

**WORKSHOP**

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| **Training Worksheet** | **Maximum Limits (MLs) as a Risk Management Tool: Management of Lead (Pb) Exposure through Spices and Herbs** |
| **Organized by** | **AIDSMO and GFoRSS, under the Arab Codex Initiative** |
| **Location** | **Muscat, Oman** |
| **Dates** | **30 – 31 July 2025** |

*This exercise is based on an excerpt of Codex document – CX/CF 25/18/18 – developed in May 2025 and related to the analysis of exposure scenarios to Lead (Pb) from spice mixtures.*

*The entire document is provided for your reference.*

**OBJECTIVE**

This workshop is designed to help participants apply the principles of **risk assessment**, with a particular focus on **dietary exposure assessment**, to evaluate the impact of **lead contamination** in food products such as **spices mixtures** and **herbs**. Following a stepwise approach consistent with **Codex Alimentarius methodology**, the exercise demonstrates how applying different **Maximum Limits (MLs)** for lead affects:

* The **estimated dietary intake** of lead,
* The **percentage reduction** in exposure,
* The **sample rejection rate**, i.e., the share of products exceeding the ML and thus excluded from the market.

The workshop exercise supports the application of the **ALARA principle** (As Low As Reasonably Achievable), helping participants understand how **MLs can be used as practical risk management tools** to minimize consumer exposure while considering **technological feasibility and local food availability**. It also emphasizes the need for **context-specific standard setting**, grounded in **representative consumption patterns and occurrence data**.

Beyond the technical skills, this exercise also supports the broader objective of **enhancing national capacities** to ensure **food safety at the local level**, by enabling regulators and technical experts to:

* 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**.

Ultimately, applying this approach will reinforce the ability of Codex Contact Points and risk assessors in Arab countries to **actively contribute to international standard-setting**, while also ensuring that **national standards remain relevant, feasible, and protective of their populations**.

**STEP 1: OCCURRENCE DATA - EXTRACTION FROM GEMS/FOOD DATABASE**

*For this exercise, consider the first approach described in Figure 1, relying on the data extraction based on GEMS/Food names.*

A Total of 14805 data points were found in the GEMS Food Data base corresponding to occurrence values for Pb in food commodities labelled as “herbs, spices and condiments”.

**Only 5,250 data points were retained. Why?**

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Identify the key performance parameters of the analytical methods used for Lead in food as reported in the database.

**Can you comment on the values?**

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**Comment on the representativeness of the data set in terms of**:

* Time period covered
* Geographical coverage

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**Based on Table 1, estimate the Rejection Rate (%) for the following scenarios**:

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| --- | --- | --- | --- |
| **ML Scenario** | **Mean Pb Concentration (mg/kg)** | **Rejection Rate (%)** | **Comment** |
| No ML |  |  |  |
| ML: 2 mg/kg |  |  |  |
| ML: 1 mg/kg |  |  |  |

**STEP 2: CONSUMPTION DATA**

Fill out the table by extracting and tabulating the relevant information on consumption data.

*Consider the consumption data of spice mixture from the FAO/WHO Chronic Individual Food Consumption database (CIFOCOss).*

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| --- | --- | --- |
|  | **Mean consumption (g/day)** | **P95 consumption (g/day)** |
| Children (------ kg) |  |  |
| Adults (------kg) |  |  |

**STEP 3: CALCULATE BASELINE INTAKE**

**Using the formula:**

**Mean Exposure (µg/kg bw/day) = (Mean concentration × Consumption) / Body weight**

What is the estimated intake before applying any ML for mean and high consumption patterns for adults and children?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No ML** | **Mean Pb Concentration (mg/kg)** | **Mean Consumption (g/day)** | **P95 Consumption (g/day)** | **Mean Exposure**  **(µg/kg bw/day)** | **High Exposure**  **(µg/kg bw/day)** |
| Children |  |  |  |  |  |
| Adults |  |  |  |  |

**STEP 4: INTAKE AFTER ML APPLICATION**

What is the estimated intake after applying an ML of 1.0 and 2.0 mg/kg for mean and high consumption patterns for adults and children?

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| **ML:**  **2 mg/kg** | **Mean Pb Concentration (mg/kg)** | **Mean Consumption (g/day)** | **P95 Consumption (g/day)** | **Mean Exposure**  **(µg/kg bw/day)** | **High Exposure**  **(µg/kg bw/day)** |
| Children |  |  |  |  |  |
| Adults |  |  |  |  |

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| --- | --- | --- | --- | --- | --- |
| **ML:**  **1 mg/kg** | **Mean Pb Concentration (mg/kg)** | **Mean Consumption (g/day)** | **P95 Consumption (g/day)** | **Mean Exposure**  **(µg/kg bw/day)** | **High Exposure**  **(µg/kg bw/day)** |
| Children |  |  |  |  |  |
| Adults |  |  |  |  |

**STEP 5: RISK CHARACTERIZATION - INTAKE REDUCTION (%)**

**Formula:**

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

**% PoD = (Intake/PoD) × 100**

How much is the intake reduced after applying the MLs?

**RISK CHARACTERIZATION OF LEAD FROM MIXED SPICES WHERE NO ML IS APPLIED**

* PoD (adults) = ------------- µg/kg bw/day
* PoD (children) = ------------- µg/kg bw/day

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No ML** | **% PoD (Mean)** | **% PoD (High)** | **% Reduction (Mean)** | **% Reduction (High)** |
| Children |  |  |  |  |
| Adults |  |  |  |  |

**RISK CHARACTERIZATION OF LEAD FROM MIXED SPICES WHERE ML: 2 mg/kg IS APPLIED**

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| --- | --- | --- | --- | --- |
| **ML:**  **2 mg/kg** | **% PoD (Mean)** | **% PoD (High)** | **% Reduction (Mean)** | **% Reduction (High)** |
| Children |  |  |  |  |
| Adults |  |  |  |  |

**RISK CHARACTERIZATION OF LEAD FROM MIXED SPICES WHERE ML: 1 mg/kg IS APPLIED**

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| --- | --- | --- | --- | --- |
| **ML:**  **1 mg/kg** | **% PoD (Mean)** | **% PoD (High)** | **% Reduction (Mean)** | **% Reduction (High)** |
| Children |  |  |  |  |
| Adults |  |  |  |  |

**STEP 6: DISCUSSION**

**Fill in the following tables with the corresponding results**

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| **ML scenario (Children)** | **% PoD (Mean)** | **% PoD (High)** | **% Reduction (Mean)** | **% Reduction (High)** |
| No ML |  |  |  |  |
| ML: 2 mg/kg |  |  |  |  |
| ML: 1 mg/kg |  |  |  |  |

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| **ML scenario (Adults)** | **% PoD (Mean)** | **% PoD (High)** | **% Reduction (Mean)** | **% Reduction (High)** |
| No ML |  |  |  |  |
| ML: 2 mg/kg |  |  |  |  |
| ML: 1 mg/kg |  |  |  |  |

**Discuss the impact of applying a lower ML on the dietary exposure to Pb?**

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**STEP 7: FINAL REFLECTION & RECOMMENDATION**

**Based on your calculations and the observed reduction in dietary exposure across different ML levels:**

**Which ML level would you recommend for lead in spice mixtures, and why?**

**Please justify your answer using:**

* The % intake reduction achieved
* The exposure compared to the Toxicological Reference Value (TRV)
* The balance between health protection and market impact (e.g., rejection rate, feasibility),
* Risk management considerations and Codex principles (e.g., ALARA – As Low As Reasonably Achievable).

**Your Recommendation**

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| ***Remember:***   * A lower ML provides greater public health protection. * But too strict ML may unnecessarily reject compliant products or impact trade. * Codex encourages a balanced, science-based decision informed by dietary exposure and actual risk. |