WORKSHOP ON DATA COLLECTION AND ANALYSIS FOR CODEX PROCEEDINGS

Data on Concentrations of Chemicals in Food

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Outline

1. **Introduction**
2. **Selecting concentration data for use in estimating acute and chronic dietary exposures**
3. **Sources of concentration data for use in estimating dietary exposure**
    a. Maximum Levels (MLs) and Maximum Residue Limits (MRLs)
    b. Measured or reported concentrations
    c. Publicly available databases for concentrations of chemicals in food
4. **Conclusion**

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Training Objectives

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

1. **Identify and select appropriate concentration data** for use in estimating dietary exposure to chemicals in food.

2. **Differentiate between sources of concentration data**, including maximum levels (MLs), maximum residue limits (MRLs) and measured or reported concentrations (supervised trials, residue depletion studies, monitoring plans and total diet studies).

3. **Explain the role and use of publicly available databases** in sourcing concentration data for dietary exposure assessments.

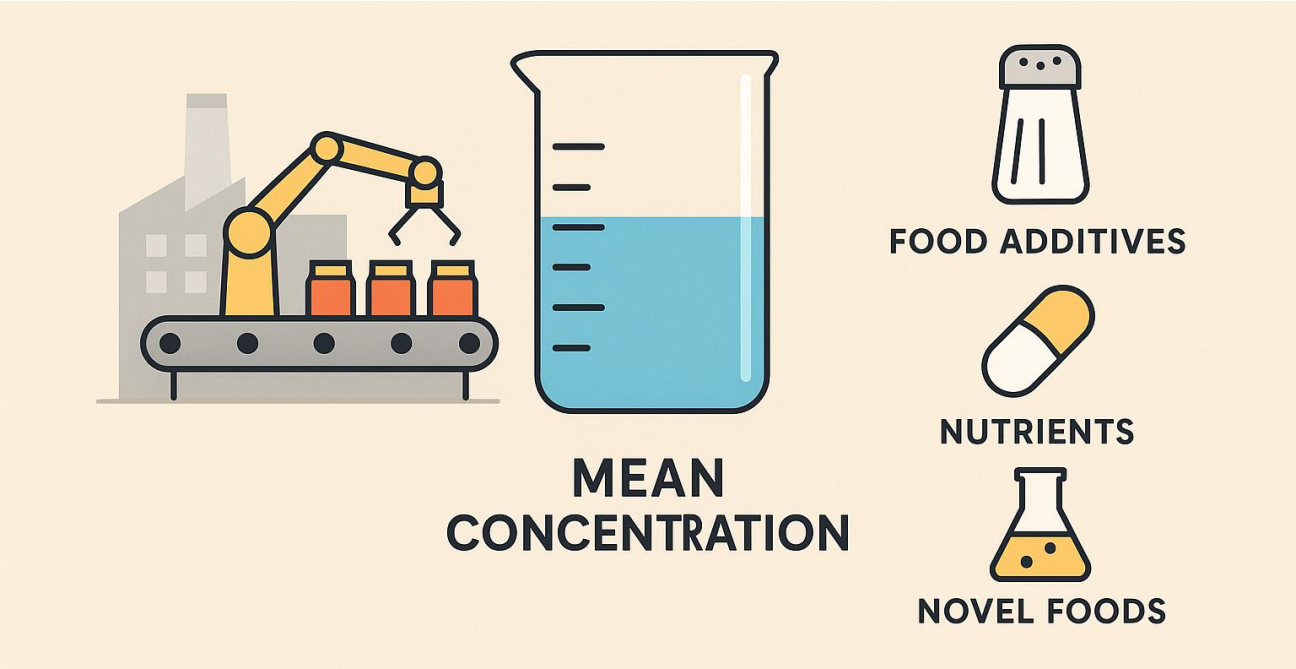
Introduction

Different **types** and **sources** of concentration data may be selected according to the purpose of the dietary exposure assessment.

- Chronic vs acute dietary exposures
- Consistent procedures
- Standardized format is employed for data submission
- It is crucial to consider sampling, analysis and reporting procedures when assessing whether data on concentrations of a chemical in food are consistent and comparable.

Concentration Data Used in Estimating Chronic Dietary Exposures

Concentrations of chemicals that are intentionally added to foods



Mean Concentration:

- Reflects **average expected concentration over time**
- Sourced from **industry use data** or **monitoring/surveillance**

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Concentration Data Used in Estimating Chronic Dietary Exposures

Nutrient Concentrations in Foods

Nutrients may:

- Occur naturally in foods
- Be added as fortificants or in supplements

Mean concentrations:

- Often listed in food composition tables

If **intentionally added**, manufacturers can:

- Provide intended concentration data
- Declare amounts on the nutrition facts label

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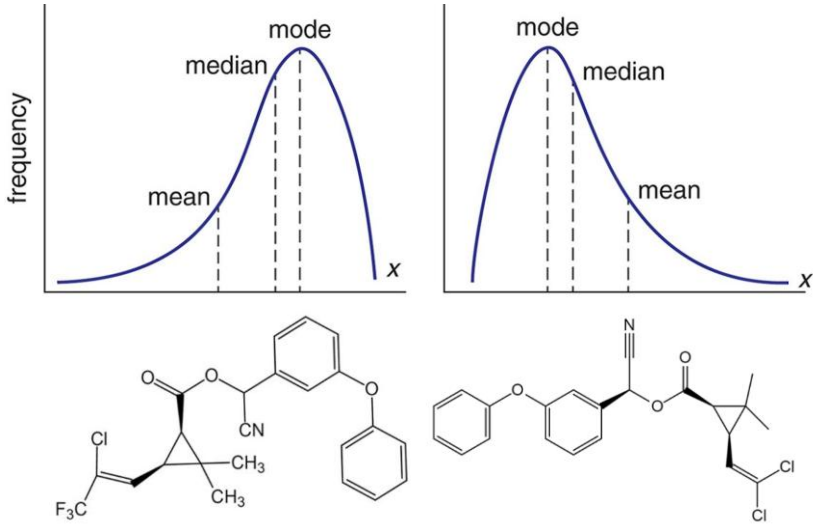
Concentration Data Used in Estimating Chronic Dietary Exposures

Concentration Data for Pesticide & Veterinary Drug Residues

Residues in food come from **pesticide** application on crops and **veterinary drugs** used in animals

- **Median levels**, not mean

- Derived from:
  - **STMR** (Supervised Trials Median Residue) for pesticides
  - **Residue depletion studies** for vet drugs



Why median?

Trial datasets are often **small**
Median is more **statistically reliable**

Alternative source:

- **Monitoring & surveillance data**
- Used when available to calculate **mean concentrations** in foods "as sold or consumed"

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Concentration Data Used in Estimating Chronic Dietary Exposures

Concentration Data for Contaminants

Mean concentration (from **monitoring/surveillance data**) is commonly used for **dietary exposure estimates** to contaminants.

Alternative approaches depending on data characteristics:

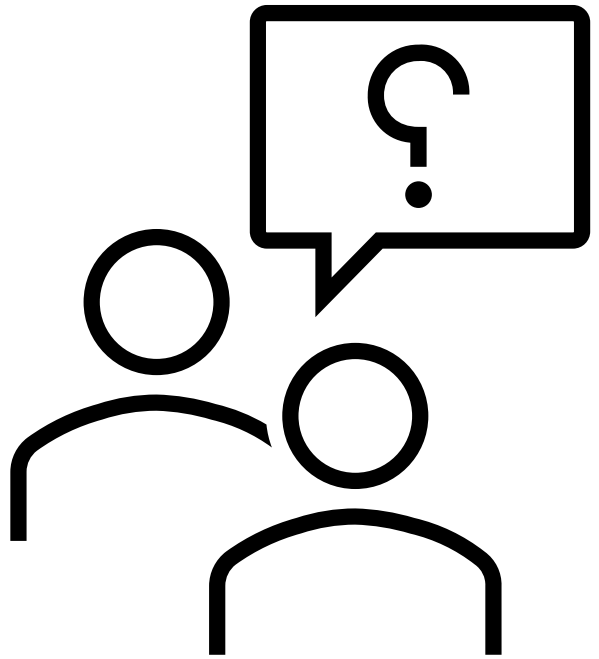
- Use median if data are highly skewed
- Use geometric mean if many results are below LOD/LOQ

Composite samples:

- Represent an **average of multiple components**
- In such cases, the **mean** may be more appropriate than the **median**

True or False

The mean is always a better measure of central tendency than the median when evaluating concentration data for dietary exposure.



Sources of Concentration Data for Use in Estimating Dietary Exposure

Maximum Levels (MLs) and Maximum Residue Limits (MRLs)

Maximum concentrations (MLs or MRLs) are used in pre-regulation dietary exposure assessments for chemicals proposed to be deliberately added to foods (additives, pesticides, veterinary drugs, added nutrients).

For contaminants, it is preferable to use monitoring or surveillance data, although MLs may occasionally be used where no other information is available.

Sources of Concentration Data for Use in Estimating Dietary Exposure

Maximum Levels (MLs) and Maximum Residue Limits (MRLs)

It is **important to understand the method of derivation of MLs or MRLs** for various food chemicals when considering the potential uncertainties in the data.

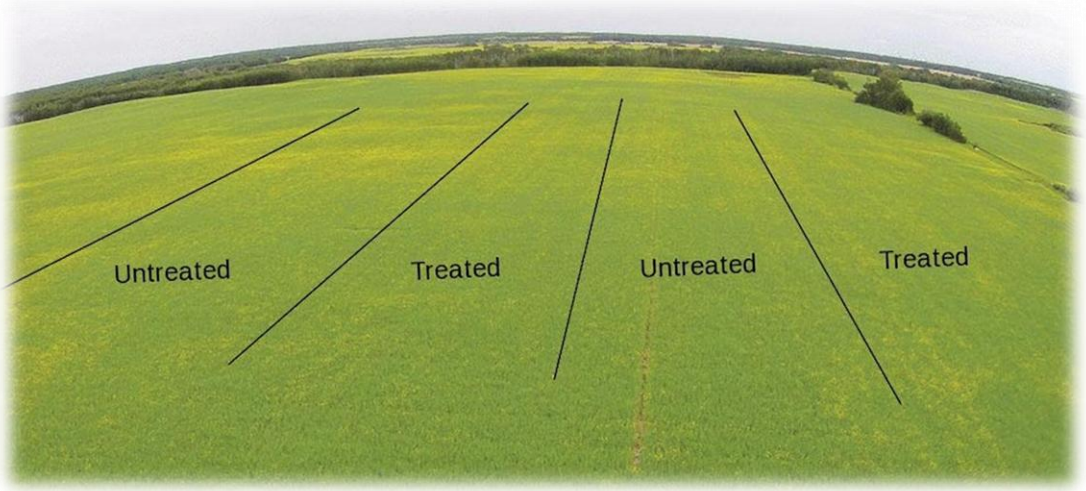
- **Food additives, novel foods, and added nutrients**: based on industry-submitted data
- **Pesticides** : field trial studies performed under Good Agricultural Practices (GAP).
- **Veterinary drugs**: evaluation from controlled residue depletion studies carried out in compliance with Good Practice in the Use of Veterinary Drugs.
- **Contaminants:** proposed MLs are generally based on the “as low as reasonably achievable” (ALARA) principle.

Sources of Concentration Data for Use in Estimating Dietary Exposure

Measured or Reported Concentrations

Supervised trials (pesticide residues):

- Designed to determine the maximum residue concentrations that may be present in the harvested product at the earliest point at which these commodities could enter commerce as food or feed for animals.
- Often overestimate the residue concentrations that are likely to occur in food as actually consumed.
- Therefore, these data are not the first choice when assessing chronic dietary exposure; instead, the **STMR level is used**.

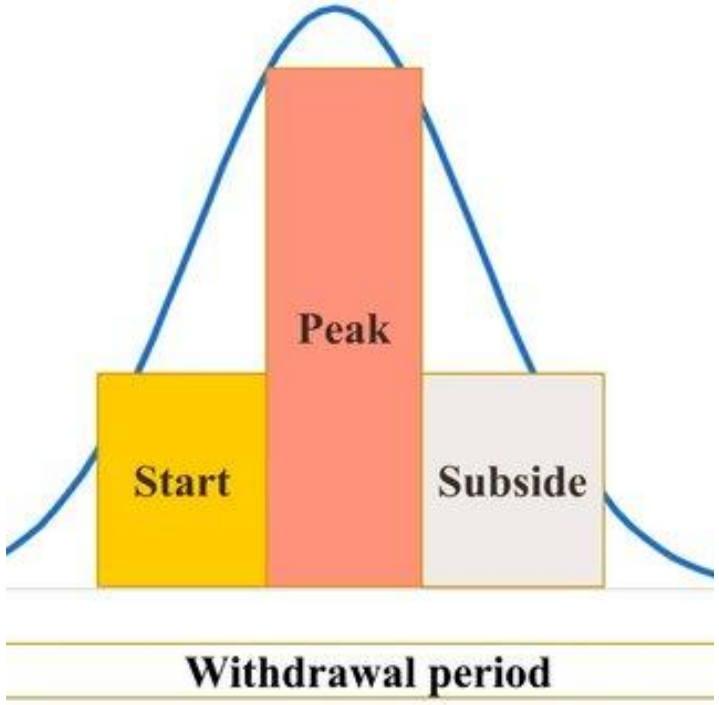


Sources of Concentration Data for Use in Estimating Dietary Exposure

Measured or Reported Concentrations

Residue depletion studies (veterinary drug residues)

- Designed to estimate the formation and depletion of residues (determined as the marker residue) of the veterinary drug in edible tissues and products.
- Serve as the basis for the derivation of the MRLs and estimation of dietary exposure.

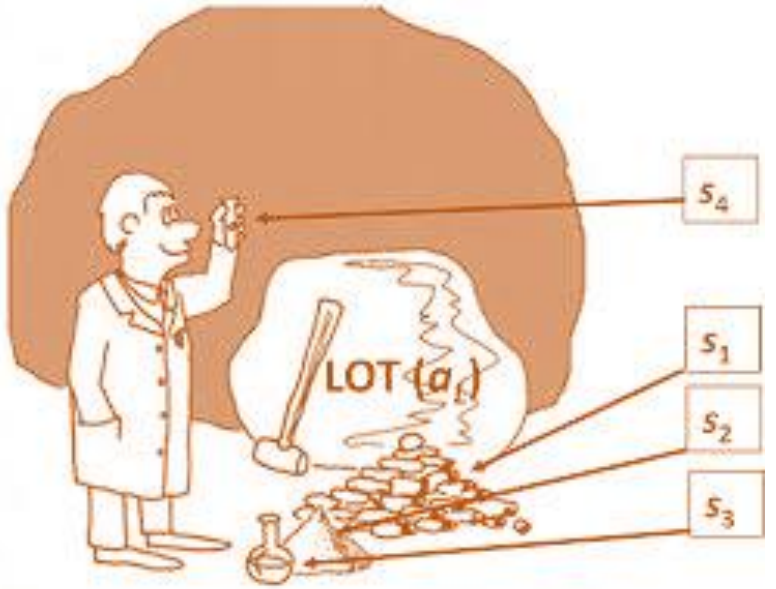


Sources of Concentration Data for Use in Estimating Dietary Exposure

Measured or Reported Concentrations

Monitoring and surveillance data

- Collected **close to point of consumption**
- More representative than early-stage commodity sampling



Targeted Samples

- Collected for enforcement purposes in response to **specific issues** (e.g. heavy metal contamination)
- **Not representative** – generally **not used** in dietary exposure assessments

Random Samples

- Collected using a **sampling plan** for representative data
- Samples are usually collected on a random basis close to the point of consumption
- Provide **better estimates** for chemical levels in food **as consumed**

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Sources of Concentration Data for Use in Estimating Dietary Exposure

Measured or Reported Concentrations

Monitoring and surveillance data

- **Pesticide and veterinary drug residues**: for post-regulation acute and chronic dietary exposure assessments, suitable monitoring and surveillance data are preferred over data from supervised trials and depletion studies.

- **Reason**: account for residue degradation during transit and storage and, in the case of pesticides, may also provide data on residues resulting from post-harvest applications of fungicides and growth regulators used as preservatives during food delivery.

Sources of Concentration Data for Use in Estimating Dietary Exposure

Measured or Reported Concentrations

Monitoring and surveillance data - Limitations

🧪 Analytical Sensitivity & Methodology

- Monitoring is often designed for compliance, not exposure assessment
- Less sensitive methods may lead to higher LOQs/LODs, increasing uncertainty
- Datasets from different purposes may be difficult to combine due to method variability

🐄 Tissue-Specific Residue Limitations

- For vet drugs, residues may be measured in marker organs (e.g., liver), not in consumed tissues
- Conversion factors can be applied, but they add uncertainty

📉 Data Gaps & Representativeness

- Monitoring covers only a small fraction of the food supply
- May miss high-residue values, affecting acute exposure estimates
- Sampling may not reflect all relevant metabolites or toxicologically active substances

📝 Implications for Risk Assessment

- Limitations must be **acknowledged and documented** in the dietary exposure report

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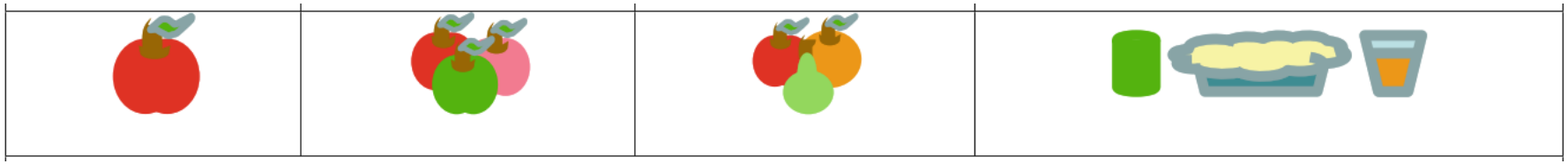
Sources of Concentration Data for Use in Estimating Dietary Exposure

Measured or Reported Concentrations

Concentration data from Total Diet Studies (TDS)

- Complementary approach to traditional monitoring and surveillance programs
- Measures chemical concentrations in foods "as consumed"
- Reflects real-life food preparation (e.g., peeling bananas, cooking)
- Accounts for loss of unstable chemicals and formation of new compounds
- Provides accurate average concentrations of pesticide residues, contaminants, nutrients, other food chemicals
- Uses most sensitive analytical methods
- Best suited for chronic dietary exposure assessments
- Not suitable for acute exposure due to averaging



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Sources of Concentration Data for Use in Estimating Dietary Exposure

Publicly Available Databases for Concentrations of Chemicals in Food

Codex online databases

The numerical Codex standards for food additives, veterinary drugs maximum residue levels and pesticide maximum residue levels, can also be accessed via databases that facilitate their use.

Pesticides Residues in Food

Veterinary Drug Residue in Food

General Standard for Food Additives (GSFA)

National and regional databases

Nutrient Databases / Food Composition Databases

Why are Total Diet Study (TDS) data generally considered superior to routine monitoring or surveillance data for dietary exposure assessment?

A. They include only raw agricultural products

B. They reflect actual consumption levels in food as prepared and consumed

C. They are collected more frequently than monitoring data

D. They focus only on contaminants in imported foods

Conclusion

The management of data plays a key role in the work of elaborating MLs and MRLs, and it is of common interest to have data of good quality.

Occurrence data should ideally be obtained through statistically based sampling, and analysis should be conducted using validated methods with appropriate LOQ and LOD in laboratories that have quality assurance systems.

Ideally, data submitted by member countries should be nationally representative (geographical representativeness)

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