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5.1 INTRODUCTION

Getting safe, nutritious, and balanced food is essential for a healthy life. The 1996 declaration of World Food Summit at Rome had reaffirmed the right of everyone to have access to safe and nutritious food, consistent with the right to adequate food, and fundamental right of everyone to be free from hunger (FAO, 1996).

After independence in 1947, India created the basic document for effective governance in 1950, that is, Constitution of India, which provided every Indian citizen a fundamental “right to food.” “Food Security Act” was implemented in September 2013, which entitled almost two-third of 1.2 billion Indian citizens, the right to sufficient, nutritious and quality food at affordable price (highly subsidized through public distribution system). In addition, Supreme Court of India in 2013, also directed that food given to Indian citizens should be safe. Food Safety and Standards Authority of India (FSSAI) has recently started working on how to implement Food Law in India.

WHO gives high priority to food safety, quality and consumer protection programs and food safety is an essential public health function. WHO aims to develop sustainable, integrated food-safety systems for reduction of health risks from the entire food chain. Food safety, in fact, is an essential activity and an integral part of any public health programme (WHO, 2000). Food-borne diseases (FBD) result in substantial burden on healthcare systems, trade and tourism, market access; and reduce economic productivity and threaten livelihood. But FBDs generally go undetected, mostly due to lack of communication among the human, veterinary, agriculture, and food sectors.

As per WHO (2015) global human movements are increasing as also the international food trade, resulting in new risks to food safety since more and more people want to eat out to try new varieties of foods. Such new trends are also modifying the
patterns of food production, distribution and consumption, integrating agricultural and food industries. Although international food trade offers many benefits to consumers, by bringing wider variety of foods to the market which are accessible, affordable, and meet consumer demands and provide opportunities for food-exporting countries to earn foreign exchange. The global value of food trade now exceeds US$500 billion. However, globalization of food trade has also brought new challenges and risks to food control and regulations and even a single source of contamination may become widespread, with global consequences. Antimicrobial resistance to food-borne pathogens; emergence of new pathogens, chemical contaminants, new technologies in food production and processing, like genetic engineering and nanotechnology, changing animal food production and animal husbandry practices, are impacting consumer safety (FAO/WHO-Provisional Edition, 2005).

On the World Health Day (Apr. 7, 2015), WHO gave a slogan “From farm to plate, make food safe.” According to Director of WHO’s Department of Food Safety and Zoonoses, it often takes a crisis for the collective consciousness on food safety to be stirred and any serious response to be taken. Impacts on public health and economies can be great. Almost one third (30%) of all deaths from FBDs, caused by 31 agents—bacteria, viruses, parasites, toxins, and chemicals, are in children under 5 years, despite the fact that they make up only 9% of the global population. The report, states that each year as many as 600 million, or almost 1 in 10 people in the world, fall ill after consuming contaminated food. Of these, 420,000 people die, including 125,000 children under the age of 5 years. Until now, such estimates of FBDs were vague and imprecise (WHO, 2015). As mentioned by Director-General of WHO “Knowing which food-borne pathogens are causing biggest problems in which parts of world can generate targeted public health action by the governments, food industry, and public.”

WHO had established Global Food-borne Infections Network (GFN) to strengthen national and regional integrated surveillance, investigation, prevention, and control of food-borne and other enteric infections. The network promotes integrated, laboratory-based surveillance and fosters intersectoral collaboration and communication among microbiologists and epidemiologists in human health, veterinary and food-related disciplines (WHO, 2013). Early warning system, based on robust risk assessment to inform action, is very useful in addressing health threats and their timely communication. In response to threats such as the avian influenza virus H5N1 and severe acute respiratory syndrome (SARS), the Global Early Warning System (GLEWS) for Transboundary Animal Diseases, including Zoonoses, was jointly established by WHO, FAO, and OIE. GLEWS builds on existing internal systems of three participating organizations to confidentially track and verify events in order to improve harmonization and decrease duplication. It embodies a unique cross-sectoral and multidisciplinary partnership for early identification and assessment of health risks at the human–animal–ecosystem interface. Joint WHO-FAO International Food Safety Authorities Network (INFOSAN), is a voluntary global network of food safety authorities and provides an important platform for rapid exchange of information in case of food safety crises and for sharing data on both routine and emerging food safety issues. It tries to insure
effective and rapid communication during food safety emergencies. To insure a comprehensive approach, GLEWS links with INFOSAN to insure and promote seamless action throughout food value chain within human–animal–ecosystem interface (WHO, 2013).

Enforcing food safety standards requires a food chain that is highly controlled and supplied with appropriate data on contaminants, hazards, and risk management strategies. Experts at FAO and WHO have observed that when incidence of FBD and number of disruptions to international trade in foodstuffs are increasing, it has never been more important for countries to implement an effective food safety system, guided by modern concept of risk analysis, to respond to current challenges (FAO/WHO-Provisional Edition, 2005), namely:

1. Traditional food safety systems are inadequate to cope with complex, persistent, pervasive, and evolving array of food safety issues existing today.
2. Modern food safety systems need to be science based to effectively cope with, and respond to wide range of food safety challenges presently confronting countries.
3. Science-based approaches are an essential part of risk analysis framework and crucial to creating a modern and effective food safety system.

Concept of “risk analysis” in food safety management needs to be understood properly to assess, manage, and communicate risks for proper implementation of food safety policies, food laws, and standards in a country. As such it is essential to understand the definitions of certain related terms. Some of the definitions related to risk analysis are enclosed as Appendix A.

The performance of an organization improves through the use of Quality Management Principles and adoption of a “process approach” besides emphasis on the role of concerned controlling authority. As per Attrey (2008), a Quality Management System (QMS) is directly linked to organizational processes. Process approach is a method of obtaining desired results, by managing activities, related resources as a process and is a key element of the QMS. It takes in to consideration the statutory and regulatory requirements and pays adequate attention to resource availability. Before discussing Food Quality, it is essential to understand certain important definitions about QMS, process, etc., which are also enclosed as Appendix A.

Food quality relates to quality characteristics of food that is acceptable to consumers. This includes external factors as appearance (size, shape, color, gloss, and consistency), texture, and flavor; factors such as federal grade standards (e.g., of eggs) and internal (chemical, physical, and microbial). Food safety is a scientific discipline describing handling, preparation, and storage of food in ways that prevent food-borne illness. This includes a number of routines that should be followed to avoid potentially severe health hazards (Wikipedia, 2015).

Food Quality Analysis is conducted for ascertaining content of nutritional, mineral, volatile and semivolatile compounds, and additives’ components, etc. Food Safety Analysis is conducted to analyze potential hazards like pesticide residues,
heavy metals, veterinary drug residues, fertilizers, growing aids, nonpermitted food additives, mycotoxins and other naturally occurring food toxicants, residues of persistent organic compounds—dioxins, PAH, PCB, etc., microbial contaminants, allergens, mycotoxins including aflatoxins, enzymes, and hormones, genetically modified content, pollutants, defective packaging and labeling, adulteration and tampering, extraneous matter (physical hazards), animal feed additives, acrylamide, etc.

New international trade agreements developed under World Trade Organization (WTO) have emphasized need for regulations governing international trade in foods to be based on scientific principles. Sanitary and Phytosanitary Agreement (SPS) permits countries to take legitimate measures to protect the life and health of consumers, animals, and plants, provided such measures can be justified scientifically and do not unnecessarily impede trade. SPS directs all countries to insure that their sanitary and phytosanitary measures are based on an assessment of the risk to human, animal, or plant life or health, taking into account risk assessment techniques developed by relevant international organizations and defines obligation of developed countries to assist less developed countries to improve their food safety systems (FSSAI, 2010).

Science-based food safety controls were controlling the food safety policies initially till early 1990s. As the awareness among the food scientists and concerned stakeholders grew, newer systems of achieving food safety were innovated during mid 1990s. Hazard Analysis Critical Control Point (HACCP), developed during mid 1990s, soon became the most popular method of achieving food safety. It is still being implemented by most organizations involved in food production across the world. However, during late 1990s, the Food Safety Approach for hygienic production of food was shifted from the routine “Food Safety Controls” to the “Risk-Based Controls.” Although this was accepted by most developed countries as the future method of achieving food safety, it has still not been adopted by developed countries (McKenzie and Hathaway, 2006).

In this context, European Union and United States have taken important steps and enacted relevant legislations for adopting risk-based preventive controls, for example, FDA under its new Act, the “Food Safety Modernization Act” (FSMA), proposed a new rule, that is, “Current Good Manufacturing Practice & Hazard Analysis and Risk-Based Preventive Controls (HARPC)” (FDA, 2013). While Food Safety Controls are based on Current Good Manufacturing Practice (cGMP) and Hazard Analysis, “risk-based preventive controls” are based on “risk assessment.”

According to Buchanan (2011), last two decades have seen emergence of risk analysis as foundation for developing food safety systems and policies. This period has witnessed a gradual shift from a “hazards-based approach” to food safety (i.e., mere presence of a hazard in a food was deemed unsafe) to a “risk-based approach” (determination whether exposure to a hazard has a meaningful impact on public health). Standard methods of analysis help in confirming that a food system is
controlling a specific hazard. Through the selection of analytical method, sampling plan, and frequency of testing, a risk-based decision is introduced. Analysis of collected information is another challenge. Traditionally, food safety systems look at the individual steps along food chain, treating each step in isolation from others. However, as the systems become more complex, interactions and synergies between components become increasingly important and decrease utility of simple analyses of individual steps. When a high level of complexity is reached, impact of individual steps cannot be analyzed without considering the entire system.

5.2 RISK ANALYSIS

As per CAC (2013), risk analysis is a process which follows a structured approach comprising three distinct but closely linked components, namely, risk assessment, risk management, and risk communication, each component being integral to overall risk analysis and playing an essential and complementary role in risk analysis process. The overall objective of risk analysis applied to food safety is to insure human health protection and it should be based on all available scientific evidence, information on perceptions, costs, environmental, cultural factors, etc., which is gathered and analyzed according to scientific principles.

As such, it should always be open and transparent and must be documented according to principles of QMS (to preserve confidentiality and accessibility to all interested parties) in a transparent manner and should be applied within the framework for management of food related risks to human health. Effective communication and consultation with all interested parties should be insured throughout the risk analysis. Precaution is an inherent part of risk analysis. Many sources of uncertainty exist in process of risk assessment and risk management of food related hazards to human health. Degree of uncertainty and variability in available scientific information should be explicitly considered in risk analysis. Needs and situations of developing countries should be specifically identified and taken into account by the responsible bodies in different stages of risk analysis.

According to FSSAI (2010) the risk analysis principles apply equally to issues of national food control and food trade, should be applied in a nondiscriminatory manner and should be made an integral part of a national food safety system. Implementation of risk management decisions at the national level should be supported by an adequately functioning food control system/program. Interaction between risk managers and risk assessors is essential for practical application of risk analysis.

National government should also use guidance and information available with Codex Alimentarius Commission (CAC), Food and Agriculture Organization (FAO), World Health Organization (WHO), and other relevant international intergovernmental organizations, including World Organization for Animal Health [formerly Office International des Epizooties (OIE)] and International Plant Protection Convention (IPPC). Accordingly appropriate programs for training, information, and
capacity building should be designed. In order to perform successful risk analysis, country needs to have a well functioning food safety system, the support and participation of key stakeholders (government, industry, academia, consumers), and basic knowledge about the three main components of risk analysis.

5.3 RISK ANALYSIS PROCESS

Risk Assessment is central scientific component of risk analysis (preferably performed by Veterinary Public Health) but risk management, defines the problem, articulates the goals of the risk analysis, and identifies the questions to be answered by the risk assessment (preferably performed by Public Health). Science-based tasks of measuring and describing nature of risk being analyzed (i.e., risk characterization) are performed during risk assessment. Risk management and risk assessment are performed within an open and transparent environment based on communication and dialog. Risk communication encompasses an interactive exchange of information and opinions among risk managers, risk assessors, the risk analysis team, consumers, and other stakeholders. Process often culminates with implementation and continuous monitoring of a course of action by risk managers (FAO/WHO-Provisional Edition, 2005).

Risk analysis is just one part of an effective food safety system. It will also be essential to develop and improve components of food safety systems including food safety policies, food legislation (encompassing food law, regulations and standards), food inspection, laboratory analysis, epidemiological surveillance of FBDs, monitoring systems for chemical and microbiological contamination in foods, and information, education, and communication. Thus use of a science-based approach shall enable governments to develop and implement a range of general improvements and interventions tailored to specific high-risk areas, which will ultimately improve food safety and reduce the burden of FBD.

As a concept, a science-based approach to food safety is not completely new. It is related to processes such as good agricultural practices, good hygienic practices, good manufacturing practices, and hazard analysis and critical control point (HACCP) system, as part of food safety management system (FSMS), which are already used in many countries. Scientific assessment of chemicals in general has also a rather long “tradition.” What is new is use of risk analysis as a framework to view and respond to food safety problems in a systematic, structured and scientific way in order to enhance the quality of decision-making throughout food chain (FAO/WHO-Provisional Edition, 2005).

An effective FSMS helps in developing an effective “risk analysis framework” to collect and analyze the best available scientific information on a hazard that presents a risk to people, animals, or plants and consider the information along with other important nonscientific information, about a chemical, biological or physical hazard, possibly associated with food in order to select the best option to manage that risk based on various alternatives identified (FAO/WHO-Provisional Edition, 2005).
Risk analysis process begins with risk management defining problem, articulating goals of risk analysis and defining questions to be answered by risk assessment. Next step is to develop a risk profile, that is, science-based tasks of “measuring” and “describing” nature of risk being analyzed (i.e., risk characterization) are performed during risk assessment. Risk management and assessment are performed in an open and transparent environment based on communication and dialog. The process often culminates with the decision for implementation and continuous monitoring of a course of action by risk managers (FAO/WHO-Provisional Edition, 2005). But the process does not end with the decision itself. Members of the risk analysis team regularly monitor the success and impact of their decision. Modifications are made as required—on the basis of new data or information or changes in the context of the problem—to achieve further reductions in adverse human health effects (FSSAI, 2010).

5.4 RISK ASSESSMENT

Risk assessment is a process consisting of (1) hazard identification, (2) hazard characterization, (3) exposure assessment, and (4) risk characterization. Risk Assessment Policy should be laid down as per the FSMS and documented as per the requirements, maintaining the scientific integrity of the process. A risk profile describes food safety problem, which identifies, characterizes and assesses exposure to hazard and its effect as potential risk.

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. Specific identification of the hazard(s) of concern is a key step in risk assessment and to begin the process of estimation of risks specifically due to that hazard(s). Hazard identification may have already been carried out to a sufficient level during risk profiling; this generally is the case for risks due to chemical hazards. For microbial hazards, the risk profile may have identified specific risk factors associated with different strains of pathogens, and subsequent risk assessment may focus on particular subtypes. Risk managers are the primary arbiters of such decisions (CAC, 2013).

Hazard characterization is qualitative and/or quantitative evaluation of nature of 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. During hazard characterization, risk assessors describe the nature and extent of the adverse health effects known to be associated with specific hazard. A dose–response relationship is established between different levels of exposure to hazard in food at the point of consumption and likelihood of different adverse health effects. Dose–response assessment is the determination of relationship between magnitude of exposure (dose) to a chemical, biological, or physical agent and severity and/or frequency of associated adverse health effects.
(response). Types of data that can be used to establish dose–response relationships include animal toxicity studies, clinical human exposure studies, and epidemiological data from investigations of illness (CAC, 2013).

Exposure assessment is qualitative and/or quantitative evaluation of likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant. It characterizes amount of hazard that is consumed by various members of the exposed population(s). Analysis makes use of levels of hazard in raw materials, in food ingredients added to primary food and in general food environment to track changes in levels throughout food production chain. These data are combined with food consumption patterns of the target consumer population to assess exposure to hazard over a particular period of time in foods as actually consumed (CAC, 2013).

Risk characterization is where outputs from the previous three steps are integrated to generate an estimate of risk. Estimates can take a number of forms and uncertainty and variability must also be described if possible. A risk characterization often includes narrative on other aspects of the risk assessment, such as comparative rankings with risks from other foods, impacts on risk of various—what if scenarios, and further scientific work needed to reduce gaps. Risk characterization for chronic exposure to chemical hazards does not typically include estimates of the likelihood and severity of adverse health effects associated with different levels of exposure. A notional zero risk approach is generally taken and where possible the goal is to limit exposure to levels judged unlikely to have any adverse effects at all (CAC, 2013).

5.5 **RISK ASSESSMENT POLICY**

According to CAC (2013), determination of risk assessment policy should be included as a specific component of risk management. Risk assessment policy should be established as per the principles of FSMS by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that risk assessment is systematic, complete, unbiased, and transparent. The mandate given by risk managers to risk assessors should be as clear as possible. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options in accordance with risk assessment policy.

5.5.1 **SAFETY ASSESSMENT AS RISK ASSESSMENT**

The well-known no-observed-adverse-effect-level/safety factor-uncertainty factor (NOAEL/SF-UF) process has long been used to understand and regulate exposure to any potentially toxic substance. In controlled exposures, substance has no apparent or observable adverse health effect. Application of SF-UF(s), which typically composed of multiples of 10, produces a level of exposure that may lead to development
of a regulatory standard such as an Acceptable Daily Intake (ADI), a Provisional Tolerable Weekly Intake (PTWI), Reference Dose (RfD), or Minimal Risk Level (MRL). Although it was first introduced by US Food and Drug Administration for the purpose of regulating food additives, NOAEL/SF-UF procedure is now widely used for other potentially toxic substances also. A key feature of NOAEL/SF-UF procedure is that at no point does it yield a quantitative prediction of harm. NOAEL/SF-UF procedure is intended to establish safety. In a legal sense, procedure often defines what the word “safe” means for the potentially toxic substance (Carrington and Bolger, 2000).

Uncertainty remains an important part of safety assessment. It is usually understood that magnitude of uncertainty increases with degree of uncertainty, since NOAEL/SF-UF procedure is designed to establish “certainty,” that a substance is safe (e.g., a food additive). However, in a safety assessment there is no attempt to state either how great the uncertainty is or precisely what the impact of the uncertainty on risk management decisions.

Carrington and Bolger (2000) have observed that ADI concept is flawed because in practice, the ADI is viewed as an “acceptable” level of exposure, and, by inference, any exposure greater than ADI is seen as “unacceptable.” ADI was the basis for a regulation on food additives. It was used to calculate how much of the additive could be added to food, with acceptance of the agency as a matter of policy. In order to deal with this “problem,” the ADI was renamed as “RfD.”

5.6 RISK MANAGEMENT

Risk management is the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for health protection of consumers and for promotion of fair trade practices and for selecting appropriate prevention and control options, that is, monitoring measures, etc. The management of food-related risks therefore involves balancing of the recommendations formulated by experts and resources of all types that social and commercial groups and manufacturers can set aside for dealing with these risks (CAC, 2013).

Risk management should follow a structured approach including preliminary risk management activities, evaluation of risk management options, monitoring, and review of decision taken. Decisions should be based on risk assessment, and taking into account, where appropriate, other legitimate factors relevant for health protection of consumers and for promotion of fair practices in food trade. Risk assessment should be presented before making final proposals or decisions on available risk management options. Relevant production, storage, and practices used throughout the food chain (including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and prevalence of specific adverse health effects) must be a part of the risk assessment process.
Risk management process should be transparent, consistent, and fully documented. Preliminary risk management activities include: 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 result of risk assessment.

There should be a functional separation of risk assessment and risk management, in order to insure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.

5.7 GENERAL PRINCIPLES OF FOOD SAFETY RISK MANAGEMENT

1. Protection of human health should be primary objective in risk management decisions.
2. Risk management should follow a structured approach.
3. Risk management decisions and practices should be transparent, consistent, and fully documented.
4. Risk management should take into account whole food chain.
5. Risk management should insure scientific integrity of risk assessment process by maintaining the functional separation of risk management and risk assessment.
6. Risk managers should take account of risks resulting from regional differences in hazards in the food chain and regional differences in available risk management options.
7. Risk management should include clear, interactive communication with consumers and other interested parties in all aspects of the process.
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 (CAC, 2013).

5.8 RISK MANAGEMENT FRAMEWORK

A generic risk management framework for food safety risk management must be functional in both strategic, long-term situations (e.g., development of international and national standards when sufficient time is available) and in the short-term work of national food safety authorities (e.g., responding rapidly to a disease outbreak). In all cases, it is necessary to strive to obtain the best scientific information available. There are four components of risk management framework:

1. Preliminary risk management activities which comprise initial process, including establishment of a risk profile to facilitate consideration of issue
within a particular context, and provide as much information as possible to guide further action. As a result of this process, risk manager may commission a risk assessment as an independent scientific process to inform decision-making.

2. Evaluation of risk management options which involves weighing of available options for managing a food safety issue in the light of scientific information on risks and other factors, and may include reaching a decision on an appropriate level of consumer protection. Optimization of food control measures in terms of their efficiency, effectiveness, technological feasibility and practicality at selected points throughout the food chain is an important goal. A cost-benefit analysis could be performed at this stage.

3. Implementation of risk management decision will usually involve regulatory food safety measures like using HACCP. Flexibility in choice of individual measures applied by industry is a desirable element, as long as overall program can be objectively shown to achieve stated goals. Ongoing verification of application of food safety measures is essential.

4. Monitoring and review is gathering and analyzing of data so as to give an overview of food safety and consumer health. Monitoring of contaminants in food and FBD surveillance should identify new food safety problems as they emerge. Where there is evidence that required public health goals are not being achieved, redesigning of food safety measures will be needed (CAC, 2013).

### 5.8.1 PRELIMINARY RISK MANAGEMENT ACTIVITIES

- identify food safety issues
- develop risk profile
- establish goals of risk management
- decide on need for risk assessment
- establish risk assessment policy
- commission risk assessment, if necessary
- consider results of risk assessment
- rank risks, if necessary
- identification and selection of risk management options
- identify possible options
- evaluate options
- select preferred option(s)
- rank risks, if necessary

### 5.8.2 IMPLEMENTATION OF RISK MANAGEMENT DECISIONS

- validate control(s) where necessary
- implement selected control(s)
- verify implementation
- rank risks, if necessary
5.9 **RISK COMMUNICATION**

Risk communication is interactive exchange of information and opinions throughout 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 explanation of risk assessment findings and basis of risk management decisions.

Risk communication should:

1. promote awareness and understanding of specific issues under consideration during the risk analysis;
2. promote consistency and transparency in formulating risk management options/recommendations;
3. provide a sound basis for understanding risk management decisions proposed;
4. improve overall effectiveness and efficiency of risk analysis;
5. strengthen the working relationships among participants;
6. foster public understanding of the process, so as to enhance trust and confidence in safety of food supply;
7. promote appropriate involvement of all interested parties; and
8. exchange information in relation to concerns of interested parties about risks associated with food.

Risk analysis should include clear, interactive, and documented communication, among risk assessors and risk managers. In fact risk communication should be more than dissemination of information. Its major function should be to insure that all information and opinion required for effective risk management is incorporated into decision-making process.

Risk communication involving interested parties should include a transparent explanation of the risk assessment policy and of assessment of risk, including uncertainty. Need for specific standards or related texts and procedures followed to determine them, including how uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis, and minority opinions that had been expressed in the course of the risk assessment (**FAO/WHO-Provisional Edition, 2005**).

5.10 **CONCLUSIONS**

Role of risk analysis and risk communication in food safety management has been discussed and all components of risk analysis need to be adopted for effective implementation of Food Control Policies. Role of various stakeholders in performing their
respective tasks like those of Public Health and Veterinary Public Health, etc. must be clearly identified and assigned.

**APPENDIX A**

Some relevant definitions according to Indian FSS Act 2006 are

- “Food” means any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food as defined in the Act.
- “Food safety” means assurance that food is acceptable for human consumption according to its intended use.
- “Food Safety Management System” means the adoption of Good Manufacturing Practices, Good Hygienic Practices, Hazard Analysis and Critical Control Point and such other practices as may be specified by regulation, for the food business.
- “Primary food” means an article of food, being a produce of agriculture or horticulture or animal husbandry and dairying or aquaculture in its natural form, resulting from the growing, raising, cultivation, picking, harvesting, collection, or catching in the hands of a person other than a farmer or fisherman.
- “Risk” in relation to any article of food, means the probability of an adverse effect on the health of consumers of such food and the severity of that effect, consequential to a food hazard.
- “Risk analysis” in relation to any article of food, means a process consisting of three components, that is, risk assessment, risk management, and risk communication.
- “Risk assessment” means a scientifically based process consisting of the following steps: (1) hazard identification, (2) hazard characterization, (3) exposure assessment, and (4) risk characterization.
- “Risk communication” means the interactive exchange of information and opinions throughout the risk analysis process concerning risks, 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” means the process, distinct from risk assessment, of evaluating policy alternatives, in consultation with all interested parties considering risk assessment and other factors relevant for the protection of health of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.
- “Unsafe food” means an article of food whose nature, substance, or quality is so affected as to render it injurious to health.

CAC (2013) has provided the authentic definitions related to Food Safety as under:

*Hazard*: a biological, chemical, or physical agent in, or condition of, food with the potential to cause an adverse health effect.

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

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

*Risk assessment*: a scientifically based process consisting of the following steps: (1) hazard identification, (2) hazard characterization, (3) exposure assessment, and (4) risk characterization.

*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.

*Interested parties*: are risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations.
**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 assessment policy**: documented guidelines on the choice of options and associated judgments for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained.

**Risk profile**: the description of the food safety problem and its context.

**Risk characterization**: 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.

**Risk estimate**: the quantitative estimation of risk resulting from risk characterization.

**Hazard identification**: 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**: 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.

**Dose–response assessment**: the determination of the relationship between the magnitude of exposure (dose) to a chemical, biological, or physical agent and the severity and/or frequency of associated adverse health effects (response).

**Exposure assessment**: 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.

**Food safety objective (FSO)**: the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).

**Performance criterion (PC)**: the effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.

**Performance objective (PO)**: the maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable.

**Attrey (2008)** has identified the definitions from QMS resources as under:

- **Quality**: is the totality of features and characteristics of a product showing its ability to meet stated or implied needs or degree to which a set of inherent characteristics fulfils customer requirements.
- **Quality management**: are the coordinated activities to direct and control an organization with regard to quality.
- **System**: is a set of interrelated and interfacing elements. Quality System is the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.
- **Management system**: management system refers to what the organization does to manage its process or activities. It is a system to establish a Quality Policy and achieve quality objectives in an organization.
- **Quality management system (QMS)**: it is a management system, which directs and controls an organization with regard to quality. QMS has a set of requirements that deal with each aspect of the activities of the organization that affect quality.
- **Quality requirements**: ISO family of standards represents an international consensus on good management practices with the aim of ensuring that the organization can time and again
deliver the product or services that meet the client’s quality requirements. These good practices are combined in a set of standardized requirements for QMS (e.g., ISO 22000, the Food Safety Management System (FSMS), which has two parts, namely, “System Requirements” and “Product Quality Requirements”).

- **Quality assurance (QA):** all activities needed to provide adequate confidence that a product or service will fulfill the requirements for quality. All activities associated with the attainment of quality, constitute Quality Assurance. It is that part of quality management which focuses on providing confidence that quality requirements will be fulfilled.
- **Quality control (QC):** actions and systems to measure and regulate the “quality,” constitute Quality Control.
- **Implementation:** means putting all the intentions (Quality Policy and Objectives) into practice.
- **Process:** consists of a series of actions, which produce a change or a set of interrelated or interacting activities which transforms inputs into outputs. A series of operations or steps that results in a product or service or a set of causes and conditions that work together to transform inputs into an output.
- **Product:** in relation to the QMS, a product is either a tangible product obtained from raw materials through a series of standardized processes or it can be an intangible process/technology, a service or an information or scientific data, etc.

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