Appendix IV

PROPOSED DRAFT REVISION OF THE *GENERAL PRINCIPLES OF FOOD HYGIENE* (CXC 1-1969)

GENERAL PRINCIPLES OF FOOD HYGIENE: GOOD HYGIENE PRACTICES (GHPs) AND THE HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

(At Step 5/8)

INTRODUCTION

1. People have the right to expect the food that they eat to be safe and suitable for consumption. Foodborne illness and foodborne injury can be severe or fatal or have a negative impact on human health over the longer term. Furthermore, outbreaks of foodborne illness can damage trade and tourism. Food spoilage is wasteful, costly, threatens food security and can adversely affect trade and consumer confidence.

2. International food trade and the flow of travellers are increasing, bringing important social and economic benefits. However, this also makes the spread of illness around the world easier. Eating habits have undergone major changes in many countries and new food production, preparation, storage, and distribution techniques have developed to reflect this. Effective food hygiene practices, therefore, are vital to avoid the adverse human health and economic consequences of foodborne illness, foodborne injury, and food spoilage. Everyone, including primary producers, importers, manufacturers and processors, food warehouse/logistics operators, food handlers, retailers, and consumers, has a responsibility to ensure that food is safe and suitable for consumption. Food Business Operators (FBOs) should be aware of and understand the hazards associated with the food they produce, transport, store and sell, and the measures required to control those hazards relevant to their business, so that food reaching consumers is safe and suitable for use.

3. This document outlines the general principles that should be understood and followed by FBOs at all stages of the food chain and that provide a basis for competent authorities to oversee food safety and suitability. Taking into account the stage in the food chain, the nature of the product, the relevant contaminants, and whether the relevant contaminants adversely affect safety, suitability or both, these principles will enable food businesses to develop their own food hygiene practices and necessary food safety control measures, while complying with requirements set by competent authorities. While it is the FBOs' responsibility to provide safe food, for some FBOs this may be as simple as ensuring that the WHO 5 keys to Safer Food are adequately implemented. The 5 keys are: 'keep clean, separate raw and cooked, cook thoroughly, keep food at safe temperatures and use safe water and raw materials.

4. FBOs need to be aware of hazards that may affect their food. FBOs need to understand the consequences of these hazards for consumer health and should ensure that they are properly managed. Good Hygiene Practices (GHPs) are the foundation of any effective control of hazards associated with their businesses. For some FBOs effective implementation of GHPs will be sufficient to address food safety.

5. The sufficiency of the implemented GHP to address food safety could be determined through conducting a hazard analysis and determining how to control identified hazards. However, not all FBOs have the expertise to do this. If the FBO is not able to conduct a hazard analysis, the FBO may rely on information on appropriate food safety practices from external sources such as that provided by competent authorities, academia or other competent bodies (e.g. trade associations or professional societies) that has been based on the identification of relevant hazards and controls. For example, requirements in regulations for production of safe food are based on hazard analysis often conducted by competent authorities. Similarly, guidance documents from trade associations and other organizations that describe food safety procedures are based on hazard analyses conducted by experts knowledgeable about the hazards and controls needed to ensure the safety of specific types of products. When external generic guidance is used the FBO should make sure that the guidance corresponds with the activities of the establishment and ensure all relevant hazards are controlled.

6. All GHPs are important but some GHPs have a greater impact on food safety. Thus, for some GHPs, based on safety concerns with the food, greater attention may be needed to provide safe food. For example, the cleaning of equipment and surfaces which come into contact with ready-to-eat food should warrant greater attention than other areas such as the cleaning of walls and ceilings, because if food contact surfaces are not properly cleaned, this could lead to direct contamination of food. Greater attention may include a higher frequency of application, of monitoring and of verification.

7. In some circumstances, the implementation of GHPs may not be sufficient to ensure food safety due to the complexity of the food operation and/or specific hazards associated with the product or process,

technological advances (e.g. extending shelf-life through modified atmosphere packaging) or end use of the product (e.g. products destined for a special dietary purpose). In such cases, when there are significant hazards identified through hazard analysis as not being controlled by GHPs, they should be addressed in the HACCP plan.

8. Chapter One of this document describes GHPs, which are the basis of all food hygiene systems to support the production of safe and suitable food. Chapter Two describes HACCP. HACCP principles can be applied throughout the food chain from primary production to final consumption and their implementation should be guided by scientific evidence of risks to human health. The table in Annex 1 provides a comparison of control measures applied as GHPs and those applied at Critical Control Points (CCPs) with examples.

OBJECTIVES

9. The General Principles of Food Hygiene: Good Hygiene Practices (GHPs) and the Hazard Analysis and Critical Control Point (HACCP) System aim to:

- provide principles and guidance on the application of GHPs applicable throughout the food chain to provide food that is safe and suitable for consumption;
- provide guidance on the application of HACCP principles;
- clarify the relationship between GHPs and HACCP; and
- provide the basis on which sector and product-specific codes of practice can be established.

SCOPE

10. This document provides a framework of general principles for producing safe and suitable food for consumption by outlining necessary hygiene and food safety controls to be implemented in production (including primary production), processing, manufacturing, preparation, packaging, storage, distribution, retail, food service operation and transport of food, and where appropriate, specific food safety control measures at certain steps throughout the food chain.

USE

General

11. The document is intended for use by FBOs (including primary producers, importers, manufacturers/processors, food warehouse/logistics operators, food service operators, retailers and traders) and competent authorities, as appropriate. It provides basic information to meet the needs of food businesses, irrespective of the nature of product and size of food business, in the context of food trade. However, it should be noted that it is not possible for the document to provide specific guidance for all situations and specific types of food businesses and the nature and extent of food safety risks associated with individual circumstances.

12. There will be situations where some of the specific recommendations contained in this document are not applicable. The fundamental question for each food business operator in every case is “what is necessary and appropriate to ensure the safety and suitability of food for consumption?”

13. The text indicates where such questions are likely to arise by using the phrases “where necessary” and “where appropriate”. In deciding whether a measure is necessary or appropriate, an evaluation of the likelihood and severity of the hazard toward establishing the potential harmful effects to consumers should be made, taking into account any relevant knowledge of the operation and hazards, including available scientific information. This approach allows the measures in this document to be flexibly and sensibly applied with a 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 food chain operations and practices and varying degrees of risk to public health involved in producing and handling food.

Roles of Competent Authorities, Food Business Operators, and Consumers

14. Competent authorities are responsible for deciding how these general principles are best applied through legislation, regulation or guidance to:

- protect consumers from illness, injury, or death caused by consumption of food;
- ensure FBOs implement an effective control system so that food is safe and suitable for consumption;
- maintain confidence in domestically and internationally traded food; and

- provide information that effectively communicates the principles of food hygiene to food business operators and consumers.

15. FBOs should apply the hygienic practices and food safety principles set out in this document to:

- develop, implement and verify processes that provide food that is safe and suitable for its intended use;
- ensure personnel are competent as appropriate to their job activities;
- build a positive food safety culture by demonstrating their commitment to providing safe and suitable food and encouraging appropriate food safety practices;
- contribute to maintaining confidence in domestically and internationally traded food; and
- ensure that consumers have clear and easily understood information to enable them to identify the presence of food allergens, protect their food from contamination, and prevent the growth/survival of foodborne pathogens by storing, handling and preparing food correctly.

16. Consumers should play their role by following relevant guidance and instructions for food handling, preparation, and storage and applying appropriate food hygiene measures.

GENERAL PRINCIPLES

(i) Food safety and suitability should be controlled using a science-based preventive approach, for example a food hygiene system. GHPs should ensure that food is produced and handled in an environment that minimizes the presence of contaminants.

(ii) Properly applied prerequisite programmes, which include GHPs, should provide the foundation for an effective HACCP system.

(iii) Each FBO should be aware of the hazards associated with the raw materials and other ingredients, the production or preparation process, and the environment in which the food is produced and/or handled, as appropriate to the food business.

(iv) Depending on the nature of the food, food process, and the potential for adverse health effects, to control hazards it may be sufficient to apply GHPs, including, as appropriate, some that require more attention than others, as they have a greater impact on food safety. When the application of GHPs alone is not sufficient, a combination of GHPs and additional control measures at CCPs should be applied.

(v) Control measures that are essential to achieve an acceptable level of food safety, should be scientifically validated[1].

(vi) The application of control measures should be subject to monitoring, corrective actions, verification, and documentation, as appropriate to the nature of the food product and the size of the food business.

(vii) Food hygiene systems should be reviewed to determine if modifications are needed. This should be done periodically and whenever there is a significant change that could impact the potential hazards and/or the control measures (e.g. new process, new ingredient, new product, new equipment, new scientific knowledge) associated with the food business.

(viii) Appropriate communication about the food and food process should be maintained among all relevant parties to ensure food safety and suitability across the entire food chain.

Management Commitment to Food Safety

17. Fundamental to the successful functioning of any food hygiene system is the establishment and maintenance of a positive food safety culture acknowledging the importance of human behaviour in providing safe and suitable food. The following elements are important in cultivating a positive food safety culture:

- commitment of the management and all personnel to the production and handling of safe food;
- leadership to set the right direction and to engage all personnel in food safety practices;
- awareness of the importance of food hygiene by all personnel in the food business;
- open and clear communication among all personnel in the food business, including communication of deviations and expectations; and

[1] *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008)

- the availability of sufficient resources to ensure the effective functioning of the food hygiene system.

18. Management should ensure the effectiveness of the food hygiene systems in place by:

- ensuring that roles, responsibilities, and authorities are clearly communicated in the food business;
- maintaining the integrity of the food hygiene system when changes are planned and implemented;
- verifying that controls are carried out and working and that documentation is up to date;
- ensuring that the appropriate training and supervision are in place for personnel;
- ensuring compliance with relevant regulatory requirements; and
- encouraging continual improvement, where appropriate, taking into account developments in science, technology and best practice.

DEFINITIONS

For the purposes of this document the following definitions apply:

Acceptable level: A level of hazard in a food at or below which the food is considered to be safe according to its intended use.

Allergen cross-contact: the unintentional incorporation of an allergenic food, or ingredient, into another food that is not intended to contain that allergenic food or ingredient.

Cleaning: The removal of soil, food residues, dirt, grease or other objectionable matter.

Competent Authority: The government authority or official body authorized by the government that is responsible for the setting of regulatory food safety requirements and/or for the organization of official controls including enforcement.

Contaminant: Any biological, chemical or physical agent, foreign matter or other substances not intentionally added to food that may compromise food safety or suitability.

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

Control:

- when used as a noun: The state wherein correct procedures are being followed and any established criteria are being met.
- when used a verb: To take all necessary actions to ensure and maintain compliance with established criteria and procedures.

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

Corrective action: Any action taken when a deviation occurs in order to re-establish control, segregate and determine the disposition of the affected product if any and prevent or minimize reoccurrence of the deviation.

Critical Control Point (CCP): A step at which a control measure or control measures, essential to control a significant hazard, is/are applied in a HACCP system.

Critical limit: A criterion, observable or measurable, relating to a control measure at a CCP which separates acceptability from unacceptability of the food.

Deviation: Failure to meet a critical limit or to follow a GHP procedure.

Disinfection: Reduction by means of biological or chemical agents and/or physical methods in the number of viable microorganisms on surfaces, in water or air to a level that does not compromise food safety and/or suitability.

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

Food business operator (FBO): The entity responsible for operating a business at any step in the food chain.

Food Handler: Any person who directly handles packaged or unpackaged food, equipment and utensils used for food, or surfaces that come into contact with food and that is expected, therefore, to comply with food hygiene requirements.

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

Food hygiene system: Prerequisite programmes, supplemented with control measures at CCPs, as appropriate, that when taken as a whole, ensures that food is safe and suitable for its intended use.

Food safety: Assurance that food will not cause adverse health effects 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.

Good Hygiene Practices (GHPs): Fundamental measures and conditions applied at any step within the food chain to provide safe and suitable food.

HACCP Plan: Documentation or set of documents, prepared in accordance with the principles of HACCP to ensure control of significant hazards in the food business.

HACCP System: The development of a HACCP plan and the implementation of the procedures in accordance with that plan.

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

Hazard analysis: The process of collecting and evaluating information on hazards identified in raw materials and other ingredients, the environment, in the process or in the food, and conditions leading to their presence to decide whether or not these are significant hazards.

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

Primary Production: Those steps in the food chain up to and including storage and, where appropriate, transport of outputs of farming. This would include growing crops, raising fish and animals, and the harvesting of plants, animals or animal products from a farm or their natural habitat.

Prerequisite programme: Programmes including Good Hygiene Practices, Good Agricultural Practices and Good Manufacturing Practices, as well as other practices and procedures such as training and traceability, that establish the basic environmental and operating conditions that set the foundation for implementation of a HACCP system.

Significant hazard: A hazard identified by a hazard analysis, as reasonably likely to occur at an unacceptable level in the absence of control, and for which control is essential given the intended use of the food.

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

Validation of control measures: Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.

CHAPTER ONE

GOOD HYGIENE PRACTICES

SECTION 1: INTRODUCTION AND CONTROL OF FOOD HAZARDS

19. The development, implementation and maintenance of GHPs provide the conditions and activities that are necessary to support the production of safe and suitable food at all stages of the food chain from primary production through to handling of the final product. Applied generally, they assist in controlling hazards in food products.

20. Knowledge of the food and its production process is essential for the effective implementation of GHPs. This Chapter provides guidance for effective implementation of GHPs, including appropriate location, layout, design, construction and maintenance of premises and facilities, and should be applied in conjunction with sector and product-specific codes.

21. GHPs manage many sources of food hazards which could contaminate food products, e.g. persons who handle food at harvest, during manufacturing, and during preparation; raw materials and other ingredients purchased from suppliers; cleaning and maintaining the work environment; storage and display.

22. As previously noted, all FBOs should be aware of and understand hazards associated with their businesses, and the control measures required to manage these hazards, as appropriate. FBOs should consider (using external resources as needed) whether the application of GHPs alone is sufficient to manage

some or all of the hazards associated with the operation through control of their sources, e.g.

- Control of water quality – minimizes the presence of many potential hazards (e.g. biological, chemical, physical);
- Control of faecal contamination – minimizes the potential for contamination with many foodborne pathogens such as *Salmonella*, *Campylobacter*, *Yersinia*, pathogenic strains of *E. coli*;
- Control of food handler practices and hygiene – prevents many potential communicable diseases that could be foodborne; and
- Control of food contact surfaces by cleaning – removes bacterial contaminants, including foodborne pathogens, and allergens.

23. After consideration of the conditions and activities in the business, it may be determined that GHPs alone may be sufficient to manage the hazards. However, it may also be determined that it is necessary to place greater attention on some GHPs that are particularly important for food safety (e.g. increased stringency of cleaning of a mincer for producing minced meat for raw or lightly cooked consumption compared to equipment used for producing meat to be cooked prior to consumption; increased monitoring and/or verification of disinfection of food contact surfaces).

24. Hazards that occur or are present at levels such that GHP procedures are not sufficient to provide safe food should be managed by an appropriate combination of control measures that are capable of preventing occurrence of hazards or eliminating or reducing them to an acceptable level. The control measures can be identified in one or more steps throughout the production process. In the case in which significant hazards are identified that need to be controlled after the implementation of GHPs, it will be necessary to develop and implement a HACCP system (see Chapter 2).

SECTION 2: 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:

- an assessment of the suitability of water used where it may pose a hazard, for example, crop irrigation, rinsing activities, etc.

− avoiding the use of areas where the environment poses a threat to the safety of food (e.g. contaminated sites);

− controlling contaminants, pests and diseases of animals and plants, to the extent practicable, to minimize the threat to food safety (e.g. appropriate use of pesticides and veterinary drugs);

− adopting practices and measures to ensure food is produced under appropriately hygienic conditions (e.g. cleaning and maintaining harvest equipment, rinsing, hygienic milking practices).

RATIONALE:

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

25. The types of activities involved in primary production may make eliminating or reducing some hazards difficult. However, by applying prerequisite programmes such as Good Agricultural Practices (GAPs) and/or GHPs, steps can be taken to minimize the occurrence and levels of hazards in the food chain, e.g. at milking for dairy production, steps taken in the hygienic production of eggs, or the controls on irrigation water used for growing salad crops. Not all provisions apply for all primary production situations and consideration will need to be given by the FBO on the appropriateness of the measures to be taken.

2.1 Environmental control

26. Potential sources of contamination from the environment should be identified. In particular, primary production should not be carried out in areas where the presence of contaminants would lead to an unacceptable level of such contaminants in food, e.g. using polluted areas[2], locating near facilities emitting toxic or offensive odours which could taint foodstuffs or near sources of contaminated water such as discharge

[2] *Code of Practice Concerning Source Directed Measures to Reduce Contamination of Food with Chemicals* (CXC 49-2001)

of waste water from industrial production or runoff from agricultural land with high faecal material or chemical residues, unless there is a measure to reduce or prevent the contamination of food.

2.2 Hygienic Production

27. 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 and, if possible, eliminate that probability.

28. Producers should as far as practicable implement measures to:

- control contamination from soil, water, feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs or any other agent used in primary production;
- protect food sources from faecal and other contamination (e.g. zoonotic foodborne agents);
- 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 (e.g. observe the withdrawal period of veterinary drugs and pesticides, keeping records where applicable); and
- manage waste and store harmful substances appropriately.

2.3 Handling, Storage and Transport

29. Procedures should be in place to:

- sort food to remove material which should not be used for human consumption;
- dispose of any rejected material in a hygienic manner; and
- protect food from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling (e.g. sorting, grading, washing), storage and transport. Care should be taken to prevent deterioration and spoilage through appropriate measures which may include controlling temperature, humidity, and/or other controls.

2.4 Cleaning, Maintenance and Personnel Hygiene

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

- cleaning and maintenance are carried out effectively and do not compromise food safety (e.g. ensuring equipment used in harvest is not a source of contamination); and
- an appropriate degree of personal hygiene is maintained to ensure personnel are not a source of contamination (e.g. by human faeces).

SECTION 3: ESTABLISHMENT - DESIGN OF FACILITIES AND EQUIPMENT

OBJECTIVES:

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

- contamination is minimized;
- design and layout permit appropriate maintenance, cleaning and disinfection and minimize airborne contamination;
- surfaces and materials, in particular those in contact with food, are non-toxic for their intended use;
- where appropriate, suitable facilities are available for temperature, humidity and other controls;
- there is effective protection against pest access and harbourage; and
- there are sufficient and appropriate washroom facilities for personnel.

RATIONALE:

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

3.1 LOCATION AND STRUCTURE

3.1.1 Location of establishment

31. Food establishments should not be located where there is a threat to food safety or suitability and hazards cannot be controlled by reasonable measures. The location of an establishment, including temporary/mobile establishments, should not introduce any hazards from the environment that cannot be controlled. In particular, unless sufficient safeguards are provided, establishments should normally be located away from:

- environmentally polluted areas and industrial activities which are reasonably likely to contaminate food;
- areas subject to flooding;
- areas prone to infestations of pests; and
- areas where wastes, either solid or liquid, cannot be removed effectively.

3.1.2 Design and layout of food establishment

32. The design and layout of food establishments should permit adequate maintenance and cleaning. The layout of premises and the flow of operations, including the movements of personnel and material within the buildings, should be such that cross-contamination is minimized or prevented.

33. Areas having different levels of hygiene control (e.g. the raw material and finished product areas) should be separated to minimize cross-contamination through measures such as physical separation (e.g. walls, partitions) and/or location (e.g. distance), traffic flow (e.g. one-directional production flow), airflow, or separation in time, with suitable cleaning and disinfection between uses.

3.1.3 Internal structures and fittings

34. Structures within food establishments should be soundly built of durable materials, which are easy to maintain, clean and, where appropriate, easy to disinfect. They should be constructed of non-toxic and inert materials according to intended use and normal operating conditions. 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 that are easy to clean and, where necessary, disinfect;
- 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 (e.g. lighting) should be constructed to be shatterproof where appropriate, 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; and
- doors should have smooth, non-absorbent surfaces, be easy to clean and, where necessary, disinfect.

35. Work 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 to disinfectants under normal operating conditions.

3.1.4 Temporary/mobile food establishments and vending machines

36. Establishments and structures covered here include market stalls, street vending vehicles, vending machines and temporary premises such as tents and marquees.

37. Such premises and structures should be located, designed and constructed to avoid, as far as reasonably practicable, the contamination of food and the harbouring of pests. Adequate facilities for toileting and washing hands should be provided, where appropriate.

3.2 FACILITIES

3.2.1 Drainage and waste disposal facilities

38. Adequate drainage and waste disposal systems and facilities should be provided and well maintained. They should be designed and constructed so that the likelihood of contaminating food or the water supply is avoided. For plumbing, steps should be taken to prevent backflow, cross-connections, and backup of sewer gases. It is important that drainage does not flow from highly contaminated areas (such as toilets or raw production areas) to areas where finished food is exposed to the environment.

39. Waste should be collected, disposed of by trained personnel and, where appropriate, disposal records maintained. The waste disposal site should be located away from the food establishment to prevent pest infestation. Containers for waste, by-products and inedible or hazardous substances should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material.

40. Containers used to hold hazardous substances prior to disposal should be identified and, where appropriate, be lockable to prevent intentional or accidental contamination of food.

3.2.2 Cleaning facilities

41. Adequate, suitably designated facilities should be provided for cleaning utensils and equipment. Such facilities should have an adequate supply of hot and/or cold water, where required. A separate cleaning area should be provided for tools and equipment from highly contaminated areas like toilets, drainage and waste disposal areas. Where appropriate, facilities for washing food should be separate from facilities for cleaning utensils and equipment, and separate sinks should be available for hand washing and food washing.

3.2.3 Personnel hygiene facilities and toilets

42. Adequate washing and toilet facilities should be available so that an appropriate degree of personal hygiene can be maintained and to avoid personnel contaminating food. Such facilities should be suitably located and should not be used for other purposes such as storage of food or items that contact food. They should include:

- adequate means of washing and drying hands, including soap (preferably liquid soap), wash basins and, where appropriate, a supply of hot and cold (or suitably temperature controlled) water;
- hand washing basins of an appropriate hygienic design, ideally with taps not operated by hands; where this is not possible, appropriate measures to minimize contamination from the taps should be in place; and
- suitable changing facilities for personnel, if needed.

43. Handwashing basins should not be used for washing food or utensils.

3.2.4 Temperature

44. 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, and, when necessary, controlling ambient temperatures to ensure the safety and suitability of food.

3.2.5 Air quality and ventilation

45. 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;
- help control ambient temperatures;
- control odours which might affect the suitability of food; and
- control humidity to ensure the safety and suitability of food (e.g. to prevent an increase in moisture of dried foods that would allow growth of microorganisms and production of toxic metabolites).

46. Ventilation systems should be designed and constructed so that air does not flow from contaminated areas to clean areas; the systems should be easy to maintain and clean.

3.2.6 Lighting

47. Adequate natural or artificial lighting should be provided to enable the food business to operate in a hygienic manner. Lighting should be such that it does not adversely impact the ability to detect defects of, or contaminants in, food or the examination of facilities and equipment for cleanliness. The intensity should be adequate to the nature of the operation. Light fittings should, where appropriate, be protected to ensure that food is not contaminated by breakages of lighting elements.

3.2.7 Storage

48. Adequate and, where necessary, separate facilities for the safe and hygienic storage of food products, food ingredients, food packaging materials and non-food chemicals (including cleaning materials, lubricants, fuels), should be provided. Storage should allow for segregation of raw and cooked foods or allergenic and non-allergenic food.

49. Food storage facilities should be designed and constructed to:

- facilitate adequate maintenance and cleaning;
- avoid pest access and harbourage;
- enable food to be effectively protected from contamination, including allergen cross-contact, during storage; and
- where necessary, provide an environment which minimizes the deterioration of food (such as by temperature and humidity control).

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

3.3 EQUIPMENT

3.3.1 General

51. Equipment and containers coming into contact with food should be suitable for food contact; designed, constructed and located to ensure that they can be adequately cleaned (other than containers which are single-use only); disinfected (where necessary); and maintained or discarded as necessary to avoid the contamination of food, according to hygienic design principles. Equipment and containers should be made of materials that are non-toxic according to intended use. Where necessary, equipment should be durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection and to facilitate inspection for pests.

3.3.2 Food control and monitoring equipment

52. Equipment used to cook, heat, 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 to maintain food temperatures effectively.

53. Such equipment should also be designed to allow temperatures to be monitored, where necessary, and controlled. Where appropriate, monitoring equipment should be calibrated to ensure that temperatures of food processes are accurate.

54. Where necessary, such equipment should have effective means of controlling and monitoring humidity, air-flow and any other characteristics likely to have an effect on the safety or suitability of food.

SECTION 4: TRAINING AND COMPETENCE

OBJECTIVE:

All those engaged in food operations who come directly or indirectly into contact with food should have sufficient understanding of food hygiene to ensure they have competence appropriate to the operations they are to perform.

RATIONALE:

Training is fundamentally important to any food hygiene system and the competence of personnel.

Adequate hygiene training, and/or instruction and supervision of all personnel involved in food-related activities contribute to ensuring the safety of food and its suitability for consumption.

4.1 Awareness and Responsibilities

55. Food hygiene training is fundamentally important to the food business. All personnel should be aware of their role and responsibility in protecting food from contamination or deterioration. Personnel should have the knowledge and skills necessary to enable them to handle food hygienically. Those who handle cleaning chemicals or other potentially hazardous chemicals should be instructed in proper use to prevent contamination of food.

4.2 Training Programmes

56. Elements to take into account in determining the extent of training required include:

- the nature of hazards associated with the food, e.g. its ability to sustain growth of pathogenic or spoilage microorganisms, the existence of potential physical contaminants or known allergens;
- the manner in which the food is produced, processed, handled and packed, including the likelihood of contamination;
- the extent and nature of processing or further preparation before consumption of the food;
- the conditions under which the food will be stored;
- the expected length of time before consumption of the food; and
- the use and maintenance of instruments and equipment associated with food.

57. Training programmes should also consider the knowledge and skill levels of the personnel being trained. Topics to be considered for training programmes could include the following as appropriate to a person's duties:

- the principles of food hygiene applicable to the food business;
- the measures relevant to the food business that are used to prevent contaminants in food;
- the importance of good personal hygiene, including proper hand washing and wearing, when needed, appropriate clothing, for food safety;
- the good hygiene practices applicable to the food business.
- appropriate actions to take when food hygiene problems are observed.

58. In addition, for retail and food service operations, whether personnel have direct customer interaction is a factor in training, since it may be necessary to convey certain information about products (such as allergens) to customers.

4.3 Instruction and Supervision

59. The type of instruction and supervision needed will depend on the size of the business, the nature of its activities and the types of food involved. Managers, supervisors and/or operators/workers should have sufficient knowledge of food hygiene principles and practices to be able to identify deviations and take necessary action as appropriate to their duties.

60. Periodic assessments of the effectiveness of training and instruction programmes should be made, as

well as routine supervision and verification to ensure that procedures are being carried out effectively. Personnel tasked to perform any activities used in food control should be trained adequately to ensure that they are competent to perform their tasks and are aware of the impact of their tasks on the safety and suitability of the food.

4.4 Refresher Training

61. Training programmes should be routinely reviewed and updated where necessary. Systems should be in place to ensure that food handlers and personnel associated with the food business, such as maintenance staff, remain aware of all procedures necessary to maintain the safety and suitability of food. Records should be kept of training activities.

SECTION 5: ESTABLISHMENT MAINTENANCE, CLEANING AND DISINFECTION, AND PEST CONTROL

OBJECTIVES:

To establish effective systems that:

- ensure appropriate establishment maintenance;
- ensure cleanliness and, when necessary, adequate disinfection;
- ensure pest control;
- ensure waste management; and
- monitor effectiveness of cleaning and disinfection, pest control and waste management procedures.

RATIONALE:

To facilitate the continuing effective control of food contaminants, pests, and other agents likely to compromise food safety and suitability.

5.1 Maintenance and Cleaning

5.1.1 General

62. Establishments and equipment should be maintained in an appropriate condition to:

- facilitate all cleaning and disinfection procedures;
- function as intended; and
- prevent contamination of food, such as from pests, metal shards, flaking plaster, debris, chemicals, wood, plastic, glass, paper.

63. Cleaning should remove food residues and dirt which may be a source of contamination, including allergens. The cleaning methods and materials necessary will depend on the nature of the food business, the food type and the surface to be cleaned. Disinfection may be necessary after cleaning, especially for food contact surfaces.

64. Attention should be paid to hygiene during cleaning and maintenance operations so as not to compromise food safety and suitability. Cleaning products suitable for food contact surfaces should be used in food preparation and storage areas.

65. Cleaning and disinfection chemicals should be handled and used carefully and in accordance with manufacturers' instructions, for example, using the correct dilutions and contact times, and stored, where necessary, separated from food, in clearly identified containers to avoid contamination of food.

66. Separate cleaning equipment and utensils, suitably designated, should be used for different hygiene zones e.g. food and non-food contact surfaces.

67. Cleaning equipment should be stored in an appropriate place and in such a manner to prevent contamination. Cleaning equipment should be kept clean, maintained and replaced periodically so as not to become a source for cross-contamination of surfaces or food.

5.1.2 Cleaning and disinfection methods and procedures

68. Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow, and vacuum cleaning (or other methods that avoid the use of water), and chemical methods using solutions of detergents, alkalis or acids. Dry cleaning or other appropriate methods for removing and collecting residues and debris may be needed in some operations and/or food processing areas where water increases the likelihood of microbiological contamination. Care should be taken to ensure cleaning procedures do not lead to contamination of food, e.g. spray from pressure washing can spread contamination from dirty areas, such as floors and drains, over a wide area and contaminate food contact surfaces or exposed food.

69. Wet cleaning procedures will involve, where appropriate:

- removing gross visible debris from surfaces;
- applying an appropriate detergent solution to loosen soil; and
- rinsing with water (hot water where appropriate) to remove loosened material and residues of detergent.

70. Where necessary, cleaning should be followed by chemical disinfection with subsequent rinsing unless the manufacturer's instructions indicate that, on a scientific basis, rinsing is not required. Concentrations and application time of chemicals used for disinfection should be appropriate for use and applied according to manufacturers' instructions for optimal effectiveness. If cleaning is not done effectively to remove soil to permit the disinfectant to contact microorganisms or if sub-lethal concentrations of the disinfectant are used, the microorganisms may persist.

71. Cleaning and disinfection procedures should ensure that all parts of the establishment are appropriately clean. Where appropriate, programmes should be drawn up in consultation with relevant experts.

72. Written cleaning and disinfection procedures should be used, where appropriate. They should specify:

- areas, items of equipment and utensils to be cleaned, and, where appropriate, disinfected;
- responsibility for particular tasks;
- method and frequency of cleaning and, where appropriate, disinfection; and
- monitoring and verification activities.

5.1.3 Monitoring of Effectiveness

73. Application of cleaning and disinfection procedures should be monitored for effectiveness and periodically verified by means such as visual inspections and audits to ensure the procedures have been applied properly. The type of monitoring will depend on the nature of the procedures, but could include pH, water temperature, conductivity, cleaning agent concentration, disinfectant concentration, and other parameters important to ensure the cleaning and disinfection programme is being implemented as designed and verify its effectiveness.

74. Microorganisms can sometimes become tolerant to disinfecting agents over time. Cleaning and disinfection procedures should follow the manufacturers' instructions. Periodic review with disinfectant manufacturers/suppliers, where feasible, should be conducted to help ensure the disinfectants used are effective and appropriate. Rotation of the disinfectants could be considered to ensure inactivation of different types of microorganisms (e.g. bacteria and fungi).

75. While effectiveness of cleaning and disinfecting agents and instructions for use are validated by their manufacturers, measures should be taken for sampling and testing the environment and food contact surfaces (e.g. protein and allergen test swabs, or microbiological testing for indicator organisms) to help verify that cleaning and disinfection programmes are effective and being applied properly. Microbiological sampling and testing may not be appropriate in all cases and an alternative approach might include observation of cleaning and disinfection procedures, including the correct disinfectant concentration, to achieve the necessary results and to make sure protocols are being followed. Cleaning and disinfection and maintenance procedures should be regularly reviewed and adapted to reflect any changes in circumstances and documented as appropriate.

5.2 PEST CONTROL SYSTEMS

5.2.1 General

76. Pests (e.g. birds, rodents, insects etc.) 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. GHPs should be employed to avoid creating an environment conducive to pests. Good building design, layout, maintenance, and location, along with cleaning, inspection of incoming materials and effective monitoring, can minimize the likelihood of infestation and thereby limit the need for pesticides.

5.2.2 Prevention

77. Establishments 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 covered. Roll up doors should close tightly against the floor. 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 food processing establishments.

5.2.3 Harbourage and infestation

78. 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 preferably away from walls. Areas both inside and outside food premises should be kept clean and free of waste. Where appropriate, refuse should be stored in covered, pest-proof containers. Any potential harbourage, such as old and unused equipment, should be removed.

79. Landscaping surrounding a food establishment should be designed to minimize attracting and harbouring pests.

5.2.4 Monitoring and detection

80. Establishments and surrounding areas should be regularly examined for evidence of infestation. Detectors and traps (e.g. insect light traps, bait stations) should be designed and located so as to prevent potential contamination of raw materials, products or facilities. Even if monitoring and detection are outsourced, FBOs should review monitoring reports and, if necessary, ensure they or their designated pest control operators take corrective action (e.g. eradication of pests, elimination of harbourage sites or invasion routes).

5.2.5 Control of pest infestation

81. Pest infestations should be addressed immediately by a qualified person or company and appropriate corrective action taken. Treatment with chemical, physical or biological agents should be carried out without posing a threat to the safety or suitability of food. The cause of infestation should be identified, and corrective action taken to prevent a problem from reoccurring. Records should be kept of infestation, monitoring and eradication.

5.3 WASTE MANAGEMENT

5.3.1 General

82. Suitable provision should be made for the removal and storage of waste. Waste should, as far as possible, be collected and stored in covered containers and should not be allowed to accumulate and overflow in food handling, food storage, and other working areas or the adjoining environment in a manner that compromises food safety and suitability. Personnel responsible for waste removal (including hazardous waste) should be properly trained so they do not become a source of cross-contamination.

83. Waste storage areas should be easily identifiable, be kept appropriately clean, and be resistant to pest infestation. They should also be located away from processing areas.

SECTION 6: PERSONAL HYGIENE

OBJECTIVES:

To ensure that those who come directly or indirectly into contact with food:

- maintain appropriate personal health;
- maintain an appropriate degree of personal cleanliness; and
- behave and operate in an appropriate manner.

RATIONALE:

Personnel 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 through food.

84. Food businesses should establish policies and procedures for personal hygiene. FBOs should ensure all personnel are aware of the importance of good personal hygiene and understand and comply with practices that ensure food safety and suitability.

6.1 Health Status

85. Personnel known or suspected to be ill or carrying a disease likely to be transmitted through food should not 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.

86. It may be appropriate for personnel to be excluded for a specific time after symptoms resolve or, for some illnesses, to get medical clearance before returning to work.

6.2 Illness and Injuries

87. Some symptoms of illnesses that should be reported to management so that the need for possible exclusion from food handling and/or medical examination can be considered include:

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

88. Personnel with cuts and wounds should, where necessary, be assigned to work in areas where they will have no direct contact with food. Where personnel are permitted to continue working, cuts and wounds should be covered by suitable waterproof plasters and, where appropriate, gloves. Appropriate measures should be applied to ensure plasters do not become a source of contamination (e.g. plasters of contrasting colour compared to the food and/or detectable using a metal detector or x-ray detector).

6.3 Personal Cleanliness

89. Personnel should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head and beard covering, and footwear. Measures should be implemented to prevent cross-contamination by personnel through adequate hand washing and, where necessary, the wearing of gloves. If gloves are worn, appropriate measures should be applied to ensure the gloves do not become a source of contamination.

90. Personnel, including those wearing gloves, should clean their hands regularly, especially when personal cleanliness may affect food safety. In particular they should wash hands:

- at the start of food handling activities;

- when returning to work after breaks;
- immediately after using the toilet; and
- after handling any contaminated material, such as waste or raw and unprocessed foods where this could result in contamination of other food items.

91. In order not to contaminate food, personnel should wash hands with soap and water and rinse and dry them in a manner that does not recontaminate the hands. Hand sanitizers should not replace hand washing and should be used only after hands have been washed.

6.4 Personal Behaviour

92. When engaged in food handling activities personnel should refrain from behaviour which could result in contamination of food, for example:

- smoking or vaping;
- spitting;
- chewing, eating, or drinking;
- touching the mouth, nose or other places of possible contamination; and
- sneezing or coughing over unprotected food.

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

6.5 Visitors and other persons from outside the establishment

94. Visitors to food businesses, including maintenance workers, in particular to food manufacturing, processing or handling areas, should, where appropriate, be instructed and supervised, wear protective clothing and adhere to the other personal hygiene provisions for personnel. Visitors should be guided through a hygiene policy of the business prior to visits and encouraged to report any type of illness/injury that may pose cross-contamination issues.

SECTION 7: CONTROL OF OPERATION

OBJECTIVES:

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

- formulating design requirements with respect to raw materials and other ingredients, composition/formulation, production, processing, distribution, and consumer use to be met as appropriate to the food business;
- designing, implementing, monitoring and reviewing effective control systems as appropriate to the food business.

RATIONALE:

If operations are not controlled appropriately, food may become unsafe or unsuitable for consumption.

95. Control of operation is achieved by having an appropriate food hygiene system in place. The following section describes practices that can assist in the identification and application of appropriate controls, as well as activities that should take place to ensure the operation is under control.

7.1 Description of products and processes

96. After consideration of the conditions and activities of the food business it may be necessary to pay greater attention to some GHPs that are particularly important for food safety. In this case, the following provisions could be considered.

7.1.1 Product description

97. An FBO that is producing, storing or otherwise handling food should have a description of the food. Products may be described individually or in groups in a manner that does not compromise the awareness of

hazards or other factors such as suitability of the products for the purpose intended. Any grouping of food products should be based on them having similar inputs and ingredients, product characteristics (such as pH, water activity (a_w)), process steps and/or intended purpose.

98. The description could include, as appropriate:

- the intended use of the food, e.g. whether it is ready-to-eat or whether it is intended for further processing either by consumers or another business, for example raw seafood to be cooked;
- products intended for specific vulnerable consumer groups e.g. infant formula or food for special medical purposes;
- any relevant specifications e.g. ingredient composition, a_w, pH, type of preservation method used (if any), or important characteristics associated with the food, such as any allergens present;
- any relevant limits established for the food by the competent authority or, in the absence thereof, set by the FBO;
- instructions provided for further use, for example keep frozen until cooking, cook to a specified temperature for a specified length of time, product shelf-life (use-by date);
- storage of product (e.g. refrigerated/frozen/shelf stable) and transport conditions required; and
- food packaging material used.

7.1.2 Process description

99. The FBO should consider all steps in the operation for a specific product. It may be helpful to develop a flow diagram, which shows the sequence and interaction of all processing steps in the operation, including where raw materials, ingredients and intermediate products enter the flow and where intermediate products, by-products and waste are released or removed. The flow diagram could be used for a number of similar food products that are produced using similar production or processing steps, to ensure all steps are captured. The steps should be confirmed as accurate by an on-site review of the operation or process. For example, for restaurants the flow diagram could be based on the general activities from the receipt of ingredients/raw material, storage (refrigerated, frozen, room temperature), preparation before use (washing, defrosting), and cooking or preparation of food.

7.1.3 Consideration of the effectiveness of GHPs

100. Having considered the product and process descriptions, an FBO should determine (using information relevant to hazards and controls from various sources as appropriate) whether the GHPs and other programmes they have in place are sufficient to address food safety and suitability or if some GHPs need greater attention. For example, a cooked meat slicer may require specific and more frequent cleaning to prevent the build-up of *Listeria* spp. on its meat contact surfaces, or a conveyor belt used in direct contact with the food, such as in sandwich production, may require an increased frequency of cleaning or a specific cleaning programme. When such increased attention on GHPs is insufficient to ensure food safety, it will be necessary to implement a HACCP system (Chapter 2).

7.1.4 Monitoring and corrective action

101. The FBO should monitor the hygienic procedures and practices as relevant to the business and as applicable to the hazard being controlled. Procedures could include defining methods of monitoring (including defining responsible personnel, frequency and sampling regime if applicable) and monitoring records to be kept. The frequency of monitoring should be appropriate to ensure consistent process control.

102. When monitoring results indicate a deviation, the FBO should undertake corrective action. Corrective action should consist of the following actions, as appropriate:

- bringing the process back into control by, for example, altering temperature or timing, or concentration of disinfectant;
- isolating any affected product and evaluating its safety and/or suitability;
- determining proper disposition of affected product that is not acceptable to market;
- identifying the cause that resulted in the deviation; and
- taking steps to prevent reoccurrence.

103. Records of corrective actions should be retained.

7.1.5 Verification

104. The FBO should undertake verification activities as relevant to the business, to check that GHP procedures have been implemented effectively, monitoring is occurring, where planned, and that appropriate corrective actions are taken when requirements are not met. Examples of verification activities could include the following, as appropriate:

- review of GHP procedures, monitoring, corrective actions and records;
- review when any changes occur to the product, process and other operations associated with the business; and
- assessment of the efficacy of cleaning.

105. Records of GHP verification activities should be kept, where appropriate.

7.2 KEY ASPECTS OF GHPS

106. Some key aspects of GHPs such as those described in Sections 7.2.1. and 7.2.2, could be considered as control measures applied at CCPs in the HACCP system.

7.2.1 Time and temperature control

107. Inadequate time and temperature control, e.g. during cooking, cooling, processing and storage, are among the most common failures of operational control. These allow survival or growth of microorganisms that may cause foodborne illness or food spoilage. Systems should be in place to ensure that temperature is controlled effectively where it impacts the safety and suitability of food.

108. Time and temperature control systems should take into account:

- the nature of the food, e.g. its a_w, pH, and likely initial level and types of microorganisms, such as pathogenic and spoilage microflora;
- the impact on the microorganisms, e.g. time in growth/dangerous temperature zone;
- 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.

109. Such systems should also specify tolerable limits for time and temperature variations. Temperature control systems that impact safety and suitability of food should be validated, and as appropriate, monitored and recorded. Temperature monitoring and recording devices should be checked for accuracy and calibrated at regular intervals or as needed.

7.2.2 Specific process steps

110. There are many individual processing steps for specific foods which contribute to the production of safe and suitable food products. These vary depending on the product and can include key steps such as cooking, chilling, freezing, drying and packaging.

111. The composition of a food can be important in preventing microbial growth and toxin production, e.g. in its formulation by adding preservatives, including acids, salts, food additives or other compounds. When formulation is used to control foodborne pathogens (e.g. adjusting the pH or a_w to a level that prevents growth), systems should be in place to ensure that the product is formulated correctly and that the controlling parameters are monitored.

7.2.3 Microbiological[3], physical, chemical and allergen specifications

112. Where microbiological, physical, chemical and allergen specifications are used for food safety or

[3] Refer to the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21- 1997).

suitability, such specifications should be based on sound scientific principles and state, where appropriate, sampling parameters, analytical methods, acceptable limits and monitoring procedures. Specifications can help ensure that raw materials and other ingredients are fit for purpose and contaminants have been minimized.

7.2.4 Microbiological contamination

113. Systems should be in place to prevent or minimize contamination of foods by microorganisms. Microbiological contamination occurs through a number of mechanisms, including the transfer of microorganisms from one food to another, e.g.:

- by direct contact or indirectly by food handlers;
- by contact with surfaces;
- from cleaning equipment;
- by splashing; or
- by airborne particles.

114. Raw, unprocessed food, where not considered ready-to-eat, which could be a source of contamination, should be separated from ready-to-eat foods, either physically or by time, with effective intermediate cleaning and, where appropriate, effective disinfection.

115. Surfaces, utensils, equipment, fixtures and fittings should be thoroughly cleaned and where necessary disinfected after raw food preparation, particularly when raw materials with a potentially high microbiological load such as meat, poultry, and fish have been handled or processed.

116. In some food operations, access to processing areas may need to be restricted or controlled for food safety purposes. For example, where the likelihood of product contamination is high, access to processing areas should be via a properly designed changing facility. Personnel may be required to put on clean protective clothing (which may be of a differentiating colour from that worn in other parts of the facility), including head and beard covering, footwear, and to wash their hands and where necessary sanitize them.

7.2.5 Physical contamination

117. Systems should be in place throughout the food chain to prevent contamination of foods by extraneous materials, such as personnel belongings, especially any hard or sharp object(s), e.g. jewellery, glass, metal shards, bone(s), plastic, wood fragments, that could cause injury or present a choking hazard. In manufacturing and processing, suitable prevention strategies such as maintenance and regular inspection of equipment, should be undertaken. Detection or screening devices which are appropriately calibrated should be used where necessary (e.g. metal detectors, x-ray detectors). Procedures should be in place for personnel to follow in the case of breakages (e.g. breakage of glass or plastic containers).

7.2.6 Chemical contamination

118. Systems should be in place to prevent or minimize contamination of foods by harmful chemicals, e.g. cleaning materials, non-food grade lubricants, chemical residues from pesticides and veterinary drugs such as antibiotics. Toxic cleaning compounds, disinfectants, and pesticide chemicals should be identified, safely stored and used in a manner that protects against contamination of food, food contact surfaces, and food packaging materials. Food additives and food processing aids that may be harmful if used improperly should be controlled so they are only used as intended.

7.2.7 Allergen Management[4]

119. Systems should be in place to take into account the allergenic nature of some foods, as appropriate to the food business. Presence of allergens, e.g. tree nuts, milk, eggs, crustacea, fish, peanuts, soybeans and wheat and other cereals containing gluten and their derivatives (not an inclusive list; allergens of concern differ among countries and populations), should be identified in raw materials, other ingredients and products. A system of allergen management should be in place at receipt, during processing and storage to address the known allergens. This management system should include controls put in place to prevent the presence of allergens in foods where they are not labelled. Controls to prevent cross-contact from foods containing

[4] See the *Code of Practice on Allergen Management for Food Business Operators*.

allergens to other foods should be implemented, e.g. separation either physically or by time (with effective cleaning between foods with different allergen profiles). Food should be protected from unintended allergen cross-contact by cleaning and line change-over practice and/or product sequencing. Where cross-contact cannot be prevented despite well-implemented controls, consumers should be informed. Where necessary food handlers should receive specific training on allergen awareness and associated food manufacturing/processing practices and preventive measures to reduce the risk to allergic consumers.

7.2.8 Incoming Materials

120. Only raw materials and other ingredients that are fit for purpose should be used. Incoming materials including food ingredients should be procured according to specifications, and their compliance with food safety and suitability specifications should be verified where necessary. Supplier quality assurance activities, such as audits, may be appropriate for some ingredients. Raw materials or other ingredients should, where appropriate, be inspected (e.g. visual examination for packages damaged during transportation, use-by-date and declared allergens, or temperature measurement for refrigerated and frozen foods) for appropriate action before processing. Where appropriate, laboratory tests could be conducted to check food safety and suitability of raw materials or ingredients. These tests may be conducted by a supplier that provides a Certificate of Analysis, the purchaser, or both. No incoming material should be accepted by an establishment if it is known to contain chemical, physical or microbiological contaminants which would not be reduced to an acceptable level by controls applied during sorting and/or processing where appropriate. Stocks of raw materials and other ingredients should be subject to effective stock rotation. Documentation of key information for incoming materials (e.g. supplier details, date of receipt, quantity etc.) should be maintained.

7.2.9 Packaging

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

7.3 Water

122. Water, as well as ice and steam made from water, should be fit for its intended purpose based on a risk-based approach.[5] They should not cause contamination of food. Water and ice should be stored and handled in a manner that does not result in their becoming contaminated, and the generation of steam that will contact food should not result in its contamination. Water that is not fit for use in contact with food (e.g. some water used for fire control and for steam that will not directly contact food) should have a separate system that does not connect with or allow reflux into the system for water that will contact food. Water recirculated for reuse and water recovered from e.g. food processing operations, by evaporation and/or filtration should be treated where necessary to ensure that the water does not compromise the safety and suitability of food.

7.4 Documentation and Records

123. Appropriate records for the food business operation should be retained for a period that exceeds the shelf-life of the product or as determined by the competent authority.

7.5 Recall Procedures - removal from the market of unsafe food

124. FBOs should ensure effective procedures are in place to respond to failures in the food hygiene system. Deviations should be assessed for the impact on food safety or suitability. Procedures should enable the comprehensive, rapid and effective identification, and removal from the market by the involved FBO(s) and/or return to the FBO by the consumers of any food that may pose a risk to public health. Where a product has been recalled because of the likely presence of hazards that may represent an immediate health risk, other products which are produced under similar conditions which may also present a hazard to public health should be evaluated for safety and may need to be recalled. Reporting to the relevant competent authority should be required and public warnings considered where product may have reached consumers and when return of product to the FBO or removal from the market is appropriate. Recall procedures should be documented, maintained, and modified where necessary based on the findings of periodic field trials.

[5] Microbiological Risk Assessment Series 33: Safety and Quality of Water Used in Food Production and Processing

125. Provision should be made for removed or returned products to be held under secure conditions until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to reduce the hazard to acceptable levels, where permitted by the competent authority. The cause and extent of a recall and the corrective actions taken should be retained by the FBO as documented information.

SECTION 8: PRODUCT INFORMATION AND CONSUMER AWARENESS

OBJECTIVES:

Appropriate information about food should ensure that:

- adequate and accessible information is available to the next FBO in the food chain or the consumer to enable them to handle, store, process, prepare and display the product safely and correctly;
- consumers can identify allergens present in foods; and
- the lot or batch can be easily identified and removed/returned if necessary.

Consumers should be given enough information on food hygiene to enable them to:

- be aware of the importance of reading and understanding the label;
- make informed choices appropriate to the individual, including about allergens; and
- prevent contamination and growth or survival of foodborne pathogens by storing, preparing and using food correctly.

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 implemented earlier in the food chain. Insufficient product information about the allergens in food can also result in illness or potentially death for allergic consumers.

8.1 Lot Identification and Traceability

126. Lot identification or other identification strategies are essential in product recall and also help effective stock rotation. Each container of food should be permanently marked to identify the producer and the lot. The *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) applies.

127. A traceability/product tracing system should be designed and implemented according to the *Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System* (CXG 60-2006), especially to enable the recall of the products, where necessary.

8.2 Product Information

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

8.3 Product Labelling

129. 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. This should also include information that identifies food allergens in the product as ingredients or where cross-contact cannot be excluded. The *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1989) applies.

8.4 Consumer Education

130. Consumer education programmes should cover general food hygiene. Such programmes should enable consumers to understand the importance of any product label information and following any instructions accompanying products, and to make informed choices. In particular, consumers should be informed of the relationship between time/temperature control, cross contamination and foodborne illness, and of the presence of allergens. Consumers should also be informed of the *WHO 5 Keys to Safer Food* and educated to apply appropriate food hygiene measures (e.g. proper hand washing, adequate storage and cooking and avoiding

cross contamination) to ensure that their food is safe and suitable for consumption.

SECTION 9: TRANSPORTATION

OBJECTIVES:

During transportation, measures should be taken where necessary to:

- protect food from potential sources of contamination, including allergen cross- contact;
- 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 hygiene practices are taken prior to and during transport, even where adequate hygiene practices have been taken earlier in the food chain.

9.1 General

131. Food should be adequately protected during transport[6]. The type of conveyances or containers required depends on the nature of the food and the most appropriate conditions under which it should be transported.

9.2 Requirements

132. 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 and dried;
- permit effective separation of different foods or foods from non-food items that could cause contamination 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 unsafe or unsuitable for consumption; and
- allow any necessary temperature, humidity and other environmental conditions to be checked.

9.3 Use and Maintenance

133. Conveyances and containers for transporting food should be kept in an appropriate state of cleanliness, repair and condition. Containers and conveyances for bulk food transport should be designated and marked for food use and used only for that purpose, unless controls are taken to ensure that the safety and suitability of the food are not compromised.

134. Where the same conveyance or container is used for transporting different foods, or non-foods, effective cleaning and, where necessary, disinfection, and drying should take place between loads.

[6] *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food* (CXC 47-2001)

CHAPTER TWO

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

INTRODUCTION

135. The first section of this Chapter sets out the seven principles of the Hazard Analysis and Critical Control Point (HACCP) system. The second section provides general guidance for the application of the HACCP system and the third section describes its application in 12 successive steps (Diagram 1), while recognizing that the details of application may vary and a more flexible approach to application may be appropriate depending on the circumstances and the capabilities of the food business operation. 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 control measures for significant hazards along the food chain, rather than relying mainly on end-product testing. Development of a HACCP system may identify the need for changes in processing parameters, in processing steps, in manufacturing technology, in end product characteristics, in method of distribution, in the intended use or in the GHPs applied. Any HACCP system should be capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

136. HACCP principles can be considered throughout the food chain from primary production to final consumption, and their implementation should be guided by scientific evidence of risks to human health. Although it is not always feasible to apply HACCP at primary production, some of the principles can be applied and may be incorporated into good practices programmes (e.g. Good Agricultural Practices (GAPs), etc.). It is recognised that implementation of HACCP may be challenging for some businesses. However, HACCP principles can be applied flexibly in individual operations, and businesses may use external resources (e.g. consultants) or adapt a generic HACCP plan provided by the competent authority, academia or other competent bodies (e.g. trade or industry associations) to the specific site circumstances. As well as enhancing food safety, implementation of HACCP can provide other significant benefits, such as more efficient processes based on a thorough analysis of capability, more effective use of resources by focusing on critical areas, and fewer recalls through identification of problems before product is released. In addition, the application of HACCP systems can aid review by competent authorities and promote international trade by increasing confidence in food safety.

137. The successful application of HACCP requires the commitment and involvement of management and personnel and the knowledge and/or training in its application for the particular type of food business. A multi-disciplinary approach is strongly recommended; this multi-disciplinary approach should be appropriate to the food business operation and may include, for example, expertise in primary production, microbiology, public health, food technology, environmental health, chemistry and engineering, according to the particular application.

SECTION 1: PRINCIPLES OF THE HACCP SYSTEM

The HACCP system is designed, validated and implemented in accordance with the following seven principles:

PRINCIPLE 1

Conduct a hazard analysis and identify control measures.

PRINCIPLE 2

Determine the Critical Control Points (CCPs).

PRINCIPLE 3

Establish validated critical limits.

PRINCIPLE 4

Establish a system to monitor control of CCPs.

PRINCIPLE 5

Establish the corrective actions to be taken when monitoring indicates a deviation from a critical limit at a CCP has occurred.

PRINCIPLE 6

Validate the HACCP plan and then establish procedures for verification to confirm that the HACCP system is

working as intended.

PRINCIPLE 7

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

SECTION 2: GENERAL GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

2.1 Introduction

138. Prior to application of a HACCP system by any FBO in the food chain, that FBO should have in place prerequisite programmes, including GHPs established in accordance with Chapter One of this document, the appropriate product and sector-specific Codex Codes of Practice, and in accordance with relevant food safety requirements set by competent authorities. Prerequisite programmes should be well-established, fully operational and verified, where possible, in order to facilitate the successful application and implementation of the HACCP system. HACCP application will not be effective without prior implementation of prerequisite programmes including GHPs.

139. For all types of food businesses, management awareness and commitment to food safety are necessary for implementation of an effective HACCP system. The effectiveness will also rely upon management and personnel having the appropriate HACCP training and competency. Therefore, ongoing training is necessary for all levels of personnel, including managers, as appropriate to the food business.

140. A HACCP system identifies and enhances control of significant hazards, where necessary, over that achieved by the GHPs that have been applied by the establishment. The intent of the HACCP system is to focus control at Critical Control Points (CCPs). By specifying critical limits for control measures at CCPs and corrective actions when limits are not met, and by producing records that are reviewed before product release, HACCP provides consistent and verifiable control beyond that achieved by GHPs.

141. A HACCP approach should be customized to each food business. Hazards, control measures at CCPs and their critical limits, CCP monitoring, CCP corrective actions and verification activities can be distinctive for a particular situation and those identified in a Codex Code of Practice or other appropriate guidelines might not be the only ones identified for a specific application or might be of a different nature.

142. The HACCP system should be reviewed periodically and whenever there is a significant change that could impact the potential hazards and/or the control measures (e.g. new process, new ingredient, new product, new equipment) associated with the food business. Periodic review should also be conducted when the application of the HACCP principles has resulted in a determination that no CCPs are needed, in order to assess whether the need for CCPs has changed.

2.2 Flexibility for small and/or less developed food businesses[7]

143. The application of the HACCP principles to develop an effective HACCP system should be the responsibility of each individual business. However, it is recognised by competent authorities and FBOs that there may be obstacles that hinder the effective application of the HACCP principles by individual food businesses. This is particularly relevant in small and/or less developed food businesses. Barriers to the application of HACCP in small and less developed businesses (SLDBs) have been acknowledged and flexible approaches to the implementation of HACCP in such businesses are available and encouraged. Some approaches may provide ways to adapt the HACCP approach to assist competent authorities in supporting SLDBs, for example, development of a HACCP-based system which is consistent with the seven principles of HACCP but does not conform to the layout or steps described in this chapter. While it is recognized that flexibility appropriate to the business is important when applying HACCP, all seven principles should be considered in developing the HACCP system. This flexibility should take into account the nature of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints, as well as the risk associated with the produced food. Applying such flexibility e.g. recording only monitoring results when there is a deviation instead of every monitoring result to reduce unnecessary burden of record keeping for certain types of FBOs, is not intended to impact negatively on the efficacy of the HACCP system and should not endanger food safety.

144. Small and/or less developed food businesses do not always have the resources and the necessary

[7] *FAO/WHO Guidance to governments on the application of HACCP in small and/or less-developed food businesses.*

expertise on site for the development and implementation of an effective HACCP system. In such situations, expert advice should be obtained from other sources, which may include trade and industry associations, independent experts and competent 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 a 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. A comprehensive explanation of the basis for the HACCP plan should be provided to the FBO. The FBO is ultimately responsible for elaboration and implementation of the HACCP system and the production of safe food.

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

SECTION 3: APPLICATION

3.1 Assemble HACCP Team and Identify Scope (Step 1)

146. The FBO should ensure that the appropriate knowledge and expertise are available for the development of an effective HACCP system. This may be achieved by assembling a multidisciplinary team responsible for different activities within the operation, e.g. production, maintenance, quality control, cleaning and disinfection. The HACCP team is responsible for developing the HACCP plan.

147. Where relevant expertise is not available in house, expert advice should be obtained from other sources, such as trade and industry associations, independent experts, competent authorities, HACCP literature and HACCP guides (including sector-specific HACCP guides). It may be possible that a well-trained individual with access to such guidance is able to implement a HACCP System in house. A generic HACCP plan developed externally may be used by FBOs where appropriate but should be tailored to the food operation.

148. The HACCP team should identify the scope of the HACCP system and applicable prerequisite programmes. The scope should describe which food products and processes are covered.

3.2 Describe product (Step 2)

149. A full description of the product should be developed, including relevant safety information such as composition (i.e. ingredients), physical/chemical characteristics (e.g. a_w, pH, preservatives, allergens), processing methods/technologies (heat-treatment, freezing, drying, brining, smoking, etc.), packaging, durability/shelf life, storage conditions and method of distribution. Within businesses with multiple products, it may be effective to group products with similar characteristics and processing steps for the purpose of development of the HACCP plan. Any limits relevant to the food product already established for hazards should be considered and accounted for in the HACCP plan, e.g. limits for food additives, regulatory microbiological criteria, maximum allowed veterinary medicines residues, and times and temperatures for heat treatments prescribed by competent authorities.

3.3 Identify intended use and users (Step 3)

150. Describe the use intended by the FBO and the expected uses of the product by the next FBO in the food chain or the consumer; the description may be influenced by external information, e.g. from the competent authority or other sources on ways in which consumers are known to use the product other than those intended by the FBO. In specific cases (e.g. hospitals), vulnerable groups of the population may have to be considered. Where foods are being produced specifically for a vulnerable population, it may be necessary to enhance process controls, monitor control measures more frequently, verify controls are effective by testing products, or conduct other activities to provide a high level of assurance that the food is safe for the vulnerable population.

3.4 Construct flow diagram (Step 4)

151. A flow diagram that covers all steps in the production of a specific product, including any applicable rework, should be constructed. The same flow diagram may be used for a number of products that are manufactured using similar processing steps. The flow diagram should indicate all inputs, including those of ingredients and food contact materials, water and air if relevant. Complex manufacturing operations can be broken down into smaller, more manageable modules and multiple flow diagrams that link together can be developed. The flow diagrams should be used when conducting the hazard analysis as a basis for evaluating the possible occurrence, increase, decrease or introduction of hazards. Flow diagrams should be clear,

accurate and sufficiently detailed to the extent needed to conduct the hazard analysis. Flow diagrams should, as appropriate, include but not be limited to the following:

- the sequence and interaction of the steps in the operation;
- where raw materials, ingredients, processing aids, packaging materials, utilities and intermediate products enter the flow;
- any outsourced processes;
- where applicable reworking and recycling take place;
- where end products, intermediate products, waste and by-products are released or removed.

3.5 On-site confirmation of flow diagram (Step 5)

152. Steps should be taken to confirm the processing activities 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.

3.6 List all potential hazards that are likely to occur and associated with each step, conduct a hazard analysis to identify the significant hazards, and consider any measures to control identified hazards (Step 6/ Principle 1)

153. Hazard analysis consists of identifying potential hazards and evaluating these hazards to determine which of them are significant for the specific food business operation. An example of a hazard analysis worksheet is provided in Diagram 2. The HACCP team should list all potential hazards. The HACCP team should then identify where these hazards are reasonably likely to occur at each step (including all inputs into that step) according to the scope of the food business operation. Hazards should be specific, e.g. metal fragments, and the source or reason for presence should be described, e.g. metal from broken blades after chopping. The hazard analysis can be simplified by breaking down complex manufacturing operations and analysing steps in the multiple flow diagrams described in step 4.

154. The HACCP team should next evaluate the hazards to identify which of these hazards are such that their prevention, elimination, or reduction to acceptable levels is essential to the production of safe food (i.e., determine the significant hazards that have to be addressed in the HACCP plan).

155. In conducting the hazard analysis to determine whether there are significant hazards, wherever possible the following should be considered:

- hazards associated with producing or processing the type of food, including its ingredients and process steps (e.g. from surveys or sampling and testing of hazards in the food chain, from recalls, from information in the scientific literature or from epidemiological data);
- the likelihood of occurrence of hazards, taking into consideration prerequisite programs, in the absence of additional control;
- the likelihood and severity of adverse health effects associated with the hazards in the food in the absence of control[8];
- identified acceptable levels of the hazards in the food e.g. based on regulation, intended use, and scientific information;
- the nature of the facility and the equipment used in making the food product;
- survival or multiplication of pathogenic microorganisms;
- production or persistence in foods of toxins (e.g. mycotoxins), chemicals (e.g. pesticides, drug residues, allergens) or physical agents (e.g. glass, metal);
- the intended use and/or probability of product mishandling by potential consumers that could render the food unsafe; and,
- conditions leading to the above.

[8] FBOs may take advantage of risk assessments and risk management matrices established by a competent authority or by international expert groups such as JEMRA.

156. The hazard analysis should consider not only the intended use, but also any known unintended use (e.g. a soup mix intended to be mixed with water and cooked but known to commonly be used without a heat treatment in flavouring a dip for chips) to determine the significant hazards to be addressed in the HACCP plan. (See Diagram 2 for an example of a hazard analysis worksheet.)

157. In some cases, it may be acceptable for a simplified hazard analysis to be carried out by FBOs. This simplified process identifies groups of hazards (biological, physical, chemical) in order to control the sources of these hazards without the need for a comprehensive hazard analysis that identifies the specific hazards of concern. There can be drawbacks to such an approach, as the controls can differ for hazards within a group, e.g., controls for pathogenic spore-formers versus vegetative cells of microbial pathogens. Generic HACCP-based tools and guidance documents provided by external sources, for example, by industry or competent authorities, are designed to assist with this step and mitigate concerns about different controls needed for hazards within a group.

158. Hazards which are such that their prevention, elimination or reduction to acceptable levels is essential to the production of safe food (because they are reasonably likely to occur in the absence of control and reasonably likely to cause illness or injury if present) should be identified and controlled by measures designed to prevent or eliminate these hazards or reduce them to an acceptable level. In some cases, this may be achieved with the application of good hygiene practices, some of which may target a specific hazard (for example, cleaning equipment to control contamination of ready-to-eat foods with *Listeria monocytogenes* or to prevent food allergens being transferred from one food to another food that does not contain that allergen). In other instances, control measures will need to be applied within the process, e.g. at critical control points.

159. 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. For example, to control *L. monocytogenes*, a heat treatment may be needed to kill the organism in the food and cleaning and disinfection may be needed to prevent transfer from the processing environment. More than one hazard may be controlled by a specified control measure. For example, a heat treatment can control both *Salmonella* and *E. coli* O157:H7 when they are present as hazards in the food.

3.7 Determine the Critical Control Points (Step 7/ Principle 2)

160. The FBO should consider which among the available control measures listed during step 6, Principle 1 should be applied at a CCP. Critical Control points are to be determined only for hazards identified as significant as of the result of a hazard analysis. CCPs are established at steps where control is essential and where a deviation could result in the production of a potentially unsafe food. The control measures at CCPs should result in an acceptable level of the hazard being controlled. There may be more than one CCP in a process at which control is applied to address the same hazard (e.g. the cook step may be the CCP for killing the vegetative cells of a pathogenic spore-former, but the cooling step may be a CCP to prevent germination and growth of the spores). Similarly, a CCP may control more than one hazard (e.g. cooking can be a CCP that addresses several microbial pathogens). Determining whether or not the step at which a control measure is applied is a CCP in the HACCP system can be helped by using a decision tree. A decision tree should be flexible, given whether it is for use in production, slaughter, processing, storage, distribution or other processes. Other approaches such as expert consultation may be used.

161. To identify a CCP, whether using a decision tree or other approach, the following should be considered:

- Assess whether the control measure can be used at the process step being analysed:
    - If the control measure cannot be used at this step, then this step should not be considered as a CCP for the significant hazard.
    - If the control measure can be used at the step being analysed, but can also be used later in the process, or there is another control measure for the hazard at another step, the step being analysed should not be considered as a CCP.
- Determine whether a control measure at a step is used in combination with a control measure at another step to control the same hazard; if so, both steps should be considered as CCPs.

162. The CCPs identified could be summarized in tabular format e.g. the HACCP worksheet presented in diagram 3, as well as highlighted at the appropriate step on the flow diagram.

163. If no control measures exist at any step for an identified significant hazard, then the product or process should be modified.

Establish validated critical limits for each CCP (Step 8/ Principle 3)

164. Critical limits establish whether a CCP is in control, and in doing so they can be used to separate acceptable products from unacceptable ones. These critical limits should be measurable or observable. In some cases, more than one parameter could have a critical limit designated at a particular step (e.g. heat treatments commonly include critical limits for both time and temperature). Criteria often used include minimum and/or maximum values for critical parameters associated with the control measure such as measurements of temperature, time, moisture level, pH, a_w, available chlorine, contact time, conveyor belt speed, viscosity, conductance, flow rate, or, where appropriate, parameters that can be observed, such as a pump setting. A deviation from the critical limit indicates that it is likely that unsafe food has been produced.

165. Critical limits for control measures at each CCP should be specified and scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level if properly implemented[9]. Validation of critical limits may include conducting studies (e.g. microbiological inactivation studies). FBOs may not always need to conduct or commission studies themselves to validate critical limits. Critical limits could be based on existing literature, regulations or guidance from competent authorities, or studies carried out by a third party e.g. studies conducted by an equipment manufacturer to determine the appropriate time, temperature and bed depth for dry roasting tree nuts. Validation of control measures is further described more fully in the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69 – 2008).

3.9 Establish a monitoring system for each CCP (Step 9/ Principle 4)

166. Monitoring of CCPs is the scheduled measurement or observation at a CCP relative to its critical limits. The monitoring procedures should be able to detect a deviation at the CCP. Further, the monitoring method and frequency should be capable of timely detection of any failure to remain within critical limits, to allow timely isolation and evaluation of the product. Where possible, process adjustments should be made when monitoring results indicate a trend towards a deviation at a CCP. The adjustments should be taken before a deviation occurs.

167. Monitoring procedures for CCPs should be capable of timely detection of a deviation from the critical limit to allow isolation of the affected products. The method and frequency of monitoring should take into account the nature of the deviation (e.g., a drop in temperature or a broken sieve, rapid drop in temperature during pasteurization, or a gradual increase in temperature in cold storage). Where possible, monitoring of CCPs should be continuous. Monitoring of measurable critical limits such as processing time and temperature can often be monitored continuously. Other measurable critical limits such as moisture level and preservative concentration cannot be monitored continuously. Critical limits that are observable, such as a pump setting or applying the correct label with appropriate allergen information are rarely monitored continuously. If monitoring is not continuous, then the frequency of monitoring should be sufficient to ensure to the extent possible the critical limit has been met and limit the amount of product impacted by a deviation. Physical and chemical measurements are usually preferred to microbiological testing because physical and chemical tests can be done rapidly and can often indicate the control of microbial hazards associated with the product and/or the process.

168. The personnel doing the monitoring should be instructed on appropriate steps to take when monitoring indicates the need to take action. Data derived from monitoring should be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.

169. All records and documents associated with monitoring CCPs should be signed or initialled by the person performing the monitoring and should also report the results and timing of the performed activity.

3.10 ESTABLISH CORRECTIVE ACTIONS (STEP 10/ PRINCIPLE 5)

170. Specific written corrective actions should be developed for each CCP in the HACCP system in order to effectively respond to deviations when they occur. When critical limits at CCPs are monitored continuously and a deviation occurs, any product being produced at the time the deviation occurs is potentially unsafe. When a deviation in meeting a critical limit occurs and monitoring was not continuous, then the FBO should determine what product may have been impacted by the deviation.

171. The corrective actions taken when a deviation occurs should ensure that the CCP has been brought under control and food that is potentially unsafe is handled appropriately and does not reach consumers.

[9] *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008).

Actions taken should include segregating the affected product and analysing its safety to ensure proper disposition.

172. External experts may be needed to conduct evaluations regarding the safe use of products when a deviation occurs. It may be determined that the product could be reprocessed (e.g. pasteurized) or the product could be diverted to another use. In other situations, the product may need to be destroyed (e.g. contamination with *Staphylococcus* enterotoxin). A root cause analysis should be conducted where possible to identify and correct the source of the deviation in order to minimize the potential for the deviation to reoccur. A root cause analysis could identify a reason for the deviation that limits or expands the amount of product impacted by a deviation.

173. Details of the corrective actions, including the cause of the deviation and product disposition procedures, should be documented in the HACCP records. Periodic review of corrective actions should be undertaken to identify trends and to ensure corrective actions are effective.

3.11. Validation of the HACCP plan and verification procedures (Step 11/ Principle 6)

3.11.1 Validation of the HACCP Plan

174. Before the HACCP plan can be implemented, its validation is needed; this consists of making sure that the following elements together are capable of ensuring control of the significant hazards relevant to the food business: identifying the hazards, critical control points, critical limits, control measures, frequency and type of monitoring of CCPs, corrective actions, frequency and type of verification and the type of information to be recorded.

175. Validation of control measures and their critical limits is performed during the development of the HACCP plan. Validation could include a review of scientific literature, using mathematical models, conducting validation studies, and/or using guidance developed by authoritative sources[10].

176. Where HACCP guidance developed by external experts, instead of the HACCP team, 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.

177. During the initial implementation of the HACCP system and after verification procedures have been established, evidence should be obtained in operation to demonstrate that control can be achieved consistently under production conditions.

178. Any changes having a potential impact on food safety should require a review of the HACCP system, and when necessary a revalidation of the HACCP plan.

3.11.2. Verification Procedures

179. After the HACCP system has been implemented, procedures should be established to confirm that the HACCP system is working effectively. These include procedures to verify that the HACCP plan is being followed and controlling hazards on an ongoing basis, as well as procedures that show the control measures are effectively controlling the hazards as intended. Verification also includes reviewing the adequacy of the HACCP system periodically and, as appropriate, when changes occur.

180. Verification activities should be performed on an ongoing basis to ensure the HACCP system functions as intended and continues to operate effectively. Verification, which includes observations, auditing (internal and external), calibration, sampling and testing, and records review, can be used to determine if the HACCP system is working correctly and as planned. Examples of verification activities include:

- reviewing monitoring records to confirm that CCPs are kept under control;
- reviewing corrective action records, including specific deviations, product disposition and any analysis to determine the root cause of the deviation;
- calibrating or checking the accuracy of instruments used for monitoring and/or verification;
- observing that control measures are being conducted in accordance with the HACCP plan;

[10] *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008).

- sampling and testing, e.g. for microorganisms[11] (pathogens or their indicators), chemical hazards such as mycotoxins, or physical hazards such as metal fragments, to verify product safety;
- sampling and testing the environment for microbial contaminants and their indicators, such as *Listeria*; and
- reviewing the HACCP system, including the hazard analysis and the HACCP plan (e.g. internal and/or third-party audits).

181. 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.

182. The frequency of verification activities should be sufficient to confirm that the HACCP system is working effectively. Verification of the implementation of control measures should be conducted with sufficient frequency to determine that the HACCP plan is being implemented properly.

183. Verification should include a comprehensive review (e.g. reanalysis or an audit) of the HACCP system periodically, as appropriate, or when changes occur, to confirm the efficacy of all elements of the HACCP system. This review of the HACCP system should confirm that the appropriate significant hazards have been identified, that control measures and critical limits are adequate to control the hazards, that monitoring, and verification activities are occurring in accordance with the plan and are capable of identifying deviations, and that corrective actions are appropriate for deviations that have occurred. This review can be carried out by individuals within a food business or by external experts. The review should include confirmation that various verification activities have been executed as intended.

3.12 Establish documentation and record keeping (Step 12/ Principle 7)

184. 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 utilized as part of the documentation, provided that those materials reflect the specific food operations of the business.

185. Examples of documentation include:

- HACCP team composition;
- hazard analysis and the scientific support for the hazards included or excluded from the plan;
- CCP determination;
- critical limit determination and the scientific support for the limits set;
- validation of control measures; and
- modifications made to the HACCP plan.

186. Examples of records include:

- CCP monitoring activities;
- deviations and associated corrective actions; and
- verification procedures performed.

187. A simple record-keeping system can be effective and easily communicated to personnel. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices, and checklists to record, for example, product temperatures. Where appropriate, records can also be maintained electronically.

[11] *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Food* (CXG 21-1997).

3.13 Training

188. Training of personnel in food businesses, government and academia in HACCP principles and applications is an essential element 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 in charge of each Critical Control Point. Training programmes should be designed to address the concepts at a level appropriate for the knowledge and skill level of the personnel being trained. Training programmes should be reviewed periodically and updated where necessary. Re-training may be needed as part of corrective actions for some deviations.

189. Cooperation between food business operations, trade groups, consumer organisations, and competent authorities is vitally important. Opportunities should be provided for the joint training of food business operators and competent authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

Annex 1 - Comparison of control measures with examples.

	Control measures applied as GHPs	Control measures applied at CCPs
Scope	General conditions and activities for maintaining hygiene, including creating the environment (inside and outside the food business) so as to ensure production of safe and suitable food. Generally, not specific to any hazard but results in reduction of likelihood of hazards occurring. Occasionally a GHP activity may target a specific hazard and this may be a GHP that requires greater attention (e.g. cleaning and disinfection of food contact surfaces for control of *Listeria monocytogenes* in a ready-to-eat food processing environment).	Specific to production process steps and a product or group of products and necessary to prevent eliminate or reduce to acceptable level a hazard determined as significant by the hazard analysis.
When identified?	After consideration of the conditions and activities necessary to support the production of safe and suitable food.	After a hazard analysis has been completed, for each hazard identified as significant, control measures are established at steps (CCPs) where a deviation would result in the production of a potentially unsafe food.
Validation of the control measures	Where necessary, and generally not carried out by FBOs themselves (*Guidelines for the Validation of Food Safety Control Measures* CXG 69-2008). Validation data provided by competent authorities, published scientific literature, information provided by manufacturers of equipment/ food processing technology etc. is adequate e.g. cleaning compounds/products/equipment should be validated by the manufacturer and it is generally sufficient for the FBO to use cleaning compounds/products/equipment according to manufacturers' instructions. The FBO should be able to demonstrate it can follow manufacturers' instructions.	Validation should be carried out (*Guidelines for the Validation of Food Safety Control Measures* CXG 69-2008).

Criteria	GHPs may be observable (e.g. visual checks, appearance) or measurable (e.g. ATP tests of equipment cleaning, concentration of disinfectant), and deviations may require an evaluation of the impact on safety of the product (e.g. whether the cleaning of complex equipment such as meat slicers is adequate).	Critical limits at CCPs which separate acceptability from unacceptability of the food: • measurable (e.g. time, temperature, pH, a_w), or • observable (e.g. visual checks of conveyor belt speed or pump settings, ice covering product).
Monitoring	When appropriate and necessary, to ensure procedures and practices are applied properly. Frequency dependent on the impact on the product's safety and suitability.	Necessary to ensure critical limit is met: • Continuously during production or • if not continuous, at appropriate frequency that ensures to the extent possible the critical limit has been met.
Corrective actions when deviation has occurred	• For procedures and practices: Necessary • For products: Usually not necessary. Corrective action should be considered on a case- by-case basis, as failure to apply some GHPs, such as failure to clean between products with different allergen profiles, not rinsing after cleaning and/or disinfecting (where needed) or post maintenance equipment checks indicating missing machinery parts, may result in action on product.	• For products: Necessary pre-determined actions. • For procedures and practices: Necessary corrective actions to restore control and prevent reoccurrence. • Specific written corrective actions should be developed for each CCP in the HACCP plan in order to effectively respond to deviations when they occur. • The corrective actions should ensure that the CCP has been brought under control and food that is potentially unsafe is handled appropriately and does not reach consumers.
Verification	When appropriate and necessary, usually scheduled (e.g. visual observation that equipment is clean before use).	Necessary: Scheduled verification of implementation of control measures, e.g. through record review, sampling and testing, calibration of measuring equipment, internal audit.
Record keeping (e.g. monitoring records)	When appropriate and necessary, to allow the FBO to assess whether GHPs are operating as intended.	Necessary to allow the FBO to demonstrate ongoing control of significant hazards.
Documentation (e.g. documented procedures)	When appropriate and necessary to ensure GHPs are properly implemented.	Necessary to ensure the HACCP system is properly implemented.

Diagram 1 – Logic Sequence for Application of HACCP

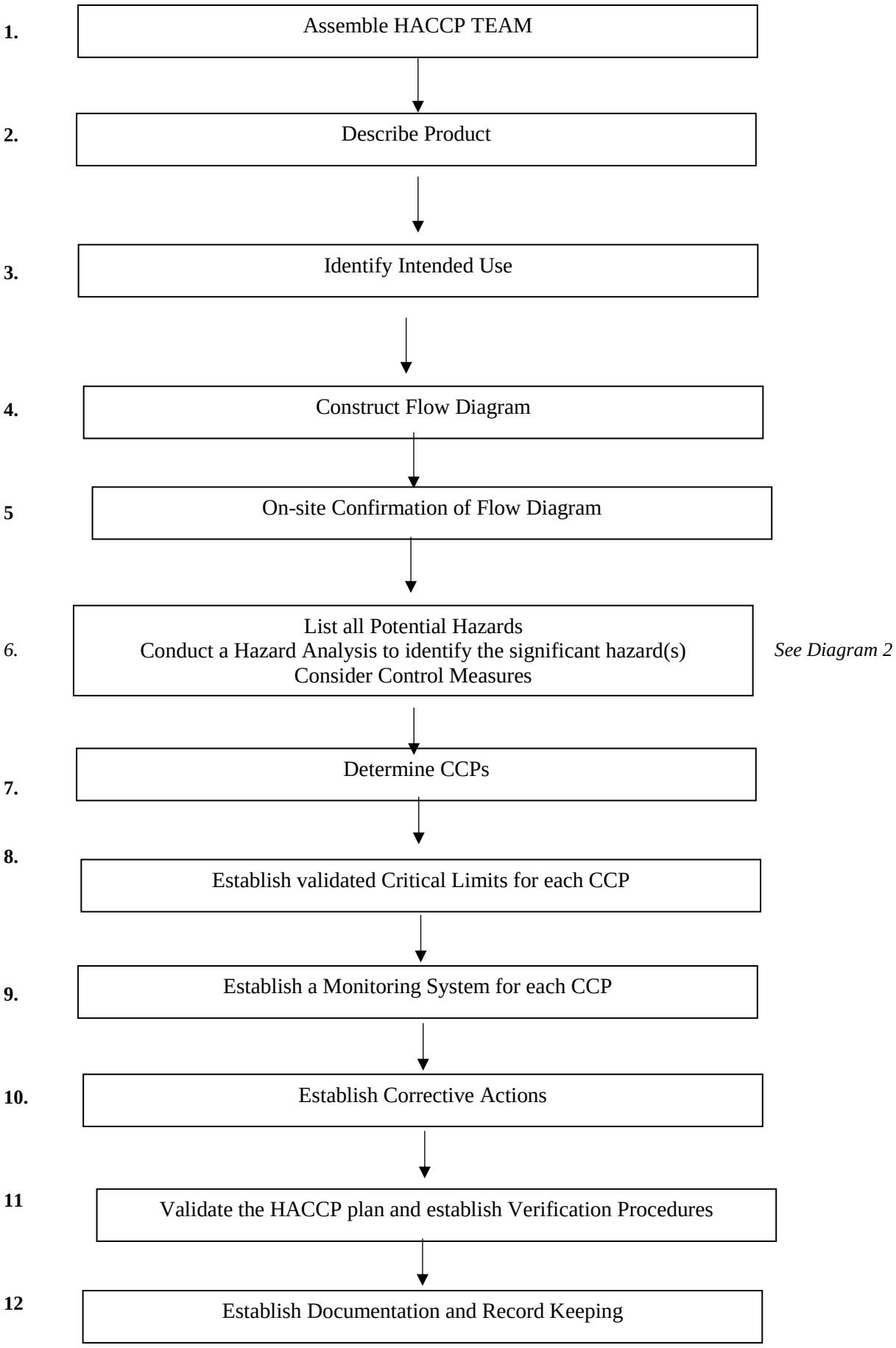

Diagram 2 – Example of Hazard Analysis Worksheet

(1) Step*	(2) Identify <u>potential</u> hazards introduced, controlled or enhanced at this step B = biological C = chemical P = physical		(3) Does this potential hazard need to be addressed in the HACCP plan? Yes	(3) No	(4) Justify your decision for column 3	(5) What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level?
	B					
	C					
	P					
	B					
	C					
	P					
	B					
	C					
	P					

*A hazard analysis should be conducted on each ingredient used in the food; this is often done at a “receiving” step for the ingredient. Another approach is to do a separate hazard analysis on ingredients and one on the processing steps.

Diagram 3 – Example of a HACCP Worksheet

Critical Control Points (CCPs)	Significant Hazard(s)	Critical Limits	Monitoring				Corrective Actions	Verification Activities	Records
			What	How	When (Frequency)	Who			