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 25/18/05 developed in May 2025 and related to the analysis of the occurrence data in spices and herbs.

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 **dried bark** and **culinary 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 **local consumption patterns and monitoring 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**.

SCENARIO BACKGROUND

Objective

Apply the Codex stepwise approach to evaluate how different MLs for lead in dried bark and culinary herbs affect rejection rates and dietary exposure.

STEP 1: DATA EXTRACTION

From the reference document provided *(maximum levels for lead in certain food categories prepared by the EWG chaired by Brazil: CX/CF 25/18/5, April 2025):*

Item	Dried Bark	Culinary Herbs
Baseline Mean Lead Level (UB)	0.68 mg/kg	0.41 mg/kg
Consumption Value (g/day)	0.4 g/day	8.89 g/day
Body Weight Assumption	70 kg	70 kg
MLs to Apply (mg/kg)	3.0, 2.5, 2.0, 1.5, 1.0	3.0, 2.5, 2.0, 1.5, 1.0
Adjusted Mean Level at ML = 3.0	0.60 mg/kg	0.38 mg/kg
Adjusted Mean Level at ML = 2.5	0.57 mg/kg	0.37 mg/kg
Adjusted Mean Level at ML = 2.0	0.49 mg/kg	0.36 mg/kg
Adjusted Mean Level at ML = 1.5	0.40 mg/kg	0.34 mg/kg
Adjusted Mean Level at ML = 1.0	0.31 mg/kg	0.29 mg/kg

STEP 2: CALCULATE BASELINE INTAKE

Use the formula:

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

Question:
What is the estimated intake before applying any ML (dried bark and culinary herbs)?

By applying the stated formula:
Intake (µg/kg bw/day) = (Mean concentration × Consumption) / Body weight
Dried bark:
Intake (µg/kg bw/day) = (0.68 mg/kg × 0.4 g/day) / 70 kg = 0.00389 µg/kg bw/day.

Culinary herbs:
Intake (µg/kg bw/day) = (0.41 mg/kg × 8.89 g/day) / 70 kg = 0.0521 µg/kg bw/day.

STEP 3: INTAKE AFTER ML APPLICATION

Question:
What is the estimated intake after applying an ML of 2.0 mg/kg (dried bark and culinary herbs)**?**

By applying the stated formula:
Intake (µg/kg bw/day) = (Mean concentration × Consumption) / Body weight
Dried bark:
Intake (µg/kg bw/day) = (0.49 mg/kg × 0.4 g/day) / 70 kg = 0.00280 µg/kg bw/day.

Culinary herbs:
Intake (µg/kg bw/day) = (0.36 mg/kg × 8.89 g/day) / 70 kg = 0.0457 µg/kg bw/day.

STEP 4: INTAKE REDUCTION (%)

Formula:

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

Question:
How much is the intake reduced after applying the ML?

Item	Scenario	Mean Lead (mg/kg)	Exposure (µg/kg bw/day)	Reduction vs. Baseline (%)
Dried Bark	Baseline	0.68	0.00389	–
	ML = 3.0	0.60	0.00343	11.8%
	ML = 2.5	0.57	0.00326	16.2%
	ML = 2.0	0.49	0.00280	28.0%
	ML = 1.5	0.40	0.00229	41.1%
	ML = 1.0	0.31	0.00177	54.5%
Culinary Herbs	Baseline	0.41	0.0521	–
	ML = 3.0	0.38	0.0483	7.3%
	ML = 2.5	0.37	0.0470	9.8%
	ML = 2.0	0.36	0.0457	12.3%
	ML = 1.5	0.34	0.0432	17.1%
	ML = 1.0	0.29	0.0368	29.4%

STEP 5: Rejection Rate

Formula:

% Rejection Rate = (Number of non-compliant samples / Total number of samples) × 100

Question:

What proportion of the commodity would be rejected when a specific Maximum Limit (ML) is applied in a trade context? Explain what this means for trade and public health.

- ✓ All the samples with higher levels than the specific ML will be rejected.
- ✓ The rejection rate shows the proportion of traded food products that exceed the ML and are therefore not accepted for import/export.
- ✓ A lower ML may lead to a higher rejection rate, especially for products from regions with higher contaminant levels.
- ✓ This reflects the impact of regulatory standards on international trade and compliance.
- ✓ A higher rejection rate may indicate the need for improved food safety controls by exporters.
- ✓ Tracking rejection rates helps evaluate the practical trade implications of setting or adjusting MLs.

STEP 6: FINAL EXERCISE TABLE – CALCULATIONS FOR ALL MLs (DRIED BARK)

Use the formula:

Intake (µg/kg bw/day) = (Mean concentration × Consumption) / Body weight
% Reduction = [1 – (Intake at ML / Intake at No ML)] × 100
% Rejection Rate = (Number of non-compliant samples / Total number of samples) × 100

DRIED BARK

ML (mg/kg)	Mean Lead Level (mg/kg)	Estimated Intake (µg/kg bw/day)	% Intake Reduction	% Rejection Rate
No ML	0.68	0.00389	0	0
3.0	0.60	0.00343	11.8	2.6
2.5	0.57	0.00326	16.2	4.0
2.0	0.49	0.00280	28.0	8.2
1.5	0.40	0.00229	41.1	14.8
1.0	0.31	0.00177	54.5	23.7

CULINARY HERBS (USE G09 DIET: 8.89 G/DAY)

ML (mg/kg)	Mean Lead Level (mg/kg)	Estimated Intake (µg/kg bw/day)	% Intake Reduction	% Rejection Rate
No ML	0.41	0.0521	0	0
3.0	0.38	0.0483	7.3	0.7
2.5	0.37	0.0470	9.8	0.9
2.0	0.36	0.0457	12.3	1.7
1.5	0.34	0.0432	17.1	3.4
1.0	0.29	0.0368	29.4	7.9

STEP 7: DISCUSSION

Question:
Why does applying a lower ML reduce the mean level and dietary exposure?

→ Because non-compliant samples with high levels are excluded, lowering the average.

What does a higher % intake reduction indicate?

→ More effective mitigation of dietary exposure through regulatory control.

What trade-offs might be involved with stricter MLs?

→ Greater health protection vs. potential product rejection and trade barriers.

STEP 8: FINAL REFLECTION & DECISION QUESTION

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

Which ML level would you recommend for lead in dried bark (or culinary herbs), 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

We may recommend **2.5 mg/kg** for **dried bark**, as it reduces exposure by **16%,** while maintaining a manageable rejection rate (<5%) and aligning with Codex risk assessment principles. Stricter MLs, like 1.0 mg/kg, offer more protection but may create unnecessary trade impacts (reduction of 23.7% intake but sample rejection rate at 55%).
We may recommend **1.5 mg/kg** for **dried culinary herbs**, as it reduces exposure by **17%,** while maintaining a manageable rejection rate and aligning with Codex risk assessment principles. Stricter MLs, like 1.0 mg/kg, offer more protection but may create unnecessary trade impacts (reduction of 27% intake but sample rejection rate 7.9% above the accepted threshold of 5% agreed upon for CCCF).

More Elaboration

Summary Table: Recommended MLs for Lead in Dried Bark & Culinary Herbs

Commodity	Region	Recommended ML (mg/kg)	Exposure Reduction (%)	Rejection Rate (Fixed)	Rationale
Dried Bark	Global	3	**12%**	**2.6%**	
		2.5	**16%**	**4%**	Achieves moderate exposure reduction, while respecting the fixed 5% rejection threshold; aligns with Codex principles.

Culinary Herbs	Global	2.0	**12%**	**~1.7%**	
		1.5	**17%**	**3.4%**	Closest ML giving a rejection rate below the 5% threshold; offers a fair intake reduction, while preserving product availability.

Key Considerations:

- For dried bark, 2.5 mg/kg is optimal globally and regionally when the 5% rejection rate cap is applied.
- For culinary herbs, 1.5 mg/kg is recommended as it offers consistent benefits without exceeding the 5% rejection ceiling.
- This approach ensures practical implementation, supports trade, and improves consumer health protection in high-consumption clusters.

Remember:

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