WORKSHOP

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 Database corresponding to occurrence values for Pb in food commodities labelled as "herbs, spices and condiments".

Only 5,250 data points were retained. Why?

The data selected (5,250 data points) included data points that reflect **Generic food name potentially describing spice mixtures** (due to the lack of specificity in the GEMS/Food naming system), and excluding all data points that reflect clearly identified individual spices, avoiding introducing confounding bias in data interpretation.

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?

The limit of detection (LOD) and the limit of quantification (LOQ) were reported in the document and ranged from 0.001 to 0.100 mg/kg and from 0.0003 to 0.401 mg/kg, respectively.

It is noted that the lowest LOQ reported was well below the lowest LOD reported. This discrepancy can be explained by the fact that the reported values did not originate from the same analytical methods. Moreover, and for some datasets, only the LOQ was provided, in line with the GEMS/Food database requirement that at least the LOQ must be submitted.

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

- Time period covered
- Geographical coverage

Time Period Covered: the sampling period ranged from 2014 to 2024 (10 years), which can be regarded as a reasonably representative time period, capturing any potential implementation of regulatory measures (e.g., Codes of Practice) aimed at mitigating lead contamination.

Geographical Coverage: Broad geographical representation, covering 12 countries and the European Union, including key producing and consuming member countries.

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

ML Scenario	Mean Pb Concentration (mg/kg)	Rejection Rate (%)	Comment
No ML	0.60	0	Rejection rate is null as no ML was set.
ML: 2 mg/kg	0.21	1.9	By setting a hypothetical ML: 2 mg/kg, rejection rate is raised to 1.9% but still within the acceptance range "Below 5%"

ML: 1 mg/kg	0.17	5.1	By lowering the hypothetical ML from 2 mg/kg to 1 mg/kg, rejection rate is potentially raised from 1.9 to 5.1, which is still acceptable.

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).

	Mean consumption (g/day)	P95 consumption (g/day)
Children (**20** kg)	3.8	10.4
Adults (**84** kg)	5.3	11.0

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	0.60	3.8	10.4	0.11	0.31
Adults		5.3	11.0	0.04	0.08

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?

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	0.21	3.8	10.4	0.04	0.11
Adults		5.3	11.0	0.01	0.03

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	0.17	3.8	10.4	0.03	0.09
Adults		5.3	11.0	0.01	0.02

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) = **1.3** µg/kg bw/day
- PoD (children) = **0.6** µg/kg bw/day

No ML	% PoD (Mean)	% PoD (High)	% Reduction (Mean)	% Reduction (High)
Children	19	52	0	0
Adults	3	6	0	0

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

ML: 2 mg/kg	% PoD (Mean)	% PoD (High)	% Reduction (Mean)	% Reduction (High)
Children	7	18	63.6	64.5
Adults	1	2	75	62.5

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

ML: 1 mg/kg	% PoD (Mean)	% PoD (High)	% Reduction (Mean)	% Reduction (High)
Children	5	15	72.7	70.9
Adults	1	2	75	75

STEP 6: DISCUSSION

Fill in the following tables with the corresponding results

ML scenario (Children)	**% PoD (Mean)**	**% PoD (High)**	**% Reduction (Mean)**	**% Reduction (High)**
No ML	19	52	-	-
ML: 2 mg/kg	7	18	63.6	64.5
ML: 1 mg/kg	5	15	72.7	70.9

ML scenario (Adults)	**% PoD (Mean)**	**% PoD (High)**	**% Reduction (Mean)**	**% Reduction (High)**
No ML	3	6	0	0
ML: 2 mg/kg	1	2	75	62.5
ML: 1 mg/kg	1	1.5	75	75

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

First, applying an **ML of 2 mg/kg** reduces the exposure (µg/kg bw/day) **to 0.01 instead of 0.04** for **adults** and **0.04 instead of 0.11 for children**, with a **% reduction** of **75 and 63.6** respectively in mean exposure scenarios. Noting that the **% of rejection rate was estimated to be 1.9**.

While applying more conservative **ML of 1 mg/kg, an additional** reduction in the exposure (µg/kg bw/day) was achieved, reaching **0.01 instead of 0.04** for **adults** and **0.03 instead of 0.11** for **children,** with nearly the **same results** in exposure reduction in "Mean scenario" for **adults** (75%), while **increases** the **% Reduction** in "Mean scenario" for children to **72.7%**. Noting that the **% of rejection rate reaches 5.1** in this case.

Applying a **lower ML for Pb** (1 or 2 mg/kg) **reduces** the dietary exposure from lead for both Children and adults significantly, which provides greater public health protection while also keeping the samples rejection rate at the acceptable levels (equal or below 5%).

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

Setting an **ML of 2 mg/kg** achieves a **% reduction in intake** equal to **75% (mean scenario)** and **62.5% (high scenario)** for **adults**, and **63.6% (mean scenario)** and **64.5% (high scenario) for children**.
While an **ML of 1 mg/kg** achieves a **% reduction in intake** equal to **75% (mean scenario)** and **75% (high scenario)** for **adults**, and **72.7% (mean scenario)** and **70.9% (high scenario)** for **children**.

Taking into consideration that when applying an **ML of 2 mg/kg**, the **% PoD** is reduced from **19% (mean)** and **52% (high)** for **children** to **7%** and **18%** respectively, and **% PoD** reduced for **adults** from **3% (mean)** and **6% (high)** to **1%** and **2%** respectively.
While Applying an **ML of 1 mg/kg** does not impact considerably the % PoD but **increases** the rejection rate of samples from **1.9%** to **5.1%**.

As indicated, setting and applying an ML of either 1 or 2 mg/kg has a **significant impact** on dietary exposure from lead for both children and adults, **the % of PoD remaining nearly the same** for both MLs for both children and adults (mean and high exposure), while increasing the rejection rates. Based on the data presented **Applying an ML of 2 mg/kg of Pb** would be more appropriate for achieving more public health protection while maintaining fair trade.

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.