FOOD SAFETY MANAGEMENT MANUAL

Asian Productivity Organization

Food Safety Management Manual

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MEANING OF ABBREVIATIONS AND ACRONYMS

AB	Accreditation Bodies
APO	Asian Productivity Organization
ASEAN	Association of Southeast Asian Nations
Aw	Water Activity
BRC	British Retail Consortium
BSE	Bovine Spongiform Encephalitis
CB	Certification Bodies
CAC	Codex Alimentarius Commission
CCP	Critical Control Point
EU	European Union
FAO	Food and Agricultural Organization
FBD	Foodborne Diseases
FSMS	Food Safety Management System
GAP	Good Agricultural Practices
GDP	Good Distribution Practices
GHP	Good Hygiene Practices
GMP	Good Manufacturing Practices
GPP	Good Production Practices
GSP	Good Storage Practices
GTP	Good Trading Practices
GVP	Good Veterinary Practices
HACCP	Hazard Analysis Critical Control Point
IAF	International Accreditation Forum
IEC	International Electro-technical Commission
IFS	International Food Standard
ISO	International Organization for Standardization
IPPC	International Plant Protection Convention
MRA	Multilateral Recognition Agreement
MP	Management and Planning
NGO	Non-Governmental Organization
OIE	Office Internationale des Epizooties (World Organization for Animal Health)
OPRP	Operational Prerequisite Programs
PDCA	Plan-Do-Check-Act
PRP	Prerequisite Program
QC	Quality Control
QCC	QC Circle
SGA	Small Group Activities
SQF	Safe Quality Food
SME	Small and Medium Enterprise
SSE	Small Scale Enterprise
WHO	World Health Organization
WTO	World Trade Organization

FOREWORD

Food safety is a global issue affecting billions of people who suffer from diseases caused by contaminated food. This is one of the most widespread health problems and an important cause of reduced economic productivity. Both developed and developing countries share concerns over food safety as international food trade and cross-border movements of people and live animals increase. Governments worldwide are intensifying their efforts to improve food safety by updating national food regulatory systems. The food industry is putting in place modern food safety management systems (FSMS) to satisfy customers and consumers. The situation of food safety in developing countries in the Asia-Pacific region remains, however, far from satisfactory.

The main impediments to enhancing food safety are lack of awareness of the socioeconomic significance of food safety, paucity of data and information on foodborne disease incidence, lack of understanding of and compliance with food safety and quality standards based on international agreements, inadequate infrastructure and resources to support scientific risk management and upgrading of national food regulatory systems, inefficient food chains and poor traceability systems, and the high cost of implementing prerequisite requirements relating to food safety, particularly for small and medium enterprises (SMEs). There is an immediate need to strengthen FSMS at the national, local, and enterprise levels to develop safe, reliable food chains.

This being the case, the APO's food safety focus is on building the capacity of both the public and private sectors to strengthen FSMS in member countries. Both multi-country and in-country activities have been designed to meet the specific needs of the agrifood industry, especially of SMEs that constitute a major portion of the industry. Several projects have been organized over the past few years to train stakeholders in the skills, tools, and techniques of food safety management. This manual is published to disseminate more widely some of the important tools and techniques to supplement the efforts of governments, public and private organizations, and food companies in member countries to strengthen their FSMS.

The Food Safety Management Manual is based on the lectures and papers presented during different APO projects. The manual contains useful information needed to implement a FSMS at the enterprise level. By publishing this manual, the APO hopes that national productivity organizations, food industry enterprises, academics, trainers, and other stakeholders in member countries and elsewhere can learn more about food safety and possibly adopt food safety tools and techniques in their training and capacity-building activities. Efforts have been made to ensure that this is a stand-alone document covering essential tools, techniques, and approaches in a lucid manner.

I would like to record my sincere appreciation to Mr. Yong Kok Seng for compiling this volume.

Shigeo Takenaka
Secretary-General
Tokyo
June, 2009

ACKNOWLEDGEMENTS

In 2008, the APO commissioned Mr. Yong Kok Seng at QMC Resource Centre Private Limited, Penang, Malaysia to compile this Food Safety Management Manual.

The APO would like to express its grateful appreciation to Mr. Yong Kok Seng for contributions in the finalization of this manual. Special acknowledgement is due to all the references consulted during the preparation of the APO Food Safety Management Manual.

CHAPTER 1
GETTING STARTED

PURPOSE OF THIS MANUAL

This Food Safety Management Manual was compiled to give readers the information they need to implement food safety management in their enterprises.

But why are you reading this manual? This question is even more important. What you get out of this manual largely depends on what you are trying to get out of it.

You may be reading this manual because someone has asked you to do so. Or, you may be reading it because you think it will provide information that will be helping in your work.

WHAT THIS MANUAL IS BASED ON

This manual is based on the many papers, lectures, and presentations delivered in the course of APO multi-country and in-country programs, several of which were presented and written by Yong Kok Seng, the editor. You will find in it the main topics of the lead papers in a shortened and simplified format that requires less time and effort to read than the original papers. The original papers were all presented at APO events including training courses, seminars, e-Learning courses, and technical expert schemes.

There are at least two ways to use this manual:

1) As reading material for a learning group or study group process within your enterprise, and
2) for learning on your own.

HOW TO GET THE MOST OUT OF YOUR READING

Follow the steps below to absorb the information in this manual.

1) Get an overview of how the whole manual is set up.
2) Read Chapter 1 for an overview of how to get started.
3) Browse through the manual to have an idea of its design, style and flow. Notice how the chapters are structured and glance at the boxes / figures.

HOW TO READ EACH CHAPTER

Follow the steps below to absorb the information in each chapter.

1) Browse through the chapter, looking at the way it is laid out.
2) Read the chapter. As you read:
   - If the manual is your own, highlight key information that you feel is important to you.
   - If the manual is not your own, take notes on a separate sheet of paper.
3) Finally, read the "Summary" at the end of each chapter to confirm what you have learned. If you don't remember something in the summary, find the section in the chapter and review.

Reading Strategy

1) Getting an overview of the contents and then flipping through the materials will give you a framework to identify and remember new information in this manual.
2) For each chapter, repeat this process, by reading the headings first, then the boxes and summary. It is easier to learn if you take it a section at a time instead of trying to absorb all the information at once.

Using the Boxes

As you may already have noticed, each chapter apart from this one contains a number of boxes. These contain material that you may want to use or modify for creating presentation slides.

In most cases, the information in the boxes comprises a definition of key words, or key points, or a summary of the information that appears just before or after the box.

Note:
Definitions of key words are consistent with those that are defined in one of the following:
[1] International Standard ISO 22000; First Edition; 2005-09-01; Food safety management systems – Requirements for any organizations in the food chain; International Organization for Standardization.
[2] International Standard ISO 9000; Third edition; 2005-09-15; Quality management systems – Fundamentals and vocabulary; International Organization for Standardization.
[3] International Standard ISO 19011; Second edition; 20011-11-15; Guidelines for auditing managment system; International Organization for Standardization.
[4] Recommended International Code of Practice General Principles of Food Hygiene; CAC/RCP 1-1969, Rev, 4-2003; CODEX Alimentarius.

SUMMARY

- The purpose of this manual is to give you the information you need to implement FSMS in your enterprise.
- To get the most out of your reading experience, ask yourself why you are reading this manual.
- This manual is based on a compilation of the materials contained in the author's past papers and presentations.
- To begin reading, familiarise yourself with the contents, structure, and design of this manual.
- Follow the specific steps for each chapter.

CHAPTER 2
INTRODUCTION AND OVERVIEW

FOOD AND ITS IMPACT

Box 1: Definition of food

- **Food** is "any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum & any substance which has been used in the manufacture, preparation or treatment of food but does not include cosmetics or tobacco or substances used only as drugs."
- Food must be suitable and safe for human consumption.

Food, of course, is a critical aspect of all human lives. Consumers worldwide are increasingly demanding improved availability, suitability, and safety of food for themselves and their families. Sufficient and safe food supplies assist in the security and health of a country. With the liberalization of trade and globalization of the world's economies, food has become an international commodity and as such is being traded across borders and seas to contribute to a nation's development and growth.

Managing food so it is suitable and safe for human consumption is an imperative for each country and its food industry.

Foodborne diseases (FBD) cause enormous suffering to human lives even in the most developed countries. The statistics are staggering. According to the WHO, contaminated food contributes to 1.5 billion cases of diarrhea in children each year.[1]

In industrialized countries, an estimated one in three people are struck by FBD each year, largely from mass-catered food. In the United States, FBD causes approximately 76 million illnesses annually, as well as 325,000 hospitalizations and 5,000 deaths.[2]

Sadly, it is even worse in less-developed countries. There are an estimated 2,163,000 deaths annually throughout the world caused by diarrheal diseases including 684,000 in the Southeast Asian region.[3]

Box 2: Deaths caused by diarrheal diseases[4]

According to the WHO's 2004 Update on "The Global Burden of Disease," diarrheal diseases caused:

- 2.2 million deaths of all ages
- Nearly 1.8 million deaths of children under the age of 5.

FBD has emerged as an important and growing public health and economic problem in many countries over the past two decades. Frequent outbreaks caused by new pathogens, the use of antibiotics in animal husbandry, and the transfer of antibiotic resistance to humans, as well as concerns about bovine spongiform encephalitis (BSE) are just a few examples. Countries with reporting systems have documented significant increases in the incidence of FBD during this time.

Some notable cases of FBD in Asia have been:

- In 1988, in China, a Hepatitis A epidemic associated with the consumption of clams infected some 292,000 people, killing nine.[5]
- In 2000, in Japan, food poisoning linked to milk products produced in an Osaka factory of the Snow Brand Company caused 14,780 people to fall sick, making it one of the largest food poisoning outbreaks ever in that country.[6]
- In 2002, in China, more than 200 schoolchildren fell sick and 38 died from the intentional contamination of bakery products after a competitor allegedly put rat poison into the breakfast snacks of a restaurant in Tangshan, a suburb of Nanjing.[7]

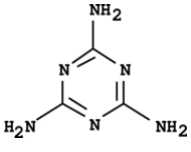
Box 3: Tainted infant formula in China [8]

As reported in September 2008 in China:

- 39,965 infants received medical treatment after consuming tainted infant formula.
- 12,892 infants were hospitalized.
- Three confirmed and one unconfirmed deaths were reported.
- Over 80% of the patients were below 2 years of age.

This scandal occurred from the intentional adulteration of milk with melamine over a number of months.

Box 4: A chemical hazard – Melamine



Melamine is a byproduct of the coal industry. It is a chemical compound with various industrial uses, including the production of plastics, dishware, kitchenware, commercial filters, laminates, adhesives, moulding compounds, coatings and flame retardants. It is high in nitrogen and this has led to its illegal addition to food and feed for the purpose of increasing the apparent protein content of food and feed products.

Faced with outbreaks and threats of FBD, governments and the food industry are making it a top priority to ensure that food is safe for consumers.

ECONOMIC COSTS RELATED TO FOOD SAFETY

FBD creates an enormous burden on the economy. Consumer costs include medical, legal, and other expenses, as well as absenteeism from work and school. For many consumers who live at a subsistence level, the loss of income due to FBD can perpetuate the cycle of poverty.[9] Chronic diseases caused by contaminated food, including reactive arthritis or temporary paralysis, can be even more damaging than the initial disease and add dramatically to medical costs and lost wages.[10]

Costs to national and local governments include increased medical expenses, outbreak investigations, food recalls, and loss of consumer confidence in food products. In developing countries, FBD leads to increased demands on already overburdened and poorly funded health care systems.

Box 5: Economic cost of foodborne diseases – some examples

- USA – USD5.6 to USD9.4 billion in lost work and medical expenses annually
- EU – EUR3 billion incurred by the health care system annually
- Australia – AUD2.6 billion from cases of food poisoning annually

The best estimates of the economic costs of FBD come from developed countries:

- In the United States, a government study of seven foodborne pathogens reported a cost of between USD5.6 billion to USD9.4 billion in lost work and medical expenses.[11]
- In the European Union, annual costs leveled on the health care system as a consequence of salmonella infections are estimated to be around EURO 3 billion.[12]
- In Australia, the cost of an estimated 11,500 daily cases of food poisoning was calculated at AUD2.6 billion annually.[13]

With the globalization of the food trade, countries also suffer economic consequences when unsafe food results in lost exports. For example, the effect on both Canadian and U.S. beef exports from findings of BSE in their cattle populations resulted in losses of USD5 billion for the Canada beef sector[14] and USD2.6 billion for the U.S. beef sector[15] in 2004.

Tourism is also of great economic importance for many countries. As a consequence of "traveler's diarrhea," FBD can damage the reputation of a country as a tourist destination and can have huge consequences on its economy.

CONCERNS AND TRENDS IN FOOD SAFETY

Food safety challenges differ by region due to differences in income level, diet, local conditions, and government infrastructure.

In developing countries, the food producer and the consumer often have a close connection. There are fewer processed and packaged foods; most fresh food is traded in traditional markets, and street vendors supply much of the food consumed outside the home. Perishable food is often prepared and consumed immediately, and there is minimal storage of prepared food.

Food safety concerns in developing countries typically include:

- inappropriate use of agricultural chemicals
- use of untreated or partially treated wastewater
- use of sewage or animal manure on crops as fertilizer
- absence of food inspection, including meat inspection
- lack of infrastructure, such as adequate refrigeration
- poor hygiene, including a lack of clean water supply

As a country's economy develops, its participation in the global food economy and capital investment in the agriculture sector increase.[16] That gives consumer access to both common and exotic/imported foods throughout the year.

Box 6: Trends in food safety challenges

- Changes in animal husbandry practices
- Changes in agronomic practices
- Increase in international trade
- Changes in postharvest food and agriculture technology
- Increase in susceptible populations
- Increase in international travel
- Changes in lifestyle and consumer demand
- Bioterrorism

The following trends, as reported by WHO[17] in both developed and developing countries, can present heightened food safety challenges.

Changes in Animal Husbandry Practices

Modern intensive animal husbandry practices have been used to maximize production. This has resulted in the emergence and increased prevalence of several human pathogens, such as Salmonella and Campylobacter, in flocks or herds of all the most important production animals (poultry, cattle, and pigs). Crowding of animals has led to increased use of antibiotics on so-called "factory farms," which in turn has been linked to the emergence of new strains

of antibiotic-resistant bacteria; feeding practices also have come under increased scrutiny as a result of BSE.

Changes in Agronomic Practices
Agricultural practices have contributed to increased health risks associated with fresh fruit and vegetables, such as the use of manure, chemical fertilizers, untreated sewage, or irrigation water containing pathogens. Outbreaks linked to fruits and vegetables have increased in some regions, especially where improvements in transportation and access to imported fruits and vegetables are giving consumers more fresh produce year round.[18] Examples include a major *E.coli O157:H7* outbreak in Japan linked to sprouts involving more than 9,000 cases in 1996, and several recent *Cyclospora* outbreaks associated with raspberries in North America and Canada, and lettuce in Germany.[19, 20, 21] Consumers are also concerned about the safety of genetically engineered plant and animal products.

Increase in International Trade
International trade allows for the rapid transfer of microorganisms from one country to another. The increased time between processing and consumption of food leads to additional opportunities for contamination and time / temperature damage, and elevates the risk of FBD. Increasing cross-border trade also means that new and unfamiliar foodborne hazards can reach consumers who have not developed immunities to those pathogens.

Changes in Postharvest Food and Agriculture Technology
Advances in processing, preservation, packaging, shipping, and storage techniques bring new forms of foods to the market, and sometimes introduce new hazards. For example, the increased use of refrigeration to prolong the shelf-life of ready-to-eat foods has contributed to the emergence of Listeria monocytogene. [22]

Increase in Susceptible Populations
Due to advances in medical treatment, people are living longer, and surviving with chronic medical conditions that previously used to kill them at an earlier age. By the year 2025, more than one billion of the world's population will be over 60 years of age, two-thirds of whom will live in developing countries. As a result, in some countries, one person in four faces a higher risk of contracting a foodborne disease.

Increase in International Travel
Persons exposed to a foodborne illness in one country can expose others to the infection in a location thousands of miles from the original source.

Changes in Lifestyle and Consumer Demand
Many trends impact the frequency and nature of FBD. Consumers like to have access to seasonable foods all year long. In many developed countries, a larger share of the food budget is spent on food prepared outside the home. In developing countries, there is a general rise in urban living and street food is

an important component of the daily diet. As a result, outbreaks associated with food prepared outside the home are increasing in many regions.

Bioterrorism

Following rising incidents of terrorist attacks in many countries in recent years, concerns about intentional adulteration of food by terrorists, criminals, or other antisocial groups have risen and led to the need for new preparedness efforts. The WHO states that "the key to preventing food terrorism is to enhance existing food safety programs. Strengthening national food safety programs requires that national policies and resources to support the infrastructure are in place and that food legislation, food monitoring and surveillance, food inspection, food disease surveillance, and education and training are adequate and up-to-date."[23]

SUMMARY

- Consumers are demanding improved availability, suitability and safety of food. Sufficient and safe food assists in the security and health of a country. Food itself is an international commodity.
- Managing food to be suitable and safe for human consumption is an imperative concern for the country and the food industry.
- Statistics and incidents show that foodborne diseases (FBD) are causing enormous suffering to human lives.
- FBD creates a burden on the economy and loss of income for many consumers. The loss of income to those who live at a subsistence level can perpetuate the cycle of poverty.
- FBD leads to increased demands on already overburdened and poorly funded healthcare systems in developing countries.
- Food safety challenges differ by region, due to differences in income level, diets, local conditions, and government infrastructure.
- Many changes and improvements happening in the world are posing new challenges to food safety.

ENDNOTES

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CHAPTER 3
KEY CONCEPTS IN FOOD SAFETY MANAGEMENT

BASIC CONCEPTS AND PRINCIPLES

Box 7: Food – intended for human consumption

Food - suitable and safe for human consumption

- Suitable for human consumption according to these criteria:
  - Has been produced under hygienic conditions
  - Is appropriate for its intended use (e.g., Halal and Vegetarian)
- Safe for human consumption according to these criteria:
  - Has been produced by applying all food safety requirements appropriate to its intended end-use
  - Does not contain hazards at levels that are harmful to human health

Food Hygiene

In order to process and handle food safely, the foremost and most fundamental consideration must be food hygiene.

"Food hygiene" refers to all conditions and measures necessary for the safety and suitability of food at all stages of the food supply chain.

Food Safety

Food safety is defined as the "concept that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use." Food safety is related to the prevention and elimination of food safety hazards.

"Food safety hazard" refers to any biological, chemical or physical agent in food, or the unsafe condition of food, with the potential to cause an adverse health effect.

(See Appendix A for examples of food safety hazards.)

Food safety involves the occurrence of food safety hazards and does not include other human health aspects such as malnutrition. However, it does include allergens. Allergens are proteins or compounds that elicit an adverse physical reaction in a segment of the population.

(See Appendix B for examples of food allergens.)

Food Chain

Box 8: Definition of food chain

The food chain is the sequence of the stages and operations involved in the:

- production
- processing
- distribution
- storage and handling

of a food and its ingredients, from primary production to consumption

The food chain includes the production of:

- feed for food-producing animals and for animals intended for food production, and
- materials intended to come into contact with food or raw materials

Food safety is related to the presence of and levels of foodborne hazards in food at the point of consumption (intake by the consumer). As the introduction of food safety hazards can occur at any stage in the food chain, adequate control throughout the food chain is essential. Thus, food safety must be ensured through the combined efforts of all parties participating in the food chain.

Enterprises within the food chain range from feed producers and primary producers through to food manufacturers, transport, and storage operators and subcontractors to retail and food service outlets (together with inter-related enterprises such as producer of equipment, packaging materials, cleaning agents, additives, and ingredients). Service providers are also included.

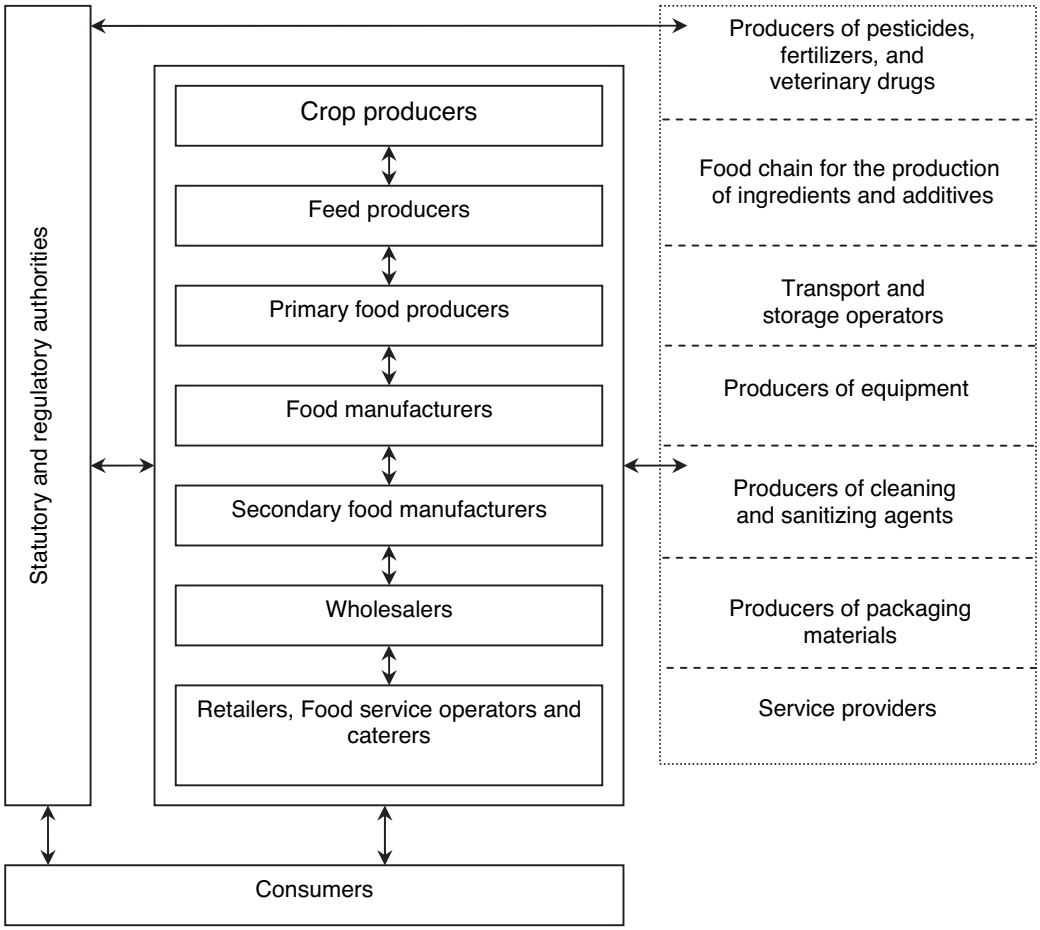


Figure 1. The food chain

GOOD HYGIENE PRACTICES

Box 9: Definition of GHP

- Refers to all practices regarding the conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain
- "Practices" simply means the actions or activities that need to be consistently carried out.

The food-processing business carries with it huge responsibilities compared to other types of business because of the risk of contaminants in food that can endanger the health and life of consumers. A contaminant is any biological or chemical agent, foreign matter, or other substance not intentionally added to food that may compromise food safety and suitability.

The practice of a high level of good hygiene eliminates the possibility of contamination from bacteria and other pathogens, hazardous chemicals,

as well as the accidental introduction of hazardous chemicals and other compounds that can leave residues in food products, and other impurities affecting product quality.

Good hygiene practices (GHP) are basic conditions and activities that are necessary to maintain a hygienic environment suitable for the production, handling, and provision of safe end products and safe food for human consumption.

Regardless of the size and type of the food processing enterprise, GHP is a prerequisite program (PRP) that will lay the foundation so that more enhanced preventive and risk-based approaches to food safety management can be pursued.

On an international basis, the fundamental document on GHP is the "Recommended International Code of Practice General Principles of Food Hygiene, CAC/RCP 1-1969, Rev. 4-2003" published by the Codex Alimentarius Commission.

(See Appendix C; the document is available for download at http://www.codexalimentarius.net/).

Box 10: Codex Alimentarius Commission

- The **Codex Alimentarius Commission** was created in 1963 by the FAO and WHO to develop food standards, guidelines, and related texts under the Joint FAO/WHO Food Standards Program.
- The main purposes of this program are protecting the health of consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.
- Texts – some very general, some very specific, some deal with detailed requirements related to a food or group of food, others with the operation and management of production processes or the operation of government regulatory systems for food safety and consumer protection.
- Codex code of practices – define the production, processing, manufacturing, transportation, and storage practices for individual or group of foods that are considered as essential to ensure the suitability and safety of food for consumption.

This document identifies the essential principles of food hygiene applicable throughout the food chain, to achieve the goal of ensuring that food is safe and suitable for human consumption. It provides a baseline structure and indicates how to implement those principles.

In reference to the above document, the principles of GHP are categorized into:

- Primary production
- Establishment: design, facilities, and equipment
- Control of operation (process control)
- Establishment: maintenance and sanitation
- Personal hygiene
- Transportation
- Product information and consumer awareness
- Training

GHP is considered to be a prerequisite program (PRP).

PREREQUISITE PROGRAMS

Prerequisite programs – PRPs – are the basic conditions and activities needed to maintain a hygienic environment throughout the food supply chain. Every organization in the food supply chain is required to have its own set of PRPs that address food safety issues in its unique environment.

The PRPs needed by an enterprise depend on the segment of the food chain in which it operates and the type of enterprise.

Box 11: Prerequisite programs

Other examples of equivalent terms are:

- Good Agricultural Practices (GAP)
- Good Manufacturing Practices (GMP)
- Good Production Practices (GPP)
- Good Storage Practices (GSP)
- Good Distribution Practices (GDP)
- Good Veterinary Practices (GVP)
- Good Trading Practices (GTP)

Intent of PRPs

An enterprise establishes, implements, and maintains one or more PRPs to assist in controlling:

- the likelihood of introducing food safety hazards to a product through the work environment
- biological, chemical, and physical contamination of the product(s), including cross contamination between products, and

- food safety hazard(s) levels in the product and product processing environment.

Box 12: Actions relating to good hygiene – some examples

Operations in food processing comprise the manufacture of value-added products from primary products.

Some actions relating to the principles of good hygiene that are crucial for food processing operations include:

- Preventing microbial contamination of raw materials, intermediate (semi-manufactured) goods, and final products through absolute cleanliness of tools, work tables, and machines as well as the hands and workclothes of personnel.
- Minimizing or reducing microbial growth by storing at a low temperature. (Semi-manufactured goods must be refrigerated during production breaks and rest periods. Processing steps take place under acclimatized conditions or ambient temperature).
- Eliminating microbial contamination by applying heat treatment at the final processing stage for extension of shelf life of products (except dried and fermented final products, which are shelf-stable through a low Aw and pH), elimination of contamination in fully sterilized (canned) products.

PRPs need to take into consideration the conditions, steps, or actions that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

PRPs must:

- be appropriate to the enterprise's needs with regard to food safety
- be appropriate according to the size, type of operation, and nature of the products being manufactured and/or handled
- be implemented across the entire production system

Selecting PRPs

The enterprise needs to identify statutory and regulatory requirements related to the above.

When selecting and/or establishing PRPs, the enterprise has to consider and utilize appropriate information from:

- statutory and regulatory requirements
- customer requirements
- recognized guidelines
- Codex principles and codes of practices
- national, international, and/or sector standards

Box 13: National framework for PRPs

- Regulatory authorities usually provide a compulsory national framework for hygiene programs (PRPs) through laws and regulations and monitor the implementation of such laws.
- At the industry level, it is the primary responsibility of individual enterprises to develop and apply effective PRPs specially adapted to their relevant range of production.

The Codex Codes are not enterprise-specific but apply to all types of food processing enterprises. Versions of PRPs that are enterprise-specific and process-specific need to be established and compiled taking into account all laws and regulations as well as recommended codes of practice.

The enterprise has to consider the following when establishing these programs:

- construction and layout of buildings and associated utilities
- layout of premises, including workspace and employee facilities
- supply of air, water, energy, and other utilities
- supporting services including waste and sewage disposal
- suitability of equipment and its accessibility for cleaning, maintenance, and preventative maintenance
- management of purchased materials (e.g., raw materials, ingredients, chemicals, and packaging), supplies (e.g., water, air, steam, and ice), disposal (e.g., waste and sewage), and handling of products (e.g., storage and transportation)
- measures for the prevention of cross-contamination
- cleaning and sanitizing
- pest control
- personal hygiene
- other aspects as appropriate

Verification of PRPs has to be planned and they need to be modified as necessary. Records of verifications and modifications must be maintained.

There is a need to have documents specifying how activities included in the PRPs are managed.

(See Appendix D: List of Codex References, which provides Examples of Prerequisite Programs and Guidance for Their Selection and Usage.)

RISK AND RISK ANALYSIS

The concepts of risk and hazard and their respective analyses are often mixed up because of their close relationships.

Box 14: Definition of food safety risk

- Risk is a function of the probability of an adverse health effect and the severity of that effect when exposed to a specified hazard.
- Risk is a combination of the probability of occurrence of harm (exposure) and the severity of that harm (adverse health effect).
  - *Probability*: The chance or likelihood of a hazard being present
  - *Severity*: The extent of the adverse health effect (e.g., death, hospitalization, absence from work, etc.)
  - *Adverse health effect*: e.g., becoming diseased
  - *Exposure*: Estimation of intake of hazard through food

Food safety is a fundamental public health concern, and achieving a safe food supply poses major challenges for national food safety officials. An array of foodborne hazards, both familiar and new, poses risks to health and obstacles to international trade. These risks must be assessed and managed to meet growing and increasingly complex sets of national objectives.

Box 15: Definition of risk analysis

A systematic approach for making food safety decisions includes three major components:

- risk assessment
- risk management
- risk communication

Food safety management at the national level deals with risk and risk analysis. It is a high-level and generic approach that food safety regulators need to understand, and for which countries need to develop their own procedures. Risk analysis is a powerful tool for carrying our science-based analysis and for reaching sound, consistent solutions to food safety problems. The use of risk analysis can promote ongoing improvements in public health and provide a basis for expanding the international trade of food.

The WHO/FAO have published a useful document entitled "*Food Safety Risk Analysis – A Guide for National Food Safety Authorities.*" This guide is targeted at food safety officials in national governments. It facilitates application of risk analysis by a codex to:

- improve food safety regulators' understanding and use of risk analysis
- assist countries in developing their own risk analysis procedures
- support training to promote the use of risk analysis at the national level

The guide is available for download from http://www.who.int/foodsafety/publications/micro/riskanalysis06/en/

Box 16: WHO/FAO publication on food safety risk analysis

HAZARD ANALYSIS AND HACCP

Food is rendered unsafe through the presence of biological, chemical, and physical hazards. In the food chain, processors must be proactive in addressing the potential for hazards to enter at the plant and processing level, usually through performing hazard analysis, and applying the Hazard Analysis and Critical Control Point (HACCP) system.

In performing hazard analysis, each identified potential hazard is assessed (or given "hazard assessment") as to its significance in connection to causing risks to human health. In other words, it means conducting a hazard assessment based on the probability of occurrence and the severity of adverse health effects.

(See Appendix E: Example of a Hazard / Risk Assessment Table)

HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. It identifies specific hazards and measures for their control to ensure the safety of food.

Box 17: Definition of hazard analysis and HACCP

- "Hazard analysis" is the process of collecting and interpreting information on hazards and conditions leading to their presence in order to decide which are significant for food safety and should be addressed in the HACCP plan.
- "HACCP" is a system which identifies, evaluates, and controls hazards which are significant for food safety.
- "HACCP Plan" is a document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration.

HACCP incorporates hazard analysis and additional steps to arrive at an HACCP Plan. There are a total of 12 application steps that include the basic seven principles of HACCP as the last steps. The first five application steps are collectively called the "preliminary steps," which aim at gathering factual and current information and data. This is very important, as the HACCP system is science-based and systematic. The final outcome of the 12 application steps is the HACCP Plan.

Box 18: Application steps and principles of HACCP

Application Step No.	Principle No.	Description
1	**-**	Assemble HACCP Team
2	**-**	Describe product
3	**-**	Identify intended use
4	**-**	Construct flow diagram
5	**-**	Confirm flow diagram on-site
6	**1**	List all potential hazards Conduct a hazard analysis Consider control measures
7	**2**	Determine Critical Control Points (CCP)
8	**3**	Establish Critical Limits for each CCP
9	**4**	Establish monitoring system for each CCP
10	**5**	Establish corrective actions
11	**6**	Establish verification procedures
12	**7**	Establish documentation and record keeping

CONTROL MEASURES

To ensure safe food, hazards have to be prevented from entering into the food supply, or if hazards are already present in it, they must be eliminated or reduced to an acceptable level. Appropriate action has to be taken accordingly.

Box 19: Definition of control measure

- Action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level

Some examples of control measures for different hazards are:

For biological hazards:

- Temperature control (e.g., proper control of refrigeration and storage time to minimize growth of pathogens)
- Thermal treatment (e.g., pasteurization)
- Cooling and freezing (e.g., cooling and freezing to retard the growth of pathogenic bacteria)
- Fermentation and/or pH control (e.g., fermentation of apple cider by yeast produces ethanol which is inhibitory to pathogenic bacteria)

- Addition of preservatives (e.g., salt and other preservatives inhibit growth of some pathogenic bacteria)
- Thermal process (e.g., sufficient heating destroys viruses)
- Drying or concentration (reduction of water activity) may remove enough water from food to prevent pathogens from developing
- Source control (e.g., the presence of pathogens in raw materials may be controlled by obtaining them from non-contaminated sources; preventing parasites from access to fruit by using GAP)
- Personal hygiene (especially handwashing) limits the spread of viruses. This is usually addressed in the PRP.
- Inactivation / removal (e.g., some parasites, such as Cryptosporidium, are resistant to chemical disinfection but can be inactivated by heating, drying, or freezing)

For chemical hazards:

- Source control (e.g., vendor certification and raw material testing)
- Production control (e.g., proper use and application of food additives)
- Process control (e.g., proper application of processes such as washing, scrubbing, and culling – separating damaged fruit from undamaged to control patulin fruit rot)
- Labeling control (finished product properly labeled with ingredients and known allergens)
- Production scheduling (e.g., running products containing allergens last in the production run)

For physical hazards:

- Source control (e.g., vendor certification and raw material testing)
- Production control (e.g., use of magnets, metal detectors, sifter screens, destoners, clarifiers, air tumblers, and x-ray equipment)

SUMMARY

- Foods must be processed under hygienic conditions and by activities that ensure food safety at all stages of the food chain.
- Good hygiene practices, prerequisite programs, risk and hazard analysis, together with control measures form the key concepts in food safety management.
- GHP, GAP, GMP, GPP, GDP, GVP, GTP are all PRPs.
- The most fundamental document on GHP is the "Recommended International Code of Practice General Principles of Food Hygiene, CAC/RCP 1-1969, Rev 4-2003" published by the Codex Alimentarius Commission.
- Regulatory authorities usually provide a compulsory national framework for PRPs through laws and regulations, and monitor the implementation of such laws.
- At the industry level, individual enterprises develop and apply effective PRPs specially adapted to their relevant range of production.
- Risk analysis is applied at the country level while hazard analysis is applied at the enterprise operational level.
- The 12 application steps of HACCP include five preliminary steps and seven principles of HACCP.
- Control measures are actions or activities that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

CHAPTER 4
PRODUCTIVITY TOOLS AND TECHNIQUES FOR FOOD PROCESSING ENTERPRISES

There are many productivity tools and techniques that can be implemented by enterprises for more efficient and effective operations. Explained below are those considered most beneficial for application by food processing enterprises.

5S

A workplace that is well organized, free of clutter and unnecessary things, arranged so that tools, containers, ingredients, etc. can be easily located, and sparkling clean is one that would augur well for a hygienic environment for a food-processing enterprise. 5S can make the workplace cleaner, more hygienic and safer, and the job simpler and more satisfying.

The 5S approach or method is simple and universal. It works in companies all over the world, in all types of enterprises. 5S activities provide essential support for successful implementation of PRPs and other important improvements in the enterprise, such as shorter process / equipment changeover, just-in-time inventory systems, and total productive maintenance.

Box 20: Meaning of 5S

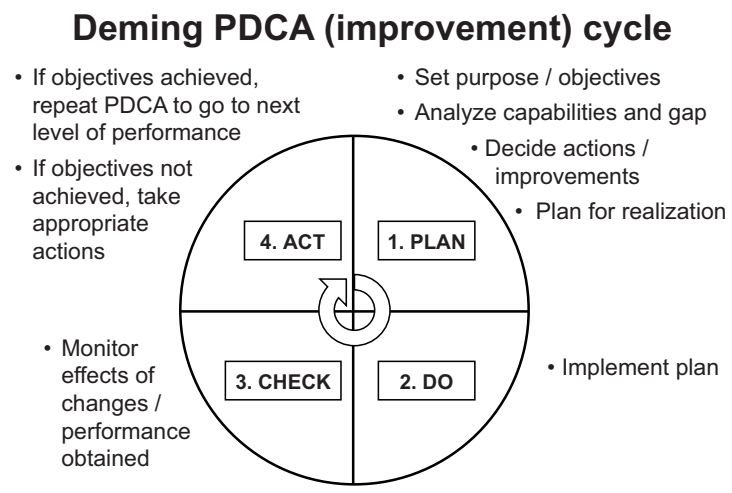
Japanese	English	Meaning	Example
Seiri	Sort	Organization	Separate necessary items from unnecessary ones and discard the latter
Seiton	Set in order	Orderliness/ Neatness	Arrange necessary items in good order so that they can be quickly retrieved for use
Seiso	Shine	Cleanliness	Individual cleaning responsibility – clean & inspect the workplace so that there is no dirt on the floor or machines
Seiketsu	Standardize	Standardized Cleanup/Hygiene	Visibility of storage – maintain a high level of workplace organization by keeping everything clean and orderly at all times
Shitsuke	Sustain	Discipline	Carry out 5S daily – practice 5S continuously so that it becomes habitual and ingrained in the culture of the enterprise

5S refers to five Japanese words that form the basic activities of this method. These activities are considered the five pillars of an effective workplace. It is the basic Japanese approach of "house-keeping" that can be used to bring about improvements to the environment of the workplace.

PDCA (PLAN-DO-CHECK-ACT)

PDCA is the basic model for a systematic approach to improvement and problem-solving. The four universal steps can be applied to any situation together with appropriate tools and techniques.

Box 21: Model of Deming PDCA



The PDCA cycle was first developed by Dr. Walter Shewhart (1891–1967), but it was Dr. William Edwards Deming (1900–1993) who made it so well known that most people now call it the Deming Cycle. In earlier days, the Japanese called it the "Kanri (Control) Cycle." It is also referred to as the "Improvement Cycle."

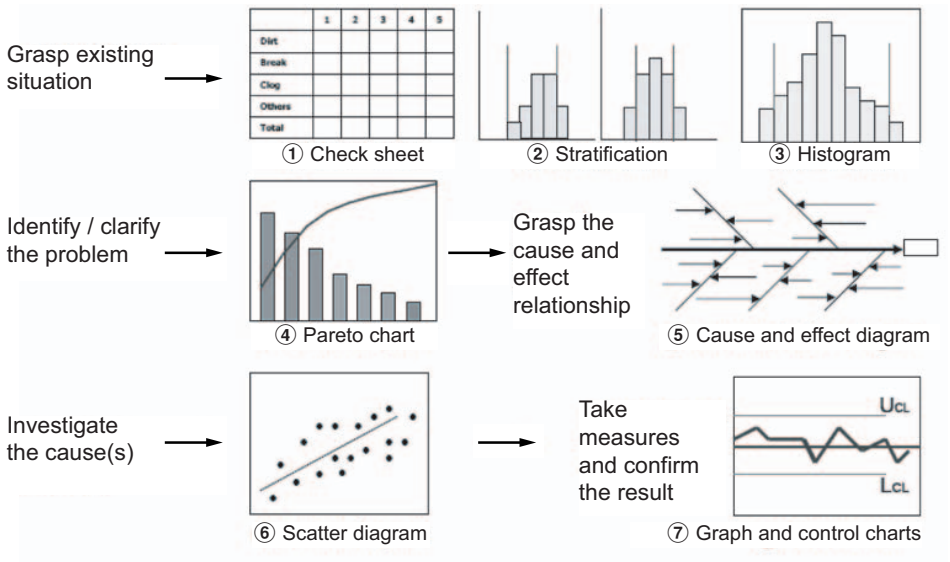
In an FSMS, PDCA can be applied to solve problems or non-conformities that relate to products, procedures, and practices of enterprises. On a proactive basis, PDCA can be used for improvement projects taking into consideration that improvement means a level far superior to any previous level.

Tools and techniques need to be used in conjunction with the steps in the cycle. The most common and basic set of Quality Control (QC) tools and techniques are the "7 QC Tools." On a more advanced basis, the "7 Management and Planning Tools" may be used as well.

THE 7 QC TOOLS

The 7 QC Tools are also known as "7 problem solving tools" or "7 improvement tools." They can be used either individually or in relation with one another to understand or solve an issue. They assist in factual approaches to decision making.

Box 22: The 7 QC Tools



The 7 QC Tools, and their respective usage according to Japanese management experts, are as follows:

- **Check sheet** (data collection) – to facilitate collection of data for ease of decision-making and/or taking action.
- **Stratification** – to separate out groups of data (e.g., by shift, by machine, by product line, etc.) which may be mixed together so as to have a clearer picture of the situation.
  Stratification is not listed as a tool for the American version of the 7 QC Tools. However, flowcharting is used.
- **Histogram** – to group numerical data in a bar / column chart so as to understand the distribution and variation of the data.
- **Pareto chart** – to identify the "vital few" items against the "useful many" so as to take action on those items which are identified as the vital few.
- **Cause and effect diagram** – also known as the "fishbone diagram" as it resembles a fish with bones, or "Ishikawa diagram," as it was developed by Prof. Kaoru Ishikawa (1915–1989) to determine the causes of a problem (effect).

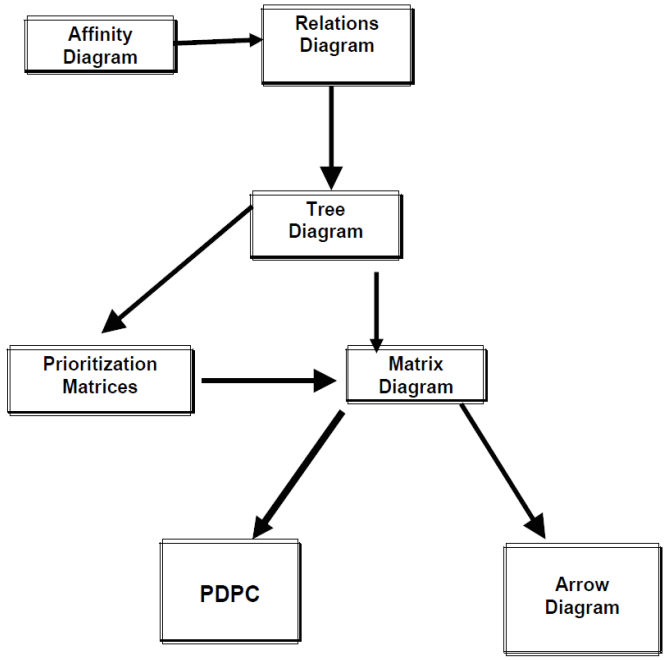
- **Scatter diagram** – to understand the correlation of two sets of variable parameters so as to understand their relationships and take action on any one of them accordingly.
- **Graph and Control charts** – are line graphs with continuous plots of data on them, plus "control limits" to predict the future performance of process and take preventive actions in advance.

THE 7 MP TOOLS

The 7 Management and Planning (MP) Tools are also known as "7 Advanced Tools" in comparison with the "7 QC Tools." They can be used either individually or in relation with one another to understand, manage, or plan a project.

In 1976, the Union of Japanese Scientists and Engineers (JUSE) felt the need for tools to promote innovation, communicate information, and successfully plan major projects and developed the seven new QC tools. Not all the tools were new, but their collection and promotion were.

Box 23: The 7 MP Tools



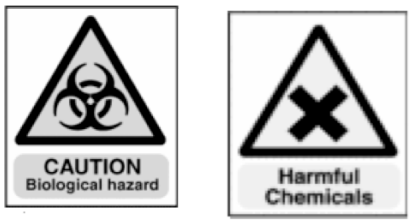
The 7 MP Tools, listed in an order that moves from abstract analysis to detailed planning, are:

- **Affinity diagram** – organizes a large number of ideas into their natural relationships.

- **Relations diagram** – also known as the interrelationship diagram; shows cause-and-effect relationships and helps to analyze the natural links between different aspects of a complex situation.
- **Tree diagram** – breaks down broad categories into finer and finer levels of detail, helping to move thinking step-by-step from generalities to specifics.
- **Matrix diagram** – shows the relationship between two, three, or four groups of information and can give information about the relationship, such as its strength, the roles played by various individuals, or measurements.
- **Matrix data analysis** – a complex mathematical technique for analyzing matrices, often replaced in this list by the similar "prioritization matrices." One of the most rigorous, careful, and time-consuming of decision-making tools. This is a useful tool to decide what to do after key actions, criteria, or critical to quality (CTQ) characteristics have been identified, but their relative importance is not known with certainty.
- **Process decision program chart (PDPC)** – systematically identifies what might go wrong in a plan under development.
- **Arrow diagram** – also known as "activity network diagram;" shows the required order of tasks in a project or process, the best schedule for the entire project, and potential scheduling and resource problems and their solutions.

VISUAL CONTROL

Box 24: Visual control



"A pictures is worth a thousand words." This is the essence of visual control. Visual control is a method by which the condition of food processing premises and food production can be judged instantly just by looking at them.

With visual control, everyone can recognize abnormalities promptly and take necessary action. Furthermore, visual information is easy to understand and promotes discipline and cooperation at the workplace especially when workers lack education or extensive training.

Some examples of visual control:

- Indication of flows of materials / products / workers and passage area
- Layout / location map showing the different level of hygienic areas
- Signboard / line demarcation of the storage places for raw materials, work-in-progress and finished products
- Signboards / line demarcation of the holding places for nonconforming / expired / quarantine / returned products
- Warning signboards of processes which are CCP, restricted areas, etc.
- Operating procedures with pictures and illustrations
- Hand washing / dressing instructions with pictures
- Limit accept / reject samples
- Charts showing acceptance / rejection rate
- Inspection / test results
- Dispatch / delivery boards
- Monthly and daily production progress

KAIZEN

Box 25: *Kaizen*

改善

Kaizen is simply the Kanji (Japanese) word for "improvement." It is composed of two parts, "change" and "better." It is the basic concept of improvement and can be implemented to achieve small and incremental improvements in an enterprise.

Kaizen can be undertaken in three main ways in the workplace (in Japanese: *gemba*), namely:

- **Individual *kaizen*** – not simply "suggestions" (for other people to implement) but actually making the improvement, which may be applied to any aspect of the working area.
- **Quality Control Circles (QCC)** – where groups of employees in the same workplace or the same function meet regularly to apply the systematic approach of PDCA and use established tools and techniques to solve a particular problem or to achieve a target set on an improvement project. Often, organizations that implement this approach call it "Small Group Activities" (SGA).

- **Workshop activity** – akin to QCC but short, sharp, and concentrated over a couple of days. Often, enterprises that implement this call it "*Kaizen* Blitz."

SUMMARY

- 5S refers to the five Japanese words *Seiri*, *Seiton*, *Seiso*, *Seiketsu,* and *Shitsuke*.
- 5S activities are the five pillars of an effective workplace. It is the basic approach of "house-keeping" that can be used to cause improvement to the workplace environment.
- PDCA is the basic model for a systematic approach to improvement and problem-solving. It can be applied to solving problems or non-conformities relating to products, procedures, and practices identified in the enterprise.
- The 7 QC Tools consist of Check-sheets, Pareto Chart, Cause and Effect Diagram, Histogram, Control Charts, Scatter diagram and Stratification.
- The 7 MP Tools consist of Affinity Diagram, Relation Diagram, Matrix Diagram, Matrix Data Analysis, Process Decision Program Chart, and Arrow Diagram.
- Visual control is using visual information (e.g., pictures, photographs, and slogans) to understand the situation of the workplace, processes, etc. promptly so as to take appropriate action.
- *Kaizen* is implemented to achieve small and incremental improvement in the workplace. Activities can include Individual *Kaizen*, QCC, and *Kaizen* Blitz

CHAPTER 5
FOOD SAFETY MANAGEMENT SYSTEM

STANDARDS AND REQUIREMENTS FOR FOOD SAFETY AND FSMS

The increasing incidence of food safety scandals and growing international competition have caused an ever-expanding and often confusing system of public and private standards of food safety and quality and FSMS. There are standards and requirements at different levels.

Box 26: Meaning of Standards

- Documents, established by consensus and approved by a recognized body, that provide for common and repeated use, rules, guidelines, or characteristics for products or related processes and production methods.
- Normative documents, broadly used in industry and trade, as a self-regulatory mechanism and as a description of the state-of-the-art practices in a specific area.

Purposes of Standards

The purposes of standards include to:

- minimize health and environmental risks through facilitation of public administration procedures
- simplify legislation through availing reference to approved and recognized standards
- reduce risks of liability through prevention of deceptive practices
- facilitate economic cooperation through reduction of transaction costs in business by providing common reference points for notions of safety, quality, authenticity, good practice and sustainability
- improve safety and quality of products through facilitation of research / promotion of innovation and technological development

Classification of Standards

There are two classifications of standards according to their relevance, namely:

- Mandatory standards are:
  - set by governments in the form of regulations that include technical requirements such as testing, certification, labeling, etc.; and standards enforced by liability rules in case of non-compliance.

- Voluntary standards are:
  - set through formal coordinated approaches of key stakeholders in the supply chain (e.g., business associations and NGO initiatives such as eco- or fair-trade-labeling), or
  - standards developed and monitored by individual enterprises.

    These voluntary standards are increasingly becoming a precondition for establishing long-term supplier/customer relationships

Types of Standards

There are four types of standards according to what they cover, namely:

- Product standards
  - These describe product characteristics such as safety, quality, performance, design, labeling, etc.
- Production and process methods
  - These describe how products should be produced.
- Generic management standards
  - These describe what enterprises do to meet customer requirements and to achieve continual improvement regardless of the size or type of the enterprise, the sector of activity, and/or its product (e.g., ISO 9001:2008, ISO 22000:2005).
- Ethical standards
  - These describe what enterprises do to meet environmental impacts, work conditions, and the like (e.g., ISO 14001:2007; SA 80001: 2008).

Standards-setting Organizations

There are four levels of organizations that set the various standards listed above.

Box 27: Standard-setting organizations

- Multilateral/International organizations
  - e.g., CAC, IPPC, OIE, ISO
- Supranational/Regional organizations
  - e.g., Trading blocs such as the EU, and ASEAN
- National organizations
  - e.g., Japan External Trade Organization
- Private Industry and Trade organizations
  - e.g., BRC, IFS, SQF, GLOBALGAP

Examples of some of the organizations and their websites are as follows:

- **Multilateral/International organizations**
  - CAC – Codex Alimentarius Commission of the FAO and WHO
    http://www.codexalimentarius.org
  - IPPC – International Plant Protection Convention
    https://www.ippc.int
  - OIE – Office Internationale des Epizooties (World Organization for Animal Health)
    http://www.oie.int
  - ISO – International Organization for Standardization

    http://www.iso.org
- **Supra-national/Regional organizations**
  - EU – European Union
    http://ec.europa.eu/food/food/foodlaw/index_en.htm
    Regulation (EC) No. 178/2002 (common name: General Food Law)
- **National organizations**
  - Most countries have national standards bodies and their websites can be a useful source of information on national regulations and standards, e.g., Japan External Trade Organization (http://www.jetro.go.jp/en/ reports/ regulations/);
    Japan Ministry of Agriculture, Forestry and Fisheries (http://www.maff.go.jp/e/jas/jas/index.html)
- **Private Industry and Trade organizations**
  - British Retail Consortium (BRC) http://www.brc.org.uk
    The BRC is the lead trade association for the UK retail industry.

    In 1998 the BRC developed and introduced the BRC Food Technical Standard to be used to evaluate manufacturers of retailers' own-brand food products. It is designed to be used as a pillar to help retailers and brand owners with their "due diligence" defense, should they be subject to prosecution by enforcement authorities. Under EU Food Law, retailers and brand owners have a legal responsibility for their brands.

    In a short period of time, this standard became invaluable to other organizations across the sector. Its use outside the UK has seen it evolving into a global standard used not just to assess retailer suppliers, but as a framework upon which many enterprises have based their supplier assessment programs and the manufacture of various branded products.

    The latest edition (Issue 6) of the standard was published recently.
    http://www.brcglobalstandards.com/GlobalStandards/Home.aspx

The majority of UK and many European and global retailers and brand owners will only consider business with suppliers who have gained certifications for the appropriate BRC Global Standard.

- International Food Standards (IFS) www.ifs-certification.com

  The IFS was initiated by the German retail federation and its French counterpart for retailer-branded food products. It is applicable to all post-farm-gate stages of food processing.

  The IFS began to be promulgated under IFS version 3 in 2003, followed by version 4 in 2004, version 5 in 2008, and the latest version 6 in 2012.

  The IFS is a standard for auditing retailer- and wholesaler-branded food product suppliers and only concerns food processing companies or companies that pack loose food products. The IFS standards can only be used when a product is "processed" or when there is a hazard for product contamination during the primary packing.

- Safe Quality Food (SQF) http://www.sqfi.com

  SQF offers two different standards, or codes, based on universally accepted Codex Alimentarius HACCP Guidelines, and provides the food sector a way to manage food safety and quality simultaneously.

  The SQF 1000 Code is designed specifically for primary producers. The SQF 2000 Code has wide appeal across the food manufacturing and distribution sectors.

  Within each code there are three levels – fundamental food safety, HACCP-based food safety plans, and comprehensive food safety and quality management systems.

  The standard places emphasis on the systematic application of HACCP for control of food safety and quality hazards.

- GLOBALGAP http://www.globalgap.org

  GLOBALGAP is a private-sector body that sets voluntary standards for the certification of agricultural products around the globe.

  The GLOBALGAP standard is primarily designed to reassure consumers about how food is produced on the farm by minimizing the detrimental environmental impact of farming operations, reducing the use of chemical inputs, and ensuring a responsible approach to worker health and safety as well as animal welfare.

GLOBALGAP is a single integrated standard with modular applications for different product groups, ranging from plant and livestock production to plant propagation materials and compound feed manufacturing.

The standard serves as a global reference system for other existing standards and can also be easily and directly applied by all parties of the primary food sector.

One common principle among most standards and requirements is that the FSMS should be the latest, up-to-date version (system) that must be both scientific- (data) and prevention-based.

THE MODERN FSMS

A Scientific Approach

Food safety is the responsibility of everyone in and along the food chain, from regulators to producers to consumers. However, governments are responsible for providing an enabling institutional and regulatory environment for food control. Traditional food safety systems are no longer sufficient to meet the food safety needs of either the developed or the developing world.

A number of developing countries have taken steps to improve and strengthen their systems for food safety management. They have moved away from the traditional approach focused on end-product control toward a science-based process. Food safety regulators in many countries are already implementing different types of science-based actions and decision making in their day-today work. Science and good data are essential to decision making in a modern food safety system.

Box 28: Examples of science-based activities

- Implementing HACCP systems
- Establishing acceptable daily intakes for chemical additives in food
- Estimating maximum allowable exposure levels to pesticides
- Using labels to warn consumers about potential food allergens
- Using risk assessment to support food safety regulations and other decision making
- Establishing product safety standards, performance standards, and specifications for use in international trade
- Resolving trade disputes based on the WTO Sanitary and Phytosanitary Agreement

Scientific evidence can be used to minimize the occurrence of food safety hazards, to reduce and manage risk, and to improve the outcomes of decision

making. A science-based approach enhances the ability of food safety regulators to perform risk analysis.

As a concept, a science-based approach to food safety is not completely new. It is related to PRPs (such as GHP, GAP, and GMP) and the HACCP system, which are already used in many countries. What is important is the use of risk analysis as a framework to view and respond to food safety.

In the absence of limitless resources it makes sense to apply the greatest attention to those aspects of the food chain where the greatest safety risks lie. Existing food safety and quality tools, applied within state-of-the-art management systems, can be quite effective at reducing the risk of foodborne illness. There are many food producers and distributors that have a track record of operating in accordance with these proven management systems. Applying risk-based criteria to regulatory and inspection efforts means that fewer resources can be directed at these producers, freeing up more resources to be directed at higher risk targets.

A Preventive Approach

"Prevention is better than cure." A preventive approach to assure safety and quality of food means a proactive rather than a reactive way of doing things.

Alternatives to a reactive, inspection-based food safety system stress preventive approaches.

Some of the elements of a prevention-based approach to food safety are already well established within industry and within the regulatory framework. These include PRPs, HACCP, and supplier programs.

KEY ELEMENTS OF A FOOD SAFETY MANAGEMENT SYSTEM

All enterprises need to manage their operations and processes effectively. In short, they need to have a management system with the basic concepts of quality management and food safety in mind.

Box 29: Definition of an FSMS

A set of interrelated or interacting elements (system) to establish policy and objectives and to achieve those objectives used to direct and control an organization with regard to food safety

Management System

There is really nothing new with respect to management systems. Every enterprise has a management system of some kind in place in order to support its business and operations.

Box 30: An ideal FSMS

- Meets the food safety policy and achieves the measurable objectives related to the policy
- Achieves "effectiveness" and "efficiency"
- Applies proven management principles

An ideal food safety management system in an enterprise should be one that:

- meets the enterprise's food safety policy (overall intentions and direction of the enterprise related to food safety as formally expressed by top management), and achieves the measurable objectives related to the policy;
- carries out "effectiveness" (extent to which planned activities are realized and planned results achieved) and "efficiency" (relationship between the results achieved and the resources needed);
- applies proven management principles (comprehensive and fundamental rules or beliefs) for leading and operating an enterprise, aimed at continually improving performance over the long term by focusing on customers while addressing the needs of all other stakeholders.

An effective FSMS is one that:

- is well-established, documented, implemented, maintained and continually improved / updated;
- has its products / services that actually meet its intended usage and are safe;
- is proactive and innovative, scientific, risk-avoiding, and prevention-oriented.

Management Principles

Box 31: Management principles to be embedded in an FSMS

- Customer-focused organization
- Leadership
- Involvement of people
- Process approach
- Systematic approach to management
- Continual improvement
- Factual approach to decision-making
- Mutually beneficial supplier relationships

Proven management principles should be embedded in the elements of the FSMS. Such principles include:

- **Customer-focused organization:** Enterprises depend on their intended users / customers of their food products and therefore should understand their current and future needs, meet their requirements, and strive to exceed their expectations.
- **Leadership:** Leaders (top management) establish unity of purpose and the direction of the enterprise. They should create and maintain the internal environment in which people can become fully involved in achieving the enterprise's food safety objectives.
- **Involvement of people:** People at all levels are the essence of an enterprise and their full involvement enables their abilities to be used for the enterprise's benefit.
- **Process approach:** A desired result is achieved more efficiently when related resources and activities are managed as a process.
- **System approach to management:** Identifying, understanding, and managing a system of interrelated processes for a given objective improves the enterprise's effectiveness and efficiency.
- **Continual improvement:** Continual improvement should be a permanent objective of the enterprise.
- **Factual approach to decision making:** Effective decisions should be based on the analysis of actual data and information.
- **Mutually beneficial supplier relationships:** An enterprise and its suppliers are interdependent, and a mutually beneficial relationship enhances the ability of both to create value.

(A very detailed explanation of the above Management Principles can be downloaded from: http://www.iso.org/iso/home/standards/management-standards/iso_9000.htm)

This means that an enterprise should establish / structure its system in a framework / model that includes:

- Policy
- Planning
- Implementation and operation
- Performance assessment
- Improvement
- Management review

Key Elements of an FSMS

Box 32: Key elements of an FSMS

- Good practices / PRPs
- Hazard analysis / HACCP
- Management element / system
- Statutory and regulatory requirements
- Communication

Some of the key elements of an effective FSMS include:

- **Good practices/PRPs** – to establish and maintain a hygienic environment
- **Hazard analysis/HACCP** – as a preventive approach
- **Management elements** – of a management system with management principles embedded in it

Other key elements would include:

- **Statutory and regulatory requirements** – where these are "mandatory standards" of which an enterprise must determine, understand, and demonstrate compliance for its FSMS. The enterprise needs to know which requirements are applicable, e.g., those of the country of the sale of their end-products, where the enterprise is established / operating and end-products are consumed / exported to or specified in contracts or by customers.
- **Communication** – where proactive, open, continuous dialog with direct, immediate suppliers, customers, and relevant parties has to be planned and maintained to:
  - ensure that all relevant food safety hazards are identified and adequately controlled at each step within the food chain through communication to all parties

- assist in substantiating customer and supplier requirements regarding feasibility, needs, and impacts on the end product, through communication with customers and suppliers

ISO 22000:2005 FSMS

ISO 22000:2005 "Food Safety Management Systems – Requirements for Any Organization in the Food Chain" was published by the International Organization for Standardization as a first edition on September 1, 2005.

The aim of ISO 22000:2005 is to harmonize on a global level the requirements for food safety management of business within the food chain. It is intended for application by enterprises that seek a more focused, coherent and integrated FSMS than is normally required by law. It requires an enterprise to meet any applicable food safety related statutory and regulatory requirements through its FSMS.

The standard is auditable, and it harmonizes national food safety standards, to ensure confidence to customers and consumers throughout the food chain anywhere in the world. It marries proven management principles with state-of-the-art food safety practices.

Box 33: Objectives of ISO 22000:2005

- Compliance with the Codex Alimentarius Commission HACCP principles
- Harmonize the voluntary international standards
- Provide an auditable standard that can be used either for internal audits, self-certification, or third-party certification
- Provide communication of HACCP concepts internationally

ISO 22000 is applicable to all organizations, regardless of size, which are involved in any aspect of the food chain and want to implement systems that consistently provide safe products.

Enterprises that have implemented an FSMS meeting the requirements of ISO 22000:2005 can seek official certification.

Box 34: Requirements of ISO 22000:2005

The "requirement" clauses are included in Clauses No. 4 to 8.

4 FSMS
- 4.1 General requirements
- 4.2 Documentation requirements

5 Management responsibility
- 5.1 Management commitment
- 5.2 Food safety policy
- 5.3 FSMS planning
- 5.4 Responsibility and authority
- 5.5 Food safety team leader
- 5.6 Communication
- 5.7 Emergency preparedness and response
- 5.8 Management review

6 Resource management
- 6.1 Provision of resources
- 6.2 Human resources
- 6.3 Infrastructure
- 6.4 Work environment

7 Planning and realization of safe products
- 7.1 General
- 7.2 Prerequisite programs (PRPs)
- 7.3 Preliminary steps to enable hazard analysis
- 7.4 Hazard analysis
- 7.5 Establishing the operational PRPs
- 7.6 Establishing the HACCP plan
- 7.7 Updating of preliminary information and documents specifying the PRP(s) and the HACCP plan
- 7.8 Verification planning
- 7.9 Traceability
- 7.10 Control of nonconformity

8 Validation, verification, and improvement of the FSMS
- 8.1 General
- 8.2 Validation of control measure combinations
- 8.3 Control of monitoring and measurement
- 8.4 FSMS verification
- 8.5 Improvement

(*A copy of the ISO 22000:2005 standard can be purchased from the International Organization for Standardization*).

SUMMARY

- Standards and requirements for food safety and FSMS are documents established by consensus and approved by a recognized body.
- Standards can be mandatory or voluntary and are product standards, production and process methods, generic management standards or ethical standards.
- Some private industry and trade organizations that set standards include BRC, IFS, SQF, and GLOBALGAP.
- A modern FSMS will be one that is using a scientific approach and a preventive approach.
- Management principles include customer-focused organization, leadership, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision-making, and mutually beneficial supplier relationships.
- Key elements of an FSMS include good practices / PRPs, hazard analysis / HACCP, management element / system, statutory and regulatory requirements, and communication.
- ISO 22000: 2005 is the latest standard of a modern FSMS that incorporates all the key elements.

CHAPTER 6
IMPLEMENTATION OF A FOOD SAFETY MANAGEMENT SYSTEM

GENERIC APPROACH TO ESTABLISHING A FOOD SAFETY MANAGEMENT SYSTEM

An enterprise may consider the following outline when developing an overall plan to establish an FSMS.

Notes:

i. The steps in the approach given below are based on the principles provided in the ISO22000: 2005 standard. However, the sequence is modified for ease of implementation.

ii. Another version of the generic approach is available at the website of PRAXIOM RESEARCH GROUP LIMITED based in Edmonton, Alberta, Canada: http://www.praxiom.com/iso.22000-intro.htm

Management Responsibility

- Define the scope (i.e. boundaries and extent) of the FSMS
- Identify, document, and control any out-source process that may affect end product conformity within the FSMS
- Demonstrate top management's commitment to the FSMS
- Establish the documentation structure (various types of documents) of the FSMS
- Establish, document and implement procedures for the control of documents
- Establish, document, and implement procedures for the control of records
- Define, document, and communicate the food safety policy
- Define and communicate responsibilities and authorities
- Appoint a competent food safety team leader (by top management)
- Establish, implement, and maintain arrangements for internal and external communication

Resource Management

- Make available the necessary resources, including human resources (competence, awareness, and training), infrastructure, and work environment

Planning and Ensuring Safe Products

- Plan, implement, and maintain prerequisite programs (PRPs)
- Constitute a food safety team with defined responsibilities and authorities
- Conduct the 5 preliminary steps to enable hazard analysis
- Identify all potential food safety hazards
- Determine acceptable levels of food safety hazards in the end product
- Conduct assessment for each food safety hazard identified
- Select actions (control measures) to prevent, reduce, and/or eliminate the hazards to defined acceptable levels
- Establish, document, and implement operational PRPs
- Conduct the remaining application steps of HACCP to complete the HACCP Plan
- Establish and implement a traceability system to enable identification of product lots
- Establish, implement, and maintain procedures to manage potential emergency situations and accidents

Validation, Verification, and Improvement of the Food Safety Management System

- Control monitoring and measuring methods and equipment
- Establish, document, and implement procedures to identify nonconforming and potentially unsafe products
- Establish, document, and implement procedures for corrections and corrective actions
- Establish, document, and implement procedures for handling of potentially unsafe products
- Validate all control measures included in the PRPs and the HACCP Plan
- Verify that the FSMS has been implemented as planned
- Evaluate and analyze the results of verification activities
- Establish, document, and implement procedures for conducting internal audits of the FSMS at planned intervals
- Conduct management review of the FSMS at planned intervals
- Implement the kaizen approach for continuous improvement of the FSMS

PROJECT PLAN FOR IMPLEMENTING AN FSMS

There is no one best standardized approach or optimal time-frame to implement an FSMS. The process is ongoing and the approach that the enterprise may take can be influenced by:

- Widely accepted international / national food safety standards and schemes
- Observations of success stories / experiences from other enterprises
- Consultants
- Other good practices / programs / management systems already in place in the enterprise
- Suggestions / advice offered by buyers and main customers

The enterprise must also consider whether it needs external resources (e.g., consultants) from the start of or during the implementation of the FSMS. An important factor that the enterprise must recognize is that the FSMS belongs to the enterprise regardless of how much assistance may be obtained from external sources. Ownership of the FSMS must be present. A good approach would be to establish a project plan after performing gap analysis.

(See Figure B for a simplified example of project schedule for implementation of an FSMS)

No.	PHASE / ACTIVITY	Schedule / Timeframe					
		1	**2**	**3**	**4**	**5**	**6**
1	MANAGEMENT AWARENESS & COMMITMENT						
1.1.	Executive briefing for management team	X					
1.2.	Establish / redefine management responsibility and food safety team	X					
2	DEVELOPMENT and DOCUMENTATION OF SYSTEM						
2.1.	Refine activities relating to PRPs		X				
2.2.	Establish / refine the HACCP plan(s)		X				
2.3.	Prepare / improve FSMS documentation		X	X			
3	IMPLEMENTATION and MONITORING OF SYSTEM						
3.1.	Validate activities and implement FSMS			X			
3.2.	Train and coach staff from relevant work areas			X	X		
3.3.	Monitor and improve FSMS				X	X	
4	AUDIT, REVIEW and IMPROVEMENT OF SYSTEM						
4.1.	Train and coach on internal audit of FSMS			X	X		
4.2.	Conduct management review				X		
4.3.	Review findings, update and improve FSMS					X	

Figure 2: Project schedule of implementation of an FSMS – example

AUDITS

Box 35: Definition of *audit*

A systematic, independent, and documented process for obtaining audit evidence, and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

The types of audit that may be conducted are:

- **Internal audit** – Often, a first-party audit that is conducted by, or on behalf of, the enterprise itself for management review and other internal purposes, and may form the basis for an enterprise's declaration of conformity.

- **External audit** – An audit that includes second- and third-party audits. Second-party audits are conducted by parties having an interest in the enterprise, such as customers or by persons on their behalf. Third-party audits are conducted by external, independent auditing organizations, such as those providing certification/ registration of conformity to a standard (e.g., ISO 22000).

Internal Audit as Part of the Verification Activities of an FSMS

> **Box 36: Definition of *verification***
>
> Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

An FSMS that is functioning properly minimizes the need for extensive product sampling and testing. Verification occurs in two stages that can be loosely classified as "ongoing" and "periodic."

Ongoing activities use methods, procedures, or tests separate from, and in addition to, those used to monitor the FSMS.

A schedule of verification activities is developed as part of the FSMS. This schedule should include procedures or methods to be utilized, the frequency, and the person(s) responsible for performing the activity.

When conducting internal audits for these verification activities, sound audit principles should be observed. Auditors should be competent to perform the audits. They should be independent of the work or processes being audited, although they may be from the same work area or department. For example, in a small business where there might be only one or two people in management positions, this requirement may not be achieved. It is suggested that in such cases, when carrying out the duties of an auditor, the manager tries to step back from direct involvement in the business operations and to be objective about the audit.

Another approach might be to seek the cooperation of another small business so that each provides an internal audit for the other. This can prove attractive if there are good relations between the two businesses. Alternatively, external parties (e.g., chambers of commerce, consultants, and inspection agencies) might be able to provide independent auditors.

Details of Internal Audit at Enterprise Level

The enterprise shall conduct internal audits at planned intervals to determine whether the FSMS:

- conforms to the planned arrangements, to the FSMS requirements established by the enterprise, and to the requirements of the standard (e.g., ISO22000: 2005), and
- is effectively implemented and updated

An audit program should be planned, taking into consideration the importance of the processes and areas to be audited, as well as any updating actions resulting from previous audits. The audit criteria, scope, frequency, and methods should be defined. Selection of auditors and conduct of audits should ensure the objectivity and impartiality of the audit process. Auditors should not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records should be defined in a documented procedure.

The management responsible for the area being audited should ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities should include the verification of the actions taken and the reporting of the verification results.

Implementing Internal Audit

In order to carry out effective and efficient internal audits of the FSMS, enterprises should adopt many of the excellent pointers from ISO 19011: 2011 – Guidelines for Auditing Management Systems.

Box 37: Five principles of auditing

- **Ethical Conduct:** The foundation of professionalism
- **Fair Presentation:** The obligation to report truthfully and accurately
- **Due Professional Care:** Application of due diligence and judgment in auditing
- **Independence:** The basis for the impartiality and objectivity of the audit conclusions
- **Evidence-based approach:** The rational method for reaching reliable and reproducible audit conclusions in a systematic audit process

The following audit activities (audit cycle) should be considered in the planning and implementing of audits:

- Initiating the audit
- Conducting document review
- Preparing for on-site audit activities
- Preparing, approving, and distributing the audit report
- Completing the audit
- Conducting audit follow-up

SUMMARY

- A generic approach in establishing an FSMS is explained
- There is no one best standardized approach or optimal time-frame to implement an FSMS. The process can be influenced by many factors.
- A good approach would be to establish a project plan after performing gap analysis.
- A project plan should include various phases, with key activities in each phase.
- There are internal (first party) audits and external (second and third party) audits.
- Internal audit is part of verification activities of an FSMS.
- An audit should consist of a planned program, audit criteria, scope, frequency, methods, and be conducted by selected auditors.
- The principles of auditing include ethical conduct, fair presentation, due professional care, independence, and an evidence-based approach.
- In planning for the implementation of an internal audit, the cycle of audits has to be taken into consideration.

CHAPTER 7
CERTIFICATION FOR A FOOD SAFETY MANAGEMENT SYSTEM

CERTIFICATION

Box 38: Definition of *certification*

Certification (or registration) is the process when an independent and competent third party certifies that a product, service, system, process, or material conforms to specific requirements.

An enterprise may decide to go for certification if it has implemented an FSMS. Often, the decision may be based on business grounds, for example:

- if it is a contractual or regulatory requirement
- if it is a market requirement or to meet customer preferences
- if it falls within the context of a risk management program
- if the organization thinks it will motivate staff by setting a clear goal for the development of an FSMS

Generally, certification is a commercially available service offered by independent third-party Certification Bodies (CB), or Registrars as they are called in North America.

Certification Criteria

Each certification is based on a specific certification criterion. It can be:

- a standard from a private industry and trade organization
  - e.g., BRC Global Standard – Food of the BRC
- a standard from a national organization
  - e.g., MS 1480: 2007 (Food Safety according to the HACCP System) of Malaysia
- one of the international standards from a multilateral organization
  - e.g., ISO22000: 2005 (Food Safety Management Systems – Requirements for Any Organization in the Food Chain) of ISO; CAC/RCP 1-1969, Rev 4-2003 (Recommended International Code of Practice General Principles of Food Hygiene – Guidelines for the Application of HACCP) of CAC

Certification Scope

Each certification is also based on the certification scope, which is the activity that has been assessed and found to be certifiable to a certain standard.

Examples of certification scope for FSMSs:

- Provision of ready-made meals in community centers
- Manufacture of bakery and confectionary products
- Production of muesli and hard nougat, packing and filling of top cuts, bags and Purepak™ containers.

Selection of Certification Body

Generally an enterprise will evaluate several CBs before selecting one for the certification. Evaluation can be based on:

- Reputation
- Accreditation (accredited by a recognized accreditation body)
- Operations (i.e., implements ISO/IEC 17021: 2006, Conformity Assessment – Requirements for Bodies Providing Audits and Certification of Management Systems)
- Competence and experience in the certification scope (i.e., having auditors with experience in the enterprise's sector of activity)
- Audit approach and user friendliness
- Cost

ACCREDITATION

Box 39: Definition of *accreditation*

Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

Accreditation is the procedure by which an authoritative body gives formal recognition that an enterprise or person is competent to carry out specific tasks. Accreditation by an International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA) member assures users that the accredited body is independent and competent, and delivers its services in the most time- and cost-effective way.

The IAF is the world association of Conformity Assessment of Accreditation Bodies (AB) and other bodies interested in conformity assessment. (http://www.iaf.nu/)

Accreditation Bodies

The structure of ABs in each country can be different. Some are part of the government; others are NGOs having a strong link with the government.

Accreditation operates according to international standards, such as ISO/IEC 17011:2004 – Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies.

Examples of ABs that are part of the government:

- China; CNAS (China National Accreditation Service for Conformity Assessment,) – http://www.cnas.org.cn
- Hong Kong; HKAS (Hong Kong Accreditation Scheme) – http://www.itc.gov.hk/en/quality/hkas
- India; NABCB (National Accreditation Board for Certification Bodies) – http://www.qcin.org
- Indonesia; KAN (Accreditation Body of Indonesia) – http://www.bsn.or.id
- Iran; IAS (Iran Accreditation System) – http://www.ias.org.ir
- Korea; KAB (Korean Accreditation Board) – http://www.kab.or.kr
- Malaysia; DSM (Department of Standards Malaysia) – http://www.dsm.gov.my
- Pakistan; PNAC (Pakistan National Accreditation Council) – http://www.pnac.org.pk
- Philippines; PAO (Philippines Accreditation Office) – http://www.bps.dti.gov.ph
- Singapore; SAC (Singapore Accreditation Council) – http://www.sac-accreditation.org.sg
- Sri Lanka; (Sri Lanka Accreditation Board of Conformity Assessment)
- Taiwan; TAF (Taiwan Accreditation Foundation) – http://www.taftw.org.tw
- Thailand; NAC (The Office of National Accreditation of Thailand) – http://www.tisi.go.th/nac
- Vietnam; VICAS (Vietnam Certification Accreditation Scheme) – http://www.boa.gov.vn/vinas_en/vicas.htm
- Australia–New Zealand; JAS-ANZ (Joint Accreditation System of Australia and New Zealand) – http://www.jas-anz.com.au

Examples of ABs that are not part of the Government:

- Japan; JAB (Japan Accreditation Board for Conformity Assessment) – http://www.jab.or.jp
- USA; ANAB (American National Accreditation Board) – http://www.anab.org
- UK; UKAS (United Kingdom Accreditation Service) – http://www.ukas.com

Accreditation Standards

Besides other requirements, the current standard used by ABs to accredit CBs providing certification of management systems is the "ISO/IEC 17021:2011 – Conformity Assessment – Requirements for Bodies Providing Audit and Certification of Management Systems." ISO/IEC 17021:2011 contains principles and requirements for the competence, consistency and impartiality of the audit and certification of management systems of all types (e.g., FSMS or quality management systems or environmental management systems) and for bodies providing these activities. CBs operating to this international standard need not offer all types of management system certification.

Certification of management systems is a third-party conformity assessment activity. Bodies performing this activity are therefore third-party conformity assessment bodies

Another ISO standard specifically relating to FSMS is "ISO/TS 22003:2007 Food Safety Management Systems – Requirements for Bodies Providing Audit and Certification of Food Safety Management Systems." ISO/TS 22003:2007 defines the rules applicable for the audit and certification of an FSMS complying with the requirements given in ISO 22000:2005 (or other sets of specified FSMS requirements), and provides the necessary information and confidence to customers about the way certification of their suppliers has been granted.

CERTIFICATION STEPS

To be certified / registered to an FSMS standard (eg., ISO 22000:2005), the selected CB needs to formally assess the enterprise's compliance with all the requirements of the standard and the enterprise's food safety policy and objectives.

Once the enterprise has fully implemented the FSMS, the CB staff will conduct an assessment of the enterprise on site. This will involve completing a pre-application questionnaire, so that the CB can identify a competent auditor for the enterprise's activities and products and determine the audit duration.

Generally, there are seven steps to achieving registration to the FSMS standard with a CB.

- Step 1 – Establish an FSMS that complies with the requirements of the FSMS standard.
- Step 2 – Upon contacting the CB, the CB will provide an estimate of costs and timescale for formal assessment.
- Step 3 – Submit a formal application to the CB.
  - (A pre-assessment visit may be a useful preparation for the initial assessment. An external auditor or a CB assessor will be able to review the enterprise progress and highlight areas where the FSMS meets the requirements of the standard).
- Step 4 – The CB will undertake an on-site stage 1 assessment to review that the enterprise policy, scope, objectives, and the PRPs and HACCP plans have been developed and are in place.

- Step 5 – The CB will undertake an on-site stage 2 assessment to determine that the enterprise adheres to its own scope, policies, objectives, plans, processes, and procedures and that the FSMS conforms to all the requirements of the standard.
- Step 6 – On successful completion of the audit, and following an independent review of the completed report, a certificate of registration is issued which identifies the scope of the FSMS.
- Step 7 – The certificate is valid for 3 years subject to demonstration at yearly continuing assessment visits of compliance to the standard.

The Stage 1 and 2 assessments to be undertaken by the CB are external (third-party) audits. Quite often, the word "assessment" instead of "audit" is used because the CB will have to form a judgment / conclusion of whether the enterprise's FSMS meets the requirements of the standard.

All CBs generally have similar requirements, procedures and steps in performing third-party auditing of management systems.

BENEFITS OF CERTIFICATION

Box 40: Benefits of certification

- Reduced cost of sales
- Lower risk of liability
- Improved overall performance

- **Reduced cost of sales**
  Compliance to an FSMS standard immediately establishes an enterprise's credibility and commitment to food safety. Demonstrating the effectiveness of an FSMS is straightforward and takes less time to earn customers' trust
- **Lower risk of liability**
  The entire food chain suffers from consumers' exposure to hazards. By implementing an FSMS, food enterprises take responsibility for consumer safety and lower the risk of insurance payments and legal costs.
- **Improved overall performance**
  A lean management system promotes continuous improvement of food products and processes, creating fewer errors, returns, withdrawals / recalls, and customer complaints. This generates improved relationships with suppliers and customers, providing a competitive advantage in the marketplace

WEAKNESSES OBSERVED IN ENTERPRISES

Common key observations (non-conformities and opportunities for improvement) that have often been raised concerning enterprises following internal audits and audits by CBs include:

- Not confirming the position of external consultants with regard to the Food Safety Team.
- Not recording external communications – e.g., telephone conversations with a supplier may need to be recorded; saving e-mails; maintaining inspection records from authorities.
- Not distinguishing between PRPs and operational PRPs in the case of ISO 22000:2005, and documenting them correctly.
- Not covering allergens in the hazard analysis.
- Not having evidence to back up the validation of control measures.
- Not developing and testing emergency preparedness and response procedures.
- Not testing or having a trial of the withdrawal / recall process.
- Not carrying out a full internal audit of the FSMS.

SUMMARY

- Certification is a commercially available service offered by *certification bodies*.
- Each certification is based on a certification criterion and scope.
- A certification body can be selected based on reputation, accreditation, operations, competence, and experience in the certification scope, audit approach and user friendliness, and cost.
- An accredited certification body is one which is accredited by an *accreditation body*.
- Accreditation bodies can be part of or not part of governments.
- Generally, there are seven steps to achieving registration to the FSMS standard with a certification body.
- Benefits of certification include reduced cost of sales, lower risk of liability, and improved overall performance.
- Some examples of common key observations about enterprises (non-conformities and opportunities for improvement) that have been raised from audits are given.

CHAPTER 8
STRATEGIES FOR ACHIEVING FOOD SAFETY BY SMALL AND MEDIUM ENTERPRISES

SMALL- AND MEDIUM-SIZE ENTERPRISES

The term "small- and medium-size enterprises" (SMEs) is applied in various ways across Asia because of industry conditions that differ from country to country. Generally, industry can be classified into four major groups: *large-*, *medium-*, and *small-size* industrial groups in addition to the *cottage, household or micro industrial group*.

Box 41: Definition of *SMEs*

- No standardized definition
- Classification normally based on:
  - features of ownership
  - site of the workforce
  - number of workers employed
  - location
  - amount of capital invested
  - annual sales turnover

Small- and medium-size industry consists of SMEs. There is no standardized definition of what is an SME. However, the word implies that such an enterprise is "limited" in size or scope or extent. SME classification differs among countries on the basis of features of ownership, the number of workers employed (with or without considering the machinery of production used), location, amount of capital invested, and/or annual sales turnover. Such classifications are more important especially for purposes of labor welfare laws, loans, and tax purposes where legislation exists.

In some countries, there is even a slight variation of definitions in different sectors.

For example, in the primary agriculture sector in Malaysia:

- A "medium enterprise" has a full-time staff of between 20 and 50 employees or annual sales turnover of between MYR1 million and MYR5 million.
- A "small enterprise" has a full-time staff of between five and 19 employees or with annual sales turnover of between MYR200,000 and less than MYR1 million; and

- A micro enterprise has a full-time staff of fewer than five employees or annual sales turnover of less than RM200,000.

Generally, a small-scale enterprise (SSE) operates with no more than 20 hired workers using motive power, or with 50 or fewer hired workers using hand power. For example, in Indonesia one classification is that an SSE employs from five to 19 workers, and a cottage industry employ up to four workers – typically family members.

A cottage industry is carried on in the home as a part-time occupation primarily by members of one family using human and/or animal power.

SMEs are of critical importance to the functioning of an economy and thus economic development. More than 90% of enterprises in the Asian Productivity Organization (APO) member countries are SMEs. They account for about 75% of the Gross Domestic Product, compared to 50% in the rest of the world. They play an important role in economic and social life, and they generate a large number of jobs, exports, sales, and value-added. Yet in most of these countries, SMEs face similar constraints and hence are low-productivity enterprises.

IMPEDIMENTS AND CHALLENGES FACED WHEN IMPLEMENTING FOOD SAFETY FOR SMEs

Most developing Asian nations have generally much smaller businesses in the food processing sector compared to major trading partners in the developed world. In order to support the potential of these micro enterprises and SSEs, it is important to understand their characteristics and pay attention to their needs.

Characteristics of SMEs

Box 42: Characteristics of SMEs

- Privately held, owner-operated, family-based
- Differences in mode of operations
- Not homogenous
- Work longer hours but pay less
- Limited number of suppliers and customers
- Resistance to implement food safety programs
- Rely on a network of individual confidants
- Suspicious of and resistant to Government programs
- Operations on a localized, regional or country basis

Regardless of the technical definitions of an SME, it is useful to recall the following characteristics of an SME:

- SMEs are usually privately held and owner-operated, and are often family-based enterprises. Decisions are therefore concentrated and personally motivated.
- SMEs are understood to be the employment and revenue growth engine of Asian economies. The difference in their mode of operation compared to larger enterprises is seen to be the reason for this success.
- SMEs exist in most economic sectors, and are therefore as disparate as farmers, processors, small retail operations, and service providers. They do not see themselves as a homogeneous group. Their individuality, combined with their limited availability of time, requires simple and easy-to-implement solutions.
- SME owner-operators work longer hours and are paid less than their larger counterparts. This may be due to the requirement that they continually reinvest in their growing business and this may make them particularly resistant to non-core spending.
- SMEs may have a proportionately limited number of suppliers and customers. This may simplify implementation among them.
- SMEs understand the factors for their business success and perceive considerable risk in external pressures that might impact them. This may result in individual resistance to implement food safety programs.
- SMEs rely on a network of individual confidants/counselors who are familiar with the SMEs' reality, and probably with the particulars of their specific businesses. Industry associations are favored for cooperative effort; market building is supported.
- SMEs are often suspicious of and resistant to government programs.
- SMEs traditionally confine their operations to a localized, regional or country basis.

Impediments Faced by SMEs

Box 43: Impediments faced by SMEs

- Confusion over new local and international regulatory requirements
- What is the cost?
- Relationship between food safety, food suitability, and food security
- The need to improve record-keeping
- Communication
- Concerns about privacy and liability
- Technology solutions

The following are generic impediments that SMEs may face:

- **Confusion over new local and international regulatory requirements**
  Very often SMEs are not aware of new regulatory requirements for food safety. Even if they are aware, they may not fully understand the requirements. A local food authority can develop an ongoing communication plan for improving communication with SMEs. Such a plan could draw on the tools available from other stakeholders (industry newsletters, meetings, etc.) and include explanation of details of the regulatory requirements:

At the same time, SMEs should have a continual process of consultation with the local food authority, perhaps by establishing a specific mechanism of an SME Working Group.

- **What is the cost?**
  This can best be answered when development of cases and cost/benefit templates are available.
- **Relationship between food safety, food suitability, and food security**
  There is ongoing confusion among many SMEs regarding the relationship between food safety, food suitability, and food security. Information materials are required to assist SMEs to understand the differences and how food safety can even help their businesses.
- **Need to improve record-keeping**
  There are some minimum data and communications necessary to be collected, kept, and shared. This means that accurate record keeping is essential. Many SMEs will need to improve their record-keeping practices.
- **Communication**
  If there is a mandate for the entire food supply chain to implement some legal requirements (e.g., traceability), this is one of the biggest challenges, as it involves hundreds of thousands of SMEs. It is communicating all the information that SMEs along the food supply chain will need in order to make decisions about implementation. Much of the responsibility for this communication will fall on the respective associations to "get the message out" to their members. Unfortunately, many SMEs do not belong to associations or, if they do, belong to associations with limited resources. There needs to be a well thought-out multi-level communication / education / training strategy that will generate the documents that associations can use to reach individual SMEs.

- **Concerns about privacy and liability**
  Food safety is linked to concerns about increased liability. As a result, issues surrounding sharing of information deemed confidential in nature are concerns to SMEs. While businesses are only being asked to share basic information that they most likely already currently provide to supply

chain partners and governments, this is not well understood by SMEs. This needs to be communicated.

- **Technology solutions**
  Incorporating information technology into an SME is challenging. The major obstacle to using new technology has always been the cost of entry. There are now much more cost-effective techniques available to assist SMEs in data collection, record keeping, and communication. SMEs are already consumed with the day-to-day activities of running a small business on tight budgets and with limited human resources. They will need assistance accessing and then justifying those technology investments. SMEs will need information about what is available.

OPTIONS TO ENHANCE FOOD SAFETY IMPLEMENTATION

Box 44: Options to enhance food safety implementation

- Develop introductory information materials on food safety
- Develop a short, concise briefing document highlighting legislation
- Develop a range of education materials
- Develop self-assessment tools and information kits
- Develop a database of service providers
- Develop an inventory listing of good practices / programs
- Provide a listing of sources of funding / assistance
- Develop materials in vernacular languages
- Communicate success stories
- Encourage to pursue "best practice"
- Establish awards to recognize SMEs and individual owners
- Develop quick reference tools like a 1-800 SME hotline

Much more can and will have to be done to encourage and motivate SMEs to improve their attitude and actions in implementing food safety in the food chain. The way forward is that relevant parties should take the lead / enhance their activities to:

- Develop introductory information materials for SMEs. These documents should elaborate on the concepts, principles, and steps involved in food safety efforts.
- Develop a short, concise briefing document that highlights current and pending local legislation regarding food safety for the food supply chain. This document should also address import / export legislation.

- Develop a range of educational materials targeting SMEs. These materials could be generated by the local food authority and individual associations and made accessible through websites. Instead of requiring travel and time to attend distant workshops, for SMEs requiring a narrower focus, various media options should be available such as web-based self-learning modules, CDs, etc.
- Develop additional practical guidance, such as self-assessment tools and information kits (perhaps customized for different sectors in the food supply chain), to help SMEs introduce their own implementation plans. Templates along these lines could perhaps be developed.
- Develop a database of service providers / consultants who offer expertise in implementing food safety.
- Encourage the development of an inventory listing good practices / programs suitable for use by SMEs.
- Provide a list of possible sources of funding / assistance for food safety initiatives by SMEs. The list should include federal, provincial, and municipal agencies and other commercial lending and incentives organizations and could include possible tax implications relative to expenditure where appropriate.
- Develop broader awareness and participation by making materials for SMEs available not only in official languages, but possibly also in some other vernacular languages, where numbers warrant.
- Identify and communicate success stories of SMEs implementing food safety throughout the food supply chain.
- Develop ideas for encouraging SMEs to pursue best practice in food safety implementation. These could include group visits to the premises of "best" organizations to observe food safety in action; development of an ongoing cluster / network of interested SMEs to share information about effective approaches, emerging issues, etc.; and the use of mentors to address common food safety issues, such as how to deal with adequate product labeling and how to handle recalls.
- Establish an award program to recognize SMEs and individual owners who are making a significant difference to enhanced food safety implementation outcomes.
- Develop quick reference tools for SMEs such as a 1-800 SME hotline.

OTHER STRATEGIES FOR ACHIEVING FOOD SAFETY

Food safety in many countries is better today than ever. Still, there remains a huge opportunity for improvement in preventing illness from known foodborne pathogens and in responding to new and emerging FBD and threats.

Some additional steps that can be taken that would have a high impact, are achievable, and are consistent with established good practices are:

- **Continuing consumer education** – Once food leaves the processor, there is also a role for consumers and others to play in maintaining basic food safety precautions. Improper food handling in the home and at retail food establishments accounts for more reported cases of foodborne illness than does failure at the food processing level.
- **Expanded partnerships** – Public perception is that governments will protect them 100% when it comes to food. The reality is that governments have to work in partnership with industry and in partnership with consumers themselves in guaranteeing safer food.
- **Greater use of economic incentives** – Economic incentives are demonstrably more effective than regulatory pressure.
- **More sharing of information and less duplication of effort** – The advent of international food safety management system standards is opening up new avenues for cooperation and sharing of data among food safety regulatory agencies, the food industry, and the network of private-sector organizations that are springing up to audit the food industry to these new standards. Multiple audits and inspections of individual facilities can be reduced. These opportunities need to be exploited.
- **Expanded diligence by food companies on supplier performance** – The recent sickening of pets from toxic ingredients blended into pet foods was more a failure of corporate supplier programs than a failure of the regulatory establishment.
- **More effective inspection (not more inspection)** – Government inspection resources are limited and the workload is growing, so these resources need to be targeted where they are needed most. Food producers and processors that do not show evidence of compliance with FSMS standards and those dealing in high-risk foodstuff should be subjected to closer surveillance.
- **Globally applicable tools for a global food chain** – Sourcing of food and food ingredients is now a global business, so it makes sense to tackle food safety issues with internationally accepted and globally applicable tools such as the ISO 22000:2005 standard.

SUMMARY

- Different countries and even industry sectors have different definitions for the classification of SMEs.
- To be able to support SMEs, it is important to understand their characteristics and the impediments they are facing and pay attention to their needs.
- There are many options to enhance food safety implementation in SMEs.
- Other strategies for achieving food safety needed to be considered.

APPENDIX A:
LIST OF FOOD SAFETY HAZARDS

There are over 200 foodborne hazards known to cause FBD.

BIOLOGICAL HAZARDS

Biological hazards are dangers from disease-causing microorganisms and from poisonous toxins that they may produce. They are the cause for most foodborne illnesses, and include bacteria, viruses, and parasites.

Bacteria

- *Aeromonas hydrophilia*
- *Bacillus cereus*
- *Campylobacter jejuni*
- *Clostridium botulinum*
- *Clostridium perfringens*
- *Escherichinia coli O157:H7*
- *Listeria monocytogenes*
- *Salmonella spp*
- *Shigella spp*
- *Staphylococcus aureus*
- *Vibrio spp*
- *Yersinia enterocolitica*

Virus

- Hepatitis A
- Norwalk virus
- Rotavirus

Parasites

- *Giardia lambia*
- *Trichinella spiralis*

CHEMICAL HAZARDS

- Naturally occurring chemicals – allergens, Mycotoxin (e.g., Aflatoxin), mushroom toxins, shellfish toxins
- Added chemicals – PCBs, agricultural chemicals, pesticides, fertilizers, antibiotics, growth hormones, prohibited substances
- Toxic elements and compounds – lead, cadmium, mercury, arsenic, cyanide
- Food additives – vitamins and minerals
- Contaminants – lubricants, cleaners, sanitizers, coatings, paints, refrigerants, pest control chemical, water treatment chemicals
- Packaging materials – plasticizers, vinyl chloride, printing coding ink, adhesives, lead, tin

PHYSICAL HAZARDS

- Glass – from bottles, jars, light fixtures, utensils, gauge covers
- Wood – from field sources, pallets, boxes, building materials, toothpicks
- Metal pieces – from broken utensils; metal staples and nails from cardboard boxes; bolts, screws, and other equipment parts; metal shavings from cans; machinery, fields, wires
- Insulation – from building / construction materials
- Bone – from improper processing of meat, fish, poultry
- Screening – from grain and cereal processing
- Plastic – from packaging, pallets, equipment
- Stones and dirt – from harvesting of vegetables
- Personal effects – from stones or settings from rings, earrings, beads, or other jewelry; buttons, pins, safety pins; tie clips and tie tacks; gum, cigarettes and ashes; hair; band aids; artificial fingernails; contact lens; pens, pencils; thread of cloth

APPENDIX B:
LIST OF FOOD ALLERGENS

More than 160 foods are reported to cause allergic reactions. However, of these cases, 90% are caused by the foods below:

- Peanuts
- Tree-nuts (almonds, walnuts, pecans, hazelnuts, Brazil nuts, cashews, pistachios, pine nuts, macadamia nuts, chestnuts)
- Soybeans
- Milk
- Egg
- Crustaceans (shrimp, prawns, crab, lobster, crayfish
- Fish
- Wheat

Others allergens include:

- Celery root (celeriac)
- Seeds (sesame, poppy, sunflower, cottonseed, mustard)
- Glutens (rye, barley, oats, pelt, kamut)

APPENDIX C:
RECOMMENDED INTERNATIONAL CODE OF PRACTICE GENERAL PRINCIPLES OF FOOD HYGIENE – CAC/RCP 1-1969, REV.4-2003

The current version of the Recommended International Code of Practice-General Principles of Food Hygiene including Annex on Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application was adopted by the Codex Alimentarius Commission in 1997. Amendments regarding rinsing were adopted in 1999. HACCP Guidelines were revised in 2003. The Code has been sent to all Member Nations and Associate Members of FAO and WHO as an advisory text, and it is for individual governments to decide what use they wish to make of the Guidelines.

RECOMMENDED INTERNATIONAL CODE OF PRACTICE
GENERAL PRINCIPLES OF FOOD HYGIENE
CAC/RCP 1-1969, Rev. 4-2003

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INTRODUCTION

People have the right to expect the food they eat to be safe and suitable for consumption. Foodborne illness and foodborne injury are at best unpleasant; at worst, they can be fatal. But there are also other consequences. Outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment and litigation. Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence.

International food trade, and foreign travel, are increasing, bringing important social and economic benefits. But this also makes the spread of illness around the world easier. Eating habits too, have undergone major change in many countries over the last two decades and new food production, preparation and distribution techniques have developed to reflect this. Effective hygiene control, therefore, is vital to avoid the adverse human health and economic consequences of foodborne illness, foodborne injury, and food spoilage. Everyone, including farmers and growers, manufacturers and processors, food handlers and consumers, has a responsibility to assure that food is safe and suitable for consumption.

These General Principles lay a firm foundation for ensuring food hygiene and should be used in conjunction with each specific code of hygienic practice, where appropriate, and the guidelines on microbiological criteria. The document follows the food chain from primary production through to final consumption, highlighting the key hygiene controls at each stage. It recommends a HACCP-based approach wherever possible to enhance food safety as described in *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application* (Annex).

The controls described in this General Principles document are internationally recognized as essential to ensure the safety and suitability of food for consumption. The General Principles are commended to Governments, industry (including individual primary producers, manufacturers, processors, food service operators and retailers) and consumers alike.

SECTION I - OBJECTIVES

1.1 THE CODEX GENERAL PRINCIPLES OF FOOD HYGIENE:

- identify the *essential* principles of food hygiene applicable *throughout the food chain* (including primary production through to the final consumer), to achieve the goal of ensuring that food is safe and suitable for human consumption;
- recommend a HACCP-based approach as a means to enhance food safety;
- indicate *how* to implement those principles; and
- provide a *guidance* for specific codes which may be needed for - sectors of the food chain; processes; or commodities; to amplify the hygiene requirements specific to those areas.

SECTION II - SCOPE, USE AND DEFINITION

2.1 SCOPE

2.1.1 The food chain

This document follows the food chain from primary production to the final consumer, setting out the necessary hygiene conditions for producing food which is safe and suitable for consumption. The document provides a base-line structure for other, more specific, codes applicable to particular sectors. Such specific codes and guidelines should be read in conjunction with this

document and *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application* (Annex).

2.1.2 Roles of Governments, industry, and consumers

Governments can consider the contents of this document and decide how best they should encourage the implementation of these general principles to:

- protect consumers adequately from illness or injury caused by food; policies need to consider the vulnerability of the population, or of different groups within the population;
- provide assurance that food is suitable for human consumption;
- maintain confidence in internationally traded food; and
- provide health education programmes which effectively communicate the principles of food hygiene to industry and consumers.

Industry should apply the hygienic practices set out in this document to:

- provide food which is safe and suitable for consumption;
- ensure that consumers have clear and easily-understood information, by way of labelling and other appropriate means, to enable them to protect their food from contamination and growth/survival of foodborne pathogens by storing, handling and preparing it correctly; and
- maintain confidence in internationally traded food.

Consumers should recognize their role by following relevant instructions and applying appropriate food hygiene measures.

2.2 USE

Each section in this document states both the objectives to be achieved and the rationale behind those objectives in terms of the safety and suitability of food.

Section III covers primary production and associated procedures. Although hygiene practices may differ considerably for the various food commodities and specific codes should be applied where appropriate, some general guidance is given in this section. Sections IV to X set down the general hygiene principles which apply throughout the food chain to the point of sale. Section IX also covers consumer information, recognizing the important role played by consumers in maintaining the safety and suitability of food.

There will inevitably be situations where some of the specific requirements contained in this document are not applicable. The fundamental question in every case is "what is necessary and appropriate on the grounds of the safety and suitability of food for consumption?"

The text indicates where such questions are likely to arise by using the phrases "where necessary" and "where appropriate". In practice, this means that, although the requirement is generally appropriate and reasonable, there will nevertheless be some situations where it is neither necessary nor appropriate on the grounds of food safety and suitability. In deciding whether a requirement is necessary or appropriate, an assessment of the risk should be made, preferably within the framework of the HACCP approach. This approach allows the requirements in this document to be flexibly and sensibly applied with a proper regard for the overall objectives of producing food which is safe and suitable for consumption. In so doing it takes into account the

wide diversity of activities and varying degrees of risk involved in producing food. Additional guidance is available in specific food codes.

2.3 DEFINITIONS

For the purpose of this Code, the following expressions have the meaning stated:

Cleaning - the removal of soil, food residue, dirt, grease or other objectionable matter.

Contaminant - any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability.

Contamination - the introduction or occurrence of a contaminant in food or food environment.

Disinfection - the reduction, by means of chemical agents and/or physical methods, of the number of micro-organisms in the environment, to a level that does not compromise food safety or suitability.

Establishment - any building or area in which food is handled and the surroundings under the control of the same management.

Food hygiene - all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

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

HACCP - a system which identifies, evaluates, and controls hazards which are significant for food safety.

Food handler - any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements

Food safety - assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Food suitability - assurance that food is acceptable for human consumption according to its intended use.

Primary production - those steps in the food chain up to and including, for example, harvesting, slaughter, milking, fishing.

SECTION III - PRIMARY PRODUCTION

OBJECTIVES:

Primary production should be managed in a way that ensures that food is safe and suitable for its intended use. Where necessary, this will include:

– avoiding the use of areas where the environment poses a threat to the safety of food;

– controlling contaminants, pests and diseases of animals and plants in such a way as not to pose a threat to food safety;

– adopting practices and measures to ensure food is produced under appropriately hygienic conditions.

RATIONALE:

To reduce the likelihood of introducing a hazard which may adversely affect the safety of food, or its suitability for consumption, at later stages of the food chain.

3.1 ENVIRONMENTAL HYGIENE

Potential sources of contamination from the environment should be considered. In particular, primary food production should not be carried on in areas where the presence of potentially harmful substances would lead to an unacceptable level of such substances in food.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

The potential effects of primary production activities on the safety and suitability of food should be considered at all times. In particular, this includes identifying any specific points in such activities where a high probability of contamination may exist and taking specific measures to minimize that probability. The HACCP-based approach may assist in the taking of such measures - see *Hazard Analysis and Critical Control (HACCP) Point System and Guidelines for its Application* (Annex).

Producers should as far as practicable implement measures to:

- control contamination from air, soil, water, feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs or any other agent used in primary production;
- control plant and animal health so that it does not pose a threat to human health through food consumption, or adversely affect the suitability of the product; and
- protect food sources from faecal and other contamination.

In particular, care should be taken to manage wastes, and store harmful substances appropriately. On-farm programmes which achieve specific food safety goals are becoming an important part of primary production and should be encouraged.

3.3 HANDLING, STORAGE AND TRANSPORT

Procedures should be in place to:

- sort food and food ingredients to segregate material which is evidently unfit for human consumption;
- dispose of any rejected material in a hygienic manner; and
- Protect food and food ingredients from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling, storage and transport.

Care should be taken to prevent, so far as reasonably practicable, deterioration and spoilage through appropriate measures which may include controlling temperature, humidity, and/or other controls.

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

Appropriate facilities and procedures should be in place to ensure that:

- any necessary cleaning and maintenance is carried out effectively; and
- an appropriate degree of personal hygiene is maintained.

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

OBJECTIVES:

Depending on the nature of the operations, and the risks associated with them, premises, equipment and facilities should be located, designed and constructed to ensure that:

– contamination is minimized;

– design and layout permit appropriate maintenance, cleaning and disinfections and minimize air-borne contamination;

– surfaces and materials, in particular those in contact with food, are non-toxic in intended use and, where necessary, suitably durable, and easy to maintain and clean;

– where appropriate, suitable facilities are available for temperature, humidity and other controls; and

– there is effective protection against pest access and harbourage.

RATIONALE:

Attention to good hygienic design and construction, appropriate location, and the provision of adequate facilities, is necessary to enable hazards to be effectively controlled.

4.1 LOCATION

4.1.1 Establishments

Potential sources of contamination need to be considered when deciding where to locate food establishments, as well as the effectiveness of any reasonable measures that might be taken to protect food. Establishments should not be located anywhere where, after considering such protective measures, it is clear that there will remain a threat to food safety or suitability. In particular, establishments should normally be located away from:

- environmentally polluted areas and industrial activities which pose a serious threat of contaminating food;
- areas subject to flooding unless sufficient safeguards are provided;
- areas prone to infestations of pests;
- areas where wastes, either solid or liquid, cannot be removed effectively.

4.1.2 Equipment

Equipment should be located so that it:

- permits adequate maintenance and cleaning;
- functions in accordance with its intended use; and
- facilitates good hygiene practices, including monitoring.

4.2 PREMISES AND ROOMS

4.2.1 Design and layout

Where appropriate, the internal design and layout of food establishments should permit good food hygiene practices, including protection against cross-contamination between and during operations by foodstuffs.

4.2.2 Internal structures and fittings

Structures within food establishments should be soundly built of durable materials and be easy to maintain, clean and where appropriate, able to be disinfected. In particular the following specific conditions should be satisfied where necessary to protect the safety and suitability of food:

- the surfaces of walls, partitions and floors should be made of impervious materials with no toxic effect in intended use;
- walls and partitions should have a smooth surface up to a height appropriate to the operation;
- floors should be constructed to allow adequate drainage and cleaning;
- ceilings and overhead fixtures should be constructed and finished to minimize the build up of dirt and condensation, and the shedding of particles;
- windows should be easy to clean, be constructed to minimize the build up of dirt and where necessary, be fitted with removable and cleanable insect-proof screens. Where necessary, windows should be fixed;
- doors should have smooth, non-absorbent surfaces, and be easy to clean and, where necessary, disinfect;
- working surfaces that come into direct contact with food should be in sound condition, durable and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent materials, and inert to the food, to detergents and disinfectants under normal operating conditions.

4.2.3 Temporary/mobile premises and vending machines

Premises and structures covered here include market stalls, mobile sales and street vending vehicles, temporary premises in which food is handled such as tents and marquees.

Such premises and structures should be sited, designed and constructed to avoid, as far as reasonably practicable, contaminating food and harbouring pests.

In applying these specific conditions and requirements, any food hygiene hazards associated with such facilities should be adequately controlled to ensure the safety and suitability of food.

4.3 EQUIPMENT

4.3.1 General

Equipment and containers (other than once-only use containers and packaging) coming into contact with food, should be designed and constructed to ensure that, where necessary, they can be adequately cleaned, disinfected and maintained to avoid the contamination of food. Equipment and containers should be made of materials with no toxic effect in intended use. Where necessary, equipment should be durable and movable or capable of being disassembled to allow

for maintenance, cleaning, disinfection, monitoring and, for example, to facilitate inspection for pests.

4.3.2 Food control and monitoring equipment

In addition to the general requirements in paragraph 4.3.1, equipment used to cook, heat treat, cool, store or freeze food should be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and maintain them effectively. Such equipment should also be designed to allow temperatures to be monitored and controlled. Where necessary, such equipment should have effective means of controlling and monitoring humidity, air-flow and any other characteristic likely to have a detrimental effect on the safety or suitability of food. These requirements are intended to ensure that:

- harmful or undesirable micro-organisms or their toxins are eliminated or reduced to safe levels or their survival and growth are effectively controlled;
- where appropriate, critical limits established in HACCP-based plans can be monitored; and
- temperatures and other conditions necessary to food safety and suitability can be rapidly achieved and maintained.

4.3.3 Containers for waste and inedible substances

Containers for waste, by-products and inedible or dangerous substances, should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material. Containers used to hold dangerous substances should be identified and, where appropriate, be lockable to prevent malicious or accidental contamination of food.

4.4 FACILITIES

4.4.1 Water supply

An adequate supply of potable water with appropriate facilities for its storage, distribution and temperature control, should be available whenever necessary to ensure the safety and suitability of food.

Potable water should be as specified in the latest edition of WHO Guidelines for Drinking Water Quality, or water of a higher standard. Non-potable water (for use in, for example, fire control, steam production, refrigeration and other similar purposes where it would not contaminate food), shall have a separate system. Non-potable water systems shall be identified and shall not connect with, or allow reflux into, potable water systems.

4.4.2 Drainage and waste disposal

Adequate drainage and waste disposal systems and facilities should be provided. They should be designed and constructed so that the risk of contaminating food or the potable water supply is avoided.

4.4.3 Cleaning

Adequate facilities, suitably designated, should be provided for cleaning food, utensils and equipment. Such facilities should have an adequate supply of hot and cold potable water where appropriate.

4.4.4 Personnel hygiene facilities and toilets

Personnel hygiene facilities should be available to ensure that an appropriate degree of personal hygiene can be maintained and to avoid contaminating food. Where appropriate, facilities should include:

- adequate means of hygienically washing and drying hands, including wash basins and a supply of hot and cold (or suitably temperature controlled) water;
- lavatories of appropriate hygienic design; and
- adequate changing facilities for personnel.

Such facilities should be suitably located and designated.

4.4.5 Temperature control

Depending on the nature of the food operations undertaken, adequate facilities should be available for heating, cooling, cooking, refrigerating and freezing food, for storing refrigerated or frozen foods, monitoring food temperatures, and when necessary, controlling ambient temperatures to ensure the safety and suitability of food.

4.4.6 Air quality and ventilation

Adequate means of natural or mechanical ventilation should be provided, in particular to:

- minimize air-borne contamination of food, for example, from aerosols and condensation droplets;
- control ambient temperatures;
- control odours which might affect the suitability of food; and
- control humidity, where necessary, to ensure the safety and suitability of food.

Ventilation systems should be designed and constructed so that air does not flow from contaminated areas to clean areas and, where necessary, they can be adequately maintained and cleaned.

4.4.7 Lighting

Adequate natural or artificial lighting should be provided to enable the undertaking to operate in a hygienic manner. Where necessary, lighting should not be such that the resulting colour is misleading. The intensity should be adequate to the nature of the operation. Lighting fixtures should, where appropriate, be protected to ensure that food is not contaminated by breakages.

4.4.8 Storage

Where necessary, adequate facilities for the storage of food, ingredients and non-food chemicals (e.g. cleaning materials, lubricants, fuels) should be provided.

Where appropriate, food storage facilities should be designed and constructed to:

- permit adequate maintenance and cleaning;
- avoid pest access and harbourage;
- enable food to be effectively protected from contamination during storage; and

- where necessary, provide an environment which minimizes the deterioration of food (e.g. by temperature and humidity control).

The type of storage facilities required will depend on the nature of the food. Where necessary, separate, secure storage facilities for cleaning materials and hazardous substances should be provided.

SECTION V - CONTROL OF OPERATION

OBJECTIVE:

To produce food which is safe and suitable for human consumption by:

– formulating design requirements with respect to raw materials, composition, processing, distribution, and consumer use to be met in the manufacture and handling of specific food items; and

– designing, implementing, monitoring and reviewing effective control systems.

RATIONALE:

To reduce the risk of unsafe food by taking preventive measures to assure the safety and suitability of food at an appropriate stage in the operation by controlling food hazards.

5.1 CONTROL OF FOOD HAZARDS

Food business operators should control food hazards through the use of systems such as HACCP. They should:

- **identify** any steps in their operations which are critical to the safety of food;
- **implement** effective control procedures at those steps;
- **monitor** control procedures to ensure their continuing effectiveness; and
- **review** control procedures periodically, and whenever the operations change.

These systems should be applied throughout the food chain to control food hygiene throughout the shelf-life of the product through proper product and process design.

Control procedures may be simple, such as checking stock rotation calibrating equipment, or correctly loading refrigerated display units. In some cases a system based on expert advice, and involving documentation, may be appropriate. A model of such a food safety system is described in *Hazard Analysis and Critical Control (HACCP) System and Guidelines for its Application* (Annex).

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Time and temperature control

Inadequate food temperature control is one of the most common causes of foodborne illness or food spoilage. Such controls include time and temperature of cooking, cooling, processing and storage. Systems should be in place to ensure that temperature is controlled effectively where it is critical to the safety and suitability of food.

Temperature control systems should take into account:

- the nature of the food, e.g. its water activity, pH, and likely initial level and types of micro-organisms;
- the intended shelf-life of the product;
- the method of packaging and processing; and
- how the product is intended to be used, e.g. further cooking/processing or ready-to-eat.

Such systems should also specify tolerable limits for time and temperature variations.

Temperature recording devices should be checked at regular intervals and tested for accuracy.

5.2.2 Specific process steps

Other steps which contribute to food hygiene may include, for example:

- chilling
- thermal processing
- irradiation
- drying
- chemical preservation
- vacuum or modified atmospheric packaging

5.2.3 Microbiological and other specifications

Management systems described in paragraph 5.1 offer an effective way of ensuring the safety and suitability of food. Where microbiological, chemical or physical specifications are used in any food control system, such specifications should be based on sound scientific principles and state, where appropriate, monitoring procedures, analytical methods and action limits.

5.2.4 Microbiological cross-contamination

Pathogens can be transferred from one food to another, either by direct contact or by food handlers, contact surfaces or the air. Raw, unprocessed food should be effectively separated, either physically or by time, from ready-to-eat foods, with effective intermediate cleaning and where appropriate disinfection.

Access to processing areas may need to be restricted or controlled. Where risks are particularly high, access to processing areas should be only via a changing facility. Personnel may need to be required to put on clean protective clothing including footwear and wash their hands before entering.

Surfaces, utensils, equipment, fixtures and fittings should be thoroughly cleaned and where necessary disinfected after raw food, particularly meat and poultry, has been handled or processed.

5.2.5 Physical and chemical contamination

Systems should be in place to prevent contamination of foods by foreign bodies such as glass or metal shards from machinery, dust, harmful fumes and unwanted chemicals. In manufacturing and processing, suitable detection or screening devices should be used where necessary.

5.3 INCOMING MATERIAL REQUIREMENTS

No raw material or ingredient should be accepted by an establishment if it is known to contain parasites, undesirable micro-organisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal sorting and/or processing. Where appropriate, specifications for raw materials should be identified and applied.

Raw materials or ingredients should, where appropriate, be inspected and sorted before processing. Where necessary, laboratory tests should be made to establish fitness for use. Only sound, suitable raw materials or ingredients should be used.

Stocks of raw materials and ingredients should be subject to effective stock rotation.

5.4 PACKAGING

Packaging design and materials should provide adequate protection for products to minimize contamination, prevent damage, and accommodate proper labelling. Packaging materials or gases where used must be non-toxic and not pose a threat to the safety and suitability of food under the specified conditions of storage and use. Where appropriate, reusable packaging should be suitably durable, easy to clean and, where necessary, disinfect.

5.5 WATER

5.5.1 In contact with food

Only potable water, should be used in food handling and processing, with the following exceptions:

- for steam production, fire control and other similar purposes not connected with food; and
- in certain food processes, e.g. chilling, and in food handling areas, provided this does not constitute a hazard to the safety and suitability of food (e.g. the use of clean sea water).

Water recirculated for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of food results from its use. The treatment process should be effectively monitored. Recirculated water which has received no further treatment and water recovered from processing of food by evaporation or drying may be used, provided its use does not constitute a risk to the safety and suitability of food.

5.5.2 As an ingredient

Potable water should be used wherever necessary to avoid food contamination.

5.5.3 Ice and steam

Ice should be made from water that complies with section 4.4.1. Ice and steam should be produced, handled and stored to protect them from contamination.

Steam used in direct contact with food or food contact surfaces should not constitute a threat to the safety and suitability of food.

5.6 MANAGEMENT AND SUPERVISION

The type of control and supervision needed will depend on the size of the business, the nature of its activities and the types of food involved. Managers and supervisors should have enough knowledge of food hygiene principles and practices to be able to judge potential risks, take

appropriate preventive and corrective action, and ensure that effective monitoring and supervision takes place.

5.7 DOCUMENTATION AND RECORDS

Where necessary, appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf-life of the product. Documentation can enhance the credibility and effectiveness of the food safety control system.

5.8 RECALL PROCEDURES

Managers should ensure effective procedures are in place to deal with any food safety hazard and to enable the complete, rapid recall of any implicated lot of the finished food from the market. Where a product has been withdrawn because of an immediate health hazard, other products which are produced under similar conditions, and which may present a similar hazard to public health, should be evaluated for safety and may need to be withdrawn. The need for public warnings should be considered.

Recalled products should be held under supervision until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to ensure their safety.

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

OBJECTIVE:

To establish effective systems to:

– ensure adequate and appropriate maintenance and cleaning;

– control pests;

– manage waste; and

– monitor effectiveness of maintenance and sanitation procedures.

RATIONALE:

To facilitate the continuing effective control of food hazards, pests, and other agents likely to contaminate food.

6.1 MAINTENANCE AND CLEANING

6.1.1 General

Establishments and equipment should be kept in an appropriate state of repair and condition to:

- facilitate all sanitation procedures;
- function as intended, particularly at critical steps (see paragraph 5.1);
- prevent contamination of food, e.g. from metal shards, flaking plaster, debris and chemicals.

Cleaning should remove food residues and dirt which may be a source of contamination. The necessary cleaning methods and materials will depend on the nature of the food business. Disinfection may be necessary after cleaning.

Cleaning chemicals should be handled and used carefully and in accordance with manufacturers' instructions and stored, where necessary, separated from food, in clearly identified containers to avoid the risk of contaminating food.

6.1.2 Cleaning procedures and methods

Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow, vacuum cleaning or other methods that avoid the use of water, and chemical methods using detergents, alkalis or acids.

Cleaning procedures will involve, where appropriate:

- removing gross debris from surfaces;
- applying a detergent solution to loosen soil and bacterial film and hold them in solution or suspension;
- rinsing with water which complies with section 4, to remove loosened soil and residues of detergent;
- dry cleaning or other appropriate methods for removing and collecting residues and debris; and
- where necessary, disinfection with subsequent rinsing unless the manufacturers' instructions indicate on scientific basis that rinsing is not required.

6.2 CLEANING PROGRAMMES

Cleaning and disinfection programmes should ensure that all parts of the establishment are appropriately clean, and should include the cleaning of cleaning equipment.

Cleaning and disinfection programmes should be continually and effectively monitored for their suitability and effectiveness and where necessary, documented.

Where written cleaning programmes are used, they should specify:

- areas, items of equipment and utensils to be cleaned;
- responsibility for particular tasks;
- method and frequency of cleaning; and
- monitoring arrangements.

Where appropriate, programmes should be drawn up in consultation with relevant specialist expert advisors.

6.3 PEST CONTROL SYSTEMS

6.3.1 General

Pests pose a major threat to the safety and suitability of food. Pest infestations can occur where there are breeding sites and a supply of food. Good hygiene practices should be employed to avoid creating an environment conducive to pests. Good sanitation, inspection of incoming materials and good monitoring can minimize the likelihood of infestation and thereby limit the need for pesticides.

6.3.2 Preventing access

Buildings should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access should be kept sealed. Wire mesh screens, for example on open windows, doors and ventilators, will reduce the problem of pest entry. Animals should, wherever possible, be excluded from the grounds of factories and food processing plants.

6.3.3 Harbourage and infestation

The availability of food and water encourages pest harbourage and infestation. Potential food sources should be stored in pest-proof containers and/or stacked above the ground and away from walls. Areas both inside and outside food premises should be kept clean. Where appropriate, refuse should be stored in covered, pest-proof containers.

6.3.4 Monitoring and detection

Establishments and surrounding areas should be regularly examined for evidence of infestation.

6.3.5 Eradication

Pest infestations should be dealt with immediately and without adversely affecting food safety or suitability. Treatment with chemical, physical or biological agents should be carried out without posing a threat to the safety or suitability of food.

6.4 WASTE MANAGEMENT

Suitable provision must be made for the removal and storage of waste. Waste must not be allowed to accumulate in food handling, food storage, and other working areas and the adjoining environment except so far as is unavoidable for the proper functioning of the business.

Waste stores must be kept appropriately clean.

6.5 MONITORING EFFECTIVENESS

Sanitation systems should be monitored for effectiveness, periodically verified by means such as audit pre-operational inspections or, where appropriate, microbiological sampling of environment and food contact surfaces and regularly reviewed and adapted to reflect changed circumstances.

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

OBJECTIVES:

To ensure that those who come directly or indirectly into contact with food are not likely to contaminate food by:

– maintaining an appropriate degree of personal cleanliness;

– behaving and operating in an appropriate manner.

RATIONALE:

People who do not maintain an appropriate degree of personal cleanliness, who have certain illnesses or conditions or who behave inappropriately, can contaminate food and transmit illness to consumers.

7.1 HEALTH STATUS

People known, or suspected, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through food, should not be allowed to enter any food handling area if there is a likelihood of their contaminating food. Any person so affected should immediately report illness or symptoms of illness to the management.

Medical examination of a food handler should be carried out if clinically or epidemiologically indicated.

7.2 ILLNESS AND INJURIES

Conditions which should be reported to management so that any need for medical examination and/or possible exclusion from food handling can be considered, include:

- jaundice;
- diarrhoea;
- vomiting;
- fever;
- sore throat with fever;
- visibly infected skin lesions (boils, cuts, etc.);
- discharges from the ear, eye or nose.

7.3 PERSONAL CLEANLINESS

Food handlers should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head covering, and footwear. Cuts and wounds, where personnel are permitted to continue working, should be covered by suitable waterproof dressings.

Personnel should always wash their hands when personal cleanliness may affect food safety, for example:

- at the start of food handling activities;
- immediately after using the toilet; and
- after handling raw food or any contaminated material, where this could result in contamination of other food items; they should avoid handling ready-to-eat food, where appropriate.

7.4 PERSONAL BEHAVIOUR

People engaged in food handling activities should refrain from behaviour which could result in contamination of food, for example:

- smoking;
- spitting;
- chewing or eating;
- sneezing or coughing over unprotected food.

Personal effects such as jewellery, watches, pins or other items should not be worn or brought into food handling areas if they pose a threat to the safety and suitability of food.

7.5 VISITORS

Visitors to food manufacturing, processing or handling areas should, where appropriate, wear protective clothing and adhere to the other personal hygiene provisions in this section.

SECTION VIII - TRANSPORTATION

OBJECTIVES:

Measures should be taken where necessary to:

– protect food from potential sources of contamination;

– protect food from damage likely to render the food unsuitable for consumption; and

– provide an environment which effectively controls the growth of pathogenic or spoilage micro-organisms and the production of toxins in food.

RATIONALE:

Food may become contaminated, or may not reach its destination in a suitable condition for consumption, unless effective control measures are taken during transport, even where adequate hygiene control measures have been taken earlier in the food chain.

8.1 GENERAL

Food must be adequately protected during transport. The type of conveyances or containers required depends on the nature of the food and the conditions under which it has to be transported.

8.2 REQUIREMENTS

Where necessary, conveyances and bulk containers should be designed and constructed so that they:

- do not contaminate foods or packaging;
- can be effectively cleaned and, where necessary, disinfected;
- permit effective separation of different foods or foods from non-food items where necessary during transport;
- provide effective protection from contamination, including dust and fumes;
- can effectively maintain the temperature, humidity, atmosphere and other conditions necessary to protect food from harmful or undesirable microbial growth and deterioration likely to render it unsuitable for consumption; and
- allow any necessary temperature, humidity and other conditions to be checked.

8.3 USE AND MAINTENANCE

Conveyances and containers for transporting food should be kept in an appropriate state of cleanliness, repair and condition. Where the same conveyance or container is used for transporting different foods, or non-foods, effective cleaning and, where necessary, disinfection should take place between loads.

Where appropriate, particularly in bulk transport, containers and conveyances should be designated and marked for food use only and be used only for that purpose.

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

OBJECTIVES:

Products should bear appropriate information to ensure that:

– adequate and accessible information is available to the next person in the food chain to enable them to handle, store, process, prepare and display the product safely and correctly;

– the lot or batch can be easily identified and recalled if necessary.

Consumers should have enough knowledge of food hygiene to enable them to:

– understand the importance of product information;

– make informed choices appropriate to the individual; and

– prevent contamination and growth or survival of foodborne pathogens by storing, preparing and using it correctly.

Information for industry or trade users should be clearly distinguishable from consumer information, particularly on food labels.

RATIONALE:

Insufficient product information, and/or inadequate knowledge of general food hygiene, can lead to products being mishandled at later stages in the food chain. Such mishandling can result in illness, or products becoming unsuitable for consumption, even where adequate hygiene control measures have been taken earlier in the food chain.

9.1 LOT IDENTIFICATION

Lot identification is essential in product recall and also helps effective stock rotation. Each container of food should be permanently marked to identify the producer and the lot. Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985, Rev. 1(1991)) applies.

9.2 PRODUCT INFORMATION

All food products should be accompanied by or bear adequate information to enable the next person in the food chain to handle, display, store and prepare and use the product safely and correctly.

9.3 LABELLING

Prepackaged foods should be labelled with clear instructions to enable the next person in the food chain to handle, display, store and use the product safely. Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985, Rev. (1991)) applies.

9.4 CONSUMER EDUCATION

Health education programmes should cover general food hygiene. Such programmes should enable consumers to understand the importance of any product information and to follow any instructions accompanying products, and make informed choices. In particular consumers should be informed of the relationship between time/temperature control and foodborne illness.

SECTION X - TRAINING

OBJECTIVE:

Those engaged in food operations who come directly or indirectly into contact with food should be trained, and/or instructed in food hygiene to a level appropriate to the operations they are to perform.

RATIONALE:

Training is fundamentally important to any food hygiene system.

Inadequate hygiene training, and/or instruction and supervision of *all* people involved in food related activities pose a potential threat to the safety of food and its suitability for consumption.

10.1 AWARENESS AND RESPONSIBILITIES

Food hygiene training is fundamentally important. All personnel should be aware of their role and responsibility in protecting food from contamination or deterioration. Food handlers should have the necessary knowledge and skills to enable them to handle food hygienically. Those who handle strong cleaning chemicals or other potentially hazardous chemicals should be instructed in safe handling techniques.

10.2 TRAINING PROGRAMMES

Factors to take into account in assessing the level of training required include:

- the nature of the food, in particular its ability to sustain growth of pathogenic or spoilage micro-organisms;
- the manner in which the food is handled and packed, including the probability of contamination;
- the extent and nature of processing or further preparation before final consumption;
- the conditions under which the food will be stored; and
- the expected length of time before consumption.

10.3 INSTRUCTION AND SUPERVISION

Periodic assessments of the effectiveness of training and instruction programmes should be made, as well as routine supervision and checks to ensure that procedures are being carried out effectively.

Managers and supervisors of food processes should have the necessary knowledge of food hygiene principles and practices to be able to judge potential risks and take the necessary action to remedy deficiencies.

10.4 REFRESHER TRAINING

Training programmes should be routinely reviewed and updated where necessary. Systems should be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety and suitability of food.

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION

Annex to CAC/RCP 1-1969 (Rev. 4 - 2003)

PREAMBLE

The first section of this document sets out the principles of the Hazard Analysis and Critical Control Point (HACCP) system adopted by the Codex Alimentarius Commission. The second section provides general guidance for the application of the system while recognizing that the details of application may vary depending on the circumstances of the food operation.[2]

The HACCP system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

HACCP can be applied throughout the food chain from primary production to final consumption and its implementation should be guided by scientific evidence of risks to human health. As well as enhancing food safety, implementation of HACCP can provide other significant benefits. In addition, the application of HACCP systems can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety.

The successful application of HACCP requires the full commitment and involvement of management and the work force. It also requires a multidisciplinary approach; this multidisciplinary approach should include, when appropriate, expertise in agronomy, veterinary health, production, microbiology, medicine, public health, food technology, environmental health, chemistry and engineering, according to the particular study. The application of HACCP is compatible with the implementation of quality management systems, such as the ISO 9000 series, and is the system of choice in the management of food safety within such systems.

While the application of HACCP to food safety was considered here, the concept can be applied to other aspects of food quality.

DEFINITIONS

Control (verb): To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

Control (noun): The state wherein correct procedures are being followed and criteria are being met.

Control measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective action: Any action to be taken when the results of monitoring at the CCP indicate a loss of control.

Critical Control Point (CCP): A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical limit: A criterion which separates acceptability from unacceptability.

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[2] The Principles of the HACCP System set the basis for the requirements for the application of HACCP, while the Guidelines for the Application provide general guidance for practical application.

Deviation: Failure to meet a critical limit.

Flow diagram: A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

HACCP: A system which identifies, evaluates, and controls hazards which are significant for food safety.

HACCP plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.

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

Hazard analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Step: A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.

Validation: Obtaining evidence that the elements of the HACCP plan are effective.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

PRINCIPLES OF THE HACCP SYSTEM

The HACCP system consists of the following seven principles:

PRINCIPLE 1

Conduct a hazard analysis.

PRINCIPLE 2

Determine the Critical Control Points (CCPs).

PRINCIPLE 3

Establish critical limit(s).

PRINCIPLE 4

Establish a system to monitor control of the CCP.

PRINCIPLE 5

Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

PRINCIPLE 6

Establish procedures for verification to confirm that the HACCP system is working effectively.

PRINCIPLE 7

Establish documentation concerning all procedures and records appropriate to these principles and their application.

GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

INTRODUCTION

Prior to application of HACCP to any sector of the food chain, that sector should have in place prerequisite programs such as good hygienic practices according to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice, and appropriate food safety requirements. These prerequisite programs to HACCP, including training, should be well established, fully operational and verified in order to facilitate the successful application and implementation of the HACCP system.

For all types of food business, management awareness and commitment is necessary for implementation of an effective HACCP system. The effectiveness will also rely upon management and employees having the appropriate HACCP knowledge and skills.

During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration must be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

The intent of the HACCP system is to focus control at Critical Control Points (CCPs). Redesign of the operation should be considered if a hazard which must be controlled is identified but no CCPs are found.

HACCP should be applied to each specific operation separately. CCPs identified in any given example in any Codex Code of Hygienic Practice might not be the only ones identified for a specific application or might be of a different nature. The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step.

The application of the HACCP principles should be the responsibility of each individual businesses. However, it is recognised by governments and businesses that there may be obstacles that hinder the effective application of the HACCP principles by individual business. This is particularly relevant in small and/or less developed businesses. While it is recognized that when applying HACCP, flexibility appropriate to the business is important, all seven principles must be applied in the HACCP system. This flexibility should take into account the nature and size of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints.

Small and/or less developed businesses do not always have the resources and the necessary expertise on site for the development and implementation of an effective HACCP plan. In such situations, expert advice should be obtained from other sources, which may include: trade and industry associations, independent experts and regulatory authorities. HACCP literature and especially sector-specific HACCP guides can be valuable. HACCP guidance developed by experts relevant to the process or type of operation may provide a useful tool for businesses in designing and implementing the HACCP plan. Where businesses are using expertly developed HACCP guidance, it is essential that it is specific to the foods and/or processes under consideration. More detailed information on the obstacles in implementing HACCP, particularly in reference to SLDBs, and recommendations in resolving these obstacles, can be found in "Obstacles to the Application of HACCP, Particularly in Small and Less Developed Businesses, and Approaches to Overcome Them" (document in preparation by FAO/WHO).

The efficacy of any HACCP system will nevertheless rely on management and employees having the appropriate HACCP knowledge and skills, therefore ongoing training is necessary for all levels of employees and managers, as appropriate.

APPLICATION

The application of HACCP principles consists of the following tasks as identified in the Logic Sequence for Application of HACCP (Diagram 1).

1. Assemble HACCP team

The food operation should assure that the appropriate product specific knowledge and expertise is available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available on site, expert advice should be obtained from other sources, such as, trade and industry associations, independent experts, regulatory authorities, HACCP literature and HACCP guidance (including sector-specific HACCP guides). It may be possible that a well-trained individual with access to such guidance is able to implement HACCP in-house. The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed (e.g. does it cover all classes of hazards or only selected classes).

2. Describe product

A full description of the product should be drawn up, including relevant safety information such as: composition, physical/chemical structure (including A_w, pH, etc), microcidal/static treatments (heat-treatment, freezing, brining, smoking, etc), packaging, durability and storage conditions and method of distribution. Within businesses with multiple products, for example, catering operations, it may be effective to group products with similar characteristics or processing steps, for the purpose of development of the HACCP plan.

3. Identify intended use

The intended use should be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population, e.g. institutional feeding, may have to be considered.

4. Construct flow diagram

The flow diagram should be constructed by the HACCP team (see also paragraph 1 above). The flow diagram should cover all steps in the operation for a specific product. The same flow diagram may be used for a number of products that are manufactured using similar processing steps. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

5. On-site confirmation of flow diagram

Steps must be taken to confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. The confirmation of the flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation.

6. List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards

(SEE PRINCIPLE 1)

The HACCP team (see "assemble HACCP team" above) should list all of the hazards that may be reasonably expected to occur at each step according to the scope from primary production, processing, manufacture, and distribution until the point of consumption.

The HACCP team (see "assemble HACCP team") should next conduct a hazard analysis to identify for the HACCP plan, which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food.

In conducting the hazard analysis, wherever possible the following should be included:

- the likely occurrence of hazards and severity of their adverse health effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;

- survival or multiplication of micro-organisms of concern;
- production or persistence in foods of toxins, chemicals or physical agents; and,
- conditions leading to the above.

Consideration should be given to what control measures, if any exist, can be applied to each hazard.

More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

7. Determine Critical Control Points

(SEE PRINCIPLE 2)[3]

There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree (e.g., Diagram 2), which indicates a logic reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other. It should be used for guidance when determining CCPs. This example of a decision tree may not be applicable to all situations. Other approaches may be used. Training in the application of the decision tree is recommended.

If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

8. Establish critical limits for each CCP

(SEE PRINCIPLE 3)

Critical limits must be specified and validated for each Critical Control Point. In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include measurements of temperature, time, moisture level, pH, A_w, available chlorine, and sensory parameters such as visual appearance and texture.

Where HACCP guidance developed by experts has been used to establish the critical limits, care should be taken to ensure that these limits fully apply to the specific operation, product or groups of products under consideration. These critical limits should be measurable.

9. Establish a monitoring system for each CCP

(SEE PRINCIPLE 4)

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in

[3] Since the publication of the decision tree by Codex, its use has been implemented many times for training purposes. In many instances, while this tree has been useful to explain the logic and depth of understanding needed to determine CCPs, it is not specific to all food operations, e.g., slaughter, and therefore it should be used in conjunction with professional judgement, and modified in some cases.

control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product.

All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

10. Establish corrective actions

(SEE PRINCIPLE 5)

Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur.

The actions must ensure that the CCP has been brought under control. Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the HACCP record keeping.

11. Establish verification procedures

(SEE PRINCIPLE 6)

Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively.

Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in house, verification should be performed on behalf of the business by external experts or qualified third parties.

Examples of verification activities include:

- Review of the HACCP system and plan and its records;
- Review of deviations and product dispositions;
- Confirmation that CCPs are kept under control.

Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP system.

12. Establish Documentation and Record Keeping

(SEE PRINCIPLE 7)

Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained. Expertly developed HACCP guidance materials (e.g. sector-specific HACCP guides) may be utilised as part of the documentation, provided that those materials reflect the specific food operations of the business.

Documentation examples are:

Hazard analysis;

CCP determination;

Critical limit determination.

Record examples are:

- CCP monitoring activities;
- Deviations and associated corrective actions;
- Verification procedures performed;
- Modifications to the HACCP plan;

An example of a HACCP worksheet for the development of a HACCP plan is attached as Diagram 3.

A simple record-keeping system can be effective and easily communicated to employees. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices and checklists to record, for example, product temperatures.

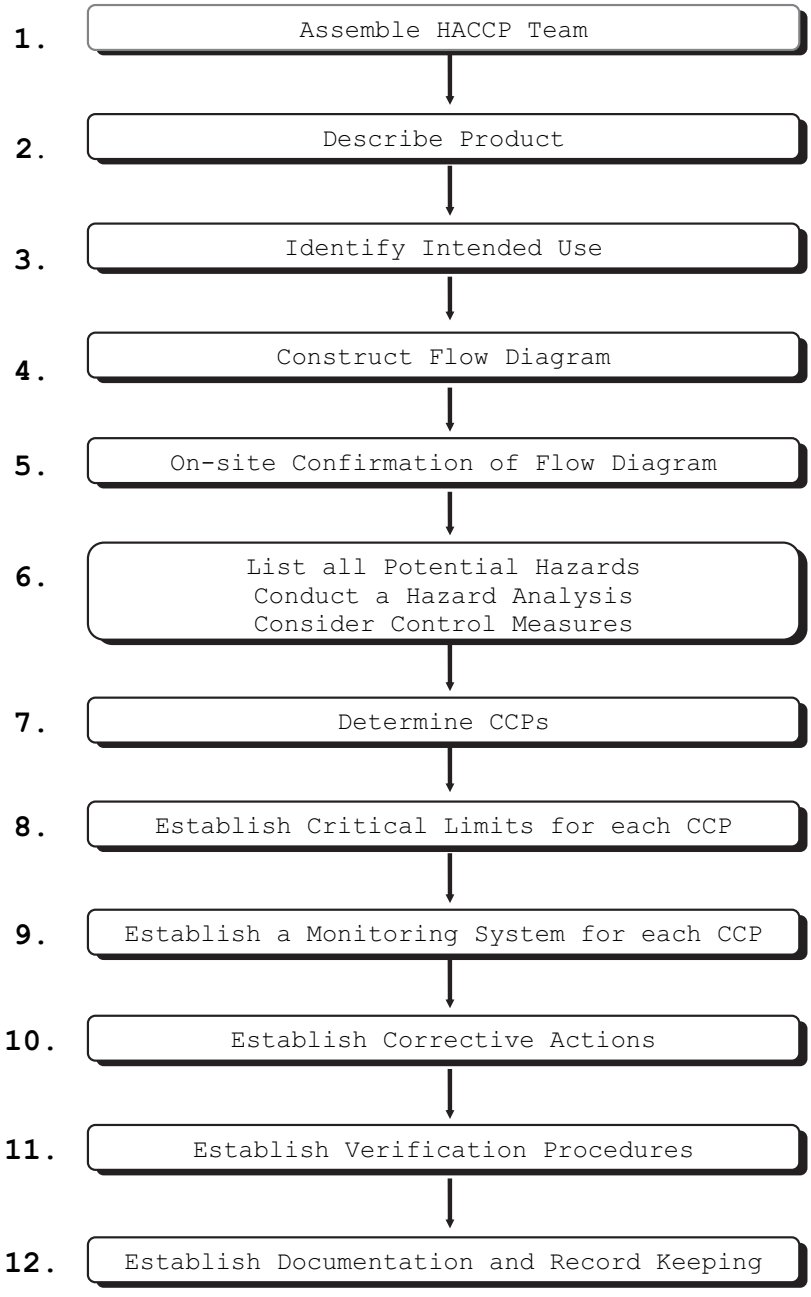
TRAINING

Training of personnel in industry, government and academia in HACCP principles and applications and increasing awareness of consumers are essential elements for the effective implementation of HACCP. As an aid in developing specific training to support a HACCP plan, working instructions and procedures should be developed which define the tasks of the operating personnel to be stationed at each Critical Control Point.

Cooperation between primary producer, industry, trade groups, consumer organisations, and responsible authorities is of vital important. Opportunities should be provided for the joint training of industry and control authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

DIAGRAM 1

LOGIC SEQUENCE FOR APPLICATION OF HACCP

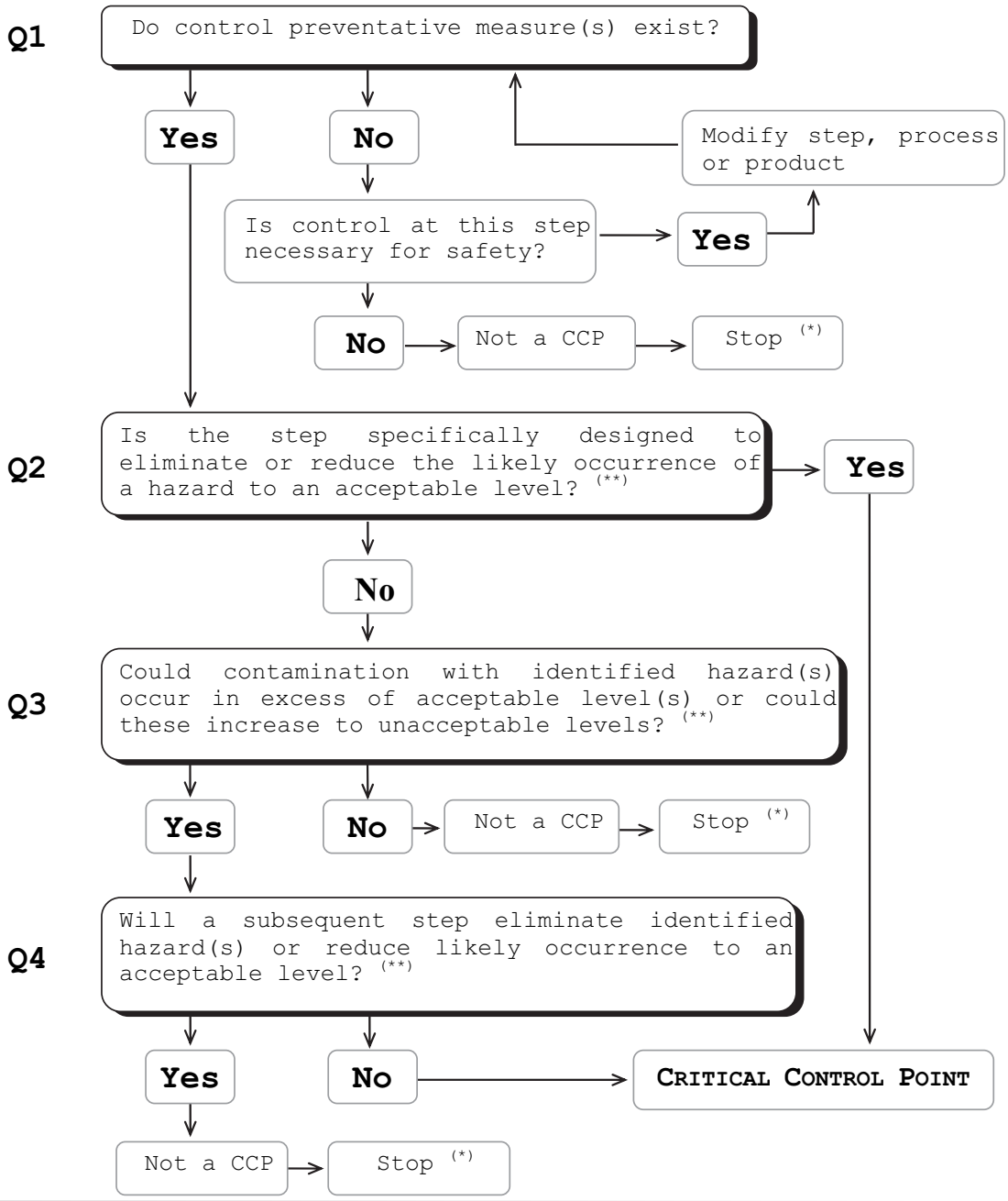


See Diagram 2

DIAGRAM 2

EXAMPLE OF DECISION TREE TO IDENTIFY CCPs

(answer questions in sequence)



(*) Proceed to the next identified hazard in the described process.

(**) Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the CCPs of HACCP plan.

DIAGRAM 3

EXAMPLE OF A HACCP WORKSHEET

1. Describe Product

2. Diagram Process Flow

3.

LIST							
Step	Hazard(s)	Control Measure(s)	CCPs	Critical Limit(s)	Monitoring Procedure(s)	Corrective Action(s)	Record(s)

4. Verification

APPENDIX D:
LIST OF CODEX REFERENCES PROVIDING EXAMPLES OF PREREQUISITE PROGRAMS AND GUIDANCE FOR THEIR SELECTION AND USE

GENERAL CODES AND GUIDELINES

Code of Practice - General Principles of Food Hygiene – CAC/RCP 1-1969, Rev. 4-2003

COMMODITY SPECIFIC CODES AND GUIDELINES

Feed

- Code of Practice for Good Animal Feeding – CAC/RCP 54-2004

Foods for special intended uses

- Code of Hygienic Practice for Powdered Formulae for Infants and Young Children – CAC/RCP 66-2008 (Supersede RCP 21/GL08)
  - Code of Hygienic Practice for Foods for Infants and Children – CAC/RCP 21-1979
  - Guidelines on Formulated Supplementary Foods for Older Infants and Young Children – CAC/GL 08-1991
- Code of Hygienic Practice for Refrigerated Pack aged Foods with Extended Shelf Life – CAC/RCP 46- 1999

Specifically processed foods

- Code of Hygienic Practice for the Processing and Handling of Quick Frozen Foods – CAC/RCP 8-1976, Rev. 3-2008
- Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods – CAC/RCP 23-1979, Rev. 2-1993
- Code of Hygienic Practice for Aseptically Processed and Packaged Low-Acid Foods – CAC/RCP40-1993

Ingredients for foods

- Code of Hygienic Practice for Spices and Dried Aromatic Plants – CAC/RCP 42-1995

Fruits and vegetables

- Code of Hygienic Practice for Canned Fruit and Vegetable Products – CAC/RCP 2-1969
- Code of Hygienic Practice for Dried Fruit – CAC/RCP 3-1969

- Code of Hygienic Practice for Desiccated Coconut – CAC/RCP 4-1971
- Code of Hygienic Practice for Dehydrated Fruits and Vegetables, including Edible Fungi – CAC/RCP 5-1971
- Code of Hygienic Practice for Tree Nuts – CAC/RCP 6-1972
- Code of Hygienic Practice for Groundnuts (Peanuts) – CAC/RCP 22-1979
- Code of Hygienic Practice for Fresh Fruits and Vegetables – CAC/RCP 53-2003

Meat and meat products

- General Principles of Meat Hygiene – CAC/RCP 58-2005 (Supersedes RCP11, RCP13, RCP14, RCP29, RCP 32 and RCP41)
  - Code of Hygienic Practice for Fresh Meat – CAC/RCP 11-1976, Rev. 1 (1993)
  - Code of Hygienic Practice for Processed Meat and Poultry Products – CAC/RCP 13-1976, Rev. 1 (1985)
  - Code of Hygienic Practice for Poultry Processing – CAC/RCP 14-1976
  - Code of Hygienic Practice for Game – CAC/RCP 29-1983, Rev. 1 (1993)
  - Code of Practice for the Production, Storage and Composition of Mechanically Separated Meat and Poultry for Further Processing – CAC/RCP 32-1983
  - Code for Ante-mortem and Post-mortem Inspection of Slaughter Animals and for Ante-mortem and Post-mortem Judgment of Slaughter Animals and Meat – CAC/RCP 41-1993
- Code of Hygienic Practice for the Processing of Frog Legs – CAC/RCP 30-1983

Milk and milk products

- Code of Hygienic Practice for Milk and Milk Products – CAC/RCP 57-2004

Egg and egg products

- Code of Hygienic Practice for Egg Products – CAC/RCP 15-1976 (amended 1978, 1985), Rev 1-2007

Fish and fishery products

- Code of Practice for Fish and Fishery Products – CAC/RCP 52-2003, Rev. 4-2008 (supersedes RCP17, RCP18, RCP26, RCP35 and RCP 37)
  - Code of Practice for Shrimps or Prawns – CAC/RCP 17-1978
  - Code of Hygienic Practice for Molluscan Shellfish – CAC/RCP 18-1978
  - Code of Practice for Salted Fish – CAC/RCP 26-1979

  - Code of Practice for Frozen Battered and/or Breaded Fishery products – CAC/RCP 35-1985
  - Code of Practice for Cephalopods – CAC/RCP 37-1989
- Code of Practice for Crabs – CAC/RCP 28-1983
- Code of Practice for Lobsters – CAC/RCP 24-1979
- Code of Practice for Smoked Fish – CAC/RCP 25-1979

Waters

- Code of Hygienic Practice for the Collection, Processing and Marketing of Natural Mineral Water – CAC/RCP 33-1985
- Code of Hygienic Practice for Bottled/Packaged Drinking Waters (Other than Natural Mineral Water) – CAC/RCP 48-2001

Transportation

- Code of Hygienic Practice for the Transport of Food in Bulk and Semi-packed Food – CAC/RCP 47-2001
- Code of Practice for the Storage and Transport of Edible Oils and Fats in Bulk – CAC/RCP 36-1987, Rev. 1-1999)
- Code of Practice for Packaging and Transport of Tropical Fresh Fruit and Vegetables – CAC/RCP 44-1995

Retail

- Code of Hygienic Practice for the Preparation and Sale of Street Foods (Regional Code – Latin America and the Caribbean) – CAC/RCP 43-1997, Rev.1-2001
- Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering – CAC/RCP 39-1993

FOOD SAFETY HAZARD SPECIFIC CODES AND GUIDELINES

- Code of Practice for Radiation Processing of Food – CAC/RCP19-1979, Rev. 2-2003
- Code of Practice for Control of the Use of Veterinary Drugs – CAC/RCP 38-1993
- Code of Practice for the Prevention and Reduction of Patulin Contamination in Apple Juice and Apple Juice – CAC/RCP50-2003
- Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisins and tricothecenes – CAC/RCP51-2003
- Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts – CAC/RCP55-2004

- Code of Practice for the Prevention and Reduction of Lead Contamination in Foods – CAC/RCP56-2004
- Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts – CAC/RCP 59-2005
- Code of Practice for the Prevention and Reduction of Tin Contamination in Canned Foods – CAC/RCP60-2005
- Code of Practice to Minimize and Control Antimicrobial Resistance – CAC/RCP61-2005
- Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feeds – CAC/RCP62-2006
- Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Wine – CAC/RCP63-2007
- Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol (3-MCPD) during the Production of Acid-Hydrolyzed Vegetable Protein (Acid-HVPs) and Products that Contain Acid-HVPs – CAC/RCP64-2008
- Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs – CAC/RCP65-2008

APPENDIX E:
EXAMPLE OF A HAZARD / RISK ASSESSMENT TABLE

Assessing the PROBABILITY (P) of an adverse health effect (Frequency of occurrence and the typical levels)

- A = FREQUENT – Occurs often to individual and population is continuously exposed
- B = LIKELY – Occurs several times and population are exposed regularly
- C = OCCASIONAL – Will occur and occurs sporadically in a population
- D = SELDOM – May occur and occurs seldom in a population
- E = UNLIKELY – So unlikely that assumption that it will not occur and occurs very rarely in a population

Assess the SEVERITY (S) of that effect (Adverse health effects that can be caused by the hazard)

- I = CATASTROPHIC – Death
- II = CRITICAL – Severe illness or harm
- III = MODERATE – Minor illness or harm
- IV =NEGLIGIBLE – Less than minor illness or harm

			PROBABILITY				
			Frequent	Likely	Occasional	Seldom	Unlikely
			A	B	C	D	E
SEVERITY	Catastrophic	I	1	2	6	8	12
	Critical	II	3	4	7	11	15
	Moderate	III	5	9	10	14	16
	Negligible	IV	13	17	18	19	20
			RISK LEVELS				

Risk Levels:

- High (H) = 1 to 3 (Red color); Moderate (M) = 4 to 8 (Blue color)
- Low (L) = 9 to 14 (Green color); Negligible (N) = 15 to 20 (White color)

SIGNIFICANCE of Risk

- **YES** if risk level is H or M (Red or Blue color)
- **NO** if risk level is L or N (Green or White color)

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