

Understanding the Scientific Basis for Codex Food Safety Standards

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Agreement on the Application of Sanitary and Phytosanitary Measures

- Article 2 Basic Rights and Obligations
- Article 3 Harmonization
- Article 5 Assessment of Risk and Determination of the Appropriate Level of SPS Protection

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Scientific Principles and Evidence

- Article 2 Basic rights and obligations:
“3. Members shall ensure that any sanitary measure is applied only to the extent necessary to protect human life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in para. 7 of Article 5.”

NB: the terms “phytosanitary”, “animal or plant” are omitted from the text.

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SPS Agreement & Codex

- Preamble
“Desiring to further the use of harmonized sanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission ..., without requiring Members to change their appropriate level of protection of human life or health.

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SPS Agreement & Codex(2)

- Annex A Definitions on “International standards, guidelines and recommendations”:

“for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drugs and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice.”

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SPS Agreement & Codex (3)

- Article 3 Harmonization
“1. To harmonize sanitary ... measures on as wide a basis as possible, Members shall base their sanitary ... measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in the Agreement, and in particular in paragraph 3”

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SPS Agreement & Codex (4)

“2. Sanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.”

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SPS Agreement & Codex (5)

- However:
“3. Members may introduce or maintain sanitary measures which results in a higher level of sanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary protection a Member determines to be appropriate”
- These measures shall not be inconsistent with any other provisions of the Agreement

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Risk Assessment

- Article 5 Risk assessment:
“1. Members shall ensure that sanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human life or health, taking into account risk assessment techniques developed by the relevant international organizations.”

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Risk Assessment (2)

- Article 5:
“2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; ...; relevant ecological and environmental conditions; and quarantine or other treatment.”

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Risk Assessment (3)

- Article 5:
“7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as sanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary measure accordingly within a reasonable period of time.”

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Implications of SPS on Codex

- Codex focuses on risk-based inspection and certification systems
 - Many of them already done (e.g., inclusion of HACCP, development of working principles for risk analysis)
- Codex reaffirms the role of science in its work ← scientific data for recommendation
- Codex revises its acceptance rules
 - Already removed

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Safety Provisions Recognized by SPS Agreement

- Maximum Residue Limits for Pesticides and Veterinary Drugs
- Maximum Levels for Contaminants
- Maximum Levels of Food Additives in Use
- Food Hygiene Requirements of Codex Standards
- Methods of Analysis and labelling for the above

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Role of Science in Codex

Role of Science in the Codex Decision-Making Process

1. Science-based: "Principle of sound scientific analysis and evidence"
2. Consideration of other legitimate factors
3. Role of food labelling
4. Right to abstention without preventing the decision of the Commission

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Independent Scientific Advisory Bodies

- Joint FAO/WHO Expert Committee on Food Additives (JECFA)
 - Food additives (toxicology, specifications)
 - Contaminants (toxicology, [exposure])
 - Veterinary drug residues (toxicology, MRLs)
- Joint FAO/WHO Meeting of Pesticide Residues (JMPR)
 - Pesticide residues (toxicology, MRLs, exposure)
- Joint FAO/WHO Meetings on Microbiological Risk Assessment (JEMRA)
 - Pathogenic bacteria & viruses, and parasites
- Ad hoc expert consultations by FAO & WHO

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Risk Analysis in Codex

Risk Analysis

Consisting of 3 components:

- Risk Assessment
- Risk Management
- Risk Communication

Codex Alimentarius Commission Procedural Manual contains:

- Definitions of Risk Analysis Terms Related to Food Safety
- Working Principles within Codex
- Risk analysis principles applied by Codex committees

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Statements of Principle Relating to the Role of Food Safety Risk Assessment

1. Risk assessment be the basis
2. **Science-based**; use of 4 steps of risk assessment; documentation for transparency
3. Functional separation of risk assessment and risk management & need for interactions between them
4. Use of quantitative information; presentation of risk characterizations in a readily understandable and useful form.

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Risk Analysis

Taken into consideration in the elaboration of recommendations on:

- > Pesticide Residues (**Maximum Residue Limits** recommended by JMPR)
- > Residues of Veterinary Drugs (**Maximum Residue Limits** recommended by JECFA)
- > Contaminants
- > Food Additives
- > Food Hygiene
- > Fortification of nutrients

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Risk Assessment by Independent Scientific Bodies (Chemicals)

Differences between Codex and Scientific bodies

- Codex Alimentarius Commission (CAC)
 - > **Risk management body**
 - > Delegations of Member governments and observer organizations participate
 - > Recommendations to Members (science-based)
 - > Also considers other legitimate factors and economic implications
- Independent scientific advisory bodies
 - > **Risk assessment bodies**
 - > **Individual scientists participate**
 - > Scientific evaluations and advice

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Process


- Compounds to be on the agenda
 - > Priority lists decided by the relevant Codex Committees and approved by the CAC
 - > Agenda determined by the Secretariat of independent scientific bodies
- Selection of experts
 - > By the Secretariat, based on expertise; regional representation is also considered
- These bodies exist only when they meet; however, monographs and reports shall be drafted for discussion before meeting

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Process

- To ensure scientific and consistent evaluation, guidance documents have been prepared.
- These documents are referred during the preparation stage as well as at the meeting
- Decisions are made through discussions at the meeting on scientific issues
- Their duties include response to questions of the related Codex Committees
- **Incorporating new scientific developments**

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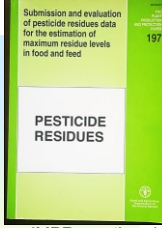


Risk Assessment of Chemicals in Food (2009)

- Risk assessment and its role in risk analysis
- Chemical characterization, analytical methods and the development of specifications
- Hazard identification and characterization: toxicological and human studies
- Dose-response assessment and derivation of health-based guidance values

- Dietary exposure assessment of chemicals in food
- Risk characterization
- MRLs for pesticides and veterinary drugs
- Principles related to specific groups of substances

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Pesticide Residue Data Evaluation by JMPR (FAO Panel)(FAO Manual, 2009)

- Selection of compounds for evaluation
- Data and information required for JMPR evaluation
- Preparation of data dossiers for consideration of the FAO Panel of JMPR

- JMPR practices in evaluation of pesticide residue data
- JMPR practices in estimation of MRLs, and residue levels for calculation of dietary intake
- Estimating dietary intake of pesticide residues
- Use of JMPR recommendations by regulatory authorities

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Who prepares data for evaluation?

- Pesticides, veterinary drugs, and food additives
 - Mostly manufacturers
 - Sometimes, governments or industry groups
- Contaminants
 - Governments
 - Research institutes and academia
 - Use of scientific literature search

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Toxicological Evaluation (ex. JMPR on pesticide residues)

■ Excretion	■ Genotoxicity
■ Distribution	■ Reproductive toxicity
■ Metabolism in laboratory animals	➢ Multi-generational
■ Acute toxicity	➢ Developmental
■ Subchronic toxicity	■ Teratogenicity
■ Chronic toxicity	■ Neurotoxicity
■ Carcinogenicity	■ Endocrine disruption

Lowest NOAEL + Safety factor (usually 100)
 ⇒ **A**cceptable **D**aily **I**ntake (intentionally used); or
Provisional **T**olerable **D**aily **I**ntake (unintentional presence) for life time (every day)

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Toxicological Evaluation (2) (ex. JMPR on pesticide residues)

- Choline esterase inhibition
- Fatality after one time oral dose
- Fetus developmental toxicity as a result of toxicity to mother
- Effect at an early stage of repeated dose
- Acute neurotoxicity
- Biochemical changes, such as effect on hormones
- NOAEL + safety factor (>25)
 ⇒ **A**cute **R**eference **D**ose (ARfD) for one day

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Evaluation of Pesticide Residue Data by JMPR

- Physical & chemical properties
- Metabolism in crops and livestock
- Environmental fate
- Analytical methods & storage stability
- Use pattern on the label(GAP)
- Supervised residue trials following GAP (residues in whole commodity and edible portion)
 ⇒ **M**RL & levels necessary for dietary intake estimates
- Monitoring data ⇒ **E**xtraneous **M**RL
- Processing studies
- Livestock feeding studies

Residue definition

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Evaluation of Pesticide Residue Data by JMPR (2)

- Determines the definition of residues taking into consideration toxicological significance of the parent and metabolites, their concentrations, ease of analysis, etc.
 - For enforcement (what to be analyzed)
 - For risk assessment (includes all toxicologically significant metabolites)
- Using the determined residue definition, estimates MRL on a basis of residue trials
 - If data are insufficient, no MRL (no detectable residue is allowed)

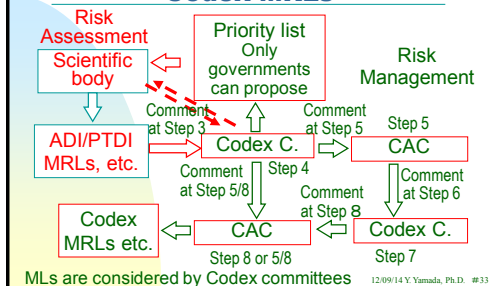
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Risk Assessment

- Validity of MRLs is determined by dietary exposure assessment
 - International Estimated Daily Intake (average total intake of a pesticide from foods) is compared with the ADI
 - International Estimated Short-term Daily Intake (97.5th percentile consumption of food with potentially highest concentration) is compared with ARfD (general population, children ≤ 6 y or women of child bearing age)
 - If the ADI or ARfD is exceeded, highlight the fact for CCPR to consider

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Elaboration Procedure of Codex MRLs



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Conclusion

- Science is the basis for Codex recommendations in the food safety area
- Using Codex recommendations is consistent with the SPS Agreement
- Toxicological endpoints recommended by the scientific advisory bodies can be commonly used
- In order to reflect your country's situations in Codex recommendations, provide scientific data to Codex or relevant scientific advisory body as necessary
- Active participation in Codex is important

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