

Overview of Risk Analysis

MAFF

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Contents

1. Globally agreed framework of risk analysis
 - a. Requirements by the SPS Agreement
 - b. Risk analysis principles in Codex
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 - b. General principles of contaminants in foods and feeds
3. Risk assessment

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Globally Agreed Framework

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Requirements by the SPS Agreement

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SPS Agreement and Science

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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SPA Agreement and 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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SPA Agreement and 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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SPA Agreement and 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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Risk Analysis Principles in Codex

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Risk Analysis in Codex

1. Implementation decided in 1991 by FAO/WHO and GATT
2. Implemented in 1993
3. Risk analysis is:
 - a. On the agendas of Codex committees dealing with food safety
 - b. Basis for Codex standards and other recommendations related to food safety
 - 1) **Contaminants and natural toxins**
 - 2) Residues of pesticides / veterinary drugs
 - 3) Food hygiene (microbiological safety)
 - 4) Food additives
 - 5) GMOs

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4. Risk analysis consists of:
 - a. Risk assessment (by JECFA)
 - b. Risk management (by CAC incl. CCCF)
 - c. Risk communication
5. **Maximum Levels (MLs)** for contaminants and toxins and **Codes of Practice** are types of risk management measures
6. Codex Committee on Contaminants in Foods = **Risk manager**
7. **Joint FAO/WHO Expert Committee on Food Additives (JECFA)** = **Risk assessor** for CCCF and other interested parties (including countries)

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Codex Working Principles

For application by the Codex Alimentarius Commission and its subsidiary bodies

1. Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius
2. Definitions of Risk Analysis Terms Related to Food Safety
3. Risk Analysis Principles Applied by the Committee on Contaminants in Foods
4. Policy of the Committee on Contaminants and Toxins in Foods or Food Groups

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For application by Codex members

1. Codex Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)

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Risk Analysis

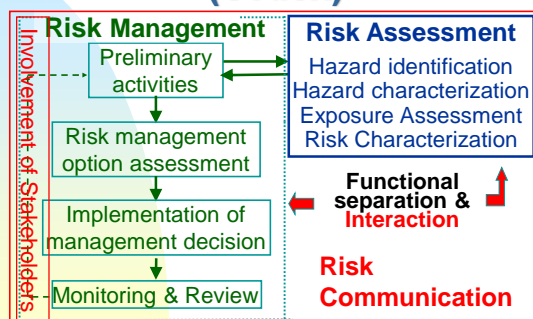
Consisting of 3 components:

- a. Risk Assessment
- b. Risk Management
- c. Risk Communication

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Risk Analysis Framework (Codex)



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General Aspects of Risk Analysis (Codex working principles)

1. Overall objective is to ensure human health protection
2. Risk analysis principles apply equally and consistently to national food control and food trade situations in a non discriminatory manner
3. Risk analysis application should be an integral part of a national food safety system
4. Implementation of risk management decisions at the national level should be supported by an adequately functioning food control system/program.

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5. Risk analysis should be applied consistently; open, transparent and documented; and evaluated and reviewed in the light of new scientific data
6. Risk analysis should follow a structured approach
7. The 3 components of risk analysis should be documented fully and systematically in a transparent manner.
8. Effective communication and consultation with all interested parties.
9. There should be a functional separation of risk assessment and risk management

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10. Risk analysis is an iterative process and interaction between risk managers and risk assessors is essential for practical application.
11. Precaution is an inherent element of risk analysis.
12. National governments should take into account relevant guidance and information obtained from risk analysis activities of Codex, FAO, WHO and other relevant international organizations, including OIE and IPPC

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13. National governments should design and/or apply appropriate **training, information and capacity building programs** with the support of international organizations where appropriate.
14. National Government should **share information and experiences** on risk analysis with relevant international organizations, other national governments to promote and facilitate a broader and more consistent application of risk analysis

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Definitions of Risk Analysis Terms by Codex

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“Hazard” and “Risk” (common in chemicals & microorganisms)

1. **Hazard**
A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect
2. **Risk**
A function of the **probability** of an adverse effect and the **severity** of that effect, consequential to a hazard(s) in food

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Risk Assessment

A scientifically based process consisting of the following steps:

- Hazard Identification
- Hazard Characterization
- Exposure Assessment
- Risk Characterization

Conducted by
Independent scientific bodies
for Codex and/or countries

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Risk Assessment Defined in the SPS Agreement

...the evaluation of the potential for **adverse effects on human health** arising from the presence of additives, contaminants, toxins or disease causing organisms in food, beverages or feedstuff.

(only food safety related part is extracted)

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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 Management

The process, **distinct from risk assessment**, of weighting policy alternatives, **in consultation with all interested parties**, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

Conducted by Codex and countries

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Risk Communication

The **interactive** exchange of information and opinions **throughout the risk analysis process** concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions

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Risk Management Process

1. **Preliminary risk management activities**
2. Evaluation of risk management options
3. Implementation
4. Monitoring and review of the decision taken

Preliminary risk management activities are the KEY for successful risk management!

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Preliminary Risk Management Activities (Codex)

1. Preliminary Risk Management Activities are taken to include:
 - a. Identification of a food safety problem
 - b. Establishment of a **risk profile**
 - c. **Ranking of the hazard for risk assessment and risk management priority**
 - d. Establishment of risk assessment policy for the conduct of the risk assessment
 - e. Commissioning of the risk assessment
 - f. Consideration of the result of the risk assessment

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Risk Management of Contaminants

Risk Management of Contaminants

1. Objectives
 - a. To protect the health of consumers
 - b. To prevent food safety accident from occurring
 - c. To make foods safer

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Need for looking out

1. The objective of risk management is to protect the health of consumers by preventing incidents or reducing risk:
2. Need to look out if there are causes of problems inside and outside of the country
3. Check the original information rather than relying on secondary info

• **Rapid Alert Information (EU) and Import Rejection Data (OASIS, FDA) are also used**

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Sources of Information

1. Regularly check the information from
 - a. Ministries, institutes, centers, universities & industries within the country and of other countries
 - b. International organizations
 - c. Academic societies, scientific/ technological groups
 - d. Consumer groups
 - e. Scientific literature
2. Use websites, news releases,

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Analysis of Collected Information

1. Information thus obtained should be analyzed for
 - a. Possibility of adverse health effect to occur
 - b. Nature and severity of such adverse health effect (chronic/acute, fatal?, reversible?, time for recovery, lasting effect?, etc.)
 - c. Potential for spread (number of affected people, etc.)

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Information Sharing

1. The collected information should be shared with related divisions, bureaus and ministries

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Preparation of Risk Profiles

1. Risk profile is the description of the food safety problem and its content
2. In Japan, a risk profile is prepared for each hazard for risk management
3. Abridged version is published on the website for use by stakeholders
4. Fixed format (use of the template) for consistency

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Identification of Lacking Information

1. When lacking information is identified, risk manager should consider how and when data are to be collected.
 - a. Surveillance for occurrence
 - 1) Need to know before initiation, what you want to know: average, violation percentage? This affects sampling.
 - b. Research
 - 1) On risk reduction technologies which should be feasible and practicable

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Preliminary Estimation of Risk

1. While preparing the risk profile,
 - a. Risk manager should preliminary estimate risk from ingesting the hazard via food, if possible
 - b. Utilizing the information to be put on the risk profile
 - 1) Acute and chronic toxicity
 - 2) Consumption of the food concerned
2. This usually results in over-estimate

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If the Preliminary Estimate Indicates Not-negligible Risk

1. Collect information on the hazard from inside and outside of the country, in particular, how the hazard has been controlled.
2. Immediately start collecting data
3. If necessary, prepare risk management options and initiate controlling the hazard (fast track)

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Prioritization of hazards for risk management

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Prioritization of hazards

1. There are many chemicals and microorganisms on the earth!
2. We cannot deal with every one of them
3. Need prioritization
 - a. Part of preliminary risk management activities
 - b. Based on scientific knowledge, such as toxicity, potential intake from food and other sources
 - c. Need for collecting information including that on incidents

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Criteria for Prioritization (in MAFF, Japan)

1. Issues to be considered for chemicals
 - a. For improving food safety
 - 1) Toxicity
 - 2) Occurrence in food/feed
 - 3) Exposure
 - b. Concerns/interests of stakeholders
Need to ask for information & opinions
 - c. International activities
Such as Codex, JECFA and other international bodies
2. Evaluate H, M or L

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Criteria for Prioritization (2)

1. Issues to be considered for microorganisms
 - a. For improving food safety
 - 1) Pathogenicity
 - 2) Number of patients
 - b. Concerns/interests of stakeholders
Need to ask for information & opinions
 - c. International activities
Such as Codex, JEMRA and other international bodies
2. Evaluate H, M or L

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Determination of Priorities

1. Finalization of Priority List
 - a. Effective for 5 years
 - b. At a time of emergency, other hazards can be added
 - c. Published on the website in Japan

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General Principles for Contaminants in Foods and Feeds

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Data to be Collected

Scientific data are essential for risk management of contaminants and toxins

1. Various data are necessary for both risk assessment and risk management
 - a. Occurrence data of hazards in foods or feeds: Representative of the country?
 - b. Information on measures to reduce risk
 - 1) Feasible technically and economically?
 - 2) Effective?
 - 3) Alternative risk?
 - c. Toxicological data incl. distribution, metabolism, chronic and acute toxicity, etc.
 - d. Food consumption data

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Data to be Collected (2)

2. For risk assessment, there should be clear guidance on what data shall be obtained and provided
3. For risk management, it is essential to determine what kind of information shall be obtained for designing the surveillance and research
4. It is under the responsibility of risk managers to plan surveillance and other research. Otherwise money and time will be wasted.

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Priorities for Surveillance (MAFF, Japan)

1. Based on the prioritized hazards
2. Important criteria
 - a. Availability of validated analytical method(s), which can also be used for enforcement
3. Medium-term Plan for 5 years &
4. Annual Plan
5. Two categories
 - a. Priority A: must conduct surveillance in the specified period
 - b. Priority B: conduct surveillance if possible

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Establishment of Risk Assessment Policy

1. If there is a need to commission risk assessment, **risk manager** should prepare a **risk assessment policy** beforehand:
 - a. How risk assessment should be conducted
 - b. Through risk communication with stakeholders and in consultation with risk assessors

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Risk Assessment Policy

1. One step included in the preliminary risk management activities
2. Documented guidelines on the choice of options and associated judgements for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained.

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Risk Assessment Policy (Codex working principles)

1. Should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent.
2. The mandate given by risk managers to risk assessors should be as clear as possible.
3. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

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Commission risk assessment

Risk assessment result

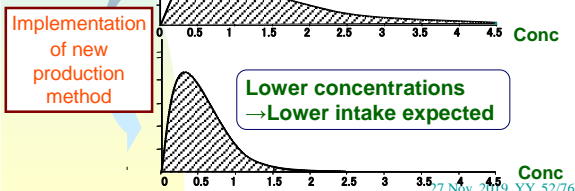
Risk management measures, as necessary, such as COP and MLs

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Effect of COP on Reduction of Concentrations

- More effective, efficient and economical to control at production stage than inspection of final products for compliance.
- Shift of distribution to lower concentration will decrease intake by consumers subsequently.



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Codex Codes of Practice

1. Prevention and Reduction of Mycotoxin Contamination in Cereals, Including Annexes on Ochratoxin A, Zearalenone, Fumonisin and Tricothecenes
2. Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feedingstuffs for Milk-Producing Animals
3. Prevention and Reduction of Aflatoxin contamination in Tree Nuts
4. Prevention and Reduction of Aflatoxin contamination in Peanuts
5. Prevention and Reduction of Aflatoxin contamination in Dried Figs

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1. Prevention and Reduction of Ochratoxin A Contamination in Wine
2. Prevention and Reduction of Ochratoxin A Contamination in Coffee
3. Prevention and Reduction of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages
4. Prevention and Reduction of Lead Contamination in Foods
5. Prevention and Reduction of Tin Contamination in Canned Foods
6. Source Directed Measures to Reduce Contamination of Foods with Chemicals

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1. Reduction of **Acrylamide** in **Foods**
2. Prevention and Reduction of **Dioxin and Dioxin-like PCB** Contamination in **Food and Feeds**
3. Prevention and Reduction of **Ethyl Carbamate** Contamination in **Stone Fruit Distillates**
4. Reduction of **3-Monochloropropane-1,2-diol (3-MCPD)** during the Production of **Acid-Hydrolyzed Vegetable Protein (Acid-HVPs)** and **Products That Contain Acid-HVPs**
5. Reduction of Contamination of **Food** with **Polycyclic Aromatic Hydrocarbons (PAH)** from Smoking and Direct Drying Processes

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Codex MLs and COP for As in Rice

1. China and Japan chaired the electronic working groups for developing:
 - MLs for inorganic arsenic in polished and husked rice
 - Code of practice for prevention and reduction of arsenic contamination of rice

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Risk Assessment

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Risk Assessment Process

1. Hazard Identification
2. Hazard characterization
3. Exposure Assessment
4. Risk Characterization

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Hazard Identification

- The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods

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Hazard Characterization

- The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

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■ For chemicals, the following is derived:

- a. Chronic toxicity
 - 1) Acceptable Daily Intake (ADI, for intentionally used chemicals)
 - 2) Provisional Tolerable Daily Intake (PTDI, for contaminants)
- b. Acute toxicity
 - 1) Acute Reference Dose (ARfD): an estimate of the amount of a substance in food which can be ingested in a period of **24 hours or less without appreciable health risk** to the consumer
 - 2) Different from LD50
In food safety, it is not at all acceptable to have the deaths of a half of population

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Dose-Response Assessment

- The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

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Exposure Assessment

- The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents **via food** as well as exposures from other sources if relevant.

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Risk Characterization

- The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

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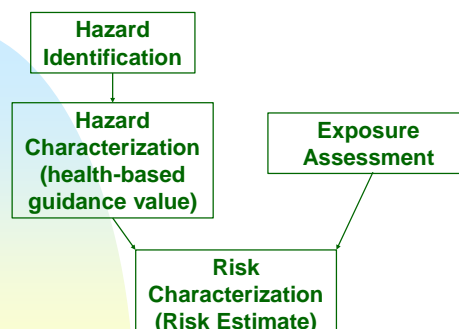
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Risk Estimate

- The quantitative estimation of risk resulting from risk characterization.

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Risk Assessment in Codex

1. Codex relies on the risk assessment conducted by the independent scientific advisory bodies (JECFA, JMPR, JEMRA)
2. Risk assessment shall be the basis for food safety related decisions
3. Good communication necessary between these risk assessment bodies and Codex committees

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Principles & Methodologies for Risk Assessment

1. Hazard Characterization for chemicals including food additives, contaminants, natural toxins and pesticide residues:
 - a. Published in the IPCS Environmental Health Criteria series 240 "Principles and Methods for the Risk Assessment of Chemicals" by WHO (2010) → now in the process of revision soon
 - b. Methodologies for dietary exposure assessment of chemicals are also included

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Risk Assessment (Data for Toxicological evaluation)

- | | |
|-----------------------------------|-----------------------------|
| 1. Acute toxicity | 7. Reproductive toxicity |
| 2. Short-term studies of toxicity | a. Multi-generation studies |
| 3. Long-term studies of toxicity | b. Developmental toxicity |
| 4. Carcinogenicity | 8. Endocrine activities |
| 5. Genotoxicity | 9. Metabolism studies |
| 6. Neurotoxicity | 10. Epidemiological data |

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Who Develops the Necessary Data?

1. For intentionally used chemicals, the manufacturers are responsible for developing data for registration or approval in a country(ies)
2. For contaminants, usually governments develop data or data in scientific literature can be used
3. For chemicals that is both a part of food additive and contaminant, data for food additive can be used.

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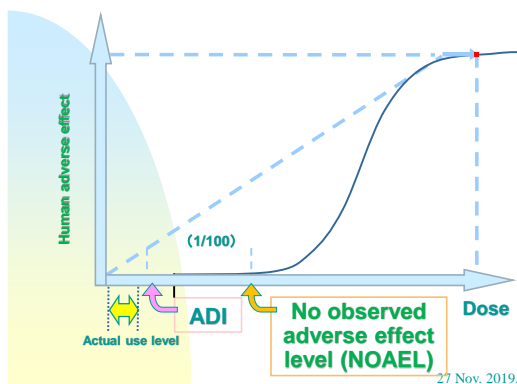
Health Based Guidance Values

1. Chronic toxicity
 - a. ADI for intentionally used chemicals
 - 1) Pesticides, Veterinary Drugs, Food Additives
 - b. PTDI/PTWI/PTMI for unintentional presence
 - 1) Contaminants
2. Acute toxicity
 - a. Acute Reference Dose (ARfD)
 - 1) Pesticides, Veterinary drugs, contaminant (so far for Deoxy nivalenol)

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Dose-Response Relationship



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Estimation of ADI/PTDI

Lowest No-observed-adverse-effect level (NOAEL) or no-observed-effect level (NOEL)



Safety factor (usually 100)
(inter-species x intra-species)

**ADI: for intentionally used products
or
PTDI/PTWI: for contaminants**

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Estimation of ADI/PTDI

ADI: amount that can be ingested daily
over lifetime without appreciable risk

PTDI: permissible human exposure
PTWI or PTMI may be estimated
depending on toxicity and nature of
chemicals (accumulate or not)

Expressed on a body weight basis

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Hazard Identification Hazard Characterization (chemicals)

1. Use ADIs, PTDIs/PTWIs, ARfDs recommended by JECFA/JMPR or other international/regional bodies
2. Propose evaluation by JECFA/JMPR
3. Regional cooperation

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Thank you for your attention!

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ADDITIONAL INFORMATION

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Codex Recommendations on Risk Analysis

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Codex Documents on Risk Analysis (available on the Codex website)

1. Adopted for Codex use (*contained in the Procedural Manual*):
 - a. Definitions of Risk Analysis Terms Related to Food Safety
 - b. "Statements of Principle Relating to the Role of Food Safety Risk Assessment"
 - c. "Working Principles for Risk Analysis for Application in the Framework of Codex Alimentarius"

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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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- a. Risk Analysis Principles Applied by the by the Committee on **Food Additives**
- b. Risk Analysis Principles Applied by the Committee on **Contaminants in Foods**
- c. Risk Analysis Principles Applied by the Committee on **Pesticide Residues**
 - 1) Annex: List of Risk Management Policies Used by CCPR

These 3 documents specify the roles of and separation of responsibilities between the related scientific advisory body and Codex Committee

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- a. Risk Analysis Principles Applied by the Committee on **Residues of Veterinary Drugs in Foods**
 - 1) Annex: Template for Information Necessary for Prioritization by CCRVDF
- b. Risk Analysis Principles and Procedures Applied by the Committee on **Food Hygiene**

These 2 documents specify principles for the steps of risk analysis

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- a. **Nutritional** Risk Analysis Principles and Guidelines for Application to the Work of the Committee on **Nutrition and Foods for Special Dietary Uses** (2009)
- b. Policy of the Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups
- c. Criteria for the **Prioritization** Process of Compounds for Evaluation by JMPR
- d. Risk Assessment Policy for the Setting of Maximum Limits for Residues of Veterinary Drugs in Foods

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Codex Documents on Risk Analysis (2) (available on the Codex website)

1. Recommendation to its members
 - a. Working Principles for **Risk Analysis for Food Safety** for Application by **Governments** (2007)
 - b. Principles and Guidelines for the Conduct of **Microbiological Risk Assessment** (1999)
 - c. Principles and Guidelines for the Conduct of **Microbiological Risk Management** (2007)

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- a. Principles for the Risk Analysis of Foods Derived from **Modern Biotechnology** (2003)
- b. Guideline for the Conduct of Food Safety Assessment of Foods Derived from **Recombinant-DNA plants** (2003)
- c. Guideline for the Conduct of Food Safety Assessment of Foods Derived Using **Recombinant-DNA Microorganisms** (2003)
- d. Guidelines for the Conduct of Food Safety Assessment of Foods Derived from **Recombinant-DNA Animals** (2008)

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- a. Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (2011)
- b. Guidelines on the Application of Risk Assessment for Feed (2012)

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