INTRODUCTION TO RISK ANALYSIS AND ITS POSITIONING IN FOOD SAFETY AND NUTRITION OVERSIGHT

Acknowledgements

These written course notes have been developed using material and information collected from different sources in particular:

- *The FAO/WHO toolkit on Food Safety Risk Analysis, FAO/WHO, 2006 ISSN 978-92-5-I05604-2*
- *The Encyclopedia of Food Safety, Mootajemi et al, 2014 – Elsevier*

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Introduction

To ensure and maintain the safety of food requires constant vigilance and interventions by industry, consumers and government (or food control competent authorities). This constant vigilance is further emphasized by the changing environment of food production and consumption. Drivers of change include: new technologies, changing consumers' interests, expanding trade opportunities, multiplication of information sources and changing populations along with their dietary patterns.

Food regulators are competent authorities to whom consumers, through relevant laws or similar decisions (decrees, executive orders, and etc.), have delegated their authority to oversee the availability of food, such that these products are considered safe, nutritious and do not misrepresent the information related to the food composition, origin and conditions of production or suitability for consumption.

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Food regulators aim to ensure that health and safety risks from food are **negligible** for the vast majority, if not for all the general population and that consumers can make informed choices, suitable to their health conditions or their preferences.

Achieving such objectives of food safety and accuracy of information and representation of food products fosters public confidence in the effectiveness of food oversight.

This confidence is maintained as long as the assertion about acceptable levels of risks associated with food consumption is based on **robust evidence**, more specifically robust **scientific evidence**.

Confidence is also maintained when there is assurance that **adequate systems, processes and procedures** are in place to monitor, analyze food and to respond when a risk is identified.

Providing assurances to consumers on the safety and adequacy of their food and maintaining their confidence and trust require:

- **Risk Assessment**: The assessment of potential risks using the best scientific data and methodologies;
- **Risk Management**: Taking the relevant management measures, based on the outputs of the risk assessment as well as any additional evidence and ensure that such measures are effective to prevent the issue and / or reduce the risk; and,
- **Risk Communication**: Clear communication throughout the process to consumers and food producers to inform them of measures they may take to protect themselves or to reduce the risks (to keep the risks as low as possible).

Risk assessment, risk management and risk communication form the three pillars of the **food risk analysis framework**.

Glossary of Key Terms Used in Food Risk Analysis:

Hazard:
A biological, chemical or physical agent in a food or affecting the production of a food (intervening at some point in the process of food production) with the potential to cause an adverse health effect. Hazards should be qualified in the same fashion regardless of who they may affect.

Risk:
A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

Risk analysis:
A process consisting of three components: risk assessment, risk management and risk communication.

Risk assessment:
A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

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.

Risk characterization:
The qualitative and/or quantitative estimation, including associated 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.

Risk communication:
The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors, and risk perceptions among those that apply the risk analysis framework (risk assessors, risk managers) and stakeholders i.e., those impacted by the results of risk analysis or involved in its development (consumers, industry, the academic community and other interested parties). Risk communication includes the explanation of risk assessment findings and the basis of risk management decisions. **Risk communication can also be an integral part of risk management** by communicating to consumers and to industry measures that need to be followed to reduce and/or eliminate the risk. If followed, such instructions contribute to risk mitigation.

Risk management:
The process, distinct from risk assessment, of weighing policy alternatives in consultation with all interested parties, considering risk assessment outcomes and other factors relevant for the health protection of consumers and for enabling trade practices. This process should lead to selecting appropriate prevention and control options to be applied to reduce or mitigate those risks.

Risk profile:
The description of the food safety problem and its context for a given hazard, in a manner that allows to position the potential risks associated to hazards amongst each other but also to identify the various determinants of such risks.

Genesis of Risk Analysis and its Application:

Risk analysis is a logical framework that supports decision-making to address all kinds of risks and not just those that pertain to food and nutrition.

The origins of risk analysis date back to the era of atmospheric nuclear testing. Risk analysis was first used by health physicists in the United States to assess the potential adverse health impact posed by the presence of radionuclides in food and water.
The approach was first described in a report entitled "*Risk Assessment in the Federal Government: Managing the Process"* published by the National Research Council of the US National Academy of Sciences.

What Risk Analysis brings to a Decision-making Framework and in Particular to Food Safety Decision-making?

- it provides structure to the process
- it is a clear and transparent framework
- It is objective because it is based on evidence (scientific and other evidence).
- It clarifies roles, responsibilities and accountabilities of all partners involved: government or competent authorities, industry and consumers. Such clarification promotes the separation of risk assessment (mainly scientific assessment) and risk management (weighing the options using additional evidence).
- It promotes communication and interaction between the various players involved in the process: risk assessors and risk managers.
- It promotes communication and interaction between and amongst those involved in applying the decision-making process and those that will be impacted by its outputs/outcomes (consumers, industry, civil society).

Figure 1: Components of Food Risk Analysis.

Why is Food Risk Analysis Important for Food Regulatory Decisions and Food Standard Setting?

The increasing level of global food trade created the need for consistency of food regulatory decisions that manage the availability of products in different markets for both raw commodities and processed foods. Such consistency is key to enable a fair trade environment. Increasing food trade also created the need to have a consistent approach to protect the health of consumers, regardless of where they come from (developing or industrialized nations). These

two objectives were embodied by an intergovernmental structure, created in 1963 called the **Codex Alimentarius Commission (CAC),** tasked with the creation of an international set of standards for food products: **a food code or *Codex Alimentarius*.**

This body was founded in 1963 by the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) and includes most countries that are food importers and exporters (over 188 countries and one international organization: the European Union). The CAC has set to itself a dual mandate:

- To protect consumers' health
- To ensure fair practices in food trade.

Compliance with Codex Alimentarius rules is voluntary. Although Codex rules were followed, trade disputes over health and safety requirements continued. In some cases, such requirements constituted **nontariff barriers to trade**. The development of trade agreements such as the General Agreement on Tariffs and Trade (GATT) led countries involved, to negotiate reductions in tariff barriers to trade of various products, including food. Throughout these negotiations, it was recognized that nontariff barriers based on health and safety requirements could constitute impediments to trade and need to be addressed. The **World Trade Organization (WTO),** which succeeded GATT in 1995, adopted as part of its founding texts the Agreement on the **Application of Sanitary and Phytosanitary Measures (often referred to as the SPS Agreement)**. This agreement set the principles of establishing **health and safety regulations for food and**, in particular, that they be based on **the sound scientific assessment of the risk**.

In addition, the SPS Agreement imposes other disciplines to be applied in developing food safety requirements, including **nondiscrimination**, **transparency**, and **acceptance of equivalent approaches** to achieve the same level of health protection. In fact, WTO considered that the standards, guidelines, and other recommendations of the *Codex Alimentarius* represent the international consensus regarding health and safety requirements for food. WTO recognizes that countries that choose to impose Codex Alimentarius requirements as their health and safety requirements for food to be in compliance with the SPS Agreement.

By virtue of the SPS Agreement, Codex standards became the reference food standards in international food trade. Countries are therefore obligated to follow the Codex Alimentarius unless they could scientifically justify the need to apply different measures, using an agreed-upon process that is **risk analysis**.

The Two-fold Effect of the SPS Agreement:

- *Codex Alimentarius* became essentially **mandatory** for nations that trade food products internationally
- Risk analysis became the foundation for standard setting at both the international and national levels.

In response, Codex has made the use of risk analysis as an explicit foundation of its work to

develop food safety and nutrition standards. The CAC has developed several guidance documents to promote the application of risk analysis principles both for domestic and international standards.

History of Development of Codex Risk Analysis Principles:

At the request of the CAC, FAO and WHO convened a number of expert consultations to provide advice to Codex and member countries on practical approaches for the application of risk analysis to food standard development. These expert consultations included expert meetings on risk assessment (in 1995), risk management (in 1997) and risk communication (in 1998). The initial consultations focused on the overall risk analysis paradigm, producing a number of definitions and broad principles for risk assessment, risk management and risk communication[1]. Subsequent consultations addressed in greater detail some specific aspects of the risk analysis paradigm[2].

The CAC adopted in **2003** the **working principles for risk analysis for application in the framework of the Codex Alimentarius[3]**, developed by the Codex Committee on General Principles (CCGP). The CAC asked relevant Codex committees to develop specific principles and guidelines on risk analysis in their specific areas. CCGP also initiated work to develop general risk analysis principles as guidance for national governments. Several subsidiary bodies of the Commission have developed specific guidance on risk analysis or are in the process of doing so, especially as regards food additives and (chemical) contaminants, food hygiene (microbial contaminants), pesticide residues, residues of veterinary drugs, and biotechnology.

As part of the body of work being carried out by FAO/WHO and the CAC, considerable progress has been made in developing a systematic framework for applying principles and guidelines for food safety risk analysis. Governments have moved quickly to incorporate much of this international work in national legislation and further developments in food safety risk analysis at the national level are ongoing.

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[1] For information, see: i) FAO/WHO. 1995. *Application of Risk Analysis to Food Standards Issues*. Report of the Joint FAO/WHO Expert Consultation. Geneva, 13-17 March 1995 (available at: ftp://ftp.fao.org/es/esn/food/Risk_Analysis.pdf); ii) FAO/WHO. 1997. *Risk Management and Food Safety*. FAO Food and Nutrition Paper No. 65 (available at: ftp://ftp.fao.org/docrep/fao/w4982e/w4982e00.pdf); iii) FAO/WHO. 1998. *The application of risk communication to food standards and safety matters*. FAO Food and Nutrition Paper No. 70. (available at: http://www.fao.org/docrep/005/x1271e/x1271e00.htm).

[2] For information, see: i) FAO/WHO. 1999. *Risk Assessment of Microbiological Hazards in Foods*. Report of the Joint FAO/WHO Expert Consultation. Geneva, Switzerland, 15-19 March 1999 (available at: http://www.who.int/foodsafety/publications/micro/en/march1999_en.pdf); ii) FAO/WHO. 2000. *The interaction between assessors and managers of microbiological hazards in food*. Report of a WHO Expert Consultation in collaboration with the Federal Ministry of Health, Germany and FAO. Kiel, Germany, 21-23 March 2000 (available at: ftp://ftp.fao.org/docrep/nonfao/ae586e/ae586e00.pdf); iii) FAO/WHO. 2002. *Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards*

[3] FAO/WHO. 2005. Working principles for risk analysis for application in the framework of the Codex Alimentarius. In *Codex Alimentarius Commission. Procedural Manual.* 15th Edition, pp 101-107 (available at: ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_15e.pdf).

Conclusion – Benefits of Applying Risk Analysis in Food Regulatory and Standards Development Decisions:

Currently, risk analysis has become the internationally agreed model for the formulation of policies and legislation to manage foodborne hazards. The risk analysis process is now used to guide the development of a range of risk management options, including both mandatory and voluntary measures. Risk analysis has had a significant impact on the regulation of the food industry as well as on the information and advice provided to consumers.

Applying risk analysis to food safety problems offers many advantages to all parties involved (competent authorities, industry and consumers). Risk analysis supports taking decisions that are **in proportion to** the public health risks involved, and **systematic evaluation** of likely **impacts of specific measures** chosen to manage those risks. Risk analysis allows likely **costs of compliance** to be compared with expected benefits, and supports setting priorities among different food safety problems. By using risk analysis where practical and feasible, governments meet their obligations under the SPS Agreement and strengthen their basis for trading foods internationally. For instance, by helping to objectively demonstrate the absence of hazards or the effective control of hazards to produce safe food, **risk analysis provides a solid basis to increase trade** access to new markets. In addition, risk analysis identifies **gaps and uncertainties** in scientific knowledge on risks, which can help set research priorities and contribute in the long term toward improved understanding of food-related impacts on public health. For all of these reasons, risk analysis is the preferred approach for establishing food safety control measures.