



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Fiftieth Session

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

Prepared by the Electronic Working Group chaired by the United Kingdom and co-chaired by France, Ghana, India, Mexico and the United States of America

Codex members and Observers wishing to submit comments at Step 3 on this draft should do so as instructed in CL 2018/69-FH available on the Codex webpage/Circular Letters 2018:

<http://www.fao.org/fao-who-codexalimentarius/circular-letters/en/>.

Background

1. The 49th Session of the Committee on Food Hygiene (CCFH49) agreed to establish an EWG, chaired by the United Kingdom and co-chaired by France, Ghana, India, Mexico and the United States of America, working in English, French and Spanish to:

- continue revision of the three parts of the document (Introduction, GHPs, HACCP) taking into account the discussions at CCFH49 and the written comments submitted;
- clarify the relationship of the three types of control measures: GHPs, control measures essential for safety that are applied at Critical Control Points (CCPs), and control measures essential for safety that are not applied at CCPs, using examples; and
- clarify how food business operators (FBO) come to understand the hazards associated with their business and determine the types of control measures needed to control the hazards.

2. CCFH49 also agreed to establish a Physical Working Group (PWG) chaired by the United Kingdom and co-chaired by France, Ghana, India, Mexico and the United States of America to be held in conjunction with CCFH50 to consider all comments received and prepare a revised proposal for consideration by the plenary.

Work of the EWG

3. All Codex members and observers were invited to participate in the EWG which was conducted through the online platform. 52 members and 19 observer organisations registered to participate (list of participants is attached as Appendix II).

4. The EWG Chair and Co-Chairs reviewed the comments received from members in conjunction with the draft text and discussions on the fundamental principles at CCFH49 and consolidated the comments in a version of the document which was posted on the EWG forum for comment.

5. Comments were received from 51 Member countries, 1 Member organisation and 19 Observer organisations. The various comments and suggestions for amendments to the text were incorporated into the revised text to the extent possible. Notes have been included throughout the document to provide explanation of major changes to the text and highlight areas where further discussion is required.

6. Given the range of opinions, the co-chairs recommended that the concept of 'enhanced GHPs' should not be included in the revised document and the text has been amended accordingly. Instead, the EWG

recommends changes to the text to highlight that some GHPs may warrant additional attention (e.g. monitoring, verification and records). This is consistent with the initial brief for the revisions to General Principles of Food Hygiene (GPFH) (CCFH47) which was to simplify the text as far as possible and for it to be useful for a global audience and all types of business. In our view, including this concept adds a level of complexity and is not consistent with the original direction from CCFH. This recommendation was supported by the EWG.

Justification

7. In the absence of an agreed and simple explanation which includes enhanced GHPs as a category of controls, we are of the view that this adds a layer of complexity which is not consistent with the original direction from CCFH that GPFH should be simplified as far as possible and accessible to all types of food business.

8. There is also no consensus on whether enhanced GHPs would be applied within either a GHP-based or HACCP-based system and practical examples provided show they could be included in either.

9. The need for increased attention to some GHPs due to their impact on safety can be included in the text and supported by recommendations for increased monitoring, verification and documentation as needed. The proposed draft text provides flexibility for FBOs to incorporate food safety controls as either GHPs or HACCP CCPs, as appropriate.

Recommendations

10. The EWG recommends that the Committee:

- considers the proposed draft revision of the General Principles of Food Hygiene presented in Appendix I and, in particular, considers the questions identified in the Appendix; and
- discusses and reaches agreement whether it is appropriate to include a category of control measures termed 'enhanced GHPs' taking into account the points raised in paragraphs 1 - 3 above.

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

(for comments at Step 3 through CL 2018/69-FH)

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

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 are at best unpleasant and, in some circumstances, 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, and lead to loss of earnings, unemployment and litigation. Food spoilage is wasteful, costly, threatens food security and can adversely affect trade and consumer confidence. Food Business Operators (FBOs) [should] [need to] be able to control hazards relevant to their business and be able to produce and provide safe food.
2. International food trade and travel are increasing, bringing important social and economic benefits. But this also makes the spread of illness around the world easier. Eating habits too, have undergone major 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. All FBOs should be aware of and understand the hazards associated with the food they produce and the measures required to manage those hazards so that food produced 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 point in the food chain, the nature of the business, 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 procedures 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 for 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. In order to ensure that the hazards associated with their business are properly managed, FBOs should undertake a review of potential hazards. The complexity of the review can be adapted to the nature of the business. At a simple level this might require an awareness that preventing illness should be addressed using basic control measures such as cooking and chilling, but in more complex businesses, this could require more comprehensive analyses and a detailed understanding of specific hazards involved and the appropriate interventions (e.g. the application of Good Hygiene Practices (Chapter 1) or HACCP principles, as described in Chapter 2).
5. Good Hygiene Practices (GHPs) lay the foundation for the production of safe and suitable food. GHPs maintain the hygiene of a process and apply broadly to all food businesses. It should be noted that for some GHPs a higher level of control (e.g. with increased monitoring and verification) may be needed to provide safe and suitable food, and thus the level of control and the frequency of monitoring and verification will need to be applied appropriately. For example, the cleaning of equipment and surfaces which come in contact with ready-to-eat food would normally warrant a greater level of control and frequency of monitoring than, say, the cleaning of walls and ceilings, because if food contact surfaces are not properly cleaned, this could lead to direct contamination of food. For some other activities, Prerequisite Programmes (PRPs), which include GHPs, Good Manufacturing Practices (GMPs) and Good Agricultural Practices (GAPs), as appropriate, should be applied.
6. It is recognised that implementation of HACCP principles may be challenging for some businesses, e.g. primary production, where it can be difficult to establish Critical Control Points (CCPs). In

reviewing operations and potential hazards, including a hazard analysis conducted within the HACCP framework, FBOs should consider the GHPs that are being, or that have been, established and how effective they are or will be at controlling the hazard. This will indicate whether GHPs are sufficient to address the safety and suitability of food associated with the operation or whether HACCP-based controls are required. FBOs without the resources to carry out a site-specific review of hazards may use external resources such as existing HACCP models provided by the competent authority or food industry¹, references, standards, regulations, or Codes of Practice and adapt these to the specific site circumstances.

7. [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 following comparison table shows the relationship of GHPs applied for food safety and suitability and HACCP control measures applied to enhance food safety.

¹ FAO/WHO guidance to governments on the application of HACCP in small and/or less developed food businesses
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Comparison of GHPs and HACCP Controls

Q1: There has been mixed views about this table –views are requested on whether it is useful or whether it should be deleted

	GHPs applied for food safety and suitability	HACCP control measures applied to enhance food safety
Scope	<p>General conditions and activities for maintaining hygiene, including creating the environment (external and internal to the food business) so as to ensure production of safe and suitable food.</p> <p>Generally, not specific to any hazard but results in reduction of likelihood of hazards occurring and in certain cases prevention of specific hazards e.g. undeclared allergens. Occasionally a GHP activity may target a specific hazard (e.g. sanitation of food contact surfaces for control of <i>Listeria monocytogenes</i> in a ready-to-eat food processing environment).</p>	<p>Specific to a product or group of products and necessary to reduce to acceptable level a hazard determined as significant by the hazard analysis.</p>
When identified?	<p>Before or during a review of hazards and in certain situations after a hazard analysis.</p>	<p>During a hazard analysis to determine hazards needing control measures at CCPs</p>
Validation of the effectiveness of the measure	<p>Where needed, and generally not carried out by FBOs themselves. Validation data provided by competent authorities, published scientific literature, information provided by manufacturers of equipment/ food processing technology etc is adequate (<i>Guidelines for the Validation of Food Safety Control Measures CXG 69-2008</i>) e.g. effectiveness of cleaning compounds/products equipment should be validated for effective use by manufacturer and it is generally sufficient for the FBO to use cleaning compounds/products/equipment according to manufacturer's instructions. The FBO should be able to demonstrate it can follow manufacturers' instructions.</p>	<p>Yes, validation should be carried out (<i>Guidelines for the Validation of Food Safety Control Measures CXG 69-2008</i>)</p>

Criteria	GHPs may be observable (e.g. visual checks, appearance) or measurable (e.g. ATP tests of equipment cleaning, concentration of disinfectant), and may require an evaluation of the impact on safety of the product (e.g. whether the frequency of cleaning complex equipment such as meat slicers is adequate).	Critical limits which separate acceptable <u>products</u> from unacceptable at CCPs: <ul style="list-style-type: none"> measurable (e.g. time, temperature, pH, a_w), or observable (e.g. visual checks of settings, appearance, quantity of ice where necessary for food safety).
Monitoring	Yes, where relevant, to ensure procedures and practices are applied properly. Usually non-continuous; frequency dependent on the impact on the product's safety and suitability.	Yes, to ensure CCP is in control <ul style="list-style-type: none"> Continuously during production or if not continuous, at appropriate frequency that ensures the critical limit has been met for every batch of products ALTERNATIVE TEXT to provide confidence the CCP is in control.
Corrective actions when deviation is indicated	<ul style="list-style-type: none"> For procedures and practices: Yes. 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.	<ul style="list-style-type: none"> For products: Yes. Pre-determined actions for products. For procedures and practices: Yes, corrective actions to restore control and prevent recurrence.
Verification	Yes, where relevant, usually scheduled (e.g., visual observation that equipment is clean before use)	Yes. Scheduled verification of implementation of control measures e.g. through record review, testing, internal audit
Record keeping (e.g. monitoring records)	Yes, where relevant to allow the FBO to assess whether GHPs are operating as intended	Yes, to allow the FBO to demonstrate ongoing control of hazards
Documentation (e.g. documented procedures)	Yes, where relevant	Yes

OBJECTIVES

8. 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 good hygiene practices 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 are established.

SCOPE

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

USE

General

10. The document is intended for use by food business operators (including primary producers, importers, manufacturers/processors, food warehouse/logistics operators, food service operators, retailers and traders) and competent authorities, as appropriate. It provides flexibility to meet the needs of food businesses, depending on their nature and size, in the context of international 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.
11. There will be situations where some of the specific requirements 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 control the hazards associated with the operation and ensure the safety and suitability of food for consumption?”
12. The text indicates where such questions are likely to arise by using the phrases “where necessary” and “where appropriate”. In deciding whether a requirement is necessary or appropriate, an evaluation of 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 requirements in this document to be flexibly and sensibly applied with a proper regard for the overall objectives of producing food which is safe and suitable for consumption. In so doing it takes into account the wide diversity of food chain operations and practices and varying degrees of risk involved in producing and handling food.

Roles of Competent Authorities, Food Business Operators, and Consumers

13. Competent authorities are responsible for deciding how best these general principles are to be applied through legislation, regulation or guidance to:
- protect consumers from illness, injury, or death caused by unsafe food;
 - provide an effective control system to ensure 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.
14. Food business operators 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 food handlers are competent as appropriate to their job activities;
 - cultivate a strong 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.

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

GENERAL PRINCIPLES

- (i) Food safety hazards should be controlled using a science based preventive approach to ensure food safety and suitability. GHPs should ensure that food is produced in a sanitary environment in order to minimise the presence of contaminants. In some cases, GHPs may be sufficient to manage hazards associated with a food business to ensure food safety and suitability.
- (ii) GHPs should provide the foundation for a HACCP system, where applied, to be effective
- (iii) Some GHPs require more attention than others, as they have a greater impact on food safety.
- (iv) 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 implement controls for significant hazards to ensure food safety.
- (v) Depending on the nature of the food business and the associated potential risks, hazards are controlled by GHPs and/or CCPs. While recognising the importance of CCPs in controlling specific hazards, some GHPs may also require more attention than others as they have a greater impact on food safety. Significant hazards not controlled by GHPs are controlled by specific control measures at CCPs.
- (vi) Controls that are critical to achieve an acceptable level of food safety, including any GHPs as appropriate, should be scientifically validated²
- (vii) The application of control measures and/or GHPs should be subject to monitoring, corrective actions, verification, and documentation, as appropriate.
- (viii) Food hygiene systems should be reviewed periodically to determine if modifications are needed and when there is a significant change in the food business that could impact the hazard analysis or control measures (e.g. new process, new ingredient, new product, new equipment).
- (ix) Communication on food safety and suitability should be maintained among all relevant parties as appropriate to ensure the integrity of the entire food chain.

Management Commitment

16. Food business managers should be committed to food safety. This can be done through a number of activities, including incorporating food safety into the overall objectives of the food business and communicating the importance of producing safe food, as fundamental to the success of any food hygiene system.
17. Management should ensure effectiveness of the food hygiene systems in place by:
 - ensuring that roles and responsibilities are clearly communicated in the food business;
 - ensuring the availability of resources;
 - maintaining the integrity of the food hygiene system when changes are planned and implemented;
 - verifying that the food safety control system is effective and documentation is up to date;
 - ensuring the appropriate training and supervision are in place for personnel;
 - ensuring compliance with relevant regulatory requirements;
 - encouraging continuous improvement, taking into account developments in knowledge and technology;
 - enabling a strong focus on food safety by all personnel in providing safe and suitable food and encouraging appropriate food safety behaviours; and
 - ensuring that food safety forms part of the strategic direction/objectives of the organisation.

² *Guidelines for the Validation of Food Safety Control measures (CXG 69-2008)*

DEFINITIONS

Note: All the definitions contained in the document have been moved to this section

[Clean water – water that does not contain biological or chemical contaminants at a level that would compromise the safety or suitability of the food.]

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

Control (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 food safety hazard or reduce it to an acceptable level.

Corrective action: Any action taken when a deviation occurs in order to re-establish control and minimize the potential for a deviation to reoccur.

Critical Control Point (CCP): A step at which a control measure essential for a significant hazard can be applied to prevent or eliminate a food safety hazard or reduce it to an acceptable level in a HACCP plan.

Critical limit: A criterion which separates acceptability from unacceptability in a HACCP plan.

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

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

Food hygiene system: The combination of hygiene practices, including those that require additional attention and that, when taken as a whole, ensures that food is safe and suitable for its intended use.

HACCP: A system which identifies, evaluates, and controls hazards which are significant for food safety through implementation of control measures at identified critical control points.

HACCP Plan: A document prepared in accordance with the principles of HACCP which identifies appropriate control measures to ensure control of hazards which are significant for food safety in the operation.

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

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

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

Prerequisite programme: programmes that provide the basic environmental and operating conditions necessary for the production of safe and suitable food and that set the foundation for implementation of a HACCP system.

[Review of hazards:?]

Significant hazard: a hazard identified through a review of hazards or a comprehensive hazard analysis, as reasonably likely to occur in the absence of control

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

Validation: Obtaining evidence that a GHP or a control measure or combination of GHPs and/or control measures, if properly implemented, are capable of controlling hazards 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

Introduction

18. 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 food safety hazards in food products.

19. As previously noted, in certain circumstances a review of the operation and its hazards (or a comprehensive hazard analysis) may indicate that GHPs alone are sufficient to manage the hazards associated with a food business. For some GHPs a higher level of control (e.g. with increased monitoring and verification) may be needed to provide safe and suitable food, and thus the level of control and the frequency of monitoring and verification will need to be applied appropriately. For example, the cleaning of equipment and surfaces which come in contact with food may warrant a greater level of control and frequency of monitoring than, say, the cleaning of walls and ceilings.
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. Where this Chapter refers to FBOs, this includes those in primary production.

Control of Food Hazards

Note: Section has been moved from Section II: Control of Operation

22. GHPs manage many 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.
23. All businesses should review operations and potential hazards to determine whether the application of GHPs, including those that require additional attention, is sufficient to manage some or all of the food hazards associated with the operation through control of their sources e.g.
 - Control of water quality – minimises the presence of many potential hazards (biological, chemical)
 - Control of faecal contamination – minimises the potential for contamination with many foodborne pathogens such as *Salmonella*, *Campylobacter*, *Yersinia*, pathogenic *E. coli*;
 - Control of food handler practices and hygiene – prevents many potential communicable diseases that could be foodborne; and
 - Control of cleaning of food contact surfaces – removes bacterial contaminants, including foodborne pathogens, and allergens.
24. Control of sources of hazards under GHP is often preventative in nature, practical, feasible and cost effective for the FBO.
25. Food safety hazards that occur or are present at such levels 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 removing or reducing them to an acceptable level. The control measures can be identified in one or more steps throughout the production. In the case that sufficient control measures through GHPs are not possible, it will be necessary to implement a HACCP plan. Such a plan may necessitate changes in processing parameters, in processing steps, in manufacturing technology, in end product characteristics, in method of distribution or in the intended use.

PRIMARY PRODUCTION

OBJECTIVES:

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

- avoiding the use of areas where the environment poses a threat to the safety of food (e.g. contamination sites);
- controlling contaminants, pests and diseases of animals and plants to the extent practicable, so as to minimise the threat to food safety (e.g. appropriate use of veterinary drugs);
- adopting practices and measures to ensure food is produced under appropriately hygienic conditions.

RATIONALE:

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

Environmental Hygiene

26. Potential sources of contamination from the environment should be considered. In particular, primary food production should not be carried on in areas where the presence of potentially harmful substances would lead to an unacceptable level of such substances in food, e.g. using land with high heavy metal contaminants or sources of contaminated water.

Hygienic Production of Food Sources

Q2: Are there any FAO/WHO programmes which can be referenced here?

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 that probability.

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; and
- 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 and grace period of veterinary drugs and pesticides, respectively, keeping records where applicable).

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

Handling, Storage and Transport

28. Procedures should be in place to:
- sort food and food ingredients to remove material which is evidently unfit for human consumption;
 - dispose of any rejected material in an acceptable and hygienic manner; and
 - protect food and food ingredients from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling (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.

Cleaning, Maintenance and Personnel Hygiene at Primary Production

29. Appropriate facilities and procedures should be in place to ensure that:
- any necessary cleaning and maintenance is carried out effectively and in a way that does 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 1: ESTABLISHMENT DESIGN AND FACILITIES

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 minimised;
- design and layout permit appropriate maintenance, cleaning and disinfection and minimise 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.

Location of establishment

30. 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 a food establishment, including temporary/mobile establishments, should not introduce any hazards from the environment that cannot be controlled. In particular, unless sufficient safeguards are provided, food establishments should normally be located away from:
- environmentally polluted areas and industrial activities which pose a serious threat of contaminating food;
 - areas subject to flooding;
 - areas prone to infestations of pests; and
 - areas where wastes, either solid or liquid, cannot be removed effectively.
31. Landscaping near a food facility should be properly designed to minimise attracting and harbouring pests. Where necessary, experts should be consulted for advice on appropriate plants for use in landscaping.

Equipment

Hygienic design and layout of food establishment [and equipment]

32. The internal design and layout of food establishments and equipment should permit good hygiene practices, permit adequate maintenance and cleaning, protect from cross-contamination and facilitate, if feasible, a linear flow of operations.
33. The clean and dirty 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, and separation in time, with suitable cleaning and disinfection between uses.

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 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;
 - doors should have smooth, non-absorbent surfaces, be easy to clean and, where necessary, disinfect;
35. For example, some 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 unless food business operators can satisfy the competent authority that they do not compromise the safety of the food provided such deviation does not result in food safety being compromised

Temporary/mobile food establishments and vending machines

36. Establishments and structures covered here include market stalls, street vending vehicles 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. In applying these specific conditions and requirements, any food hygiene hazards associated with such facilities should be adequately controlled to ensure the safety and suitability of food. Adequate facilities for washing hands should be provided.

FACILITIES

Water supply

Q3: Original text from CXC 1–1969 has been moved to the section on water. Is there agreement that this text fits here?

Drainage and waste disposal

38. Adequate drainage and waste disposal systems and facilities should be provided and well maintained. They should be designed and constructed so that the risk of contaminating food or the potable or clean 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 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 malicious or accidental contamination of food.

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 cold potable water.

Personnel hygiene facilities and toilets

42. Adequate personnel hygiene facilities and toilets should be available so that an appropriate degree of personal hygiene can be maintained and to avoid 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 sinks of an appropriate hygienic design with taps not operated by hands (where this is not possible a disposable paper towel can be used to turn the taps off);
 - adequate changing facilities for personnel; and
 - where necessary, separate sinks should be available for hand washing and food washing.

Temperature control

Q4: Do we need a paragraph to discuss monitoring of temperature of premises, equipment and food?

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

Air quality and ventilation

44. 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).
45. 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 and, for example, use industry-approved filters.

Lighting

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

Storage

47. 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 for the manufacturing of raw and cooked foods or allergenic and non-allergenic food.
48. Where appropriate, food storage facilities should be designed and constructed to:
- permit adequate maintenance and cleaning;
 - avoid pest access and harbourage;
 - enable food to be effectively protected from contamination during storage; and
 - where necessary, provide an environment which minimizes the deterioration of food (such as by temperature and humidity control).
49. The type of storage facilities required will depend on the nature of the food. Where necessary, separate, secure, storage facilities for cleaning materials and hazardous substances should be provided.

EQUIPMENT

General

50. Equipment and containers coming into contact with food, should be suitable for food contact, designed and constructed and located to ensure that they can be adequately cleaned (other than containers which are single-use only) and disinfected (where necessary) and maintained 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.

Food control and monitoring equipment

51. 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 maintain food temperatures effectively. Where appropriate, equipment should be calibrated to ensure that food processes are monitored consistently and accurately.

52. Such equipment should also be designed to allow temperatures to be monitored, where possible, and controlled.
53. 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 2: 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, processing, distribution, and consumer use to be met in the manufacture and handling of specific food items;
- designing, implementing, monitoring and reviewing effective control systems.

RATIONALE:

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

Product description

54. An FBO that is producing or preparing food should provide a description of the food. Products may be described individually or in groups in a manner that will not compromise the identification and review of food safety hazards or other factors such as suitability of product. Grouping of food products should be based on having similar inputs and ingredients, product characteristics (such as pH, a_w), process steps and intended purpose.
55. For some FBOs, the descriptions may be basic, e.g. primary production could describe products as “fresh vegetables,” “cattle,” “milk,” etc., restaurants could describe products as “sandwiches,” “hot meals,” “cold salads,” etc.
56. The description should identify, 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;
 - any specific vulnerable consumer groups e.g. infants, elderly, immuno-compromised individuals;
 - 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 acceptable limits required 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. fresh/frozen/shelf stable) and transport conditions required; and
 - food packaging material used.

Process description

57. The FBO producing food should consider all steps in the operation for a specific product. It may be helpful to develop a flow diagram which could also be used for a number of similar products (see product description above) that are produced using similar production or processing steps to ensure all steps are captured. The steps should be confirmed as accurate by checking against the actual 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 (cold storage, frozen, room temperature), preparation before use (washing, defrosting), and cooking or preparation of food.

Monitoring procedures

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

Corrective actions

59. The FBO should develop corrective action procedures as relevant to the business that are implemented when a deviation is identified. Procedures could include:
- who is responsible for taking action;
 - immediate action to be taken;
 - any product disposition to be considered including traceability of disposal, eliminating any risk of re-use/tampering;
 - any notification needed to a competent authority;
 - any action to prevent reoccurrence; and
 - records to be retained.

Verification of GHP

60. The FBO should develop verification procedures as relevant to the business, which ensure that GHP procedures have been implemented effectively, monitoring is occurring and that appropriate corrective actions are taken when requirements are not met. Procedures could include:
- who is responsible for conducting the activity;
 - 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
 - the verification records to be kept.

KEY ASPECTS OF FOOD HYGIENE SYSTEMS

Time and temperature control

61. Inadequate time and temperature control are among the most common hygiene failures. These allow survival or growth of microorganisms that are causes of foodborne illness or food spoilage. Such controls include time and temperature control during cooking, cooling, processing and storage. Systems should be in place to ensure that temperature is controlled effectively where it impacts the safety and suitability of food and that processes are conducted without undue delay.
62. 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 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.
63. Such systems should also specify tolerable limits for time and temperature variations. Temperature control systems that impact safety and suitability of food should be monitored. Temperature monitoring and recording devices should be checked for accuracy and calibrated as needed.

Specific process steps

64. 61. Many specific processing steps, as described in various Codes of Hygienic Practice for specific foods, contribute to the production of safe and suitable food products, including, for example:
- cooking,
 - chilling,
 - drying, and
 - packaging.
65. The composition of a food, e.g. formulation by adding preservatives, including acids, salts, food additives or other compounds, can be useful in preventing microbial growth and toxin production. When formulation is used to control foodborne pathogens (e.g. adjusting the pH or water activity to a level that prevents growth), systems should be in place to ensure that the product is formulated correctly.

Microbiological³, chemical and physical specifications

66. Where microbiological, chemical or physical specifications are used in the control of food safety or suitability, such specifications should be based on sound scientific principles and state, where appropriate, 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 to the extent possible. FBOs should consider that when the initial overall contamination level in raw material is low (e.g. 10^3 cfu/g), the required degree of heat treatment (in this case, for example, 5 log reduction) is also low.

Microbiological contamination

67. Microbiological cross-contamination occurs through a number of mechanisms, including the transfer of microorganisms from one food to another, either by direct contact or indirectly by food handlers, or by contact with surfaces, from cleaning equipment, or via splashing or airborne particles. Raw, unprocessed food, which could pose a contamination risk, should be effectively separated from ready-to-eat foods, either physically or by time, with effective intermediate cleaning and where appropriate effective disinfection.
68. Surfaces, utensils, equipment, fixtures and fittings should be thoroughly cleaned and where necessary disinfected after raw food preparation, particularly when raw materials with a high microbiological load such as meat and poultry and fish have been handled or processed.
69. In some food operations, access to processing areas may need to be restricted or controlled for food safety purposes. For example, where risks are high, access to processing areas should be only via a properly designed changing facility. Personnel may be required to put on clean protective clothing (which may be of a differentiating colour from other parts of the facility), including hair wear, footwear, and wash their hands before entering.

Physical contamination

70. Systems should be in place throughout the food chain to prevent contamination of foods by extraneous materials, especially any hard or sharp object(s) e.g. glass, metal shards, bone(s), plastic, insects, wood fragments etc. that could cause injury or present a choking hazard. In manufacturing and processing, suitable prevention strategies such as maintenance and regular inspection and detection or screening devices should be used where necessary (e.g. metal detectors, sieves, etc.). Procedures should be in place for food handlers to follow in the case of breakages (e.g. breakage of glass or plastic containers, etc.).

Chemical contamination

71. Systems should be in place to prevent or minimise contamination of foods by harmful chemicals, e.g. cleaning materials, non-food grade lubricants, chemical residues from veterinary drugs such as antibiotics and anthelmintic etc. 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, food processing aids and preservatives that may be harmful if used improperly should be controlled so they are only used as intended.

Allergenic Cross-contact

Note: Placeholder to reference allergen guidance

72. Hazard identification should take into account the allergenic nature of some foods. Presence of allergens e.g. nuts, milk, eggs and cereals containing gluten (not an inclusive list; allergens of concern differ among countries) should be identified in raw materials, other ingredients and products. A system of allergen management should be in place starting from receipt of foods that are, or that contain, known allergens, during processing, and during storage of food products. Controls should be put in place to prevent their presence in foods where they are not labelled. Controls to prevent cross-contact from foods containing allergens to other foods should be implemented e.g. separation either physically or by time (with intervening effective cleaning between foods with different allergen profiles). Where cross-contact cannot be prevented despite well-implemented controls, consumers should be informed.

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

Incoming Materials

73. 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. Incoming raw materials or other ingredients should, where appropriate, be inspected (e.g. visual check of damaged packages during transportation, use by date and declared allergens, or temperature checks for refrigerated and frozen foods,) and sorted before processing. Where necessary, laboratory tests should be conducted to verify food safety and suitability of raw materials or ingredients e.g. the compliance against specifications. 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 where appropriate processing. 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.

Packaging

74. 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, disinfect.

WATER

Note: EWG has amended the Original text from CXC 1–1969 in paras 51 to 58. However, it should be further developed taking account of information from FAO/WHO consideration of water e.g. reference could be made to FAO/WHO guidance as far as possible and basic information provided here with references to specific commodity codes.

Note the Co-Chairs understand that the definition of water is currently under revision by WHO. Is 'potable' better understood by most people as this seems to be the term used in the regulations of several countries, but is there a more appropriate term?

Water supply

75. An adequate supply of potable water and/or clean water with appropriate facilities for its storage, distribution and temperature control, should be available whenever necessary to ensure the safety and suitability of food. Potable water should meet the requirements as specified in the latest edition of WHO Guidelines for Drinking Water Quality, or water of a higher standard.
76. Non-potable water (for use in, for example, fire control, steam production, refrigeration and other similar purposes where it would not contaminate food), should have a separate system. Non-potable water systems need to be clearly identified and should not connect with, or allow backflow into, potable and/or clean water systems.

Water in contact with food

77. The quality of water used in primary production should be suitable for its intended purpose. For additional information on water for primary production see relevant codex texts⁴.
78. Only potable water should be used in food handling and processing, except in certain food processes, e.g. chilling, and in food handling areas, where this does not constitute a hazard to the safety and suitability of food (e.g. the use of clean sea water, or clean water or recirculated water).
79. Water recirculated for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of food results from its use (i.e. recirculated water should be "clean water"). The treatment process should be effectively monitored. Recirculated water which has received no further treatment and water recovered from processing of food by evaporation or drying may be used, provided its use does not constitute a risk to the safety and suitability of food.

⁴ e.g. the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003) and *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

As an ingredient

80. Potable water should be used to avoid food contamination. The potable water may be treated where this is required by the production process.

Ice and steam in direct contact with food

81. Ice in direct contact with food should be made from water that is fit for purpose e.g. clean sea water for fish, or potable water. In cases where it is used to refrigerate whole fishery products, ice can be made with clean water. Ice should be produced, handled and stored so it is protected from contamination.
82. Steam used in direct contact with food or food contact surfaces should not constitute a risk to the safety and suitability of food.

MANAGEMENT AND SUPERVISION**Documentation and Records**

83. Appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf-life of the product or as determined by the competent authority. Documentation can enhance the credibility and effectiveness of the food hygiene system and demonstrate that all reasonable care and due diligence have been taken to protect the health of consumers.

Withdrawal and Recall Procedures

84. Managers should ensure effective procedures are in place to respond to any deviation from GHPs. Failure to apply the controls effectively should be assessed for the impact on food safety or suitability. Procedures should enable the comprehensive, rapid and effective withdrawal of any food from the market that may pose a hazard to public health. Where a product has been recalled because of an immediate health hazard, 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. The need for public warnings should be considered where product may have reached consumers. Recall procedures should be documented and maintained, and modified where necessary based on the findings of periodic field trials etc.’.
85. Provision should be made so recalled products can 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.

SECTION 3: ESTABLISHMENT [CLEANLINESS] [SANITATION], MAINTENANCE AND PEST CONTROL

Q5: Further discussion is required to determine whether the word ‘Sanitation’ should be used or whether it should be defined as there may be an issue when this term is translated. As a suggestion, the word ‘Cleanliness’ has been used in the title – is this acceptable? If it is, it can be used within the text.

3.1 MAINTENANCE AND CLEANING**OBJECTIVES:**

To establish effective systems that:

- ensure appropriate maintenance?
- ensure cleanliness, and when necessary, adequate disinfection
- ensure pest control;
- ensure waste management; and
- monitor effectiveness of sanitation (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 contaminate food.

General

86. Establishments and equipment should be maintained in an appropriate condition to:
- facilitate all sanitation procedures;
 - function as intended; and
 - prevent contamination of food, such as from pests, metal shards, flaking plaster, debris, chemicals, etc.

87. Cleaning should remove food residues and soil which may be a source of contamination, including allergens. The necessary cleaning methods and materials will depend on the nature of the food business, the food type and the surface to be cleaned. Disinfection may be necessary after cleaning.
88. Attention should be paid to hygiene during cleaning and maintenance operations so as not to compromise food safety. Cleaning products suitable for food contact surfaces should be used in food preparation areas.
89. 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 the risk of contaminating food.
90. Separate cleaning equipment, suitably designated, should be used for different hygiene zones.
91. Cleaning equipment should be stored in a way to prevent contamination. Cleaning equipment should be maintained and replaced periodically so as not to become a source for contamination of surfaces or food.

Sanitation methods and procedures

92. 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 enhances the risk 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.
93. Cleaning procedures will involve, where appropriate:
 - removing gross visible debris from surfaces;
 - applying an appropriate detergent solution to loosen soil and bacterial film (cleaning); and
 - rinsing with water (hot water where appropriate) to remove loosened soil and residues of detergent.
 - 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.
94. 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.
95. Where written cleaning and disinfection programmes are used, 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.

Monitoring Effectiveness

96. Application of cleaning and disinfection procedures should be monitored for effectiveness and periodically verified by means such as visual inspections and audits to ensure they are applied properly. The type of monitoring of sanitation programmes 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 ensuring the programme is being implemented as designed.
97. Microorganisms can develop resistance to disinfectant agents and the food production environment can change over time, so periodic review with disinfectant suppliers will help ensure the disinfectants used are effective and appropriate.
98. While effectiveness of cleaning and disinfectant agents and instructions for use will be validated by their manufacturers, sampling and testing of the environment and food contact surfaces (e.g. ATP, protein, and allergen test swabs, or microbiological testing for indicator organisms such as *Listeria* species or for pathogens) can help verify that sanitation 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 sanitation procedures to make sure protocols are being followed. Sanitation

and maintenance procedures should be regularly reviewed and adapted to reflect any changes in circumstances and documented as appropriate.

3.2 PEST CONTROL SYSTEMS

General

99. 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 and location, sanitation, inspection of incoming materials and good monitoring can minimize the likelihood of infestation and thereby limit the need for pesticides.

Preventing access

100. Buildings should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access should be sealed. 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.

Harbourage and infestation

101. The availability of food and water encourages pest harbourage and infestation. Potential food sources should be stored in pest-proof containers and/or stacked above the ground and away from walls. Areas both inside and outside food premises should be kept clean and free of spillages. Where appropriate, refuse should be stored in covered, pest-proof containers. Any potential harbourage, such as old, unused equipment should be removed.

Monitoring and detection

102. 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 the report of monitoring, if necessary, and ensure corrective action (e.g. eradication of pests, elimination of harbour sites, or invasion routes) is taken by the FBO or designated pest control operators.

Prevention

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

3.3 WASTE MANAGEMENT

General

104. 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 except so far as is unavoidable for the proper functioning of the business. Personnel responsible for waste removal should be properly trained so they do not become a source of cross-contamination.
105. Waste storage areas should be kept appropriately clean and free of pests and be resistant to pest infestation.

SECTION 4: 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:

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

106. 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 controls that need to be applied.

Health Status

107. People known, or suspected to be suffering from or to be a carrier of a [disease or illness] [communicable disease] likely to be transmitted through food should not be allowed to enter any food handling area if there is a likelihood of their contaminating food. Any person so affected should immediately report illness or symptoms of illness to the management.
108. It may be appropriate for food handlers to be excluded for a specific time after symptoms resolve or, for some illnesses, to get medical clearance before returning to work.

Illness and Injuries

109. Some illnesses that should be reported to management so that any need for medical examination and/or possible exclusion from food handling can be considered include:
- jaundice;
 - diarrhoea;
 - vomiting;
 - fever;
 - sore throat with fever;
 - visibly infected skin lesions (boils, cuts, etc.);
 - discharges from the ear, eye or nose.
110. Cuts and wounds, where personnel are permitted to continue working, should be covered by suitable waterproof plasters and hand gloves.

Personal Cleanliness

111. Food handlers 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 food handlers 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.
112. 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.
113. To clean the hands, personnel should wash them with soap and water by wetting hands with water and applying sufficient soap to cover all surfaces; rinse hands with clean (preferably potable), running water and dry them thoroughly with a clean single-use towel or other method that does not re-contaminate hands. Multiple use cloth drying towels where used should be subject to washing at appropriate

frequency. Hand sanitizers should not replace hand washing and should be used only after hands have been washed.

Personal Behaviour

114. People engaged in food handling activities 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.

115. 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.

Visitors and other persons from outside the establishment

116. Visitors to food businesses, and, 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 employees. 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 5: TRANSPORTATION

OBJECTIVES:

During transportation, measures should be taken where necessary to:

- protect food from potential sources of contamination;
- protect food from damage likely to render the food unsuitable for consumption; and
- provide an environment which effectively controls the growth of pathogenic or spoilage micro-organisms and the production of toxins in food.

RATIONALE:

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

General

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

Requirements

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

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

Use and Maintenance

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

120. Where appropriate, particularly in bulk transport, containers and conveyances should be designated and marked for food use only and be used only for the purpose of transporting foods.

SECTION 6: PRODUCT INFORMATION AND CONSUMER AWARENESS

OBJECTIVES:

Products should bear appropriate information to ensure that:

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

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

RATIONALE:

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

Lot identification and Traceability

121. 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.
122. A traceability/product tracing system should be designed and implemented according to the *Principles for Traceability/Products tracing as a tool within a Food Inspection and Certification System* (CXG 60-2006), especially to enable the recall of the products, where necessary.

Product Information

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

Product Labelling

124. Pre-packaged 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-1985) applies.

Consumer Education

125. Consumer education programmes should cover general food hygiene. Such programmes should enable consumers to understand the importance of any product 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 and foodborne illness, and of the presence of allergens. Consumers should also be educated to apply appropriate food hygiene measures (e.g. proper hand washing, adequate storage and cooking and avoiding cross contamination etc.) to ensure that their food is safe and suitable for consumption.

SECTION 7: TRAINING

OBJECTIVE:

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

RATIONALE:

Training is fundamentally important to any food hygiene system.

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

Awareness and Responsibilities

126. 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. Food handlers should have the necessary knowledge and skills to enable them to handle food hygienically. Those who handle cleaning chemicals or other potentially hazardous chemicals should be instructed in safe handling techniques.

Training Programmes

127. Factors to take into account in assessing the level of training required include:
- the nature and risk of the food, in particular its ability to sustain growth of pathogenic or spoilage microorganisms;
 - whether known allergens or potential physical contaminants could be present;
 - 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 final consumption of the food;
 - the conditions under which the food will be stored; and
 - the expected length of time before consumption of the food.
128. In addition, for retail and food service operations whether persons have direct customer interaction is a factor in training, since they may need to convey certain information about products (such as allergens) to customers.

Instruction and Supervision

129. The type of supervision needed will depend on the size of the business, the nature of its activities and the types of food involved. Managers and/or supervisors should have the necessary knowledge of food hygiene principles and practices to be able to judge potential hazards and take the necessary action to remedy deficiencies.
130. Periodic assessments of the effectiveness of training and instruction programmes should be made, as well as routine supervision and checks to ensure that procedures are being carried out effectively. Personnel tasked to monitor the equipment 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 to the safety and suitability of the food.

Refresher Training

131. 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.

[CHAPTER TWO]**HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION****Preamble**

132. The first part of this [Chapter] sets out the seven principles of the Hazard Analysis and Critical Control Point (HACCP) system. The second part provides general guidance for the application of the system 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 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 prevention of hazards rather than relying mainly on end-product testing. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.
133. HACCP principles can be considered throughout the food chain from primary production to final consumption and its 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. 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 or adapt a generic HACCP plan provided by the competent authority or food industry 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 inspection by competent authorities and promote international trade by increasing confidence in food safety.
134. The successful application of HACCP requires the commitment and involvement of management and the workforce. A multi-disciplinary approach is strongly recommended; this multi-disciplinary approach should be appropriate to the food business operation e.g., expertise in agronomy, veterinary health, production, microbiology, public health, food technology, environmental health, chemistry and engineering, according to the particular application. The application of HACCP is the system of choice in the management of food safety within broader quality management systems.
135. 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 described in the FAO/WHO Guidance to governments on the application of HACCP in SLDBs⁵. It provides 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 section.

Q6 Validation has been added to Principle 6 on verification because the application text for Principle 6 included a statement on validation. However, it may be more appropriate to include 'Validation' under Principle 3. What do members think?

The Definitions which were here have been moved to an earlier section.

PRINCIPLES OF THE HACCP SYSTEM

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

PRINCIPLE 1

Conduct a hazard analysis.

PRINCIPLE 2

Determine the Critical Control Points (CCPs).

⁵ FAO/WHO. Guidance to governments on the application of HACCP in small and/or less-developed food businesses. FAO Food and Nutrition Paper 86. 2006.

PRINCIPLE 3

[Establish critical limit(s)] or [Determine and validate critical limit(s)].

PRINCIPLE 4

Establish a system to monitor control of the CCP.

PRINCIPLE 5

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

PRINCIPLE 6

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

PRINCIPLE 7

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

GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM**Introduction**

136. Prior to application of HACCP to any sector of the food chain, that sector should have in place GHPs in accordance with Chapter I of this document, the appropriate product and sector-specific Codex Codes of Practice, and appropriate food safety requirements set by competent authorities. These prerequisite programmes to HACCP, including training, 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 GHPs.
137. 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 employees having the appropriate HACCP knowledge and skills.
138. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration should be given to the impact of raw materials and other ingredients, food production practices, food manufacturing practices (including whether processes control hazards adequately under GHP or whether significant hazards remain and require control under HACCP), likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.
139. HACCP is a systematic approach that enhances control of specific food safety 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). Redesign of the operation should be considered if a [food safety] hazard is identified which is not controlled by the process. As described in the GHP Section, some food hazards may be controlled adequately by GHP-based controls.
140. HACCP should be applied to each individual operation separately. CCPs can be distinctive for a particular situation and those identified in any given example in any Codex Code of Hygienic Practice might not be the only ones identified for a specific application or might be of a different nature.
141. The HACCP system should be reviewed periodically and when there is a significant change in the food business that could impact the hazard analysis or control measures (e.g. new process, new ingredient, new product, new equipment) to determine if modifications are needed when any modification is made in the product, process, or any step. Amendments should be made, as appropriate. The system should also be reviewed, and modified as appropriate, when the HACCP system has failed to produce a safe product, e.g., a pathogen is detected in a ready-to-eat product.

Flexibility for small and/or less developed food businesses

142. 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 businesses. This is particularly relevant in small and/or less developed businesses. While it is recognized that flexibility appropriate to the business is important when applying HACCP, all seven principles should be applied in developing the HACCP system. This flexibility should take into account the nature [and size] of the operation, including the human and financial resources, infrastructure, processes, knowledge

and practical constraints, as well as the risk associated with the produced food. The flexibility is not intended to reduce CCPs and should not endanger food safety.

143. Small and/or less developed businesses do not always have the resources and the necessary expertise on site for the development and implementation of an effective HACCP plan. In such situations, expert advice should be obtained from other sources, which may include: trade and industry associations, independent experts and 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.⁶ A comprehensive explanation of the basis for the HACCP plan should be provided to the FBO.
144. The efficacy of any HACCP system will nevertheless rely on management and employees having the appropriate HACCP knowledge and skills, therefore ongoing training is necessary for all levels of employees and managers, as appropriate to the food business. The correct application of hygiene practices is essential for the HACCP system to function properly.

APPLICATION

Assemble HACCP Team and Identify Scope (Step 1)

145. The food business operator should assure that the appropriate product specific knowledge and expertise are available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team that includes individuals conducting different activities within the operation, e.g., production, maintenance, quality control, sanitation, etc.
146. As mentioned earlier where such expertise is not available on site, 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 HACCP in-house. A generic HACCP-plan developed externally may be used by FBOs where appropriate, but should be tailored to the food operation.
147. The HACCP team should identify the scope of the HACCP system and applicable prerequisite programmes and is responsible for writing the HACCP plan. The scope should describe which segment of the food chain is involved and the general classes of hazards (biological, chemical, physical) to be addressed (e.g. does it cover all classes of hazards or only selected classes).

Describe product (Step 2)

148. A full description of the product should be developed, including relevant safety information such as composition, physical/chemical characteristics (including a_w , pH, preservatives etc.), processing methods/technology (heat-treatment, freezing, 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 already established for food safety 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.

Identify intended use (Step 3)

149. The intended use should describe the use intended by the FBO and the expected uses of the product by the next user in the food chain or the consumer (they are the end user); it should also include ways in which consumers are known to use the product other than those intended by the FBO. In specific cases, vulnerable groups of the population, e.g. institutional feeding, may have to be considered. In instances where foods are being produced specifically for a vulnerable population, it may be necessary to pay greater attention to GHPs, 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.

⁶ FAO/WHO Guidance to governments on the application of HACCP in SLDBs.

Construct flow diagram (Step 4)

150. The flow diagram should be constructed by the HACCP team. The flow diagram should cover all steps in the production of a specific product, including rework. The same flow diagram may be used for a number of products that are manufactured using similar processing steps. When applying HACCP to a given step, consideration should be given to steps preceding and following the specified step. The flow diagram should indicate all the flows, including those of ingredients, personnel, water and air. 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 food safety 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;
- any outsourced processes;
- where raw materials, ingredients, processing aids, packaging materials, utilities and intermediate products enter the flow;
- where reworking and recycling take place;
- where end products, intermediate products, by-products and waste are released or removed.

On-site confirmation of flow diagram (Step 5)

151. 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.

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

152. Hazard analysis consists of identifying potential hazards and evaluating these hazards to determine which hazards are significant for the specific food business operation. The HACCP team should list all of the hazards reasonably likely to occur at each step according to the scope of the food business operation. To identify potential hazards that may be associated with ingredients, "receiving" the ingredients can be considered as the step. One way to simplify a hazard analysis is to break down complex manufacturing operations into smaller, more manageable modules with separate flow diagrams, and analysing the steps in each flow diagram.

153. The HACCP team should next evaluate the hazards to identify which of these hazards are of such a nature that their prevention, elimination, or reduction to acceptable levels is essential to the production of safe food (i.e., determine the significant hazards that need to be addressed in a HACCP plan) taking the effect of GHPs in place into account.

154. In conducting the hazard analysis (i.e. hazard identification and hazard evaluation) to determine whether there are significant hazards, wherever possible the following should be considered:

- hazards historically 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, or from information in the scientific literature);
- adverse health effects (including their severity) historically associated with the hazards in the type of food or its ingredients;⁷
- the likely occurrence of hazards;
- the likelihood that the hazard, if present, would cause illness or injury and the severity of the same;
- the nature of the facility and the equipment used in making a food product if not controlled
- survival or multiplication of microorganisms of concern;
- production or persistence in foods of toxins (e.g. mycotoxins), chemicals (e.g. pesticides, drug residues, undeclared allergens) or physical agents (e.g. glass, metal); and,

⁷ *Principles and Guidelines for the Conduct of Microbiological Risk Management (CXG 63-2007).*

- conditions leading to the above.
155. 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 be used without a heat treatment in flavouring a dip for chips) to determine the significant hazards to be addressed in the HACCP plan. Consideration should also be given to whether the food itself could be a choking hazard for the intended consumers based on size, shape, and texture of the food.
156. In some cases, it may be acceptable for a more simplified hazard analysis to be carried out by FBOs. This simplified process identifies groups of hazards (microbiological, 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 externally, 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.
157. Hazards which are of such a nature 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 control measures designed to prevent, eliminate, or reduce them to an acceptable level. As noted previously, 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 when the two foods are processed on the same equipment. In other instances, control measures will need to be applied at critical control points. An illustrative example of a decision-tree is attached at Appendix 1:
158. 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 and more than one hazard may be controlled by a specified control measure. 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; a heat treatment can control both *Salmonella* and *E. coli* O157:H7 that present a hazard in raw meat.

Determine Critical Control Points (Step 7 and Principle 3)

Q7 decision tree at Diagram 2 provided by Brazil and amended by UK. Are Members content with this inclusion?

159. Critical control points are to be determined for each of the hazards identified as significant in the hazard analysis. CCPs are established at steps where control is essential and where a loss of control could result in the production of a potentially unsafe food. 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 facilitated by the application of a decision tree (e.g., Diagram 2). Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other processes. Other approaches may be used. Training in the application of the decision tree is recommended.
160. If a significant hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other step, then the product or process should be modified to include a control measure.

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

161. Critical limits that separate acceptable products from unacceptable ones should be specified for each Critical Control Point. 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 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, and, where appropriate, parameters which can be observed, such as a pump setting.

162. Control measures and their critical limits should be scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level if probably implemented.⁸ FBOs may not always need to commission studies themselves to validate control measures. Critical limits could be based on existing literature or carried out by a third party e.g. cleaning compounds validated for effective use by the manufacturer.
163. Where HACCP guidance developed by 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.

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

164. Monitoring is the scheduled measurement or observation at a CCP relative to its critical limits. The monitoring procedures should be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in real-time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs.
165. If monitoring is not continuous, then the amount or frequency of monitoring should be sufficient to ensure the CCP is in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are 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.
166. 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.
167. All records and documents associated with monitoring CCPs should be signed by the person performing the monitoring. In addition, the records and documents should be reviewed and signed by a responsible reviewing official of the company as a verification of control (see Step 11).

Establish corrective actions (Step 10 and Principle 5)

168. Specific written corrective actions should be developed for each CCP in the HACCP system in order to effectively respond to deviations when they occur.
169. 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. Actions taken should include segregating the affected product and analysing the safety of the product to ensure proper disposal of the affected product. External experts may be needed to conduct such evaluations. In some cases, the evaluation may indicate that the product is safe and can be released into commerce. In other cases, it may be determined that the product could be reprocessed (e.g., re-pasteurised) or the product could be diverted to another use (e.g., contaminated minced meat intended to be sold fresh used in a cooked product that destroys pathogenic *E. coli*). 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. Details of the corrective actions, including the cause of the deviation and product disposal procedures should be documented in the HACCP record keeping. Periodic review of corrective actions should be undertaken to identify trends and to ensure corrective actions are effective.

Establish validation and verification procedures (Step 11 and Principle 6)

Q8: This section has been retitled and includes additional text – are members content with the amendments?

170. Establish validation and verification procedures for individual control measures, as well as the HACCP system as a whole. Validation involves obtaining scientific and technical evidence that control measures are capable of controlling a hazard whereas verification involves activities to verify on an ongoing basis that the hazard control measures are being implemented as intended (i.e. in accordance with the HACCP plan). Verification also includes reviewing the adequacy of the HACCP system periodically and, as appropriate, when changes occur.

⁸ *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008).

171. Where possible, validation is performed during development of the HACCP plan. In addition to obtaining the evidence that the control measures are capable of controlling the hazard, it includes obtaining evidence in operation during the initial implementation of the HACCP system to show that control can be achieved consistently under production conditions. Validation is applied during the establishment of critical limits to ensure that the appropriate values are chosen. This could include a review of scientific literature, using mathematical models, conducting validation studies, or using “safe harbours” developed by authoritative sources. Validation is also done on a periodic basis when the plan is reanalysed and when changes indicate the need for re-validation. Validation is described more fully in the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69 – 2008).
172. After validation, 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, 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:
- review of monitoring records to confirm that CCPs are kept under control;
 - review of corrective action records, including specific deviations, product disposals and any analysis to determine the root cause of the deviation;
 - calibration or checking the accuracy of instruments used for monitoring and verification;
 - observation that control measures are being conducted in accordance with the HACCP plan;
 - sampling and testing, e.g., for microorganisms⁹ (pathogens or their indicators) or chemical hazards such as mycotoxins to verify product safety;
 - sampling and testing the environment for microbial contaminants and their indicators, such as *Listeria*; and
 - review of the HACCP system, including the hazard analysis and the HACCP plan (e.g. internal and/or third-party audits).
173. 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.
174. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. Verification of the implementation of hazard control measures should be conducted with sufficient frequency to determine that the HACCP plan is being implemented properly.
175. Verification activities 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 hazard 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.

Establish documentation and record keeping (Step 12 and see Principle 7)

176. Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained. Expertly developed HACCP guidance materials (e.g. sector-specific HACCP guides) may be utilised as part of the documentation, provided that those materials reflect the specific food operations of the business.
177. 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;

⁹ *Principles and guidelines for the establishment and application of microbiological criteria related to food* (CXG 21-1997).

- validation of control measures; and
- modifications made to the HACCP plan.

178. Examples of records include:

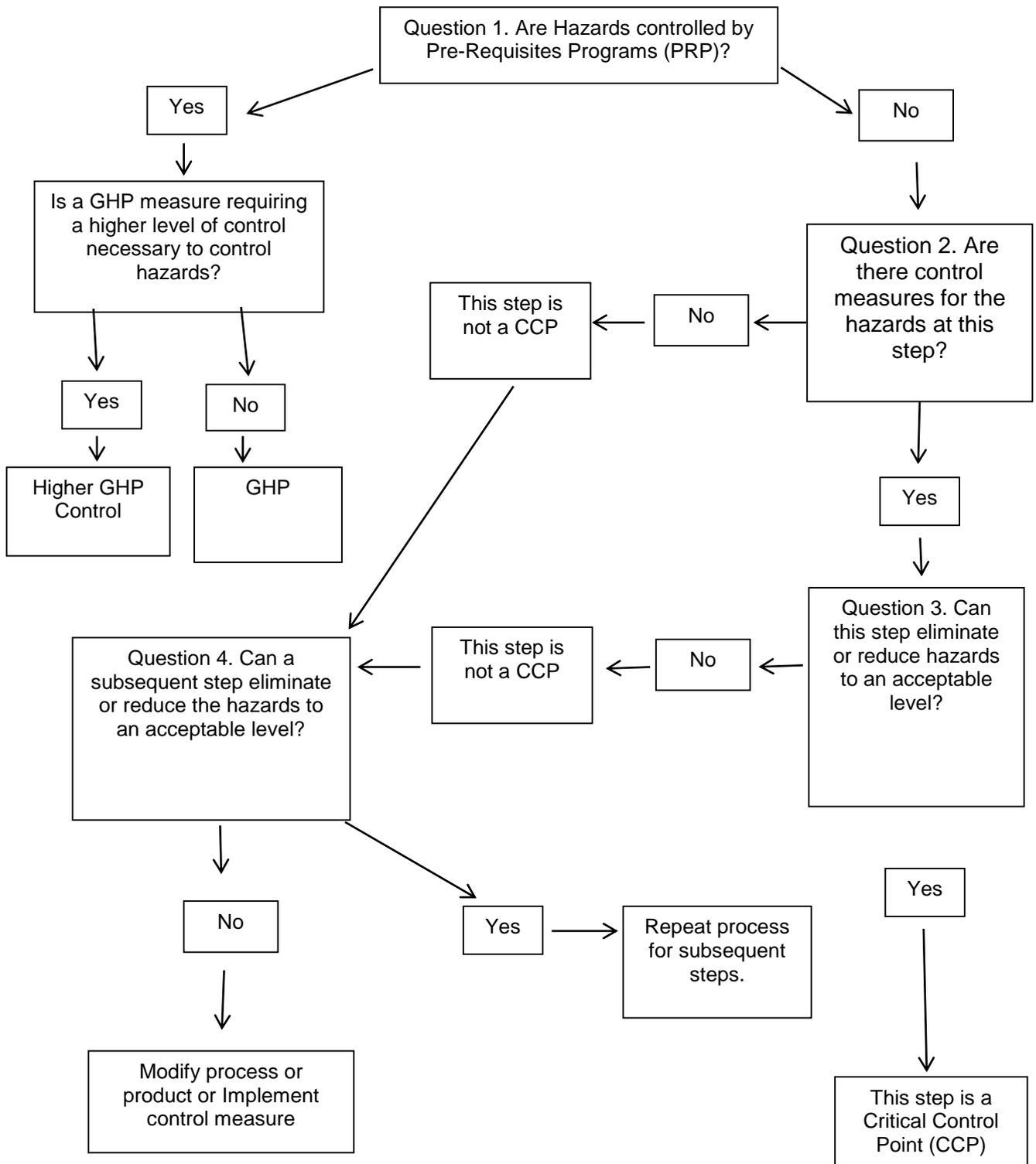
- CCP monitoring activities;
- deviations and associated corrective actions; and
- verification procedures performed.

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

Training

180. Training of personnel in industry, 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 programs should be reviewed periodically and updated where necessary. Re-training may be needed as part of corrective actions for some deviations.
181. Cooperation between primary producer, industry, trade groups, consumer organisations, and responsible authorities is vitally important. Opportunities should be provided for the joint training of industry and competent authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

Suggested by Brazil (modified) – see paragraph 157
Flowchart to determine whether a particular step or procedure is a
CCP or requires higher GHP Control



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