

UNIT 12 RISK ANALYSIS

Structure

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12.1 INTRODUCTION

In Unit 10 we learnt about the various hygiene and sanitation factors that need to be considered to ensure food safety in a food service establishment. Unfortunately, there is no such thing as 'zero risk' for food (or for anything else). Since microorganisms were first recognized by man to cause food borne diseases and spoil the foods, microbiologists have been concerned with assessing risks associated with foods and identifying means for their reduction, management and control. Consequently, risk analysis has been designed to determine what the hazards are and to identify their immediate, interim and long-term effects on human health. In this unit we will focus on risk analysis – the new paradigm in food safety assurance. Risk analysis, a process consisting of three components – *risk assessment*, *risk management* and *risk communication* – will be emphasized, with a detailed discussion presented subsequently on each of the three components.

Objectives

After studying this unit, you will be able to:

- describe the steps involved in risk assessment,
- discuss the elements of risk management,
- enlist the general principles of food safety risk management, and
- explain the objectives and principles of risk communication.

12.2 RISK ANALYSIS: THE NEW PARADIGM IN FOOD SAFETY ASSURANCE

In the early part of the 20th Century, safety concerns led to the development of performance criteria for thermally processed foods based on an estimation of the microbial kill needed to produce a safe food. The best known examples of these are the *Botulinum Cook*, a thermal process designed to reduce the probability of survival of spores of *Clostridium botulinum* by a factor of 10^{12} . A detailed discussion on this

aspect is presented in the Course Principles of Food Science, in Unit 11. Similarly, pasteurization of milk to reduce the pathogenic organisms was developed. This has lead to the development of microbiological criteria to assess whether an amount of food contains a concentration of microorganism or a microbial toxin in excess of that regarded as acceptable. However, this criterion was not sufficient to assess the risk.

In the later part of 20th Century, the *Codex Alimentarius Commission* of the FAO/WHO has developed a science based approach to establish a quantitative or semi-quantitative risk assessment. The Codex Alimentarius Commission is "...the body responsible for compiling the standards, codes of practice, guidelines and recommendations that constitute the Codex Alimentarius," which is the International food code. You will get to know more about Codex Alimentarius later in Unit 14.

Efforts are on in the 21st Century. Modern biology is being applied to the issues of food safety. Distinctions among chemistry, toxicology, nutrition, microbiology and molecular biology are being removed. Evaluation of food safety through this integrated mechanism has permitted generic and ultimately predictive outcomes. To a significant extent, all of these processes have come to focus on the development of risk-based approaches for the management of public health hazards in food. One of the approaches used is called *risk analysis*. Risk analysis, what's it all about? Let's find out.

First what is a risk? Risk is 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 is defined for the purposes of the Codex Alimentarius Commission as "a process consisting of three components: risk assessment, risk management and risk communication."

The diagram in Figure 12.1 illustrates the relationship between the three components of risk analysis.

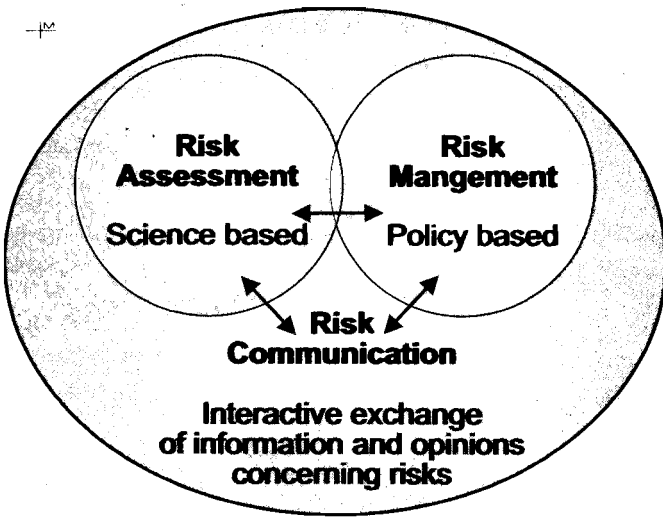


Figure 12.1: Risk analysis framework

As illustrated, risk analysis includes risk assessment, risk communication and risk management. Risk assessment is a scientifically based process which involves hazard identification. Risk management deals with policy alternatives considering the risk assesment and the information and opinion on risk associated with the hazard in food is risk communication. Before we go into understanding these components of risk analysis, we should familiarize ourselves with the vocabulary and definitions of various terms used in risk analysis related to food safety. Let us get to know about them next.

<i>Food</i>	:	Any substance, whether processed, semi-processed or raw which is intended for human consumption, including drinks, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but excluding cosmetics, tobacco and substances used only as drugs.
<i>Hazard</i>	:	A biological, chemical or physical agent in or property of food that may have an adverse health effect.
<i>Risk</i>	:	A function of the probability of an adverse effect and the magnitude of that effect, consequential to hazard(s) in food.
<i>Risk Analysis</i>	:	A process consisting of three components: risk assessment, risk management and risk communication.
<i>Risk Assessment</i>	:	The scientific evaluation of known or potential adverse health effects resulting from human exposure to food borne hazards. The process consists of the following steps: (i) hazard identification (ii) hazard characterization (iii) exposure assessment, and (iv) risk characterization. The definition includes quantitative risk assessment, which emphasizes reliance on numerical expressions of risk and also qualitative expression of risk, as well as, an indication of the attendant uncertainties.
<i>Hazard Identification</i>	:	The identification of known or potential health effects associated with a particular agent.
<i>Hazard Characterization</i>	:	The qualitative and/or quantitative evaluation of the nature of the adverse effects associated with biological, chemical and physical agents which may be present in food.
<i>Exposure Assessment</i>	:	The qualitative and/or quantitative evaluation of the degree of intake likely to occur.
<i>Risk Characterization</i>	:	Integration of hazard identification, hazard characterization and exposure assessment into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainties.
<i>Risk Management</i>	:	The process of weighing policy alternatives to accept, minimize or reduce assessed risks and to select and implement appropriate options.
<i>Risk Communication</i>	:	An interactive process of exchange of information and opinion on risk among risk assessors, risk managers and other interested parties.
<i>Dose-Response Assessment</i>	:	The determination of the relationship between the magnitude of exposure and the magnitude and / or frequency of adverse effects.

Now that we have defined the risk analysis key terms related to food safety, let us next discuss the components of risk analysis. We shall begin with risk assessment and the steps involved in it.

12.3 RISK ASSESSMENT

Risk assessment has been described as the process of organizing information concerning a particular risk in a systematic way so that the decision makers can better understand those factors that contribute to the risk and any uncertainties that may affect the outcome of an assessment.

Risk assessment is a scientifically based process of evaluating hazards and the likelihood of exposure to those hazards, and then estimating the resulting public health impact. It provides a scientific framework for understanding the impact of a wide variety of variables by considering several key questions, such as:

- What are the factors that result in risk to the public's health?
- What is the likelihood of harm?
- How much harm could occur?
- How much can that harm be reduced by various intervention strategies?

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

What do these four steps entail? Let's find out.

Hazard identification is "the identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods."

Hazard characterization is "the qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable."

Exposure assessment is "the qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food, as well as, exposures from other sources if relevant."

Risk characterization is "the qualitative and/or quantitative estimation, including attendant 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."

What is the goal of risk assessment?

The goal of risk assessment is to provide risk managers, who might be, for example, government regulatory officials, industry health and safety directors or public health officials, with a rational basis for making decisions about managing the use of chemicals or physical agents in order to protect health and the environment. The decision-making process often involves factors in addition to the risk assessment results, such as social values, technical feasibility and economic factors. Risk assessment is used as a part of the decision-making process to ensure public protection against unacceptable risks and to allow the use of products whose benefits outweigh the risks associated with their use. Examples include medicines which may produce side effects.

Next, what is involved in risk assessment?

Risk assessment, as you may have realized by now, is a structured and formal procedure for identifying and characterizing a hazard and quantifying the effects of that hazard in a population. In other terms, the risk assessment process is *a means of providing an estimate of the probability and severity of illness attributable to a particular pathogen-commodity combination*. The four-step process enables this to be carried out in a systematic manner, but the extent to which the steps are carried out will be dependent on the scope of the risk assessment. The application of these four steps vary depending upon the type of hazard i.e., physical, chemical or biological.

A discussion on the risk assessment steps for chemical and biological hazards is presented herewith, which will help you understand the risk assessment component.

12.3.1 Risk Assessment of Chemical Agents

As you may recall, the chemical agents in foods include food additives, pesticide residues, veterinary drug residues, chemical contaminants from any source, natural toxins like mycotoxins, cigua toxin etc. Now let us learn about risk assessment of chemical agents through the application of the four steps, as highlighted above. We start with hazard identification.

1) *Hazard identification*

We start the process of risk assessment by first identifying the hazard. The goal of hazard identification is to identify potential adverse health effects in humans associated with exposure to a chemical, the likelihood of such effects occurring and the certainty or uncertainty associated with such effects. In this context, the hazard identification does not imply the quantitative extrapolation of risk for exposed human populations as in the dose-response and risk characterization step, but rather an evaluation of the qualitative likelihood of the effect occurring in exposed human populations.

Because data are often insufficient, hazard identification is best conducted using the weight-of-evidence approach. The approach requires an adequate and documented review of relevant scientific information obtained from appropriate databases, peer-reviewed literature and, if available, unpublished studies from other sources, such as industry. This approach places an emphasis on studies in the following order: epidemiological studies, animal toxicological studies, in-vitro assays and lastly, quantitative structure-activity relationships. A brief review of a few of these studies is presented in Box 1.

Box 1: Studies for Hazard Identification

- *Epidemiological studies*

The use of available data from the positive epidemiological studies in the risk assessment is encouraged. Data derived from human clinical studies, should also be utilized in the hazard identification step, as well as, other steps. However, clinical and epidemiological data are unlikely to be available for most chemicals. In addition, negative epidemiological data may be difficult to interpret for risk assessment purposes because the statistical power of most epidemiological studies is inadequate to detect effects at relatively low levels in human populations. Finally, a positive data indicates that an adverse effect has already occurred thus, risk management decisions should not be delayed pending the development of epidemiological studies. Epidemiological studies from which data for risk assessment are derived should be based on recognized standardized protocols.

The factors that need to be considered during the design of epidemiological studies are the variability in human susceptibility, genetic predisposition, age-related and gender-related susceptibility, socio-economic status, nutritional status and other possibly confounding factors.

Due to the cost of epidemiological studies and due to the paucity of data which such studies provide, hazard identification will ordinarily need to rely on the data derived from animal and in-vitro studies. Let us look at the animal studies next.

- *Animal studies*

Most toxicological data for risk assessment are derived from the animal studies and it is, therefore, essential that these studies be conducted following widely accepted, standardized testing protocols. While many such protocols already exist e.g., Organization for Economic Cooperation and Development (OECD) and Environmental Protection Agency (EPA), guidance is not available concerning the selection and use of specific protocols for food safety risk assessment. Regardless of which protocols are used, all studies should follow Good Laboratory Practices (GLP) and standardized Quality Assurance/Quality Control (QA/QC) procedures.

Adequate minimum data sets including specification of the number of species/strains/stocks, use of more than one sex, appropriate selection of doses (see below), route of exposure and adequate sample size are available and should be used for food safety risk assessment.

Animal data from long-term (chronic) studies are critical and should address significant toxicological effects/end points including cancer, reproductive/developmental effects, neurotoxic effects, immunotoxic effects (one which is potentially harmful to the immune system) and others. Animal data from short-term (acute) toxicity studies will also be useful and should be generated. In general, the animal studies should:

- facilitate identification of the range of toxicological effects/end points (including those listed).
- be able to gather data on the relationship between toxicity and essentiality for the substances which are required to meet the nutritional requirements e.g., copper, zinc and iron.
- be designed to identify a no-observed-effect level (NOEL), a no-observed-adverse-effect level (NOAEL) or a benchmark dose. Doses should also be selected at levels high enough to reduce the likelihood of false-negatives as much as possible. However, the selection of highest dose in some studies, such as, bioassays, is being debated. Therefore, mid-range doses should be selected to provide relevant information on the shape of the dose-response curve.

Finally, these studies should identify not only the potential adverse effects for human health but also provide information on the relevance of these effects for human risk.

- *In-vitro studies*

Mechanistic data may be supplemented by data from in-vitro studies, such as information on genotoxicity derived from reversion assays or other similar assays. These studies should be conducted following GLP and other widely accepted protocols. However, data from in-vitro studies should not be used as the sole source of information to predict the human risk.

The results of in-vitro studies can enhance the understanding of mechanisms and pharmacokinetics/dynamics. However, such information may not be available in many cases and the risk assessment process should not be delayed pending development of mechanistic and pharmacokinetic/dynamic data.

- *Structure-activity relationships*

Structure-activity relationships may be useful to increase the weight-of-evidence for human health hazards identification. Where classes of compounds are of interest (e.g., polycyclic aromatic hydrocarbons, polychlorinated biphenyls and dioxins) and where adequate toxicological data are available on one or more members of the class, a toxic equivalence approach may be useful to predict the human health hazard associated with exposure to other members of the class.

With a discussion on the various studies, we come to an end of our study of the hazard identification step.

The next step in risk assessment is *hazard characterization*. Let us get to know about this step.

2) *Hazard characterization*

The chemicals in the food being considered include food additives, pesticides, veterinary drugs and contaminants. They are often present in food at low levels – typically at a part per million or less. However, to obtain adequate sensitivity, animal toxicological studies must be conducted at high levels which may exceed, depending on the intrinsic toxicity of the chemical, to several thousand parts per million. The significance that the adverse effects detected in the high-dose animal studies have for low-dose human exposures is the major question posed in the hazard characterization of chemicals. Let us now study how we can actually collect the relevant data and conduct these toxicological studies. These are presented in Box 2.

Box 2: Toxicological Studies

- *Dose-response extrapolation*

In order to be compared to human exposure levels, the animal data need to be extrapolated to doses much lower than those studied. This extrapolation procedure is uncertain both qualitatively and quantitatively. The nature of the hazard may change with dose or may disappear entirely. The selected dose-response model may be incorrect if the nature of the response in animals and humans is qualitatively the same. Not only is the equivalent dose estimate in animals and humans a problem in comparative pharmacokinetics, but also is the change in metabolism with dose. The metabolism of chemicals at high and low doses may differ. For example, high doses often overwhelm normal detoxification/metabolism pathways and produce adverse effects that would not occur at lower levels. High doses can induce higher rates of enzyme production, physiological changes and dose-related pathological changes. The toxicologist must consider the potential impact of these and other possible dose-related changes on the extrapolation of the adverse effect to lower doses.

- *Dose-scaling*

Toxicological equivalent doses in animals and humans are a debatable issue. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) and Joint FAO/WHO Meetings on Pesticide Residues (JMPR) have typically used mg per kg of body weight for interspecies scaling. Recently, regulatory authorities in the USA have proposed a scaling equivalent to mg per 0.75 kg of body weight, which is based on more recent pharmacokinetic information. The ideal scaling factor would be obtained by measuring tissue concentrations and clearance rates in the target organ of the animal and human. Generic interspecies scaling factors should be recognized as default values that are used in the absence of better information, which is seldom available.

- *Genotoxic and non-genotoxic carcinogens*

Traditionally, toxicologists have accepted the existence of thresholds for adverse effects with the exception of carcinogenicity. The tradition extends from the early 1940s, when it became evident that the initiating event in carcinogenesis could be a somatic mutation. In theory, a few molecules, even a single molecule, could cause a mutation that could persist in the animal or human and ultimately be expressed as a tumour. Theoretically, there may be no safe dose for a carcinogen that acts through this mechanism.

In recent years, it has been possible to discriminate between carcinogens and to identify a category of non-genotoxic carcinogens that are themselves not capable of producing mutations but act at later stages of the cancer process on cells, already "initiated" by other carcinogens or other processes e.g., radiation. In contrast, other carcinogens induce genetic alterations in somatic cells with the activation of oncogenes and/or inactivation of cancer suppressor genes. Thus, genotoxic carcinogens are defined as *chemicals which can cause genetic alterations in target cells, either directly or indirectly*. While the major target of genotoxic carcinogens is genetic material, non-genotoxic carcinogens act at extra-genetic sites, leading presumably to enhanced cell proliferation and/or sustained hyperfunction/dysfunction at the target sites. Regarding species differences in carcinogenic effects, a large body of data has been reported indicating that quantitative differences exist in both genotoxic carcinogens and non-genotoxic carcinogens. In addition, certain non-genotoxic carcinogens, called *rodent-specific carcinogens* can be raised as examples of substances for which there are qualitative differences in the ultimate carcinogenic effects. In contrast, no such clear-cut examples have been reported for genotoxic carcinogens.

Toxicologists and geneticists have devised tests to detect chemicals capable of causing mutations in DNA— the *Ames test* is a well known example. Several such tests, both in-vitro and in-vivo tests are used, typically in the form of a battery, to determine the mutagenic potential of chemicals. While the exact tests to include in such a battery may be debatable, in general these tests have been useful in distinguishing between genotoxic and non-genotoxic carcinogens.

Food safety authorities in many countries now make a distinction between genotoxic and non-genotoxic carcinogens. While this distinction cannot be applied in all instances due to insufficient information or knowledge on carcinogenesis, the concept can still contribute to the establishment of evaluation strategies for cancer risks posed by exposure to chemicals. In principle, non-genotoxic carcinogens may be regulated using a threshold approach, such as the NOEL approach. In addition to the demonstration that the substance is not likely to be a genotoxic agent, scientific information is often required on the mechanism of carcinogenicity.

- *Threshold approaches*

A safe level or an Acceptable Daily Intake (ADI) is derived from an experimental NOEL or NOAEL by applying the appropriate safety factors. What do we mean by ADI? The Acceptable Daily Intake (ADI) is *a measure of the quantity of a particular chemical in food which, it is believed, can be consumed on a daily basis over a lifetime without harm*. It is usually expressed in milligrams of the chemical per kilogram of body weight. The conceptual basis for their use is that thresholds will exist at reasonably comparable doses in both humans and experimental animals. For humans, however, sensitivity may be greater, genetic out-breeding may be larger and dietary habits may be more variable. As a consequence, a safety factor is applied by JECFA and JMPR to take into account these uncertainties. A safety factor of 100 is typically applied when data from long-term animal studies are available but other safety factors are used by different

health agencies. JECFA also uses a larger safety factor when the data are minimal or when the ADI is assigned on a temporary basis. Other health agencies adjust the ADI for the severity or irreversibility of the effect. These differences in ADI values constitute an important risk management issues which deserves some attention by the appropriate international bodies.

The message communicated with an ADI is that there is no significant risk if the chemical is ingested at or below the ADI. The safety factor, as indicated, is selected to subsume the anticipated variations in human responses. It is, of course, theoretically possible that some individuals are even more sensitive than provided for by the safety factor. The safety factor approach, like the quantitative risk approach discussed herewith, cannot guarantee absolute safety for everyone.

Another approach to ADI development has been to move away from reliance on the NOEL/NOAEL and towards the use of a lower effective dose, such as effective dose for 10% response above the background (ED_{10}) or effective dose for 5% response above the background (ED_{05}). This approach, called the '*benchmark dose*', draws more heavily on data near the observed dose-response range, but is still subjected to the application of safety factors. Thus, while it may allow a more accurate prediction of low dose risk, the benchmark dose-based ADI may not differ significantly from a NOEL/NOAEL-based ADI. Special population groups, like children, are protected by an appropriate choice of the intra-species conversion factor and by special consideration of their exposures, if necessary.

- *Non-threshold approaches*

For genetic carcinogenes, the "NOEL-safety factor" approach is generally not considered a suitable method for setting the acceptable intake levels. The consensus is predicted on the anticipated presence of risk at all doses, even the lowest. At this point, two management approaches are available: (1) to ban the chemical from commercial use, or (2) to establish a level of risk that is sufficiently small to be deemed negligible, insignificant or societal acceptable. The implementation of the latter approach has given rise to quantitative risk assessment for carcinogenes.

Various extrapolation models have been utilized for this purpose. Currently, models use experimental measurements of tumour incidence and dose, and virtually no other biological information. None of these models have been validated beyond the experimental range. No correction for high dose toxicity, enhanced cellular proliferation, or DNA repair is made. For these reasons, the current linear models are considered to be the conservative estimates of risk. This is usually expressed by characterizing the risks generated by such models as "plausible upper bounds" or "worst-case estimates". It is acknowledged by many regulatory agencies that actual or probable human risks are not being predicted. Some countries attempt to reduce the conservatism inherent in linear extrapolation by using non-linear models. An essential component of this approach is the determination of an acceptable risk level. In the USA, Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) have chosen the risk level of one in a million (10^{-6}). This acceptable level was chosen because it was considered to represent an insignificant risk. But the choice of a risk level is ultimately a risk management's decision for each country to decide.

For food additives and residues of pesticides and veterinary drugs, a fixed level of risk is practical, as the substances can be disallowed if the estimated risk exceeds the regulatory acceptable level. But for contaminants, including discontinued pesticides which have become environmental contaminants, an established acceptable level can easily be exceeded. For example, in the USA, dioxins are estimated to present a worst case risk of around 10^{-4} . For ubiquitous carcinogenic contaminants like polycyclic aromatic hydrocarbons and nitrosamines, the 10^{-6} risk level is also exceeded.

Having looked at hazard characterization, the next step in hazard assessment is exposure assessment. Let us learn about this aspect.

3) *Exposure assessment*

Estimates of dietary intakes of food additives, residues of pesticides and veterinary drugs and contaminants require information on the consumption of relevant foods and the concentrations of the chemical of interest in those foods. In general, three approaches are available in exposure assessment: (1) total diet studies (2) selective studies of individual foods, and (3) duplicate portion studies. Guidelines for the study of dietary intake of chemical contaminants are available from WHO. In recent years, direct monitoring of human tissues and body fluids has been increasingly used to assess exposure. For example, the determination of levels of organochlorine compounds in breast milk, which are mainly derived from the diet, has provided an integrated assessment of human exposure to these substances.

Dietary intake determination can be relatively straight-forward for additives, pesticides and veterinary drugs as the relevant foods and their use levels are specified by their approved conditions of use. However, the actual levels of additives and residues of pesticides and veterinary drugs present in foods are often well below the maximum levels permitted. Data on the levels of food additives in foodstuffs can be obtained from the manufacturers. The dietary intake of contaminants requires information on their distribution in foods that can only be obtained by analyzing representative samples of foods with sufficiently sensitive and reliable analytical methods. Guidelines for establishing or strengthening national food contamination monitoring programmes have been elaborated by the Global Environmental Monitoring System (GEMS) for Food of the WHO.

Maximum Residue Limits (MRLs) for pesticides and veterinary drugs and Maximum Levels for additives can be established from their conditions of use. In the simplest case, a food additive used at a specific level would be stable in the food until consumption. The maximum level would then equal the intake level. However, in many cases, the amount of the chemical of interest may change prior to consumption. For example, food additives may degrade during storage or react with the food. Pesticide residues in raw agricultural products may degrade/accumulate during further processing. The fate of veterinary drug residues in food products is influenced by the metabolism, kinetics, distribution and withdrawal periods required for the treated animals.

The establishment of Maximum Residue Limits (MRLs) must take into account any changes in the nature or level for the residue that may occur prior to a commodity entering commerce or that may occur under any anticipated conditions of subsequent use. Contaminants have no intended technological effect in the food and guideline levels are usually set 'As Low As Reasonably Achievable' (ALARA).

The theoretical total dietary intake of additives, pesticides and veterinary drugs must be below their corresponding ADIs. Frequently, the actual intake is well below the ADI. Setting guideline levels for contaminants present special problems. There is usually a paucity of data to establish a provisional tolerable intake. On occasion, the levels of the contaminants are higher than what an established provisional tolerable intake would permit. In these cases, the guideline levels are set on economic and/or technical considerations.

Reliable food intake data are essential for exposure assessments based on measuring levels of chemical agents in food. Detailed food consumption data for the average and median consumer, as well as, for different population groups are important for assessing exposure, particularly by sensitive groups. In addition, comparable food consumption data, particularly with respect to staple foods from different regions of

the world, are essential for developing an international risk assessment approach to food safety.

WHO currently maintains a database of five regional diets, as well as, a composite "global" diet. Daily dietary intakes of nearly 250 individuals, primary and semi-processed food commodities are available. The African, Asian, East Mediterranean, European and Latin American regional diets are based on the selected national data from FAO Food Balance Sheets. Consumption data derived using this approach provide no information on extreme consumers. No information is available in GEMS for food on the intake of food additives, although intakes in developed countries are anticipated to be greater than in developing countries because of the higher portion of processed foods in the diet.

Finally, let us look at the risk characterization, the last aspect of risk assessment.

4) *Risk characterization*

The outcome of the risk characterization is an estimate of the likelihood of adverse health effects in human populations as a consequence of the exposure. The risk characterization is performed by taking into consideration the results of the hazard identification, hazard characterization and exposure assessment. For threshold acting agents, population risk is characterized by comparison of the ADI (or other measures) with exposure. In this case, the likelihood of adverse health effects is notionally zero when exposure is less than the ADI. For non-threshold acting agents, population risk is the product of exposure and potency.

At the risk characterization step, the uncertainties involved in each step of the risk assessment process should be described. Uncertainty in risk characterization will reflect the uncertainties in the proceeding steps. The extrapolation of results of animal studies to the human situation may produce two types of uncertainties: (i) uncertainties with respect to the relevance of the experimental findings to the humans. For example, for stomach tumours in rats fed with Butylated Hydroxy Anisole (BHA) and neurotoxic effects in mice produced by aspartame may not have human parallels, and (ii) uncertainties with respect to specific human sensitivity for effects of a chemical that cannot be studied in experimental animals. In this case, hypersensitivity to glutamate is an example. In practice, these uncertainties are dealt with by expert judgment and by additional studies, preferably in humans. These studies may be performed during the pre-marketing phase, as well as, during the post-marketing phase.

The process above describes the risk assessment of chemical hazards. On the same lines, let us next look at the steps involved in risk assessment of biological hazards.

12.3.2 Risk Assessment of Biological Hazards

Biological hazards of concern to public health include pathogenic strains of bacteria, viruses, helminths, protozoa, algae and certain toxic products they may produce. Among these, presence of pathogenic bacteria in foods presents unique features for risk assessment. The method used to assess the risk of hazards from food borne bacteria will be complicated by factors measuring from methods used to grow, process, store and prepare food for consumption. These can vary greatly depending upon the cultural and geographical differences. Let us look at the four steps involved with risk assessment of biological hazards.

Hazard identification

Bacterial agents known to cause food borne disease have been identified by using epidemiological and other data to link the organism and its source to illness.

Hazard characterization

The purpose of this step is to provide a qualitative and quantitative estimate of the severity and duration of adverse effects due to the presence of a pathogen in food. Dose response data is useful when addressing toxigenic bacteria. For many food borne pathogenic bacteria, dose response data is limited or non-existent. Information on dose response estimates is difficult to obtain and may also be inaccurate, for the reasons cited below:

- 1) Host susceptibility to pathogenic bacteria is highly variable
- 2) Attack rates from a specific pathogen vary widely
- 3) Variance of a pathogenic species is highly variable
- 4) Pathogenicity is subject to genetic variation resultant from frequent mutation, and
- 5) Antagonism from other bacteria in foods and the digestive system may influence pathogenicity.
- 6) Food will modulate the ability of bacteria to infect and or otherwise affect the host.

Exposure assessment

Levels of chemical agents may vary slightly during the processing of food. While bacterial populations are dynamic, they may increase or decrease dramatically in food. The factors responsible for these changes are as follows:

- 1) ecology of the bacterial pathogens of concern
- 2) processing, packaging and storing of food
- 3) processing of foods, such as cooking, may kill the pathogen, and
- 4) cultural practices relating to consumers.

Risk characterization

Characterizing the risk associated with biological pathogens will depend on the considerations and information described in the hazard identification, hazard characterization and exposure assessment steps. In view of so many factors affecting the risk assessment, it has not yet been determined whether quantitative risk assessment is possible. However, qualitative risk assessment is possible and depends on the experience with a specific food, a knowledge of ecology of bacterial pathogens, epidemiological data and expert judgment regarding hazards associated with the manner in which the food is produced, processed, stored and prepared for consumption.

The four steps involved in risk assessment of any hazard have been clearly defined and explained in the section above. Though the process must have been a bit technical, we hope it would have given you a deep insight into how risk assessment is crucial for food safety. Next, we shall read about the second component of risk analysis i.e. *risk management*. But before that, take a break and recapitulate what you have learnt so far.

Check Your Progress Exercise 1

- 1) What is risk analysis?

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- 2) Why is risk assessment important? List the four steps involved in risk assessment.
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- 3) What is the goal for conducting the following four steps of risk assessment:
 - a) Hazard identification
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 - b) Hazard characterization
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 - c) Exposure assessment
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 - d) Risk characterization
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- 4) What are the chemical and biological hazards associated with risk assessment?
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- 5) List the three approaches available in exposure assessment.
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- 6) What are the two factors on which the establishment of Maximum Residue Limit (MRL) for additives depends on?
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12.4 RISK MANAGEMENT

The second component of risk analysis in food safety is the risk management. Risk management is defined as *the process of weighing policy alternatives in the light of the results of risk assessment and selecting and implementing appropriate control options, including regulatory measures.*

Risk management is defined for the purposes of the *Codex Alimentarius Commission* as “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.”

There are various elements involved in the risk management process. These elements are highlighted next.

12.4.1 Elements of Risk Management

You may have realized that this phase of risk analysis identifies, selects and implements measures that can be applied to reduce the risk identified during the assessment. Let us see how it is done. The elements of risk management include:

A) *Risk evaluation*: The risk evaluation involves:

- 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 conduct of risk assessment
- commissioning of risk assessment, and
- consideration of risk assessment result

B) *Risk management option assessment*: This second element deals with:

- identification of available management options
- selection of preferred management option, including consideration of an appropriate safety standard. “Safety standard” here refers to ‘the level of acceptable risk, which is adopted by risk managers or implicit in the chosen risk management option’. Examples include “Zero-risk” standards [such as are usually implicit in *de minimis* and Acceptable Daily Intake (ADI) levels], “balancing” standards [such as cost-benefit, cost-effectiveness and as low as reasonably achievable (ALARA)], “threshold” standards (where a non-zero level of risk is stipulated as acceptable), or “procedural” standards (where the acceptable risk level is determined by an agreed process, such as a negotiation or referendum), and
- final management decision.

C) *Implementation of management decision*

D) *Monitoring and review*: This final step involves:

- assessment of effectiveness of measures taken, and
- review risk management and/or assessment, as necessary.

The outcome of the risk evaluation process should be combined with the evaluation of available risk management options, in order to reach a decision on management of the risk. In arriving at this decision, human health protection should be the primary consideration, with other factors (e.g. economic costs, benefits, technical feasibility, risk perceptions etc.) being considered as appropriate. Implementation of the management decision should be followed by monitoring both the effectiveness of the control measure and its impact on risk to the exposed consumer population, to ensure that the food safety objective is being met.

It is important that all the stake holders who are likely to be affected by risk management decisions have an opportunity for input into the risk management process.

These groups may include (but should not be limited to) consumer organizations, representatives of the food industry and trade, education and research institutions, and regulatory bodies. A consultative process can be implemented in many ways, ranging from public meetings to opportunities to comment on public documents. Inputs from interested parties can be introduced and considered at every stage of the risk management policy formulation process, including evaluation and review.

Managing food safety risk employs certain principles. Let us study each of these principles and try to understand their significance in the process of food safety, next.

12.4.2 General Principles of Risk Management

The various principles and their significance in food safety risk management include:

Principle 1: Risk management should follow a structured approach

The elements of a structured approach to risk management, as you have already studied above, are risk evaluation, risk management, option assessment, implementation of management decision, and monitoring and review. In certain circumstances, not all of these elements will be included in risk management activities (e.g. standard setting by Codex, with the implementation of control measures by National governments).

Principle 2: Protection of human health should be the primary consideration in risk management decisions

Decisions on acceptable levels of risk should be determined primarily by human health considerations and arbitrary or unjustified differences in the risk levels should be avoided. Consideration of other factors like economic costs, benefits, technical feasibility, and societal preferences are appropriate in many risk management contexts, particularly in the determination of measures to be taken. These considerations should not be arbitrary and should be made explicit.

Principle 3: Risk management decisions and practices should be transparent

Risk management should include the identification and systematic documentation of all elements of the risk management process including decision-making, so that the rationale is transparent to all interested parties.

Principle 4: Determination of risk assessment policy should be included as a specific component of risk management

Risk assessment policy sets the guidelines for value judgments and policy choices which may need to be applied at specific decision points in the risk assessment process, and preferably should be determined in advance of risk assessment, in collaboration with risk assessors.

Principle 5: Risk management should ensure the scientific integrity of the risk assessment process by maintaining the functional separation of risk management and risk assessment

Functional separation of risk management and risk assessment serves to ensure the scientific integrity of the risk assessment process and reduce any conflict of interest between risk assessment and risk management. However, it is recognized that risk analysis is an iterative process, and interactions between risk managers and risk assessors are essential for practical application.

Principle 6: Risk management decisions should take into account the uncertainty in the output of the risk assessment

The risk estimate should, wherever possible, include a numerical expression of uncertainty, and this must be conveyed to risk managers in a readily understandable form so that the full implications of the range of uncertainty can be included in decision-making. For example, if the risk estimate is highly uncertain, the risk management decision might be more conservative.

Principle 7: Risk management should include clear, interactive communication with consumers and other interested parties in all aspects of the process

On-going reciprocal communication among all interested parties is an integral part of the risk management process. Risk communication is more than dissemination of information, and a major function is the process by which information and opinion essential to effective risk management is incorporated into the decision.

Principle 8: Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions

Subsequent to the application of a risk management decision, periodic evaluation of the decision should be made to determine its effectiveness in meeting food safety objectives. Monitoring and other activities will be likely to be necessary to carry out the review effectively.

Having looked at the principles and process of risk management we move to the last aspect of risk analysis, which is risk communication.

12.5 RISK COMMUNICATION

Effective communication of information and opinion on risks associated with real or perceived hazards in food is an essential and integral component of the risk analysis process. Risk communication may originate from official sources at international, national and local levels or from industry, trade consumers and other interested parties. Interested parties may include government agencies, industrial representatives, the media, scientists, professional societies, consumer organizations and other public interest groups and concerned individuals. What exactly are we dealing with when we talk about risk communication? Let us find out by first defining risk communication.

What is risk communication?

Risk communication is *an interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties*. Risk communication has also been described as all those integrated processes and procedures that:

- involve and inform all interested parties within the risk analysis process
- assist the development of transparent and credible decision-making processes, and
- can instill confidence in risk management decisions.

A more simplified definition of risk communication would be:

Risk communication is *'the exchange of information and opinions concerning risk and risk related factors among risk assessors, risk managers, consumers and other interested parties.'*

Risk communication is defined for the purposes of the *Codex Alimentarius Commission* as "the interactive exchange of information and opinions throughout the

risk analysis process concerning hazards and risks, risk-related factors, 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.”

What is the goal/objective of risk communication? Like in any communication process, the objectives of risk communication are also the same, which are highlighted next.

Objectives of risk communication

The fundamental goal of risk communication, as you may have realized, is to *provide meaningful, relevant and accurate information, in clear and understandable terms targeted to a particular audience*. The specific objectives include:

- 1) promote awareness and understanding of the specific issues under consideration during the risk analysis process, by all participants
- 2) promote consistency and transparency in arriving at and implementing risk management decisions
- 3) provide a sound basis for understanding the risk management decisions, proposed or implemented
- 4) improve the overall effectiveness and efficiency of the risk analysis process
- 5) contribute to the development and delivery of effective information and education programmes, when they are selected as risk management options
- 6) foster public trust and confidence in the safety of the food supply
- 7) strengthen the working relationships and mutual respect among all participants
- 8) promote the appropriate involvement of all interested parties in the risk communication process, and
- 9) exchange information on the knowledge, attitudes, values, practices and perceptions of interested parties concerning risks associated with food and related topics.

Having read about the objectives, let us move on to the roles/responsibilities for risk communication. Who is responsible for risk communication? Let's find out.

12.5.1 Roles and Responsibilities for Risk Communication

Various Departments of Government, industry and non governmental agencies are responsible for the process of risk communication. Let us study the role of each of these. We shall begin with the role of the Government.

1) *Governments*

Governments have a fundamental responsibility for risk communication when managing public health risks, regardless of the management methods used. With the responsibility of managing risks, comes the responsibility to communicate information about risks to all interested parties to an acceptable level of understanding. Decision-makers within governments have an obligation to ensure effective communication with the interested parties, when developing scientific and technical analysis and to appropriately involve the public and other interested parties in the risk analysis process. Risk managers also have the obligation to understand and respond to the underlying basis of public concerns about health risks.

Governments should work towards a consistent and transparent approach when communicating risk information. Communication strategies may differ for different issues and different target audiences. This is most apparent when dealing with issues

where a specific group has differing views of a risk. These differences in perception, which may be due to economic, social or cultural differences, should be recognized and respected. It is the outcome, i.e. effectively managed risk, which is most important. Differing methods of reaching the outcome may be acceptable.

2) *Industry*

Industry is responsible for the quality and safety of the food it produces. It also has a corporate responsibility to communicate information regarding risks to affected consumers. Industry participation in all aspects of risk analysis is essential for effective decision making and can serve as a major source of information for risk assessment and risk management. The routine information flow between industry and government usually involves communications necessary to set standards or gain approvals for new technologies, ingredients, or labels. In that connection, food labels have been and are routinely used to communicate information on the ingredients and instructions on the safe handling of food products, as a form of risk management using the label as the communicating device.

3) *Consumer and Consumer Organizations*

Broad and open participation in risk analysis at the National level is viewed by the public as an essential element of what constitutes appropriate public health protection. Early participation in the risk analysis process by the public or consumer organizations can help to ensure that consumer concerns are addressed and will generally result in a better public understanding of the risk assessment process and how risk-based decisions are made. It can further provide support for the risk management decisions that result from the assessment. Consumers and consumer organizations have a responsibility to present their concerns and opinions on health risks to risk managers. International consumer organizations that are Codex observers have a direct input into Codex discussions on these matters. International and National consumer organizations play an important role in disseminating information on health risks directly to consumers. Consumer organizations also often work with governments and industry to ensure that risk messages addressed to consumers are appropriately formulated and delivered.

4) *Academic and Research Institutions*

Members of the academic and research community may play an important role in risk analysis by contributing scientific expertise on health and food safety matters and assisting in the identification of hazards. They may be asked by the media or other interested parties to comment on government decisions. They often have a high level of credibility with the public and the media, and may serve as an independent source of information. Researchers involved in studies of consumer perception or communication methods and the assessment of communication effectiveness, may also be helpful to risk managers seeking expert advice on risk communication approaches and strategies.

5) *Media*

The media clearly plays a critical role in risk communication. Much of the information that the public receives on food-related health risks comes to them through the media. The many varieties of mass media have roles which vary depending on the issue, the context and the type of media involved. The media may merely transmit a message, or they may create or interpret a message. They are not limited to official sources of information and their messages often reflect the concerns of the public and other sectors of society. This can and does facilitate risk communication since risk managers may become aware of concerns of which they were not previously cognizant. In India, the vernacular press plays a critical rôle. In the absence of an effective government surveillance system for reporting food borne diseases, the media, specially

the print media, often reports the outbreak of a food borne disease and can act as a valuable base for communicating with the general public.

After having an understanding on the roles and responsibilities of various organizations, let us move on to our next section which deals with the principles of risk communication.

12.5.2 Principles of Risk Communication

In this section, our primary focus will be to have a brief understanding and knowledge on some of the basic principles involved in the process of risk communication. The first step is to know your audience. Let us learn about these principles.

- *Know the Audience*

In formulating risk communication messages, the audience should be analyzed to understand their motivations and opinions. Beyond knowing in general who the audience is, it is necessary to actually get to know them as groups and ideally as individuals to understand their concerns and feelings and to maintain an open channel of communication with them. Listening to all interested parties is an important part of risk communication.

- *Involve the Scientific Experts*

Scientific experts, in their capacity as risk assessors, must be able to explain the concepts and processes of risk assessment. They need to be able to explain the results of their assessment and the scientific data, assumptions and subjective judgements upon which it is based, so that the risk managers and other interested parties clearly understand the risk. They further must be able to clearly communicate what they know and what they do not know, and to explain the uncertainties related to the risk assessment process. In turn, the risk managers must be able to explain how the risk management decisions are arrived at as well.

- *Establish Expertise in Communication*

Successful risk communication requires expertise in conveying understandable and usable information to all interested parties. Risk managers and technical experts may not have the time or the skill to perform complex risk communication tasks, such as responding to the needs of the various audiences (public, industry, media, etc.) and preparing effective messages. People with an expertise in risk communication should therefore be involved as early as possible. This expertise will be likely to be developed by training and experience.

- *Be a Credible Source of Information*

Information from credible sources is more likely to influence the public perception of a risk than is information from sources that lack this attribute. The credibility accorded to a source, by a target audience may vary according to the nature of the hazard, culture, social and economic status, and other factors. If consistent messages are received from multiple sources then the credibility of the message is reinforced. Factors determining source credibility include recognized competence or expertise, trustworthiness, fairness and lack of bias. For example, the terms that consumers have associated with high credibility include factual, knowledgeable, expert, public welfare, responsible, truthful, and good "track record". Trust and credibility must be nurtured and can be eroded or lost through ineffective or inappropriate communication. In studies, consumer has indicated that distrust and low credibility resulted from exaggeration, distortion and perceived vested interest.

Effective communications acknowledge current issues and problems, are open in their content and approach, and are timely. Timeliness of the message is most important since many controversies become focused on the question, "why didn't you tell us

sooner”, rather than on the risk itself. Omissions, distortions and self-serving statements will damage credibility in the longer term.

- *Share Responsibility*

Regulatory agencies of governments at the national, regional and local levels have a fundamental responsibility for risk communication. The public expects the government to play a leading role in managing public health risks. This is true when the risk management decision involves regulatory or voluntary controls, and is even true when the government decision is to take no action. In the latter event, communication is still essential to provide a reason why taking no action is the best option. In order to understand the public concerns and to ensure that risk management decisions respond to those concerns in appropriate ways, the government needs to determine what the public knows about the risks and what the public thinks of the various options being considered to manage those risks.

The media plays an essential role in the communication process, as we have already seen above, and therefore shares these responsibilities. Communication on immediate risks involving human health, particularly, when there is a potential for serious health consequences, such as food-borne illnesses, cannot be treated the same as less immediate food safety concerns. Industry also has a responsibility for risk communication, especially when the risk is as a result of their products or processes. All parties involved in the risk communication process (e.g. government, industry, media) have joint responsibilities for the outcome of that communication even though their individual roles may differ. Since science must be the basis for decision making, all parties involved in the communication process should know the basic principles and data supporting the risk assessment and the policies underlying the resulting risk management decisions.

- *Differentiate between Science and Value Judgement*

It is essential to separate “facts” from “values” in considering risk management options. At a practical level, it is useful to report the facts that are known at a time, as well as, what uncertainties are involved in the risk management decisions being proposed or implemented. The risk communicator bears the responsibility to explain what is known as a ‘fact’ and where the limits of this knowledge begin and ends. Value judgments are involved in the concept of acceptable levels of risk. Consequently, risk communicators should be able to justify the level of acceptable risk to the public. Many people take the term ‘safe food’ to mean food with zero risk, but zero risk is often unattainable. In practice, ‘safe food’ usually means food that is ‘safe enough’. Making this clear is an important function of risk communication.

- *Assure Transparency*

For the public to accept the risk analysis process and its outcomes, the process must be transparent. While respecting legitimate concerns to preserve confidentiality (e.g. proprietary information or data), transparency in risk analysis consists of having the process open and available for scrutiny by interested parties. Effective two-way communication between risk managers, the public and the interested parties is both an essential part of risk communication and a key to achieving transparency.

- *Put the Risk in Perspective*

One way to put a risk in perspective is to examine it in the context of the benefits associated with the technology or process that poses the risk. Another approach that may be helpful is to compare the risk at issue with other similar, more familiar risks. However, this latter approach can create problems if it appears that the risk comparisons have been intentionally chosen to make the risk at issue seem more acceptable to the public. In general, risk comparisons should not be used unless:

- both (or all) risk estimates are equally sound
- both (or all) risk estimates are relevant to the specific audience
- the degree of uncertainty in all risk estimates is similar
- the concerns of the audience are acknowledged and addressed, and
- the substances, products or activities themselves are directly comparable, including the concept of voluntary and involuntary exposure.

With this, we have come to the end of our study on risk analysis and its components.

Check Your Progress Exercise 2

1) What are the elements of risk management?

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2) Give the principles of risk management.

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3) Define the following terms:

a) Risk Management

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b) Safety Standard

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4) What is risk communication and what are some of its integrated processes and procedures?

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5) List the principles of risk communication.

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6) Explain the role of following in the process of risk communication:

a) Government

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b) Industry

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c) Media

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12.6 LET US SUM UP

In this unit, we studied about risk analysis, its components and important definitions of risk analysis terms related to food safety. The process of risk assessment, one of the components of risk analysis, was described in terms of its four important steps, as hazard identification, hazard characterization, exposure assessment and risk characterization. This was further explained through various studies that were conducted to substantiate the understanding of the processes of assessing the risk involved in food safety.

The elements involved in food safety risk management were next discussed along with the few of the general principles. The concept of risk communication, its definitions and objectives were explained followed by the roles and responsibilities of various agencies such as government, industry, media etc. Finally, the principles, of risk communication were enlisted.

12.7 GLOSSARY

- Botulinum Cook** : a thermal process designed to reduce the probability of survival of spores of *Clostridium botulinum* by a factor of 10^{12} .
- Epidemiological studies** : the study of the distribution and determinants of health-related states or events in specific populations and the application of this study to control health problems.
- Extrapolation** : an inference about the future or some hypothetical situation based on known facts and observations.
- Food borne diseases** : the diseases transmitted by the ingestion of food containing toxic or infectious agents.
- Genotoxic carcinogens** : chemicals which can cause genetic alterations in target cells, either directly or indirectly.
- Global Environmental Monitoring System** : one of the pivotal programmes of United Nations Environment Programme, which is involved in collecting, validating, storing and systemizing data from various monitoring programmes at global scale.
- Mycotoxin** : naturally-occurring toxins produced by moulds which may grow on cereals and other materials used as animal feeds.

NOAEL	: the NOAEL stands for no-observed adverse effect level. Greatest concentration or amount of a substance found by experiment or observation, which causes no detectable adverse alteration of morphology, functional capacity, growth development or life span of the target organism under defined conditions of exposure
NOEL	: the NOEL stands for no-observed effect level. Greatest concentration or amount of a chemical, found by experiment or observation that causes no detectable adverse of life span of the target.
Pharmacodynamic studies	: studies relating to drug action.
Pharmacokinetic studies	: studies relating to the disposition of drugs in the body (i.e., their absorption, distribution, metabolism, and elimination).
Safety standard	: the level of acceptable risk, which is adopted by risk managers or is implicit in the chosen risk management option.
Acceptable Daily Intake	: a measure of the quantity of a particular chemical in food which, it is believed can be consumed on a daily basis over a lifetime without harm.
As Low As Reasonably Achievable (ALARA)	: a basic concept of radiation protection, according to which exposure to ionizing radiation and release of radioactive materials should be reduced as far below regulatory limits as is reasonably achievable considering economic technological and societal factors.

12.8 ANSWERS TO CHECK YOUR PROGRESS EXERCISES

Check Your Progress Exercise 1

- 1) Risk analysis is a new paradigm in food safety assurance, which involves processes like risk assessment, risk management and risk communication.
- 2) Risk assessment is important as it provides risk managers with a rational basis for making decisions about managing the use of chemicals or physical agents in order to protect health and the environment. It is used as part of the decision-making process to ensure public protection against unacceptable risks. The four steps involved in it are hazard identification, hazard characterization, exposure assessment and risk characterization.
- 3)
 - a) The goal of hazard identification is to identify biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.
 - b) The goal of hazard characterization is to evaluate the qualitative and/or quantitative nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food.
 - c) The goal of exposure assessment is to evaluate the qualitative and/or *quantitative intake of biological, chemical, and physical agents via food* as well as exposures from other sources if relevant.

- d) Risk characterization is used for the qualitative and/or quantitative estimation, including attendant 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.
- 4) The chemical and biological hazards associated with risk assessment are food additives, pesticide residues, veterinary drug residues, chemical contaminants from any source, natural toxins like mycotoxins, cigua toxin, bacteria etc.
- 5) The three approaches available in exposure assessment are total diet studies, selective studies of individual foods and duplicate portion studies
- 6) The two factors on which the establishment of MRL depends are conditions of use of additives and changes in the nature or level of the residue.

Check Your Progress Exercise 2

- 1) The elements of risk management are: risk evaluation, risk management option assessment, implementation of management decision and monitoring and review.
- 2) The general principles of risk management are:
 - Management to follow a structured approach
 - Protection of human health as the primary consideration in risk management decisions
 - Transparent decisions and practices
 - Determination of risk assessment policy as a specific component of risk management
 - Ensure the scientific integrity of the risk assessment process
 - Consider the uncertainty in the output of the risk assessment
 - Inclusion of clear, interactive communication with consumers, and
 - A continuing process
- 3)
 - a) The process of weighing policy alternatives in the light of the results of risk assessment and selecting and implementing appropriate control options, including regulatory measures is referred to as risk management.
 - b) Safety standard is the level of acceptable risk, which is adopted by risk managers or is implicit in the chosen risk management option.
- 4) Risk communication is the exchange of information and opinions on risk and risk-related factors among risk assessors, risk managers, consumers and other interested parties. Risk communication has integrated processes and procedures that involve and inform all interested parties within the risk analysis process, assist the development of transparent and credible decision-making processes and can instill confidence in the risk management decisions.
- 5) The principles of risk communication are:
 - Know the audience
 - Involve the scientific experts
 - Establish expertise in communication
 - Be a credible source of information
 - Share the responsibility

- Differentiate between science and value judgment
 - Assure transparency, and
 - Put the risk in perspective.
- 6) a) The Government has a responsibility of managing risks, communicating information about risks to an acceptable level of understanding, appropriately involving the public and other interested parties, understanding and responding to the underlying basis of public concerns about health risks and working towards a consistent and transparent approach.
- b) Industry is responsible for quality and safety of the food it produces, communicating the information regarding risks to the affected consumers and informing about the ingredients and instructions on the safe handling of food products.
- c) Media can play a role through informing the public on food-related health risks and reflecting the concerns of the public and other sectors of society.