



RISK ANALYSIS

Points of Discussion

- ✓ Describe what is meant by risk analysis.
- ✓ Understand and identify the risk analysis terms used in Codex.
- ✓ Describe the steps included, and the main components of risk analysis.
- ✓ Understand the importance of risk analysis in the development of Codex standards.



Introduction

The **risk analysis paradigm** provides a framework to ensure that food safety and health aspects of Codex standards and related texts are based on risk analysis principles and that there is a **scientific basis** for Codex standards.



This presentation provides an overview of risk analysis as it is understood within Codex, explaining what it is and defining common terms.

Risk Analysis in Codex

From the very beginning, the Codex Alimentarius has been a science-based activity.



Risk analysis evolved within the CAC during the 1990s and is now considered an **integral part of the decision-making process of Codex**.

In 1995 the World Trade Organization Agreement on Sanitary and Phytosanitary Measures was adopted.

Risk Analysis in Codex (2)

Important policy documents adopted by the Commission related to risk analysis and science:

- **Statements of Principle concerning the role of science in the Codex decision making process and the extent to which other factors are taken into account 1995 (Appendix of the Codex procedural manual).**
- **Statements of Principle related to the role of food safety risk assessment, 1997 (Appendix of the Codex procedural manual)**
- **Definitions of Risk Analysis Terms related to food safety (Definitions section of Codex procedural manual).**
- **The Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, 2003.**

What is Risk Analysis?

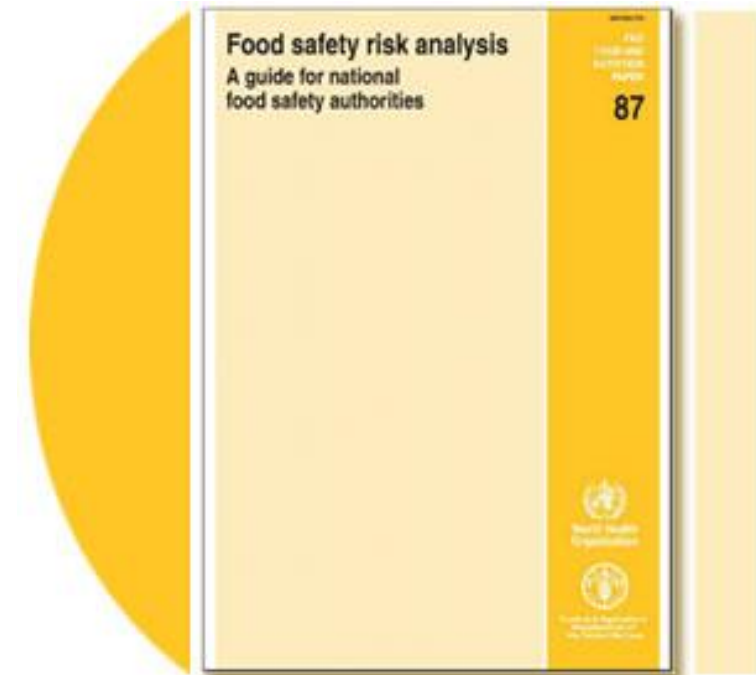
- **Risk analysis** is used to:
 - Develop an estimate of the risks to human health and safety;
 - Identify and implement appropriate measures to control the risks;
 - Communicate with stakeholders about the risks and measures applied.

It provides food safety regulators with the information and evidence they need for **effective decision-making**, contributing to **better food safety outcomes** and **improvements in public health**.

What is Risk Analysis? (2)

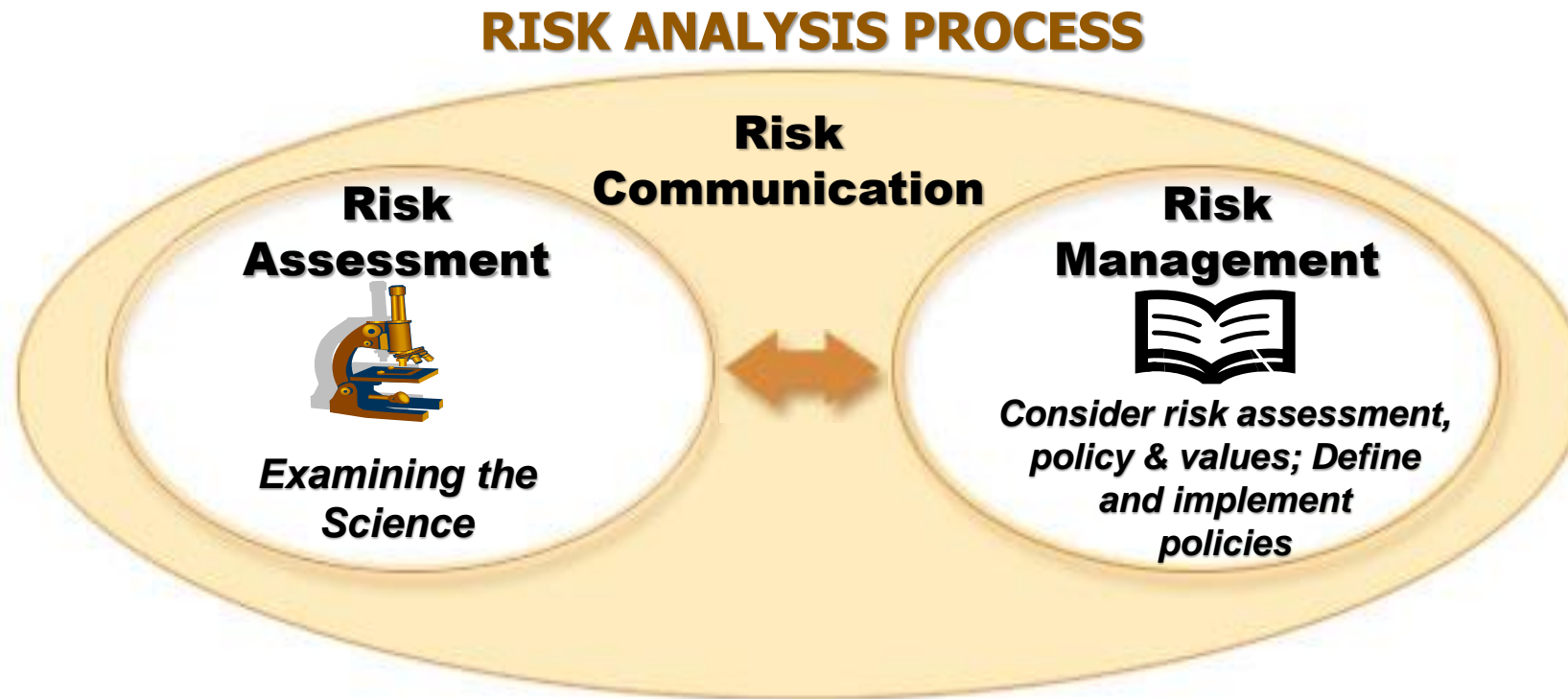
FAO and WHO have prepared **practical guidance** on the application of risk analysis.

This publication provides relevant background information and guidance for national regulators and other officials to assist in their capacity-building efforts.



How Risk Analysis Supports Codex Work

Risk analysis within Codex is a structured, systematic process that examines the potential adverse health effect consequential to a hazard or condition of a food, and develops options for mitigating that risk.



Risk Analysis Components

- Within Codex, **risk analysis** is defined as a process consisting of three distinct but closely linked **components**:



**Risk
assessment**



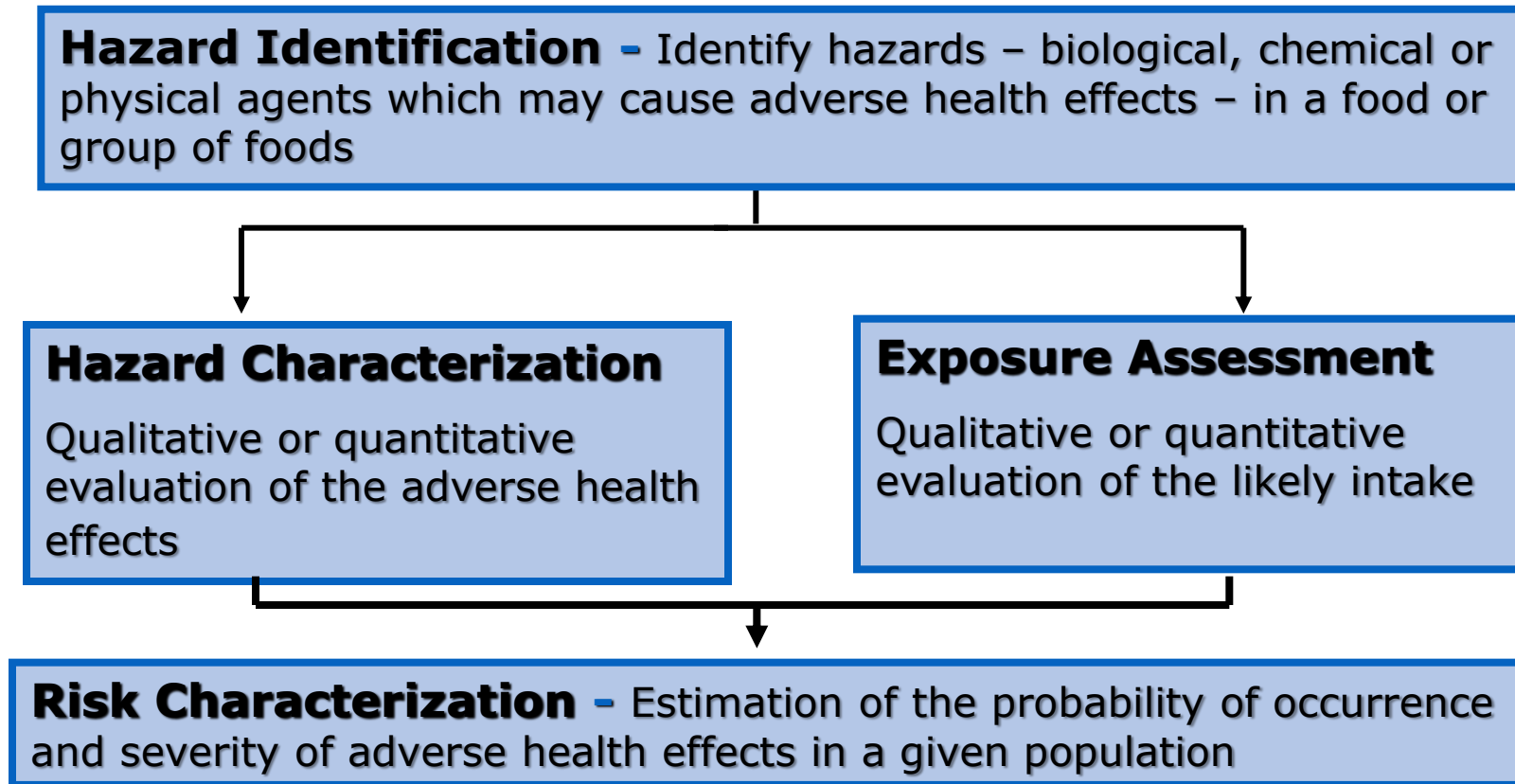
**Risk
management**



**Risk
communication**

1. Risk Assessment

- The finding of the risk assessment forms the basis of risk management decisions.
The **4 steps in the risk assessment** are:



2. Risk Management

Risk management is the process of weighing 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**
- **Selecting appropriate prevention and control options.**



2. Risk Management (2)

- **Risk management options will vary and they can include:**

- **Implementation of regulatory standards; as well as**
- **Some non-regulatory options such as quality assurance schemes at the farm level, consumer education, or packaging for safe handling in the home.**

Once the control measure (risk management option) has been implemented, **monitoring and review activities** should be carried out.

In the case of Codex, available risk management options do not include enforcement or inspection.

3. Risk Communication

- Risk communication consists in the **interactive exchange of information** and opinions throughout the risk analysis process concerning:

- Risks;
- Risk-related factors and risk perception among risk assessors;
- Risk managers, consumers, industry, the academic community and other interested parties;
- The explanation of risk assessment findings and the basis of risk management decisions.

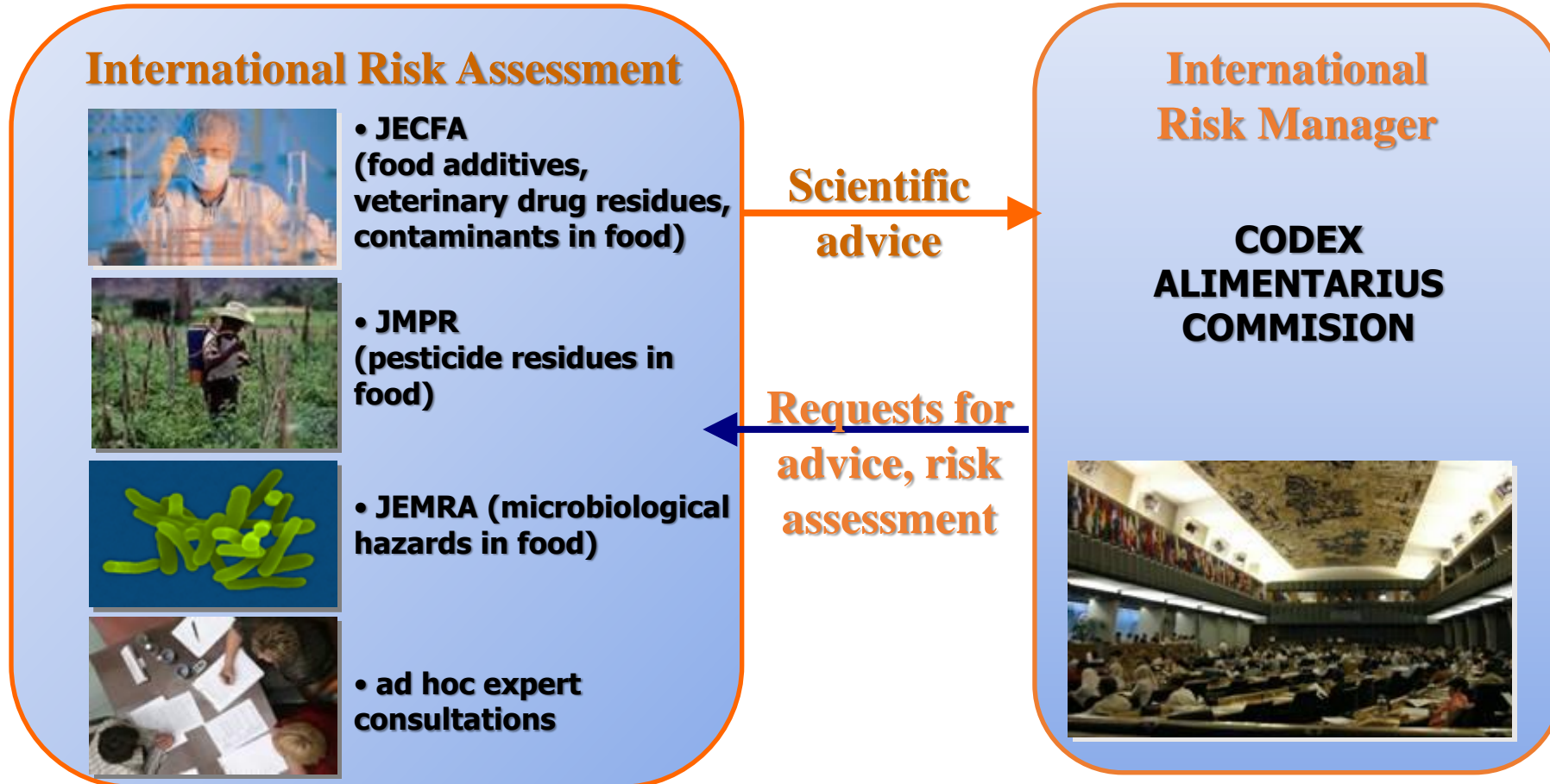


Risk Analysis Process

The following are the basic steps in the **risk analysis process**:

- ✓ A hazard in, or condition of, a food is identified as a possible risk to health.
- ✓ Preliminary risk management activities are carried out.
- ✓ A risk assessment is conducted if required (note this is usually considered in parallel with preliminary risk management activities)
- ✓ Risk management options to address the risk are identified.
- ✓ The options are evaluated and a decision is made as to which option is the most appropriate, including the option to take no action.
- ✓ The risk management option is implemented.
- ✓ The decision is monitored and reviewed to verify that the selected risk management option is effective.
- ✓ Throughout the process, iterative communication among all interested parties (risk assessors, risk managers, consumers, industry, etc.) is implemented and maintained.

Risk Managers and Risk Assessors



Risk Managers and Risk Assessors (2)

Examples of Risk Analysis in Codex

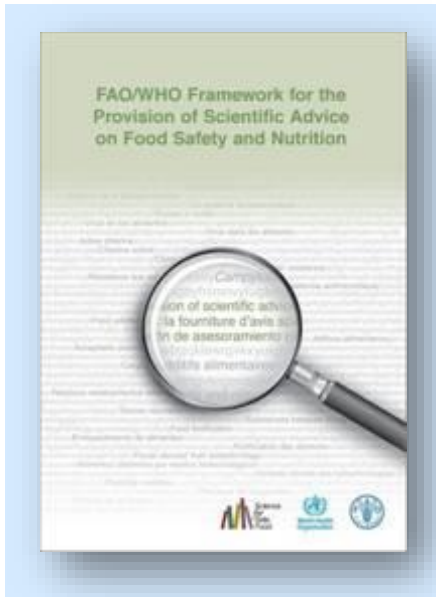
	Vet Drug Residues in Food	Food derived from GMOs
Conduct of Risk Assessment	JECFA (FAO and WHO)	Governments
Standards setting (risk management)	Codex (CCRVDF and CAC)	Codex (and governments)
Enforcement	Governments	Governments

Risk Analysis – Documentation

Codex Procedural Manual – governing the interaction between Codex and expert bodies (includes Statements of Principle, Definitions of Risk Analysis and the Working Principles for Risk Analysis in the Framework of Codex)



Internal rules within the expert bodies (FAO/WHO Framework for the provision of scientific advice on food safety and nutrition)



Guidance addressed to governments (Working Principles for Risk Analysis for Food Safety for Application by Government, and the FAO/WHO publication "Food safety risk analysis – A guide for national food safety authorities")



Summary

Risk analysis is a structured, systematic process that examines the potential adverse health effect consequential to a hazard or condition of a food, and develops options for mitigating that risk.

The risk analysis process consist of three components:

- 1. Risk Assessment** - the scientific evaluation of known or potential adverse effects resulting from human exposure to food-borne hazards.
- 2. Risk Management** - the process of weighing policy alternatives in consultation with all interested parties.
- 3. Risk Communication** - the interactive exchange of information and opinions throughout the risk analysis process

Recognizing the importance of risk assessment in the elaboration of its standards, Codex has adopted a number of important policy documents to ensure the application of risk analysis principles and scientific basis to the standards process.



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