



## CODEX CAPSULE 13

### *Slide 1:*

*In this Session we will discuss the importance of relying on Risk Analysis in Codex Proceedings*

### Slide 2

We will aim to Describe what is meant by risk analysis, To Understand and identify the risk analysis terms used in Codex.

And to discuss the importance of risk analysis in the development of Codex standards.

### Slide 3

We will aim to provide an overview of risk analysis as it is understood within Codex, to explain what it is and to define common terms.

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.

It is in fact due to this scientific basis and the robust foundation of the Decision-Making Process that Codex is referenced by WTO as the international benchmark for food safety standards.

## Slide 4

From the very beginning, the Codex Alimentarius has been a **science-based activity**. Experts and specialists in a wide range of disciplines have contributed to every aspect of the codex texts to ensure that its standards withstand the most rigorous scientific scrutiny.

The first Statement of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account says:

“The food standards, guidelines and other recommendations of the Codex Alimentarius shall be based on the principle of sound scientific analysis ...”.

These Statements are in the Appendix to the Codex Procedural Manual.

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

The importance of developing Codex standards according to risk analysis principles was further compounded in 1995, with the adoption

## of the World Trade Organization **Agreement on Sanitary and Phytosanitary Measures.**

The SPS Agreement states:

Sanitary measures applied by WTO members should be based on scientific principles (art. 2.1) and on risk assessments (art. 5.1).

Sanitary measures conforming to international standards are deemed necessary to protect human health (art. 3.2).

For food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission are the reference standards (Annex A).

The logical conclusion is that **international standards and related texts have to be developed according to risk analysis principles.**

### Slide 5

**Several policy documents were developed and adopted by the Commission related to risk analysis and science:**

**The 17th Session (April 2002) of the Codex Committee on General Principles agreed to develop two separate sets of principles:**

- 1. for the application within the framework of the Codex Alimentarius (i.e. guidance to Codex Committees); and**
- 2. for use by government.**

**The principles for application by Codex Committees were adopted in July 2003 and are incorporated into the Codex Procedural Manual (in Section III)**

**Discussions on the Proposed Working Principles for Risk Analysis for Food Safety for Application by Governments were also completed by**

**CCGP and were made available for use by Food Competent Authorities.**

**There are also several texts that are worth noting and that represent a reference for the way Codex standards rely on scientific assessments and on a clear decision-making approach for key areas of the mandate of Codex**

**For example The Risk Analysis Principles Applied for Food Additives and Contaminants**

**A Guidance on Exposure Assessment of Contaminants and Toxins in Foods or Food Groups**

**Guidance on Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues**

**Guidance on Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods**

**And another example pertain to The Risk Assessment Policy for the Setting of Maximum Limits for Residues of Veterinary Drugs in Foods.**

**Slide 6 :**

**Risk Analysis is Used to develop an estimate of the risks to human health and safety;**

**It offers a clear direction on the way we ought to follow to identify and implement appropriate measures to control the risks; and**

**How we should plan to communicate with stakeholders about the risks and measures applied.**

**Overall Risk Analysis is a framework for decision-making that 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**

**Slide 7:**

**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.**

**Slide 8:**

**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.**

**It is important to remember some Key definitions:**

**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 health effect and the severity of that effect, consequential to a hazard in food.**

**Risk Assessment is the scientifically based process that supports to Characterize the Risk Associated with a Given Food Hazard**

**Risk management is the process by which measures to control the risks or mitigate them are identified, characterized, selected and implemented.**

**Communicating the risk is the interactive exchange among all interested parties involved in the process.**

**Once again Risk Analysis is made up of these 3 components: risk assessment, risk management and risk communication.**

**There should be a functional separation of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest.**

## **Slide 9**

**Once again let us review these 3 components :**

**Risk Assessment is the scientifically based process consisting of the following steps:**

- 1) hazards identification;**
- 2) hazard characterization;**
- 3) exposure assessment; and finally combining these aspects leading to risk characterization.**

**In short, it is the science-based task of “measuring” and “describing” the nature of the risk being analyzed.**

- Risk management is The process distinct from risk assessment, 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, if needed, selecting appropriate prevention and control options.**
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**Risk Management includes a definition of the problem, articulation of the goals to be achieved and the identification of questions to be answered and the best way to address them.**

### **3. Risk communication is**

**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 for risk management decisions.

## **Slide 10**

**Risk assessment is the central scientific component of risk analysis and has evolved primarily because of the need to make decisions to protect health in the face of scientific uncertainty.**

**Risk assessment characterizes the potential adverse effects to life and health resulting from exposure to hazards over a specified time period.**

**The finding of the risk assessment forms the basis of risk management decisions.**

**One Again the steps in the risk assessment are:**

- 1. Hazard identification;**
- 2. Hazard characterization;**
- 3. Exposure assessment; and**
- 4. Risk characterization.**

## **Slide 11;**



**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.**

**Most stages of risk management require extensive communication, coordination and collaboration, both between risk managers and risk assessors, and with external stakeholders.**

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**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.**

**Selecting the most appropriate option is complex at times, and may include weighing the results of the risk assessment, as well as any economic, legal, ethical, environmental, social and political factors.**

**Once the control measure (risk management option) has been implemented, monitoring and review activities should be carried out to determine whether the measures that were selected and implemented are in fact achieving the risk management goals and whether they are having any other unintended effects.**

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

**Also Risk Management Considerations can not have national or local considerations but ought to have a Global Validity for International Standards and Regional Applicability for Regional Standards**

**Slide 13:**

**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 communication is a powerful but often underutilized element of risk analysis. In 1998, a Joint FAO/WHO Expert Consultation on Risk**

**Communication identified the following as key components of risk communication:**

- **know the audience;**
- **involve the scientific experts;**
- **establish expertise in communication;**
- **be a credible source of information;**
- **share responsibility;**
- **differentiate between science and value judgment; AND**
- **assure transparency and put the risk in perspective.**

**Slide 14:**

**These are the basic steps in the risk analysis process:**

- 1. A hazard in, or condition of, a food is identified as a possible risk to health.**
- 2. Preliminary risk management activities are carried out.**
- 3. A risk assessment is conducted if required (note this is usually considered in parallel with preliminary risk management activities).**
- 4. Risk management options to address the risk are identified.**

- 5. The options are evaluated and a decision is made as to which option is the most appropriate, including the option to take no action.**
- 6. The risk management option is implemented.**
- 7. The decision is monitored and reviewed to verify that the selected risk management option is effective.**
- 8. Throughout the process, iterative communication among all interested parties (risk assessors, risk managers, consumers, industry, etc.) is implemented and maintained.**

### **What do we mean by Preliminary risk management activities**

**Some use the term risk evaluation to refer to “preliminary risk management activities”.**

**In fact these activities are carried out by risk managers to collect the information on the issue, before communicating with risk assessors ..**

**Depending on the nature of the problem to be addressed, some of all of the following actions will be undertaken:**

- identify and describe the food safety issue;**
- develop a risk profile;**
- establish broad risk management goals;**
- decide whether a risk assessment is necessary;**
- establish a risk assessment policy;**
- commission the risk assessment;**

- **consider the results of the risk assessment;**

**rank food safety issues and set priorities for risk management.**

#### **Slide 15:**

**Within Codex Alimentarius Commission and its procedures, the responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies (risk managers), while the responsibility for risk assessment lies primarily with the joint FAO/WHO expert bodies and consultations (risk assessors).**

#### **Slide 16 :**

**Let us take the example of Veterinary Drug Residues in Food and Discuss how the components of Risk Analysis are to be Implemented:**

**Risk Assessment within Codex is Covered by JECFA**

**Whereas the Risk Management is Carried out by CCRVDF**

**Of course Enforcing the measures developed by CCRVDF such as MRLs for Residues is left to Governments and Member countries of Codex**

## **Slide 17:**

**Several Documents have been developed to support the Consistent Application of Risk Analysis for Decision Making in Codex and are used as a reference.**

**Of course the most important reference is the Codex Procedural Manual which governs 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)**

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

**And Of course**

**The Guidance addressed to governments such as the Working Principles for Risk Analysis for Food Safety for Application by Government, and the FAO/WHO publication known as “Food safety risk analysis – A guide for national food safety authorities”)**

## **Slide 18:**

## **In 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.**