



## **IMPORTANCE OF RISK PROFILE IN RISK MANAGEMENT**

**MAFF, JAPAN**



## **RISK PROFILING AS A PRELIMINARY RISK MANAGEMENT ACTIVITY IN RISK ANALYSIS**

**MAFF, JAPAN**

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1. Globally Agreed Framework of Risk Analysis
2. Risk Management

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## (1) Globally Agreed Framework of Risk Analysis

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## Risk Analysis and SPS

- **Members** of WTO shall ensure that food safety measures are **based on a risk assessment** taking into account risk assessment techniques developed by Codex
- **Codex** recommendations shall base on assessment of risks to human and science evidence

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## Risk Analysis in Codex

- Risk analysis is:
  - On the agendas of Codex committees dealing with food safety
  - The Basis for Codex standards and other recommendations related to food safety
    - ✧ Residues of pesticides / veterinary drugs
    - ✧ Contaminants and natural toxins
    - ✧ Food additives
    - ✧ Food hygiene (microbiological safety)
    - ✧ GMOs

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## Codex Documents on Risk Analysis (1)

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

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

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- Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (2011)
- Guidelines on the Application of Risk Assessment for Feed (2012)
- There are also many Codex documents on risk analysis for use within the Codex system. They are contained in the *Codex Alimentarius Commission Procedural Manual*.

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## Definition of the terms “Hazard” and “Risk” in Codex

### ■ Hazard

A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect

### ■ 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 Analysis in Codex

Consisting of 3 components:

- Risk Assessment
- Risk Management
- Risk Communication

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## General Aspects of Risk Analysis (Codex Working Principles)

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

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

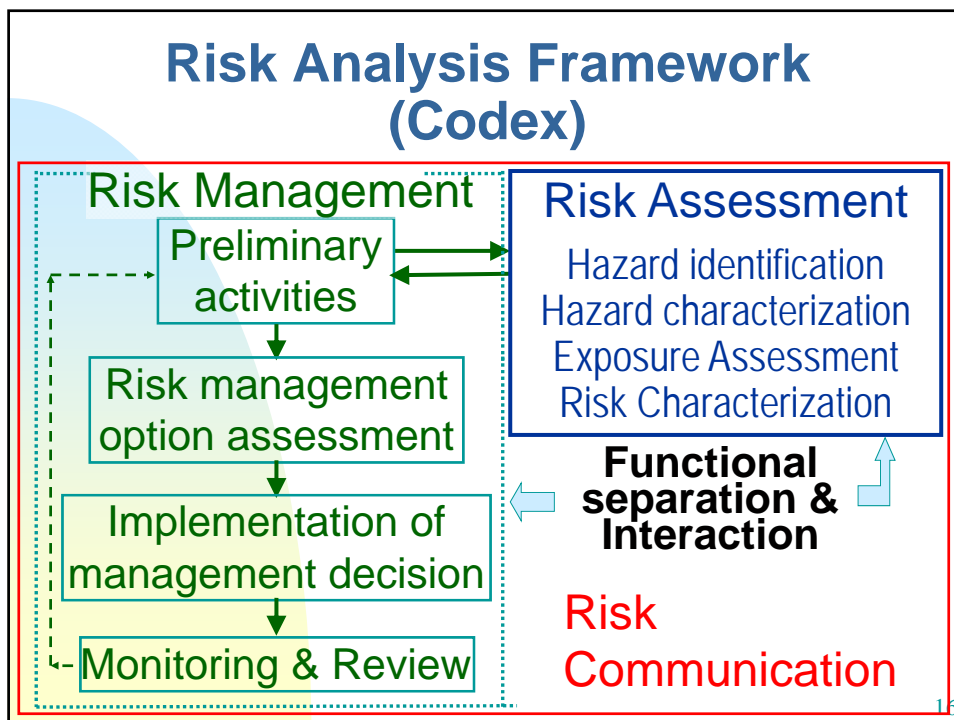
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- Risk analysis is an iterative process and **interaction between risk managers and risk assessors is essential** for practical application.
- **Precaution is an inherent element** of risk analysis.
- National governments should take into account relevant 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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- National governments should design and/or apply appropriate **training, information and capacity building programs** with the support of international organizations where appropriate.
- 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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## (2) Risk Management

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### Risk Management (Codex definition)

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.

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## Risk Management Process (Working Principles)

- Preliminary risk management activities
- Evaluation of risk management options
- Implementation
- Monitoring and review of the decision taken
- The decisions should be based on risk assessment, and should be proportionate to the assessed risk, taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers

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## Preliminary Risk Management Activities

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

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## Risk Profile

- Risk profile is the description of the food safety problem and its content
- It serves as a basis for prioritization of hazards for risk assessment and further risk management
- It serves as reference in risk management processes
  - To identify what data should be collected and/or developed
- Useful for the initial stage of risk assessment
- It provides information to the government, scientists and any interested parties

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## Risk Assessment Policy

- 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

- 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.
- The mandate given by risk managers to risk assessors should be as clear as possible.
- 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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## Evaluation of Risk Assessment Results

- Evaluate if all the questions are answered and the assessment followed the risk assessment policy.
- Determine if it is necessary to proceed with risk management
  - If found to be negligible risk, terminate risk management for the time being
- Determine if the results is useful for proceeding with risk management.

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## Risk Management

- Codex decision making
  - Based on risk assessment
  - Risk management
  - Based on scientific data
- Different factors may need to be considered at the national level

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## Main Variables in Countries

- Occurrence of hazards
- Dietary intakes (exposure assessment)
- Infrastructure and national capacity
- Public knowledge & opinion
- Religion, culture, tradition

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## Risk Management Options

- Codes of practice
  - Prevention/reduction of contamination in whole food chain
  - Source-directed measures

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## Risk Management Options

- Maximum levels
  - ALARA principles + Surveillance/ Monitoring data
  - For contaminants that present significant risk
  - For foods that are significant for the total exposure
  - Available validated methods

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## Risk Management (Working Principles)

- Decisions on risk management should have as their primary objective the protection of the health of consumers. Unjustified differences in the measures selected to address similar risks in different situations should be avoided.
- Risk management should follow a structured approach
- The decisions should be based on risk assessment, and should be proportionate to the assessed risk

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- In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.
- Risk management should take into account the economic consequences and the feasibility of risk management options.

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- The risk management process should be transparent, consistent and fully documented.
- The outcome of the preliminary risk management activities and the risk assessment should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk.
- Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.

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- Risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages.
- Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions.
- The relevance, effectiveness, and impacts of risk management decisions and their implementation should be regularly monitored

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## Risk Management Measures

- Protection of the health of consumers is of utmost importance
- Need to consider feasibility and implications to food supply
  - Technical feasibility
  - Economic impact, effects on culture
- Need to consider risk vs benefit
- Need to consider alternative risk
- Need to involve stakeholders in decision making
- Availability of method of analysis for checking compliance

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## Risk Management Summary

- Objective
  - Protect the health of consumers
  - Prevent incidents to occur
- Base decisions on scientific principle
  - Collect necessary scientific data
  - Allow for emergency response without sufficient data
  - Measures should be proportionate to risk to achieve appropriate level of protection

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- 
- Consider
    - Steady food supply
    - Feasibility
    - Cost
    - Alternative risk
  - Document the process/decision and keep records
  - Communicate with stakeholders and involve them in the process
  - Collaborate with other ministries
  - Be consistent with the SPS Agreement
  - Be consistent
- Multi-disciplinary**

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**WHAT IS A RISK PROFILE?  
WHO DEVELOPS IT AND WHO  
USES IT?**

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- (1) Preliminary Activities
- (2) Risk Profile
- (3) Use of Risk Profile for Prioritization  
(Ranking) of Hazards

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## (1) Preliminary Activities

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## Risk Analysis

Codex definition:

A process consisting of 3 components

- Risk Assessment
- Risk Management
- Risk Communication

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## Risk Management Process (Working Principles)

- Preliminary risk management activities
- Evaluation of risk management options
- Implementation
- Monitoring and review of the decision taken

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## Preliminary Risk Management Activities

- Preliminary Risk Management Activities are taken to include:
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  - Ranking of the hazard for risk assessment and risk management priority
  - Establishment of risk assessment policy for the conduct of the risk assessment
  - Commissioning of the risk assessment
  - Consideration of the result of the risk assessment

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## Sources of Information (to be put in the Risk Profile)

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

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## In MAFF, Japan

- Information is collected from websites of
  - Subsidiary bodies of MAFF
  - Ministry of Health, Labour & Welfare and its subsidiary bodies
  - Related ministries including the Food Safety Commission
  - Codex, WHO, FAO, OIE, OECD, ISO, etc.
  - Local governments
  - Japanese Embassies outside of Japan
  - Academic societies and meetings
  - Industry groups and agricultural COOP
  - Consumer groups

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## Analysis of Collected Information

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

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## Information Sharing

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

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## (2) Risk Profile

## Risk Profile

- Risk profile is the description of the food safety problem and its content
- It serves as a basis for prioritization of hazards for risk assessment and further risk management
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- Useful for the initial stage of risk assessment
- It provides information to the government, scientists and any interested parties

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## Is there any fixed way of establishing Risk Profiles?

- No.
  - They are prepared for the purpose
  - Countries may have different purposes
  - Levels of details may be different
  - First need to agree on the purposes

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## For Hazards or for Foods?

- Mostly for hazards
  - Risk assessment is conducted for hazards
  - A food item may contain many kinds of hazards (chemical, microbiological, etc.)
- By establishing a risk profile, risk managers can understand for what food items/groups further data should be collected and on what food items/groups risk assessment and risk management should focus.

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## Fixed Format?

- If a format is determined for categories of hazard,
- It is easier for risk managers to know what kind of information shall be collected and how they shall be analyzed.
- For those interested (consumers, industries, government offices), it is easier to find information they look for.

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## Who Prepares Risk Profile?

- Codex defined that establishment of risk profile is one of preliminary risk management activities -> indicate that this is the task of risk managers
- However, in some countries, it may be done by risk assessors in relation to risk assessment; and in some other countries done by both risk managers and risk assessors for different purposes

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## When Is Risk Profile Prepared?

- As necessary for risk management
  - News about new hazard from within Japan or from other countries
  - Information on adverse health effects or incidents from other countries
    - ✧ Need for reducing dietary exposure
  - Codex activities
- Even if the data set is not complete

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## Preparation of Risk Profiles

- In Japan, a risk profile is prepared for each hazard for risk management by MAFF officers
  - The Food Safety Commission prepares “fact sheet”: out-sourcing
- Established formats are used for consistency in MAFF for categories of hazard
  - Mycotoxins, other contaminants, some ex- and old pesticides, microorganisms (viruses, bacteria, parasites)
- Abridged version is published on the website of MAFF for use by stakeholders.

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## What Information in Risk Profile?

- A wide range of information
- “Guidance for preparing risk profile” in MAFF
- Example for a chemical in MAFF, Japan:
  - Name\* and identity
  - Physicochemical properties
  - Stability
  - Maximum levels (national, overseas)\*
  - Cause of interest to the hazard\*
  - Occurrence data (national\* overseas)
  - Producing fungus/fungi (for mycotoxins)
  - Methods of analysis and sampling

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- Toxicological evaluation\*
  - ✧ ADME
  - ✧ Chronic (various), sub-chronic, acute, etc.
  - ✧ Target organs
- Toxicological endpoint\*
- Dietary exposure assessment\*
- Margin of exposure\*
- Effect of preparation, processing or cooking on the hazard
- Pathway or conditions of contamination
- Production information of fresh produce/foods with potential of contamination

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- Measures for prevention of contamination and/or risk reduction\*
- Lacking data necessary for proceeding with risk management\*
- Social and economic implications of contamination of foods
- Interests and concerns of consumers\*
- Notes (incl. references)
- Dates of updating

■ Similar format for microorganisms

\*: information published on the MAFF website

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## Identification of Lacking Information

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

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## Preliminary Estimation of Risk

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

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## Preliminary Exposure Assessment

- Use as much information as possible
  - Occurrence in food items/groups
  - Food consumption data
- To know the rate of contribution of food items/groups
- To know for what food items/groups risk management should be continued

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## If the Preliminary Estimate Indicates Not-negligible Risk

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

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### **(3) Use of Risk Profile for Prioritization (Ranking) of Hazards**



### **Prioritization of hazards**

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

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## Prioritization of Hazards

- Preparation of a priority list
  - Based on the risk profiles
    - ✧ Preliminary risk estimate
    - ✧ Severity of adverse health effect
    - ✧ Volume of scientific data
    - ✧ Economic implications if no action is taken
    - ✧ Risk management measures taken in other countries
    - ✧ Impact on importation of the related food

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## Determination of Priorities

- Decided through a meeting with stake holders
  - Core members
    - ✧ Consumers
    - ✧ Agriculture sector
    - ✧ Food manufacturer
    - ✧ Big-scale retailer
    - ✧ Restaurant operator
  - Ad hoc members depending on the topic in roster

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## Determination of Priorities

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

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## Establishment of Risk Assessment Policy

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

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## Risk Assessment Policy

- Questions from the risk manager to the risk assessor, such as
  - NOAEL/NOEL, Benchmark dose
  - Susceptible population
  - If there is any metabolite that also need to be controlled, and its toxicity
  - Effect of risk management options in risk reduction

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## Commissioning of Risk Assessment

- Request the risk assessor to conduct risk assessment
  - Follow the country's bureaucratic system
  - Provide data necessary for risk assessment (toxicology, occurrence)
  - Communicate with the risk assessor on the purpose, target, potential risk management measures, and data

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## During Risk Assessment

- Usually risk assessment is a lengthy process
- Communicate well with the risk assessor on the progress of risk assessment
- If necessary or required, provide additional data

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## Data to be Collected

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

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## Data to be Collected

- For risk assessment, there should be clear guidance on what data shall be obtained and provided
- For risk management, it is essential to determine what kind of information shall be obtained for designing the surveillance and research
- 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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## For Conducting Surveillance in MAFF

- Clear requirements included in the document for public tender
  - Internal quality assurance implemented in the laboratory
  - Participation in proficiency testing (same analyte, same or similar matrix)
  - Validated method for the analyte/matrix combinations
  - Accreditation, if available
- MAFF gives guidance on sampling

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## Surveillance

- Sampling
  - Representative samples for a country
  - Statistically sound number of samples  
“Codex General Guidelines on Sampling”(CAC/GL 50-2004)
- Analytical methods
  - Validated methods  
esp. for submission to Codex/JECFA
- Good laboratory management
  - Many recommendations from Codex

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## Use of Occurrence Data

- In risk assessment, in particular, in exposure assessment
- In preliminary risk management activities to see the need for risk management
- In establishing maximum levels
- In monitoring the effectiveness of measures taken
- How sampling was done influences the usefulness of the data

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# **RISK PROFILING FOR CHEMICAL FOOD SAFETY RISK MANAGEMENT**

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## **Contents**

- (1) Template used in MAFF, Japan
- (2) Guidance for Preparing and Updating Risk Profile in MAFF

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## (1) Template used in MAFF, Japan

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## Template

- Established for
  - Consistent information collection
  - Easier updating of the information
  - Easier for readers
  - Easier comparison
- Created using the Word
  - Information can be added and changed
  - Issue names cannot be modified
- See the one for chemical contaminants

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## What Information in Risk Profile?

- A wide range of information
- “Guidance for preparing risk profile” in MAFF
- Example for a chemical in MAFF, Japan:
  - Name\* and identity
  - Physicochemical properties
  - Stability
  - Maximum levels (national, overseas)\*
  - Cause of interest to the hazard\*
  - Occurrence data (national\* overseas)
  - Producing fungus/fungi (for mycotoxins)
  - Methods of analysis and sampling

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- Toxicological evaluation\*
  - ✧ ADME
  - ✧ Chronic (various), sub-chronic, acute, etc.
  - ✧ Target organs
- Toxicological endpoint\*
- Dietary exposure assessment\*
- Margin of exposure\*
- Effect of preparation, processing or cooking on the hazard
- Pathway or conditions of contamination
- Production information of fresh produce/foods with potential of contamination

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- Measures for prevention of contamination and/or risk reduction\*
- Lacking data necessary for proceeding with risk management\*
- Social and economic implications of contamination of foods
- Interests and concerns of consumers\*
- Notes (incl. references)
- Dates of updating

■ Similar format for microorganisms

\*: information published on the MAFF website

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## **(2) Guidance for Preparing and Updating Risk Profile in MAFF**

## General Principles

- Risk profile is referred to during the whole process of risk management. responsible officers shall collect the latest information and check the risk profile regularly to keep it up-to-date.
- Risk profile covers a vast range of information: scientific information, such as toxicity and exposure, production volume and socio-economic impacts by contamination (obtained from the responsible bureaus)
- Even if information is not sufficient for the hazard of concern, in order to identify information to be collected for risk management, a risk profile shall be created for that hazard.

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## Procedures

- Allocation of responsibilities to a primary and secondary officers within the “risk management team” (team work)
- Detailed procedures for preparation / update, saving the files, and upload on to the MAFF website
- Priorities of preparing the risk profiles should be given to those included in the “List of hazards prioritized for risk management”
- Regular update: in less than 1 year after the previous update
- As new information becomes available, the risk profile needs to be updated accordingly

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## Points to Note

- Use of the fixed templates
  - No change in the width of the template
  - No addition or deletion of items
- Font and its size (exemption for tables)
- In the tables, decimal tab should be used
- Complex tables (tables in a table) should be made as appendices
- Significant figures/digits
- Use of the SI units except other units in the laws (values in the SI units should also be included in parentheses); per body weight, use “bw”
- Use consistent units throughout the profile as feasible

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- Use correct scientific terms in Japanese, regardless of the term used in the related laws (sometimes the laws state “content” while they talk about the “concentration”)
- Punctuation
- Rules for “and” and “or” in the Japanese language
- Use of the Christian style year (not the Japanese style)
- If multiple compounds are described in a risk profile, make clear what compound is described; if appropriate in tables with the references
- Multiple source of information: in the order of (1) inside Japan, (2) international organizations, and (3) overseas governments

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## What to Put in

- |  |  |
|--|--|
| 1 Name of hazard *                       | Common name and, for pesticides, use the ISO common name   |
| 2 Chemical name and structure            |  |
| (1)IUPAC                                 | According to the IUPAC Guide of 1993   |
| (2)CAS                                   | Chemical Abstract Service name database  |
| (3)CAS number                            | Check regularly on the Internet as it is often changed   |
| (4)Molecular formula, Structural formula | In addition to the molecular formula and structural formula, for those analyzed with Mass chromatography, include the molecular weight. Use appropriate structural formula drawing software. |
| (5)Synonyms and trade names *            | State other well-known names than those in 1, 2(1)-(4) above   |

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### 3 Physicochemical characteristics

- |                                   |  |
|-----------------------------------|--|
| (1)Melting point                  | If the temperature is outside of the temp. range of food manufacturing / processing, no need. When decomposition occurs, state this after the temperature. |
| (2)Boiling point                  | If the temperature is outside of the temp. range of food manufacturing / processing, no need. State pressure if not at the normal atmospheric pressure.    |
| (3)Water solubility               | State the conditions. If no quantitative information available, include qualitative information.   |
| (4)Solubility in organic solvents | Similar as above. Indicate solvent names   |
| (5)LogP <sub>ow</sub>             |  |
| (6)Vapor pressure                 | If available. State the conditions.  |
| (7)Henry's constant               |  |
| (8)Other relevant information     | If any.  |

4	Stability	
	(1)Thermal stability	Include information about decomposition etc. at or lower than 350 degrees. Qualitative data OK.
	(2)Hydrolysis	Include info on hydrolysis in water, acid and base with the conditions. Qualitative data OK.
	(3)Other relevant information (such as stability in photolysis)	Considering the processing and storage of related foods, include info on decomposition.
5	Maximum levels or other risk management measures *	
	(1)National *	Include info on national measures on risk management measures on foods, feeds, drinking water and the environment.
	(2)Overseas *	Same as the above. Include info from Code, USA, EU, AU, CA, CN & KR. If available, include info of other countries

6	Cause of interest to the hazard *	Describe briefly within 6 lines
7	Occurrence data *	
	(1)National *	Describe the results of surveillance and monitoring. If too much data are available, summarize the data and attach the data in a separate file.
	(2)International	Similar as above
	(3)Producing fungus/fungi (for mycotoxin only)	Only for mycotoxin risk profiles. State genus and species according to the regions of concern.
8	Methods of analysis and sampling	
	(1)Methods of analysis	Describe the analytical method(s) used in the surveillance & monitoring above.
	(2)Methods of sampling	Same for sampling.

9 Toxicological Evaluation *	<ul style="list-style-type: none"> <li>- In principle, include the results from oral ingestion. If info is available for other pathway, include the results.</li> <li>- Include the methods and conditions for each study</li> <li>- If human data are available, state the fact and study conditions. Include the label location of the molecule.</li> <li>- For animal studies, include the study with the lowest NOAEL, and if the study is older than 1990, include appropriate study; and if no appropriate study is available, include the study result with the indication of inappropriateness</li> <li>- When no studies are available, type "-".</li> <li>- Include the NOAEL (or BMDL, LOAEL), target organ, animal species/variety, age and gender in the study results.</li> </ul>
------------------------------	---

(1)Absorption, distribution, excretion and metabolism*	
a. Oral ingestion	Absorption rate and site (organ), time to reach the max concentration in blood, and dosing regime
b. Inhalation	Absorption rate, time to reach the max conc. in blood. If the intake from the air is significant ( $\geq 10\%$ ), look for information beyond JECFA
c. Distribution	Describe distribution of the absorbed hazard from oral dose among organs/tissues.
d. Excretion	Half-life of the hazard or toxic metabolite(s), excretion route after oral ingestion.
e. Metabolism	Metabolites identified in organs/tissues after oral ingestion.
f. Transfer and accumulation in edible animal tissues	If info is available on the relationship between the concentrations in feed and in foods of animal origin

g. Compounds of toxicological significance	If there is any metabolite(s) showing significant toxicity, state the name of the metabolite(s). If a hazard is a mixture of compounds or isomers, state the main toxicological compound.
(2) Acute toxicity *	
a. LD <sub>50</sub> * (mg/kg bw)	Include the value and animal species/ varieties and gender in parentheses.
b. Lowest NOAEL	Lowest NOAEL in acute toxicity studies.
c. Target organ /adverse health effect	Describe the toxicity of (b)
(3) Sub-chronic toxicity *	
a. Lowest NOAEL or BMDL	Same as for (2)
b. Target organ /adverse health effect	Same as for (2)

(4) Chronic toxicity *	Other info than (2) or (3)
a. Genotoxicity	State positive when i) in most of the studies positive, and ii) positive in vivo and in vitro. State negative when i) in most of the studies negative, and (2) no positive results in vivo. Describe all other available study results
b. Carcinogenicity	
i) Lowest NOAEL or BMDL	Include the lowest NOAEL or BMDL in the long-term studies (24 months for rats and 18 months for mouse). If no long-term studies are available, describe other studies.
ii) Target organ/adverse health effect	State the organ where carcinogenicity was observed.
iii) IARC Group (1, 2a, 2b, 3)	If available. State the exposure route.

c. Reproductive toxicity	
i) Lowest NOAEL or BMDL	Deformation and dysfunction of reproductive organs, effect on mortality rate of fetus, mutation or dysfunction of fetus or new-born
ii) Target organ/adverse health effect	
d. Other toxicity	
i) Lowest NOAEL or BMDL	Neuro-toxicity, immuno-toxicity, endocrine disrupter, etc. available
ii) Target organ/adverse health effect	

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10 Toxicological endpoint*	
(1) Toxicological endpoint (mg/kg bw) *	
a. PTDI, PTWI, or PTMI? *	Those established by JECFA/JMPR or in Japan. If none available, use those established in EFSA, USFDA, USEPA, etc. and state which.
b. Basis for PTDI, PTWI or PTMI *	Basis of the value in (1)
c. Safety factor (uncertainty factor)	For (a) above
(2) Acute Reference Dose (ARfD)	
a. ARfD (mg/kg) *	If established by JECFA/JMPR or in Japan
b. Safety factor	For (a) above

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11	Exposure Assessment (Dietary intake) * (1) Estimated daily dietary intake * (2) Estimation method *	Describe the dietary intake estimates by the risk assessment bodies (also international ones) or calculated by MAFF, or the results of total diet studies of MHLW or MAFF. If there is significant intake from other sources than foods, describe.
12	Margin of exposure (MOE) (1) MOE * (2) NOAEL or BMDL used for estimating MOE	If available from risk assessment bodies, describe with the name of the body, year, and the relevant NOAEL/BMDL.
13	Effect of preparation, processing or cooking on the hazard	If any information on the decrease (decomposition, degradation, etc.) or increase (synthesis) of the hazard during the preparation/processing, cooking.

14	Pathway or conditions of contamination (1) Production stage (2) Processing and distribution stages	Describe how and at what stage foods are contaminated by the hazard. If the conditions are known, state the related fact (such as the concentration in soil).
15	Production information of fresh produce/foods with potential of contamination * (1) Name of fresh produce/food (or group thereof) * (2) Production in Japan * (3) Production in other countries and importation into Japan	Considering information from stakeholders and other government authorities, state the names of food or agricultural produce, their production places and volumes in Japan or overseas.

16	Measures for prevention of contamination and/or risk reduction *	Include information on the measures for prevention and reduction of the hazards in certain foods. Codex and country Codes of Practice, recommendations of JECFA, research results, etc.
17	Lacking data necessary for proceeding with risk management *	Examples include occurrence data in Japan, toxicological information, feasibility of and means for reduction of contamination
18	Social and economic implications of contamination of foods (1) Implication to fresh produce/foods (2) Implication to others	State any other impacts than adverse health effects caused by the contamination of foods and feeds by the hazard
19	Interests and concerns of consumers *	State the consumers recognition of the hazard and how much concerns they have

20	Notes (1) References	Include all sources of data: such as reports of JECFA, JMPR and other international organizations; risk assessment reports and occurrence data of other countries; risk assessment reports of FSC, Japan; reports of surveillance by MAFF and MHLW; and scientific literature. In the fixed format and using the reference function of MS Word. Details instructions.
	(2)Others *	
21	Year of update	Describe the date as well as the content of update

## Sources of Information (to be put in the Risk Profile)

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

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## In MAFF, Japan

- Information is collected from websites of
  - Subsidiary bodies of MAFF
  - Ministry of Health, Labour & Welfare and its subsidiary bodies
  - Related ministries including the Food Safety Commission
  - Codex, WHO, FAO, OIE, OECD, ISO, etc.
  - Local governments
  - Japanese Embassies outside of Japan
  - Academic societies and meetings
  - Industry groups and agricultural COOP
  - Consumer groups

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