WORKSHOP ON DATA COLLECTION AND ANALYSIS FOR CODEX PROCEEDINGS

Data Analysis for the Development of Maximum Levels (MLs) – Part 3

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Outline

1. Introduction
2. Estimation of Hypothetical MLs
3. Calculation of rejection rates at the hypothetical MLs
4. Conclusion

Training Objectives

By the end of this training module, participants will be able to:

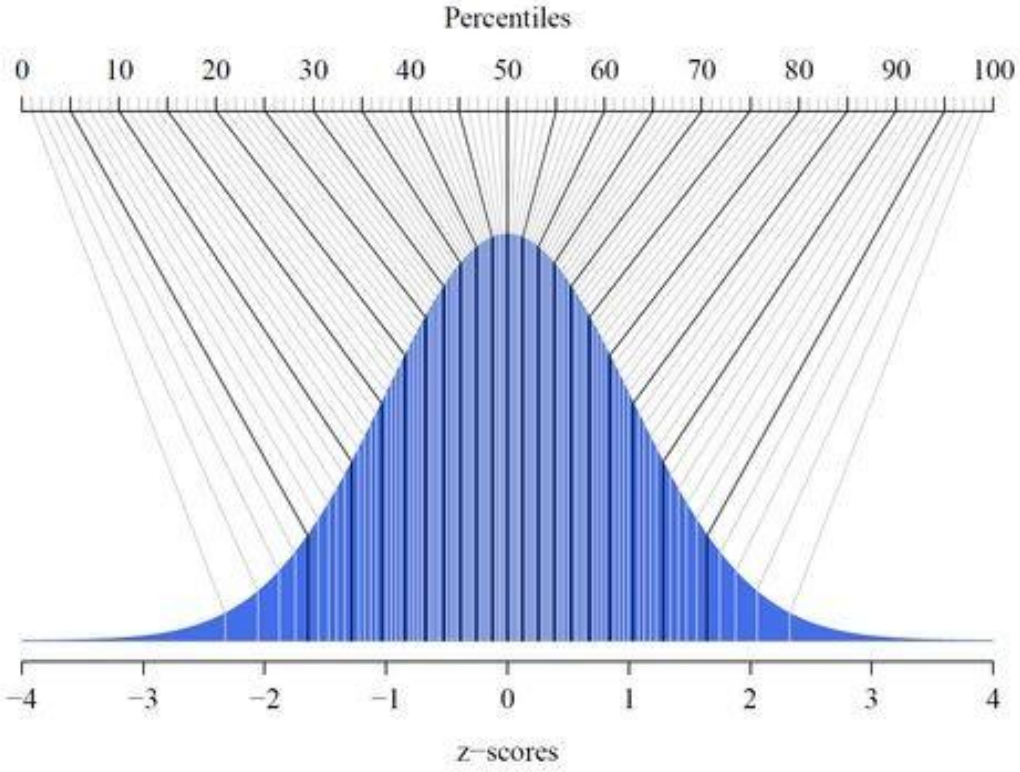
1. Understand the approach used to estimate **hypothetical Maximum Levels (MLs)** based on occurrence data.

2. Perform calculations to determine **rejection rates** of food products using these hypothetical MLs.

3. Interpret the implications of rejection rates.

Estimation of Hypothetical MLs

- A candidate value for an ML is identified from a high percentile value (usually slightly higher than 95th percentile) of the target dataset.
- The precision of the current analytical method and significant figures of the analytical results should be taken into consideration.
- Numerical values for MLs should preferably be regular figures in a geometric scale (0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1, 2, 5, etc.).



Preferable to have more than 2 hypothetical MLs

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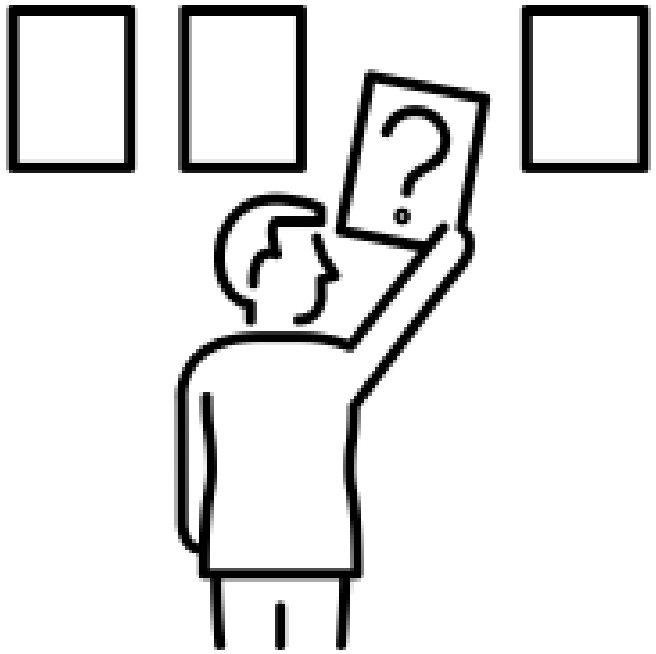
Estimation of Hypothetical MLs

- Once the numerical candidate value of an ML has been determined, the next higher and lower values can also be suggested as hypothetical MLs. For example, for a candidate ML of 0.5 mg/kg, additional hypothetical MLs could be 0.4 and 0.6 mg/kg.

- In the case of revision to existing MLs, the existing ML should also be added as one of the hypothetical MLs.

- Further, values obtained by from the high percentile values (e.g. 95th, 97th and 98th percentile values) can also be used directly as hypothetical MLs.

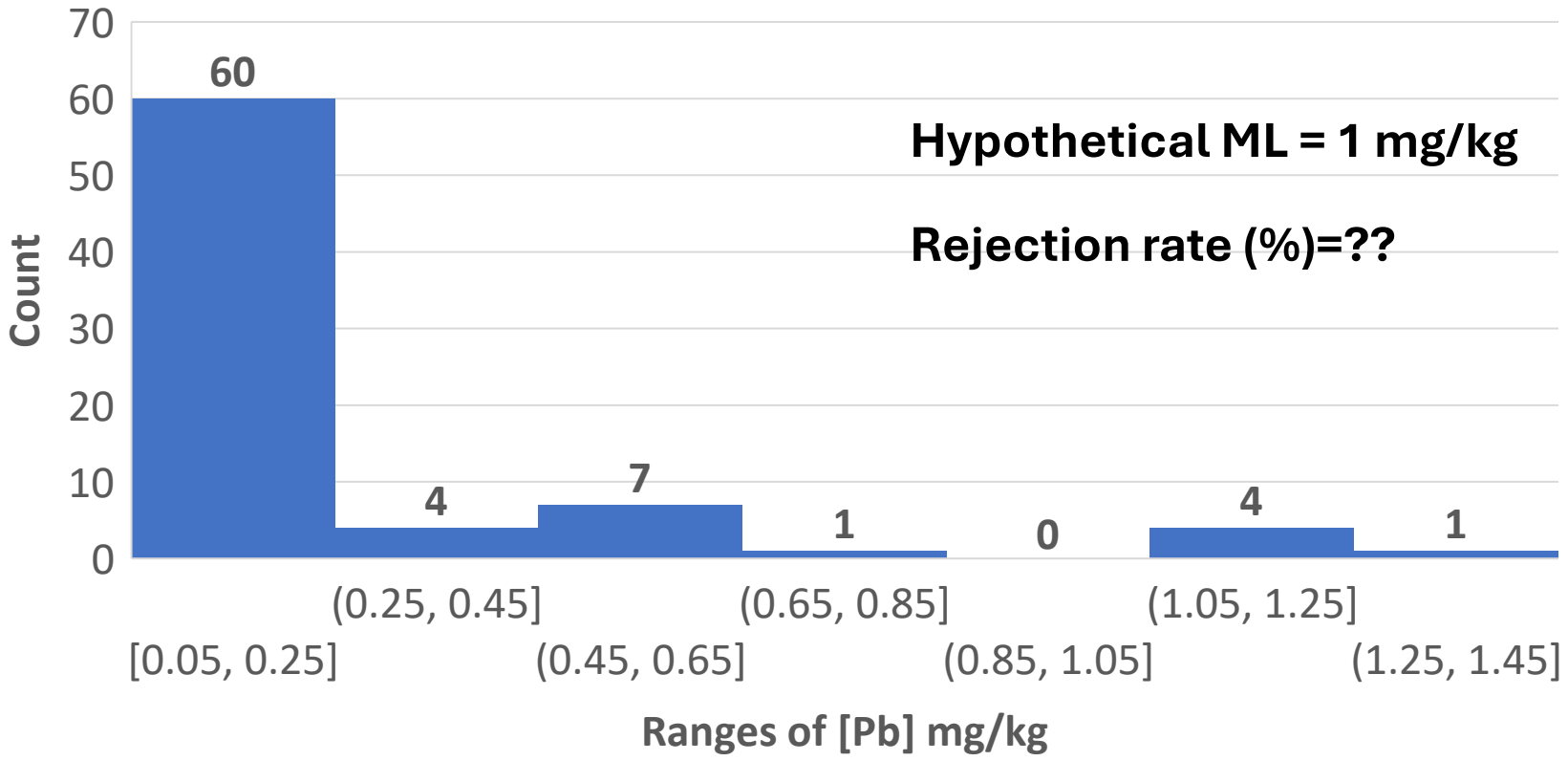


Calculation of Rejection Rates at the Hypothetical MLs

$$\text{Rejection rate (\%)} = \frac{\text{(number of data points > hypothetical ML)}}{\text{(total number of data points)}} \times 100$$

- **Assumption:** samples that exceed the hypothetical ML are excluded from the market with 100% probability by enforcement of the ML.
- To assess the impact on international trade of the commodity, the combined global dataset should be used, and if necessary, datasets for each region. Calculating rejection rates on a country-by-country basis is not recommended.
- For contaminants known to have large annual variation in concentrations, the rejection rate should be calculated for the dataset of each year, if possible, for year-to-year comparison of rejection rates.

Calculation of Rejection Rates at the Hypothetical MLs



Conclusion

Hypothetical MLs can be estimated using available data to explore the impact of potential regulatory limits.

Calculating rejection rates provides insight into the **practical consequences** of setting specific MLs.

These tools support **evidence-based decision-making** by balancing food safety objectives with trade and feasibility considerations.

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