

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 4

CRD05

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

Forty-ninth Session

Chicago, Illinois, United States of America, 13 - 17 November 2017

### PROPOSED DRAFT REVISION OF THE *GENERAL PRINCIPLES OF FOOD HYGIENE* (CAC/RCP 1-1969)

*Comments of Australia*

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

**Note:** Revised text on General Principles of Food Hygiene has been developed by the EWG following direction provided by CCFH48 and the PWG (November 2016). Notes have been included to provide explanation for major changes to the text and highlight areas where further discussions are required.

**Further consideration of some fundamental principles is required, in particular, whether all food businesses should carry out a hazard analysis and whether additional concepts e.g. enhanced GHPs should be introduced. The text will be further developed as agreement on these principles has been reached. Development of supporting definitions and changes to the structure of the document including the relationship with ISO 22000 should also be considered as the text develops.**

#### **INTRODUCTION**

1. People have the right to expect the food they eat to be safe and suitable for consumption. Foodborne illness and foodborne injury are at best unpleasant and in some circumstances can be severe or fatal or have a negative impact on human health over the long 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.
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 assure that food is safe and suitable for consumption.
3. This document outlines the general principles that should be understood and followed by food business operators (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 operation; the relevant contaminants; and whether the relevant contaminants adversely affect safety, suitability or both; these principles will enable food businesses, to develop their own food hygiene practices and appropriate food safety control measures, while complying with requirements set by competent authorities.

**Note:** Alternative paragraphs 4A and 4B are suggested to cover the possible outcomes of further discussions on whether all food businesses should be required to complete a hazard analysis.

4.

OR [4B is a Substitute paragraph if delegations support the approach that all FBOs do a hazard analysis]

4. B.[ Prerequisite Programmes (PRPs), which include Good Hygiene Practices (GHPs), Good Manufacturing Practices (GMPs), and Good Agricultural Practices (GAPs), as appropriate, lay the foundation for producing safe and suitable food.] [GHPs apply broadly to all food businesses. Following a hazard analysis, it may be decided that GHPs are sufficient for some FBOs to control all food safety hazards. In other cases there may be a need to pay particular attention to certain hazards determined as significant and to apply [enhanced GHPs or control measures at critical control points (CCPs) within a Hazard Analysis and Critical Control Point (HACCP) system (see Comparison Table below). FBOs without the resources to carry out a site-specific hazard analysis may use existing models, references, standards, regulations, or Code of Practices or generic HACCP plans provided by the competent authority or food industry<sup>2</sup> subject to adaptation to the site.]

Note: A decision tree has been added to support understanding of control measures other than CCPs that require additional attention which are referred to as 'enhanced GHPs'.

(Annex 1 provides a flow chart of the steps involved in a hazard analysis)

5. [Chapter One] of this document describes GHPs. GHPs can be stand-alone food hygiene measures or programs prerequisite to HACCP. [Chapter Two] describes HACCP. HACCP principles can basically 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.

Note: A comparison table has been introduced as requested by CCFH to support understanding of the relationship between GHP and HACCP.

6. The following table compares GHPs, enhanced GHPs and CCPs. <sup>1</sup>FAO/WHO guidance to governments on the application of HACCP in small and/or less developed food businesses ISSN 0254-4725

**Commented [blenmp1]:** What happened to enhanced GHPs?  
Where will hazard analysis be discussed?

<sup>2</sup> FAO/WHO guidance to governments on the application of HACCP in small and/or less developed food businesses ISSN 0254-4725

**Comparison of GHPs, [Enhanced GHPs] and Control Measures at CCPs**

Note: Reference to Control Measures at Places other than CCPs or enhanced GHPs has been included in the table. However, further discussions are required to reach agreement on whether this concept should be introduced into the document, and if agreement is reached, how this should be done.

	<b>Good Hygiene Practices (GHPs)</b>	<b>[Control Measures at Places Other than CCPs][Enhanced GHPs]</b>	<b>Control Measures at Critical Control Points (CCPs)</b>
<b>Scope</b>	General basic conditions and activities to create the environment (external and internal) for safe food.  Not specific to any hazard but results in some prevention of contaminants.	Control measures for significant hazard(s) in food and/or the processing environment.	Controls at production steps that are critical to reduce significant hazards in foods to an acceptable level.
<b>When identified?</b>	Before hazard analysis, or Adaptation after hazard analysis.	[After basic hazard analysis [at places other than CCPs][enhanced GHPs]] After Hazard analysis [for control measures at CCPs]	
<b>Validation of the effectiveness of the control measure</b>	Where needed, generally not carried out by FBOs themselves, e.g. cleaning products validated for effective use by manufacturer.	Yes, validation should be carried out ( <i>Guidelines for the Validation of Food Safety Control Measures CAC/GL 69-2008</i> )	
<b>Criteria</b>	Some aspects of GHPs may be measurable or observable e.g. hand washing	Criterion measurable or observable which separates acceptable procedure from questionable and that requires an evaluation of the impact on product (e.g., cleaning).	Critical limit which separates acceptable products from unacceptable  <ul style="list-style-type: none"> <li>• measurable (e.g. temperature, pH, a<sub>w</sub>), or</li> <li>• observable (e.g. visual checks, appearance, texture).</li> </ul>
<b>Monitoring</b>	Yes, where relevant [and feasible]	Yes, but usually non-continuous. Frequency dependent on the operation.	Yes, in real time;  <ul style="list-style-type: none"> <li>• continuous, or</li> <li>• at frequency sufficient to ensure CCP in control</li> </ul>

**Commented [blenmp3]:** Are they?

**Commented [blenmp2]:** Overly complicated – this is scope, not a definition section.

<b>Corrective actions when loss of control is indicated</b>	<input type="checkbox"/> For procedures and practices: Yes, [where relevant]. <input type="checkbox"/> For products: Usually not necessary.	<input type="checkbox"/> For procedures and practices: Yes. <input type="checkbox"/> For products: When necessary, based on the situation evaluation. Product should not be introduced into commerce until the evaluation is completed.	<input type="checkbox"/> For products: Yes. Pre-determined actions for products. <input type="checkbox"/> For procedures and practices: Yes, corrective actions as appropriate to restore control and prevent recurrence.
<b>Verification</b>	Yes, where relevant, usually scheduled	Yes. Scheduled verification of implementation of control measures	
<b>Record keeping (e.g. monitoring records)</b>	Yes, where relevant	Yes	
<b>Documentation (e.g. documented procedures)</b>	Yes, where relevant	Yes	

## OBJECTIVES

7. *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, taking account of the size and nature of the food business operation and the level of food safety risk; and
- provide the basis on which sector and product-specific codes of practice are established.

## SCOPE

8. This document provides a framework of general principles for producing safe and suitable food for human consumption by outlining necessary hygiene and food safety conditions to be implemented in the manufacture of food products and recommending, where appropriate, specific food safety control measures at certain steps throughout the food chain.

## USE

### General

9. The document is intended for use by food business operators (including primary producers, manufacturers/processors, food service operators and retailers) and competent authorities, as appropriate. This document is generally applicable to food businesses and to competent authorities that provide oversight, and provides flexibility to meet the needs of different types of food businesses in the context of international food trade.

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

11. 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 scientific information available. 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 practices and varying degrees of risk involved in producing and handling food.

### Roles of Competent Authorities, Food Business Operators, and Consumers

12. Competent authorities should decide how best they should apply these general principles of food hygiene through legislation, regulation or guidance to:

- protect consumers from illness or injury caused by unsafe food;
- provide an effective control system to ensure food is safe and suitable for human 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.

13. Food business operators should apply the hygienic practices and food safety principles set out in this document to:

- develop, implement and review 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;
- 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 it correctly; and
- contribute to maintaining confidence in domestically and internationally traded food.

**Commented [blenmp4]:** To avoid confusion with the principles listed under paragraph 14.

**Commented [blenmp5]:** Are these the principles under paragraph 14?

14. Consumers should play their role by following relevant guidance and instructions for food preparation and applying appropriate food hygiene measures to ensure that their food is safe and suitable for consumption.

#### OVERARCHING PRINCIPLES

- (i) Food safety hazards (biological, chemical, physical) should be controlled using a preventive approach to ensure food safety and suitability.
- (ii) GHPs should ensure that food is produced in a sanitary environment in order to reduce the presence of contaminants.
- (iii) GHPs should provide the foundation for a HACCP system, where applied, to be effective.
- (iv) Hazard analysis should identify all potential hazards associated with the ingredients, the production process and its related environment (e.g. people, equipment and facility) and specify the [significant hazards] that should be controlled to ensure food safety.
- (v) [Significant hazards] should be controlled by [specific] control measures.
- (vi) These control measures should be validated<sup>3</sup>
- (vii) The application of control measures should be subject to monitoring, corrective actions, verification, and documentation, as appropriate.
- (viii) Food hygiene systems should be reviewed periodically and when there is a change in the food business (e.g. new process, new ingredient, new product, new equipment) to determine if modifications are needed.
- (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

Note: This section has been moved from the HACCP section to the Introduction to strengthen the references to management commitment and food safety culture.

15. Fundamental to the successful functioning of any food hygiene system is the commitment from management to commit to making safe food a priority, incorporate food safety into the business objectives of the food business and to communicate the importance of producing safe food, both for the consumer and the business.

16. Managers should continually improve the 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 controls are working and documentation is up to date;
- ensuring the appropriate training and supervision are in place for personnel;
- ensuring compliance with relevant regulatory requirements; and
- enabling a strong food safety culture by demonstrating commitment to providing safe and suitable food and encouraging appropriate food safety behaviours.

#### Definitions

[To be developed based on terms used in Parts 2 and 3]; include here the definitions that already exist in the RCP-1, Section 2.3 to facilitate discussion on them.

#### Enhanced GHP [if this expression is retained]

**Food hygiene system** - The combination of hygiene practices and control measures that, when taken as whole, ensures that food is safe and suitable for its intended use.

**Food safety control system**<sup>4</sup> - The combination of control measures that, when taken as whole, ensures that food is safe for its intended use.

#### Control measure

<sup>3</sup> Guidelines for the Validation of Food Safety Control measures (CAC/GL 69-2008)

<sup>4</sup> Guidelines for the Validation of Food Safety Control measures (CAC/GL 69-2008)

**Commented [blenmp6]:** Include a definition of food safety culture in the document (Global Food Safety Initiative technical working group on Food Safety Culture has a definition)

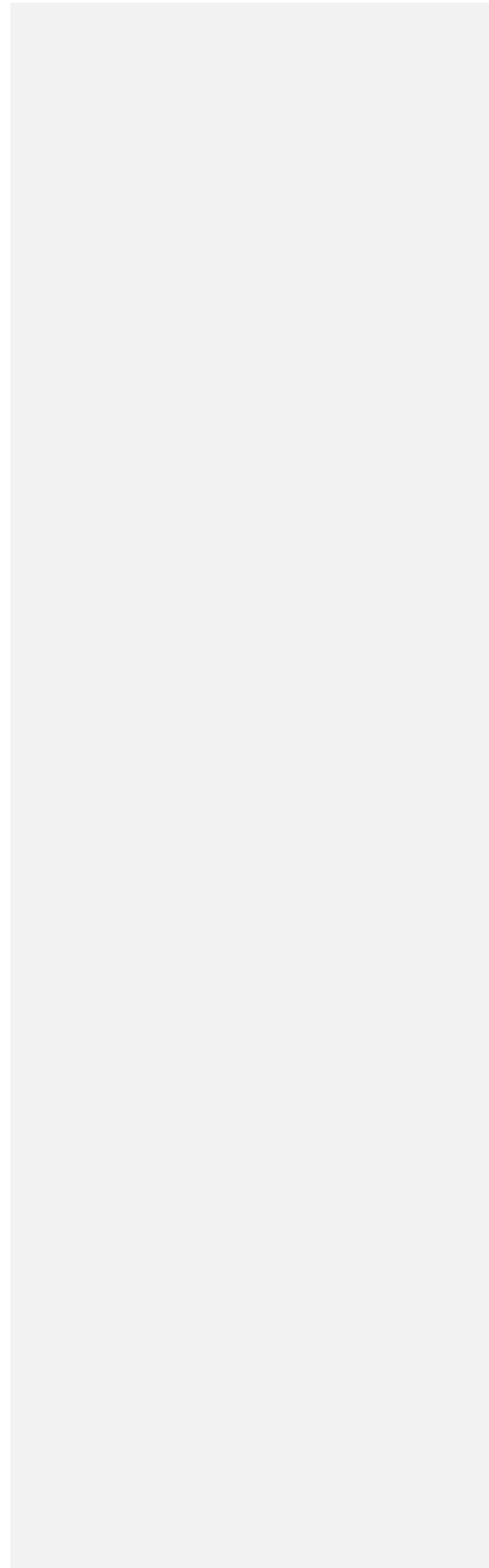
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**Hazard control measures**

**Significant hazard**

**[Basic Hazard Analysis]**

**ANNEX I**



**[CHAPTER ONE]****GOOD HYGIENE PRACTICES****Introduction**

1. 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 in the work environment.
2. A GHP-based system may be sufficient to control all hazards in the operation. Where significant food safety hazards are identified in the operation, these should be controlled either through application of enhanced GHPs designed to control a specific food safety hazard or, where appropriate, in combination with the application of HACCP.
3. An appropriate location, layout, design, construction and maintenance of premises and facilities are essential for implementation of GHPs to be effective. Knowledge of the food and its production process is also essential. This [Chapter] provides guidance for effective implementation of GHPs and should be applied in conjunction with sector and product-specific codes.
4. Where this Chapter refers to food business operators, this includes primary production

settings. **PRIMARY PRODUCTION**

Note: The section on primary production was deleted with the expectation that this would be replaced with short overarching paragraph to make it clear that the document applies to primary production where this is appropriate and text throughout the document would be written in such a way that it is clear primary production is included. However EWG members have differing views and further discussions are required to reach agreement on the revisions required to clarify how the guidance applies to primary production e.g. whether there is a specific section on primary production based on previous text included in CAC/RPC1 – 1969 complimented by cross references where appropriate or whether this could be achieved by references throughout the text.

**SECTION I: 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 minimises airborne contamination;
- surfaces and materials, in particular those in contact with food, are non-toxic in intended use and, where necessary, suitably durable and easy to maintain and clean;
- where appropriate, suitable facilities are available for temperature, humidity and other controls; and
- there is effective protection against pest access and harbourage.

**RATIONALE:**

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

**Location of establishment**

5. Establishments should not be located anywhere 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, 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 unless sufficient safeguards are provided;
  - areas prone to infestations of pests; and
  - areas where wastes, either solid or liquid, cannot be removed effectively.

6.



**Equipment**

Note: original text from CAC/RPC1–1969 has been incorporated into subsequent sections.

**Design and layout of food establishment [and equipment]**

7. The internal design and layout of food establishments and equipment should permit good food hygiene practices, permit adequate maintenance and cleaning, and protect from cross-contamination.
8. 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**

9. 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;
  - 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;
  - work surfaces that come into direct contact with food should be in sound condition, durable, easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent, materials.

**Temporary/mobile food establishments and vending machines**

10. Establishments and structures covered here include market stalls, street vending vehicles and temporary premises such as tents and marquees.
11. 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.

**FACILITIES****Water supply**

Note: Original text from CAC/RPC1–1969 has been moved to the section on water. This should be considered further when the document is more developed as agreement has not been reached on the appropriate location for the text.

**Drainage[and waste disposal]**

12. 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. It is important that drainage does not flow from highly contaminated areas to areas where finished food is exposed to the environment]
13. Waste should be collected, disposed of by trained personnel and, where appropriate, disposal records maintained. The waste [collection] 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.
14. 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**

15. Adequate, suitably designated facilities should be provided for cleaning [food], utensils and equipment coming into contact with food. Such facilities should have an adequate supply of hot and cold potable water where appropriate.

**Personnel hygiene facilities and toilets**

16. Adequate personnel hygiene facilities should be available in order that an appropriate degree of personal hygiene can be maintained and to avoid contaminating food. Where appropriate, facilities should include:

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

17. Such facilities should be suitably located and designated. Where necessary, separate sinks should be available for hand washing and food washing.

**Temperature control**

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

**Air quality and ventilation**

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

- minimize air-borne contamination of food, for example, from aerosols and condensation droplets;
- control ambient temperatures;
- control odours which might affect the suitability of food; and
- control humidity, where necessary, to ensure the safety and suitability of food (e.g. to prevent an increase in moisture of dried foods that would allow growth of microorganisms and production of toxic metabolites).

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

**Lighting**

21. 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

**Storage**

22. 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.

23. 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).

24. 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**

25. 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 those which are single-use only) and where necessary, disinfected and maintained to avoid the contamination of food. 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

26. Equipment used to cook, heat treat, cool, store or freeze food should be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and maintain them effectively. Where appropriate, equipment should be calibrated to ensure that food processes are monitored consistently and accurately

27. Such equipment should also be designed to allow temperatures to be monitored and controlled. Where necessary, such equipment should have effective means of controlling and monitoring humidity, air-flow and any other characteristics likely to have a detrimental effect on the safety or suitability of food.

#### SECTION II: CONTROL OF OPERATION

Note: Text in this Section II will be revised as the document develops. Some changes have been made but further amendments will be required to ensure clarity and consistency and reflect agreed structure. Objectives and rationale should also be revised.

##### OBJECTIVES:

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

- formulating design requirements with respect to raw materials, composition, processing, distribution, and consumer use to be met in the manufacture and handling of specific food items;
- designing, implementing, monitoring and reviewing effective control systems.

##### RATIONALE:

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

Note: Further consideration is required to reach agreement on whether additional sections on product description, process description and monitoring procedures should be included or whether they are adequately addressed in other parts of the text. If agreement is reached these paragraphs 28 to 33 should be developed to ensure the appropriate level of detail is provided.

#### • CONTROL OF FOOD HAZARDS

Note: As noted previously, further discussion is required to reach agreement on the expectations around the level of hazard analysis required for application of GHP and whether new concepts for controls e.g. enhanced GHPs should be introduced. Once agreement is reached text in this section can be developed.

Note: The EWG has agreed that guidance on carrying out a basic hazard analysis should be developed and included in the guidance to support this section

34. |

#### KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

Note: title may need amending in line with text as it develops. Restructuring of sections and additional sections on Humidity control and control of air have been suggested and should be discussed further

##### Time and temperature control

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

39. Temperature control systems should take into account:

- the nature of the food, e.g. its water activity, pH, and likely initial level and types of microorganisms such as pathogenic and spoilage micro flora;
- the intended shelf-life of the product;
- the method of packaging and processing; and

**Commented [blenmp7]:** This should be part of the annex on doing a hazard analysis – have moved text to annex 1.

**Commented [blenmp8]:** Have moved papras 34,35,31,32,33 in that order to after para 102.

**Commented [blenmp9]:** Move this text on enhanced GHPs into a section on Enhanced GHPs.

**Commented [blenmp10]:** This text box and papras 36 and 37 have been moved to annex 1 on doing a hazard analysis.

- how the product is intended to be used, e.g. further cooking/processing or ready-to-eat.

40. Such systems should also specify tolerable limits for time and temperature variations. [Critical]  
Temperature recording devices should be checked for accuracy, [and where appropriate calibrated] at regular intervals.

**Specific process steps** Note: Original text from CAC/RPC1-1969 has been deleted as this is covered in specific codes.

#### **Formulation**

41. The composition of a food, e.g. adding acids, salts, sugars or preservatives, can be useful in preventing growth and toxin production by microorganisms. 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.

#### **Microbiological<sup>5</sup> and other specifications**

Note: Further discussions required to reach agreement on the Title and text at para 42

42. 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, monitoring procedures, analytical methods and critical limits.

#### **Microbiological cross-contamination**

43. Microbiological contamination occurs thorough the transfer of microorganisms from one food to another, either by direct contact or indirectly by food handlers, contact surfaces, cleaning equipment or via splashing or airborne particles. Raw, unprocessed food, which could pose a contamination risk, should be effectively

separated, either physically or by time, from ready-to-eat foods with effective intermediate cleaning and where appropriate disinfection.

44. In some food operations, access to processing areas may need to be restricted or controlled. Where risks are particularly high, access to processing areas should be only via a changing facility. Personnel may need to be required to put on clean protective clothing including footwear and wash their hands before entering.
45. 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.

#### Physical contamination

46. Systems should be in place to prevent contamination of foods by foreign bodies such as insects, glass, metal shards and any hard and sharp object(s) e.g. bone(s), rubber plastic. In manufacturing and processing, suitable prevention strategies such as maintenance and regular inspection and detection or screening devices should be used where necessary. Procedures should be in place for food handlers to follow in the case of breakage.

#### Chemical contamination

Note: Text to be developed to give equal prominence to chemical contamination and guidance on control of chemicals used in premises, additives, veterinary residues and checks on incoming materials etc.

47. Systems should be in place to prevent contamination of foods by harmful

chemicals. **Allergenic Contamination**

Note: New text has been proposed in response to CCFH comments. Text should be developed further e.g. considering the examples of allergens, references to precautionary labelling and supplier management programmes and verification through audit to ensure consistency with sections on other contamination

48. [Hazard identification should take into account the allergenic nature of some foods. Presence of allergens e.g. nuts, milk, eggs and cereal grains should be identified in raw materials, other ingredients and products. A system of allergen management should be in place starting from receipt and raw materials, 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-contamination from foods containing allergens to other foods should be implemented e.g. separation either physically or by time (with intervening cleaning between foods with different allergen profiles. Where cross-contamination cannot be prevented, consumers should be informed.)

#### INCOMING MATERIALS

49. Only raw materials and other ingredients that are fit for purpose should be used. Incoming materials including food ingredients should be purchased[procured] according to specifications and their compliance with food safety and suitability specifications should be verified. Incoming materials or ingredients should, where appropriate, be inspected and sorted before processing. Where necessary, laboratory tests should be conducted to verify food safety and suitability of raw materials or ingredients. 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 ingredients should be subject to effective stock rotation.

#### PACKAGING

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

#### WATER

Note: EWG has developed the Original text from CAC/RPC1–1969 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.

**Water supply**

51. An adequate supply of potable [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.
52. 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 should be identified and should not connect with, or allow reflux into, potable water systems.

**Water in contact with food**

53. 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 texts e.g. the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003) and *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).
54. 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).
55. Water recirculated for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of food results from its use. The treatment process should be effectively monitored. Recirculated water which has received no further treatment and water recovered from processing of food by evaporation or drying may be used, provided its use does not constitute a risk to the safety and suitability of food.

**As an ingredient**

56. 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**

57. Ice [in direct contact with food] should be made from potable water. Ice and steam should be produced, handled and stored so they are protected from contamination.
58. Steam used in direct contact with food or food contact surfaces should not constitute a threat to the safety and suitability of food.

**MANAGEMENT AND SUPERVISION**

Note: Original text from CAC RPC1-1969 from this section has been moved to training and management

**DOCUMENTATION AND RECORDS**

59. 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 safety control system and demonstrate that all reasonable care and due diligence has been taken to protect the health of consumers

**RECALL PROCEDURES**

60. Managers should ensure effective procedures are in place to deal with any food safety hazard and to enable the comprehensive, rapid and effective recall of any implicated lot of the finished food from the market. 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.
61. Recalled products should be held under supervision until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to ensure product safety.

### SECTION III: ESTABLISHMENT MAINTENANCE, SANITATION AND PEST CONTROL

Note: Further discussion is required to determine whether a definition should be provided for 'Sanitation' to clarify that this includes cleaning and where appropriate disinfection or whether this should be clarified in the text.

#### OBJECTIVES:

To establish effective systems that:

- ensure adequate and appropriate maintenance and sanitation;
- monitor effectiveness of maintenance, cleaning procedures and pest control;
- control pests; and
- manage waste.

#### RATIONALE:

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

#### General

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

- facilitate all sanitation procedures;
- function as intended; and
- prevent contamination of food, such as from metal shards, flaking plaster, debris and chemicals.

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

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

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

66. [Separate cleaning equipment, suitably designated, should be used for highly contaminated areas e.g. toilets]

#### Cleaning procedures and methods

67. 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 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.

68. Cleaning procedures will involve, where appropriate:

- removing gross visible debris from surfaces;
- applying a detergent solution to loosen soil and bacterial film (cleaning);
- rinsing with water (hot water where appropriate) to remove loosened soil and residues of detergent; and
- where necessary, cleaning should be followed by chemical disinfection with subsequent rinsing unless the manufacturer's instructions indicate on scientific basis that rinsing is not required. Concentrations of chemicals used for disinfection should be appropriate for use and applied according to manufacturers' instructions.

#### Sanitation [Cleaning and disinfection] Programmes

69. Cleaning and disinfection programmes should ensure that all parts of the establishment are appropriately clean, and should include the cleaning of cleaning equipment. Where appropriate, programmes should be drawn up in consultation with relevant specialist expert advisors

70. Where written cleaning programmes are used, they should specify:

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

#### **Monitoring Effectiveness**

71. Sanitation programmes should be monitored for effectiveness and periodically verified by means such as audits or pre-operational inspections. Where appropriate, microbiological sampling and testing of the environment and food contact surfaces should be carried out to verify the effectiveness of cleaning programmes. [Insert additional examples of types of monitoring e.g. conductivity, pH, water temperature, cleaning agent concentration.] Cleaning [Sanitation] and maintenance procedures should be regularly reviewed and adapted to reflect any changes in circumstances and documented as appropriate.

#### **PEST CONTROL SYSTEMS**

##### **General**

72. 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. Good hygiene practices 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**

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

##### **Harbourage and infestation**

74. 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**

Note: Consideration should be given to expanding the text to include more details on monitoring and detection including where this is outsourced e.g. attention to key areas of infestation, main pests and trends.

75. Establishments and surrounding areas should be regularly examined for evidence of infestation. Detectors and traps [e.g. insect light traps, baits stations] should be designed and located so as to prevent potential contamination of materials, products or facilities.

##### **Eradication**

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

##### **Waste Management**

77. Suitable provision should be made for the removal and storage of waste. Waste [should as far as possible be collected in covered containers and should] not be allowed to accumulate and overflow in food handling, food storage, and other working areas and the adjoining environment except so far as is unavoidable for the proper functioning of the business.

78. Waste stores should be kept appropriately clean and free of pests and be resistant to pest infestation]. **MONITORING EFFECTIVENESS**

Note: Original text from CAC RPC-1 1969 has been moved to section on cleaning



**SECTION IV: PERSONAL HYGIENE****OBJECTIVES:**

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

- Maintain appropriate personal health;
- maintaining 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.

**Health Status**

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

**Illness and Injuries**

81. Conditions which should be reported to management so that any need for medical examination and/or possible exclusion from food handling can be considered include:
- jaundice;
  - diarrhoea;
  - vomiting;
  - fever;
  - sore throat with fever;
  - visibly infected skin lesions (boils, cuts, etc.);
  - discharges from the ear, eye or nose.

82. Cuts and wounds, where personnel are permitted to continue working, should be covered by suitable waterproof dressings.

**Personal Cleanliness**

83. Food handlers should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head [and beard] covering, and footwear. [Controls should be implemented to prevent cross-contamination by food handlers through adequate hand washing and, where necessary, wearing gloves. If gloves are worn, appropriate measures will also need to be applied to ensure the gloves do not become a source of contamination.]
84. Personnel should clean and, when appropriate, wash their hands regularly, especially when personal cleanliness may affect food safety, in particular:
- at the start of food handling activities;
  - 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

- [85. When required, personnel should wash hands with soap and water by wetting hands with water and applying sufficient soap to cover all surfaces. Rinse hands with clean, running water and dry thoroughly with a single-use towel or other method that does not re-contaminate hands. Multiple use cloth drying towels should not be used. Hand sanitizers should not replace hand washing and should be used only after hands have been washed.]

**Personal Behaviour**

86. People engaged in food handling activities should refrain from behaviour which could result in contamination of food, for example:
- smoking;

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

87. 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

88. Visitors to food businesses, and in particular, to food manufacturing, processing or handling areas, should, where appropriate, wear protective clothing and adhere to the other personal hygiene provisions in paras 79-87.

### SECTION V: TRANSPORTATION

#### OBJECTIVES:

Measures should be taken where necessary to:

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

#### RATIONALE:

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

#### General

89. 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

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

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

checked. **Use and Maintenance**

91. 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.

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

**SECTION VI: PRODUCT INFORMATION AND CONSUMER AWARENESS**

Note: Consideration should be given to expanding the Objectives and Rationale to include allergens

**OBJECTIVES:**

Products should bear appropriate information to ensure that:

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

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

- understand the importance of product information;
- make informed choices appropriate to the individual; and
- prevent contamination and growth or survival of foodborne pathogens by storing, preparing and using it correctly.

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

**RATIONALE:**

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

**Lot identification**

93. Lot identification is essential in product recall and also helps effective stock rotation. Each container of food should be permanently marked to identify the producer and the lot. The *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) applies.
94. 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* (CAC/GL 60 2006), especially to enable the recall of the products, where necessary.

**Product Information**

95. 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**

96. 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* (CODEX STAN 1-1985) applies.

**Consumer Education**

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

**SECTION VII: TRAINING****OBJECTIVE:**

Those engaged in food operations who come directly or indirectly into 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.

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

**Awareness and Responsibilities**

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

**Training Programmes**

99. 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;
- the manner in which the food is handled and packed, including the probability of contamination;
- the extent and nature of processing or further preparation before final consumption;
- the conditions under which the food will be stored; and
- the expected length of time before consumption.

**Instruction and Supervision**

100. 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 risks and take the necessary action to remedy deficiencies.

101. 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**

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

**Management Commitment**

Note: Original text from CAC RPC-1 1969 has been moved to the Introduction in response to CCFH comments

**B. Enhanced GHPs**

34. GHPs control most food hazards which may [contaminate] food products, e.g. through food handlers, incoming raw materials or other ingredients or the work environment. A basic hazard analysis should determine whether the application of GHPs is sufficient [adequate] for some FBOs to control all of the relevant food hazards.
35. Where significant food safety hazards are identified, and a more targeted approach is necessary, hazard-specific control measures should be implemented. Such hazard [specific] control measures may be based on GHPs designed to control a specific food safety hazard e.g. cleaning of a meat slicer to control *Listeria monocytogenes*. These 'enhanced' GHPs should be subject to monitoring, corrective actions and verification and where appropriate, be documented.

**Monitoring procedures**

30. The FBO should document procedures for monitoring control measures as relevant to the business. Procedures could include responsible personnel, method 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.

**Validation of GHP****Preventative and Corrective actions**

32. The FBO should document preventative and corrective action procedures as relevant to the business, which are implemented when a non-compliance is identified. Procedures could include:
- who is responsible;
  - immediate action to be taken;
  - any product disposition to be considered;
  - any escalating response needed;
  - any action to prevent reoccurrence; and
  - records to be kept.

**Verification of GHP**

33. The FBO should document verification procedures as relevant to the business, which ensure that GHP has been implemented effectively, monitoring is occurring and that appropriate corrective action is taken when requirements are not met. Procedures could include:
- who is responsible;
  - 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.]

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

1. The first part of this [Chapter] sets out the principles of the Hazard Analysis and Critical Control Point (HACCP) system adopted by the Codex Alimentarius Commission. The second part provides general guidance for the application of the system while recognizing that the details of application may vary depending on the circumstances of the food operation.<sup>6</sup>
2. The HACCP system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention 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.
3. HACCP can be applied throughout the food chain from primary production to final consumption and its implementation should be guided by scientific evidence of risks to human health. As well as enhancing food safety, implementation of HACCP can provide other significant benefits, 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 regulatory authorities and promote international trade by increasing confidence in food safety.
4. The successful application of HACCP requires the full [strong] commitment and involvement of management and the work force. It also requires a multidisciplinary approach; this multidisciplinary approach should include, when appropriate, expertise in agronomy, veterinary health, production, microbiology, public health, food technology, environmental health, chemistry and engineering, according to the particular application. The application of HACCP is compatible with the implementation of quality management systems, such as the ISO 9000 series, and is the system of choice in the management of food safety within such systems. While the application of HACCP to food safety was considered here, the concept can be applied to other aspects of food quality.

Note: Text has been added introduce flexibilities for small businesses. This should be developed further and supported by examples of adaptations that can be made and by drawing on existing guidance.

5. 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, including HACCP-based systems at farm level, are described in the FAO/WHO Guidance to governments on the application of HACCP in SLDBs<sup>7</sup>. 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.

**DEFINITIONS**

Note: Consideration should be given to moving all definitions to a single section in the document. Definitions to be developed as drafting progresses.

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

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

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

**[Hazard control measure]:** (to be developed)

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

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

<sup>6</sup>The Principles of the HACCP System set the basis for the requirements for the application of HACCP, while the Guidelines for the Application provide general guidance for practical application.

<sup>7</sup>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.

**Critical limit:** A criterion which separates acceptability from unacceptability. **Deviation:** Failure to meet a critical limit.

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

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

**[Hazard Control 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. This could support a system of control measures based on GHPs alone or a combination of GHPs and CCP controls.

**[HACCP plan]:** A hazard control plan which has identified critical control points.]

**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 [hazard control plan] / HACCP plan.

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

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

**Validation:** Obtaining evidence that hazard control measures, if properly implemented, are capable of controlling hazards to an acceptable level.

**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.

#### **PRINCIPLES OF THE HACCP SYSTEM**

The HACCP system consists of the following seven principles:

##### **PRINCIPLE 1**

Conduct a hazard analysis.

##### **PRINCIPLE 2**

Determine the Critical Control Points (CCPs).

##### **PRINCIPLE 3**

Establish critical limit(s).

##### **PRINCIPLE 4**

Establish a system to monitor control of the CCP.

##### **PRINCIPLE 5**

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

##### **PRINCIPLE 6**

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

##### **PRINCIPLE 7**

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

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

Note: The text in paras 6-45 has been developed to some extent but further consideration is required to clarify the relationship between the 12 step plan and GHP as some of the steps are also applicable to a lesser extent GHP-based systems. It is likely that some text will move into the Introduction or [Chapter 1]. Also further discussions are required on whether the 12 step flow chart is still appropriate, and how to incorporate flexibilities for SLDBs.

## INTRODUCTION

6. Prior to application of HACCP to any sector of the food chain, that sector should have in place GHPs according to 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 programs to HACCP, including training, should be well established, fully operational and verified in order to facilitate the successful application and implementation of the HACCP system. HACCP application will not be effective without prior implementation of GHPs.
7. For all types of food business, management awareness and commitment is necessary for implementation of an effective HACCP system. The effectiveness will also rely upon management and employees having the appropriate HACCP knowledge and skills.
8. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration should be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.
9. 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 which must be controlled is identified but no control measures are found. As described in the GHP Section, food hazards may be controlled adequately by GHP-based control measures. Some GHPs may need to be 'enhanced' where they are designed to control a significant hazard in the food or the processing environment, but not to the level of a CCP step e.g. [cleaning a meat slicer to control *Listeria monocytogenes*].
10. HACCP should be applied to each individual operation separately. CCPs identified in any given example in any Codex Code of Hygienic Practice might not be the only ones identified for a specific application or might be of a different nature. The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step.

### Flexibility for small and/or less developed food businesses

11. The application of the HACCP principles should be the responsibility of each individual business. However, it is recognised by governments and food business operators that there may be obstacles that hinder the effective application of the HACCP principles by individual business. This is particularly relevant in small and/or less developed businesses. While it is recognized that when applying HACCP, flexibility appropriate to the business is important, all seven principles should be applied in the HACCP system. This flexibility should take into account the nature [and size] of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints, as well as the risk of the products being produced.
12. 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 the HACCP plan. Where businesses are using expertly developed HACCP guidance, it is essential that it is specific to the foods and/or processes under consideration.<sup>§</sup>
13. 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.

### Scope

Note: Scope has been added to clarify text and add reference to flexibilities

14. This section sets out the seven principles of the HACCP system and provides general guidance for the application of the system, while recognising that a more flexible approach to application may be appropriate depending on the capabilities of the food business operator.

<sup>§</sup>FAO/WHO Guidance to governments on the application of HACCP in SLDBs.



**APPLICATION**

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

**(Step 1)**

16. 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.
17. Where such expertise is not available on site, expert advice should be obtained from other sources, such as trade and industry associations, independent experts, regulatory authorities, HACCP literature and HACCP guidance (including sector-specific HACCP guides). It may be possible that a well-trained individual with access to such guidance is able to implement HACCP in-house. Generic HACCP-based systems developed externally may be used by FBOs where appropriate and should be tailored to the food operation.
18. The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed (e.g. does it cover all classes of hazards or only selected classes).

**Describe product (Step 2)**

19. A full description of the product should be drawn up, including relevant safety information such as composition, physical/chemical characteristics (including  $A_w$ , pH, etc.), microbiocidal/static treatments (heat-treatment, freezing, brining, smoking, etc.), packaging, [durability/shelf life] and storage conditions and method of distribution. Within businesses with multiple products, for example, catering operations, it may be effective to group products with similar characteristics or processing steps, for the purpose of development of the HACCP plan. Any limits already established for food safety hazards should be considered and accounted for in the HACCP plan, e.g. [insert example].

**Identify intended use (Step 3)**

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

**Construct flow diagram (Step 4)**

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

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

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

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

Note: This section needs to be developed following further discussions on the extent to which all businesses need to carry out a hazard analysis and should build on text provided in the GHP Section. This should draw on guidance in existing Codex documents e.g. CAC/GL 63 2007.

**(SEE PRINCIPLE 1)**

23. should list all of the hazards that may be reasonably expected to occur at each step according to the scope of the food business operation.
24. should next conduct a hazard analysis to identify which of the potential hazards are present at unacceptable levels so that their elimination or reduction to acceptable levels is essential to the production of safe food. In conducting the hazard analysis, wherever possible the following should be included:
  - the likely occurrence of hazards and severity of their adverse health effects;
  - the qualitative and/or quantitative evaluation of the presence of hazards<sup>9</sup>;

<sup>9</sup> Principles and Guidelines for the Conduct of Microbiological Risk Management CAC/GL 63-2007.

**Commented [blenmp11]:** Emphasis on HACCP team should be deleted. First step is about gathering information and having appropriate resources and expertise – someone should take responsibility for this.

- survival or multiplication of microorganisms of concern;
  - production or persistence in foods of toxins, chemicals or physical agents; and,
  - conditions leading to the above.
25. In some cases, it may be acceptable for a more basic hazard analysis to be carried out by FBOs which identifies groups of hazards (microbiological, physical, chemical) in order to control the sources of these hazards without the need for a full hazard analysis. Generic HACCP-based tools provided externally, for example, by industry or regulators, are designed to assist with this step.
26. [Significant hazards] which are of such a nature that their elimination or reduction to acceptable levels is essential to the production of safe food should be identified and controlled by hazard control measures designed to remove or reduce significant hazards to an acceptable level. This may be achieved with the application of good hygiene practices, some of which may need to be enhanced to target a specific hazard, [for example, cleaning equipment to control contamination of ready-to-eat foods with *Listeria monocytogenes*] include example and cross refer to guidance (under development by the EWG) on hazard analysis). In other instances, hazard control measures will need to be applied at critical control points.]
27. Consideration should be given to what control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

#### Determine Critical Control Points (Step 7)

(SEE PRINCIPLE 2)<sup>10</sup>

Note: EWG has agreed that the current decision tree applied to identify CCPs should be reviewed.

28. There may be more than one CCP at which control is applied to address the same hazard. Similarly, a CCP may control more than one hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree (e.g., Diagram 2), which indicates a logic reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other. It should be used for guidance when determining CCPs. This example of a decision tree may not be applicable to all situations. Other approaches may be used. Training in the application of the decision tree is recommended.
29. If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

#### Establish critical limits for each CCP (Step

8) (SEE PRINCIPLE 3)

30. Critical limits should be specified for each Critical Control Point which separates acceptable procedures and products from unacceptable. In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include measurements of temperature, time, moisture level, pH,  $A_w$ , available chlorine, and sensory parameters which can be observed, such as visual appearance and texture.
31. Critical limits should be scientifically validated to obtain evidence that hazard control measures, if properly implemented, are capable of controlling hazards to an acceptable level.<sup>11</sup> FBOs may not always need to commission studies themselves to validate control measures. They could be based on existing literature or carried out by a third party e.g. cleaning products validated for effective use by the manufacturer.
32. Where HACCP guidance developed by experts has been used to establish the critical limits, care should be taken to ensure that these limits fully apply to the specific operation, product or groups of products under consideration. These critical limits should be measurable or observable.

**Commented [blenmp12]:** All of this could be included in a section on hazard analysis. Determining enhanced GHPs or CCPs is then the next step.

<sup>10</sup>Since the publication of the decision tree by Codex, its use has been implemented many times for training purposes. In many instances, while this tree has been useful to explain the logic and depth of understanding needed to determine CCPs, it is not specific to all food operations, e.g. slaughter, and therefore it should be used in conjunction with professional judgement, and modified in some cases.

<sup>11</sup> Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69-2008).

**Establish a monitoring system for each CCP (Step 9)**

(SEE PRINCIPLE 4)

33. Monitoring is the scheduled measurement or observation of 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. Data derived from monitoring should be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.
34. If monitoring is not continuous, then the amount or frequency of monitoring should be sufficient to guarantee 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 they may be done rapidly and can often indicate the microbiological control of the product.
35. All records and documents associated with monitoring CCPs should be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

**Establish corrective actions (Step 10)**

(SEE PRINCIPLE 5)

36. Specific corrective actions should be developed for each CCP in the HACCP system in order to deal with deviations when they occur.
37. The actions should ensure that the CCP has been brought under control. Actions taken should include proper disposition of the affected product and identify the root cause of the loss of control to prevent a recurrence. Deviation and product disposition procedures should be documented in the HACCP record keeping.

**Establish verification procedures (Step 11)**

Note: Further discussion is required on Validation and Verification to allow this text to be developed further so that appropriate text is included under Principle 1 and here.

(SEE PRINCIPLE 6)

38. Establish procedures for verification of the HACCP system as a whole, as well as individual control measures. Verification, which includes observations, auditing, sampling and testing, and records review, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively.
39. Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in house, verification should be performed on behalf of the business by external experts or qualified third parties. Examples of verification activities include:
- Review of the HACCP system and plan and its records;
  - Review of deviations and product dispositions;
  - Confirmation that control measures, particularly those at CCPs, are kept under control; and
  - Microbiological sampling and testing to verify product safety<sup>12</sup>
40. Where possible, verification activities should include actions to confirm the efficacy of all elements of the HACCP system (e.g. through an audit of the HACCP system).

**Establish documentation and record keeping (Step 12)**

(SEE PRINCIPLE 7)

41. 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

<sup>12</sup> Principles and guidelines for the establishment and application of microbiological criteria related to food (CAC/GL21 1997.

HACCP guides) may be utilised as part of the documentation, provided that those materials reflect the specific food operations of the business.

42. Examples of documentation include

- Hazard analysis;
- CCP determination;
- Critical limit determination.

43. Examples of records include:

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

44. An example of a HACCP worksheet for the development of a HACCP plan is attached as Diagram 3. (see diagram 3 of CAC/RCP1-1969).

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

**TRAINING**

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

47. 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