Consumption})}{\text{Body weight}}$$

Use deterministic approaches depending on data availability.

Codex stepwise methodology

Step 5: Estimate Exposure Under the hypothetical MLs

Quantifies the risk management benefit.

% Reduction = (1 – New intake / Baseline intake) × 100

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Codex stepwise methodology

Step 6: Document and Present Results

- Summarize exposure estimates under all scenarios.
- Highlight:
  - Exposure reductions
  - Feasibility of MLs
  - Potential impact on Trade
- Provide clear, evidence-based recommendations.

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Recommendation Arab Countries

With appropriate investments in data generation systems, Arab countries can adopt this methodology to enhance consumer safety while supporting food trade and regulatory harmonization.

1. **Strengthen national contaminant monitoring programs** and encourage regional data-sharing to improve the quality of occurrence data.
2. **Conduct national food consumption surveys** to generate reliable, representative intake data, especially for key population groups.
3. **Enhance regional cooperation** for **technical capacity building** and harmonized risk assessment practices.
4. **Use the approach to set science-based MLs**, protecting consumer health while supporting fair food trade.
5. **Integrate the methodology into national food safety regulations** to ensure consistent and transparent decision-making.

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