

CODEX ALIMENTARIUS COMMISSION

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Agenda Item 4

CX/FH 17/49/5 Add.1

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) AND ITS HACCP ANNEX

Comments submitted by:

Argentina, Australia, Brazil, Canada, Chile, Colombia, Ecuador, Japan, New Zealand, Norway, Paraguay, Philippines, Switzerland, United States of America, Uruguay, FoodDrinkEurope, IAF, SSAFE

Argentina

(i) **GENERAL COMMENTS**

Argentina agrees with the EWG members that further consideration of fundamental principles is required to support development of the text.

As regards the issues for consultation:

i. All businesses should complete a hazard analysis and, if so, how this can be adapted so it is appropriate to the nature and size of the business and whether GHP-based or HACCP-based and food safety control systems are being applied.

Argentina does not support the idea that all food business operators (FBOs) should complete a hazard analysis according to the HACCP system, but it suggests that FBOs should be able to "identify hazards" inherent in their activities in order to implement GHPs adequately.

In addition, after the implementation of GHPs and where appropriate, FBOs should complete a hazard analysis to determine whether GHPs sufficed or other control measures should be implemented.

ii. The current approach in the *General Principles of Food Hygiene* (GHPs plus HACCP where needed) remains appropriate or the concept of control measures at other places than CCPs (provisionally named enhanced GHPs) should be introduced. Options would include adapting current text to indicate there are some GHP controls that require greater attention, developing new terminology and specific text focusing on control measures at other places than CCPs, and explaining the relationship of the different types of control measure with GHP and HACCP.

The difference between the control points (CPs) of HACCP and the proposed "enhanced Good Hygienic Practices" is not clear to Argentina.

The concept of "enhanced Good Hygienic Practices" is not clear in this draft; therefore, in these conditions we do not consider it appropriate to add this new terminology until it is not clearly defined, in the understanding that further discussion is needed on this matter.

iii. Controls for primary production should be addressed by a specific section in the document and/or the document should be developed to strengthen references throughout to demonstrate how the guidance applies at all stages of the food chain.

Argentina suggests that the section on section primary production should be kept, but worded as a general paragraph.

In relation to the recommendation of the EWG:

iii. Determine next steps including whether a Physical or Electronic Working Group should be established, for continuing the revision of CAC/RCP 1-1969 so text is adopted at Step 5 in 2019 and Step 8 in 2021.

Argentina considers that further work is needed by the EWG to revise CAC/RCP 1-1969 and by a physical working group that should meet at the 50th session.

(ii) SPECIFIC COMMENTS

INTRODUCTION

~~4. [A. 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 without the need for conducting a hazard analysis. Referring to external resources (existing models, references, standards, regulations, or Codes of Practice provided by the competent authority, Codex or food industry), it may be determined that GHPs are sufficient for some FBOs to control all food safety hazards. Yet, since not all hazards pose the same risk, there may be a need to pay particular attention to certain hazards determined as significant by a site-specific hazard analysis and to apply [control measures at critical control points (CCPs) and/or at places other than CCPs] OR [HACCP control measures] within a Hazard Analysis and Critical Control Point (HACCP) system (see Comparison Table below). FBOs without the resources to carry out a hazard analysis may use external resources as listed above or generic HACCP plans provided by the competent authority or food industry¹, subject to adaptation to the site].~~

~~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 basic hazard analysis and an assessment of food hygiene measures, 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 by a site-specific hazard analysis and to apply [control measures at critical control points (CCPs) and/or at places other than CCPs] OR [HACCP control measures] 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 industry² subject to adaptation to the site.]~~

Argentina suggests the following paragraph:

4. Prerequisite Programmes (PRPs), which include Good Hygiene Practices (GHPs), Good Manufacturing Practices (GMPs), and Good Agricultural Practices (GAPs), as appropriate, are the foundation for producing safe and suitable food. GHPs apply broadly to all food businesses without the need for conducting a hazard analysis. However, they should be able to identify hazards inherent in their activities in order to implement GHPs adequately. Following their implementation, where necessary, a hazard analysis should be completed to determine whether GHPs suffice to control all food safety hazards or whether special attention should be paid to certain hazards that have been found and considered significant through a site-specific hazard analysis and that would require the implementation of a Hazard Analysis and Critical Control Point (HACCP) system. FBOs without the resources to carry out a site-specific hazard analysis might use existing models, references, standards, regulations, or Code of Practices or generic HACCP plans provided by the competent authority or food industry subject to adaptation to the site.

SECTION II: CONTROL OF OPERATION

Argentina believes that the section should be kept and paragraphs 28 to 37 should be reworded describing the controls relevant to GHPs.

Rationale

According to their current wording in the document, it is a control of operation equivalent to the control in a HACCP.

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~~ **as should be the** need to be recalled. The need for public warnings should be considered.

61. Recalled products should be held under supervision until they are **determined to be safe for human consumption and their final destination is determined (destruction, use destroyed, used for purposes other than human consumption, reprocessing reprocessed in a manner to ensure product safety or reincorporation into the market)**.

SECTION III: ESTABLISHMENT MAINTENANCE, SANITATION AND PEST CONTROL

Note: Further discussion is needed to determine whether a definition of "sanitation" should be provided to clarify what cleaning includes and, where appropriate, disinfection, or whether this should be clarified in the text itself.

Argentina suggests including the definitions of sanitation (cleaning and disinfection).

74. Harbourage and infestation

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.

Argentina suggests that the text should be expanded.

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.~~

[CHAPTER TWO]

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

PREAMBLE

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.~~

INTRODUCTION

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*].~~

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.]~~

Australia

General Comments

- Australia supports that all businesses complete a hazard analysis (as appropriate) and a specific section/guidance included in the document.
- Australia supports the concept of enhanced GHPs and incorporating new text in the document to explain this.
- Australia supports primary production being incorporated throughout the document and text written that it is clear primary production is included.
- Australia suggests a section on enhanced GHPs needs to be developed and included in the document (could be Part B of Chapter 1 with Part A covering GHPs).
- Australia suggests a section/ annex on hazard analysis should be developed to provide further guidance and would be overarching for both enhanced GHPs and control measures at CCPs.
- Australia suggests that further discussion and agreement is required on Chapter 2, particularly on retaining the seven principles of HACCP noting that conducting a hazard analysis not only determines CCPs, but also enhanced GHPs. Aligning more with ISO 22000 and the requirements for a food safety management system (rather than HACCP system) would help.

Specific Comments

Specific comments included below and in track changes to document (see CRD05).

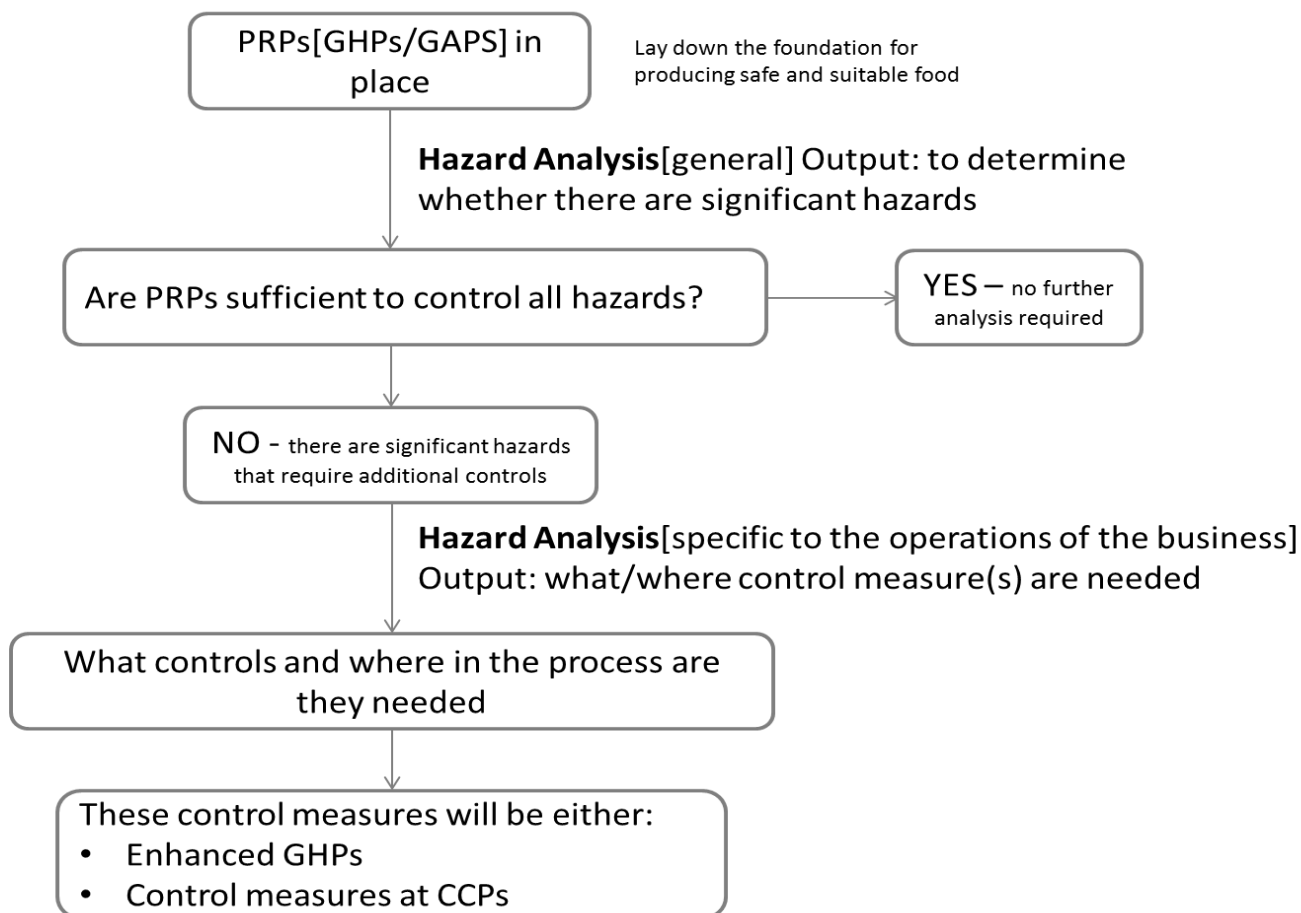
Paragraph	Comment	Rationale
4. - Introduction	Australia supports paragraph 4B - editorial changes are proposed (outlined below and included at Attachment 2.)	All food businesses should understand the nature of their operations and potential food safety risks. It should be noted however that the analysis required would depend on the nature of the business (e.g. for low risk businesses this would be minimal/provided) and competent authorities can provide assistance, particularly for small businesses.
4.introduction	Paragraph 4 is quite detailed, raising a number of concepts, compared to preceding introductory text. Australia suggests that an additional paragraph is included to provide better linkage between paragraphs 3 and 4 or the text is further simplified.	Introduction should be easy to follow and introduce concepts simply.
4B. -Introduction	Two types of hazard analysis are introduced in the introduction – suggest just use hazard analysis. Further discussion and decision required on hazard analysis (including the need for a section/annex on hazard analysis to support businesses) Australia has prepared a flow diagram (Attachment 1) to illustrate our understanding of where hazard analysis is used and for what purpose.	Introduction should be easy to follow and introduce concepts simply.
	Australia prefers the terminology “enhanced GHPs” rather than “control measures at places other than CCPs”	Potentially confusing - “control measures at places other than CCPs” would also include GHPs. “Enhanced GHP”s is a simpler term

Decision tree	The decision tree (Annex 1) is not needed and potentially confusing. Identifying enhanced GHPS and CCPs comes after GHPs are in place and a hazard analysis done to identify significant hazards.	Comparison table is adequate at this point.
5. Introduction	Paragraph 5 does not reflect discussion in previous paragraph - will need to be reworked to include enhanced GHPs and hazard analysis once these have been agreed and document structured to incorporate this approach.	Structure and content of document still to be agreed.
6. - Introduction	Remove the wording "shows the relationship of GHPs applied for food safety and suitability and HACCP control measures applied to enhance food".	The table does not show this relationship – it compares GHPs, enhanced GHPS and CCPs.
Table	Change title to "Comparison of GHPs, Enhanced GHPs and control measures at CCPs.	Title should reflect the wording used within the table.
14.- Introduction	Change "General Principles" to "Overarching Principles".	Avoids confusion with the reference to general principles in paragraph 12.
14. (vi)	What are control measures "critical to achieve an acceptable level of food safety"? Following on from (v), just need to say "these control measures should be validated..."	Simplify
15 - Introduction	Incorporate wording that management "commit to making safe food a priority"	Strengthen management responsibility.
16 - Introduction	The concept "food safety culture" is raised here – suggest a definition is included in the document (note the Global Food Safety Initiative have a definition for Food Safety Culture [Food safety culture technical working group]).	Food safety culture is an important concept and should be clearly understood.
Annex 1	Delete decision tree for identifying enhanced GHPs. Suggest a process for hazard analysis would provide greater clarity and guidance.	Hazard analysis is an important overarching principle in this document – needs more explanation and guidance. Enhanced GHPs and CCPs can be incorporated into the one decision tree (rework existing Diagram 2)
Chapter 1 - Primary Production	Support deletion of the section on Primary Production – general principles should apply throughout the chain (as appropriate) with text written to cover primary production activities.	Short overarching paragraph sufficient.
6. – Chapter 1	This paragraph should be deleted.	Too detailed
Control of operation	Support the review of objectives and rationale.	
28. 29. 30. – Control of operation	These paragraphs should be removed and incorporated into an annex/specific section on hazard analysis.	A general introduction/ overview to control food hazards through a food safety management system all that is required here. These sections fit within a section that can step through hazard analysis more clearly.

31.	Suggest this paragraph is moved to the end of the section (after paragraph 58), following discussion of controls.	Logical flow
32. & 33. – Control of operation	Text on validation and verification of GHPs not applicable here (see comparison table) Further guidance on verification and validation (particularly around enhanced GHPs and CCPs) should be included where relevant and useful.	Not appropriate at this stage in the document.
34. 35.	Include in a section on enhanced GHPs	
36. & 37. – Control of operation	These paragraphs should be removed and incorporated into an annex/specific section on hazard analysis.	Not appropriate at this stage in the document.
Chapter 2		
Definitions	Australia supports that all definitions should be moved to a single section in the document.	
Principles of the HACCP system	Further discussion required.	

Attachment 1

Flow diagram illustrating the role of hazard analysis in a food safety management system



Brazil

General Comments

Brazil supports developing a specific section for primary production, because not all HACCP procedures are applicable for all sectors of primary production. We are the opinion that this issue still need more discussion and clarification.

After the decision to what term will be used, “enhanced GHP” or “control measures at places other than CCPs”, all the text should be revised to reflect this decision.

The decision tree to identify “Enhanced GHP” should be deleted or revised, considering that “Enhanced GHP” was not defined yet and the term customized and the symbol are not clear.

Brazil believes that the hazard analysis to be carried out should be complete, so the word "basic" should be removed from the entire document when referring to the term "basic hazard analysis".

Specific Comments

INTRODUCTION

Par.4:

We support option B with modifications, because the option A excludes the need to perform hazard analysis by food producing companies, however, Brazil understands that the need to implement a HACCP plan or the option to adopt only GHP measures can only be taken after a hazard analysis well conducted.

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 basic hazard analysis and an assessment of food hygiene measures, 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 by a site-specific hazard analysis and to apply [control measures at critical control points (CCPs) and/or at places other than CCPs] ~~OR [HACCP control measures]~~ 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 ~~subject to adaptation~~ adapted to the site.]

CHAPTER I

Par. 6:

The substitution proposal was made considering that the issue of pest control is already covered in paragraph 5 and to introduce monitoring as an effective way of verifying environmental contaminants.

~~[Site boundaries should be clearly defined. Landscaping near a food facility should be properly designed to minimise attractants and pest harbourage. Where necessary, experts should be consulted for advice on appropriate plants for use in landscaping.]~~ Appropriate site/facility boundaries should be clearly identified. Regular monitoring of the effectiveness of measures to control contaminants from local environment should be performed.

Par 8: Insert the sentence below so that there is a rationale regarding the definition of area separation (clean x dirty).

Criteria for definition of separation requirements should be defined through zoning risk assessments.

Par. 55: For clarity, we suggest adding additional reference to other FAO / WHO documents dealing with the use of reuse water.

Par. 71: For better understanding, we suggest examples of parameters that can be monitored in sanitation procedures.

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. Monitoring of effectiveness should consider different acceptance criteria e.g. micro hygiene, allergen removal, colour removal etc. Monitoring effectiveness methods (Ex. conductivity, pH, water temperature, cleaning agent concentration, ATP, visual inspection) may vary depending on nature and objective of cleaning / sanitation procedure. Cleaning

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

Par 73: The presence of animals should not be allowed. 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.

Par. 83: Inclusion of the term "mustache" together with the "beard".

Food handlers should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head, [~~beard and moustache~~] covering, and footwear. [Controls should 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.

Par 85: Hand washing is a procedure that must always be performed. This kind of flexibility is unacceptable. As the paragraph dealt only with cleanliness, we thought it appropriate to insert a phrase that referred to the procedure of asepsis of the hands

[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. When appropriate, hand sanitizers should be used. Hand sanitizers should not replace hand washing and should be used only after hands have been washed.]

CHAPTER II

Par 17: HACCP is a complex tool that should preferably be developed by a multi-professional team, we suggest that the individual term be deleted.

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-personal~~ 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.

Par 21: We suggest to include the sentence to qualify the information of the diagram.

The flow diagram should be constructed by the HACCP team. Flow diagrams should be clear, accurate and sufficiently detailed to the extent needed to conduct the hazard analysis. 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.

Par 25: Delete the paragraph as it suggests that a complete hazard analysis may not be necessary. Brazil understands that generic HACCP tools may be used for certain categories of foods, however, these plans should be modified and, if necessary, carried out the complete hazard analysis, depending on the differences between the mode of production adopted in generic HACCP and the site of the food production.

Par 30: Add sentence emphasizing that observable parameters should be avoided in the monitoring of a CCP. Although they may be used, it is preferable to use measurable parameters.

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, Aw, available chlorine, and sensory parameters which can be observed, such as visual appearance and texture. Observable parameters should be avoided in the monitoring of a CCP. Although they may be used, it is preferable to use measurable parameters.

Canada

General Comments

The electronic working group (EWG) recommended that the Committee discuss and reach agreement on the fundamental concepts highlighted at Paragraph 8 under the heading **Work of the EWG**, to which we respond below:

- Whether all businesses should complete a hazard analysis and, if so, how this can be adapted so it is appropriate to the nature and size of the business and whether GHP-based or HACCP-based and food safety control systems are being applied;

We support an approach where all food business operators (FBOs) should complete a hazard analysis. FBOs should be able to demonstrate through a hazard analysis that they have a good understanding of the food safety hazards associated with their food operation and of the controls they need to have in place to ensure food safety. Furthermore, we agree that small and less developed businesses should be supported in this endeavour with tools and resources developed by governments or industry associations.

- Whether the current approach in the *General Principles of Food Hygiene* (GHPs plus HACCP where needed) remains appropriate or the concept of control measures at other places than CCPs (provisionally named enhanced GHPs) should be introduced.

We support introducing control measures at other places than CCPs, if hazard analysis identifies such need. We believe that the EWG has made significant progress in the development of the fundamental concepts and we agree that further discussions are needed to reach agreement and to allow further development of the text. We suggest the following approach for consideration: information on hazard analysis would be developed within Section II: of the GHPs section (Control of Operation) and therefore, the HACCP section would not describe enhanced GHPs.

- Whether controls for primary production should be addressed by a specific section in the document and/or the document should be developed to strengthen references throughout to demonstrate how the guidance applies at all stages of the food chain.

We would prefer to keep the Primary Production section and to update or expand the section as needed. Deleting entire sections and changing section titles and numbers in the *General Principles of Food Hygiene* will have an impact on numerous Codex documents, which refer to the *General Principles of Food Hygiene* for that information. We suggest that the Codex Secretariat provides advice and clarification on how deletion of sections could be achieved (if needed) and that information could be considered by the Committee to make their decision.

We have noted a number of grammatical and typographical errors throughout the document and we recommend that these are adjusted in the next draft of the document.

Specific Comments**INTRODUCTION****Paragraph 4**

Comment: We support option B and recommend the following edits.

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 ~~basic~~ hazard analysis and an assessment of food hygiene measures, 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 by a ~~site-specific~~ hazard analysis and to apply [control measures at critical control points (CCPs) and/or at places other than CCPs] ~~OR [HACCP control measures]~~ within a Hazard Analysis and Control Plan Critical Control Point (HACCP) system (see Comparison Table below). FBOs ~~without the limited resources and knowledge~~ 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 industry² subject to adaptation to the site.]

Rationale: We support an approach where all food business operators (FBOs) should complete a hazard analysis. We believe that the words “basic” and “site-specific” in front of hazard analysis are not necessary. What makes a

hazard analysis “basic” may not be obvious. The complexity of the hazard analysis will be determined by the nature of the operation. The hazard analysis is always site-specific given that a flow diagram is developed to cover the steps in the food operation for a specific product. We believe the terminology “Hazard Analysis and Control Plan” is more appropriate in this sentence since both CCPs and enhanced GHPs are described.

Paragraph 6

Comparison Table

Second Column, under the row “Scope”

Comment: We suggest an addition in the sentence.

Control measures that are based on general basic conditions and activities to create the environment (external and internal) for safe food.

Rationale: For clarification, as the current wording could imply that control measures do not include GHPs.

Paragraph 7

First bullet

Comment: We suggest adding a word in the sentence.

- 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 human consumption;

Definitions

Enhanced GHP

Comment: We agree that enhanced GHP would be a good term to describe the types of control measures described in the middle column of the comparison table.

Food hygiene system

Food safety control system

Comment: We suggest only using one expression. We support the proposal to use a term that is already defined in the *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69-2008) however; we need to consider that the definition in that document does not include “hygienic practices” and “suitable”.

Hazard control measures

Comment: We suggest removing the word hazard and keeping “control measures”.

Rationale: The definition of control measure already includes the word “hazard”. “Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level”. We noted that this expression has been removed in the proposed introduction and chapter one, and we support these deletions.

GOOD HYGIENIC PRACTICES

ANNEX I Proposed Decision Tree to Identify [Enhanced GHPs]

Comment: We suggest modifying the tree to reflect the principles and narrative within the text.

For example, paragraph 35 states that a GHP designed to control a specific food safety hazard is an enhanced GHP, whereas in the Tree, when the GHP is specific to a food safety hazard it leads us to “Apply HACCP”. Another example is Question 4, “Is this customized generic GHP sufficient to eliminate the hazard or reduce it to an acceptable level”? This implies that enhanced GHPs could be quantifiable; this is contrary to the information provided in the comparison table (p.5) under the third column.

Paragraph 26

Comment: We suggest deleting the last sentence of the paragraph.

~~Where necessary, equipment should be calibrated to ensure that food processes are monitored consistently and accurately.~~

Rationale: This recommendation is related to the control of operation and does not belong in the section on establishment design and facilities.

Paragraph 28 to 33 and 34 to 37

Comment: Paragraphs 28 to 37 contain good information that should be reviewed, re-arranged and modified, as appropriate. Find below our proposal for further discussion.

We support the addition of paragraphs 28 to 33 with modifications. We propose changing the order of paragraphs 28-37 as presented below with the title for this section: "Control of Food Hazards". As a result of this re-organization, we propose modifications to the text under these paragraphs to eliminate duplication and we also propose additional modifications to clarify some concepts.

CONTROL OF FOOD HAZARDS

Product description (paragraphs 28 and 29)

Process description (paragraph 30)

Basic Hazard analysis (paragraphs 34, 35, 36 and 37)

Validation of GHP

Monitoring procedures (paragraph 31)

Preventative and Corrective actions (paragraph 32)

Verification of GHP (paragraph 33)

Validation of GHP

Comment: We propose the following text:

GHPs that are not specific to any hazards should be validated where needed. The validation may be carried out by a third party (e.g., cleaning products validated for effective use by the manufacturer). Enhanced GHPs should be validated to obtain evidence that control measures are capable of controlling significant hazards in food and/or processing environment. FBOs may not always need to commission studies themselves. They could be based on existing literature, guidance from competent authority or carried out by a third party. (Refer to the Guidelines for the Validation of Food Safety Control Measures CAC/GL 69-2008).

Rationale: There is currently no text under this heading.

Paragraph 32

Comment: We suggest removing the word "preventative" in the title of this section and in the text.

The FBO should document ~~preventative~~ and corrective action procedures as relevant to the business, which are implemented when a non-compliance is identified.

Rationale: This paragraph is for corrective action procedures, which include preventing re-occurrence of the problem.

Paragraph 34 and 36

Comment: We suggest deleting the word "basic".

~~A basic hazard analysis~~

Rationale: We believe the word "basic" is not needed. What makes a hazard analysis "basic" may not be obvious. The complexity of the hazard analysis will be determined by the nature of the operation.

Paragraph 35

Comment: We propose the following modifications.

Where significant food safety hazards are identified, and a more targeted approach is necessary, ~~hazard-specific control measures designed to control a specific food safety hazards~~ 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 validation, monitoring, corrective actions and verification and where appropriate, be documented.

Rationale: The definition of control measure already includes the word "hazard". The word "validation" was missing.

Paragraph 36

Comment: We propose the following modifications in bullets 1 to 4.

- i. ~~Describing the Product~~ Gathering the information obtained in the previous steps (Product description and Process description).
- ii. Applicable regulatory requirements,
- iii. ~~Identifying the intended usage — Ready to eat or as a material [product] that would undergo further processing;~~
- iv. ~~Constructing a flow chart~~

Rationale: To delete duplication. The information in bullets 1, 3 and 4 is already in paragraph 28 to 30.

Paragraph 36

Comment: We propose the following modification to bullet 7.

- vii. ~~Categorizing the GHP controls as generic or hazard-based controls to be managed as either Enhanced GHPs or by application of principles of HACCP using a Decision Tree Model as given in [Annex I to the introduction].~~ Identifying significant hazards and determining if enhanced GHPs can be used to control the hazards.

Rationale: The recommendation in this bullet was not useful and we therefore propose an alternative.

Paragraph 36

Comment: We suggest deleting bullet 8.

- viii. ~~Validating / effectiveness of the Enhanced GHPs: Enhanced GHPs should be validated to obtain evidence that GHP control measures are capable of controlling hazards. FBOs may not always need to commission studies themselves to validate GHP control. They could be based on existing literature, guidance from competent authority or carried out by a third party e.g. cleaning products validated for effective use by the manufacturer etc. (Aligned with new text created in the Section II for HACCP)~~

Rationale: The information in bullet 8 was moved to the **Validation of GHP** section.

Paragraph 36

Comment: We propose modifications to bullet 9.

- ix. Establishing a **GHP Hazard Analysis and Control** Plan for validating, monitoring, initiating corrective actions, verification of GHPs and Enhanced GHPs.]

Rationale: To avoid introducing new terminology (“GHP Plan”). Also, validation should be included in the plan.

Paragraph 37

Comment: We propose the following modification.

~~Where~~ ~~When~~ hazard control measures for significant hazards [GHPs or enhanced GHPs] are identified in the hazard analysis as ~~being unable to reduce the food hazard to an acceptable level~~ are quantifiable, a food hygiene system [food safety control system] based on HACCP should be implemented and this is discussed further in [Chapter 2].

Rationale: HACCP systems should be implemented when control measures are quantifiable at CCPs, not when GHPs or enhanced GHPs are unable to reduce the hazard to an acceptable level. The sentence was implying that enhanced GHPs could be quantifiable; this is contrary to the information provided in the comparison table (p.5) under the third column. In addition, Chapter 2 is the HACCP system, it is not a food safety control system “based” on HACCP.

Paragraph 40

Comment: We support the addition of the words in bracket in the second sentence.

Temperature recording devices should be checked for accuracy, [and where appropriate calibrated] at regular intervals.

Paragraph 43

Comment: Microbiological cross-contamination occurs ~~through~~ through 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.

Paragraph 45

Comment: 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 and processed.

Paragraph 49

Comment: Incoming materials, including food ingredients, should be ~~purchased [procured]~~ obtained according to specifications and their compliance with food safety and suitability specifications should be verified.

Water supply

Paragraph 51

Comment: We suggest moving the first sentence of paragraph 51 to its original location under Water supply in SECTION I: ESTABLISHMENT DESIGN AND FACILITIES.

Rationale: We believe this recommendation for water supply is related to the design and layout of the establishment rather than SECTION II: CONTROL OF OPERATION.

Paragraph 52

Comment: We suggest moving paragraph 52 to its original location under Water supply in SECTION I: ESTABLISHMENT DESIGN AND FACILITIES.

Rationale: We believe this recommendation for water supply is related to the design and layout of the establishment rather than SECTION II: CONTROL OF OPERATION.

Paragraph 60

Comment: ~~Managers should ensure~~ Effective procedures should be ~~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.

Rationale: For consistency in the tone used in this section. Also consider adding a point about notifying the competent authority when health and safety is a concern.

Paragraph 63

Comment: We prefer not to include the new text in bracket.

Cleaning should remove food residues and dirt which may be a source of contamination ~~[including with allergens].~~

Rationale: We believe this addition is not necessary because contaminants include allergens, as per paragraph 48.

Paragraph 73

Comment: Animals should, wherever possible, be excluded from the grounds of ~~factories and~~ food processing plants establishments.

Rationale: For consistency within the text.

Personal Cleanliness

Paragraph 83

Comment: We support the addition of the text in bracket. We also suggest adding the words “be”.

Controls should be implemented to prevent cross-contamination by food handlers through adequate hand washing and, where necessary, wearing gloves.

Paragraph 85

Comment: We support the addition of this new text.

Paragraph 88

Comment: 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 ~~para 79-87.~~ this section.

HACCP AND GUIDELINES FOR ITS APPLICATION

DEFINITIONS

Comment: We believe the proposal to move the definitions to a single section in the document is possible, but should be further discussed once the structure of the document is established. We should keep in mind that some definitions will have to be modified if they are moved to a single section. For example, the current definition of “corrective action” within the HACCP section which refers to CCP would have to be modified accordingly.

Hazard control measure

Comment: We suggest removing the word hazard and keep “control measure”.

Rationale: The definition of control measure already includes the word “hazard”. “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 plan

HACCP plan

Comment: We propose to have only one definition. We are proposing a definition for further discussion.

Hazard analysis and control plan: a document prepared in accordance with the principles of HACCP which identifies appropriate control measures to ensure food safety in the operation. The hazard analysis and control plan will identify control measures that are based on GHPs alone or a combination of GHPs (including enhanced GHPs) and CCPs.

Monitor

Comment: We suggest modifying the definition as per the Codex document *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69-2008).

Validation

Comment: We suggest modifying the definition as per the Codex document *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69-2008).

Principles of the HACCP system

Principle 1

Comment: Conduct a hazard analysis and identify control measures

Principle 4

Comment: Establish a system to ensure monitor control measure(s) of the at CCP is/are monitored continuously/in real-time.

Rationale: For added clarity and to reflect revisions to the document with regards to hazard analysis and enhanced GHPs.

Paragraph 11

Last sentence

Comment: Although small businesses should be supported in performing an accurate hazard analysis and developing effective control measures, size should not be a factor in the actual application of HACCP. Small businesses may still produce very high risk products and the HACCP system should be robust in those cases. To help them, we should encourage governments to develop tools and resources targeted to SLDBs but still maintain the same expectations for effective control measures.

Paragraph 23

Comment: In light of the information gathered at the previous steps (1 to 5), the HACCP team should list all of the hazards that may be reasonably expected to occur at each step of the flow diagram according to the scope of the food business operation.

Rationale: To clarify that the information collected in steps 1 to 5 is used here to help determine the hazards that should be considered. This will help link the previous steps with step 6.

Paragraph 25

Comment: We suggest deleting the entire paragraph.

Rationale: The information in this paragraph is already described in paragraph 12. We believe that this section should focus on the application of the HACCP system.

Paragraph 26

Comment: We suggest deleting the second and third sentences. We also suggest moving this paragraph after paragraph 27, to improve the flow of the hazard analysis section.

~~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.]~~

Rationale: This information is already mentioned under Hazard Analysis in SECTION II: CONTROL OF OPERATION. We suggest leaving the information separate, i.e., the hazards analysis for GHP in chapter 1 and the hazard analysis for HACCP in chapter 2.

Paragraph 30:

Comment: We suggest a deletion in the first sentence.

~~Critical limits should be specified for each Critical Control Point which separates acceptable procedures and products from unacceptable.~~

Rationale: We believe it is not necessary to define a CCP. CCP can be defined in the definition section. Also, the word "procedures" does not apply to a CCP.

Paragraph 31:

Comment: We suggest a modification in the first sentence.

~~Control measures and their 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.~~

Rationale: We believe control measures, and not only critical limits, should be validated.

Paragraph 31:

Comment: We suggest a deletion in the last sentence.

~~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.~~

Rationale: We believe this example does not apply for a CCP.

Chile

I. General Comments

- Although we agree to harmonized concepts with ISO 22000 series, but conserving the simplicity of HACCP that should be safeguarded, allowing its application in less developed or less resource-intensive food business.
- Although it is important to add some emphasis to some good hygiene practices controls, the terminology "Enhanced Good Hygiene Practices" and "basic hazard analysis" should be eliminated from the text to avoid confusion and only use Good Hygiene Practice and Hazard Analysis and give the importance or simplicity with the following text. Therefore, we recommend to eliminate the decision tree and the Enhanced Good Hygiene Practice from the comparative table.
- Throughout the Spanish version of the document change APPCC acronyms for HACCP as it was set in the last version of **CAC/RCP 1-1969**.

- Don't delete primary production section, leave a paragraph and strengthen activities throughout the document

ii. Specific Comments

- **Paragraph 4a or 4b:** We propose the paragraph 4b but with the following deletions and insertions:

....”4. [B. Prerequisite Programmes (PRPs), which include Good Hygiene Practices (GHPs), Good Manufacturing Practices (GMPs), and Good Agricultural **and Veterinary** Practices (GAPs), as appropriate, lay the foundation for producing safe and suitable food.] [GHPs apply broadly to all food businesses. Following a ~~basic~~ hazard analysis and an assessment of food hygiene measures, 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 by a site-specific hazard analysis and to apply [control measures ~~at critical control points (CCPs) and/or at places other than CCPs~~] ~~OR [HACCP control measures]~~ 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 industry¹ subject to adaptation to the site.~~]

Rationale: A hazard analysis is specific to each type of production, food industry or business and should not be adapted or copied from other sources.

General principles, iv and v numeral

(iv) Hazard analysis should identify all potential **[Translator's note: the change in Spanish does not affect the English]** 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.

(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 **or in associated hazards**) to determine if modifications are needed.

Paragraph 36

v. Conducting a basic hazard analysis for identifying the food safety hazards as microbiological, chemical or physical at each step of the flow chart;

vi. Identifying and defining the Good Hygienic Practices ~~for controlling these hazards,~~ **which control specific hazards.**

vii. ~~Categorizing the GHP controls as generic or hazard-based controls to be managed as either Enhanced GHPs or by application of principles of HACCP using a Decision Tree Model as given in [Annex I to the introduction].~~

viii. Validating / effectiveness of the ~~Enhanced~~ GHPs: ~~Enhanced~~ GHPs should be validated to obtain evidence that GHP control measures are capable of controlling hazards. FBOs may not always need to commission studies themselves to validate GHP control. They could be based on existing literature, guidance from competent authority or carried out by a third party e.g. cleaning products validated for effective use by the manufacturer etc. (Aligned with new text created in the Section II for HACCP).

ix. Establishing a ~~GHP Plan for monitoring, initiating corrective actions, verification of GHPs and Enhanced GHPs.]~~ **Prerequisite Program based on hygiene best practices and documented operational procedures.**

Paragraph 46, 47, 48:

The sections on Physical Contamination, Allergens and Chemical Contamination should be further elaborated.

- Rationale: This is already indicated in the Allergens Note, which mentions that reference should be made to preventive labeling and supplier management programs and audit verification.

¹ FAO/WHO guidance to governments on the application of HACCP in small and/or less developed food businesses ISSN 0254-4725

- For example, in the case of physical contamination, the preventive role of the prevention of foreign bodies, as well as the type of classification and detection equipment (screening, metal detectors, x-rays, etc.) should be highlighted. The pest control system should also be mentioned.
- The chemical contamination section should include the risks associated with primary production (veterinary drugs, pesticides, etc.) and manufacturing risks (process contaminants, chemical cleaning agents, etc.).

Colombia

SECTIONS	PROPOSED POSITION	OBSERVATIONS OR COMMENTS
<p>4. [A. 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 without the need for conducting a hazard analysis. Referring to external resources (existing models, references, standards, regulations, or Codes of Practice provided by the competent authority, Codex or food industry), it may be determined that GHPs are sufficient for some FBOs to control all food safety hazards. Yet, since not all hazards pose the same risk, there may be a need to pay particular attention to certain hazards determined as significant by a site-specific hazard analysis and to apply [control measures at critical control points (CCPs) and/or at places other than CCPs] OR [HACCP control measures] within a Hazard Analysis and Critical Control Point (HACCP) system (see Comparison Table below). FBOs without the resources to carry out a hazard analysis may use external resources as listed above or generic HACCP plans provided by the competent authority or food industry, subject to adaptation to the site].</p> <p>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 basic hazard analysis and an</p>	<p>We suggest adopting proposal "B."</p>	<p>To apply GHPs, we must determine the points of the process requiring more attention, to prevent loss of product safety. To this end, it is essential to identify, in basic terms, the hazards that could affect food safety, in order to take actions to minimize risks.</p>

SECTIONS	PROPOSED POSITION	OBSERVATIONS OR COMMENTS
<p>assessment of food hygiene measures, 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 by a site-specific hazard analysis and to apply [control measures at critical control points (CCPs) and/or at places other than CCPs] OR [HACCP control measures] 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 industry² subject to adaptation to the site.]</p>		
<p>Definitions Enhanced GHP [if this expression is retained] ANNEX I Proposed Decision Tree to Identify [Enhanced GHPs]</p>	<p>We suggest using "Identification of Key GHP Measures" or "Identification of GHP Measures of Greatest Interest"</p>	<p>The current terminology could be interpreted as looking to implement an additional measure for GHP compliance and, in a way, link it to a system equivalent to the HACCP; however, the aim is the application of preventive measures, monitoring, and greater control of certain operations conducted in the establishment to ensure food safety.</p>
<p>PRIMARY PRODUCTION Note: The section on primary production was deleted with the expectation that this would be replaced with a 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</p>	<p>Use the text in the current standard and make the relevant references in the section on primary production.</p>	<p>The other food hygiene standards were developed based on the existing recommendations in the current code of practice CAC/RPC1 – 1969, such that the essential reference parameters for preventing food contamination may be stricken.</p>

SECTIONS	PROPOSED POSITION	OBSERVATIONS OR COMMENTS
could be achieved by references throughout the text.		
<p>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:</p> <ul style="list-style-type: none"> • 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. 	<p>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, f Facilities should include:</p> <ul style="list-style-type: none"> • 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 and necessary items. 	<p>The recommendations noted in the draft proposal are necessary to prevent the entry of food handlers that could affect food safety, regardless of the type of process used. Hand washing, availability of easily-cleaned and disinfected restrooms or toilets, as well as an area to change from outside clothing to company clothing, are essential preventive measures (primarily in terms of cross-contamination).</p>
<p>CONTROL OF FOOD HAZARDS</p> <p>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.</p> <p>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.</p>	<p>We support advancing the work that would allow for incorporating guidelines for a basic hazard analysis, as this is the phase at which it should be included in the draft proposal.</p>	<p>Colombia supports including the need to conduct a basic hazard analysis for implementation of the GHPs; to this end, it is imperative to further actions to minimize health risks to consumers.</p>
<p>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).</p>	<p>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]</p>	<p>The work conducted by the FAO/WHO on water quality is necessary to enrich the document, in keeping with the best GHP, to prevent food contamination and, thus, loss of food safety.</p>
<p>Cleaning procedures and methods</p> <p>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</p>	<p>Cleaning and disinfection procedures and methods</p> <p>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</p>	<p>The section of the draft standard addresses disinfection-related issues and the term should, thus, be added to the title. Depending on the decision made regarding the use of "sanitation," this term would replace "cleaning and disinfection" throughout the document.</p> <p>Furthermore, an important aspect to include when referring to</p>

SECTIONS	PROPOSED POSITION	OBSERVATIONS OR COMMENTS
<p>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.</p> <p>68. Cleaning procedures will involve, where appropriate</p> <ul style="list-style-type: none"> • 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. <p>Sanitation [Cleaning and disinfection] Programmes</p> <p>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.</p> <p>70. Where written cleaning programmes are used, they should specify:</p> <ul style="list-style-type: none"> • areas, items of equipment and utensils to be cleaned; • responsibility for particular tasks; • method and frequency of cleaning; and • monitoring and verification activities. 	<p>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.</p> <p>68. Cleaning procedures will involve, where appropriate</p> <ul style="list-style-type: none"> • 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. <p>Sanitation [Cleaning and disinfection] Programmes</p> <p>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.</p> <p>70. Where written cleaning and disinfection programmes are used, they should specify:</p> <ul style="list-style-type: none"> • areas, parts of equipment and utensils to be cleaned; • responsibility for particular tasks; • concentrations of chemicals used. • method and frequency of cleaning and disinfection; and 	<p>disinfection is the use of different disinfectant concentrations, to prevent either antimicrobial resistance or not fulfilling the objective of the procedure.</p>

SECTIONS	PROPOSED POSITION	OBSERVATIONS OR COMMENTS
	<ul style="list-style-type: none"> • monitoring and verification activities. 	
<p>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.]</p>	<p>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.]</p>	<p>The work conducted by the FAO/WHO on water quality is necessary to enrich the document, in keeping with the best GHP, to prevent food contamination and, thus, loss of food safety.</p>
<p>Product Labelling</p> <p>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.</p>	<p>Product Labelling</p> <p>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 not be excluded. The General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) applies.</p>	<p>Colombia proposes striking the text referring to the food allergens statement where cross-contact cannot be excluded. This would transfer the responsibility for any failures arising during storage, the manufacturing process, or the implementation of cleaning and disinfection programs to the consumer.</p>
<p>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 <i>Listeria monocytogenes</i>].</p>	<p>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" emphasized 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 <i>Listeria monocytogenes</i>].</p>	<p>The current terminology could be interpreted as looking to implement an additional measure for GHP compliance and, in a way, refer to a system equivalent to the HACCP; while the aim is the application of preventive measures, monitoring, and greater control of certain operations conducted in the establishment to ensure food safety.</p>

Ecuador

GENERAL COMMENT:

Ecuador generally agrees with the document, but does have some comments on the substance to submit to the consideration of the members.

SPECIFIC COMMENTS:

Paragraph 13. Waste should be collected, disposed of by trained personnel and, where appropriate, disposal records maintained. The waste **collection and** disposal site should be located away from the food establishment to prevent pest infestation.

Rationale: In Ecuador, the sites designated for storing waste until it is collected by waste management are known as "temporary waste storage sites." Thus, the importance of including the term "collection."

Paragraph 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 **in the food processing and storage areas should be protected, where appropriate**, to ensure that food is not contaminated by breakages.

Rationale: Ecuador believes that the terms "where appropriate" is a very broad phrase, which leaves it up to the discretion of each individual, and there are zones or areas that should have protected lighting fittings.

Paragraph 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.~~ **The equipment should be designed to allow for maintenance, cleaning, and disinfection and, where necessary, should be movable or capable of being disassembled.**

Ecuador feels that the size of the company should not be the only factor considered; other factors should be taken into account, such as type of product, marketing, and others.

Japan

General Comments

- We recall that one of the main objectives of this new work (the revision of GPFH and HACCP guidelines) was to assist SLDBs in the implementation of food hygiene principles, and we would like to emphasize that we should continue our work bearing that point in mind and keep the texts as simple and user-friendly as possible.
- In line with the above comment, we believe that we should keep the original structure as much as possible as agreed before.
- Though we generally understand the concept of so-called "enhanced-GHPs", we have some doubts about the usefulness to fully elaborate this concept as one of the three pillars (together with GHP and CCP) in the Codex texts as it might create more confusions especially among SLDBs. Briefly touching upon the concept in the HACCP chapter might be sufficient.
- We propose to restore the entire section on primary production since that section included recommendations specific to primary production stage and is heavily referred to by various Codex texts related to food hygiene, including Code of Hygienic Practices for Fresh Fruits and Vegetables (CAC/RCP 53-2003). This proposal is in line with the decision made during the in-session WG at the CCFH 48 (See A3, CRD 14 of 48th CCFH).

Specific Comments**INTRODUCTION**

Comment: We find that INTRODUCTION part well describes the relationship between GHP and HACCP.

Para 4A:

Comment: We support the Option 4A.

Rationale: There are cases where we can determine GHPs are sufficient for some FBOs to control all food safety hazards without conducting hazard analysis by referring existing models or guidance etc. Also, we oppose introducing a new concept of “basic” hazard analysis (as in Option B) since it might create another argument about what is basic, and what isn’t.

Para 4B, Annex1:

Comment: We propose to delete this decision tree.

Rationale: The flow of the tree is not logical as it is and rather confusing.

Para 6, Comparison Table:

Comment: We propose to keep this comparison table in square brackets during the work and to decide its fate (keep it or delete it) upon completion of the text.

Definitions, “Food hygiene system” and “Food safety control system”:

Comment: We propose to consider whether the Committee should create a new term to cover GHP, enhanced GHP (if the CCFH agrees) and HACCP. The proposed term in the draft “food hygiene system” may cause confusions since HACCP covers more than food hygiene. One quick fix could be to use the existing term “food safety control system” as a term encompassing both hygiene practices and control measures.

Chapter 1 (GOOD HYGIENE PRACTICES)

Comment: It would be desirable to construct this chapter in a manner that this chapter alone would suffice in order for FBOs without the need for conducting a hazard analysis to apply essential food hygiene control.

PRIMARY PRODUCTION:

Comment: We propose to restore the entire section on primary production.

Rationale: Refer to the General Comments.

Para 28-33:

Comment: We propose to move the paragraphs 28-33 to the HACCP section to maintain the original format and structure as much as possible as agreed before.

Rationale: Refer to the General Comments.

PEST CONTROL SYSTEMS, Monitoring and detection:

Comment: We do not see the clear necessity to further elaborate the text on monitoring and detection of pests.

Rationale: Major pests, trends, key areas of infestation etc. should be different depending on the type of food or facility.

SECTION IV: PERSONAL HYGIENE

OBJECTIVES:

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

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

Rationale: Editorial.

SECTION VI: PRODUCT INFORMATION AND CONSUMER AWARENESS

OBJECTIVES, 5th line~:

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

The WHO Five Keys to Safer Food assists in this process.

Information for industry or trade users...

Rationale: We believe that the WHO Five Keys are useful educational tools for consumers and already referred to in other Codex food hygiene-related documents.

Chapter 2 (HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION)

Para 5:

Comment: We support the introduction of this paragraph.

Rationale: It would be a realistic approach for SLDBs, who have difficulties in fully introducing HACCP system in accordance with 12 steps, to utilize external resources (such as existing models, guidance etc.), and then gradually adapt it to suit their own facilities' situation.

Para 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.

Rationale: From a logical perspective, this should be “in-time”, not “in real-time”. (i.e., Information should be available in time to make necessary adjustments before actual loss of control at CCPs occurs.)

New Zealand

General comments:

In relation to the consideration of fundamental concepts as outlined in Paragraph 8 (Page 2):

- i. New Zealand supports the concept that all food businesses across the food chain have a hazard identification and analysis associated with their business food production or process. This should be appropriate to the nature (in terms of food safety risk) and size of the business and may be assisted by the competent authority providing technical information and /or guidance to a food business sector.
- ii. New Zealand supports the current approach of GHP, plus HACCP to the extent needed (i.e. determined by the presence of one or more CCPs). GHP comes in many forms and may be simple to very sophisticated, depending on the food business and the level of food safety risk associated with that business. It is expected that a food business will implement GHP to the level appropriate to the nature and type of food business it is.

If another layer of GHP should be added, then it will be essential for the criteria for application to be clearly defined with clear explanation of the relationship of different types of control measure within GHP, enhanced GHP and HACCP

- iii. New Zealand supports the document being developed to strengthen references throughout to demonstrate how the guidance applies at all stages of the food chain, rather than specifying a separate section on primary production. Primary production is just another part of the food chain that may be simple or sophisticated depending on the nature of the food being produced.

In relation to the format and structure of the document, as expressed in Paragraph 9 (Page 2), if other documents provide a more practical approach in terms of terminology and definitions and add value to the application of GHP and/or HACCP then these should be considered in order to improve Codex guidance. Additional benefits should be transparent to competent authorities and food businesses.

“Food hygiene system” infers both food safety and food suitability in line with the Codex Committee on Food Hygiene’s mandate. This is more appropriate terminology for a system covering GHP and HACCP. Whilst “food safety control system” has been defined in the **Validation of Food Safety Control Measures** (CAC/GL 69 – 2008), this only refers to food safety control measures within a food business, not the whole of food hygiene.

Specific comments on the draft text presented in Appendix 1:

Paragraph	Comment	Rationale
INTRODUCTION NZ supports Para 4B		All FBOs across the food chain should have a basic hazard analysis assisted as necessary by the competent authority. This adds value to the next stage in the food chain, which uses this information to input into their hazard analysis.
Para 4B	<p>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 <u>and lay the foundation for producing safe and suitable food</u>. Following a basic hazard analysis and an assessment of food hygiene control measures, 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 by a site-specific hazard analysis and to apply [control measures at critical control points (CCPs) and/or at places other than CCPs] OR [HACCP control measures] within a Hazard Analysis and Critical Control Point (HACCP) system or elsewhere under GHP (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 industry² subject to adaptation to the site.]</p> <div style="border: 1px solid black; padding: 5px;"> <p>Note: A decision tree has been added to support understanding of application of control measures other than at CCPs that require additional attention which are referred to as 'enhanced GHPs'.</p> </div> <p>(Annex 1 provides a decision tree to identify control measures applied at places other than CCPs, indicated under the name ["enhanced GHPs"]).</p>	<p>?</p> <p>A robust hazard analysis should still be done. The difference between a basic hazard analysis and a hazard analysis as mentioned in the comparison table, needs to be explained</p> <p>Control measures should apply for GHP.</p> <p>As shown in table</p> <p>Decision tree needs to clearly show rationale for differentiation of the application of control measures</p>
Para 6 Comparison table Scope	General basic conditions and activities to create the environment (external and internal) for safe food. <u>Knowledge of the product or group of products and the process must be understood.</u>	The scope at any level needs to be associated with knowledge of the product or group of products, not just for the CCPs
Para 6 Comparison table Scope	Control measures for significant hazard(s) in food and/or the processing environment that are not specifically quantifiable or where a specific limit does not relate directly to a quantifiable level of hazard control.	What does this mean? Please clarify

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

Para 6 Comparison table When identified?	[After basic hazard analysis [at places other than CCPs][enhanced GHPs]] After Hazard analysis [for control measures at CCPs]	Clarification is required between basic hazard analysis and hazard analysis
Para 6 Comparison table Monitoring	3 columns in Yes, but usually non-continuous. Frequency dependent on the operation (Non CCP) Vs Real time monitoring (at CCP)	Clarification is required between monitoring for places other than CCPs and CCP monitoring (real time monitoring) when both involve significant hazards Batch product and product disposition in relation to monitoring
Para 8. Scope	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 provision of food products and recommending, where appropriate, specific food safety control measures at certain steps throughout the food chain.	'Manufacture' is usually associated with manufacturing industry and not across whole of food chain. 'Provision' is more generic and can be applied across the whole of food chain
Para 13, 4th bullet point	- 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 and toxins by storing, handling and preparing it correctly; and	The conditions of storage, handling and preparation should be appropriate to prevent the growth of food pathogens and their toxins.
General Principles	Food safety hazards (biological, chemical, physical) should be controlled using a preventive approach as much as is practicable, to ensure food safety and suitability .	Food safety hazards only relate to food safety, not food suitability
Annex 1		Clarification is required as to how this decision tree works. Examples would be useful. GHP should be routine for all steps. Generic vs specific GHP needs explanation. Generic vs customised generic needs explanation Customised generic GHP vs specific reduction of food safety hazard needs explanation Enhanced GHP vs customised generic GHP needs explanation
Good Hygienic Practices [Chapter one]		
Primary Production	Primary Production	New Zealand supports deletion of a specific primary production section in favour of primary production being considered as relevant and appropriate under any section of this document, just like any other

		part of the food chain. Primary production can be simple through to complex in its operation and the application of GPFH and HACCP will vary depending on the nature of the food business and the food being produced.
Para 6	6. [Site boundaries should be clearly defined. Landscaping near a food facility should be properly designed to minimise attractants and pest harbourage. Where necessary, experts should be consulted for advice on appropriate plants for use in landscaping.]	Paragraph 5 provides enough guidance
Para 16 first bullet point	<ul style="list-style-type: none"> 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; 	Hot water isn't necessarily going to be available at 'in field' horticultural settings. Efficacy of cold water has been shown to be similar to cold in terms of handwashing.
Section II Control of Operation	RATIONALE: To reduce the risk of unsafe and unsuitable food by taking preventive measures to assure the safety and suitability of food at an appropriate stage in the operation by controlling food hazards	Makes sentence less cumbersome and relate to both risks (unsafe and unsuitable).
Product description, Process description		New Zealand supports inclusion and strongly believes that all food business operators should know and provide this information as part of the process to ensure safe and suitable food fit for intended use. This is applicable to the application of the general principles of food hygiene and HACCP.
Para 31. Monitoring procedures	The FBO should document procedures for monitoring control measures as relevant to the business <u>and the level of food safety risk.</u>	Provides further clarification as to when monitoring procedures would be relevant and should be documented. This also aligns with the comparison table provided.
Validation of GHP	Refer to Validation of Food Safety Control Measures (CAC/GL 69 – 2008)	This would be a useful reference
Control of food hazards Para 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. <u>A hazard ID should be done for those sources of hazards (e.g. people, pests, water supply, air) common to the operational environment, where source control is the most practical way of managing potential hazards.</u>	Suggest a hazard ID for those sources (e.g. people, pests, water supply, air) common to the operational environment, where source control is the most practical way of managing potential hazards. Suggest a hazard ID and analysis for each process step

	basic hazard analysis s <u>A hazard ID and analysis for each process step focusing on each input (raw materials, ingredients and food packaging), and the influence of the process step itself</u> should determine whether the application of GHPs is sufficient [adequate] for some FBOs to control all of the relevant food hazards.	focusing on each input (raw materials, ingredients and food packaging), and the influence of the process step itself.
Para 35	Where significant food safety hazards are identified, <u>and a CCP is not appropriate (not part of direct process or not able to be monitored in real time)</u> a more targeted approach is necessary and 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 <u>cooked</u> meat slicer to control <i>Listeria monocytogenes</i> .	This should either lead into either: 1) the more targeted hazard-specific control measures such as for the specific cleaning example, or 2) CCP determination - see HACCP section.
Para 36	Deleted	Already covered by Paras 28 – 34, including validation of any GHP measures
Para 37		Unsure how this would work in practice as there is a conflict between hazard control measures being unable to control to acceptable level under GHP and what HACCP could do further to rectify this. i.e. the CCP would still have to have effective hazard control measures (plus CLs, and be able to be monitored in real time...).
Para 43 Micro cross contamination	Microbiological contamination occurs through <u>may occur through</u> the transfer of microorganisms	“occurs through” suggests certainty where it is not.
Para 48	[Hazard identification should take into account the allergenic nature of some foods. Presence of allergens e.g. nuts, milk, eggs, <u>seafood</u> 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 of raw materials <u>and ingredients</u> , during processing, and during storage of food products.	Clarifies the intent of the paragraph.
Para 49	Only raw materials and other ingredients that are fit for purpose should be used. Incoming materials including food ingredients should have a be purchased <u>procured</u> 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.	The deletion makes it clear that all incoming materials, regardless of whether they are purchased externally etc, should have specifications.
Para 51	Potable vs clean vs clean seawater	Water should be fit for purpose

Para 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 compromise constitute a hazard to the safety and suitability of food (e.g. the use of clean sea water or clean water)	Confusing with definition of hazard for food safety. Use alternative wording that covers both safety and suitability
Para 56	Potable water should be used to avoid food contamination. The potable water may be treated where this is required by the production process.	Further clarification is required to determine the intent of this paragraph, is it that water of a standard higher than potable water can be used or treated, e.g. deionised, etc. or is the intent that the production process itself can treat the water to make it of a potable standard?
Para 60	Where a product has been recalled because of an immediate health risk hazard , other products which are produced under similar conditions which may also present a risk hazard to public health should be evaluated for safety and may need to be recalled	Correct terminology is 'risk' not 'hazard' when referring to public health
Para 65	Cleaning and disinfection sanitation chemicals should be handled and used carefully and in accordance with manufacturers' instructions, for example, using the correct dilution and contact time , and stored, where necessary, separated from food, in clearly identified containers to avoid the risk of contaminated food.	For sanitation chemicals to be effective they are often required to be used at the correct dilution and for the appropriate contact time with the surface.
Para 66	[Separate cleaning equipment, suitably designated, should be used for highly contaminated areas e.g. toilets and non-food processing areas.]	It is good practice to use separate cleaning equipment for food processing and non-food processing areas to avoid the introduction of microbiological hazards.
Para 70	Where documented written cleaning programmes are used, they should specify:	Consistent with use elsewhere. Also not all parts of the programme may be written. Pictures, photos and diagrams can be used.
Para 73	Buildings should be kept in good repair... 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 food handling areas. grounds of factories and food processing plants.	Consistent with the whole food chain approach
Section VI: Product information and consumer awareness	<p>Objectives:</p> <p>Products should bear appropriate information to ensure that:</p> <ul style="list-style-type: none"> • Potential allergens are clearly defined <p>Consumers should have enough knowledge of food hygiene to enable them to:</p>	NZ supports the expansion of the Objectives and Rationale to highlight allergens.

	<ul style="list-style-type: none"> understand the importance of product information <u>including the presence of potential allergens</u>; <p>Rationale: Insufficient product information, <u>including about potential allergens</u>, and/or inadequate knowledge of general food hygiene, can lead to products being mishandled at later stages in the food chain, <u>causing</u> 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.</p>	
Para 95 & 96 New sentence in relation to the 'next person in the food chain'	<u>This could also be the consumer</u>	FBO or the end of food chain, i.e. the consumer
Para 100	Managers and/or supervisors should have the necessary competency in knowledge of food hygiene principles and practices to be able to judge potential risks and take the necessary <u>corrective actions</u> action to remedy deficiencies.	Should be competent (includes training knowledge, skills and ability) to judge and carry out necessary corrective actions. 'Competent' is used elsewhere
Chapter Two		
Preamble Paragraph 2	HACCP is a tool to assess hazards and establish control systems that focus on managing significant prevention of hazards rather than relying mainly on end-product testing.	HACCP focuses on identifying and managing significant hazards to ensure acceptable levels of those hazards on an ongoing basis.
Assemble HACCP team		This needs to be considered in light of hazard ID and analysis for the whole of the food business operations, i.e. GHP and HACCP so may be better placed in GPFH section.
Para 18 – 22 Scope Product description Identify intended use Construct flow diagram On-site confirmation of flow diagram		NZ suggests that these need to be considered with GHP and HACCP application in mind as they are important to both.
Para 21 second sentence	The flow diagram should cover all steps in the operation for a specific product, <u>including all product inputs, rework loops and all outputs.</u>	The level of detail for the process flow diagram is very important. Additional wording provides that detail.
Para 21 & 22		These should be combined for the process flow diagram

Para 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. A hazard may not have any control measures and should be identified as uncontrolled, noting that no unacceptable level has been defined for the hazard.	Recognise that some hazards are not controlled but they are also not considered to be at unacceptable levels either for that process. Also see Para 29
Para 30	Critical limits should be specified for each Critical Control Point which separates <u>the acceptable level of relevant processing parameters</u> procedures and products from unacceptable.	Critical limits define the acceptable level of relevant processing parameters in order to deliver the hazard reduction required (and validated)
Para 34	If monitoring is not continuous, then the amount or frequency of monitoring should be sufficient to guarantee the CCP is in control.	Please clarify what this means in reality.
Para 34	Physical and chemical measurements are usually preferred to microbiological testing because they may be done rapidly and <u>will have been validated as delivering or contributing to an acceptable level of hazard</u> and can often indicate the microbiological control of the product.	This is not only applicable to biological hazards
Para 39	<ul style="list-style-type: none"> <u>Review of the HACCP system, whenever a change is made to the product, or process, or when an emerging hazard has been identified</u> 	This is an important example of a HACCP verification activity
Para 43	<ul style="list-style-type: none"> <u>Validation reports</u> 	This is an important record for the HACCP system.
Para 46	As an aid in developing Specific training to support a HACCP plan, <u>should include</u> working instructions and procedures should be developed which define the tasks of the operating personnel involved with the HACCP system to be stationed at each Critical Control Point.	Tasks defined should include: <ul style="list-style-type: none"> Overall HACCP coordinator HACCP system verifier HACCP supervisors HACCP CCP monitoring and corrective action personnel.

Norway

Paragraph 8.

i.

We are of the opinion that all businesses should complete Principle 1 of the HACCP study in order to identify biological, chemical and physical hazards to be controlled. Following the assessment to identify hazards and food hygiene measures, it may be decided that GHPs and GMP's/ OPRP`s are sufficient for some FBOs to control all food safety hazards. This assessment is called a basic hazard analysis in the document. If this term is used, it needs to be clearly defined and described in the definitions. In other cases, there may be a need to pay particular attention to certain hazards determined as significant by a site-specific hazard analysis and to apply control measures at critical control points. Site-specific hazard analysis should also be defined and described in the definitions.

It should be emphasized that hazards can be controlled by one or more of the three control measures categories . The prerequisite programs have to be planned to control the food safety hazard levels in the product and in the processing environment.

ii.

We are of the opinion that control measures should be broadened in order to include more than GHPs plus HACCP. In order to be consistent with ISO 22000:2005 and avoid confusion, we suggest using, Operational Prerequisite Programmes (oPRPs). We do not support the wording enhanced GHPs, because it is not consistent with ISO 22000:2015 and does not include GMPs.

iii.

We support addressing the controls for primary production both by a specific section in the document and text developed to strengthen references throughout to the document. It is important to demonstrate that the guidance applies at all stages of the food chain. However, it is important to keep certain sections because many other Codex documents makes cross-referrals to specific sections in CAC/RCP 1-1969.

Paragraph 9.

We are of the opinion that the document should be revised and aligned with other relevant documents. The revision should take into consideration the relationship to the ISO 22000:2005, as this is a well-established global standard for food safety in the food chain. There should be an integrated approach within the frame of a Food Safety Management System. The document should describe the connection between Critical Control Points (CCPs), Operational Prerequisite Programmes (oPRPs) and Prerequisite Programmes (PRPs) in the context of a Food Safety Management System (FSMS).

We agree that the term "food hygiene system" could cause confusion. In order to be consistent with ISO 22000:2005 we prefer using the term "food safety management system", but we could also be in agreement with the wording "food safety control system".

For consistency, CCP and HACCP in CCFH documents and CCFFP documents should as much as possible be in line and harmonized.

Paraguay

Paraguay agrees with the document in general and appreciates the opportunity to make the following comments, particularly on the EWG's recommendations regarding the following items:

- Paragraph 8 of the circular letter:
 - i) A hazard analysis is not necessary for primary production, prior to the application of the GHPs. Food business operators (FBO) and primary production should be able to identify hazards to establish appropriate GHPs and, where appropriate, should conduct a hazard analysis.
 - ii) Paraguay does not agree with including the new term "Enhanced Best Practices," as the concept of such practices is not clear. Management of GHPs and hazard management should be kept separate in the HACCP.
 - iii) We agree with keeping the Primary Production section, but using the short-overarching paragraph.
- We support the need to continue working on the document through an EWG and with a PWG at the 50th CCFH meeting.

Specifically, on [CHAPTER TWO] HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION

FLEXIBILITY

Paragraph 11:

General comment: application of the document should consider not only the size of the business, but also other criteria like target population and product type.

Philippines

General Comments:

We are generally in agreement with the draft position and we would like to propose addition of the following points under General comments:

- We suggest an alignment with ISO 22000/22002 for some items that may cause confusion with Food Business Operators (FBO) following the mentioned standard
- The terminology of ‘enhanced GHP’ should be re-considered to avoid confusion, especially for those FBO who are aligned with ISO 22000/22002.
- Further alignment in terms of format, structure and definitions to ISO 22000/22002 should be considered, for example, the notion of food safety control system would be preferred to food hygiene system.

Specific Comments:

1. In Appendix I, Introduction, page 4, paragraph4

From	To
<p>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 basic hazard analysis and an assessment of food hygiene measures, 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 by a site-specific hazard analysis and to apply [control measures at critical control points (CCPs) and/or at places other than CCPs] OR [HACCP control measures]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 industry¹subject to adaptation to the site.]</p>	<p>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 basic hazard analysis and an assessment of food hygiene measures, 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 by a site-specific hazard analysis and to apply [control measures at critical control points (CCPs) and/or at places other than CCPs]—OR [HACCP control measures]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 industry¹subject to adaptation to the site.]</p>

Rationale:

We propose the removal of the brackets in the paragraph as the Philippines supports paragraph 4.B.

2. Introduction, Comparison Table; page 5,

Row on “Validation of the effectiveness of the control measure”

Column on “Control measures at Places other than CCPs”

From:

	Good Hygiene Practices (GHPs)	[Control Measures at Places Other than CCPs][Enhanced GHPs]	Control Measures at Critical Control Points (CCPs)
Validation of the effectiveness of the control measure	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>)	carried out (<i>Guidelines for the Validation of Food Safety Control Measures CAC/GL 69-2008</i>)

To:

	Good Hygiene Practices (GHPs)	[Control Measures at Places Other than CCPs][Enhanced GHPs]	Control Measures at Critical Control Points (CCPs)
Validation of the effectiveness of the control measure	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>)	<u>Where needed, generally not carried out by FBOs themselves, e.g. cleaning products validated for effective use by manufacturer.</u>

Rationale:

Based on the Food Safety Modernization Act and Current Good Manufacturing Practice Hazard Analysis and Risk Based Preventive Controls for Human Food – CFR 117.160 sec 2c, the food allergen controls and sanitation controls, recall plan, and supply chain program need not be validated.

3. Introduction, Comparison Table; page 6

Row on “Corrective actions when loss of control is indicated”

Column on “Control measures at Places other than CCPs”

From:

	Good Hygiene Practices (GHPs)	[Control Measures at Places Other than CCPs][Enhanced GHPs]	Control Measures at Critical Control Points (CCPs)
Corrective actions when loss of control is indicated	<ul style="list-style-type: none"> For procedures and practices: Yes, [where relevant]. For products: Usually not necessary. 	<ul style="list-style-type: none"> For procedures and practices: Yes. For products: When necessary, based on the situation evaluation. Product should not be introduced into commerce until the evaluation is completed. 	<ul style="list-style-type: none"> For products: Yes. Pre-determined actions for products. For procedures and practices: Yes, corrective actions as appropriate to restore control and prevent recurrence.

To:

	Good Hygiene Practices (GHPs)	[Control Measures at Places Other than CCPs][Enhanced GHPs]	Control Measures at Critical Control Points (CCPs)
Corrective actions when loss of control is indicated	<ul style="list-style-type: none"> For procedures and practices: Yes, [where relevant]. For products: Usually not necessary. 	<ul style="list-style-type: none"> For procedures and practices: Yes. For products: When necessary, based on the situation evaluation. Product should not be introduced into commerce until the evaluation is completed. 	<ul style="list-style-type: none"> For products: Yes. Pre-determined actions for products. For procedures and practices: Yes, corrective actions as appropriate to restore control and prevent recurrence. <p><u>Correction</u> <u>Yes. Pre-determined actions for products (for GHP, OPRP, CCP)</u></p>

Rationale: We propose the addition of a statement on the specifics on correction to differentiate it with corrective action for clarity.

4. General Principles, (iv) and(v), Page 8.

From	To
(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.	(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.	(v){Significant hazards}—should be controlled by {specific} control measures

Rationale: We propose the removal of the brackets as we support the statements indicated in (iv) and (v).

5. General Principles,(vii), Page 8.

From	To
(vii)The application of control measures Should be subject to monitoring, corrective actions, verification, and documentation, as appropriate	(vii)The application of control measures Should be subject to monitoring, correction , corrective actions, verification, and documentation, as appropriate

Rationale: We propose to add the word “correction” to be consistent with ISO22000:2005clause3.13.

6. Good Hygiene Practices, Section I, Establishment Design and Facilities, page 10, paragraph6

From	To
6.[Site boundaries should be clearly defined. Landscaping near a food facility should be properly designed to minimise attractants and pest harbourage. Where necessary, experts should be consulted for advice on appropriate plants for use in landscaping.]	6.{Site boundaries should be clearly defined. Landscaping near a food facility should be properly designed to minimise attractants and pest harbourage. Where necessary, experts should be consulted for advice on appropriate plants for use in landscaping.}

Rationale: We propose the removal of the brackets as wesupportparagraph6 to compliment the Philippine DOH-FDA Administrative Order No.153S. 2004;Subject:Revised Guidelines on current Good Manufacturing Practice in Manufacturing Practice in Manufacturing, Packing, Repacking or Holding Food, Part IV. General Guidelines, B. Premises,1.Grounds.

7. Good Hygiene Practices, Section I: Establishment Design and Facilities, Drainage [and waste disposal] , page 11,paragraph13

From	To
<p>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.</p>	<p>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.</p>

Rationale: We propose the deletion of the word “collection” in brackets for more clarity.

8. Good Hygiene Practices, Section I: Establishment Design and Facilities, Drainage [andwaste disposal], page 12,paragraph15

From	To
<p>15.Adequate,suitablydesignatedfacilities shouldbeprovidedforcleaning [food], utensilsandequipmentcominginto contactwith food.Suchfacilitiesshould have anadequatesupplyof hotandcold potablewater where appropriate.</p>	<p>15.Adequate,suitablydesignatedfacilities shouldbeprovidedforcleaning - [food], utensilsandequipmentcominginto contactwith food.Suchfacilitiesshould have anadequatesupplyof hotandcold potablewater where appropriate. <u>Aseparate cleaning facility should be provided for tools andequipmentfrom highlycontaminatedareas liketoilets,drainage andwastedisposalareas.</u></p>

Rationale: We propose the addition of the statement to prevent cross-contamination during cleaning of tools and equipment used for food production.

9. Good Hygiene Practices,Section II:Control of Operation, page 13, paragraph 28-33

Rationale: We propose the removal of the brackets on this text as we support the statement.

10.Good Hygiene Practices,Section II:Control of Operation,page14, paragraph34

From	To
<p>34.GHPscontrol most food hazards which May [contaminate]food products, e.g. though food handlers, in coming 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.</p>	<p>34.GHPscontrol most food hazards which May [contaminate] food products, e.g. through food handlers, in coming 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.</p>

Rationale:

We support the use of the word “adequate” instead of “sufficient” as it is more appropriate.

11. Good Hygiene Practices, Section II: Control of Operation, page 14, paragraph 35

From	To
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 <i>Listeria monocytogenes</i> . These 'enhanced' GHPs should be subject to monitoring, corrective actions and verification and where appropriate, be documented.	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 <i>Listeria monocytogenes</i> . These 'enhanced' GHPs should be subject to monitoring, corrective actions and verification and where appropriate, be documented.

Rationale: We propose the removal of the brackets in the word "specific" as we support the addition of the word because it refers to significant food safety hazards as compared to the generic GHP.

12. Good Hygiene Practices, Section II: Control of Operation, page 15, paragraph 40

From	To
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.	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.

Rationale: We propose the deletion of the word "Critical" and the phrase "where appropriate" to ensure that all temperature recording devices are calibrated at regular intervals.

13. Good Hygiene Practices, Section II: Control of Operation, page 16, paragraph 47 and 48

We agree on the Notes that the texts for paragraphs 47 and 48 need to be developed further.

14. Good Hygiene Practices, Section II: Control of Operation, page 16, paragraph 49

From	To
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.	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.

Rationale: We support the use of the word "purchased" as it is more commonly used than the word "procured."

15. Good Hygiene Practices, Section II: Control of Operation, page17,paragraph51

From	To
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.	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.

Rationale: We support the use of “potable” water for consistency with reference to the WHO Guidelines for Drinking Water Quality.

16. Good Hygiene Practices, Section II: Control of Operation, page 17,paragraph 57

From	To
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.	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.

Rationale: We propose the deletion of the phrase “in direct contact with food” to avoid redundancy as this was already indicated in the title “Ice and steam in direct contact with food”.

17. Good Hygiene Practices, Section III: Establishment Maintenance, Sanitation and Pest Control, page18, paragraph 63

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

Rationale: We propose the removal of the brackets as we support removal of allergens that are identified as source of cross contamination.

18. Good Hygiene Practices, Section III: Establishment Maintenance, Sanitation and Pest Control, page18,paragraph 66

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

Rationale: We propose the removal of the brackets as we support the statement.

19. Good Hygiene Practices, Section III: Establishment Maintenance, Sanitation and Pest Control, page18, paragraph 69

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

Rationale:

Editorial correction: Addition of letter “W” to complete the word “Where” in the last sentence.

We propose deletion of the phrase “relevant specialist” and retain “expert advisors” to eliminate redundancy.

20. Good Hygiene Practices, Section III: Establishment Maintenance, Sanitation and Pest Control, page19, paragraph 78

From	To
78. Waste stores should be kept appropriately clean and free of pests and be resistant to pest infestation]	78.Waste containers and facilities Stores should be kept appropriately clean and free of pests. And be resistant to pest infestation].

Rationale:

We propose the replacement of the word “stores” with “containers and facilities” for clarity.

We propose the deletion of the phrase “and be resistant to pest infestation” as this might not be achieved by the SLDB.

21. Good Hygiene Practices, Section IV: Personal Hygiene,page20, paragraph83

From	To
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 handwashing 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.	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.

Rationale:

We propose the removal of the brackets as we support the paragraph.

We propose the addition of the word **be** between “should” and “implemented” in the last sentence for clarity.

22. Good Hygiene Practices, Section IV: Personal Hygiene, page 20, paragraph 85

From	To
[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.]	{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.}

Rationale: Removal of brackets as we support the inclusion of a detailed guideline on handwashing.

23. Good Hygiene Practices, Section VI: Product Information and Consumer Awareness, page 22, paragraph 97

From	To
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 product, 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]	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 <u>the</u> product, 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}.

Rationale:

We propose the addition of the article “the: between “accompanying” and “product” in the second sentence of the paragraph for clarity.

We propose the removal of the brackets in the phrase “and the presence of allergens as we support this statement.

24. Definitions, Page 24, Correction

Correction: Action to eliminate a detected nonconformity.

Rationale: We propose the addition of “Correction” in the definition of terms based on ISO 22000:2005 clause 3.13.

25. Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application, Definition, page 25, Hazard Control Plan

From	To
[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.	{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.

Rationale: We propose the removal of the brackets as we support the definition. This provides differentiation from the HACCP Plan document.

26. Hazard Analysis and Critical Control Point (HACCP)System and Guidelines for its Application,Definition,page25,HACCP Plan

From	To
<i>[HACCP plan:</i> A hazard control plan which has identified critical control points.]	<i>{HACCP plan:</i> A hazard control plan which has identified critical control points.]

Rationale: We propose the removal of the brackets as we support the definition. This provides differentiation from the Hazard Control Plan document.

27. Hazard Analysis and Critical Control Point (HACCP)System and Guidelines for its Application,Definition,page25,Hazard

From	To
<i>Hazard:</i> A biological, chemical or physical agent in [, or condition of,] food with the potential to cause an adverse health effect.	<i>Hazard:</i> A biological, chemical or physical agent in food {,or condition of} food, with the potential to cause an adverse health effect.

Rationale: We propose the removal of the brackets as we support the definition to be consistent with ISO22000:2005clause 3.3.

28. Hazard Analysis and Critical Control Point (HACCP)System and Guidelines for its Application, Definition, page 25, Hazard analysis

From	To
<i>Hazard analysis:</i> The process of collecting and evaluating information on hazards identified in the environment ,in the processor 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.	<i>Hazard analysis:</i> The process of collecting and evaluating information on hazards identified in the environment, in the processor 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.

Rationale: We propose the removal of the brackets as we support the addition of the phrase “hazard control plan”.

29. Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application, Introduction, page 26, paragraph 9

From	To
<p>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 <i>Listeria monocytogenes</i>].</p>	<p>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 <i>Listeria monocytogenes</i>].</p>

Rationale: We propose the removal of the brackets as we support the paragraph, including the example given for enhanced GHP.

30. Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application, Introduction, page 26, paragraph 11

From	To
<p>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.</p>	<p>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.</p>

Rationale:

We propose the removal of the brackets in the phrase “and size” as we support the addition of this phrase because even small business may carry a high risk.

31. Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application, Introduction, page 27, paragraph 19

From	To
<p>19. A full description of the product should be drawn up, including relevant safety information such as composition, physical/chemical characteristics (including Aw, 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].</p>	<p>19. A full description of the product should be drawn up, including relevant food safety information such as composition, physical/chemical characteristics (including Aw, 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].</p>

32. Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application, Introduction, page 28, paragraph 30

From	To
<p>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, Aw, available chlorine, and sensory parameters which can be observed, such as visual appearance and texture.</p>	<p>30. Critical limits should be specified for each Critical Control Point which separates acceptable procedures processes 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, Aw, available chlorine, and sensory parameters which can be observed, such as visual appearance and texture.</p>

Rationale: We propose the replacement of the word “procedures” to “processes” as the CCP is part of a process and not of a procedure.

Switzerland

General Comments:

While it is considered important to emphasize the added importance of some hazard controls, the terminology of “enhanced GHP” should be re-considered to avoid confusion, especially for those food businesses who are aligned with ISO 22000/22002.

Further alignment in terms of format, structure and definitions to ISO 22000/22002 should be considered, for example the notion of “food safety control system” would be preferred to “food hygiene system”.

We would like to provide the below specific comments.

Specific comments:

Appendix I of CX/FH 17/49/5

Chapter 1

Paragraph 4: We propose to retain paragraph 4B and delete paragraph 4A

Rationale: We consider it appropriate that all businesses are aware of the need to, and do perform Hazard Analysis – the use of ‘where appropriate’ or ‘if necessary’ would not be suitable in these instances. Albeit, it is understood that the intensity of such a HA will vary by each player in the food chain and the use of external resources are admissible.

Paragraphs 28 to 33: Propose to retain this text which is in brackets in the current version of the document.

Rationale: Process control details referred to in para 28-33 are important elements to be described thoroughly in the text but in many cases this detail may be included in the HACCP study/plan for food businesses.

Paragraphs 46, 47 and 48: The sections on Physical contamination, allergens and chemical contamination needs to be elaborated further. This is already indicated in the Note on Allergens, where reference must be made to supplier management, transport and manufacturing – the use of HACCP to establish controls such as validated cleaning to prevent allergen cross contact and the necessary labelling (as foreseen in paragraph 96), etc. For Physical hazards, it should be emphasized the preventative role for foreign body prevention as well as sorting and detection equipment (sieves, screens, metal detectors, X-ray etc). Integrated pest management and hygienic engineering should also be referred to here or cross referenced to pest control system (para 72). The chemical contamination sections should mention the risks from primary production (vet drugs, pesticides etc.) through manufacturing (process contaminants, chemical agents for cleaning, etc.).

Chapter 2

Paragraph 14: Propose to change wording of this paragraph to read:

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~~ **the nature and size** of the food business operator.

Rationale: Making reference to the capabilities of the food business operator seems inappropriate.

United States of America

GENERAL COMMENTS

The United States appreciates the efforts of the electronic working group (EWG) in revising the *General Principles of Food Hygiene* (GPFH). The U.S. also appreciates the opportunity to serve as one of the 5 co-chairs of the EWG. Based on our review of comments from the EWG members and discussions we have had with others on this document, we recognize that although much progress has been made, there is still much to be done. We look forward to the discussions at the 49th Session of the Codex Committee on Food Hygiene (CCFH49).

While the U.S. supports providing flexibility to address the challenges of small and less-developed businesses (SLDBs), we urge caution that this not come at the expense of food safety. All businesses need to make safe food. The U.S. believes that the document can be made more useful to SLDBs primarily by providing additional guidance on the application of the HACCP principles. We are providing suggested text that we believe will be helpful in accomplishing this.

With respect to the issues in paragraph 8 of the EWG report, we offer the following points.

- i. **Whether all businesses should complete a hazard analysis and, if so, how this can be adapted so it is appropriate to the nature and size of the business and whether GHP-based or HACCP-based food safety control systems are being applied.**

The U.S. believes that it is important that all businesses be aware of the hazards that exist for the food products they are producing. This does not mean that every food business must conduct a hazard analysis as described in the principles for HACCP (or even a “basic hazard analysis,” which is not fully developed in this document). Understanding what the hazards are is critical to a food business operator (FBO) being able to control hazards using GHPs and, where necessary, HACCP. However, this outcome can be achieved without every FBO having to conduct a hazard analysis. For example, industry guidance often describes appropriate food safety procedures applicable for food businesses, and competent authorities often set specific requirements that address the hazards. Even a “simplified” or “basic” hazard analysis is likely to be beyond the technical capabilities of some FBOs, but an approach that focuses on FBOs knowing what the hazards are or what procedures are critical to achieving safe food may be sufficient.

- ii. **Whether the current approach in the General Principles of Food Hygiene (GHPs plus HACCP where needed) remains appropriate or the concept of control measures at other places than CCPs**

(provisionally named enhanced GHPs) should be introduced. Options would include adapting current text to indicate there are some GHP controls that require greater attention, developing new terminology and specific text focusing on control measures at other places than CCPs, and explaining the relationship of the different types of control measure with GHP and HACCP.

The U.S. strongly believes that there are control measures for hazards that apply at places other than CCPs. This is supported by looking at the root causes of some of the food safety issues that have occurred and determining that the issues did not stem from failures at HACCP CCPs but from failures elsewhere in the food safety system. In 2015 FDA published a final rule on “preventive controls” for human food that applies the principles of HACCP more broadly and in a flexible manner to include control measures other than those at CCPs. With respect to the approach taken within Codex, we are prepared to be flexible. However, it is important that this document recognize that while most GHPs are broadly applicable across a facility to minimize hazards and are generally not targeted to controlling a specific hazard, there are measures that have been considered GHPs that are essential for controlling specific significant hazards and that warrant attention similar to that provided at CCPs. Because these measures are critical for food safety, it would be useful to find an approach that includes control measures other than those at CCPs within the HACCP system and use the term “hazard control measures” to include both control measures applied at CCPs and those control measures that target a specific hazard but are not applied at a CCP (as that term is currently defined). If such control measures are incorporated into the HACCP system, it may be best not to use the term “enhanced GHPs,” as this could cause confusion with respect to the relationship between GHPs and HACCP. In our discussions with others we are hearing a strong preference to minimize the incorporation of new terms such as “enhanced GHPs.” One approach could be to revise the term “critical control point” to be “critical control point/procedure (CCP)”; this could be defined as “a step or a procedure at which a control measure can be applied and that is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.” (We could also consider simply using this as a definition for a CCP and explaining that any operation critical to controlling a hazard is termed a CCP, whether it is applied at a specific point during production of the food or at other times.) There would need to be many consequential changes to account for differences in control measures applied at CCPs and those applied at places other than CCPs (listed in the comparison table) if both types of controls are included in a HACCP system (e.g., revisions in paragraph 9 in the HACCP “chapter”). Based on decisions made about such control measures, we will need to revise the comparison table and the decision tree for “enhanced GHPs.”

- iii. **Whether controls for primary production should be addressed by a specific section in the document and/or the document should be developed to strengthen references throughout to demonstrate how the guidance applies at all stages of the food chain.**

The U.S. would like to retain the section in the GHPs on primary production. We believe that food hygiene practices to ensure safe and suitable food begin at primary production. It is unclear how we would address some of the aspects currently covered under primary production in other places in the document (for example, considering potential sources of contamination from the environment and implementing measures to control contamination from soil, fertilizers, pesticides, and veterinary drugs). It may be possible to refer to primary production in later sections with respect to cleaning, maintenance and personnel hygiene at primary production. Another reason to retain this section is to maintain alignment with the other documents that have been promulgated following the format of the *General Principles of Food Hygiene*, in particular the *Code of Hygienic Practice for Fresh Fruits and Vegetables* and the Annex to the *Code of Hygienic Practice on Low-Moisture Foods on Spices and Dried Aromatic Herbs*. We can accept limiting the primary production section to a paragraph or two that captures aspects that would not be considered elsewhere in the GHP “chapter.”

With respect to the format and structure, we suggest that “Chapter” be changed to “Part” so the document consists of an Introduction, Part 1 on Good Hygiene Practices and Part 2 on HACCP. We also suggest retuning to a numbering system similar to that in CAC/RCP 1-1969 (e.g., Section II with subsections 2.1, 2.2, etc.) in order to better follow the structure of the document; this will clarify which “headers” fall within each specific section and allow readers to easily identify the section to which a provision applies. We would also recommend that all paragraphs be numbered sequentially from the beginning to the end of the document rather than starting over with each section to avoid confusion.

While it may be advantageous to align terminology with ISO 22000 where possible, we think it more important that Codex develop a clearly understood document; new ISO terminology could be more confusing than helpful. We agree that CCFH49 should re-look at the use of the terms “food hygiene system” and “food safety system” in the document and consider the term “food safety control system” as used in the Codex validation document. It seems reasonable to consider “food hygiene system” as being broader (focusing on both safety and suitability) and “food safety system” or, preferably, “food safety control system” as the aspect of the system that focuses on food safety. The definitions of these in the document seem appropriate. The document should be reexamined to determine which term to use wherever reference is made to a control system to ensure consistent use of the terms.

SPECIFIC COMMENTS

INTRODUCTION

Paragraph 4:

Recommendation: We suggest using paragraph 4A with minor modifications:

~~{A. 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 without the need for conducting a hazard analysis.}~~
By rReferring to external resources (existing models, references, standards, regulations, or Codes of Practice provided by the competent authority, Codex or food industry), it may be determined that GHPs are sufficient for some FBOs to control all food safety hazards. Yet, since not all hazards pose the same risk, there may be a need to pay particular attention to certain hazards determined as significant **based on information provided by external resources and/or** by a site-specific hazard analysis and to apply [control measures at critical control points (CCPs) and/or at places other than CCPs] **OR [HACCP hazard control measures]** within a Hazard Analysis and Critical Control Point (HACCP) system (see Comparison Table below). FBOs without the resources to carry out a hazard analysis may use external resources ~~as listed above~~ or generic HACCP plans provided by the competent authority or food industry **sectors**, subject to adaptation to the site}.

Rationale: We do not think it practical for all FBOs to conduct a hazard analysis (even a “basic” hazard analysis). This paragraph would eliminate the text specifying that a basic hazard analysis is needed to determine whether GHPs are sufficient but retains guidance for small and less developed businesses (SLDBs) related to resources for controlling hazards. We believe that the external resources not only provide information that GHPs are sufficient, but also can indicate when GHPs are not sufficient and a HACCP system should be applied. External resources are also useful in providing guidance on the need for a site-specific hazard analysis. We have retained square brackets with respect to the term to use – “hazard control measures” or “control measures at critical control points (CCPs) and/or at places other than CCPs” – pending further discussion. We support defining “hazard control measures” as “control measures for significant hazards applied at critical control points (CCPs) and/or at places other than CCPs.” (However, note our previous comments about the definition of CCP.)

GENERAL PRINCIPLES

Paragraph 14:

Recommendation: We suggest removing the square brackets from “significant hazard” in principles (iv) and (v) and around “specific” in principle (v). We also recommend adding “by the FBO” in principle (iv) after “controlled.” These changes are as follows:

(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 **by the FBO** to ensure food safety.

(v) ~~{Significant hazards}~~ should be controlled by ~~{specific}~~ control measures.

Rationale: We support the use of the term “significant hazard” to refer to those hazards identified through a hazard analysis as reasonably likely to occur in the absence of control and needing specific control measures at CCPs and/or at places other than CCPs (in a food safety plan such as a HACCP plan). We think it useful to specify that the controls are applied by the food business operator.

DEFINITIONS

Recommendation: We support putting all definitions from the document in this section. In general we are not identifying definitions or commenting on many definitions at this time pending the outcome of discussions at CCFH49.

Rationale: We think having all definitions in one place shows a better integration of the former HACCP annex into the document and is less confusing.

GOOD HYGIENE PRACTICES

Introduction

Paragraph 2:

Recommendation: This paragraph will need modification if we decide to include control measures other than those at CCPs within the HACCP system. We are not providing changes until a decision has been made on the approach.

PRIMARY PRODUCTION

Recommendation: Retain the existing box with Objectives and Rationale. Retain the text in sections 3.1 (Environmental Hygiene) and 3.2 (Hygienic Production of Food Sources), with modification as needed (e.g., omit reference to an annex on HACCP). We are not opposed to changing sections 3.1 and 3.2 into a paragraph.

Rationale: As noted previously, we think food hygiene at primary production contributes to safe and suitable food.

SECTION 1: ESTABLISHMENT DESIGN AND FACILITIES

Paragraph 5:

Recommendation: Revise the sentence that introduces the bullets and the second bullet as follows:

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 ~~unless sufficient safeguards are provided~~;
- areas prone to infestations of pests; and
- areas where wastes, either solid or liquid, cannot be removed effectively.

Rationale: While it is desirable to locate food establishments away from specific areas, in many cases controls can be put into place to address the potential for contamination; this is not limited to areas subject to flooding.

Paragraph 6:

Recommendation: Revise as follows:

~~[Site boundaries should be clearly defined. Landscaping near a food facility should be properly designed to minimise attractants and pest harbourage. Where necessary, experts **knowledgeable in this area** should be consulted for advice on appropriate plants for use in landscaping.]~~

Rationale: We deleted the first sentence since it is unclear how defining site boundaries is related to food hygiene. We have revised the last sentence to address our concern that many landscaping experts may not be knowledgeable about plantings to minimize problems from pests of concerns to food establishments.

Paragraph 12 Header:

Recommendation: Remove the square brackets:

Drainage [and waste disposal]

Rationale: Paragraphs 12-14 are about both drainage and waste disposal. This also retains the header in the current *General Principles of Food Hygiene*.

Paragraph 13:

Recommendation: Delete the text in square brackets in the second sentence as follows:

The waste ~~[collection]~~ disposal site should be located away from the food establishment to prevent pest infestation.

Rationale: Waste collection often takes place inside a food establishment prior to disposal.

Personnel hygiene facilities and toilets

Paragraph 16:

Recommendation: Revise as follows

Adequate personnel hygiene facilities **and toilets** should be available in order that an appropriate degree of personal hygiene can be maintained and to avoid contaminating food.

Rationale: The header suggests that toilets are separate from “personnel hygiene facilities” but the term “toilets” does not appear in the text. The text refers to “lavatories” which are rooms with a toilet and a sink. We suggest adding “toilets” as indicated or consider adding text on toilets.

Paragraph 25:

Recommendation: Revise as follows:

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 (**where necessary**) and maintained to avoid the contamination of food.

Rationale: Text moved to make it clear that “where necessary” applies only to “disinfected” and not also to “being maintained to avoid contamination.” Other changes minor editorial changes.

CONTROL OF OPERATION**Paragraphs 28-33 and paragraphs 36-37:**

Recommendation: We recommend that CCFH49 discuss these paragraphs in the GHP part that deal with FBOs documenting details about the product and process, including developing a flow diagram, monitoring procedures, preventive and corrective actions and verification and validation. We recommend that these paragraphs be deleted.

Rationale: These are activities that have been associated with HACCP. HACCP is about focusing attention on significant hazards. While some aspects covered here are reasonable for any FBO to consider, documentation (while ideal) may not always be needed. Moreover, applying the same activities, and having to document them, for GHPs and in developing a HACCP plan blurs the distinction between what applies for a GHP and what applies to significant hazards in HACCP; this could dilute the focus on food safety. The “basic hazard analysis” in paragraphs 36-37 is only marginally simpler than the hazard analysis in HACCP. In addition, the paragraphs go beyond hazard analysis and essentially apply the HACCP principles to “enhanced GHPs,” which argues for finding an approach to integrate these controls into the HACCP part.

CONTROL OF FOOD HAZARDS**Paragraph 34:**

Recommendation: Revise as follows:

GHPs control ~~most~~ **many** food hazards which may ~~contaminate~~ **be introduced into** food products, e.g. though food handlers, incoming raw materials or other ingredients or the work environment.

Rationale: We question whether GHPs actual control most food hazards, especially when these come in with raw materials and other ingredients. GHPs function best to prevent the introduction of contaminants.

Paragraphs 36-37:

Recommendation: See comments for paragraphs 28-33. We recommend that this part focus on verification of GHPs and taking corrective actions as appropriate.

KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

Recommendation: Revise the header as follows:

KEY ASPECTS OF FOOD HYGIENE CONTROL SYSTEMS

Rationale: Editorial

Paragraph 40:

Recommendation: Revise as follows:

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

Rationale: Temperature devices for monitoring, as well as those that record, should be checked for accuracy, and calibrated when the accuracy check indicates a need to do so.

Paragraph 42:

Recommendation: Revise as follows

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~~ **acceptable** limits.

Rationale: This paragraph refers to specification for safety and suitability; the term “critical limits” is commonly associated with HACCP.

Paragraph 43:

Recommendation: Revise as follows

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

Rationale: This paragraph seems to suggest that all microbial contamination is from one food to another, when frequently the contamination is from the food processing environment.

Paragraph 44:

Recommendation: Revise the first sentence as follows

In some food operations, access to processing areas may need to be restricted or controlled **for food safety purposes**.

Rationale: Explain why access may need to be controlled.

Paragraph 46:

Recommendation: Revise as follows:

Systems should be in place to prevent contamination of foods by foreign bodies **extraneous materials, especially** such as ~~insects, glass, metal shards and any hard and~~ **or** sharp object(s) e.g. **glass, metal shards**, 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 **(e.g., breakage of glass or plastic containers, metal equipment)**.

Rationale: Since bones are not foreign bodies, a term such as extraneous materials is broader. Glass and metal shards are also hard, sharp objects, so sentence was rearranged. Insects were deleted because of the way the text was revised to focus on hazardous physical contaminants (they are not hard or sharp). Clarified “breakage.”

Paragraph 47:

Recommendation: Add the following:

Systems should be in place to prevent contamination of foods by harmful chemicals. **Toxic cleaning compounds, disinfectants, and pesticide chemicals should be identified, stored and used in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials. Food additives that may be harmful if used improperly should be controlled so they are only used as intended.**

Rationale: Provide additional text on chemical contamination.

Paragraph 48:

Recommendation: Revise as follows:

~~{Hazard identification~~ **FBOs** 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~~ **of foods that are or that contain 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-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 **despite GHPs**, consumers should be informed.}

Rationale: Clarification. It is the FBO that identifies the hazards and takes allergens into account. Not all cereal grains are food allergens; if the desire is to keep an example from this type of food, we suggest including “wheat.” In the last sentence, we are concerned that labeling could be used as a substitute for poor GHPs. We strongly believe that precautionary labeling should be limited to those situations in which allergen cross-contact cannot be assured even with rigorous GHPs. (Note, the U.S. prefers the term “cross-contact” to “cross-contamination” with respect to food allergens because allergens are foods that present no risk to most consumers.)

Paragraph 49:

Recommendation: Revise as follows:

Only raw materials and other ingredients that are fit for purpose should be used. **Where appropriate, specifications for raw materials and other ingredients should be identified and applied.** ~~Incoming materials including food ingredients should be purchased~~~~[procured]~~ according to specifications and their **Compliance of incoming materials** with food safety and suitability specifications should be verified **where necessary.** ~~Incoming Raw materials or other 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 other 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 **other** ingredients should be subject to effective stock rotation.

Rationale: Not all ingredients need purchase specifications. Thus, we prefer the sentence about specifications in the existing GPFH document. We do not think that all sorting and processing should be referred to as “controls.” We have made editorial changes to use consistent terminology – raw materials are ingredients, but not all ingredients are raw materials.

Paragraph 51:

Recommendation: Delete “or clean.”

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 **be** water of a higher standard.

Rationale: This paragraph should be limited to the requirements for potable water. The next paragraph covers non-potable water. We may add specific text related to clean water at a later date if needed, pending information from FAO/WHO.

Paragraph 57:

Recommendation: Delete square brackets around “in direct contact with food.”

Rationale: Only ice that directly contacts food needs to be made from potable water.

Paragraph 59:

Recommendation: Revise last sentence as follows:

Documentation can enhance the credibility and effectiveness of the food safety control system and demonstrate that all reasonable care and due diligence ~~has~~ **have** been taken to protect the health of consumers

Rationale: Editorial

SECTION III: ESTABLISHMENT MAINTENANCE, SANITATION AND PEST CONTROL

Box with Objectives

Recommendation: Change the order of bullets 2 and 3 and revise to read as follows:

- control pests;
- monitor effectiveness of maintenance, ~~cleaning~~ **sanitation** procedures and pest control; and

Rationale: The bullet on controlling pests should come before the one on nonrioting pest control. The Section title uses “sanitation,” which we consider to include both cleaning and disinfection; both should be monitored for effectiveness. We think that the term “sanitation” should be added to the definitions rather than being clarified in the text since the term is used in multiple places.

Paragraph 62:

Recommendation: Revise bullet number 1 as follows:

- facilitate all sanitation (**i.e., cleaning and, where appropriate, disinfection**) procedures

Rationale: To emphasize that sanitation includes both cleaning and, where appropriate, disinfection.

Paragraph 63:

Recommendation; Remove the square brackets around “including with allergens.”

Rationale: We think that it is critical the cleaning remove residues that are food allergens.

Paragraph 67

Recommendation: Revise as follows:

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 **solutions of** detergents, alkalis or acids.

67 bis. 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.

Rationale: Editorial and to provide a better lead in for paragraph 68 on wet cleaning.

Paragraph 68

Recommendation: Revise as follows:

Cleaning procedures will involve, where appropriate:

- removing gross visible debris from surfaces;
- applying a 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; ~~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.

Rationale: The last bullet on disinfection is not part of cleaning.

Paragraph 69

Recommendation: Revise as follows:

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.**

Rationale: Correct typographical error.

Paragraph 70

Recommendation: Add “and disinfection” and revise bullets as follows:

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.

Rationale: Include information on disinfection.

Paragraph 71

Recommendation: Revise as follows:

Sanitation programmes should be monitored for effectiveness and periodically verified by means such as audits or pre-operational inspections. **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.** Where appropriate, microbiological sampling and testing of the environment and food contact surfaces should be carried out to verify the effectiveness of ~~cleaning~~ **sanitation** 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.

Rationale: Provide additional examples of monitoring procedures for sanitation programs.

SECTION IV: PERSONAL HYGIENE

Box with Objectives

Recommendation: Revise bullet 2 to change “maintaining” to “maintain.”

- ~~maintaining~~ an appropriate degree of personal cleanliness; and

Rationale: Consistency with the other bullets.

Paragraph 83

Recommendation: Revise last sentence as follows:

If gloves are worn, appropriate measures ~~will~~ **should** ~~also need to~~ be applied to ensure the gloves do not become a source of contamination.

Rationale: Editorial

Paragraph 84

Recommendation: Revise sentence leading into bullets as follows:

Personnel should ~~clean and, when appropriate,~~ wash their hands regularly, especially when personal cleanliness may affect food safety, in particular:

Rationale: We believe that the way to clean hands is by washing them (not just wiping them off); for the activities listed in the bullets that follow this statement, washing hands is appropriate.

Paragraph 88

Recommendation: Revise as follows:

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 **this section** ~~paras 79-87.~~

Rationale: Editorial. Paragraph numbers will be removed in the final text.

SECTION VI: PRODUCT INFORMATION AND CONSUMER AWARENESS

Box with Objectives

Recommendation: Add a new bullet as the second bullet:

- **allergic consumers can identify allergens present in foods; and**

Rationale: This is critical information that should be provided to consumers.

Box with Objectives

Recommendation: Add a sentence at the end of the Rationale in the box:

Insufficient product information about the allergens in a food can also result in allergic consumers becoming ill.

Rationale: Explains why consumers need information about allergens in a product.

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

PREAMBLE

Recommendation: Change “Preamble” to “Introduction” and incorporate all HACCP introductory text here. (We have not made these extensive revisions at this time.)

Rationale: For consistency in format in the document overall and to consolidate introductory information and reduce redundancy.

Paragraph 4

Recommendation: Revise the 3rd and 4th sentences as follows:

~~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.~~

Rationale: We do not see a need to refer to quality management systems and we disagree with the application of HACCP beyond food safety.

DEFINITIONS

Recommendation: move all definitions to a single section in the Introductory part of the document. We support developing a definition of “hazard control measure” and broadening the term “control measure” to address measures applied for suitability as well as safety. We also recommend defining the term “significant hazard” and revising the definition of “corrective action”. Other definitions will also need to be provided once an agreed approach is determined.

[Hazard control measure]: **a control measure for a significant hazard applied at a CCP and/or at places other than CCPs.**

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.~~ **maintain compliance with GHP and HACCP procedures.**

Corrective action: Any action ~~to be taken when the results of monitoring at the CCP indicate a loss of control.~~ **a deviation occurs in order to correct the problem and minimize the potential for it to reoccur.**

Significant hazard – a hazard identified through a hazard analysis as reasonably likely to occur in the absence of control and needing specific control measures at CCPs and/or at places other than CCPs.

Rationale: Having all definitions in a single section of the document shows a better integration of the former HACCP annex into the document and is less confusing, allowing readers to more easily find a definition. Moreover, some definitions apply in more than one part of the document. A more general definition for corrective actions that captures any action that is taken when there is a problem, not just when monitoring at a CCP indicates loss of control, is appropriate for this document. GHP implementation can also require corrective actions. Similarly, control measures apply within GHPs as well as HACCP, and can apply to controls related to suitability as well as for food safety hazards.

Paragraph 8

Recommendation: Revise to include food production practices.

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 production practices**, food manufacturing practices **(including whether manufacturing processes control hazards or result in hazards**

requiring control), ~~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.

Rationale: As written, the paragraph seems limited to manufacturing operations. The practices involved in primary production, including the controls applied, should be considered during hazard analysis. Manufacturing processes can be a source of hazards requiring control, as well as providing controls for hazards.

Paragraph 11

Recommendation: In the second sentence, change “food business operators” to “FBOs” and “individual business” to “individual businesses.” Remove the square brackets from “size.”

Rationale: When applying flexibility, it is important to consider both the nature and size of the operation. Other changes are editorial.

Scope

Recommendation: Delete or incorporate into a revised “Introduction for the HACCP “chapter.”

Rationale: This text appears to be misplaced. It says the section sets out the seven principles of the HACCP system, but the principles appear prior to this. It is also redundant with respect to flexibility, which was covered in the 3 previous paragraphs.

Paragraph 17

Recommendation: Change “regulatory authorities” to “competent authorities” in the first sentence. Change “and” to “but” in the last sentence.

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 **competent** 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~~ **but** should be tailored to the food operation.

Rationale: Editorial. The term “competent authority” is used in many places elsewhere in the document.

Paragraph 19

Recommendation: Revise the last sentence as follows:

Any limits already established for food safety hazards should be considered and accounted for in the HACCP plan, e.g. **limits for food additives and times and temperatures for heat treatments prescribed by competent authorities** ~~[insert example].~~

Rationale: provides examples of established limits not specific to requirements by an individual country.

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

Recommendation: Revise this section on hazard analysis as follows:

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)

(SEE PRINCIPLE 1)

23. 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 **potential** hazards that may be reasonably expected 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.**

24. The HACCP team should next ~~conduct a~~ **evaluate the** hazards analysis to identify which of the potential hazards are ~~present at unacceptable levels~~ **of such a nature** so that their 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).**

24 bis. 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 ~~included~~ **considered**:

- hazards historically associated with the type of food or its ingredients (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;
- the likely occurrence of hazards and severity of their adverse health effects;
- the nature of the equipment used in making a food product;
- ~~the qualitative and/or quantitative evaluation of the presence of hazards ;~~
- survival or multiplication of microorganisms of concern;
- production or persistence in foods of toxins (e.g., mycotoxins), chemicals (e.g., pesticides, drug residues) or physical agents (e.g., glass, metal);
- potential contamination of food from exposure to the processing environment and,
- conditions leading to the above.

24 tris. 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 flavoring a dip for chips) to determine the significant hazards to be addressed in the HACCP plan.

25. [In some cases, it may be acceptable for a ~~more basic~~ **simplified** 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 that identifies the specific hazards of concern**. Generic HACCP-based tools **and guidance documents** 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 (**because they are reasonably likely to occur in the absence of control**) 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~~ control measures, some of which may ~~need to be~~ good hygiene practices enhanced to 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.** ~~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 **[hazard]** 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. **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.**

Rationale: To provide additional guidance on conducting a hazard analysis. Clarifies that hazard analysis consists of hazard identification and hazard evaluation to determine which hazards need to be addressed in a HACCP plan (“significant hazards”). (We have left paragraph 25 in for now, but would support its deletion.)

Determine Critical Control Points (Step 7)

Recommendation: Revise this section to include determining critical procedures that are essential for the safety of the food but are not applied at critical points during production. We are not providing specific text at this time, pending agreement by CCFH on the desired approach.

Rationale: As noted previously, we strongly believe that there are hazard control measures that are not applied at CCPs. We think it may be less confusing to acknowledge these within the HACCP system.

Establish critical limits for each CCP (Step 8)

Recommendation: Revise paragraph 30 as follows:

30. Critical limits that separate acceptable procedures and products from unacceptable ones 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 (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, Aw, available chlorine, contact time, conveyor belt speed, and, where appropriate, ~~sensory parameters which can be observed, such as~~ a pump setting ~~visual appearance and texture.~~

Rationale: To clarify that the limits involve values for parameters such as temperature, etc. In general, sensory parameters are not true critical limits for safety; although color and texture can be measured objectively, they generally are used for quality and not safety. We have substituted a pump setting as an observable critical limit – it serves as a means of monitoring a flow rate (time) once the pump setting have been correlated to flow rate.

Establish a monitoring system for each CCP (Step 9)

Recommendation: Revise this section as follows:

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 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 they may be done rapidly and can often indicate the ~~microbiological control of~~ microbial hazards associated with the product.

34 bis. 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.

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 as a verification of control (see Step 11).

Rationale: To clarify and provide additional information. The last sentence in paragraph 34bis was moved from paragraph 33.

Establish corrective actions (Step 10)

Recommendation: Revise this section as follows:

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

37. The corrective actions used to address the deviation should ensure that the CCP has been brought under control. Actions taken should include segregating the affected product and analyzing the safety of the product to ensure proper disposition 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-pasteurized); in other situations the product may need to be destroyed (e.g., contamination with *Staphylococcus enterotoxin*) and identify the root cause of the loss of control to prevent a recurrence. 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, actions taken to correct the deviation, and product disposition procedures should be documented in the HACCP record keeping. ~~identify the root cause of the loss of control to prevent a recurrence.~~ Periodic review of corrective actions should be undertaken to identify trends and to ensure corrective actions are effective.

Rationale: To provide additional guidance.

Establish verification procedures (Step 11)

Recommendation: Revise this section as follows:

38. Establish procedures for verification of the ~~HACCP system as a whole, as well as individual~~ **hazard control measures, as well as the HACCP system as a whole. Verification includes validation, i.e., obtaining scientific and technical evidence that hazard control measures are capable of controlling a hazard, as well as 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, 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. ~~Verification also includes reviewing the adequacy of the HACCP system periodically and, as appropriate, when changes occur.~~**

38 bis. Validation is performed during development of the HACCP plan, and, in addition to obtaining the evidence that the control measures are capable of controlling the hazard, 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 harbors developed by authoritative sources. Validation is also done on a periodic basis when the plan is reanalyzed 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 (CAC/GL 69 – 2008)*.

~~38 tris.~~ 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. **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. Examples of verification activities include:

- Review of the **[CCP] [hazard control measure] monitoring records to confirm that hazard control measures, particularly those at CCPs, are kept under control;**
- Review of **corrective action records, including specific deviations, and product dispositions and any analysis to determine the root cause of the deviation;**
- **Calibration or checking the accuracy of instruments used for monitoring and verification;**
- Confirmation **Observations** that **hazard** control measures, particularly those at CCPs, are kept under control; and **being conducted in accordance with the plan;**
- Microbiological ~~s~~ **Sampling and testing, e.g., to verify product safety for microorganisms³ or chemical hazards such as mycotoxins;**
- **Sampling and testing the environment for microbial contaminants such as *Listeria*; and**
- **Review of the HACCP system, including the hazard analysis and the HACCP plan (e.g., internal or third-party audits).**

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.

39bis. 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.

40. Where possible, 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 (e.g. through an audit of the HACCP system). **This review of the HACCP system should confirm that the appropriate 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**

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

actions are appropriate for deviations that have occurred. This review can be carried out by individuals within a food business or by external experts.

Rationale: To provide additional guidance and better explain verification and validation. The U.S. can provide a diagram to illustrate initial validation, ongoing verification and review (the 3 components we see as verification).

Establish documentation and record keeping (Step 12)

Recommendation: Revise paragraphs 42 and 43 as follows:

42. Examples of documentation include:

- Hazard analysis;
- CCP determination;
- Critical limit determination;
- **Validation of hazard control measures; and**
- **Modifications made to the HACCP plan.**

43. Examples of records include:

- CCP monitoring activities
- Deviations and associated corrective actions; **and**
- Verification procedures performed.

Rationale: While records are a form of documentation, the examples seem to be divided into supporting information for the HACCP plan (which we think is also documentation) and the implementation records. We think the information on validation of hazard control measures should be included, as this may go beyond determination of critical limits and include determination of other critical factors needed to ensure control. Reanalysis of the HACCP plan and any modification made are more appropriate in the documentation examples than in the examples of records.

TRAINING

Paragraph 46

Recommendation: Revise the first sentence as follows:

Training of personnel in industry, government and academia in HACCP principles and applications ~~and increasing awareness of consumers~~ **is an** essential elements for the effective implementation of HACCP.

Rationale: We do not agree that increasing awareness of consumers is an essential element for effective implementation of HACCP.

Uruguay

General comments:

Uruguay believes the document should be clear and easily-accessible for stakeholder use and understanding.

To this end, we underscore the importance of the document including examples and hyperlinks to access official documents mentioned throughout the document (through the Codex website: www.fao.org/fao-who-codexalimentarius). This will promote access to the information in other Codex documents, as well as FAO and WHO guidelines.

Given the complexity of the document, our comments will cover the first chapter, through paragraph 78.

1. With regard to the matters proposed in paragraphs 8 and 9 of the eWG Report (CX/FH 17/49/5):

8 i. All businesses should complete a hazard analysis and, if so, how this can be adapted so it is appropriate to the nature and size of the business and whether GHP-based or HACCP-based and food safety control systems are being applied.

Uruguay believes that all links in the food chain should have a control system based on the identification and assessment of the hazards associated with their type of production. It may not be necessary for the organization itself (depending on its nature and size, among others) to do this; they may use sector-generic hazard identification and assessment, with the endorsement of the relevant competent official body for the sector in question.

8 ii. The current approach in the General Principles of Food Hygiene (GHPs plus HACCP where needed) remains appropriate or the concept of control measures at other places than CCPs (provisionally named enhanced GHPs) should be introduced. Options would include adapting current text to indicate there are some GHP controls that require greater attention, developing new terminology and specific text focusing on control measures at other places than CCPs, and explaining the relationship of the different types of control measure with GHP and HACCP.

Uruguay feels it would be appropriate to include the concept of “control measures at other places than CCPs (provisionally named enhanced GHPs)” and clearly explain the concept of the different types of control measures to avoid confusion between the two. We suggest providing specific, practical examples for ease of understanding.

8 iii. Controls for primary production should be addressed by a specific section in the document and/or the document should be developed to strengthen references throughout to demonstrate how the guidance applies at all stages of the food chain.

Uruguay feels that, if it is necessary to make specific clarifications for a certain sector or stage of the food chain, “the document should be developed to strengthen references throughout to demonstrate how the guidance applies at all stages of the food chain.”

9. There is also a need to consider the format and structure of the document to reach agreement on the extent to which this should be revised and aligned with other documents such as ISO 22000. Terminology and definitions should be considered further as the text develops to ensure these are consistent and well defined, for example, the term ‘food hygiene system’ (which was agreed at CCFH48) is causing confusion and this could either be defined or replaced by ‘food safety control system’ a term which has been defined in the Codex validation document.

Regarding this point, Uruguay believes it would be appropriate to migrate to more modern safety management systems, which would foster standardization and, thus, facilitate the use of these internationally-recognized documents.

Regarding the example posed, we prefer replacing “food hygiene system” with “food safety control system.”

2. Uruguay prefers replacing the Spanish term “idóneo” or “idoneidad” with “**apto**” [Translator’s note: this is not applicable to the English version] or using “**authentic**” as it is more common and more easily-understood.

Definition of authentic food in Decree 315/1994 on the National Bromatological Regulation: 1.1.21
“Authentic food. Food deemed to be an authentic product. Its sensory characteristics, ingredients, and nutritional value should reflect those typical of the type of food in question and its designation, packaging, labelling, and presentation shall comply with the regulation.”

3. Throughout the document, good hygiene practices (GHPs) are confused with prerequisite programmes (PRPs). The text should clarify at some point that GHPs consider prerequisite programmes, including the GMPs, GAPs, good dairy farming practices, among others.

This is seen in paragraph 4 (A and B), which includes GHPs, GMPs, and GAPs as part of the prerequisite programmes.

Uruguay believes that when the document mentions GHPs, it refers to PRPs.

Specific comments

INTRODUCTION

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. [Translator’s note: the change in Spanish does not affect the English.]

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.

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~~ **authenticity***. Taking into account the point in the food chain; the nature of the ~~operation~~ **activity**; 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.

4. Define what the prerequisite programmes include:

“Prerequisite Programmes (PRPs), which include Good Hygiene Practices (GHPs), Good Manufacturing Practices (GMPs), and Good Agricultural Practices (GAPs), **among others, depending on the link of the chain in question**, as appropriate, lay the foundation for producing safe and ~~suitable~~ **authentic** food.”

Uruguay feels that the wording of paragraph 4, options A and B, is not clear, in part due to what was mentioned in the previous paragraph.

OBJECTIVES

7. The *General Principles of Food Hygiene: ~~Good Hygiene Practices (GHPs)~~ The Prerequisite Programmes (PRP) and the Hazard Analysis and Critical Control Point (HACCP) System* aim to:

- provide principles and guidance on the application of ~~good hygiene practices~~ **prerequisite programmes** applicable throughout the food chain to provide food that is safe and suitable for consumption;
- clarify the relationship between GHPs and HACCP, taking account of the size and nature of the food business ~~activity operation~~ and the level of food safety risk; and

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 **throughout the entire food chain in the manufacture of food products** and recommending, where appropriate, specific food safety control measures at certain steps throughout the food chain.

USE

General comments

9. The document is intended for use by food business operators (including primary producers, manufacturers/processors, food service operators and retailers), **see definition**, and competent authorities, as appropriate. [Translator's note: the change in Spanish from "incluso" to "incluyendo a" does not affect the English.]

GENERAL PRINCIPLES

(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~~ **significant hazards** that should be controlled to ensure food safety.

(v) ~~Significant hazards~~ **Significant hazards** should be controlled by ~~specific~~ control measures.

(vii) The application of control measures should be subject to monitoring **or follow-up**, corrective actions, verification, and documentation, as appropriate. [Translator's note: the change in Spanish from "medidas" to "acciones" does not affect the English.]

(viii) Food ~~hygiene~~ **safety control** systems should be reviewed periodically and when there is a change in the food business **to determine if modifications are needed** (e.g. new process, new ingredient, new product, new equipment) ~~to determine if modifications are needed~~.

Definitions

Consider broadening the definition of **FBO (food business operators)** to include all organizations involved in food production and whether they include providers along the food chain (cleaning services, chemicals, etc.) and animal feed producers.

PRP (Prerequisite Programme)

ANNEX I Proposed Decision Tree to Identify [Enhanced GHPs]

Uruguay feels it would be very useful to include a decision tree at this stage.

The proposal is not understood and leads to confusion, e.g. by answering NO to P1 and P3, it takes you back to the beginning without explaining what to do.

[CHAPTER ONE]

GOOD HYGIENE PRACTICES

Introduction

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**.

Uruguay suggests clarifying the term “settings,” as it is not clear.

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~~ **guarantees** are provided;
- areas prone to infestations of pests; and
- areas where wastes, either solid or liquid, cannot be removed effectively.

6. ~~Site boundaries should be clearly defined. Landscaping near a food facility should be properly designed to minimise attractants and pest harbourage. Where necessary, experts should be consulted for advice on appropriate plants for use in landscaping.~~

Equipment

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. [Translator's note: the change in Spanish does not affect the English.]

Internal structures and fittings

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

Temporary/mobile food establishments and vending machines. [Translator's note: the change in Spanish does not affect the English.]

FACILITIES

Drainage ~~and waste disposal~~

12. Adequate drainage and, waste disposal systems and facilities should be provided and well maintained. [Translator's note: the change in Spanish does not affect the English.] 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. [Translator's note: the change in Spanish does not affect the English.] The waste [collection and] disposal site should be located away from the food establishment to prevent pest infestation. [Translator's note: the change in Spanish does not affect the English.] Containers for waste, by-products and inedible or hazardous substances, should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material, **allowing for washing and disinfection**.

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. [Translator's note: the changes in Spanish do not affect the English.]

Cleaning facilities

15. Adequate, suitably ~~designated~~ **designed** facilities should be provided for cleaning ~~[food]~~, utensils and **equipment** [Translator's note: the changes in Spanish do not affect the English.] 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 [Translator's note: the change in Spanish does not affect the English.]
- adequate changing facilities for personnel.

17. Such facilities should be **suitably located and designated**. [Translator's note: the change in Spanish does not affect the English.] Where necessary, separate sinks **and basins** should be available for hand washing and food washing.

Air quality and ventilation

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. [Translator's note: the change in Spanish does not affect the English.]

Storage

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. [Translator's note: the change in Spanish does not affect the English.]

EQUIPMENT [Translator's note: the change in Spanish does not affect the English.]

Uruguay suggests replacing "**equipo**" with "**equipamiento**" throughout this section in Spanish.

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. [Translator's note: the change in Spanish does not affect the English.] Equipment and containers should be made of materials that are non-toxic according to intended use. Where necessary, equipment should be **durable resistant** 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 **to promote** ~~in the interests of~~ food safety and suitability, and **to** maintain the **temperatures** effectively. ~~Where appropriate, equipment should be calibrated to ensure that food processes are monitored consistently and accurately.~~ **Where appropriate, equipment should be calibrated to ensure that temperatures are accurately measured in food processes.** ~~that food processes are monitored consistently and accurately.~~

SECTION II: CONTROL OF OPERATION

Validation of GHP:

Uruguay deems it necessary to include the following paragraph, which would shift the numbering for the subsequent paragraphs:

Food business operators should validate the GHPs/control measures, prior to application, to ensure that they are capable of achieving the necessary control of identified hazards. Each food business will select

its validation methodology, according to the "Guidelines for the Validation of Food Safety Control Measures CAC/GL 69-2008." The defined methodology should be documented and the outcomes obtained from validation activities should be recorded.

6—

7 **Preventative and Corrective actions** [Translator's note: the change in Spanish does not affect the English.]

8

9 Uruguay suggests moving paragraph 32, on Preventative and Corrective Actions, to follow paragraph 33, on Verification of GHP.

10

11 ~~32.~~ **33.** The FBO should document preventative and corrective action procedures as relevant to the business, which are implemented when a non-compliance is identified. [Translator's note: the change in Spanish does not affect the English.] 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 [Translator's note: the change in Spanish does not affect the English.]
- records to be kept. [Translator's note: the change in Spanish does not affect the English.]

12

13 **Verification of GHP**

14 ~~33.~~ **32.** 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. [Translator's note: the change in Spanish does not affect the English.] Procedures could include:

- who is responsible;
- ~~review~~ **review proposed verification methodology** for ~~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. [Translator's note: the change in Spanish does not affect the English.]

15

16 **34.** GHPs control most food hazards which may ~~contaminate~~ **contaminate** food products, e.g. though 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.

17

18 **35.** Where significant food safety hazards are identified, and a more targeted approach is necessary, ~~hazard-specific~~ control measures **for the hazards identified** 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*. [Translator's note: the change in Spanish does not affect the English.] These 'enhanced' GHPs should be subject to monitoring, **validation, verification**, corrective actions and ~~verification~~ and where appropriate, be documented.

19

20 **36.** [FBO should control food hazards through a basic hazard analysis system, **developed by the FBOs**

themselves (depending on their nature and size, among others) or use models applicable to the sector, with the endorsement of the relevant competent official body, that involves:

21 i. Describing the Product;

22 ii. Applicable regulatory requirements;

23

24 iii. Identifying the intended usage – Ready to eat or as a material [product] that would undergo further processing;

25 iv. Constructing a flow chart;

26 v. Conducting a basic hazard analysis for identifying the food safety hazards as microbiological, chemical or physical at each step of the flow chart;

27 vi. Identifying and defining the Good Hygienic Practices for controlling these hazards;

28 vii. Categorizing the GHP controls as generic or hazard-based controls to be managed as either Enhanced GHPs or by application of principles of HACCP using a Decision Tree Model as given in [Annex I to the introduction].

29 viii. Validating / effectiveness of the Enhanced GHPs: Enhanced GHPs should be validated to obtain evidence that GHP control measures are capable of controlling hazards. FBOs may not always need to commission studies themselves to validate GHP control. They could be based on existing literature, guidance from competent authority or carried out by a third party e.g. cleaning products validated for effective use by the manufacturer etc. (Aligned with new text created in the Section II for HACCP).

30 ix. Establishing a GHP Plan for monitoring, initiating corrective actions, verification of GHPs and Enhanced GHPs.] **To study with the group**

31

32 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; [Translator's note: the changes in Spanish do not affect the English.]
- the intended shelf-life of the product; [Translator's note: the change in Spanish does not affect the English.]
- the method of packaging and processing; and
- how the product is intended to be used, e.g. further cooking/processing or ready-to-eat.

33

34 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.

35

36 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. [Translator's note: the change in Spanish does not affect the English.]

37

38 Microbiological cross-contamination

39 43. Microbiological contamination occurs through 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. [Translator's note: the changes in Spanish do not affect the English.]

40

41 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. [Translator's note: the changes in Spanish do not affect the English.]

42

43 Allergenic Contamination

44

45 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. [Translator's note: the change in Spanish does not affect the English.] 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).]

46

47 INCOMING MATERIALS RECEIPT OF MATERIALS

48

49 49. Only raw materials and other ingredients that are fit for purpose should be used. ~~Incoming~~ **Received** materials including food ingredients should be ~~purchased~~ **[procured]** according to specifications and their compliance with food safety and suitability specifications should be verified. ~~Incoming~~ **Received** 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 **not** 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 **stored** raw materials and ingredients should be subject to effective stock rotation.

50

51 Water supply

52 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.

53

54 Ice and steam in direct contact with food

55 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.

56

57 General comments

58 62. Establishments and equipment should be kept in an appropriate state of repair and condition to: [Translator's note: the change in Spanish does not affect the English.]

59 • facilitate all sanitation procedures;

60 • function as intended; and [Translator's note: the change in Spanish does not affect the English.]

61 • 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.

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

68. Cleaning procedures will involve, where appropriate

- 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. [Translator's note: the change in Spanish does not affect the English.] 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.
- **Records of activities kept, where appropriate.**

NOTE: In the Spanish version, replace the word "equipo" with "equipamiento" throughout the entire document. [Translator's note: this is not applicable to the English version.]

PEST CONTROL SYSTEMS

General comments

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 **received** incoming materials and good monitoring can minimize the likelihood of infestation and thereby limit the need for pesticides.

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. [Translator's note: the change in Spanish does not affect the English.]

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]. [Translator's note: the change in Spanish does not affect the English.]

General Comments:

1. This revision will significantly extend the scope beyond 'food hygiene', the umbrella term that includes food safety, which we support: (i) references to management commitment and food safety culture and (ii) integration of hazard control across hygiene and HACCP systems. We therefore suggest that the title be revised (eg General Principles of Integrated Food Safety Control Systems and Management Commitment) to better reflect this evolution. Also, it is requested to harmonize wording across the document.

2. There is an attempt to modernize the HACCP system, which we support: (i) clarifying that GHPs constitute prerequisite programmes to HACCP, (ii) introducing the concept of hazard control measures / hazard control plan, and (iii) recognizing that some hazard control measures may be applied at other places than CCPs. However the way this is structured and the wording used should be re-considered and better aligned with ISO 22000 in order to avoid divergence of terms and concepts:

- 2.1. The terminology and concept of 'basic hazard analysis' can cause confusion with the hazard analysis of HACCP. It is unlikely that FBOs themselves will have the capability to decide, upon a 'basic hazard analysis', whether HACCP is required or not. If HACCP is required, because of laws and regulations, then they will conduct their hazard analysis as part of HACCP. In case where laws and regulations don't specify a particular requirement for HACCP but the type of food combined with the intended consumer would, an FBO may need to draw on external expertise to determine the need for HACCP. Authorities may decide (most likely upon a risk assessment rather than a hazard analysis) whether a FBO (given its sector, its size, etc.) is subject to HACCP
- 2.2. The terminology and concept of 'enhanced GHP' (hazard control measures at other places than CCPs) is confusing. It should be clarified that this type of hazard control measures is for controlling a significant food safety hazard identified by the hazard analysis of HACCP and therefore lays out of the scope of GHPs. Users of ISO 22000 would call it 'OPRP'.
- 2.3. The terminology related to 'control measures' should be harmonized and properly defined as many different terms exist across the documents and seem to refer to the same concept: 'control measures', 'food safety control measures', 'HACCP control measures', 'food hygiene measures'. The term 'control measure' should be limited to those measures identified by hazard analysis and therefore not include GHPs. For the avoidance of any doubt, we suggest to systematically insert the word 'hazard' before.

3. Management-related elements could be grouped in a dedicated chapter: split the 2 chapters 1.GHPs and 2.HACCP into 1.GHPs, 2.HACCP, and 3.Management (include there the management-related elements that are spread across the document 'management commitment', 'management and supervision', 'training')

Specific comments:

INTRODUCTION

Paragraph 4

Retain option B with the following changes:

~~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 basic hazard analysis and an assessment of food hygiene measures, 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 by a site-specific hazard analysis and to apply **hazard** control measures at critical control points (CCPs) and/or at places other than CCPs] ~~OR [HACCP control measures]~~ 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 industry² subject to adaptation to the site.

Paragraph 5

[Chapter One] of this document describes GHPs, which are the basis of all food hygiene **safety control** systems to support the production of safe and suitable food. GHPs can be stand-alone food hygiene measures or ~~prerequisite programmes~~ prerequisite **programmes (PRPs)** to HACCP

[-> these terms to harmonize throughout]

Paragraph 6

The following comparison table shows the relationship of GHPs applied for food safety and suitability and ~~HACCP~~ **hazard** control measures applied to ~~enhance food safety~~ **control significant food safety hazards**

Comparison of GHPs, ~~[Control Measures at Places Other than CCPs]~~ **[Enhanced GHPs]** and HACCP **Hazard** Control Measures

	Good Hygiene Practices (GHPs)	[Control Measures at Places Other than CCPs][Enhanced GHPs]	Control Measures at Critical Control Points (CCPs)
		[After basic hazard analysis [at places other than CCPs][enhanced GHPs]] After Hazard analysis [for control measures at CCPs]	

[-> these terms to harmonize throughout]

Paragraph 9

The document is intended for use by food business operators (including primary producers, manufacturers/processors, **supply chain operators**, food service operators and retailers) and competent authorities

GENERAL PRINCIPLES (between Paragraphs 14 and 15)

- (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] hazard control measures.
- (vi) **Hazard** Control measures ~~that are critical to achieve an acceptable level of food safety~~ should be scientifically validated³
- (vii) The application of **hazard** control measures should be subject to monitoring, corrective actions, verification, and documentation, as appropriate.
- (viii) Food ~~hygiene~~ **safety control** 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.

Paragraphs 15 and 16

Move to a new Chapter 3. Management

Definitions

~~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 system⁴ - The combination of **GHPs and, if appropriate, hazard** control measures that, when taken as whole, ensures that food is safe for its intended use.

~~Control measure~~

Hazard control measure (→ See definition of ISO/DIS 22000)

~~[Basic Hazard Analysis]~~

ANNEX I

Delete the decision chart. A chart may be developed in Chapter 2 to identify the need for hazard control measures and whether the steps where they apply are CCPs or not.

CHAPTER ONE

Paragraph 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 by **hazard control measures** ~~either through application of enhanced GHPs designed to control a specific food safety hazard or, where appropriate, in combination with the application of HACCP.~~

Paragraphs 28-37

These paragraphs make no more sense now that the HACCP is not an annex anymore. To address in Chapter 2.

Paragraph 42

Where [...], such specifications should be based on sound scientific principles and state, where appropriate, monitoring procedures, analytical methods and ~~critical~~ limits

[+ add reference to CAC/GL 21 – “Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods”.]

Paragraphs 59 to 61

Can be moved to Section VI if retitled to “Communication and documentation”

Paragraphs 98 to 102

Move to a new Chapter 3. Management

CHAPTER TWO

This chapter needs to be revised to introduce 2 types of hazard control measures: those applied at CCPs and those applied at other places than CCPs.

IAF (International Accreditation Forum)

General Comments:

The report of the EWG in paragraphs 7, 8 and 9 poses a series of questions and statements. Our responses or comments are as follows:

- IAF supports the inclusion of references to management commitment and food safety culture (para 7) and believes that these elements require further strengthening in the revised text. In addition, we recommend that document structure be further developed to include a chapter 3 that would encompass the proposed elements on management commitment, food culture, training, verification activities and documented information (including records).
- IAF supports the inclusion of the text concerning “Management Commitment” [page 8, para 15 & 16] and suggests that this be further elaborated by including key management system concepts such as structured management reviews, internal audits, systematic analysis of verification results, etc. [See ISO DIS 22000:2017].
- IAF supports, in principle, the principle (page 2, para 8.i.) that “all businesses should complete a hazard analysis”. However, it also agrees with the conclusions drawn in the proposed Chapter Two in the Preamble (page 24) and in the Introduction (page 26), in particular with the statements respecting the application of the HACCP approach by small and less developed businesses (paras 5, 11, and 12). The use of “externally developed combinations of control measures” (ISO 22000:2005) and “externally developed elements” (ISO DIS 22000:2017) based on a rigorously developed generic hazard analysis is an example of this approach.
- IAF supports the use phrase “food safety control system” (page 2 para 8.i.). In doing so it urges the EWG and CCFH to go further than the current text does by incorporating more elements of a food safety management system approach such as that embodied in ISO 22000.
- IAF believes that the EWG could provide additional clarity by revising the definitions used through the document respecting HACCP. For example on pages 26 and 27 alone, the following terms are used:
 - “application of HACCP” (para 6)
 - “HACCP system” (para 6, 7) or “HACCP systems (para 8)
 - “HACCP knowledge and skills” (para 7)
 - “HACCP application” (para 10)
 - “HACCP principles” (para 11)
 - “HACCP plan” (para 12)
 - “HACCP literature”, “HACCP guides”, “HACCP guidance” (para 12)

- “HACCP team” (Heading/Step 1, prior to para 16, 21, 23, 24)
- “Generic HACCP” and “HACCP-based” (para 17)

This the use of the acronym “HACCP” could be significantly simplified if it were modernized and its use confined solely to the concepts set out in the current set of principles. If this approach was taken, then the “HACCP team” would become the “food safety team” and the “HACCP plan would come the “hazard control plan”. These terms would be consistent with proposals to revise ISO 22000.

- IAF supports the use of the phrase “food safety control system”. This would be consistent with the proposed approach to the use of a hazard analysis as a primary activity prior to determining whether or not the final “food safety control system” will be composed only of prerequisite programmes (including GHPs) or of prerequisite programmes and hazard control measures (e.g. CCPs and enhanced GHPs).
- In supporting the use of “food safety control system” IAF suggests that this phrase or variations of its (e.g. “food safety controls”) be used throughout the text instead of “food hygiene practices”. An example would be in the 3rd sentence of para 2 on page 3 where instead of “~~Effective food hygiene practices, therefore are vital to avoid~~” the sentence would read “*An effective food safety control system is vital to avoid*”.
- Adopting this phrase “food safety control system” would also suggest that the title of the document could be changed to “General Principles of Food Safety and the development of Food Safety Control Systems”.
- IAF supports recognizing in the text the concepts of “hazard control measures” page 2, para 8.ii) and “hazard control plan (page 25, definition). The inclusion of two types of “hazard control measures”, those implemented at a step and having clearly defined parameters respecting monitoring (i.e. CCPs) and those “at other places than CCPs” would modernize the Codex toolkit.
- We note that the current text refers to the new type of “hazard control measure” as “enhanced GHPs”. ISO 22000:2005 calls these “Operational Prerequisite Programmes”, which recognizes that they may include control measures that are not strictly “hygiene practices”. The text of the DIS Version of ISO 22000:2017 simply calls them OPRPs and sets out specific parameters for their design. These should be considered by the EWG.
- IAF supports use of the substitute paragraph (Page 4, 4.B.] concerning Prerequisite Programmes.

SSAFE (Safe Supply of Affordable Food Everywhere)

GENERAL COMMENT	While it is considered important to emphasize the added importance of some controls, the terminology of ‘enhanced GHP’ should be re-considered to avoid confusion, especially for those FBOs who are aligned with ISO 22000/22002.	Further alignment in terms of format, structure and definitions to ISO 22000/22002 should also be considered. For example, the notion of food safety control system would be preferred to food hygiene system.
GENERAL COMMENT	This revision will significantly <u>extend the scope beyond ‘food hygiene’</u> , which we support: references to management commitment and food safety culture and more focus on hazard control. We therefore suggest that the title be revised (e.g. General Principles of Food Safety Control Systems) to better reflect this evolution. Also, harmonize wording across the document.	

GENERAL COMMENT	<p>There is an attempt to <u>modernize the HACCP system</u>, which we support: (i) clarifying that GHPs constitute prerequisite programmes to HACCP, (ii) introducing the concept of hazard control measures / hazard control plan, and (iii) recognizing that some hazard control measures may be applied at other places than CCPs. However the way this is structured and the wording used should be re-considered and better aligned with ISO 22000:</p> <p>The terminology and concept of '<u>basic hazard analysis</u>' can cause confusion with the hazard analysis of HACCP. It is unlikely that FBOs themselves will decide, upon a 'basic hazard analysis', whether HACCP is applicable or not. If HACCP is required, essentially by laws and regulations, then they will directly conduct their hazard analysis as part of HACCP. Authorities may decide (most likely upon a risk assessment rather than a hazard analysis) whether a FBO (given its sector, its size, etc.) is subject to HACCP</p> <p>The terminology and concept of '<u>enhanced GHP</u>' (hazard control measures at other places than CCPs) is confusing. It should be clarified that this type of hazard control measures is for controlling a significant food safety hazard identified by the hazard analysis of HACCP and therefore lays out of the scope of GHPs. Users of ISO 22000 would call it 'OPRP'.</p> <p>The terminology related to '<u>control measures</u>' should be harmonized and properly defined as many different terms exist across the documents and seem to refer to the same concept: 'control measures', 'food safety control measures', 'HACCP control measures', 'food hygiene measures'. The term 'control measure' should be limited to those measures identified by hazard analysis and therefore not include GHPs. For the avoidance of any doubt, we suggest to systematically insert the word 'hazard' before.</p>	
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GENERAL COMMENT	Management-related elements could be grouped in a dedicated chapter: split the 2 chapters 1.GHPS and 2.HACCP into 1.GHPs, 2.HACCP, and 3.Management (include there the management-related elements that are spread across the document 'management commitment', 'management and supervision', 'training')	
Appendix I of CX/FH 17/49/5 Paragraph 4	Would consider it appropriate that all Businesses are aware of the need to, and do perform Hazard Analysis – the use of 'where appropriate' or 'if necessary' would not be suitable in these instances. Albeit, it is understood that the intensity of such a HA will vary by player in the food chain.	We propose to retain the paragraph 4B as mentioned in Appendix I of CX/FH 17/49/5 and delete paragraph 4A I agree to this comment.
Paragraph 4	Retain option B with the following changes	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 basic hazard analysis and an assessment of food hygiene measures, 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 by a site-specific hazard analysis and to apply [hazard control measures at critical control points (CCPs) and/or at places other than CCPs] OR [HACCP control measures] 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 industry2 subject to adaptation to the site.
Paragraph 5	[Chapter One] of this document describes GHPs, which are the basis of all food hygiene safety control systems to support the production of safe and suitable food. GHPs can be stand-alone food hygiene measures or programs prerequisite programmes (PRPs) to HACCP <i>[-> these terms should be harmonized throughout]</i>	

<p>Paragraph 6</p>	<p>The following comparison table shows the relationship of GHPs applied for food safety and suitability and HACCP hazard control measures applied to enhance food safety control significant food safety hazards</p> <p>Comparison of GHPs, [Control Measures at Places Other than CCPs][Enhanced GHPs] and HACCP Hazard Control Measures</p>	<table border="1"> <tr> <td data-bbox="850 149 1127 233">Good Hygiene Practices (GHPs)</td> <td data-bbox="1135 149 1411 233">[Control Measures at Places Other than CCPs][Enhanced GHPs]</td> <td data-bbox="1419 149 1468 233">Control Control</td> </tr> <tr> <td data-bbox="850 243 1127 327">☐</td> <td data-bbox="1135 243 1411 327">[After basic hazard analysis at places of GHPs]</td> <td data-bbox="1419 243 1468 327">☐</td> </tr> <tr> <td data-bbox="850 338 1127 422">☐</td> <td data-bbox="1135 338 1411 422">After Hazard analysis for Control measures</td> <td data-bbox="1419 338 1468 422">☐</td> </tr> </table> <p><i>[-> these terms should be harmonized throughout]</i></p>	Good Hygiene Practices (GHPs)	[Control Measures at Places Other than CCPs][Enhanced GHPs]	Control Control	☐	[After basic hazard analysis at places of GHPs]	☐	☐	After Hazard analysis for Control measures	☐
Good Hygiene Practices (GHPs)	[Control Measures at Places Other than CCPs][Enhanced GHPs]	Control Control									
☐	[After basic hazard analysis at places of GHPs]	☐									
☐	After Hazard analysis for Control measures	☐									
<p>Page 11 Paragraph 8</p>	<p>Should add to traffic flow example people flow</p>	<p>...traffic flow (e.g. one-directional production flow, zoned people flow), ...</p>									
<p>Paragraph 9</p>	<p>The document is intended for use by food business operators (including primary producers, manufacturers/processors, supply chain operators, food service operators and retailers) and competent authorities</p>										
<p>GENERAL PRINCIPLES (between Paragraphs 14 and 15)</p>	<p>(iii) GHPs should provide the foundation for a HACCP system, where applied, to be effective.</p> <p>(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.</p> <p>(v) [Significant hazards] should be controlled by [specific] hazard control measures.</p> <p>(vi) Hazard Control measures that are critical to achieve an acceptable level of food safety should be scientifically validated³</p> <p>(vii) The application of hazard control measures should be subject to monitoring, corrective actions, verification, and documentation, as appropriate.</p> <p>(viii) Food hygiene safety control 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.</p>										
<p>Paragraphs 15 and 16</p>	<p>Move to a new Chapter 3. Management</p>										

Paragraph 28-33	Process control details referred to in para 28-33 are important elements to be described thoroughly in the text, but in many cases this detail may be included in the HACCP study/plan for FBOs.	Propose to retain and expand the details of this text which is in brackets in the current version of the document.
Page 14 Paragraph 32	Need to correct spelling of "Preventative" to Preventive in both the title and first line of paragraph.	Use preventive
Page 14 Paragraph 35	Should validation be included here?	All control measures need to be validated.
Paragraph 42	The structure of document can be improved.	Ensure appropriate cross references are made to relevant Codex documents and here cross reference could be made to CAC/GL 21 – "Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods".
Paragraph 46, 47, 48	The sections on Physical contamination, allergens and chemical contamination needs to be elaborated further. This is already indicated in the Note on Allergens, where reference must be made to supplier management, transport and manufacturing – the use of HACCP to establish controls such as validated cleaning to prevent allergen cross contact and the necessary labelling (as ingredient or as Precautionary labelling), etc. For Physical hazards, it should be emphasized the preventive role for foreign body prevention as well as sorting and detection equipment (sieves, screens, metal detectors, X-ray etc). This preventive approach covers the whole value chain from primary production through to processing, manufacturing, and downstream. Integrated pest management and hygienic engineering should also be referred to here or cross referenced to pest control system (para 72). The chemical contamination sections needs to mention the risks from primary production (vet drugs, pesticides etc.) through manufacturing (process contaminants, chemical agents for cleaning, etc.).	

Page 16 Paragraph 49	There is no mention of raw materials being accepted with a known hazard and not controlled until the next customer which could include the final consumer such as with raw meat and flour.	<i>"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."</i> Does this processing mean steps in the chain later or at the next step?
Page 18 Paragraph 66	Add another example of drains.	"[Separate cleaning equipment, suitably designated, should be used for highly contaminated areas e.g. toilets, drains]"
Page 19 Paragraph 78	Remove the bracket at the end of the sentence as I do not see the paired one.	78. Waste stores should be kept appropriately clean and free of pests and be resistant to pest infestation.
Page 20 Objectives box	Correct phase of verb of maintaining to maintain.	OBJECTIVES: To ensure that those who come directly or indirectly into contact with food: <ul style="list-style-type: none"> • Maintain appropriate personal health; • maintain an appropriate degree of personal cleanliness; and • behave and operate in an appropriate manner.
Page 20 Paragraph 79	Correct English	... should not be allowed to enter any food handling area if there is a likelihood of them contaminating food
Page 20 Paragraph 83	Remove the bracket at the beginning of the sentence as I do not see the paired one.	... footwear. Controls should implemented to prevent cross-contamination by food handlers through adequate hand washing ...
Page 24 Paragraph 4 Last sentence	This sentence is not clear as to what it means or is about. A solution to this sentence is provided, but not sure if this is what this sentence is trying to say?	<i>While the application of HACCP to food safety was considered here, the concept can be applied to other aspects of food quality.</i> While the application of HACCP to food safety was considered in this document, the concept of HACCP can be applied to food quality as well.
Page 24 Definitions' Note Box	Agree to moving all definitions to a single section in the document. Also, as the definitions are written, they should be updated to not just speak about CCPs, but control measures.	
Page 24 Control Measure	A control measure does not have to be both an action AND activity, so would it not be better to say "OR"?	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.
Page 25 Critical Limit	To help make this term more understandable examples should be added.	Critical limit: A criterion which separates acceptability from unacceptability. Typically these are operational parameters such as time, temperature, flow.

Definitions	<p>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.</p> <p>Food safety control system⁴ - The combination of GHPs and, if appropriate, hazard control measures that, when taken as whole, ensures that food is safe for its intended use.</p> <p>Control measure</p> <p>Hazard control measure (→ See definition of ISO/DIS 22000) [Basic Hazard Analysis]</p>	
ANNEX I	Delete the decision chart. A chart may be developed in Chapter 2 to identify the need for hazard control measures and whether the steps where they apply are CCPs or not.	
Page 25 Principles of the HACCP System	Will these need to be updated if other control measures are included, not just CCPs?	
Paragraph 2	<p>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 by hazard control measures either through application of enhanced GHPs designed to control a specific food safety hazard or, where appropriate, in combination with the application of HACCP.</p>	
Page 26 Paragraph 10	Need to remove or add a bracket as only one is in the sentence and area.	HACCP should be applied to each individual] operation separately.
Page 27 Paragraph 18	<p>What are the general CLASSES of hazards? Need to define somewhere or give examples.</p> <p>Also thought the scope of HACCP should define the PRODUCT and the PROCESS?</p>	The scope should describe which segment of the food chain is involved, the process, and the types of hazards to be addressed (e.g. Physical, Chemical, Microbiological).

Page 28 Paragraph 26	What about prevention as it is not mentioned here? Fix and remove parenthesis throughout.	[Significant hazards] which are of such a nature that their prevention, 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 prevent, 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 <i>Listeria monocytogenes</i> (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.]
Page 28 Paragraph 27	Should this paragraph say SIGNIFICANT hazards?	Consideration should be given to what control measures, if any exist, can be applied to each significant hazard. More than one control measure may be required to control a specific significant hazard(s) and more than one significant hazard may be controlled by a specified control measure.
Paragraphs 28-37	These paragraphs make no more sense now that the HACCP is not an annex anymore. To address in Chapter 2.	
Page 28 Note Box	Agree decision tree needs to be modified, not just reviewed, if other control measures will be allowed than just CCPs.	
Page 28 Paragraph 29	Should there be a statement about Not Ready To Eat products that get the identified hazard mitigated by the next customer or consumer or later down the food chain?	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 (including further down the food chain at a different customer or consumer), to include a control measure.
Page 29 Paragraph 34	The term “guarantee” is a very strong word in some countries, so suggest to change this word to “determine”. Open to other words.	If monitoring is not continuous, then the amount or frequency of monitoring should be sufficient to determine the CCP is in control.
Paragraph 42	Where [...], such specifications should be based on sound scientific principles and state, where appropriate, monitoring procedures, analytical methods and critical limits [+ add reference to CAC/GL 21 – “Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods”.]	
Paragraphs 59 to 61	Can be moved to Section VI if retitled to “Communication and documentation”	

Paragraphs 98 to 102	Move to a new Chapter 3. Management	
CHAPTER TWO	This chapter needs to be revised to introduce 2 types of hazard control measures: those applied at CCPs and those applied at other places than CCPs	