UNIT 5 INTRODUCTION TO RISK ANALYSIS

Structure

5.0 OBJECTIVES

After studying this unit, we shall be able to:

- describe the changing global factors that affect food safety systems;
- define key terms related to risk analysis;
- explain structure of risk analysis;
- describe latest developments at international level in the area of risk analysis; and
- identify challenges and benefits in the application risk analysis.

5.1 INTRODUCTION

Risk analysis is the key in identifying the potential hazards which may lead to food-borne illness. During the last several decades, risk assessment, risk management and risk communication have been formalized and incorporated into the specific discipline known as food safety risk analysis. This approach has now gained wide acceptance as the preferred way to assess possible links between hazards in the food chain and actual risks to human health, and takes into account a wide range of inputs to decision-making on appropriate control measures. Application of harmonized risk analysis principles and methodologies in different countries also facilitates trade in foods. In recent years, food safety has become a subject of increasing importance internationally. This stems in part from a number of recent prominent "food scares" globally: in the United States (outbreaks of *Salmonella* and *Escherichia coli 0157:H7*) and Europe (notably the spread of Bovine Spongiform Encephalopathy or BSE). There is a growing public perception, shared by some members of the scientific community, that incidences of food-borne disease are on the rise. In a parallel development, the Uruguay Round of international trade talks, concluded in 1994, which resulted in the establishment of World Trade Organization (WTO) brought food safety to the

forefront of debates concerning trade in food and agricultural products. It became necessary that international trade of food follow guidelines provided in WTO Agreements.

5.2 CHANGING INTERNATIONAL ENVIRONMENT

The application of risk analysis to the development of food regulation is a key element in ensuring that a country fulfils its rights and obligations under the World Trade Organization (WTO) trade agreements. In the context of food safety risk analysis, the WTO agreement of most relevance to food regulation is the agreement on the application of Sanitary and Phytosanitary Measures (the SPS Agreement). The SPS Agreement requires that regulatory measures adopted by a member country must be based on scientific principles and not to be maintained without sufficient scientific evidence. Member countries are required to base their measures on a scientific assessment of the risks to human life and health. Risk assessments performed at the national level should take into account risk assessment methodologies developed by the relevant international organizations and be appropriate to the circumstances. In the case of food safety, the relevant international standards setting body is the Codex Alimentarius Commission (CAC). The Codex and its various committees and other bodies are generically referred to as 'Codex'.

Codex standards are the benchmarks against which national food measures and regulations are evaluated. Member countries can introduce measures which achieve a higher level of protection than that achieved by a Codex standard, but only if there is a scientific justification, or as a consequence of setting a higher appropriate level of protection (ALOP). In determining ALOP, countries must take into account the objective of minimizing negative trade effects.

5.3 INCREASING DEMAND OF "SAFE AND WHOLESOME FOOD"

Today, governments and other parties involved in food control are developing new methods and applying and enhancing a wide variety of existing administrative systems, infrastructures and approaches to ensuring safe food as across the globe consumer is asking for only safe and wholesome food. While the main focus of these efforts remains improving food safety, food control programmes must increasingly take other goals into account. For example, "Competent Authorities" now have to review the cost-effectiveness of their structure and operations so that they do not impose unjustified compliance costs on industry. Also, such authorities must keep in mind the fair trading requirements of international agreements and establish mechanisms to ensure that domestic and import standards are consistent in intent and application.

5.4 RISK ANALYSIS DEFINITIONS RELATED TO FOOD SAFETY

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

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

b) **Risk management**: 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.

c) **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.

5.5 RISK ANALYSIS

Risk analysis is used to develop an estimate of the risks to human health and safety, to identify and implement appropriate measures to control the risks, and to communicate with stakeholders about the risks and measures applied. It can be used to support and improve the development of standards, as well as to address food safety issues that result from emerging hazards or breakdowns in food control systems. 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.

Regardless of the institutional context, the discipline of risk analysis offers a tool that all food safety authorities can use to make significant gains in food safety.

Risk analysis is comprised of three components: risk management, risk assessment and risk communication. Each of these components has been applied in essentially even before they came to be called by these names. During the past two decades or so, the three components have been formalized, refined and integrated into a unified discipline, developed at both the national and international levels, now known as “risk analysis.” This section provides a broad introduction to food safety risk analysis, structure of risk analysis, carrying out risk analysis and risk analysis at international level for its successful implementation.

5.5.1 Structure of Risk Analysis

Risk analysis represents a structured decision-making process with three distinct but closely connected components:

1) Risk Management,

2) Risk Assessment, and

3) Risk Communication (see Fig. 5.1).

The three components are essential, complementary parts of the overall discipline. Although the figure shows them as separate entities, in reality they are highly integrated. In the course of a typical food safety risk analysis, almost constant interactions occur between risk managers and risk assessors within an environment characterized by risk communication. Risk analysis is most effective when all the three components are successfully integrated by the risk managers directing the process.

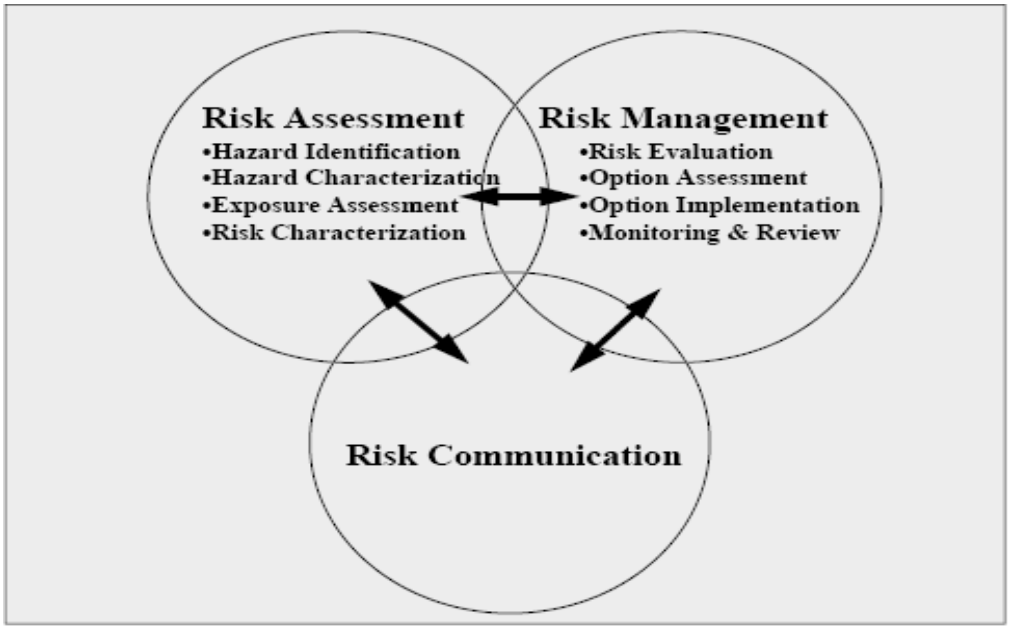

Fig. 5.1: Structure of Risk Analysis

Risk assessment is considered to be the "science-based" component of risk analysis, while risk management is the component in which scientific information and other factors, such as economic, social, cultural and ethical considerations, are integrated and weighed in choosing the preferred risk management options. In fact, risk assessment may also involve judgments and choices that are not entirely scientific, and risk managers need a sound understanding of scientific approaches used by risk assessors. The interactions and overlaps of science and non-scientific values at various stages in risk analysis will be explored in more detail in subsequent units concerned with risk management and risk assessment.

5.5.2 Carrying Out Risk Analysis

The risk analysis process normally begins with a risk management step, to define the problem, articulate the goals of the risk analysis and identify questions to be answered by the risk assessment, if and when one is required (see Unit 6, Section 6.4). The science-based tasks of "measuring" and "describing" the nature of the risk being analyzed are performed during the risk assessment phase (see Unit 7). Risk management and risk assessment are performed within an open and transparent environment involving extensive communication and dialogue, in which a variety of interested parties may participate at appropriate points. The risk analysis process often results in the implementation of risk-reducing measures and continuous monitoring of their effectiveness by government, the industry and other stakeholders.

5.5.3 Risk Analysis at International and National Levels

Food safety risk analysis is carried out by national, regional and international food safety authorities. There are some important differences between these processes at the different levels. Internationally, Codex committees that recommend food safety standards (for example, the Committees on Food Hygiene, Meat Hygiene, Food Additives, Contaminants in Foods, Pesticide Residues, and Residues of Veterinary Drugs in Foods) act as risk managers. Risk assessments to support the development of Codex food safety standards are provided by the three Joint FAO/WHO Expert Bodies: the Joint Expert

Committee on Food Additives (JECFA); the Joint Meeting on Pesticide Residues (JMPR); and the Joint Expert Meeting on Microbiological Risk Assessment (JEMRA). Additional risk assessments may be provided, on occasion, by *ad hoc* expert consultations, and by member governments that have conducted their own assessments, for consideration by these expert bodies.

National food safety authorities, in contrast, generally are responsible for carrying out risk analysis in its entirety. Some governments have their own institutions and infrastructure for conducting risk assessments, choosing among risk management options, implementing and enforcing decisions, and monitoring and reviewing the impacts of decisions. Other countries may have fewer resources available to carry out risk analysis tasks. In such cases, and even where governments have their own capacities, components of risk analysis carried out at the international level can be very usefully applied in the national context.

a) Working principles of risk analysis at Codex level: In order to promote application of risk analysis globally Codex has come out with various documents on application of risk analysis at Codex level as well as at government level. The working principles state that risk analysis used in Codex should be:

- applied consistently;
- open to all concerned, transparent and documented;
- conducted in accordance with both the Statement of Principles Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account and the Statement of Principle Relating to the Role of Food Safety Risk Assessment; and
- evaluated and reviewed as appropriate in light of newly generated data.

Further principles are elaborated to the effect that the risk analysis should be based on global data, structured around its three components and there should be a functional separation of risk assessment and risk management in order to avoid any confusion regarding functions, to avoid conflicts of interest, and to ensure the scientific integrity of the risk assessment. In relation to Codex, experts bodies and consultations have been assigned the role of risk assessors and various Codex Committees are the risk manager. Finally, because of the many uncertainties that may exist in the process of risk assessment and risk management, any risk management options that are selected should take account of the level of certainty and the characteristics of the hazard.

List of documents available for application of risk analysis by the Codex are as given below:

- Working principles for risk analysis for food safety for application in the framework of the Codex Alimentarius.
- Risk analysis principles applied by the Codex Committee of Pesticides residues.
- Risk analysis principles applied by the Codex Committee of Residues of Veterinary Drugs in Foods.

- Risk analysis principles applied by the Codex Committee of Food Additives and Codex Committee on Contaminants in Foods.

b) Application of risk analysis at the national level: At the national level, government bodies may play dual role of risk assessor as well as risk manager although there is clear functional separation between the two.

The Codex document 'Working principles for risk analysis for food safety for application by governments' provides guidance for application of risk analysis at the national level.

5.6 CHALLENGES AND BENEFITS IN THE APPLICATION OF RISK ANALYSIS

There are a number of challenges and benefits in the application of risk analysis at the national level. Some of these are listed below:

5.6.1 Challenges

- The availability of data at the national level. Many countries like USA, Australia, New Zealand have invested quite heavily in systems to obtain and analyze data relating to both food consumption and food contamination. However, difficulties are still sometimes encountered in obtaining sufficient high quality quantitative information for risk analysis that is specific to food supply and community. This point is closely linked with infrastructure issues such as laboratory capabilities. Outside the national infrastructure, there are additional sources of data to draw on, including international expert bodies (e.g., JECFA, JMPR and JEMRA), assessments undertaken by other countries, and regional diets developed by the WHO. These can all be utilized by countries in the region.

- Availability of adequately trained staff – competencies in a broad range of scientific and other professional skills are required to effectively apply risk analysis in the context of food safety. The scientific skills required include microbiology, toxicology, food technology, nutrition, immunology and molecular genetics, as relevant. Other professional skills such as legal, economic and communications are also required. Many countries like EC member states offer technical assistance in upgrading skills through training programme in scientific risk assessment and risk management to government officials applying risk analysis techniques in the region.

- Difficulty in communicating complex concepts, especially scientific and technical concepts, to the broader community restrict effective risk communication.

5.6.2 Benefits

- Better identification and targetting of public health problems ultimately facilitate improvements in managing food safety.

- Better utilization of resources by focusing on addressing the highest food safety risks.

- Trade opportunities – risk analysis provides a solid basis for negotiating access to markets in other countries by objectively demonstrating the

absence of hazards or the effective control of hazards to produce a safe food.

- A community better informed about food safety issues, leading to improving production, manufacturing and trading practices.

Check Your Progress Exercise 1

Note: a) Use the space below for your answers.
b) Check your answers with those given at the end of the unit.

1) Define the term 'risk analysis'.

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2) What is the structure of risk analysis?

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3) Explain various challenge and benefits in the application of risk analysis?

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4) Enumerate various documents available in Codex on application of risk analysis?

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5.7 LET US SUM UP

Food safety is a fundamental public health concern, and achieving a safe food supply poses major challenges for food safety officials. Changing global patterns of food production, international trade, technology, public expectations for health protection and many other factors have created an increasingly demanding environment in which food safety systems operate. An array of food-borne hazards, both familiar and new, poses risks to health and obstacles to international trade in foods. These risks must be assessed and

managed to meet growing and increasingly complex sets of food safety objectives. Risk analysis, a systematic, disciplined approach for making food safety decisions developed primarily in the last two decades, has a structure having three major components: risk management, risk assessment and risk communication. Risk analysis is a powerful tool for carrying out science-based analysis and for reaching sound, consistent solutions to food safety problems. The use of risk analysis has certain challenges which need to be looked into so that it can promote ongoing improvements in public health and provide a basis for expanding international trade in foods.

5.8 KEY WORDS

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 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.

Risk Management : 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.

5.9 ANSWERS TO CHECK YOUR PROGRESS EXERCISE

Your answer should include following points:

Check Your Progress Exercise 1

1) Risk Analysis: A process consisting of three components: risk assessment, risk management and risk communication.

2) Risk analysis represents a structured decision-making process with three distinct but closely connected components:
   - Risk Management,
   - Risk Assessment, and
   - Risk Communication.

3) Sections 5.6.1 and 5.6.2.

4) Documents listed in the Section 5.5.3 for the application of risk analysis at the Codex and the national level.

5.10 SUGGESTED READING

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).

FAO/WHO. 1997. *Risk Management and Food Safety*. Report of a Joint FAO/WHO Consultation. Rome, Italy, 27-31 January 1997. FAO Food and Nutrition Paper No. 65
(available at: http://www.fao.org/docrep/W4982E/w4982e00.htm).